MAHI Muckamore Abbey Hospital Inquiry

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02 May 2023

By Email Only
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Dear Ms McManus

Re Evidence Modules 2023: Oral Evidence for Module 3

As you know, the evidence of Mr Chris Hagan obo BHSCT for Module 3 commenced on 20 April 2023 and remains part heard. The Inquiry is grateful for Mr Hagan's attendance. The following topics remain to be addressed in oral evidence:

- 3(a)-Policies for delivering health and social care to learning disability patients 1999-2021.
- 3(c)-Policies regarding restraint/seclusion.
- 3(g)-Policies and procedures re psychological treatment, speech and language therapy, occupational therapy and physiotherapy.
- 3(h)-Resettlement policies and the provision for the monitoring of resettlement.
- 3(i)-Complaints and whistleblowing: policies and procedures.
- 3(j)-Overview of mechanisms for identifying and responding to concerns.
- 3(k)-Risk assessments and planning regarding changes of policy.
- 3(l)-Procedures to provide assurance regarding adherence to policies.
- 3(m)-Policies and procedures for further training for staff/continuing professional development.

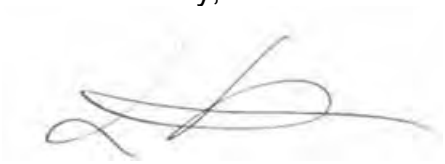
It is intended that a further evidence session (or sessions) will be scheduled for June 2023. You will be aware that, during the course of his evidence on 20 April 2023, Mr Hagan indicated that he could not speak to some issues raised with him. If Mr Hagan is unable to provide oral evidence in respect of any of the remaining matters please revert to me with the identity of a witness, or witnesses, who will give oral evidence in

respect of those topics. Please note that the Inquiry is not inviting further statements of evidence (save as indicated below); rather it wishes to ensure that a suitable witness attends to give oral evidence in respect of the matters already addressed in documentary form by the statements of Mr Hagan.

In addition to the above, the Panel wishes to hear evidence in respect of the following matter that would fall within the ambit of Topic 3e (Policies and procedures re medication/ auditing of medication), but that has not been specifically addressed in the statements to date: policy or policies relating to the administration of PRN sedation, including how staff were assessed as competent to make decisions about using PRN and processes in place for assurance that PRN was being used properly. It may be that Mr Hagan or another suitable witness will be in a position to address this matter in a supplementary statement to be filed in advance of the oral evidence. If it is proposed to address this matter in a statement, the statement should be provided by Friday 26 May 2023.

The evidence of Mr Hagan, or another identified witness (or witnesses) will be scheduled within the current Evidence Module sessions. I would therefore be grateful if you would respond to me by Friday 05 May 2023.

Yours faithfully,



Lorraine Keown
Solicitor to the Inquiry

Violence

The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments

This guideline was commissioned by the National Institute for Health and Clinical Excellence (NICE)

February 2005

CLINICAL PRACTICE GUIDELINES

Violence

The short-term management of disturbed/violent behaviour in in-patient psychiatric settings and emergency departments

This guideline was commissioned by the National Institute for Health and Clinical Excellence (NICE)

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National Collaborating Centre for Nursing and Supportive Care

This work was undertaken by the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) and the Guideline Development Group (GDG) formed to develop this guideline on behalf of the National Institute for Health and Clinical Excellence (NICE). Funding was received from the National Institute for Health and Clinical Excellence. The NCC-NSC consists of a partnership between: the Centre for Evidence-Based Nursing (University of York), the Clinical Effectiveness Forum of Allied Health Professionals, the Healthcare Libraries (University of Oxford) the Health Economics Research Centre (University of Oxford), the Royal College of Nursing and the UK Cochrane Centre.

Disclaimer

As with any clinical guideline, recommendations may not be appropriate for use in all circumstances. A limitation of a guideline is that it simplifies clinical decision-making (Shiffman 1997). Decisions to adopt any particular recommendations must be made by the practitioners in the light of:

- available resources
- local services, policies and protocols
- the patient's circumstances and wishes
- available personnel
- clinical experience of the practitioner
- knowledge of more recent research findings.

Royal College of Nursing

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Guideline Development Group membership and acknowledgements

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The NCC-NSC would also like to thank the following people who contributed to the guideline:

Paul Hewitson, project manager until August 2002

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Dave Branford for reworking the introduction to rapid tranquillisation.

Terminology

1. Where the term 'carer' is used, this refers to unpaid carers as opposed to paid carers (for example, caseworkers).
2. Where the term 'service user' is used, this refers to users of mental health services.
3. Where the term 'staff member' or 'health care professional' is used, this refers to any nursing or allied health care professions or other medical staff, including health care assistants.

Legal review

These guidelines have been referred to principles of law summarised by NICE solicitors and have undergone a legal review as part of the stakeholder and validation process.

Abbreviations

Technical terms

ABS	agitated behaviour scale (Corrigan 1989)
AED	automated external defibrillators
ALS	advanced life support
ARP	aggression risk profile (Kay et al. 1987)
BARS [1]	behavioural activity rating scale (Swift et al. 1998)
BARS [2]	Barnes akathisia rating scale (Barnes 1989)
BLS	basic life support
BPRS	brief psychiatric ratings scale (Overall & Gorham 1962)
BVC	Brøset violence checklist (Almvik 1996)
CGI	clinical global impressions scale (Guy & Bonato 1970)
CGI-I	clinical global impression of improvement – subscale of CGI (Guy & Bonato 1970)
CGI-S	clinical global impressions severity of illness scale – subscale of CGI (Guy & Bonato 1970)
CO	constant observation
CPR	cardiopulmonary resuscitation
EAQ	environment assessment questionnaire (Lanza 1996)
EPS	extrapyramidal symptoms
GCI	global clinical impressions scale
GDG	Guideline Development Group
HCR-20	historical/clinical/risk – 20-item scale, version 2 (Webster et al. 1997)
HIV	human immunodeficiency virus
IFP	information for the public version
ILS	immediate life support
i/m	intramuscular injection
i/v	intravenous injection
MBPRS	modified brief psychiatric ratings scale (Tariot et al. 1993)
MMSE	mini mental state examination (Folstein et al. 1975)
MOAS	modified overt aggression scale (Kay et al. 1988)
NOSIE-30	nurses observation scale for in-patient evaluation (Honigfeld et al. 1966)
OAS	overt agitation scale (Yudofsky 1997)
PANSS	positive and negative syndrome scale (Kay et al. 1987)
PANSS-EC	positive and negative syndrome scale exited component -subscale of PANSS (Kay et al. 1987)
PICU	psychiatric intensive care unit
PCF	patient characteristic form b (Lanza 1996)
PCL-SV	psychopathy checklist: screening version (Hart et al. 1995)
PRN	pro-re-nata medication
QNS	quantified neurological scale (Convit et al. 1994)
RAPP	routine assessment of patient progress (Ehmann et al. 1995)
RCT	randomised controlled trial
RSU	regional secure unit
SO	special observation
SOAS	staff observation aggression scale (Palmestierna & Wistedt 1987)
SOAS-E	extended staff observation aggression scale (Hallenstinsen et al. 1998)
SOAS-R	staff observation aggression scale revised (Nijman et al. 1999)
SORS	special observation record sheets
SPC	summary of product characteristics
TSRS	target symptom rating scale (Barber et al. 2002)
VAS	any visual analogue scale, for example, likert scale
VRAG	violence risk appraisal guide (Harris et al. 1993; Webster et al. 1994).

Organisations

BNF	British National Formulary
DH	Department of Health
MHRA	Medicines and Healthcare Products Regulatory Agency (formerly Medical Devices Agency)
NCC-NSC	National Collaborating Centre for Nursing and Supportive Care
NICE	National Institute for Health and Clinical Excellence
NIMHE	National Institute for Mental Health in England
NMC	Nursing and Midwifery Council (formerly the United Kingdom Central Council for Nurses, Midwives and Health Visitors (UKCC), formerly the Standing Nursing and Midwifery Advisory Committee (SNMAC).
NPSA	National Patient Safety Agency
NSF	National Service Framework
RCN	Royal College of Nursing
RCPsych	Royal College of Psychiatrists
SMS	the NHS Security Management Service
ScHARR	School of Health and Related Research, University of Sheffield
UKCC	The United Kingdom Central Council for Nurses, Midwives and Health Visitors. The role of this body has now been taken over by the Nursing and Midwifery Council (NMC).

General glossary

(This is partially based on *Clinical epidemiology glossary* by the Evidence Based Medicine Working Group, www.ed.ualberta.ca/ebm; *Information for national collaborating centres and guideline development groups*, (NICE 2001).

Acute care setting: short-term (approximately 30 days) in-patient care or emergency services or other 24-hour urgent care settings.

Admission unit: type of unit into which a service user is admitted either directly from emergency departments or from ambulance services.

Actuarial: a statistical method.

Actuarial prediction: this involves the use of statistical models and risk factor tools to predict an individual's behaviour. Risk factors measured by actuarial tools can be static (unchangeable) or dynamic (changeable).

Advance directive: a document that contains the instructions of a person with mental health problems setting out their requests in the event of a relapse, an incident of disturbed/violent behaviour etc. It sets out the treatment that they do not want to receive and any treatment preferences that they may have in the event that they become violent. It also contains people who they wish to be contacted and any other personal arrangement that they wish to be made.

African Caribbean: of or pertaining to both Africa and the Caribbean; used to designate the culture, way of life, etc or the characteristic style of music of those people of black African descent who are, or whose immediate forebears were, inhabitants of the Caribbean (West Indies) (Oxford English Dictionary Online).

Aggression: a disposition, a willingness to inflict harm, regardless of whether this is behaviourally or verbally expressed and regardless of whether physical harm is sustained.

Anaesthetised: general anaesthesia is a state of narcosis (unconsciousness), analgesia (lack of awareness of pain) and muscle relaxation. It is one stage beyond deep sedation. It implies loss of airway control and protective reflexes, and requires the constant attention of trained personnel to keep the patient safe. There is normally no verbal contact. There are, of course, various depths of anaesthesia, and the risk of obstructed or depressed respiration increases as the anaesthesia deepens.

Antecedents: warning signs that indicate a service user is escalating towards a violent act.

Antipsychotics: a class of prescription medications used to treat psychotic conditions.

Benzodiazepines: refers to any of several similar lipophilic amines used as tranquillizers or sedatives or hypnotics or muscle relaxants.

Bias: a tendency for the results to depart systematically, either lower or higher, from the 'true' results. Bias either exaggerates or underestimates the 'true' effect of an intervention or exposure. It may arise for several reasons, such as errors in design or the conduct of the study.

Bipolar disorder: a condition formerly known as manic depressive disorder, that involves the presence of depressive episodes, along with periods of elevated mood known as mania. Symptoms of mania include an abnormally elevated mood, irritability, an overly inflated sense of self-esteem, and distractibility.

Black: refers to those members of ethnic minority groups who are differentiated by their skin colour or physical appearance, and may therefore feel some solidarity with one another by reason of past or current experience, but who may have many different cultural traditions and values.

Breakaway: a set of physical skills to help separate or breakaway from an aggressor in a safe manner. They do not involve the use of restraint.

Calming: reduction of anxiety/agitation.

Cardiovascular compromise: failure of the heart and circulatory system to produce adequate blood flow to the vital organs leading to collapse and often to death.

Cardiopulmonary resuscitation: combined artificial ventilation and cardiac massage technique for reviving a person whose heart and breathing have stopped and who is unconscious.

Case-control study: a study in which the effects of a treatment or management approach in a group of patients is compared with the effects of a similar group of people who do not have the clinical condition (the latter is called the control group).

Clinical effectiveness: the extent to which an intervention (for example, a device or treatment) produces health benefits (i.e. more good than harm).

Cochrane collaboration: an international organisation in which people retrieve, appraise and review available randomised controlled trials. The Cochrane database of systematic reviews contains regularly updated reviews on a variety of issues. The Cochrane Library is the database for the collaboration. It is electronic and regularly updated.

Cohort study: follow-up of exposed and non-exposed groups of patients (the 'exposure' is either a treatment or condition), with a comparison of outcomes during the time followed-up.

Common law: is that body of legal doctrines and principles developed by the courts through their decisions. For example, the common law doctrine of necessity and the principles of negligence have been developed by the courts over time.

Co-morbidity: co-existence of a disease or diseases in a study population in addition to the condition that is the subject of study.

Confidence interval (CI): the range of numerical values in which we can be confident that the population value being

estimated were found. Confidence intervals indicate the strength of evidence; where confidence intervals are wide they indicate less precise estimates of effects.

Cost effectiveness: the cost per unit of benefit of an intervention. In cost effectiveness analysis, the outcomes of different interventions are converted into health gains for which a cost can be associated – for example, cost per additional pressure ulcer prevented.

Cost impact: the total cost to the person, the NHS or to society.

Crash bag: the equipment necessary to resuscitate an individual if they suffer a cardiac arrest.

David Bennett Inquiry: public inquiry into the death of David Bennett, a 38 year old black man, who died while being restrained in a medium secure unit in the early hours of Saturday 31 October 1998.

De-escalation: a complex range of skills designed to abort the assault cycle during the escalation phase, and these include both verbal and non-verbal communication skills (CRAG 1996).

De-escalation room: this should be a low stimulus room, where a service user can go to calm down. It should not normally be the seclusion room, which is a specific room set aside for the purpose of seclusion, and which must meet specifications that are principled in the Mental Health Act Code of Practice. Seclusion of an informal patient should be taken as an indicator of the need to consider formal detention. This is not the case when a service user is asked to use the de-escalation room.

Deep sedation: a reduction of consciousness and motor and sensory activity, where verbal contact is progressively lost, and then (dangerously) if excessive airway control and protective reflexes are lost.

Disturbed: to be experiencing emotions and exhibiting behaviours that deviate from the accepted norm as a result of mental ill health.

Dystonia: a slow movement or extended spasm in a group of muscles.

Economic evaluation: comparative analysis of alternative courses of action in terms of both their costs and consequences.

Effectiveness: the extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do. Clinical trials that assess effectiveness are sometimes called management trials (NICE 2002).

Efficacy: the extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate.

Emergency departments: any care setting designed to provide emergency treatment and care (previously known as accident and emergency).

Environment: the physical and therapeutic external conditions or surroundings.

Epidemiological study: a study that looks at how a disease or clinical condition is distributed across geographical areas.

Exceptional circumstances: those circumstances that cannot reasonably be foreseen and as a consequence cannot be planned for.

Extrinsic: factors that are external to the individual.

Follow-up: observation over a period of time of an individual, group or population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables.

Forensic services: mental health services based on authority derived from judicial actions.

Gender: those characteristics of women and men that are socially determined, as opposed to 'sex' which is biologically determined (*Mainstreaming gender and women's mental health implementation guide 2003*).

Gold standard: a method, procedure or measurement that is widely accepted as being the best available.

Good practice point: a recommendation for good practice, based on the experience of the Guideline Development Group.

Guideline recommendation: a systematically developed statement that is derived from the best available research evidence, using predetermined and systematic methods to identify and evaluate evidence relating to the specific condition in question.

Health technology assessment: the process by which evidence on the clinical effectiveness and the costs and benefits of using a technology in clinical practice is systematically evaluated.

Incidence: the number of new cases of illness commencing, or of persons falling ill during a specified time period in a given population.

Intrinsic: factors present within the individual.

Key worker: the health care professional who is the first line of contact for a person with mental illness.

Light sedation: a state of rest and reduction of psychological activity, but verbal contact is maintained.

Low secure units: low secure units deliver intensive, comprehensive, multidisciplinary treatment and care by qualified staff for patients who demonstrate disturbed/violent behaviour in the context of a serious mental disorder and who require the provision of security (Department of Health, Mental health policy implementation guide 2002).

Mania: an irrational but irresistible motive for a belief or action. It can also be used to refer to a mood disorder and an affective disorder in which the victim tends to respond excessively and sometimes violently.

Mechanical restraint: a method of physical restraint involving the use of authorised equipment applied in a skilled manner by designated health care professionals. Its purpose is to safely immobilise or restrict movement of

part/s of the body of the individual concerned.

Medium secure unit: usually houses service users who are detained under the Mental Health Act, but who do not need to be detained in high security hospitals.

Meta-analysis: a statistical method of summarising the results from a group of similar studies.

Minority ethnic group: a group which is numerically inferior to the rest of the population in a state, and in a non-dominant position, whose members possess ethnic, religious or linguistic characteristics which differ from those of the rest of the population and who, if only implicitly, maintain a sense of solidarity towards preserving their culture, traditions, religion or language. (F. Capotorti (1985) 'Minorities', in Bernhardt R et al. (editors) *Encyclopedia of public international law*. Amsterdam: Elsevier, vol.8, p.385.)

Negative predicative value: the probability that an individual is truly disease-free given a negative screening test.

NHS Security Management Service (SMS) also known as the Counter Fraud and Security Management Service: is a special health authority which has responsibility for all policy and operational matters relating to the prevention, detection and investigation of fraud and corruption and the management of security in the National Health Service (http://www.cfsms.nhs.uk/).

Number needed to harm: the number of people (calculated statistically) who need to be treated to cause one bad outcome. The lower the number needed to harm, the higher the likelihood of harm (NICE, Schizophrenia guideline 2002).

Number needed to treat: the number of patients who need to be treated to prevent one bad outcome (i.e. a good outcome). It is the inverse of the risk difference (NICE, Schizophrenia guideline 2002).

Observation: a two-way relationship, established between a service user and a nurse, which is meaningful, grounded in trust, and therapeutic for the service user (*The recognition, prevention and therapeutic management of violence in mental health care,* (2002) London: United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting).

Occulogyric crisis: sudden spasm of conjugate movement, mainly upward, so that the eye rolls upwards into the back of the head.

Odds ratio (OR): ratio of the odds of the outcome in the treatment group to the corresponding odds in the control group. Again, for an adverse outcome, an odds ratio below one indicates that the treatment reduces the risk (Glasziou 2001).

Pain compliance: a method of physical intervention that employs skills and techniques, such as thumb locks, which deliberately involve inducing pain. These techniques are only permitted in exceptional circumstances, as part of the short-term management of disturbed/violent behaviour. They are only used once other methods have been tried and proved unsuccessful and must be a proportionate, reasonable and justifiable response to a situation.

Parenteral: method of administering medication or nutrition other than via the digestive tract, such as intravenous, subcutaneous or intramuscular.

Patient: the term 'service user' is preferred to refer to people with mental illness in this guideline. The term 'patient' is used under the following conditions:

- generic and typical usage, such as 'NICE programme for patients', 'Patient Bill of Rights'
- NICE recommendations that are required to be quoted verbatim
- frequently used noun compounds – for example, patient sample (NICE, Schizophrenia guideline 2002).
- in the sections that describe accident and emergency settings, the term 'patient' is normally used.

Phase 3 studies: are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in phase 2. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug, before undertaking a licensing application with an appropriate regulatory authority.

Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and are the basis for product communication to the physician. Phase 3 studies usually include several hundred to several thousand people.

Physical intervention: is a skilled hands-on method of physical restraint involving trained designated healthcare professionals to prevent individuals from harming themselves, endangering others or seriously compromising the therapeutic environment. Its purpose is to safely immobilise the individual concerned.

PICU (psychiatric intensive care unit): psychiatric intensive care is for patients compulsorily detained usually in secure conditions, who are in an acutely disturbed/violent phase of a serious mental disorder (Department of Health, Mental health policy implementation guide 2002).

Positive/therapeutic engagement: may be defined as a skilled nursing intervention that aims to empower the patient to actively participate in their care. Rather than 'having things done to them' – like observations – the patient negotiates the level of engagement that will be most therapeutic.

Positive predicative value: the probability that a person actually has the disease, given that they test positive using a given screening test.

Predictive validity: a risk assessment tool would have high predictive validity if the predictions it makes of disturbed/violent behaviour in a sample became true (i.e. it has both high sensitivity and specificity).

Prevalence: the proportion of persons with a particular disease within a given population at a given time.

Principle of proportionality: requires that one should not go beyond what is necessary to achieve the object pursued.

PRN (Prorenata): medication that may be used as the occasion arises; when necessary.

Psychiatric in-patient settings: any care setting in which psychiatric treatment is given to inpatients.

Psychosocial interventions: the term is used to refer to a range of social, educational, occupational, behavioral, and cognitive interventions. Within the short-term management of disturbed/violent behaviour, the two main psychosocial interventions are de-escalation and observation.

QT interval: the period in the cardiac cycle between depolarisation (causing contraction) and repolarisation of the heart muscle. Some drugs prolong this interval. This can lead to the development of arrhythmias (abnormal electrical activity in the heart), which may cause cardiovascular collapse and death.

Randomised controlled trial (RCT): a clinical trial in which the treatments are randomly assigned to subjects. The random allocation eliminates bias in the assignment of treatment to patients and establishes the bias for the statistical analysis.

Rapid tranquillisation: the use of medication to calm/lightly sedate the service user, reduce the risk to self and/or others and achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, and allowing comprehension and response to spoken messages throughout the intervention. Although not the overt intention, it is recognised that in attempting to calm/lightly sedate the service user, rapid tranquillisation may lead to deep sedation/anaesthesia.

Relative risk: an estimate of the magnitude of an association between exposure and disease that also indicates the likelihood of developing the disease among persons who are exposed, relative to those who are not. It is calculated by the ratio of incidence of disease in the exposed group divided by the corresponding incidence in the non- exposed group.

Respiratory effect: the changes in thoracic or abdominal circumference that occurs as the subject breathes.

Retrospective cohort study: a study in which a defined group of persons with an exposure, and an appropriate comparison group who are not exposed, are identified retrospectively and followed from the time of exposure to the present, and in which the incidence (or mortality) rates for the exposed and unexposed are assessed.

Seclusion: the supervised confinement of a patient in a room, which may be locked to protect others from significant harm. Its sole aim is to contain severely disturbed/violent behaviour that is likely to cause harm to others. Seclusion should be used as a last resort, for the shortest possible time. Seclusion should not be used as a punishment or threat; as part of a treatment programme; because of shortage of staff; where there is any risk of suicide or self-harm. Seclusion of an informal patient should be taken as an indicator of the need to consider formal detention.

Seclusion room: this is a room that is fit for purpose, as defined by the principles laid out in the Mental Health Act Code of Practice. It should only be used for the purpose of carrying out seclusion. As such, it should be distinguished from a low stimulus room, where a service user can go simply for the purpose of de-escalation.

Sensitivity: percentage of those who developed a condition who were predicted to be at risk.

Sleep: a condition of body and mind such as that which normally recurs for several hours every night, in which the nervous system is inactive, the eyes closed, the postural muscles relaxed, and consciousness practically suspended (Oxford English Dictionary).

Specificity: percentage of those correctly predicted not to be at risk.

Systematic review: a way of finding, assessing and using evidence from studies (usually RCTs) to obtain a reliable overview.

Threat control override symptoms: a combination of feeling threatened and losing the sense of internal control of our own thoughts and actions. This cluster of symptoms tends to be most related to an increased risk of disturbed/violent behaviour toward others.

Torsade de pointes: is a medical condition, the name of which means in French 'twisting of the points'. It is a potentially deadly form of ventricular tachycardia. On the electrocardiogram (ECG/EKG), it will present like ventricular tachycardia, but the QRS complexes will swing up and down around the baseline in a chaotic fashion – which prompted the name.

Validity: the extent to which a variable or intervention measures what it is supposed to measure or accomplish.

Internal validity: of a study referring to the integrity of the design.

External validity: of a study referring to the appropriateness by which its results can be applied to non-study patients or populations.

Violence: the use of physical force that is intended to hurt or injure another person (Wright 2002).

Vulnerability: specific factors that relate to the likelihood of an individual being victimised, taken advantage of, or exploited by others. Vulnerable individuals may be subject to verbal abuse or harassment, physical or sexual abuse or intimidation, coercion into unwanted acts and bullying. Assessment of vulnerability may include consideration of mental state, physical/physiological conditions, psychological or social problems, cultural or gender issues.

1. Executive summary

The National Institute for Health and Clinical Excellence (NICE) commissioned the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) to develop guidelines on the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments for mental health assessments. This follows referral of the topic by the Department of Health and Welsh Assembly Government. This document describes the methods for developing the guidelines and presents the resulting recommendations. It is the source document for the NICE short-form version, the Quick reference guide (the abridged version for health professionals) and the Information for the public (the version for patients and their carers), which will be published by NICE and be available on the NICE website (www.nice.org.uk). The guidelines were produced by a multidisciplinary Guideline Development Group (GDG) and the development process was undertaken by the NCC-NSC.

The main areas examined by the guideline were:

- environment and alarm systems
- prediction: antecedents, warning signs and risk assessment
- training
- working with service users
- de-escalation techniques
- observation
- physical interventions
- seclusion
- rapid tranquillisation
- post-incident review
- emergency departments
- searching.

Recommendations and good practice points based on the best available evidence of clinical and cost effectiveness are presented. However, there was a dearth of evidence in all areas covered by this guideline and all recommendations and good practice points were arrived at by the GDG using formal consensus methods.

Evidence published after 2003 was not considered, with the exception of rapid tranquillisation, where evidence published up to 2003 was considered to ensure that up-to-date trials could be included for medications.

Subsequently no further evidence has been submitted as relevant or likely to impact on the recommendations prior to publication.

Health care professionals should use their clinical judgement and consult with service users when applying the recommendations and good practice points described in this guideline, which aim at reducing the negative physical, social and financial impact of managing disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments in the short-term (within 72 hours).

2 Principles of practice

The principles outlined below describe the ideal context in which to implement the recommendations and good practice points contained in this guideline. These have been adapted from the NICE clinical practice guideline: *Pressure ulcer prevention* (2003). The principles in the NICE clinical practice guideline: *Pressure ulcer prevention* (2003) went through a consensus process, were refined and published in order to describe the ideal context in which to implement guideline recommendations. (Adapted from the Royal College of Nursing (2001) clinical practice guidelines: *Pressure ulcer risk assessment and prevention. Recommendations*.)

Person-centred care

- Service users and their carers should be made aware of the guideline and its recommendations and be referred to the *Information for the public* version (IFP).
- Service users and their carers should be involved in shared decision-making about the preferred choice of intervention for the short-term management of disturbed/violent behaviour through the use of their care plans or advance directives.

A collaborative inter-disciplinary approach to care

- All members of the inter-disciplinary team should be aware of the guidelines and all interventions should be documented in the service users' health care records.

Organisational issues

- An integrated approach should be taken to the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings, with a clear strategy and policy supported by management.
- Care should be delivered in a context of continuous quality improvement where improvements to care following guideline implementation are the subject of regular feedback and audit.
- Commitment to and availability of education and training are needed to ensure that all staff, regardless of profession, are given the opportunity to update their knowledge base and are able to implement the guideline recommendations.
- Service users should be cared for by personnel who have undergone appropriate training and who know how to initiate and maintain correct and suitable preventative measures. Staffing levels and skill mix should reflect the needs of service users and health care professionals.

3 Key priorities for implementation

The reader is referred to the evidence reviews for a summary of the supporting evidence and evidence statements (Section 7). The grading systems can be found in 7.4 and 7.5. A full account of all the recommendations in the guideline can be found in Section 8. (The key recommendations follow the order in which they appear in Section 8.)

The following nine recommendations have been identified as priorities for implementation.

Prediction

- Measures to reduce disturbed/violent behaviour need to be based on comprehensive risk assessment and risk management. Therefore, mental health service providers should ensure that there is a full risk management strategy for all their services.

Training

- All service providers should have a policy for training employees and staff-in-training in relation to the short-term management of disturbed/violent behaviour. This policy should specify who will receive what level of training (based on risk assessment), how often they will be trained, and also outline the techniques in which they will be trained.
- All staff whose need is determined by risk assessment should receive ongoing competency training to recognise anger, potential aggression, antecedents and risk factors of disturbed/violent behaviour, and to monitor their own verbal and non-verbal behaviour. Training should include methods of anticipating, de-escalating or coping with disturbed/violent behaviour.
- All staff involved in administering or prescribing rapid tranquillisation, or monitoring service users to whom parenteral rapid tranquillisation has been administered, should receive ongoing competency training to a minimum of immediate life support (Resuscitation Council UK). This covers airway, cardio-pulmonary resuscitation [CPR] and use of defibrillators.
- Staff who employ physical intervention or seclusion should, as a minimum, be trained to basic life support (Resuscitation Council UK).

Commentary

No studies were identified that specifically addressed the issues described in the five key priorities above – the extent to which risk assessment and risk management reduce the risk of disturbed/violent behaviour; the effectiveness of policies on training or training itself in relation to the management of disturbed/violent behaviour; or training in relation to resuscitation in psychiatric settings. The GDG carefully considered the available evidence and used formal consensus techniques to extrapolate and develop these recommendations. In the opinion of the GDG the fulfilment of the last two recommendations above constitutes a duty of care (see also the legal preface, page 20).

Working with service users

- Service users should have access to information about the following in a suitable format:
  - which staff member has been assigned to them and how and when they can be contacted
  - why they have been admitted and, if detained, the reason for detention; the powers used and their extent; and rights of appeal
  - what their rights are with regard to consent to treatments, complaints procedures, and access to independent help and advocacy
  - what may happen if they become disturbed/violent.

  This information needs to be provided at each admission, repeated as necessary and recorded in the notes.

Commentary

Although no studies were identified that specifically addressed the issue of information provision for service users, the GDG viewed this as an important issue requiring guidance. The GDG maintains it is a legal right that detained service users are given this information and that this information should be viewed as a right for all service users (see also the legal preface, page 20).

- Service users identified to be at risk of disturbed/violent behaviour should be given the opportunity to have their needs and wishes recorded in the form of an advance directive. This should fit within the context of their overall care and should clearly state

what intervention(s) they would and would not wish to receive. This document should be subject to periodic review.

Commentary

Although no studies were identified that specifically addressed the issue of advance directives, the GDG – in particular those with personal experience of the issue – felt that it was important for service users to be able to have input into their care. The GDG did not consider that discussing these issues with appropriate service users would cause unnecessary anxiety. The GDG used formal consensus techniques to develop this recommendation.

Rapid tranquillisation, physical intervention and seclusion

- Rapid tranquillisation, physical intervention and seclusion should only be considered once de-escalation and other strategies have failed to calm the service user. These interventions are management strategies and are not regarded as primary treatment techniques. When determining which interventions to employ, clinical need, safety of service users and others, and, where possible, advance directives should be taken into account. The intervention selected must be a reasonable and proportionate response to the risk posed by the service user.

Commentary

There is a lack of evidence relating to the effectiveness of these three interventions, particularly for physical intervention and seclusion. Therefore the GDG felt the need to stress caution when implementing these interventions, and used formal consensus techniques to derive this recommendation (see also the legal preface, page 20).

Physical intervention

- During physical intervention, one team member should be responsible for protecting and supporting the head and neck, where required. The team member who is responsible for supporting the head and neck should take responsibility for leading the team through the physical intervention process, and for ensuring that the airway and breathing are not compromised and that vital signs are monitored.

Commentary

There is limited evidence in this area. However, a number of high profile inquiries – most recently, the inquiry into the death of David Bennett – have stressed the need for staff to protect a service user's head and airway during the physical intervention process. The inquiry suggests that failure to do so, and the application of pressure to certain parts of the body, may endanger the life of the service user. The focus groups conducted for this guideline also heard reports from participants who described finding it difficult to breathe during physical intervention, due to their head not being sufficiently supported. After consultation with experts, including trainers, the GDG used formal consensus techniques to develop recommendations in this area. The GDG considers the protection of the head when appropriate to constitute a duty of care (see also the legal preface, page 20).

- A number of physical skills may be used in the management of a disturbed/violent incident.
  - The level of force applied must be justifiable, appropriate, reasonable and proportionate to a specific situation and should be applied for the minimum possible amount of time.
  - Every effort should be made to utilise skills and techniques that do not use the deliberate application of pain.
  - The deliberate application of pain has no therapeutic value and could only be justified for the immediate rescue of staff, service users and/or others.

Commentary

There is limited evidence in this area. A great deal of discussion took place in the course of the development of the guideline concerning this issue. To ensure a balanced representation at guideline development meetings, experts holding differing perspectives were invited to give presentations. Using formal consensus techniques, the GDG derived a recommendation that restricts the use of pain to the immediate rescue of staff, service users or others.

4 Background to the guideline

Background to commissioning of the guideline

In March 2002, the National Collaborating Centre for Nursing and Supportive Care (NCC-NSC) was commissioned by NICE to develop cost effective and clinically relevant guidelines on the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments. The remit from the Department of Health and Welsh Assembly Government was as follows:

> To prepare clinical guidelines for the NHS in England and Wales for the short-term management of disturbed/violent behaviour in in-patient psychiatric settings, including consideration of pharmacological, physical (including seclusion and restraint), preventative and psychosocial interventions.

Relationship to other key developments, such as National Service Frameworks (NSFs), other guidelines and policies

The short-term management of violence is a key Government target. This is outlined in the recently developed Mental Health National Service Framework (1999), which stipulates that staff should be competent to assess the risk of violence, manage individuals who may become disturbed/violent, and that staff should know how to assess and manage risk and ensure safety. The effective short-term management of disturbed/violent behaviour is a means of helping to minimise the risk of injury to the individual service user, other service users and staff involved in these types of incident.

The short-term management of violence is also a key aim in the cross-Government NHS zero tolerance zone campaign, which was launched in 1999. The aim of this initiative is to combat violence against NHS staff, where violence is defined as:

Any incident where staff are abused, threatened or assaulted in circumstances related to their work, involving an explicit or implicit challenge to their safety, well-being or health. (www.nhs.uk/zerotolerance/definitions.htm)

In the light of the serious nature of disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments, the interventions for the short-tem management of disturbed/violent behaviour in adult psychiatric in-patient settings and related topics were selected as the focus for this NICE guideline.

The Royal College of Psychiatrists produced a guideline (RCPsych guideline) on the short-term management of disturbed/violent behaviour, The management of imminent violence in 1998, which was due to be updated. All the archive material for this guideline was obtained, search strategies and critical appraisal sheets examined, and copies of the original evidence reviews were considered. The original appraisal of the guideline undertaken by St George's hospital was also obtained (see Appendix 12). The guideline and all archive material were then appraised using the agree tool (see Appendix 11). On this basis, it was decided that the RCPsych guideline should be used as a basis for the current guideline, meaning that this guideline would update and replace the RCPsych guideline, while also extending it into new areas. Searches for this guideline did not therefore go back further than 1995, unless otherwise stated, as this period was covered by the RCPsych searches. All studies included from RCPsych guideline can be found in the evidence tables of included studies for this guideline (Appendix 5). All evidence statements in this guideline take into account both the evidence base contained in the RCPsych guideline and that generated from any new studies included here.

The NICE guideline on schizophrenia (2002) also reviewed rapid tranquillisation in relation to the treatment of schizophrenia. This current guideline builds on this work developed by the National Collaborating Centre for Mental Health (NCC-MH).

The NICE guideline on bipolar disorder (forthcoming 2006) will also review the issue of rapid tranquillisation in relation to the treatment of mania.

In addition to this guideline, several further initiatives are also currently underway which seek to improve the short-term management of disturbed/violent behaviour in adult

psychiatric in-patient settings. These are:

- The collaborative work being undertaken by the National Institute for Mental Health in England (NIMHE) and the NHS Security Management Service (SMS) which are in the process of establishing a core training curriculum for the short-term management of disturbed/violent behaviour, and a national accreditation scheme for trainers. The core training curriculum is expected to be announced in 2005 and the accreditation scheme is expected to come into force in 2005. The NCC-NSC and the GDG have worked closely with these agencies in developing this guideline and the recommendations and good practice points within it.
- A national audit of the short-term management of disturbed/violent behaviour is being carried out by the Royal College of Psychiatrists on behalf of the Healthcare Commission. The first phase of the audit was scheduled to run concurrently with the development of this guideline. The NCC-NSC liaised closely with the Royal College of Psychiatrists and is grateful to them for helping develop the audit criteria listed in this guideline (see Section 9).
- The David Bennett Inquiry raised important concerns about the treatment of black service users within the NHS. While the inquiry examined the whole of Mr Bennett's care, many of the recommendations produced by the inquiry are relevant to the scope of this guideline. Each of these recommendations has been carefully considered and reflected upon when developing the recommendations and good practice points in this guideline.
- Additional consultation work with black service users was also undertaken by the NCC-NSC in the course of the development of this guideline. We are grateful to Black Orchid in Bristol and Footprints UK in Walthamstow for running focus groups for us. This work was used to inform the recommendations and good practice points – see, in particular, the section on working with service users found in Section 8.4. The NCC-NSC also ran a focus group with health care professionals experienced in the area of black mental health (see Appendix 14).

Clinical need for the guideline

Disturbed/violent behaviour by an individual in an adult in-patient psychiatric setting poses a serious risk to the individual, other service users and staff. In 1998/99, an NHS Executive survey found that there were approximately 65,000 violent incidents against staff across the NHS.

The scope of the guideline discusses the short-term management of disturbed/violent behaviour in adult psychiatric settings, excluding learning disabilities (72 hours). The guidance applies to all adult persons aged 16 or more.

5 Aims of the guideline

5.1 Aims of the guideline

These are to:

- evaluate and summarise the clinical and cost evidence for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments (for mental health assessment)
- highlight gaps in the research evidence
- formulate evidence-based and, where possible, cost-effective clinical practice recommendations on the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings, based on the best evidence available to the GDG
- provide audit criteria to assist with the implementation of the recommendations.

5.2 Who is this guideline for?

As detailed in the guideline scope (see Appendix 2), the guideline is of relevance to:

- mental health care professionals and other staff who work in adult psychiatric in-patient settings and emergency departments
- service users
- families and carers
- managers and those responsible for service delivery.

5.3 Groups covered by the guideline

The recommendations made in the guideline cover the care of:

- Adults (>16)

Groups not covered

- Children and adolescents below the age of 16 years
- Adults with learning disabilities
- Patients with a primary diagnosis of substance abuse
- Patients with organic brain disorders or progressive neurological disease.

Health care setting

The recommendations apply to health care professionals who are involved in the short-term (72 hours) management of disturbed/violent behaviour across the range of adult psychiatric in-patient settings and emergency departments in the UK.

Interventions and related topics covered

- Environment and alarm systems
- Prediction: antecedents, warning signs and risk assessment
- Training
- Working with service users
- De-escalation techniques
- Observation
- Physical interventions
- Seclusion
- Rapid tranquillisation
- Post-incident review
- Emergency departments
- Searching.

Interventions not covered

- Interventions for the short-term management of disturbed/violent behaviour in community psychiatric settings, non-psychiatric in-patient settings and learning disability settings.
- Interventions for the long-term management of disturbed/violent behaviour in psychiatric settings.

Audit support

The guideline provides audit criteria for the key priorities drawn up in conjunction with the Royal College of Psychiatrists Healthcare Commission audit team. (See section 9).

5.4 Guideline Development Group

The guideline recommendations were developed by a multidisciplinary and lay Guideline Development Group (GDG), convened by the NICE-funded National

Collaborating Centre for Nursing and Supportive Care (NCC-NSC), with membership approved by NICE. Members include representatives from:

- service user groups
- nursing
- field of psychiatric medicine and emergency medicine
- allied health
- pharmacy
- legal training
- training
- researchers
- staff from the NCC-NSC.

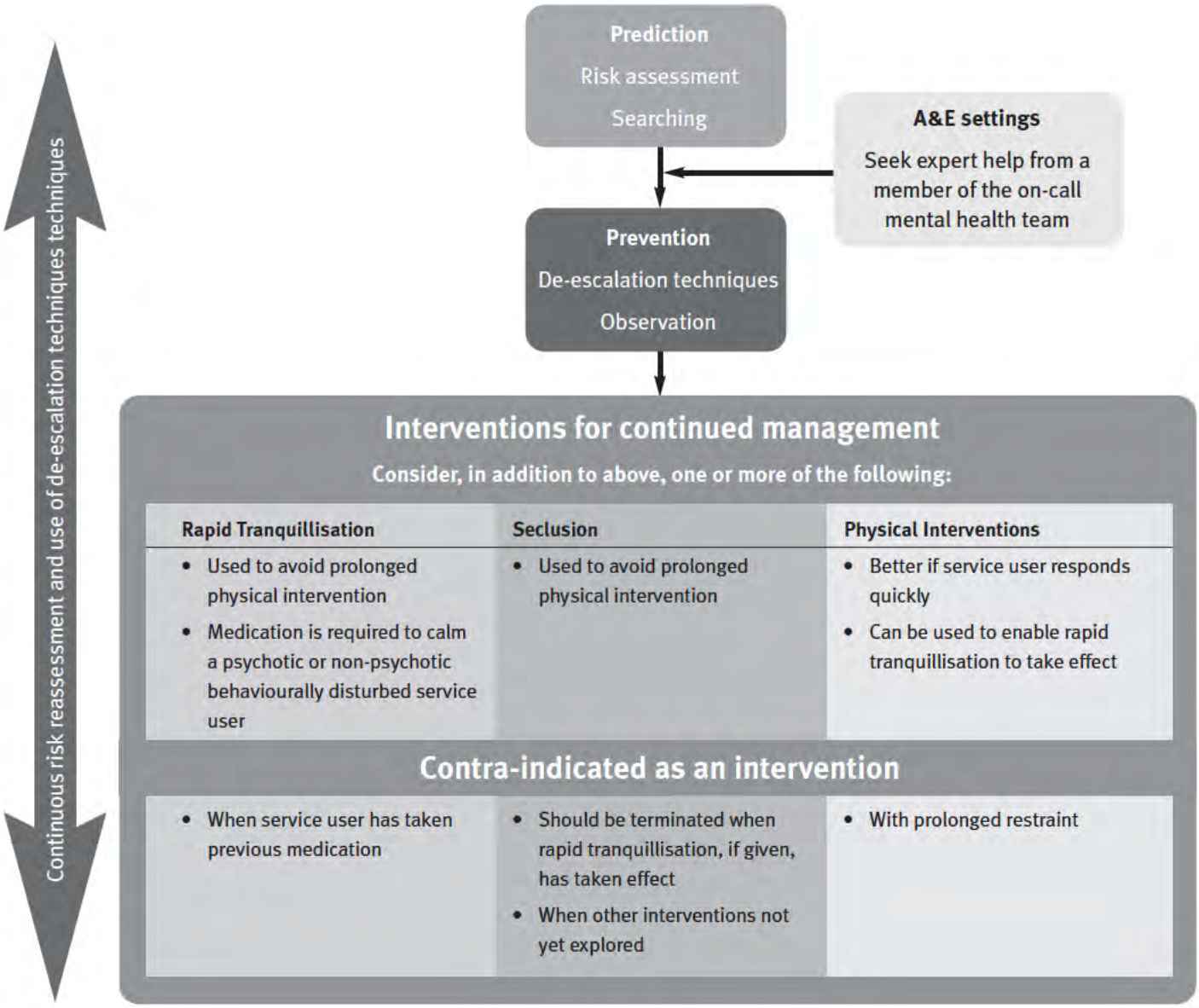
A list of GDG members is attached (Appendix 1).

The GDG met 15 times between May 2002 and November 2004.

All members of the GDG were required to make formal declarations of interest at the outset, and at the beginning of each GDG meeting. This information was recorded in the meeting minutes and kept on file at the NCC-NSC.

6 Care pathway for the short-term management of disturbed/violent behaviour

Overview algorithm for the short-term management of disturbed/violent behaviour



6.1 Introduction

This guideline considers the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings and emergency departments (for mental health assessments). It considers a number of interventions and related issues. Although separate from one another, each of the interventions and related issues described here form part of an integrated pathway of care. It is hoped that the order in which these topics are discussed will facilitate this pathway of care.

The algorithm on page 19 represents an overview of this integrated pathway of care from a starting point of predicting violence, to its prevention and if necessary to the selection of interventions for the continued management of disturbed/violent behaviour. Emphasis is placed on the importance of maintaining risk assessment and de-escalation techniques throughout the care pathway process. Also this guidance focuses on the importance of staff training and service user perspectives.

This full version of the guideline presents the methodology and results of the systematic reviews of the evidence on which the recommendations have been based, in conjunction with expert review and consensus techniques. The structure of this version of the guidance begins from the pretext that prevention is the most desirable management strategy for the short-term management of disturbed/violent behaviour. Firstly, the following areas are examined: the environment, organisation and alarms, and then prediction, which is sub-divided into three areas, namely: antecedents of disturbed/violent behaviour, warning signs and risk assessment. Since none of the interventions discussed in this guideline can be safely practiced without adequate training, the guideline then turns to staff training needs. This is followed by an examination of service user perspectives, and issues raised in relation to black and minority ethnic groups, gender and other related concerns, all of which staff need to be conversant with before employing the interventions described in this guideline. The guideline then turns to preventative psychosocial interventions for continued management of disturbed/violent behaviour: de-escalation techniques and observation, before examining the other interventions: physical intervention, seclusion and rapid tranquillisation. It then considers post-incident reviews. Finally the guideline considers special issues relating to the short-term management of disturbed/violent behaviour in emergency departments for those requiring mental health assessments only, and the issue of searching.

The following background information is offered to contextualise the issues addressed in the evidence reviews, the recommendations, and good practice points that follow.

6.1.1 Legal preface

This takes place within a multi-faceted legal framework. Compliance is a core measure of quality and good practice. For example, the management of disturbed/violent behaviour frequently involves interventions to which an individual does not – or cannot – consent. It is especially important that such interventions are in accordance with best practice.

Failure to act in accordance with the guideline may not only be a failure to act in accordance with best practice, but in some circumstances may have legal consequences. For example, any intervention required to manage disturbed behaviour must be a reasonable and proportionate response to the risk it seeks to address.

The service should ensure access to competent legal advice when required, in relation to the management of disturbed/violent behaviour.

The law provides the authority to respond to disturbed/violent behaviour in some circumstances, and it sets out considerations that are extremely important when service providers have to decide what action they may take. The contribution of the law to the management of disturbed/violent behaviour should be recognised as positive and facilitative.

All those involved in the short-term management of disturbed/violent behaviour in psychiatric in-patient settings and emergency departments should:

- be familiar with, in particular:
  - the relevant sections of the Mental Health Act 1983 and its current Code of Practice
  - the principles underlying the common law doctrine of 'necessity'
  - the requirements of the relevant articles of the European Convention on Human Rights, including Article 2 (right to life) and Article 3 (the right to be free from torture or inhuman or degrading treatment or punishment), Article 5 (the right to liberty and security of person save in prescribed cases) and Article 8 (the right to respect for private and family life), and the principle of 'proportionality'
  - the Health and Safety at Work Act 1974, which place duties on both employers and employees, and applies to the risk of violence from patients and the public
  - the Management of Health and Safety at Work Regulations 1992, which places specific duties on the employer to ensure suitable arrangements for the effective planning, organisation, control, maintenance and review of health and safety (these

duties include ensuring that the risk assessments are undertaken and implemented)

- receive regular training on the legal aspects of the management of disturbed/violent behaviour
- ensure that a comprehensive record is made of any intervention necessary to manage an individual's disturbed/violent behaviour, including full documentation of the reason for any clinical decision
- ensure or contribute to ensuring that all aspects of the management of disturbed/violent behaviour are monitored on a regular basis, and that any consequential remedial action is drawn to the attention of those responsible for implementing it
- be aware of the obligations owed to a service user while their disturbed/violent behaviour is being managed, and of parallel obligations to other service users affected by the disturbed/violent behaviour, to members of staff, and to any visitors
- ensure or contribute to ensuring that any service user who has exhibited disturbed/violent behaviour should not be the subject of punitive action by those charged with providing them with care and treatment, and that where the disturbed/violent behaviour is thought to warrant criminal sanction, it is drawn to the attention of the proper authority.

6.2 Prevention

6.2.1 Environment and alarm systems

Environmental factors are believed to be important determinants of disturbed/violent behaviour in psychiatric in-patient settings. A therapeutic environment is one that allows individuals to enjoy safety and security, privacy, dignity, choice and independence, without compromising the clinical objectives of the service. Comfort, noise control, light, colour and access to space will all have an impact on the well-being of both staff and service users. However, to date there has been very little research conducted to ascertain how the environment affects staff and service users of in-patient psychiatric settings.

The little existing research in this area has suggested that high traffic areas in in-patient units are the location of the largest number of assaults. Several studies have indicated that the highest proportion of assaults occur in either the day room/communal room or in the corridors (Carmel 1989; Coldwell and Naismith 1989; Lanza et al. 1993; Rosenthal et al. 1992), suggesting that assault frequency is related to either a chance encounter or that crowding (service user population density) is a significant factor. Studies of temporal variation show that most assaults occur during mealtimes and afternoons and increase in frequency until late evening (Carmel 1989; Lanza et al. 1993; Manfredini et al. 2001).

Recent national guidance documents have highlighted the need for in-patient psychiatric settings to not only be safe and secure for staff and service users, but further have recommended that the quality of design and finish should also be a prime consideration. Indeed, recent audit reports have indicated that many UK psychiatric in-patient facilities have failed to meet basic standards for a decent working or residential care environment and these wards are rated by staff, service users and visitors as noisy, hot, smelly and dirty (College Research Unit 2000; 2001).

Alarm systems are also an essential environmental safety feature in psychiatric in-patient settings. The report Violence and aggression to staff in health services, outlines three types of alarm system:

Panic buttons

Panic button systems are hardwired systems operated by strategically placed buttons installed throughout the area where a threat exists. When they are activated, an audible or visual alarm is triggered on a monitoring console. [...] panic buttons may be useful in treatment and consulting rooms, where their location is known only to members of staff (Health & Safety Commission 1997, p21).

Personal alarms

Personal alarms may be of the simple 'shriek' type or may form part of more complex systems. [...] They are most effective in situations where other people may hear them and can respond (Health & Safety Commission 1997, p21).

More complex personal alarms

More complex systems may be suitable in particularly high-risk areas. They include personal alarms linked to fixed detection systems by infra red or radio systems (Health & Safety Commission 1997, p23).

The RCPsych guideline suggested that personal and institutional alarms and communication devices are a useful means of pre-empting disturbed/violent behaviour and of protecting staff when instances of disturbed/violent behaviour arise. However, there is a paucity of research in this area.

6.2.2 Prediction: antecedents, warning signs and risk assessment

While most service users in psychiatric in-patient settings are not disturbed/violent, a small minority place health care professional and other service users at serious risk of assault. Therefore the prediction of short-term disturbed/violent behaviour is not an outcome that is measured for its own sake, but is part of a risk management plan that works towards minimising disturbed/violent behaviour and aggression, allowing both service users and staff to feel safe. As a consequence, risk

assessment must be seen as an essential intervention, possibly the single most important intervention, in the therapeutic management of disturbed/violent behaviour. Worryingly, a survey conducted in 1999 by the Standing Nursing and Midwifery Advisory Committee (SNMAC) found that risk management, which should logically follow from risk assessment, is poorly defined and practice is highly variable (SNMAC, 1999). Furthermore, they found that risk assessment was not regarded as an essential aspect of clinical practice (SNMAC, 1999). While nothing can ever be predicted with 100 per cent accuracy, prediction of short-term disturbed/violent behaviour and risk assessment is integral to the management of disturbed/violent behaviour in psychiatric in-patient healthcare settings. The recent UKCC – now the Nursing and Midwifery Council (NMC) – report stresses:

> While it is absolutely clear that violence is often unpredictable, the use of comprehensive risk assessment materials, followed by a properly developed plan is an absolute pre-requisite for the recognition, prevention, and therapeutic management of violence (*The recognition, prevention and therapeutic management of violence in mental health care* (2002) London: United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting, p15, p22).

Much of the research pre-1995 (the cut-off point for the majority of the searches underlying the original RCPsych guideline) suggested that risk factors of short-term psychiatric in-patient disturbed/violent behaviour can be identified. Key risk factors appear to include a history of disturbed/violent behaviour, young age and number of admissions. However, Stein (1998) argues that the real challenge is not their identification, but in how they should be combined and weighted. He states:

> The prediction of [...] harm to others is a complex and unreliable synthesis of observed past behaviour (both inside and outside of hospital [...]). The key predictors are well understood but there is much less agreement about how they should be weighed [...]

Therefore the issue that faces mental health care professionals is how the best predictive validity can be attained. Three main approaches have been adopted:

- the clinical approach ('first generation')
- the actuarial approach ('second generation'), which includes actuarial tools or checklists
- structured clinical judgement ('third generation').

Most of the literature prior to 1995 suggests that clinical judgement has poor positive predictive validity of around 33 per cent (Doyle and Dolan 2002). Therefore a 'second generation' of risk assessment studies adopted actuarial measures, in an attempt to raise the positive predictive validity of short-term psychiatric in-patient disturbed/violent behaviour. This actuarial approach depends on 'assessors reaching judgements based on statistical information according to fixed and explicit rules' (Doyle and Dolan 2002). Actuarial checklists have been created to enhance this process. Both the use of checklists and this general approach have been suggested to improve predictive validity (Doyle and Dolan 2002). However, there are noticeable disadvantages to this approach, in particular the tendency it generates to focus on static factors, such as history of disturbed/violent behaviour, demographic information and diagnosis, without taking individual service user needs into consideration.

Most recently, it has been suggested that prediction needs to be carefully slotted into a more holistic approach, which places emphasis on the empirical or static factors isolated by the actuarial approach, whilst combining it with clinicians' judgements. This 'third generation' approach, described by Doyle and Dolan (2002) as 'structured clinical judgement' has the advantage of placing emphasis on the service user as an individual and allowing risk to be seen as a moving rather than static entity, so that stage of disease, and any fluctuations in personal and environment factors are taken into consideration. Such an approach seems to mirror the objectives of the UKCC report, where it states that:

> The assessment of risk is an essential part of the care and treatment of all patients. It is most important to stress that risk levels change. Therefore, [...] the nature and level of risk should be subject to regular review (*The recognition, prevention and therapeutic management of violence in mental health care* (2002) London: United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting, p15, p22).

6.3 Training

There are currently no formal regulations governing training for the short-term management of disturbed/violent behaviour in the UK. There are more than 700 training providers in the UK. The David Bennett Inquiry (2004) recommended that a national approach to training should be set up in the next year. The National Institute for Mental Health in England (NIMHE) is currently mapping the various training packages on offer in the UK and, in conjunction with the NHS Security and Management Service (SMS), is drawing up a core training curriculum for the UK and setting up an accreditation scheme for trainers.

At present, very few of the training programmes are based

on evidence of either the effectiveness of training or the benefits perceived by staff and/or service users. As Leadbetters and Perkin (2002) states:

> The assumption that training is the key element in reducing risk and increasing safety is common [...] Such simplistic populist assumptions support quick-fix organisational solutions [...] and are challenged by conclusions from emergent research across the human services (Leadbetter and Perkins 2002, p20-21).

As training is expensive, it is necessary that services are able to measure its benefits. Without such an evidence base, there is a danger that training that is beneficial and possibly life-saving will not be sought or offered.

6.4 Working with service users

6.4.1 Service user perspectives

In recent years a great deal has been written within guidance material on the need to involve service users in their care. One of the guiding principles of the National Service Framework (NSF) on mental health is to involve service users and their carers in the planning and delivery of care (Mental Health National Service Framework 1999). This principle is echoed by the Department of Health, which argues that:

> In order to create a genuinely patient-centred service several processes should be created to enable users to contribute to the design and delivery of care. The aim is to promote a non-judgemental, non-patronising, collaborative approach to care (Department of Health, Mental health policy implementation guide 2002, p14).

The UKCC has laid out a number of principles that they believe need to be met in order to fulfil such aims in relation to adult service users in psychiatric in-patient settings. It argues that:

- The prevention and management of disturbed/violent behaviour should primarily be viewed as an occupational problem, requiring a cohesive, multi-faceted organisational approach. The safety and homeliness of clinical areas, the quality of life in clinical areas and the nature of staff interventions with patients and the assessment of the needs of patients and their clinical management are at least as important in this regard as training in and use of any specific intervention strategies. The importance of these factors needs to be recognised and emphasised in training and practice (*The recognition, prevention and therapeutic management of violence in mental health care* 2002).
- Service users, their advocates, and their carers should be involved in reviews of policies, and their contribution to the planning and provision of training should be seen as essential. The inquiry into the death of David Bennett highlighted once more the need to consider race, culture, and ethnicity in all areas of policy, practice and training. The input by service users, advocates and carers noted above must be incorporated into these perspectives (*The recognition, prevention and therapeutic management of violence in mental health care* 2002).

6.4.2 Minority ethnic groups

The David Bennett Inquiry (2004) highlighted the importance of considering the needs of black and minority ethnic groups when managing disturbed/violent behaviour in the short-term. For the purpose of this guideline, the following definition of minority ethnic group has been adopted:

> **Minority ethnic group:** A group which is numerically inferior to the rest of the population in a state, and in a non-dominant position, whose members possess ethnic, religious or linguistic characteristics which differ from those of the rest of the population and who, if only implicitly, maintain a sense of solidarity towards preserving their culture, traditions, religion or language. (F. Capotorti (1985) 'Minorities', in Bernhardt R et al. (editors) *Encyclopedia of public international law.* Amsterdam: Elsevier, vol.8, p.385.)

The importance of this area is widely recognised by health care professionals (Fernando 1998) and has recently been highlighted by a number of high profile inquiries. The most recent of which is the inquiry into the death of David 'Rocky' Bennett, an African Caribbean service user who died whilst being restrained on a secure unit.

The literature, around mental health and minority ethnic groups, highlights particular concerns relating to black and African Caribbean service users. For the purpose of this guideline the following definition of black, taken from *They look after their own, don't they?* (DH/Social Service Inspectorate 1998), has been adopted:

> **Black:** refers to those members of the ethnic minority groups who are differentiated by their skin colour or physical appearance, and may therefore feel some solidarity with one another by reason of past or current experience, but who may have many different cultural traditions and values.

For this purpose of this guideline, the following definition of African Caribbean has been adopted:

> Of or pertaining to both Africa and the Caribbean; used to designate the culture, way of life, etc or the

> characteristic style of music of those people of black African descent who are, or whose immediate forebears were, inhabitants of the Caribbean (West Indies) (Oxford English Dictionary Online).

It is maintained that black and particularly African Caribbean service users are over-represented within the mental health services in the UK, particularly in forensic settings. A variety of reasons have been advocated, including:

- prevalence of schizophrenia amongst African Caribbean service users (Ndegwa 2000)
- institutional racism (Sashidharan 2003; Department of Health 2005).

It is also suggested that recent shifts in Government policy have led to a more punitive approach within mental health services, particularly secure settings, and that young black African Caribbean men have been made to bear the burden of this altered approach (Fernando et al. 1998). Again it has been asserted that this burden reflects racial stereotyping that regards young African Caribbean men as 'big, black and dangerous' (Prins H, *Big, black and dangerous? Report of the Committee of Inquiry into the death in Broadmoor hospital of Orville Blackwood and a Review of the deaths of two other Afro-Caribbean patients* 1993). It is suggested that this stereotyping affects the treatment of African Caribbean service users within many mental health settings. (Littlewood and Lipsedge 1997).

As a result of the concerns relating to the treatment of African Caribbean service users, the review in this guideline has given particular attention to the short-term management of the disturbed/violent behaviour of African Caribbean service users in psychiatric in-patient settings. However, it has not done so to the exclusion of other ethnic groups.

6.4.3 Gender

As far as possible, gender needs must also be taken into consideration in the short-term management of disturbed/violent behaviour in psychiatric in-patient settings. For the purpose of this guideline the following definition of gender has been adopted:

> Gender describes those characteristics of women and men that are socially determined, as opposed to 'sex', which is biologically determined. (*Mainstreaming gender and women's mental health implementation guide* 2003).

While general differences between men and women in terms of mental health have been recognised, (for example, women are more likely to self-harm and suffer from depression, and men more likely to experience earlier onset and more disabling courses of schizophrenia), a recent report by the Department of Health, *The women and mental health strategy* (2003) stresses that these differences should be used to inform our understanding of an individual, rather an obscure their individuality. A further report reinforced the message that women's mental health needs to be conducted in relation to an individual woman's experiences, beliefs and struggles, as well as her ethnic group, age and sexual preferences (*Good practices in mental health* 1996).

In terms of managing disturbed/violent behaviour in psychiatric in-patient settings, the main concern raised in *The women and mental health strategy* has been to identify gender specific needs, such as single-sex facilities, and to ensure that both male and female service users feel safe, listened to and involved in identifying and meeting gender related needs (*Mainstreaming gender and women's mental health implementation guide* 2003).

6.4.4 Other special concerns

This evidence review focuses specifically on disabilities, other than learning disabilities (excluded from this guideline), and aims to consider the effects of sensory impairment. It has been noted that service users with such sensory impairments are particularly vulnerable when managed using the interventions discussed in this guideline. One such example is the restraining of a deaf service user's hands, thereby preventing them from communicating.

Very little has been written on the needs of service users with a disability in relation to the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

6.5 Psychosocial intervention

6.5.1 De-escalation techniques

De-escalation (also referred to as 'defusing' or 'talk-down') involves the use of various psychosocial short-term techniques aimed at calming disruptive behaviour and preventing disturbed/violent behaviour from occurring. Every effort is made to avoid confrontation. This can include talking to the service user, often known as verbal de-escalation, moving service users to a less confrontational area, or making use of a specially designated space for de-escalation. Stevenson and Otto (1998) offer the following definition of verbal de-escalation:

> What is verbal de-escalation? A nurse might describe it as "talking the patient down," but it is actually a complex, interactive process in which a patient is redirected towards a calmer personal space.

There are competing theoretical approaches to de-escalation, including verbal de-escalation. Some approaches make use of communication theory (for example, Paterson and Leadbetter 1997), others of situational analysis (Rix 2001). All approaches emphasise the need to observe for signs and symptoms of anger and agitation, approaching the person in a calm controlled manner, giving choices and maintaining the service users dignity. Some approaches suggest mirroring the patient's mood. De-escalation techniques also emphasise the therapeutic use of the nurse's own personality and relationship with the person (use of self) as one method to interact therapeutically with the patient.

In all approaches to de-escalation, stress is laid on the need for training and self-awareness. For example, Rix (2001) comments:

> Becoming competent at de-escalation is in itself a sophisticated activity requiring much more than just a theoretical understanding of aggression. It cannot be considered in purely academic terms. The practitioner must undertake a developmental process, resulting in highly evolved self-awareness enabling the skills of de-escalation to become instinctive.

However, a recent report notes that, despite the emphasis that is often placed on the importance of de-escalation, little research has been carried out into the effectiveness of any given approach, leaving nurses to contend with conflicting advice and theories:

> Unfortunately, there has been little research conducted into the effectiveness of different approaches to de-escalation, or, for that matter, into the effectiveness of training in any given approach. As Paterson and Leadbetter (1999) note, there is no standard approach to de-escalation. At the same time, practitioners may be faced with contradictory advice provided in the context of differing theoretical explanations for the violent event (National Institute for Social Work Research Unit 2000, p24).

6.5.2 Observation

Although much of the research carried out on observation has been undertaken in relation to the management of suicide and self-harm, the UKCC report (Feb 2002), which focuses on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings, argues that these principles form a good basis for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings. The UKCC report (Feb 2002) recommends that the principles of observation found in *Addressing acute concerns* (1999) – a report that focuses on the management of suicide and self-harm – should be adopted nationwide.

> Although the focus of the work on observation in *Addressing acute concerns* was on suicide and self-harm, there are obvious implications for the use of observation in recognising the possibility of violence occurring and for preventing interventions (*The recognition, prevention and therapeutic management of violence in mental health care* (2002) London: United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting, p24).
>
> […] observation (carried out as set out in Addressing acute concerns) should underpin all other strategies (*The recognition, prevention and therapeutic management of violence in mental health care* (2002) London: United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting, p24).

Addressing acute concerns defines observation as "'regarding the patient attentively' while minimising the extent to which they feel that they are under surveillance" (p2). The UKCC report (Feb 2002), regards observation as a 'core nursing skill' and 'arguably a primary intervention in the recognition, prevention and therapeutic management of violence' (*The recognition, prevention and therapeutic management of violence in mental health care* 2002) It suggests that observation must be a two-way relationship, established between a service user and a nurse, which is meaningful, grounded in trust, and therapeutic for the service user. This relationship is considered to be the basis on which risk assessment, violence management and a programme of supportive observation can then be undertaken (*The recognition, prevention and therapeutic management of violence in mental health care* 2002).

Addressing acute concerns outlines four levels of observation – general observation, intermittent observation, within eyesight, within arms length – which, with slight modification, have been adopted within this current guideline. Other reports and studies detail a variety of other terms and levels of observation. The UKCC report, *The recognition, prevention and therapeutic management of violence in mental health care* (2002) argues that there is a need for the terminology to be standardised, quoting the following passage from *Addressing acute concerns*:

> Research on the nursing practice of observing patients who are at risk from self harm, or of causing harm to others, shows that there is no consistency in the definition of terms, principles or processes. In some trusts there is no written policy

> for observation. Trusts vary greatly in the indications for observation and in the personnel that are thought appropriate to perform it. Where policies and procedures do meet reasonable standards, they may not be implemented properly (*Addressing acute concerns* 1999, p15).

Whilst the UKCC report, *The recognition, prevention and therapeutic management of violence in mental health care* (2002) has stressed the value of observation, *Addressing acute concerns* suggests that both nurses and service users have found this a difficult intervention with many nurses considering it custodial and lacking in therapeutic value (*Addressing acute concerns* 1999).

6.6 Other interventions

6.6.1 Physical interventions

In the UK the physical intervention primarily used in the short-term management of disturbed/violent behaviour is manual holding, rather than the use of mechanical devices such as belts, body vests or handcuffs. These devices are rarely and only used in exceptional circumstances, usually within high security settings. Physical intervention is predominantly described in the literature as restraint. In this guideline, this terminology is avoided because of its association with particular techniques, associated with control and restraint (C&R) and its various modifications. C&R was originally developed in 1981 for prison staff and was taken up by the special hospitals in the mid 1980s. It is still widely used in the NHS, although modifications have been developed to make these techniques more appropriate to the therapeutic care of service users – for instance, C&R general services, which modifies uses of pain as a restraint technique (Wright 1999). Although still widely used, we believe that the association of the term 'restraint' with this approach is unhelpful, as a wide range of physical interventions are now currently employed, many very different from C&R or its modifications, such as MAPA, which makes use of therapeutic holding.

The use of pain compliance as a method of managing violent behaviour is controversial amongst health care professionals and service providers. Although practice currently continues in some services, the recommendations in this guideline severely restrict its use for rescue purposes only (see Section 8, para 1.8). For the purpose of this guideline, physical intervention is defined as:

> A skilled hands-on method of physical restraint involving trained designated health care professionals to prevent individuals from harming themselves, endangering others or seriously compromising the therapeutic environment. Its purpose is to safely immobilise the individual concerned.

The current Code of Practice to the Mental Health Act 1983 states that physical intervention should be a last resort:

> Physical restraint should be a last resort, only being used in an emergency where there appears to be a real possibility of significant harm if withheld. It must be of the minimum degree necessary to prevent harm and be reasonable in the circumstances. (18.10-18.11)

There appears to be a dearth of knowledge about current practice. The literature review undertaken for the UKCC report in 2002, found 'no high quality studies that evaluated either the use of restraint or of seclusion in those with mental illness' (*The recognition, prevention and therapeutic management of violence in mental health care* 2002) The rate of physical interventions per annum in the UK is currently unknown. At present the National Institute for Mental Health in England (NIMHE) is compiling a register of all the techniques used in the UK.

6.6.1.1 Staff injury

A significant issue relating to the use of physical interventions is the possibility of injury to staff or service users. A US study in a maximum security forensic hospital found costs incurred in relation to staff injury from violent incidents accounted for 2 per cent of the hospital budget; 45 per cent of injuries were sustained during physical interventions (Hillbrand et al. 1996).

6.6.1.2 Sudden death

Sudden death can occur when physical intervention is used, although this is a rare event. The David Bennett Inquiry drew attention to the need for a central agency to record physical intervention-related deaths in the UK. The national reporting and learning system is a non-mandatory system set up by The National Patients Safety Agency (NPSA) which records anonymised data on sudden death in in-patient settings. The confidential inquiry has also now extended its recording of homicides and suicides to cover all sudden and unexplained deaths involving mental health service users.

6.6.2 Seclusion

Seclusion is the formal placing of a service user in a specially designated room for the short-term management of disturbed/violent behaviour. While it is recognised that this intervention is unpopular with service users, it is sometimes the preferred course of action to prevent prolonged physical intervention where rapid tranquillisation is contra-indicated or when service users have indicated a preference for it in advance directives.

The RCPsych Council Report (41) argues that the definition of seclusion needs to be broad to allow for the

seclusion room door being open, closed but unlocked or locked. Therefore, for the purpose of this guideline, the following definition of seclusion has been taken from the Code of Practice:

> Seclusion is the supervised confinement of a patient in a room, which may be locked to protect others from significant harm. Its sole aim is to contain severely disturbed behaviour, which is likely to cause harm to others. Seclusion should be used as a last resort; for the shortest possible time. Seclusion should not be used as a punishment or threat; as part of a treatment programme; because of shortage of staff; where there is any risk of suicide or self-harm. Seclusion of an informal patient should be taken as an indicator of the need to consider formal detention.

Seclusion must be differentiated from asking a service user to go to a designated room for the purpose of calming down. The latter is a de-escalation technique and the seclusion room should not routinely be used for this purpose. Seclusion, if chosen, is not viewed as a therapeutic intervention. It simply allows for a period of calming in the service user and should always be managed in a designated room for seclusion, separating the service user from other service users and placing them in a positive milieu (Cashin 1996).

6.6.3 Rapid tranquillisation

6.6.3.1 Definitions

Rapid tranquillisation (also called urgent sedation): the use of medication to calm/lightly sedate the service user and reduce the risk to self and/or others. The aim is to achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, whilst allowing comprehension and response to spoken messages throughout.

Calming: a reduction of anxiety/agitation.

Light sedation: a state of rest and reduction of psychological activity, but verbal contact is maintained.

Deep sedation: a reduction of consciousness and motor and sensory activity, where verbal contact is progressively lost.

Anaesthetised: a state of narcosis (unconsciousness), analgesia (lack of awareness of pain) and muscle relaxation. It is one stage beyond deep sedation. It implies loss of airway control and protective reflexes, and requires the constant attention of trained personnel to keep the patient safe. There is normally no verbal contact.

Sleep: a condition of body and mind such as that which normally recurs for several hours every night, in which the nervous system is inactive, the eyes closed, the postural muscles relaxed, and consciousness practically suspended.

Of all these terms, sleep is the one with the greatest terminological inexactitude. For the purposes of this guideline we have adopted this definition from the Oxford English Dictionary. However, because of its inexactitude, we have generally avoided using this term.

6.6.3.2 Rapid tranquillisation

Rapid tranquillisation – or urgent sedation (Broadstock 2001) as it is sometimes called – is used in situations requiring the rapid control of agitation, aggression or excitement. In the UK, deep sedation/sleep is not considered a desirable endpoint for rapid tranquillisation. A state of calm is preferred, with the service user remaining conscious where possible.

For the purposes of this guideline, rapid tranquillisation describes the use of medication to control severe mental and behavioural disturbance, including aggression associated with the mental illness of schizophrenia, mania and other psychiatric conditions. It is used when other less coercive techniques of calming a service user, such as verbal de-escalation or intensive nursing techniques, have failed. It usually involves the administration of medication over a time-limited period of 30-60 minutes, in order to produce a state of calm/light sedation. Other medication regimes would be administered over longer periods of time and not time limited.

Rapid tranquillisation differs from rapid neuroleptisation, which is the practice of giving a high dose antipsychotic at the beginning of ongoing treatment with the aim of rapidly stabilising symptoms. Rapid neuroleptisation has been found to be hazardous and no more effective than standard treatment (Royal College of Psychiatrists 1997).

The medications used for rapid tranquillisation should ideally have a low level of side effects and rapid onset of action. At present, there is no worldwide formal agreement on which drugs should be used as first line for rapid tranquillisation. As a consequence, there is a wide variation in the type of medications used in rapid tranquillisation throughout the world. This has been compounded by changes in the stated aims of rapid tranquillisation over recent years – that is to calm rather than put to sleep (Cunnane 1994; Pereira et al. 2003).

There is also little agreement about the doses to be used. Rapid tranquillisation is not a recognised clinical procedure in the British National Formulary (BNF). Although the use of high dose antipsychotics has been criticised by several inquiries (Royal College of Psychiatrists 1995), expert clinician opinion may from time to time support prescribing outside the dose limits set by the BNF or SPC (RCPsych draft report on

antipsychotic drugs). The BNF has been formally consulted in the preparation of these guidelines and will carefully consider the findings to decide whether to incorporate any of the recommendations into its guidance at a future date, following the publication of this guideline.

This lack of standardisation also reflects the fact that very few randomised controlled trials have been conducted that examine the efficacy of medicines used for the purpose of rapid tranquillisation. Their use is often based purely on clinical experience. Overall there is a lack of high quality clinical trial evidence surrounding the drugs used for rapid tranquillisation and their safety, a point which has been noted in a number of recently conducted systematic reviews (Cure and Carpenter 2002; Carpenter 2002; Carpenter and Berk 2002). Clinical trials that examine the effectiveness and safety of drugs used for rapid tranquillisation encounter a number of ethical issues. Service users recruited into these clinical trials should ideally represent those with highly agitated states in circumstances similar to those encountered in normal clinical practice. Unfortunately such service users are normally unable to give consent, due to their highly agitated states.

6.6.3.3 Route of administration

It is generally accepted that oral formulations should be offered in the first instance. If these are refused or are inappropriate, medication should be administered parenterally. This involves administration by intramuscular (i/m) injection or, in exceptional circumstances, intravenously. The latter should only be done with extreme caution and with appropriate supervision and monitoring, as clarified by the recommendations in this guideline.

6.6.3.4 Drugs used for rapid tranquillisation

The classes of drugs commonly used in the UK for rapid tranquillisation are benzodiazepines and antipsychotics.

6.6.3.4.1 **Benzodiazepines**

Benzodiazepines are frequently used as first line treatments for rapid tranquillisation. Some, such as diazepam, have erratic and slow absorption intramuscularly and are associated with prolonged sedation following repeated doses. Lorazepam has a shorter elimination half-life than many other benzodiazepines, which limits the risk of excessive sedation due to the cumulative effects of the drug. For this reason it is often chosen as the first drug of choice in rapid tranquillisation. There is a risk of respiratory depression when benzodiazepines are given in high doses or when used in combination with other hypnosedatives, including alcohol and some illicit drugs (Broadstock 2001).

6.6.3.4.2 **Antipsychotics**

Antipsychotics are commonly used as second line treatments for rapid tranquillisation and, in some cases, as first line treatments if benzodiazepines are contraindicated or have proven ineffective in the past. Older antipsychotics (commonly called conventional antipsychotics) have a greater propensity to cause extrapyramidal side effects than the newer (commonly called atypical) antipsychotics.

6.6.3.4.3 **Combination of drugs**

Combinations of a benzodiazepine, an antipsychotic, and other drugs may be given either deliberately or inadvertently in rapid tranquillisation. It has become common practice to co-administer both a benzodiazepine and antipsychotic together. There is no evidence of a higher incidence of adverse effects with this combination and it is considered to have advantages, such as allowing a lower dose of the antipsychotic to be given when administered with a benzodiazepine (Beer et al. 2001). It has also been noted that there are other problems with combinations such as olanzapine and lorazepam, which will addressed in the recommendations.

In pharmaceutical practice it is stated that if combinations of intramuscular (i/m) injections are used they should not be mixed together in the same syringe.

Users may also inadvertently receive combinations of drugs through poor control of PRN prescribing. The practice of routinely prescribing a wide range of drugs for PRN use, without clear guidelines or preference, may lead to users inadvertently receiving combinations of drugs.

6.6.3.4.4 **High doses**

Sometimes it is necessary to knowingly exceed the BNF upper dose limits and knowingly use drugs outside of their marketing authorisation (off-label). In such circumstances, clinicians are referred to the recommendations of the Royal College of Psychiatrists' consensus statement of the use of high dose antipsychotic medication. For the purpose of rapid tranquillisation, care must be taken to ensure that high doses do not accidentally occur through the use of PRN medication given in combination with regular medication. If PRN medication is given, it is important to allow time for the drug to work before giving further doses by either oral or intramuscular means. In addition, clinicians must bear in mind that the plasma concentration of the antipsychotic is not only affected by the total dose, but also the route of administration. Clinicians should also be aware that absorption from intramuscular administration (i/m) can occur far more rapidly when a service user is agitated, excited or physically overactive (Keck 1991).

6.6.3.4.5 **Dangers associated with antipsychotics**

There are two main areas of concern with the use of antipsychotics for rapid tranquillisation – extrapyramidal effects and cardiac effects.

Extrapyramidal side effects are mostly associated with conventional antipsychotics. Side effects such as dystonia and occulogyric crisis are very unpleasant for the service user and may adversely affect their future preparedness to access either treatment or services. Fortunately the side effects can mostly be rapidly reversed by administration of antimuscarinic drugs such as procyclidine. The availability of atypical antipsychotic drugs provides an opportunity to avoid these side effects.

The second main issue of concern relevant to rapid tranquillisation is the rare occurrence of drug induced arrhythmias and sudden cardiac death. This happens because of the manner in which some antipsychotic drugs affect cardiac ventricular repolarisation in susceptible individuals. The main measure of ventricular repolarisation is the QT interval – the time from the onset of ventricular depolarisation to complete repolarisation. A number of cardiac, metabolic and other factors, such as physical exertion and stress, impact on the QT interval. Where the service user has a prolonged QT interval, they may be at increased risk of cardiac arrhythmias, particularly torsade de pointes. The cardiac QT interval usually measured as the QTc interval (QT corrected for heart rate) is a useful if somewhat imprecise indicator of the risk of cardiac events. This prolongation can be congenital or acquired however, service users who already have prolonged QT repolarisation are at risk of developing arrhythmia when given drugs which further lengthen the QT interval. Service users who have had Torsade de Pointes are at an increased risk, even where this was caused by a different drug. Service users with left ventricular dysfunction or hypertrophy are also at an increased risk as are service users with liver disease (Day et al. 1993). Diuretics also appear to increase risk. Women who have a longer QT interval on average than men appear to be at an increased risk of Torsade de Pointes (Rautaharju et al. 1992; Makkar et al. 1993).

An issue that further complicates the relationship between antipsychotics, ventricular tachycardia and sudden cardiac death is that service users are known to be a high-risk group for cardiovascular death (Hensen et al. 1997). However, it is known that QT prolongation and resulting arrhythmias are drug concentration related (Drici et al. 1998; Warner et al. 1996; Reilly 2000; Ray et al. 2001). It is also important to note that several case reports of sudden death involved agitated service users who were subject only to physical interventions. As discussed above, physical interventions have been linked to increased risk of arrhythmia, as has the use of illicit drugs, such as ecstasy (Drake and Broadhurst 1996) and cocaine (Pereira 1997).

6.6.3.5 Acute manic or mixed episodes in bipolar affective disorder

For service users with bipolar affective disorder the British Association of Psychopharmacology (BAP) guidelines should be taken into consideration.

6.6.3.6 PRN medication

Although only rapid tranquillisation is mentioned directly in the scope, PRN medication pro re nata (as needed) medication is also sometimes used in a similar way to rapid tranquillisation in psychiatric in-patient settings. A recent editorial suggests that very little has been written on the effectiveness of PRN medication as a short-term measure for managing disturbed/violent behaviour and that those studies that do consider this issue contain serious flaws (Ray and Meador 2002).

6.6.3.7 Service user views

Service user satisfaction with rapid tranquillisation was rarely, if ever, measured as a part of the few existing clinical trials.

6.7 Emergency departments

This guideline also considers the short-term management of disturbed/violent behaviour for adults with psychiatric illness who present in emergency departments for mental health assessment, immediately prior to admission to an adult psychiatric in-patient setting.

All the interventions and related topics (excluding environment, observation and seclusion) are relevant to emergency departments. However, emergency settings sometimes have special requirements in addition to those addressed in psychiatric in-patient settings. These requirements are considered in the specific recommendations in Section 8.

7 Methods and findings

7.1 Summary of development process

The methods used to develop this guideline are based on those outlined by Eccles and Mason (2001) and in the NICE technical manual (www.nice.org.uk).

The following sources of the evidence were used to inform the guideline:

- Cochrane reviews: Salias and Fenton (2002), Carpenter and Berk (2002), Cure and Carpenter (2002), Aleman and Kahn (2001)
- The Royal College of Psychiatrists' *Clinical guidelines on the prevention and management of imminent violence* (see agree tool in Appendix 11 and summary of St George's report in Appendix 12)
- Other recent guidelines and reports (see Section 14)
- Reviews of assessment processes, tools, tests and instruments for identifying those at risk (NCC-NSC)
- Reviews of the interventions currently used in the UK for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings (NCC-NSC)
- Reviews of studies examining patients' views and experiences of the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings (NCC-NSC)
- Reviews of the evidence on costs and economic evaluations (ScHARR)
- Reviews on other topics and areas related to the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings in the UK (NCC-NSC)
- The minority ethnic groups section was further informed by *Breaking the circles of fear*, Sainsbury's Centre for Mental Health (2002) – see Appendix 13 for appraisal with agree tool – and focus groups, run through black service user organisations and with relevant health care professionals, organised by the NCC-NSC (see Appendix 14).

The stages used to develop this guideline were as follows:

- Develop scope of guideline
- Convene multidisciplinary GDG
- Review submission of evidence from stakeholders
- Develop review questions
- Identify sources of evidence
- Retrieve potential evidence
- Evaluate potential evidence
- Undertake systematic reviews of the evidence
- Extract relevant data from studies meeting methodological and clinical criteria
- Interpret each paper, taking into account the results including, where reported, the beneficial and adverse effects of the interventions; costs and acceptability to service users; level of evidence; quality of studies; size; precision of effect and relevance; and generalisability of included studies to the scope of the guideline
- Prepare evidence reviews and tables which summarise and grade the body of evidence
- Draw up evidence statements
- Formulate conclusions about the body of available evidence, based on the evidence reviews by taking into account the factors above
- Trawl any recent and relevant guidance literature in areas where evidence is weak or lacking and present this to the GDG for comment
- Send out evidence reviews for peer review
- Agree final recommendations by formal consensus voting and apply recommendation gradings
- Submit first drafts (short version and full versions) of guidelines for feedback from NICE registered stakeholders
- Consideration by GDG of stakeholders comments following first stage consultation
- Submit final drafts of all guideline versions (including Information for the public version and quick reference guide with algorithms) to NICE for second stage of consultation. The Guideline Review Panel (GRP) also comment at this stage
- Consideration by GDG of stakeholders and GRP's comments
- Final copy of the short form version is submitted to NICE for sign off, prior to publication of all edited versions.

7.2 Key clinical questions

The GDG identified the key clinical questions that were raised by the scope. Each of these questions related to an

intervention or area addressed in the scope.

An algorithm detailing how the scope was translated into clinical questions can be found in Appendix 3.

Each of the clinical questions is outlined in the relevant methods section of this guideline.

7.3 Review methods

7.3.1 Search strategies

Search strategies were devised to identify the best available evidence for the interventions and related topics discussed in the guideline (see Appendix 4). It was recognised very early within the process that, in most instances, this evidence would not constitute meta-analyses, systematic reviews or randomised controlled trials (RCTs). Therefore searches were not limited to these study designs.

Where little evidence was available, studies were included in related areas, from which evidence could be extrapolated.

Searches were not limited to English language citations. Relevant European foreign language papers were translated. Unpublished and published papers were included.

The search strategies were structured as follows:

- an overarching strategy for interventions – covering environment, prediction, de-escalation, observation, physical interventions, seclusion and rapid tranquillisation, along with service user and staff perspectives on these interventions – across a wide range of databases
- a search of additional databases to identify guidance and reports not indexed in databases searched
- a topic specific search strategy on major databases – see Appendix 4 for more details.

Hand searching was not undertaken, following NICE advice that exhaustive searching on every guideline review topic is not practical or efficient (Mason 2002).

Reference lists of relevant order papers were checked for articles of potential relevance.

Each evidence review was sent for peer review, prior to the first consultation phase, in an attempt to identify any further relevant papers. GDG members were invited to nominate any relevant research that may have been missed.

The databases searched, logs of results and all search strategies can be found in Appendix 4. Unless otherwise stated, all searches were run from 1985-2002/3. Searches began from this date as this guideline updates the RCPsych guideline, *The management of imminent violence* (1998), which was due for review. GDG members were asked throughout out the guideline development process whether any further relevant research had been identified, post search, that might impact on the recommendations.

For each intervention and related topic evidence of effectiveness, evidence of harm and cost effectiveness information was sought.

7.3.2 Sifting and reviewing the evidence

Once articles were retrieved, the following sifting process took place:

- 1st sift: sift for material that potentially meets eligibility criteria on basis of title/abstract by two reviewers
- 2nd sift: full papers ordered that appear relevant and eligible or where relevance/eligibility not clear from abstract
- 3rd sift: full articles critically appraised and checked by one reviewer. More than 50 per cent of all articles in the guideline were then critically appraised by an independent reviewer as a quality check.

7.3.3 Data extraction

Study appraisal and methodological quality were assessed using checklists designed with assistance from the Centre for Statistics in Medicine at Oxford University. (Quality principles can be found in Appendix 10.) Data was abstracted by a single reviewer and evidence tables compiled. More than 50 per cent of all articles were then subject to a second quality assessment by a second reviewer. Any discrepancies between reviewers were resolved by discussion. Where needed, a third reviewer assisted with decisions on the inclusion or exclusion of a study.

The following were extracted where possible (the reporting of many studies sometimes lacked essential detail) and relevant:

> Author, setting, number of participants at baseline and follow-up, methods and details of baseline and outcome measures, results including summary statistics and 95 per cent confidence intervals, and comments made on methodological quality.

Masked assessment, whereby data extractors are blind to the details of the journal, authors etc., was not undertaken because there is no evidence to support the claim that this minimises bias (Cullum et al. 2003).

7.3.4 Data synthesis

All studies were put into evidence tables and summarised using a qualitative narrative approach. No quantitative

analysis was carried out for this review. Summary statistics of significance were reported in the evidence tables.

7.3.5 Appraisal of methodological quality

Very limited evidence for each of the review questions listed below was found. Therefore the resulting evidence reviews must be viewed as mapping exercises that aimed to highlight the range of research undertaken (which was often of mixed quality), in order to facilitate informed discussion by the GDG, to assist with deliberations around recommendation formulation and also to identify research gaps. Where a study was particularly weak it was excluded (see Appendix 6). It was considered particularly weak where the number of confounders and flaws were great enough to jeopardise the results. Concerns regarding the quality of individual studies are detailed in the relevant evidence table.

A large range of quality related concerns were commonly found across many of the studies included in these review. These included:

- inappropriately small sample sizes
- inter-rater reliability not always quantified where applicable
- conclusions do not always appear to be supported by a study's results
- methodologies are not always sound (that is, don't adhere to standard processes)
- designs do not always appear appropriate – sometimes this is recognised by the authors
- methods of analysis are not always clearly outlined
- under-reporting
- lack of detail about follow-up duration, losses to follow-up and drop-out rates
- descriptions of interventions are not always adequate
- description of how outcomes were measured are not always adequate or are sometimes lacking
- poor reporting.

Where the studies in a review raise other, more specific, quality concerns, these are mentioned under the evidence summary for each review.

Authors were not contacted about any of the included studies, due to time constraints and the age of many of the studies.

In areas without sufficient evidence, previous guideline material was collated to help facilitate informed discussion by the GDG.

Clinicians and service users were also invited to give presentations on areas without sufficient evidence at guideline development group meetings to facilitate discussion. They acted as experts in these capacities. They sat within the group and entered fully into discussion. However, they were not GDG members and did not have voting rights, nor were they involved in drawing up the final wording of the recommendations.

The GDG then considered the evidence statements derived from the evidence reviews and used formal consensus methods (see Section 7.7) to derive recommendations and good practice points, particularly for those areas where research evidence was lacking or weak. They drew upon their own and others' clinical expertise and experience as necessary.

7.4 Evidence grading

Once individual papers had been assessed for methodological quality and relevance in terms of the clinical questions, they were graded according to the levels of evidence currently used by NICE.

Classification of evidence:

Level of evidence	Type of evidence
1++	High quality meta-analyses, systematic review of RCTs, or RCTs with a very low risk of bias.
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias.
1-	Meta-analyses, systematic review of RCTs, or RCTs with a high risk of bias*.
2++	High quality systematic reviews of case-control or cohort studies. High quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal.
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal.
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal.*
3	Non-analytic studies (for example, case reports, case series).
4	Expert opinion, formal consensus.

*Studies with a level of evidence '-' should not be used as a basis for making a recommendation

The available evidence for each intervention and related topic was compiled into individual evidence reviews, including health economics information. A summary of all

recent reports and guidelines on the topic was also compiled. All this information was then presented to the GDG. The methods and findings from each of these reviews are outlined in Section 7.8.

7.5 Grading recommendations

The grading of recommendations involves a process of assessment in which the available evidence is interpreted in relation to the clinical questions asked. Where evidence is lacking or is not directly related to every area covered by the clinical question, the recommendation will demand some degree of consensus. For example, it is possible to have sound methodological evidence in an area that is not particularly relevant to the target audience of the guideline. When applied to the target audience, this would therefore result in a lower grade of recommendation than the evidence might initially seem to suggest, since inferences would have to be made from the available evidence that are beyond the empirical data. This will be the case where the evidence only partially covers the clinical question that the guideline sets out to answer. Where no, or insufficient evidence is available, recommendations have to be arrived at using formal consensus methods alone.

In this guideline, D grade recommendations are differentiated from good practice points (GPP), which also have little or no evidence. Both carry a D grade status, but unlike D grade recommendations, GPPs are principles of practice.

The recommendations for this guideline were graded A to D, using the current NICE approach.

A At least one meta-analysis, systematic review or RCT rated as 1++, and directly applicable to the target population, **or**
A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results.Evidence drawn from a NICE technology appraisal.

B A body of evidence including studies rated as 2++, directly applicable to the target population and demonstrating overall consistency of results, **or**
Extrapolated evidence from studies rated as 1++ or 1+.

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results, **or**
Extrapolated evidence from studies rated as 2++.

D Evidence level 3 or 4, **or**
Formal consensus.

D (GPP) A good practice point (GPP) is a recommendation for best practice based on the experience of the GDG.

The schizophrenia guideline used an older grading system that had only three grades A-C. Some recommendations that carry a C grade in the schizophrenia guideline carry a D grade in the current guideline. However, there is no difference in evidence level.

In the current guideline, good practice points, as well as D grade recommendations were arrived at using a formal consensus method.

7.6 Cost effectiveness review and analysis

7.6.1 Identification of papers

Searches were undertaken by ScHARR, alongside the clinical literature reviews, to identify relevant cost effectiveness, cost utility and cost-benefit analyses. Details of the databases searched and the search strategies can be found in Appendix 9. Titles and abstracts were sifted and relevant papers ordered by one reviewer.

7.6.2 Reviewing the evidence

Eligible papers were assessed by one reviewer using the Drummond checklist (Drummond et al. 1996). Evidence tables of the included studies were also produced by one reviewer.

7.6.3 Estimation of cost effectiveness

The scope of the guideline is broad and includes the assessment of risk, as well as the short-term management of disturbed/violent behaviour across the whole of range of adult in-patient settings. Little if any economic evidence was found for most areas of the guideline. Limited primary economic analysis was undertaken in relation to immediate life support (ILS) training. However, in many areas the evidence base was too weak to allow even limited primary economic analysis. See full details in Appendix 9.

7.7 Consensus process

Due to a dearth of good quality evidence, many of the recommendations in this guideline were arrived at solely, or in large part, by means of formal consensus methods. Three consensus meetings were held in March 2004.

A modified nominal group technique was used to finalise the recommendations and good practice points. An external facilitator was used to chair the meeting. The consensus process was facilitated by computerised voting consoles, which assured anonymity and allowed percentages to be quickly calculated. It also allowed the

GDG to view the range of responses in the form of a graph immediately voting had occurred. Consensus was set at 80 per cent, unless a significant group within the GDG all voted against a recommendation. For example, if all the psychiatrists voted against a recommendation, even though 80 per cent agreement was achieved overall, it was considered that consensus had not been reached.

Prior to voting on each recommendation and good practice point, a discussion took place and modifications were made as necessary. The wording was re-typed if necessary and then displayed on a screen so that GDG members could see the recommendation or good practice point they were voting on. If consensus was achieved, the GDG moved on to discuss the next recommendation or good practice point. However, if consensus was not achieved, the recommendation or good practice points was discussed a second time, modifications made to reflect the concerns of the GDG and another vote took place. After debate on some areas, consensus was achieved for all recommendations.

7.8. Methods for individual evidence reviews

7.8.1 Introduction

This guideline is divided into a number of interventions and related topics. For most of these areas separate literature searches were undertaken (see Appendix 4). The number of papers found, included and excluded and the details of the resulting evidence base are discussed separately for each area. Section 7.3 details the reviewing process that was common to all areas of the guideline. Where there were deviations from this process, this is highlighted in the following relevant sections.

7.8.2 Prevention

7.8.2.1 Environment

7.8.2.1.1 **Objectives**

The original RCPsych evidence base on environment was examined. The following hypothesis was used to inform search strategies:

RCPsych hypothesis

- Characteristics of the human and physical environment have powerful effects in mitigating and preventing, or exacerbating and precipitating the manifestation of violence.

After sifting and quality appraisal 17 papers were included by the RCPsych reviewer. However, the evidence base was too weak to offer support for this hypothesis.

Current guideline (update of RCPsych guideline)

Three review questions were identified by the GDG and used to inform all searches (see Appendix 4 for search strategies, databases searched and search logs). Unlike the RCPsych review, this review did not consider staff characteristics associated with an increased rate of disturbed/violent behaviour. Instead these were considered in the prediction review.

Review questions

- What factors in the physical environment of adult psychiatric in-patient settings contribute to either the promotion or reduction of disturbed/violent behaviour?
- What factors in the physical environment of psychiatric in-patient settings reduce the risks in relation to disturbed/violent behaviour?
- What are staff and service users' views about the role of the ward environment in promoting or reducing disturbed/violent behaviour in psychiatric in-patient settings?

The studies had to meet the following inclusion criteria:

7.8.2.1.2 **Selection criteria**

Types of studies

Systematic reviews through to before and after designs. Qualitative studies were also included (evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Measurement of environmental factors that may impact on the short-term management of disturbed/violent behaviour.
- Service users' and clinicians' views.

7.8.2.1.3 **Clinical evidence**

Seventy-five articles were identified, after combining the results of the main 'intervention' searches and the specific search for the 'physical environment'. Thirty-two articles were ordered. Nine of the ordered articles were not directly related to the research questions and were therefore not included for the present review. Seven of the remaining 23 articles were included in the evidence review. In addition,

seven papers from the RCPsych review were considered relevant and were included in this review. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Appraisal of methodological quality

In addition to the quality concerns mentioned in Section 7.3.5, the studies raised the following methodological concerns:

- All of the studies are largely descriptive in content and none had a controlled comparison group.
- The variation between studies in regard to the methods of data collection, outcome variables and statistical analysis make it impossible to aggregate the results.
- Overall, the methodological quality, execution and reporting of the included studies are poor.

Included studies

Three of the studies are uncontrolled before-and-after designs with one an interrupted time-series design, one a correlation study and two qualitative studies.

Three of the studies (Rauter et al. 1997; Haller et al. 1996; Velasco et al. 1996) were concerned with the effects of a cigarette-smoking ban in in-patient psychiatric settings. Two of the studies (Haller et al. 1996; Velasco et al. 1996) concluded that smoking bans on locked in-patient wards do not have an effect on increased violence by service users. Haller et al. (1996) indicated that although staff were in favour of the intervention, service users held decidedly negative feelings towards the smoking ban. There was no increase in aggressive behaviour in the outcome measures used in the study. The prospective study by Velasco et al. (1996) found the number of verbal assaults increased after implementing the ban, as did the consumption of nicotine replacement products by the service users. The authors suggest that dangerous behaviour did not follow the implementation of the smoking ban. The methodological quality of the study by Rauter et al. (1997) is insufficient to draw any reliable conclusions regarding smoking bans in psychiatric in-patient facilities.

An interrupted time-series design was used to evaluate the effects of removing the Music Television (MTV) channel from the television of a maximum-security facility (Waite et al. 1992). The analysis indicated that there was a significant reduction in aggressive behaviour following the removal of MTV from the television. Although the study is well designed and executed, the relevance of these findings to the UK context is uncertain (for example, the number of psychiatric settings in the UK where a music television station is received is unknown).

Mistral et al. (2002) conducted a qualitative study in a intensive psychiatric care environment to evaluate the effect a £70,000 ward refit, training on risk assessment and control and restraint techniques, and clarity on rules and sanctions on staff illness, staff turnover, patient aggression and the rate of seclusion. Although results were not significant, there was a positive trend for all outcomes.

Johnson et al. (1997) conducted a qualitative study to explore service users and experiences prior to an aggressive incident. A phenomenological approach was used. Five key themes emerged: lack of space; relationships; restrictions on privileges; lack of power versus feelings of powerfulness during aggressive incidents; and ineffective self-empowerment strategies.

The study by Nijman (1999) is concerned with crowding in psychiatric in-patient units and aggressive behaviour. However, the study is poorly designed and the statistical methodology is flawed. The study is essentially a correlation study. The RCPsych review also included three studies that examined the issue of crowding (Palmstierna and Wistedt 1995; Lanza et al. 1994; Palmstierna et al. 1991). These studies suggested that crowding increased the rate of violent incidents.

A further study in the RCPsych review – Hunter and Love (1996) – used an uncontrolled before and after study to evaluate the effectiveness of procedural changes at mealtime on the number of violent incidents at mealtimes. A number of suggestions were implemented: plastic utensils were substituted for silverware; music selected by the hospital music therapists was played; the dinning room, gym and courtyard were left open after meals for service users with special privileges; and food service workers were trained in therapeutic communication. This study showed a significant (40 per cent) reduction in violent incidents.

Two further studies in the RCPsych review considered staff roles. A participant observer study by Katz and Kirkland (1990) suggested that good leadership, structured staff roles and predictable routines are associated with less violence on wards. While a retrospective cohort study (James et al. 1990) suggested that high staff turnover and extensive use of agency staff was associated with an increase in violent incidents.

Another descriptive study included in the RCPsych review found that video cameras detected more, but milder, episodes of violence than nurses (Crowner et al. 1994).

None of the above studies significantly changed the findings of the RCPsych review.

Evidence statements

Level of evidence	Evidence statement
Level 4	The evidence suggests that environmental factors – such as crowding, banning smoking, high staff turnover and limit setting – affect on the incidence of disturbed/violent incidents. However, further research is needed to identify additional environmental factors.
Level 4	The evidence suggests that both staff and service users believe that environmental factors – such as banning smoking, limit setting, medication, seclusion, physical interventions and communication – affect the incidence of disturbed/violent incidents. Further research is needed to identify additional factors.

7.8.2.1.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.2.2 Alarm systems

7.8.2.2.1 **Objectives**

No specific searches on alarm systems were undertaken in the RCPsych guideline. Any papers would have been included under the environment review.

In the current guideline, three review questions were identified by the GDG and used to inform all searches (see Appendix 4 for search strategy, databases searched and search log).

Review questions

- Are personal and institutional alarms and communication devices an effective means of alerting staff to occurrences of disturbed/violent behaviour in adult psychiatric in-patient settings?
- What principles of practice are necessary to ensure the effectiveness of personal and institutional alarms and communication devices in reducing disturbed/violent behaviour in psychiatric in-patient settings?
- What are staff and service users' views about the effectiveness of alarms in reducing disturbed/violent behaviour in psychiatric in-patient settings?

7.8.2.2.2 **Selection criteria**

Types of studies

Systematic reviews through to before and after designs. Qualitative studies were also included (evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Any measures of change to management of short-term disturbed/violent behaviour or rates of disturbed/violent episodes as a result of alarms.
- Service users' and clinicians' views of alarms.

7.8.2.2.3 **Clinical evidence**

Eighty-one studies were identified in the initial sift. These were then subjected to two further sifts by two reviewers. After sifting for relevance and duplicates, 70 full papers were ordered. However, most were opinion pieces, anecdotal reports or fell outside the inclusion criteria for this review.

Seven papers were primary research studies. However, after critical appraisal and quality assessment only one of these contained information relevant to the research questions. References were checked for missing articles but no further studies were identified. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6.)

Included studies

- The only included study did not address the question of effectiveness of alarms as measured by changes in incidence rates or impact on management and could have been excluded on this basis.
- A summary of this study has been included to provide information on the existing research in this area.

A postal survey of 122 NHS and 19 private acute admission wards within the M25 area was conducted (Bowers et al. 2002), with the aim of assessing current safety and security measures. The questionnaire was divided into four sections: survey of banned items; searching policy; practice (for example, locking doors, counting cutlery); items present or absent (for example, alarms, intercom systems, CCTV). Response rate was 70 per cent, not including 17 discarded responses, because they were not from acute admissions wards. Results were analysed with descriptive statistics and Pearson correlation tests. Fifty-six percent of respondents had panic alarms that sounded in the whole unit. In 18 per

cent they sounded in the ward only while 13 per cent of wards did not have any. Personal alarms were issued in 44 per cent of trusts whilst 45 per cent didn't use them. Forty-two percent of trusts had an emergency telephone extension and 45 per cent did not. Panic alarms were found in all rooms in 36 per cent of trusts, some rooms for 32 per cent and in only one room for 20 per cent. Whilst 3 per cent of trusts had panic alarms only in the office, 87 per cent did not. The authors note two types of unrelated security systems were identified by the report: type A (door security, restrictions and banned items) and type B (searches, guards and alarms).

In nine wards that had taken part in a previous study (Bowers et al. 2002), type A was associated positively with absconding rates and type B negatively with aggressive/angry behaviour. However, these results should be tested in a larger sample. The survey does not discuss the efficiency of alarms. The survey has been replicated in Northern Ireland. However, the results were only published in 2004. As such, they fall outside the cut-off point for searching on this topic, which was 2002. This study will be considered in the update.

Evidence statements

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine whether personal and institutional alarms and communication devices are an effective means of alerting staff to occurrences of disturbed/violent behaviour.
Level 4	There is insufficient evidence to determine which principles of practice are necessary to ensure the effective use of personal and institutional alarms and communication devices.
Level 4	There is insufficient evidence to ascertain staff and service users' views about the effectiveness of alarms in reducing disturbed/violent behaviour in psychiatric in-patient settings.

7.8.2.2.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.2.3 Prediction: antecedents, warning signs and risk assessment

7.8.2.3.1 **Objectives**

The original RCPsych guideline evidence base on prediction was examined. A list of excluded studies was available in the archived information received from the Royal College of Psychiatrists Research Institute. The following information was taken from the final report in the RCPsych guideline, which states that this hypothesis was used to inform the search strategies:

RCPsych hypothesis:

- It is possible, in acute clinical settings, to predict with reasonable accuracy which patients are more likely to become aggressive or violent in the near future.

After sifting and quality checks, 16 references on prediction were included in the RCPsych evidence review.

However, the included studies did not offer generalisable criteria in support of this hypothesis, so the RCPsych guideline concluded that:

The studies do not provide a clear consensus on items that would be clinically useful for short-term prediction across a variety of clinical settings. This does not mean that prediction (still less assessment) is impossible; only that no generalisation can be made from these results. (Royal College of Psychiatrists, 1998, p45)

Current guideline

The current guideline aims to assess whether research undertaken since 1995 now offers consensus on items and tools that are clinically useful in the short-term prediction of violent/aggressive behaviour. Four review questions were identified and used to inform the search strategy (see Appendix 4 for search strategy, databases searched and search logs).

Review questions:

- What are the risk factors and antecedents for disturbed/violent behaviour in psychiatric in-patient settings? Do they have good predictive validity?
- Which instruments most reliably predict disturbed/violent behaviour in psychiatric settings in the short-term? Do they have good predictive validity?
- Are there any identifiable staff characteristics that act as risk factors for disturbed/violent behaviour?
- What factors do service users and staff report as increasing the risk of disturbed/violent behaviour?

The studies had to meet the following inclusion criteria:

7.8.2.3.2 **Selection criteria**

Risk factors/antecedents/staff characteristics

Types of study

Prospective cohort studies (with or without controls) to before and after studies, and qualitative studies (level 2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Measurement of risk factors/antecedents.
- Staff characteristics associated with disturbed/violent behaviour.

Predictive instruments

Types of study

Prospective cohort studies (with or without controls) (level 2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of interventions

Actuarial checklists/tools and structured clinical judgement checklists/tools.

Types of outcome

- Sensitivity.
- Specificity.
- Positive and negative predictive values.

Service user and staff perspectives

Types of study

Systematic reviews through to before and after designs. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

Staff and service user views on risk factors, antecedents, predictive instruments and staff characteristics associated with disturbed/violent behaviour.

7.8.2.3.3 **Clinical evidence**

The same search strategy covered all the review questions. One thousand and twenty five studies were identified in the initial sift. After sifting for relevance and duplicates 290 full papers were ordered. However 40 further duplicates were later identified.

On scrutiny, 120 were opinion pieces, anecdotal reports, or fell outside the inclusion criteria for this review (see Appendix 7 for all primary research papers that fell outside the inclusion criteria). There were also 14 letters or editorials. A further 19 studies were on topics to be considered elsewhere in the guideline and were critically appraised in subsequent evidence reviews. Seventy-three primary research papers were identified; 61 met the inclusion criteria. No study offered evidence above level 2. References were checked but no further studies were identified. In addition, all papers (16) from the RCPsych prediction review, five papers from the RCPsych environment review and two papers from the RCPsych review of restraint and seclusion were considered relevant and were included in this review. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Included studies

I Antecedents or warning signs

Eight studies were included that considered the antecedents or warning signs of short-term disturbed/violent behaviour. Four were UK studies, set in a variety of psychiatric in-patient environments. Three were US studies; two were set in veterans' medical centres; the other in a general psychiatric unit. The final study was undertaken in Norway, set in a secure unit. A range of study designs was used. One study was a prospective cohort, four were retrospective cohorts, one was a cross-sectional study within a prospective cohort, one was a survey and the other used semi-structured interviews. Although most of the studies associated violence with verbal abuse and aggressive/agitated behaviour, only the prospective cohort study is a sufficient design to allow predictors of violence to be discussed. The one prospective cohort study (Whittington and Patterson 1996) found no significant difference in behaviour between non-violent and violent cohorts in the 24 hours prior to an aggressive incident, although aggressive behaviour was the best predictor of short-term violence. However, they did note significant differences in behaviour three days prior to an

aggressive incident. The violent cohort showed increased levels of anger and aggression (p=0.0001), verbal abuse, P<0.05), threatening gestures/stance (p<0.01) and abnormal activity level (p<0.05) compared to the non-violent cohort. This study was set in a rural hospital in the UK. The predictive validity of this study and the generalisability of these findings need to be validated by further prospective cohort studies that examine antecedents of short-term violence across a variety of settings. Three further studies in the RCPsych review examined antecedents. Only one study (Sheridan et al. 1990) noted anything different, commenting that staff limit setting often preceded violent incidents.

None of the above studies significantly change the findings of the RCPsych review.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that the following may act as antecedents/warning signs for the occurrence of disturbed/violent incidents: verbal abuse, aggressive/agitated behaviour, threatening gestures and abnormal activity levels and staff-limit setting.

II Clinical approaches to prediction ('first generation')

The literature searches yielded seven prospective cohort studies investigating clinical judgement as a means of violence prediction. One study (McNiel and Binder 1991), included in the RCPsych review, did not offer information on predictive validity. Two studies (McNiel and Binder 1995, included in the RCPsych review; Haim 2002) suggested low positive predictive values for clinical prediction. The first study was set in a locked facility in the US and the other in a forensic psychiatric hospital in Israel. Three studies (Nijman et al. 2002; Rabinowitz et al. 1999; McNiel et al. 1998) suggested that clinicians' judgement had a better predictive validity than the earlier analysis allowed and demonstrated positive predictive values of 41 per cent, 58 per cent and 75 per cent and negative predictive values of 76.9 per cent, 86 per cent and 98 per cent respectively. The three studies were conducted in a range of adult psychiatric in-patient settings, and were undertaken in different countries – the first in Israel, the second in Holland and the third in the US. In a final study (Hoptman et al 1999) the overall specificity arrived at by clinicians was 79 per cent, with a corresponding sensitivity of 54 per cent. This study was set in the US, in a forensic psychiatric hospital. It is a distinctive study in that 57.4 per cent of the participants were African-American and only 35 per cent Caucasian. In most of the other studies the majority of participants were of Caucasian origin.

Whilst four of the seven of the included studies suggest that clinicians are able to predict violence with a greater degree of accuracy than has previously been suggested, there are no identifiable features to explain the greater degree of clinician predictive accuracy found in these four studies. One study relates accuracy to confidence, but does not state if this is also related to experience. Another study admits that the inability of the study to provide an underlying reason for the high predictive value is a key weakness of the design. In order for clinicians' judgements alone to be recommended over and above other approaches to prediction, further studies that are tested across a variety of settings are required to validate these findings. Whilst the general trend of the studies stresses that clinicians may be able to predict violence with some degree of accuracy, there is a lack of consensus amongst the studies.

None of the studies significantly change the findings of the RCPsych review in which five further studies (Kirk 1989; Janofsky et al. 1988; McNiel et al. 1988; Apperson et al. 1983; Yesavage 1983) also indicated the low predictive validity of clinicians' judgement.

Evidence statement

Level of evidence	Evidence statement
Level 4	The evidence suggests that clinicians' judgement has a relatively low predictive validity, only slightly better than chance.

III Actuarial approaches ('second generation')

III.i Risk factors

Whilst antecedents or warning signs are risk factors, in this review they are distinguished from more static variables which could be used to predict violence – such as diagnosis, demographic variables etc – which are referred to as risk factors. It is such risk factors that this next group of studies examines.

The literature search identified the following relevant studies: eight prospective cohort studies; six retrospective cohort studies; one cross-sectional study; two prospective case-controlled studies; and one retrospective/historic case-controlled study.

Seven prospective cohort studies identified the following significant risk factors:

- community violence, male gender, young age, younger age at first hospitalisation, more frequent visitors – at least monthly, not having own clothing, low level of self-care functioning, number of admissions, duration of admission, coercive behaviour and lack of satisfaction of care, a diagnosis of organic psychotic condition, personality disorder, schizophrenia, and bi-polar affective disorder.

Five further studies in the RCPsych reviews also examined risk factors. The studies noted the following risk factors:

- history of violence, hostile suspiciousness, agitation-excitement, thinking disturbances, use of intoxicants, command hallucinations, impostor delusions and delusions about personal targets.

Only prior community violence/history of violence was mentioned in more than one study as a risk factor, and it was then only regarded as a risk factor within the first one to two days of admission and not afterwards.

The other prospective cohort study (Owen et al. 1998a) examined the risk factors amongst adult recidivists in psychiatric acute care settings, including geriatrics. It identified the following significant risk factors: being older, widowed, having personality disorder, or organic brain disorder, being detained under the Mental Health Act, and being highly sedated prior to the incident.

Within the studies there are no risk factors that consistently emerge, except for prior community violence. There is also no consensus within the studies as to how these various risk factors ought to be weighted. These studies only serve to illustrate that a huge range of variables are possible risk factors. However, most of the studies did suggest that demographic variables were largely irrelevant in risk prediction.

Most of the studies did not discuss the predictive validity of this approach. One study, which discusses community violence as a risk factor (Beck and Bonner 1988), notes a positive predictive validity for the first day of admission of 31 per cent – slightly worse than that averaged by clinicians' judgement in the studies discussed in Section II. One study (McNiel et al. 1998), notes that the actuarial approach was significantly better than clinician prediction. However, in this study clinician prediction was particularly low (true positives = 26.7 per cent, false positives = 73.3 per cent). Only one study (Rabinowitz and Garelik-Wyler 1999) shows a higher positive predictive value of 61.6 per cent and a negative predictive value of 69.3 per cent in predicting the violent group of service users. On the basis of these results it has not been possible to establish risk factors for the prediction of violence.

None of the studies significantly change the findings of the RCPsych review.

Evidence statements

Level of evidence	Evidence statement
Level 2+ to 2-	The evidence suggests that the following may be risk factors for disturbed/violent behaviour: community violence, male gender, young age, younger age at first hospitalisation, not having own clothing, low level of self-care functioning, number of admissions, duration of admission, coercive behaviour + lack of satisfaction of care, a diagnosis of organic psychotic condition, personality disorder, schizophrenia, and bi-polar affective disorder. However, further research is needed to reliably determine additional factors that may need to be considered across different populations.
Level 4	There is insufficient evidence to determine how various risk factors associated with disturbed/violent behaviour in psychiatric in-patient settings ought to be weighted.

III.ii Predictive actuarial tools

Eleven prospective cohort studies were identified through the literature searches. These studies assessed the predictive validity of a range of actuarial tools or checklists in adult in-patient psychiatric settings as a means of predicting violence (see Table 1, page 42). A wide range of risk factors was considered. Echoing the findings from the review of the actuarial approaches to determining risk factors considered in Section III.i above, there is no agreement amongst the tools examined here as to which risk factors are most important, or how the various risk factors ought to be weighted.

None of the studies took place in the UK. Five took place in the US; one in Australia; one in Sweden; one in Norway; one in Spain; one in Italy; and one in Taiwan. There is a need to test these actuarial tools in a European and a UK context. Research into prediction of violence in psychiatric in-patient settings involving the use of these tools is still at a preliminary stage. None of the studies considered whether prediction with a particular tool led to a decrease in disturbed/violent behaviour/incidents.

On the basis of the clinical evidence, no one tool emerged as the 'gold standard'. Six studies (Chou et al. 2002; Ehmann et al. 2001; Arango et al. 1999; Krakowski et al. 1999; Almvik et al. 1998; Yesavage 1984) reported on the positive and negative predictive values established using this approach. With the exception of the Brøset violence checklist, which is still in a preliminary stage of development, the various actuarial tools showed consistently higher positive and negative predictive values than those established by clinical judgement alone in the aforementioned analysis (see Table 1, page 42). These results suggest that important developments have been made since the RCPsych guideline. Whilst more research is

needed to validate the findings of these studies, and to test the instruments across a range of settings, the clinical evidence suggests that there is a trend towards greater predictive accuracy with actuarial tools than with clinical judgement alone.

Only three studies in the RCPsych review considered the use of actuarial tools. Since the completion of the RCPsych review, more studies as outlined here have examined the predictive accuracy of actuarial tools These studies suggest that actuarial tools offer greater predictive accuracy that clinical judgement alone.

Evidence statements

Level of evidence	Evidence statement
Level 4	There is insufficient evidence on which to determine a 'gold standard' predictive actuarial tool.
Level 4	The current evidence suggests a trend towards greater predictive accuracy with actuarial tools than with clinical judgement alone. However, further comparative research is needed.

Table 1

Tool	Number of studies	Purpose of tool	Significant results/ predictive validity	Known advantages	Known limitations
SOAS (Palmstierna; Wistedt 1989)	Three (Palmstierna, 1989; Chou et al. 2002; Grassi et al. 2001)	Records individual incidents. Includes verbal and physical aggression and property damage. These are not rated separately (Bowers 1999).	**Study 1** highlighted history of violence against property and substance abuse. **Study 2** highlighted history of violence, psychotic diagnosis and history of smoking. **Study 3** highlighted younger age, single, living with nuclear family and acute psychosis.	Tries to separate means, aims and results of aggressive incidents. Good inter-rater reliability (0.96) Some evidence for predictive validity. The most widely used scale, therefore allowing comparison between studies (Bowers, 1991)	Conflates severity with outcome. Means and aims of aggression incompletely conceptualised (Bowers 1991).
SOAS-E (Hallenstinsen et al. 1998)		Same as SOAS	Authors argue that the new categories are exhaustive.	Same as SOAS.	Adds 11 additional warning signs.
SOAS-R (Nijman 1999)	One (Grassi et al. 2001)	Same as SOAS	Highlighted acute psychosis.	Same as SOAS	Has a new scoring system to objectify the severity of a violent episode.
RAPP (Ehmann et al. 1995)	One (Ehmann et al. 2001)	21-item scale that assesses symptoms and functional domains.	RAPP total negative predictive value = 95 per cent, positive predictive values of 78 per cent and 62 per cent in two random subsets. RAPP safety score (sensitivity = 81 per cent, specificity = 96 per cent, positive predictive value = 87 per cent improvement over change = 62 per cent).	No information available.	No information available.
MOAS (Kay et a., 1988; Bowers 1999)	One (Ehmann et al. 2001)	Retrospective record of most serious incidents in pat week. Includes four dimensions: verbal and physical aggression, property damage and self-harm.	Rating 3 or 4 was used to determine aggressive behaviour. The following were noted as risk factors: female, alcohol abuse and non-paranoid schizophrenia.	Easy to collect and does not need a heavy commitment from ward nurses. Good inter-rater reliability (0.85-0.94). Moderate longitudinal correlations for the same patient (Bowers 1999).	Loss of information on individual incidents, their antecedents and consequents. Conflates severity with outcome. Diverse behaviours grouped together.
NOSIE (Honigfield 1966)	Two (Swett & Mills 1977; Krakowski et al. 1999)	Measures three positive factors: social competence, social interest and neatness; and three negative factors: irritability, psychosis and motor retardation.	**Study 1** – irritability scale significant predictor (positive predictive value = 78 per cent, negative predictive value = 79 p er cent). **Study 2** – irritability, difficulty following ward instructions.	No information available.	No information available.

Table 1 (continued)

Tool	Number of studies	Purpose of tool	Significant results/ predictive validity	Known advantages	Known limitations
BPRS(Overall, Gorham 1962)	Five (Swett & Mills 1977; Krakowski et al. 1999; Yesavage 1984; McNeil 1995; Werner 1983)	24-items. Ratings range from 1-7 with higher rating indicating More severe symptoms.	**Study 1** – schizophrenia rating was significant in combination with low neuroleptic serum levels and violence prior to admission. **Study 2** – Total BPRS score was not significantly related to assault. **Study 3** – Severe psychotic symptoms were significant. **Study 4** – sensitivity – 55 per cent, specificity – 64 per cent. **Study 5** – true positives (0.27), true negatives (0.39).	No information available.	No information available.
MMSE (Folstein et al. 1975)	One (Swett & Mills 1977)	11 'yes-no' questions asked by psychiatrist to service user.	Total MSME score was not significantly related to assault.	No information available.	No information available.
QNS (Convit 1994)	One (Krakowski et al. 1999)	Assesses neurological symptoms.	Severe neurological symptoms were significantly related to assault.	No information available.	No information available.
BVC (Almvik 1996)	One (Almvik & Woods 1998)	Assessed whether service users were confused, irritable, boisterous, physically threatening, verbally threatening, attacking objects.	Sensitivity = 74 per cent, specificity = 91 per cent, false positives = 66 per cent, (true positives = 70 per cent, false negatives = 24 per cent, true negatives = 71 per cent).	Simple six-item checklist.	Authors comment tool was at a preliminary stage of development in 1998.
PANSS(Kay et al, 1992)	Two (Ehmann et al. 2001; Arango et al. 1999)	Assesses psychopathology.	**Study 1** – sensitivity = 67 per cent, specificity = 91 per cent, positive predictive value = 71 per cent, base rate = 24 per cent, improvement over chance = 47 per cent. **Study 2** – total PANSS score – sensitivity = 31.3 per cent, specificity = 91.5 per cent, positive predictive value = 55.5 per cent, negative predictive value = 79.6 per cent. Insight into psychotic symptoms, general psychopathy score and violence in previous week correctly classified 84.1 per cent of service users (sensitivity = 50 per cent, specificity = 95.7 per cent, positive predictive value = 80 per cent, negative predictive value = 79.6 per cent.	No information available.	No information available.
PCF (Lanza et al. 1996)	One (Chou et al. 2002)	Scale includes: sociodemographic data, medical diagnosis, time since admission, history of assaults and history of drug and alcohol abuse.	Significant service user characteristics: history of violence (OR=4.14) psychotic diagnosis (OR=2.07), history of smoking (OR=1.45) and duration of admission (OR=0.99).	No information available.	No information available.

Table 1 (continued)

Tool	Number of studies	Purpose of tool	Significant results/ predictive validity	Known advantages	Known limitations
EAQ (Lanza et al. 1996)	One (Chou et al. 2002)	Scale includes: location time, date, number of patients on ward and their acuity level, space density, and number of staff on ward.	Severity of assault was related to space density and staff/patient ratio.	No information available.	No information available.
ARP (Kay et al. 1987)	One (Kay et al. 1988)	39 item tool covering four main areas: demographics, current psychiatric diagnosis, history of aggression and clinical profile.	Physical aggression was predicted by anger, hostility, history of attacks on others, history of greater total aggression (p<0.01). Verbal aggression was predicted by motor excitement, difficulty with gratification, depressed feelings (p<0.025) Total aggression was predicted by younger age, more acutely ill, more threatening of violence by history, previously rated more agitated and labile in affect (p<0.05).		

IV Structured clinical judgement instruments ('third generation')

Three studies examined the usefulness of instruments that measure structured clinical judgement. Two were European studies – one set in Sweden and the other in the UK – and the third was a US study. Two of these were prospective cohort studies and are described here.

The first prospective cohort study was undertaken in Sweden, (Belfage et al. 2000). It considered both the HCR-20 (historical/clinical/risk – 20-item scale, version 2) and the PCL:SV (psychopathy checklist: screening version) within a maximum security correctional setting. The study found that history of violence was not a good predictor of future violence. The authors suggest that this is unsurprising in a setting where all patients will score highly on the H-10 – the historical part of the tool. The R-5 showed the best predictive validity (p=0.004). Thirty of 41 participants were psychopaths for whom the R-5 was the only tool with any predictive validity (p = 0.002). The PCL:SV showed a higher score for violent recidivists and was significant when considered in conjunction to older age (p<0.1).

The second prospective cohort study (Hill et al. 1996) was conducted in the US in a state hospital to assess whether the PCL:SV was a good predictor of aggression amongst 55 male forensic psychiatric service users. The authors found that the PCL:SV total was a significant predictor of aggression. The PCL:SV was then reduced to presence or absence of psychopathy, where it again predicted aggression (multiple r = 0.69; R2=0.48; Beta = 0.69).

Three other studies that examine the effect size of the PCL and the PCL: SV are mentioned by Doyle and Dolan (2000). They also note a good predictive validity for the tool in a forensic setting. However, as of yet, insufficient research has been carried out to test the predictive validity of these instruments in UK adult psychiatric in-patient settings. More studies also need to be undertaken to validate the results of these studies. All studies are detailed in Table 2, page 45.

All these studies have taken place since the RCPsych review. They suggest that structured clinical judgement gives a greater predictive accuracy than clinicians' judgement alone, similar to that achieved by the use of actuarial tools.

Evidence statements

Level of evidence	Evidence statement
Level 4	The evidence suggests that there is trend towards greater predictive accuracy with structured clinical judgement tools than with clinical judgement alone, similar to that achieved by the use of actuarial tools.
Level 4	There is insufficient evidence on which to determine a 'gold standard' structured clinical judgement instrument.

Table 2

Tool	Number of studies	Purpose of tool	Results/predictive validity	Known advantages	Known limitations
PCL:SV (Hart et al. 1995)	Three (Doyle et al, 2002; Belfrage 2000; Hill 1996)	12-item instrument to assess psychopathy. Scored 0 (not present) 1 (maybe) 2 (present).	**Study 1** PCL:SV total score and interpersonal subscale = best predictors of any violence (sensitivity = 0.76, sensitivity = 0.50) Interpersonal subscale = best predictor of violence against persons resulting in injury (sensitivity = 0.76, sensitivity = 0.50) (compared with VRAG and H-10). **Study 2** High scores on part 2 suggested recidivism. **Study 3** The PCL:SV total was a significant predictor of aggression. The PCL:SV when reduced to presence or absence of psychopathy again predicted aggression (multiple r = 0.69; R2 = 0.48; Beta = 0.69).	Quicker, shorter and easier to administer than the psychopathology checklist revised (PCL-R). Psychometrically sound. Not so concerned with overt criminal acts as the PCL and the PCL-R.	No information available.
VRAG (Harris et al. 1993; Webster et al. 1994)	One (Doyle 2002)	Includes 12 variables including: PCL-R score, elementary school maladjustment, age (negative associated with violence) personality disorder, separation from parents before 16, failure on previous conditional release, history of non-violent offences, never married, diagnosis of schizophrenia, severity of injury to victim during index offence, alcohol abuse, male victim of index offence. All items are given integer weights.	Did not show good predictive validity (but this was a retrospective study).	No information available.	No information available.
HCR-20 (Webster et al. 1997)	Two (Doyle et al. 2002; Belfrage, 2000) (one study only considered the H-10)	A 20-item checklist, divided into 10 historical items (H-10), five clinical items (C-5) and five risk management items (R-5), allowing the scale to examine past, present and future times. It is scored either 0 (no) 1 (maybe) 2 (yes)	**Study 1** Risk management sub-score had best predictive validity in correction maximum security institutions. **Study 2** H-10 did not show better predictive validity that the PSL:SV (see above).	No information available.	No information available.

Three further studies examine the predictive validity of the PCL and PCL: SV and note the effect size for this instrument amongst forensic psychiatric patients. The effect sizes are given as follows: d = 0.63, d = 1.92, AUC of ROC at 3 month = 0.75 (Dolan, Doyle 2000).

V Staff characteristics associated with the likelihood of aggressive incidents

Nine studies were identified which examined the relationship between staff characteristics and assault (Flannery et al. 1995; Flannery et al. 2001; Chou et al. 2001; Chou et al. 2002; Lanza et al. 1997; Owen et al. 1998b; Soares et al. 2000; Augestad and Vatten 1994; Ray 1988; Morrisson 1998). In addition a further five studies were identified in the RCPsych review (Whittington and Wykes 1996; Binder and McNeil 1994; Whittington 1994; Whittington and Wykes 1994; Carmel and Hunter 1991). All the studies, except one (Lanza, 1997), surveyed staff in a range of psychiatric settings. Lanza (1997) was set in a neuropsychiatric department in a veterans' hospital in the US. This study found no relationship between staff characteristics and assault. The other 12 studies identified the following characteristics as significant correlates of staff characteristics and the occurrence of aggressive incidents:

> younger age, between youngest and oldest age, work experience, training in the management of violence, and grade, lack of training and limit setting/confrontation, authoritarianism, social restrictiveness, young age, limited supervision and gender. (It was also suggested that gender was non-significant (Binder and McNeil 1994). The study (Augestad and Vatten 1994) which emphasises gender as significant notes that whilst overall risk for men was significantly higher, the relative risk according to ward type was similar for men and women). Several other correlates were identified, but were not significant.

There was no consistency across the studies.

None of the studies significantly change the findings of the RCPsych review.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that the following staff characteristics may be associated with increased occurrence of incidents of disturbed/violent behaviour: younger age, level of experience, training and grade, gender, and involvement in limit-setting activities. However, further research is needed.

VI Service user perspectives on reasons for assault

Seven studies were identified which examined service user perspectives on the causes of disturbed/violent behaviour.

One Canadian study surveyed a heterogeneous group of 12 thought-ordered individuals across two hospitals. Service users reported that factors that caused violence tended to be external rather than internal (that is caused by factors on the ward rather than by illness). The results of this study would need to be validated on a larger scale and replicated across other settings, before any evidence-based conclusions could be drawn about service user perspectives on the causes of aggressive incidents.

Another study (Whittington and Wykes 1996) conducted semi-structured interviews with staff in the UK to ascertain whether aversive stimulation (such as limit setting) had occurred prior to an assault. The results were verified by interviews with some service users and witnesses, indicating that some form of aversive stimulation often precedes an assault. However, the study is unclear about the number of service users who were interviewed or the extent to which they agreed with staff. The study reports that many staff believed that aversive stimulation trigger the majority of the aggressive incidents (see staff perspectives below).

One survey (Gillig et al. 1998) found that service users saw less of a causal connection between their own verbal abuse of staff and the physical abuse of staff than staff ($p<0.05$). However, they saw more of a causal connection between verbal abuse of service users by staff and physical violence against staff, than staff ($p<0.05$). This pattern and significance was echoed with regards to hostility and threats. Service users identified staff use of drugs and alcohol ($p<0.05$), the use of forced medication ($p<0.05$), restraints ($p<0.05$) and seclusion ($p<0.05$) as causes underlying violent incidents. They also stressed cross-cultural racism as a cause of violence.

Another study that used incident forms, a survey and interviews for data collection (Duxbury 2002) noted that service users believed that external and situational factors (such as interactions with staff and restrictive regimes) were largely to blame for violent incidents ($p<0.001$).

A further study using semi-structured interviews (Bensley et al. 1995), noted that service users, like staff, considered restrictions on service users' smoking, access to outdoors, defective staff clinical skills, service users not being treated with respect, as well as the use of seclusion and restraint, to contribute to violent incidents. Service users were also concerned that rules were not adequately explained.

Using video footage and interviews (Crowner et al. 1995) it was found that 12 per cent of service users argued that they had been playing with the victim, 12 per cent claimed that they had been subjected to verbal abuse, and 8 per cent claimed that they had been subjected to objectionable behaviour. The other 41 per cent gave a range of responses – from no response to anger at ward rules, and anger at

unwanted sexual attention.

Ilkiwa-lavelle and Grenyer, (2003) found that service users believe improved handling of inter-personal conflicts would prevent violent incidents.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that service users regard external factors (such as limit setting, verbal abuse by staff and other service users, lack of respect by staff and harassment) as likely reasons for assault rather than internal factors (that is, caused by illness).

The RCPsych review did not specifically consider this issue.

VII Staff perspectives on reasons for assault

Nine studies were identified which examine staff perspectives on reasons for assault.

Four studies (Gim et al. 1999; Duxbury 1999; Gillig et al.1998; O'Sullivan and Meagher 1998) carried out questionnaire surveys to assess health care professionals' views on the risk factors associated with psychiatric in-patient violence. The first study is set in Ireland; the second in Singapore; the third in the UK; and the fourth in the US. The following were proposed as risk factors by staff but not validated:

> personality disorder, schizophrenia, substance abuse, intoxication, violent lifestyles, active hallucinations, paranoid ideas against others, non-compliance with treatment, internal factors and provocation.

Only personality disorder was mentioned in two of the studies, although all studies mention internal factors, including diagnosis. These suggest that staff emphasise diagnosis over other variables. However, more studies are needed before the generalisability of these findings can be assessed.

Two studies (Whittington 1996; Bensley 1995) conducted semi-structured interviews with staff. One study (Whittington 1996) attempted to assess whether they had caused aversive stimulation prior to an assault. After validating the results of the interviews by interviewing service users and witnesses, it was noted that 86 per cent of all assaults were preceded by some form of aversive stimulation (such as limit setting), although the authors suggest an interplay with diagnosis. These results require validation and replication across a variety of settings.

Using semi-structured interviews (Bensley 1995) found that staff believed inadequate staffing levels was the single factor that most contributed to assaults on staff. Like service users, staff were also concerned about service user restrictions on smoking, access to outdoors, staff clinical skills, service users being treated with respect, as well as the use of seclusion and restraint on the wards. Staff also mentioned a need for training in the management of violence, as well as concerns about the general physical environment. However, the study was of low quality.

Using incident forms, questionnaires and interviews (Duxbury 2002) noted that staff most commonly reported problematic interaction and restrictive environments as the causes of violence/aggression. However, staff did not consider their own personal interactions with service users to be problematic. Staff were unable to identify a cause for 26 per cent of all incidents. Staff attributed much more weight to internal factors (that is, illness) as underlying causes of violence/aggression than service users.

Using focus groups and surveys (Delaney et al. 2001), the following were noted as impacting on the possible risk of violence: service user history; service user status and mode of arrival; ongoing informal nurse assessment; individualised care; peer support and administrative responsiveness; nursing stress; and current policies/manuals. However, the study was of low quality.

Ilkiwa-lavelle (2003) found that staff believed the service user's illness to be a key causal factor, whereas service users believed inter-personal conflicts were relevant. Staff believed improved medical management would prevent violent incidents.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that staff users regard internal factors (that is, caused by illness) and the interplay between internal and external factors (such as staff limit setting) as contributing to disturbed/violent behaviour.

The RCPsych review did not specifically consider this issue.

7.8.2.3.4 Economic evidence

No studies containing relevant economic data were found (see Appendix 9).

7.8.3 Training

7.8.3.1 Objectives

No specific searches on training systems were undertaken in the RCPsych guideline.

Current guideline

Two review questions were identified by the GDG and used to inform all searches:

- What are the most effective and safe training programmes for the prevention of and the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings?
- What are the views of staff and service users about the various training programmes in adult psychiatric in-patient settings and their content?

Included studies were subdivided into more specific review questions that related to each of the interventions and related topics covered in this guideline.

7.8.3.2 Selection criteria

Types of studies

Systematic reviews to controlled before-after studies. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcomes

- Effectiveness of training packages in managing or reducing disturbed/violent behaviour.
- Safety of training packages managing or reducing disturbed/violent behaviour.
- View of staff and service users on the various training programmes for managing or reducing disturbed/violent behaviour.
- Increased staff knowledge resulting from training.
- Staff attitude change resulting from training.
- Reduction in the number of disturbed/violent incidents.
- Reduction in the number of staff days lost through illness.

7.8.3.3 Clinical evidence

Two hundred and thirty nine papers were identified in the initial sift. Eighty-four studies were ordered. After quality checking, 22 studies were included in the review. Eight studies were excluded. The remaining studies were overviews. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Appraisal of methodological quality

In addition to those mentioned in section 7.3.6, the following methodological concerns were raised by these studies:

- All the studies included in this review have relatively small sample sizes.
- For most of the studies the training package was not specified.
- Where the training package was specified, insufficient details were provided to allow meaningful comparisons to be made with other training packages.
- Long-term outcomes, such as improvement in service user care, were not measured.

Included studies

Fourteen before and after studies were included in this review. One of these before and after studies (Perkins and Leadbetter 2002) is conducted in an area outside of the scope of the guideline. However, this study is included here because the CALM technique that it evaluates is one of many training packages used in the UK for the short-term management of violence. Two pilot studies are also included. The first study (Frey and Weller 2000) is included, despite only being a pilot study, since it is the only study that considers the effectiveness of training service users, rather than staff, as a means of reducing in-patient violence in adult psychiatric settings. The second study (Bournemouth University, unpublished) is included since it is one of only two studies to evaluate the effectiveness of training in a clinical environment. Of the other studies included, one study is a retrospective cohort study, and seven are cross-sectional surveys.

As the studies often address multiple issues, the findings of the studies have been grouped together under topics. This means that some studies are referred to a number of times.

I.a Review question: what are the most effective and safe training programmes for the prevention of and the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings?

The effectiveness of training staff in interventions for the short-term management of violence: general outcomes.

Increased knowledge

In a before and after study (Calabro et al. 2002), significant

increases were noted immediately after training in non-violent crisis intervention (CPI) in post-test knowledge scores ($p<0.001$), positive change of attitude towards the techniques taught ($p<0.001$), self-efficacy ($p<0.01$) and positive change in behavioural intention ($p<0.05$). A further before and after study (Ilkiw-Lavalle et al. 2002), found that staff knowledge improved significantly immediately after training, with ancillary staff improving by the largest effect size (2.25). Staff with no prior training had the greatest improvements immediately after training ($p<0.01$) A before and after study (Paterson et al. 1992) noted a significant increase in knowledge immediately after training in post-test knowledge scores ($p=<1\%$). Stress, as assessed by a general health questionnaire, was also significantly reduced ($p=<1\%$). In a controlled before and after study (Rice 1985), significant improvements were found in all areas of knowledge (self-defence and patient restraint written test $p<0.0001$ for lesser security staff only) immediately after training.

None of these studies assess the effectiveness of training in a clinical environment.

Attitude changes

A before and after study (Collins 1994), found that staff were less likely to hold service users entirely responsible for their behaviour, and acknowledge facts such as service user fear as causative immediately after training and at six months post training. In a before and after study using the CALM techniques in a school for children with learning difficulties (Perkins 2002), no significant changes in staff attitude toward pupil aggression were noted.

In a before and after study (Collins 1994), staff confidence was found to increase immediately after training. Staff remained more confident six months post training. In a before and after study using the CALM techniques in a school for children with learning difficulties (Perkins and Leadbetter 2002), it was noted that 82 per cent of staff interviewed expressed increased confidence in their ability to deal with an aggressive incident six months post training.

None of these studies assess the effectiveness of training in a clinical environment

Number of disturbed/violent incidents

In a retrospective cohort study (Carmel and Hunter 1990), training in managing aggressive behaviour and CPR was not found to be significantly linked to the number of violent incidents on the wards. In a before and after study (Sjöström et al. 2001), no significant reduction in the number of aggressive incidents using the social dysfunction aggression scale (SDAS-9) was noted six weeks after training.

In a controlled before and after study (Rice 1985), there was a significant reduction in violent incidents ($p<0.05$) for the 18 months after training. Taxis (2002) shows a dramatic decrease in the use of seclusion and restraint after a 42 month period of training.

In a before and after study (Whittington and Wykes 1996), it was noted that wards that sent the majority of their staff to a one-day training course that did not involve restraint training noticed a significant reduction in assaults ($p<0.05$) for the 28 days after training. Staff who took part in training had a 31 per cent lower rate of assault after training than those who did not take part. The decrease was unusual but did not reach significance.

Staff injuries and missed workdays

In a retrospective cohort study (Carmel and Hunter 1990), when wards highly compliant with training were compared to wards with low training compliance, a significant positive relationship was noted between those trained in managing aggressive behaviour and the number of staff injuries ($p<0.005$).

In a retrospective cohort study (Carmel and Hunter 1990), a significant relationship was noted between individual staff who were trained in either managing aggressive behaviour or CPR and a reduction in staff injuries based on monthly reports over the course of a year ($p<0.001$).

In a before and after study (Martin 1995), it was noted that two years after a training programme was initiated, although the number of aggressive incidents increased along with the level of aggression, the number of staff injuries fell and the number of missed work days fell resulting in a saving (in relation to missed workdays) of $173,960 (year 1); $2,478 (year 2); $2,414 (year 3). (NB: Not enough information reported to assess quality).

In a controlled before and after study (Rice 1985), there was a significant reduction in lost work days on wards that took part in the training relative to those that did not ($p<0.001$) for the 18 months post training.

In a before and after study, Sjöström et al. (2001) noted that six weeks after training, no significant reduction in the number of staff on sick leave was noted.

Prediction and risk assessment

In a cross-sectional survey of 193 UK trusts providing mental health services (Davis 2001), just over 50 of the 84 per cent replying provided training on risk assessment for harm to others.

A before and after study (Ilkiw-Lavalle et al. 2002), found that staff knowledge of prediction was significantly increased immediately after training ($p<0.01$).

None of these studies assess the effectiveness of training in a clinical environment.

De-escalation techniques

In a before and after study (Paterson et al. 1992), 'blinded' raters judged that there was a significant increase in staff competence in de-escalation immediately after training.

In a before and after study (Philips and Rudestam 1995), judges rated that immediately after training, the experimental group of staff who received training placed significantly more value on non-aggressive responses to service user violence/aggression ($p=0.05$) than a control group who were not trained, or a control group who received only didactic training.

A controlled before and after study (Wondrak and Dolan 1992), trained student nurses to deal with verbal abuse. Using role-play, blind raters noted that there was significant improvement for those trained immediately after training, compared to those not trained in all areas except empathy, eye contact and anger levels. Post test, the attendees appeared more relaxed to blind raters ($p=0.031$), less upset ($p=0.001$) and had a more effective use of posture ($p=0.005$). On self-reported questionnaires, three areas achieved significance in those trained: feeling less angry ($p=0.002$); feeling less out of control ($p=0.005$); and feeling less threatened ($p=0.035$); in a similar situation.

In a before and after study using the CALM techniques in a school for children with learning difficulties (Perkins and Leadbetter 2002), semi-structured interviews suggested that verbal de-escalation appeared to have increased six months after training.

None of these studies assess the effectiveness of training in a clinical environment.

Restraint

In a before and after study (Paterson et al. 1992) 'blinded' raters judged that there was a significant increase in staff competence in control and restraint and disengagement immediately after training.

In a before and after study (Philips and Rudestam 1995), immediately after training, judges rated the experimental group of staff who received training as significantly more competent in physical skills as well, as displaying less fear and aggression ($p=0.05$), than a control group who were not trained, or a control group who received only didactic training.

In a controlled before and after study (Rice 1985), there were significant improvements in areas of skill (sensitive situations skill test $p<0.001$) and audiotaped simulations test ($p<0.01$) immediately after training. There was also a significant increase in the on-ward job reactions scale six weeks after training for maximum security workers, compared to controls ($p<0.01$). This scale measures how comfortable participants are in their interactions with service users.

In an unpublished pilot study conducted by Bournemouth University, the effectiveness of restraint and breakaway techniques were considered in a psychiatric intensive care unit (PICU). The study used a prospective cross-sectional approach over 32 months. During this period, 346 adverse incident forms were collected. They did not record the use of breakaway techniques, however, when 19/22 staff were interviewed retrospectively, three recalled using recognised breakaway techniques, one a restraint technique and one an unrecognised technique. Staff did not recall any techniques used being inappropriate or ineffective. They recalled problems with taking the client to the floor. All were satisfied with the training they had received, but wanted more frequent refresher courses and a greater emphasis on de-escalation.

Parkes (1996) conducted a before and after study in a 44-bed medium secure unit to assess the effectiveness of a four-day C&R training course. Interviews were conducted with all staff involved in a restraint incident for the 18 months prior to training and the 12 months after all staff had been trained. Data was collected on all 340 incidents involving physical restraint. One hundred and forty-nine incidents involving restraint occurred after training. For statistical purposes these were compared with 149 incidents immediately prior to training. Staff injuries during the restraint phase increased after training ($p<0.05$). Injuries to service users during restraint phase did not significantly alter post training. No other significant changes in injury rates were noted. Overall changes in injury rates were not significant. There were no significant changes in difficulty rating or risk rating after training. The modal number of staff restraining a person increased to three after training. The highest number of staff involved in a single restraint decreased from 10 to six after training.

Only two studies – Bournemouth University, (unpublished) and Parkes (1996) – assessed the effectiveness of training in a clinical environment. However, the first was a pilot.

Evidence statements

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that short-term improvements in knowledge, skills and reduction in stress occur after staff training in the management of disturbed/violent behaviour.
Level 4	The lack of evaluations of the effectiveness of training in a clinical environment mean that a 'gold standard' training package for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings cannot be determined.

I.b Review question: how effective was training service users in the management of their disturbed/violent behaviour?

One before and after pilot study (Frey and Weller 2000) examined the effect on incidences of aggressive and violent behaviour of training service users to respect themselves, peers and staff. Service users demonstrated a significant increase in knowledge, based on a questionnaire immediately after the training ($p<0.05$). A nurses' survey indicated a reduction in aggressive behaviour in the week after training ($p<0.05$). Authors claim that the training inadvertently led staff to alter their behaviour. It caused staff to become more aware of the causes of service user aggression, through examining the feedback. It is therefore unclear whether changes of staff behaviour or training service users had the most impact on reducing violence.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that training service users to respect themselves, peers and staff may reduce the occurrence of disturbed/violent incidents.

I.c Review question: What are the views of staff about the various training programmes in adult psychiatric in-patient settings and their content?

General perspectives

Staff assessment of training needs

In a Canadian cross-sectional survey (Chaimowitz and Moscovitch 1991) of medical students to assess the adequacy of training to deal with violent incidents, 34.3 per cent thought that staff psychiatrists were adequately trained; 24.4 per cent thought that psychiatric residents were adequately trained; 50.4 per cent thought that nurses were adequately trained; and 79.5 per cent wanted improvements in education and training for staff. In a cross-sectional survey of medical trainees in New Zealand (Coverdale et al. 2001), only 30 per cent had training in the management of violence and only 36 per cent of these viewed it as adequate. Only 62 per cent of those who were psychiatry trainees had received training in the management of violence.

PICU ward managers at a PICU conference took part in a UK cross-sectional survey (Clinton et al. 2001). Eighty-one percent of respondents stated that they would attend a course on violence management, however only 17 per cent were aware of relevant courses in their locality.

In a before and after study (Ilkiw-Lavalle et al. 2002), it was noted that staff with previous training would have preferred to focus on special skills rather than repeat basic training.

In a cross-sectional study using semi-structured interviews (Southcott et al. 2000), it was noted that staff wanted more frequent refresher courses (three to six monthly). In an unpublished pilot study by Bournemouth University, it was noted that, of the staff interviewed, 19/22 wanted more frequent refresher courses and a greater emphasis on de-escalation.

Staff satisfaction with training

In a before and after study (Goodykoontz and Herrick 1990), it was found that staff felt more confident in their ability to handle violent situations after training. They stated, four months after training, that they were more likely to intervene than they had been, rather than waiting for hospital security. After training, they felt that they had a plan of how to proceed when faced with a violent incident.

In a controlled before and after study (Rice 1985), the training course was well received (mean = 5.5 on a 6-point scale where 6 is the best possible score). The results were little altered at six weeks and 15 months.

In a cross-sectional study using semi-structured interviews (Southcott et al. 2000), it was noted that staff were generally satisfied with the training that they had received and felt that the techniques that they had learnt were both effective and appropriate immediately after training. (All staff received training in control and restraint and breakaway techniques).

In an unpublished cross-sectional pilot study with retrospective interviews (Bournemouth University) it was noted that of all staff interviewed, 19/22, were satisfied with the training they had received.

In a before and after study using interviews with a standard form (Parkes, 1996), staff felt safer and more in control when relocating the service user after having received training. They felt that C&R techniques appeared more professional to observers than unauthorised holds. Staff felt that training made it easier to hold the service user for a protracted length of time.

Staff perspectives relating to specific interventions

Prediction and risk assessment

In a before and after study (Collins 1994), nurses believed that some prediction of violence was possible immediately after the training course and six months post training.

De-escalation techniques

In a before and after study (Beech 1999), students nurses were confident that they could manage verbal aggression immediately after training ($p=0.0000$).

In a cross-sectional study using semi-structured interviews four months after training (Southcott et al. 2002), it was noted that staff felt that de-escalation training should be provided before breakaway training.

Restraint

In a cross-sectional study using semi-structured interviews four months after training (Southcott 2002), it was noted that staff felt that the process of restraint was often messy and unco-ordinated and could be improved with better planning. (All staff received training in control and restraint and breakaway techniques).

Self-defence

In a before and after study (Beech 1999), immediately after training, student nurses believed that they would be able to protect themselves using reasonable force ($p<0.0000$).

Evidence statements

Level of evidence	Evidence statement
Level 4	Staff perceive that training in the short-term management of disturbed/violent behaviour is beneficial and that it also increases confidence in dealing with disturbed/violent behaviour
Level 4	The evidence suggests that staff often feel that their need for training is not met.

I.d Review question: what are the views of service users about the various training programmes in adult psychiatric in-patient settings and their content?

In a controlled before and after study (Rice 1985), it was noted that after staff training, service users showed positive changes on a modified Coppersmith self-esteem inventory – a scale measuring depression and anxiety from an adjective checklist and on a modified feelings scale. The results were significant on maximum secure wards ($p<0.05$). The questions were given to each service user weekly from six weeks before training until six weeks after training. The researcher had wanted to assess service user responses to staff training through a ward atmosphere scale, but staff objected.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine service user perspectives on service user training to help service users manage their aggressive and/or disturbed/violent behaviour.

II Current practices in training in the UK

Four cross-sectional studies were found that examined current training arrangements in the UK.

Wright et al. (2000) examined the policies for the management of violence in PICUs and RSUs. One hundred and twelve wards were surveyed, 33 policies were returned (representing a good geographical spread). Nine percent of policies were current and not awaiting update; 9 per cent were out of date; 27 per cent were undated. Less than two-thirds of the policies had a stated aim or a definition of violence. Three-quarters of the policies stressed the need to report incidents, have post-incident team support, review the incident, outlined expectations and responsibilities of staff, emphasised prevention and de-escalation and had a commitment to train all appropriate staff. Just over half also mentioned the need for refresher courses. However, where a commitment to training was mentioned, less than half stated who was responsible for ensuring training was provided. Ninety four percent of policies listed physical restraint as an acceptable method for managing violence. However, less than half the policies listed unacceptable methods of restraint.

Lee et al (2001) investigated the training that is undertaken in PICUs and RSUs. One hundred and twelve units were contacted (760 staff) and there was a 47 per cent response rate. It was noted that it was possible to identify a core curriculum of 12 techniques across a range of courses: taking the patient to the floor, three-person restraint team, sitting and standing the patient, negotiating stairways and doors, restraining hold, roles within team, turning the patient over, breakaways, entry into and exit from seclusion, blocking punches, blocking kicks, separating fighting patients. Eighty-two percent of staff were able to identify the organisation that provided their training. Most initial courses lasted for five days. Respondents in RSUs were significantly more likely to be taught breakaway techniques ($p=0.03$), entry and exit from vehicles ($p=0.00017$) and defence against weapons ($p=0.02$) than respondents in PICUs. The three techniques most commonly used in practice were verbal de-escalation, restraining holds and use of three-person team. Thirty one percent of respondents did not state that their courses contained ethical and safety issues or verbal de-escalation. While 39 per cent received training within three months of taking up post, 21 per cent did not receive training for a year or more and 8 per cent had received no training at the time of the survey. Ninety-eight percent stated that they expected to attend a refresher course. Confidence in the skills learnt was high (mean = 4.63 on a six-point scale).

Davis et al. (2001) approached clinical directors in 193 NHS trusts that provide mental health services to assess

how much risk assessment training takes place. The survey had an 82 per cent response rate. Just over 50 per cent provided training on risk assessment for harm of others. Most trusts provided training on mental health legislation. Most trusts provided annual training courses, but these were not compulsory. Clinical directors noted that staff attendance was low, but that many staff received additional training as part of routine clinical work or courses such as MRCPsych. Around 50 per cent provided follow-up courses. The existence of written policies varied; most trusts had policies on observation.

Bleetman and Boatman (2001) conducted a cross-sectional questionnaire survey across 305 acute and community trusts, 30 ambulance trusts, 40 personal training organisations, and 63 corporate organisations. Mental health trusts were excluded. The aim was to provide an overview of control and restraint issues in the health services. The response rate was low. Acute and community trusts – 29 per cent; ambulance trusts – 30 per cent; training organisations – 45 per cent; corporate organisations – 13 per cent. The following results were noted: no significant difference in levels of confidence in the reporting process was found between those trusts using a specific aggressive/violent incident form and those using a general form. No significant results were found on the use of PPE or personal alarms. Training organisations reported the following results: 72 per cent stated staff were certificated to deliver training – but no standardisation; 56 per cent reported trainers were qualified first aiders; 78 per cent offered non-physical conflict management; and 67 per cent offered training in physical skills (types of skills outlined). Fifty percent knew skills taught were operationally effective. The evaluation of content of training packages appears subjective. This demonstrates the lack of standardisation in the UK. Authors note that it was not possible to reach any firm conclusions about the effectiveness of training techniques employed in the UK on the basis of this study.

Taken together, these four studies suggest that the following constitute the core curriculum of training courses in the UK:

- taking the patient to the floor
- three-person restraint team
- sitting and standing the patient
- negotiating stairways and doors
- restraining hold
- roles within team
- turning the patient over
- breakaways
- entry into and exit from seclusion
- blocking punches
- blocking kicks
- separating fighting patients.

However, the limited scope of these studies limits the generalisability of their findings.

Evidence statement

Level of evidence	Evidence statement
Level 4	The evidence on current training practices in the UK indicates that there is a lack of standardisation in the way staff are targeted for courses, and in the range of interventions covered. In addition, the effectiveness of training has not been adequately evaluated in a clinical environment.

7.8.3.4 Economic evidence

No studies containing relevant economic data were found. The following additional exploratory cost analysis was carried out (for full details see Appendix 9).

- The cost effectiveness of life support training was considered. It was concluded that the cost per QALY of immediate life support (ILS) training with automated external defibrillators (AED) under scenario 1 is around £23,000. Sensitivity analysis shows that this may be cost effective (i.e. cost per QALY of £20K or less), if one or other of the factors are favourably different from scenario 1.
- Scenario 5 suggests that advanced life support (ALS) training (where cost of training will be more than twice ILS) is highly unlikely to be cost effective.

7.8.4 Staff and service user perspectives

7.8.4.1 Staff and service user perspectives – general

7.8.4.1.1 **Objectives**

No specific searches on staff and service user perspectives were undertaken in the RCPsych guideline.

Current guideline

Three review questions were identified by the GDG to be addressed in this review:

Review questions

- Do staff and service users perceive themselves to be safe in psychiatric in-patient settings?
- What impact does disturbed/violent behaviour in psychiatric in-patient settings have on staff and/or service users?
- What are staff and service users' attitudes towards the

short-term management of disturbed/violent behaviour?

7.8.4.1.2 **Selection criteria**

Types of studies

Systematic reviews to before and after studies. Qualitative studies were also included (level 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

General staff and service user perspectives on the short-term management of disturbed/violent behaviour.

7.8.4.1.3 **Search strategy**

No specific searches were undertaken to identify papers that discussed staff and/or service user perspectives on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings, since all searches were broad enough to retrieve papers that examined staff and/or service user perspectives. The articles that form the basis of this review were identified by the various searches for each of the interventions covered in this guideline. However, rather than looking at a single intervention or area, we considered this topic in relation to the short-term management of disturbed/violent behaviour as a whole.

7.8.4.1.4 **Clinical evidence**

Eleven papers that examine general staff and service users' perspectives on the short-term management of disturbed/violent behaviour were identified by our searches. After critical appraisal, nine papers were included in this review. One was excluded. The other papers were overviews of a general nature, and were therefore ineligible. (Evidence tables of studies included only in this review can be found in Appendix 5. Evidence tables of studies excluded only from this review can be found in Appendix 6).

General: staff and service user attitudes towards disturbed/violent behaviour in psychiatric in-patient settings

Nine studies were identified which considered staff attitudes towards disturbed/violent behaviour. A range of study designs and perspectives were examined, making the results difficult to synthesise.

I.a Review question: do staff and service users perceive themselves to be safe in psychiatric in-patient settings?

In a survey (Baxter et al. 1992), it was noted that staff felt uncomfortable with the belief that they should be able to predict violent incidents and were concerned about the frequency with which violence occurred. They felt that there was a lack of support/protection from the hospital.

One cross-sectional study (Thomas et al. 1995) examined staff attitudes toward service user safety. Seventy five percent of nurses rated both themselves and service users as safe. However a smaller (unspecified) number of nurses stated that they believed that service users actually felt safe.

An overt researcher-as-participant study (Quirk et al. 2004) considered strategies used by service users to keep safe in adult psychiatric in-patient settings. The study was supplemented by interviews with staff, service users and advocacy work, as well as by results from a national audit. The following strategies for managing risk of violence were identified: avoiding risky situations, avoiding service users who explicitly warned others to keep away, finding a safe haven (like a bedroom), getting 'specialled' or not resisting it, using de-escalation techniques, allying oneself with someone high in the 'pecking order', making risk assessments of other service users (including proactive information gathering), warning staff about another service user, and getting discharged. The authors note that avoidance tactics were harder to employ in certain circumstances, like the canteen, where service users had to rely more heavily on staff. The authors concluded that service users take an active role in making a safe environment for themselves and are not passive recipients of safety interventions by staff. They suggest that, in part, this results from feeling unable to rely on staff to ensure their safety.

I.b Review question: what impact does disturbed/violent behaviour in psychiatric in-patient settings have on staff and or service users?

Using mostly interviews and/or questionnaires one study (Wykes and Whittington 1998), used a case-control design; one study (Cheung et al. 1997), used a cross-sectional approach; eight studies were identified which sought to examined the impact of violence on staff. None were found that looked at the general impact of violence on service users.

Two studies looked specifically at the impact of physical assault. Poster and Ryan (1989) tracked staff responses to physical assault over the course of a year. Although the authors noted that 82 per cent of nurses had resolved the crisis by week six, they also noted that 21 per cent of staff met responder criteria six months after the event, and 16 per cent met responder criteria one year after the event. The authors argue that there is a need to support staff to help them cope with their responses to physical assault. Omérov (2002) used interviews to assess the impact of physical attack and found that 43 per cent of staff felt insulted by the attack and one-third of staff felt angry. Men were more likely to be frightened ($p<0.05$) and women were more likely to feel surprised ($p<0.01$) regardless of the outcome of the assault. Most staff felt very uncomfortable after the assault, brought the incident home, found it hard to relax, had frequent nightmares and found returning to work difficult. All but one staff member would have welcomed self-defence training and refresher courses. The majority of staff requested some kind of post-incident debriefing. Interviews were performed three days after an incident. There was no long-term follow-up.

Wykes and Whittington (1998) noted a significant difference between non-assaulted and assaulted nurses in terms of psychological distress in relation to the general health questionnaire anxiety scale. Participants were assessed twice – once within 10 days of the incident and once approximately four weeks later. Comparisons were made with baseline scores in a control group. There was a decrease in distress levels between the first time and the second. However, two new victims met the diagnosis criteria for post-traumatic stress disorder (PTSD) at the second time, according to the post-traumatic stress scale (PTSS).

In debriefing procedures, it was noted (Flannery et al. 1995) that staff who had been verbally assaulted had similar PTSD-like symptoms and disruption in mastery and meaning similar to those who had suffered physical or sexual assault. Time between debriefing and incident is not specified. There was no long-term follow-up.

Using SOAS, Cheung et al. (1997) noted that one-third of staff were emotionally shaken by the incidents they had been involved in, even though the rate of injuries requiring treatment was low.

Gillig et al. (1998) noted that 18 per cent of the staff they interviewed were considering changing their careers because of the emotional impact of violence/aggression.

In a questionnaire survey of Swedish and UK nurses (Nolan et al. 2001) it was found that less support was available for UK nurses following an incident ($p<0.01$), although they were significantly more likely to experience violence ($p<001$), sustain minor injuries and experience violence involving a weapon ($p<0.05$) than Swedish nurses. UK nurses reported lower self-esteem ($p<0.05$), and if they had experienced violence in the preceding 12 months were more likely than their Swedish counterparts to always find their jobs psychologically taxing ($p<0.05$). In the study overall, a significant positive correlation was found between self-esteem and feedback from line managers ($p<0.05$).

In a further questionnaire survey of Swedish nurses (Soares et al. 2000), it was noted that victims of violence were more likely to be less satisfied with their salary ($p<0.05$), complain of insufficient lighting and poor ventilation ($p<0.001$) complain about noise ($p<0.001$), find their psychological environment taxing ($p<0.005$), report that their work site was unpleasant ($p<0.005$), feel restless ($p<0.05$), feel less proud of their organisation ($p<0.005$), and state that they lacked resources ($p<0.005$).

I.c Review question: what are staff and service users' attitudes towards the short-term management of disturbed/violent behaviour?

Eight studies attempted to elicit nurses' attitudes toward the management of disturbed/violent incidents.

Support/control emerged as a major theme in one survey (Lowe et al, 2002). Junior nurses were more likely to place an emphasis on limit setting and controlling strategies than senior nurses. Roper and Anderson (1991) conducted an ethnographic study on an in-patient emergency psychiatric unit to explore the variables underlying service user/staff interactions that might lead to violent incidents. Staff control emerged as a key theme, along with staff tension, helplessness/hopelessness, and counter-transference.

In a phenomological study, Cutcliffe (1999) noted a relationship between a nurse's ability to deal with an incident in a manner that promoted a therapeutic outcome and the nurse feeling supported in their work. Whilst there may not be a causal relationship between these two outcomes, this finding suggests the importance to nurses of being able to maintain a therapeutic relationship with service users.

Using semi-structured interviews, Spokes et al. (2002) found that nurses identified three key areas related to violence management: their clinical skills, personal characteristics (such as an ability to remain calm), and interpersonal skills.

Employing causal modelling, Morrison (1993) noted that psychiatric nurses disagree amongst themselves over how to define the seriousness of an incident.

Cutcliffe (1998) also noted that the decision to report an incident as violent depended on the therapeutic

relationship between nurse and service user. Using unstructured interviews, Critchon (1997) noted that nurses' management strategies were dependent on the diagnosis and gender of the service users, as well as the seriousness of the aggressive action. For example, seclusion was felt more appropriate for male service users.

Again using unstructured interviews, this time with video vignettes, Critchon et al. (1998) noted that Canadian nurses tended to advocate more controlling measures – like PRN medication and seclusion – whilst UK nurses tended to opt for less controlling techniques – like de-escalation. UK nurses were also more likely to talk to the service user about what had happened.

Using a phenomenological approach, Carlsson et al. (2000) identified seven themes underlying nurses management strategies: respecting one's fear, respecting the client, touch, dialogue, situated knowledge, stability, mutual regard, and pliability.

Five studies examined service user perspectives of violence in psychiatric in-patient settings. Three studies used questionnaires; one study (Kumar and Ng 2001) conducted a focus group; and one study (Lancee 1995) used role-play scenarios.

One survey (Svensson and Hansson 1994) assessed the effect of personality traits, diagnosis and perceived coercion on service users' satisfaction with psychiatric in-patient settings. It was noted that service users with a higher level of 'trait aggressive nonconformity' were significantly less satisfied with the ward's physical and psychosocial environment ($p<0.05$), the treatment design ($p<0.05$) and the treatment programme ($p<0.05$). Service users with a higher level of trait sociability were more satisfied with the treatment programme ($p<0.05$). Service users with affective disorders had significantly better satisfaction than service users with schizophrenia concerning: information and influence ($p=0.004$), ward environment ($p=0.005$) and general satisfaction ($p=0.003$). Service users who were involuntarily admitted were less satisfied with care in the areas of staff-patient relationship, ward environment, treatment programme and general satisfaction ($p<0.001$). A significant two-way interaction was detected between perceived coercion and the personality trait, aggressive nonconformity ($p=0.05$). Service users who perceived improvement in their condition had higher satisfaction with ward environment ($p<0.01$), treatment design ($p<0.01$), treatment programme ($p<0.001$) and general satisfaction ($p<0.01$). The phenomenon of acquiescence was not related to reported levels of satisfaction. The authors comment that careful consideration needs to be given to how to collect satisfaction scores from service users with schizophrenia or who perceived coercion in connection with their treatment.

Another survey (Gillig et al. 1998) noted that service users reported more depression and worry ($p<0.05$) and a change in appetite ($p<0.05$) than staff as a result of violence in psychiatric in-patient settings.

A further survey (Thomas et al. 1995) investigated service user reactions to being assaulted. They noted that female service users were more likely than their male counterparts to feel happy with staff responses to an incident (39 per cent vs. 23 per cent). However, they noted that women were less likely than men to feel safe on the wards (57 per cent vs. 81 per cent).

Six service users took part in a focus group (Kumar 2001) to discuss the experiences of being either perpetrators, victims or witnesses of violence. Several members fell into several or all of these categories. Six overarching themes were identified: firstly, that an imbalance of power exists in the mental health system; secondly, that violence has psychological sequelae; thirdly, that the mental health service is not geared to help victims of 'institutional violence'; fourthly, that the present mental health system fosters violence; fifthly, that a radical change is needed in the infrastructure of the mental health system; and sixthly, that reinforcement and reform may come from parallel efforts by staff and service users. Although acknowledging that the results may not be generalisable to a wider population, the authors argue that information saturation was achieved.

Role-play was used (Lancee 1995) to assess service user responses to different limit setting styles. Ninety-six service users participated, with limit setting styles ranging from belittlement to affective involvement with options. Service user anger at a particular limit setting style was the primary outcome variable. Three independent variables were considered: limit setting style, impulsivity and diagnosis. All proved significant (limit setting $p<0.001$, impulsivity $p<0.001$, diagnosis, $p<0.05$). The interaction between diagnosis and style had a greater significant ($p<0.01$). For all diagnostic groups, belittlement was most likely to cause anger. Impulsive service users were more likely to respond with anger to all limit setting styles than non-impulsive service users; non impulsive users had low anger for three limit setting styles – solution with options, affective involvement without options, and affective involvement with options. Service users with high impulsivity only responded with low anger to affective involvement with options. The same was also true of service users with schizophrenia. The sample size was too small to make other diagnosis specific observations. The authors argue that the study confirms that interpersonal factors play an important role in the management of anger in adult psychiatric in-patient settings.

Lanza et al. (1994) used interviews to compare staff and service user recollection of a violent incident. She found that with regard to 'objective' measures – such as limit setting and service users' actions during assault – there was general agreement between staff and service users. However, with regard to 'subjective' measures – such as the relationship between staff and service users, content of service users' speech, loudness of speech, number of staff and service users involved, and the cause of the incident – there was much less agreement.

Evidence statements

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that staff and service users believe that building therapeutic relationships, in which service users feel respected, leads to less disturbed/violent incidents. Key areas to be addressed in building such relationships include limit setting, and imbalance of power.
Level 4	The limited evidence suggests that service users are adversely affected by in-patient disturbed/violent behaviour.

7.8.4.1.5 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.4.2 Minority ethnic groups

7.8.4.2.1 **Objectives**

No specific searches on minority ethnic groups were undertaken in the RCPsych guideline.

Current guideline

Two review questions were identified and used to inform all searches (see Appendix 4 for search strategies, databases searched and search logs).

- Does race/ethnicity of a service user or staff member make a difference to how they are treated when they are involved in a disturbed/violent incident in adult in-patient settings?
- Do staff and/or service users perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a disturbed/violent incident in adult psychiatric in-patient settings?

7.8.4.2.2 **Selection criteria**

Types of studies

Systematic reviews to before and after studies. Qualitative studies were also included. (Evidence level 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Impact of ethnicity on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
- Staff and service user perspectives on the impact of ethnicity on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
- Bias in treatment or diagnosis, (prevalence/incidence rates).
- Effects of ethnicity/race on service users and/or staff.

7.8.4.2.3 **Clinical evidence**

One hundred and sixty eight papers were identified by our searches. After sifting for duplicates and papers outside the scope, 41 were ordered. Only 23 of these papers were included. Ten were excluded. The rest were overviews or outside the scope of the review. There were 13 UK studies and 10 US studies. Some of the US studies are based in psychiatric services for veterans (ex-military), a specialised population. Study settings varied from general acute psychiatric to specialist services – forensic or psychiatric intensive care. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

To supplement the evidence base for this review we also conducted three focus groups, two with black service users and one with health care professionals with expertise in working with black service users (see Appendix 14).

Included papers covered three broad areas that fall within the scope of the guideline: prediction, interventions and admission. Special review questions were devised to focus the review in each of these areas.

I Prediction

Seventeen studies were identified which addressed these questions. A range of study designs and perspectives were examined, making the results difficult to synthesis.

I.a Review question: can disturbed/violent behaviour in psychiatric in-patient settings be linked to ethnicity?

The following studies suggested that black and minority ethnic service users exhibited higher levels of violence toward others than white service users: Dixon (2000); Commander et al. (1997a), (1997b); Sheehan et al. (1995); Lloyd and Moodley (1992); Chen et al. (1991); Chu, (1985); Lawson et al. (1984). Six of these were UK studies Dixon et al. (2000); Commander et al. (1997a); Commander et al. (1997b); Sheehan et al. 1995, Lloyd and Moodley 1992; Chen et al. (1991); and two were US studies (Chu, 1985; Lawson 1984). Four were prospective studies: Commander et al. (1997a); Commander et al. (1997b); Chu (1985); Lawson et al. (1984); two retrospective chart reviews (Dixon 2000; Sheehan et al. 1995); one cross sectional (Lloyd and Moodley 1992) and one case-control (Chen 1991).

The following studies found that levels of violence towards others were not related to ethnicity: Kho et al. (1998), a UK prospective study; and Feinstein and Holloway (2002), a UK cross sectional study. In addition, a qualitative UK study by Morley et al. (1991) found that 53 per cent of service users who were sectioned were not considered dangerous by their relatives.

The following studies suggested that other ethnic groups exhibited higher levels of violence toward others than black and minority ethnic service users: Kho et al. (1998) showed Asian patients to be more aggressive. Lawson et al. (1984) showed whites to be more violent, to make more threats and to commit more self-destructive acts.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence from these studies is conflicting; it is therefore not possible to ascertain if different cultural groups exhibit higher or lower levels of disturbed/violent behaviour than other groups.

I.b Review question: are the tools used to predict disturbed/violent behaviour in psychiatric in-patient settings ethnically/racially biased?

A large number of tools were identified in the prediction evidence review. The majority of these make no mention of testing for racial bias. Therefore, it must be presumed that they have not been tested for racial bias. This is the case for the following tools which were found to indicate that black service users were more likely to be violent than white service users: Chu (1985) using the brief psychiatric rating scale and the Itil-Keskiner psychopathology rating scale.

Hutton et al. (1992) found that the overt hostility scale tended to suggest a greater propensity for aggressive or violent acts amongst black service users than occurred amongst white service users, and could lead to an erroneous interpretation as race was the only variable to emerge as a determinant of over hostility.

Choca et al. (1990) tested the cultural sensitivity of the Millon clinical multiaxial inventory to assess whether it was culturally fair. This personality instrument has weighted scores to provide different norms for black, white and Hispanic individuals to address potential bias. This study concluded that this test was a useful tool for prediction that takes account of racial bias, however some adjustment is needed to the item and scale levels.

Clinician prediction was also found to be at risk of racial bias: Hoptman et al. (1999) a US prospective study; McNiel and Binder (1995) a US retrospective chart review; and Strakowski et al. (1995) a US retrospective chart review. Minnis et al. (2001) surveyed British psychiatrists to test assessment bias in relation to violence. They suggested that racial stereotyping did not occur at first interview. Silver (2000) illustrates the effect of confounding according to the locality of the individual's residence and how this may effect reporting of results of violent incidents. Reubin et al. (1997) suggested that elevated levels of the enzyme creatine kinase can be used as a biological marker to predict aggression amongst African Americans. This finding could not verified from any other study.

Evidence statement

Level of evidence	Evidence statement
Level 4	On the basis of the available evidence, it is not possible to determine a 'gold standard' tool for the prediction of disturbed/violent behaviour appropriate for use amongst different ethnic groups.

II Interventions

II.a Review question: is intervention choice for the short-term management of disturbed/violent behaviour ethnically/racially biased?

One study specifically addressed this question.

Chen et al. (1991) found a significantly higher number of African Caribbean service users were given high dose neuroleptic medication for disturbed/violent behaviour than service users from other ethnic backgrounds ($p<0.03$).

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence (one study) to assess whether African Caribbean service users are given rapid tranquillisation more often than service users from other ethnic backgrounds.

II.b Review question: do staff and/or service users perceive that the race/ethnicity of a service user or staff member makes a difference to how they are treated when they are involved in a disturbed/violent incident in adult psychiatric in-patient settings?

Three studies examined attitudes of service users towards violence management in psychiatric in-patient settings in relation to ethnicity.

A qualitative UK study (Secker and Harding 2002), proposed key themes arising from interviews with African Caribbean service users relating to loss of control, experiences of racism and relationships with staff. Relationships with staff are very rarely experienced as positive.

A prospective UK study (Commander et al. 1997a), found that Asian and white service users are significantly more satisfied with in-patient treatment than black service users.

A UK descriptive survey (Wilson and Francis 1997), found that African Caribbean service users and African service users felt misunderstood as a consequence of being feared, ignored or stereotyped.

The two focus groups that the NCC-NSC commissioned from black service user organisations found that black service users perceived that they were given more restrictive interventions because of their race/ethnicity (see Appendix 14).

No studies were identified that examined staff perspectives on race/ethnicity in relation to the use of the interventions considered in this guideline for the short-term management of disturbed/violent behaviours in psychiatric in-patient settings.

The focus group which the NCC-NSC ran with nine health care professional who had experience of working with black and minority ethnic service users found that these health care professionals felt that the short-term management of disturbed/violent behaviour in the UK is racially/ethnically biased (see Appendix 14).

Evidence statements

Level of evidence	Evidence statement
Level 4	The limited evidence base suggests that black/ethnic service users perceive that there is racial/ethnic bias in staff choice of intervention for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings. Staff-service user relationships, and feelings of being stereotyped, ignored and afraid, are key areas of concerns for this group.
Level 4	Limited evidence from a focus group suggest that staff perceive that there is racial/ethnic bias in staff choice of intervention for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

III Admission

III.a Review question: are admission procedures ethnically/racially biased?

Commander et al. (1997a) mapped the pathways to admission for three ethnic groups (black, white and Asian). This study found that black service users were less likely to be receiving care from a health care professional prior to admission and that two-thirds of admissions involved the police.

Involvement of the police was examined in two studies, both from the US. Morley (1991) identified the role of police in admissions to hospital for African Caribbean service users experiencing psychotic symptoms. Commander et al. (1997a) noted that two-thirds of African Caribbean service user admissions involved the police and that the admission of Asian service users also had a higher level of police involvement than the admission of white service users. As both are US studies, it is difficult to generalise from them to the UK population. However, the two focus groups that the NCC-NSC ran with black service users also found that police involvement was often mentioned in connection with admission (see Appendix 14). Again, it is not possible to generalise on the basis of this small study to the UK population in general.

Evidence statement

Level of evidence	Evidence statement
Level 4	Limited evidence suggests that black service users may be likely to have experienced police involvement during the admission process.

7.8.4.2.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.4.3 Gender

7.8.4.3.1 **Objectives**

No specific searches on gender were undertaken in the RCPsych guideline.

Current guideline

Two review questions were identified and used to inform all searches (see Appendix 4 for search strategies, databases searched and search logs).

- What impact does gender have on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?
- What are staff and service users' perspectives on whether gender has an impact on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?

7.8.4.3.2 **Selection criteria**

Types of studies

Systematic reviews to before and after studies. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcomes

- Impact of gender on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
- Staff and service user perspectives on the impact of gender on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

7.8.4.3.3 **Search strategy**

Searches were run from 1998-2003/6, to capture current legislation, attitudes and organisation of care.

Three hundred and seventeen studies were identified in the initial sift. After sifting for relevance and duplicates, 20 full papers were ordered. Three met the inclusion criteria and 14 were excluded. All the other papers were opinion pieces, anecdotal reports, or fell outside the inclusion criteria for this review. References were checked but no further studies were identified. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Included studies

I Review question: what impact does gender have on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?

One study was included that considered the gender differences among perpetrators of violent assaults resulting in injury to staff: a case-control study in the US (Lam et al. 2000). This study showed no difference in the proportion of male and female psychiatric in-patients perpetrating such violence (20 per cent of male patients vs. 18 per cent of female patients).

No studies were found that answered the question of whether male and female perpetrators of violence in the in-patient psychiatric setting were treated differently.

One small cross-sectional survey of 59 psychiatric inpatients (31 males, 28 females, representing only 39 per cent of eligible patients) was included that considered the different experiences of male and female patients who were potential or actual victims of other patients (Thomas et al. 1995). A similar proportion of the men and women reported harassment (physical or verbal or sexual) by other patients (68 per cent of males and 75 per cent of females) or having been hit (42 per cent of males and 36 per cent of females). More women were molested sexually (32 per cent of females and 7 per cent of males, p=0.01) and fewer females felt safe on the wards (57 per cent vs. 81 per cent of males, p=0.05). While many incidents were not reported to staff, more females were satisfied with the staff response when they did report an incident (25 per cent vs. 7 per cent of males, p=0.05). However, the small and possibly unrepresentative sample precludes generalisation from this data.

One case-control study from the US, involving more than 200 staff over a period of 2.5 years, examined whether the gender of staff was a factor in the risk of being assaulted by a psychiatric in-patient (Binder and McNiel 1994). In this study, staff gender was not associated with the risk of being assaulted for doctors, nurses or both disciplines together, but nurses were more likely to be assaulted than doctors.

7.8.4.3.4 **Clinical evidence**

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that the gender of staff or service users does not impact on the incidence of disturbed/violent behaviour in psychiatric in-patient settings.

II. Review question: what are staff and service users' perspectives on whether gender has an impact on the short-term management of disturbed/violent in in-patient psychiatric settings?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence to determine staff and service user perspectives on the impact or influence of gender on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

7.8.4.3.5 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.4.4 Other special concerns

7.8.4.4.1 **Objectives**

No specific searches on other special concerns were undertaken in the RCPsych guideline.

Current guideline

Two review questions were identified and used to inform all searches (see Appendix 4 for search strategies, databases searched and search logs).

- What special considerations are needed in the short-term management of disturbed/violent behaviour where the service user has physical disabilities?
- What are the staff and service users' perspectives of the considerations needed for the short-term management of disturbed/violent behaviour where the service user has physical disabilities?

7.8.4.4.2 **Selection criteria**

Types of studies

Systematic reviews to before and after studies. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Impact of special concerns on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
- Staff and service user perspectives on the impact of special concerns on the interventions used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

7.8.4.4.3 **Search strategies**

Searches were run from 1998-2003/6, to capture current legislation, attitudes and organisation of care.

7.8.4.4.4 **Clinical evidence**

Nine papers were found in our searches. However all were excluded as none of them addressed the review questions.

Evidence statements

Level of evidence	Evidence statement
Level 4	There is no evidence that identifies the special considerations that are needed in relation to the short-term management of disturbed/violent behaviour where the service user has physical disabilities.
Level 4	There is no evidence to determine staff and service users' perspectives on what special considerations are required in relation to the short-term management of disturbed/violent behaviour where the service user has physical disabilities.

7.8.4.4.5 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.5 Psychosocial interventions

Original RCPsych guideline

The original RCPsych evidence review covering all psychological interventions, including both de-escalation techniques and observation, was examined. Their searches were undertaken based on the following review questions and hypotheses:

RCPsych review questions

- Can psychological interventions have the effects of reducing aggressive behaviour?
- Are particular psychological interventions more effective in reducing aggressive behaviour?

RCPsych hypotheses

- That psychological interventions can have the effect of reducing levels of disturbed/violent behaviour.

RCPsych sub-hypotheses

- That psychological interventions have no effect in reducing levels of aggressive behaviour.
- That particular psychological interventions are more effective in reducing levels of aggressive behaviour.
- That psychological interventions are similar in terms of reducing aggressive behaviour.

After sifting and quality checks, only eight papers relating to psychological interventions were included by the RCPsych reviewer.

The reviewer indicated that no evidence had been found on which evidence-based recommendations could be made:

> In conclusion, I found it impossible to answer our original hypotheses. We had no good evidence to support any of our original hypotheses. [...] We are unable to comment on whether any intervention is more effective that any other in reducing levels of aggression (RCPsych unpublished evidence review).

7.8.5.1 De-escalation techniques

7.8.5.1.1 Objectives

Current guideline

The current guideline focuses more specifically on particular psychological interventions – that is, de-escalation and observation. Two review questions were identified and used to inform the search strategy (see Appendix 4 for search strategy, databases searched and search logs).

Review questions:

- Are psychosocial techniques, such as de-escalation, effective in pre-empting, dissipating or preventing disturbed/violent behaviour in adult psychiatric in-patient settings?
- What are staff and service users' views about the effectiveness and appropriateness of de-escalation techniques as a means of diffusing disturbed/violent and potentially violent situations in adult psychiatric in-patient settings?

7.8.5.1.2 Selection criteria

Types of studies

Systematic reviews through to before and after designs. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- The effectiveness of de-escalation techniques at decreasing the number of disturbed/violent incidents and potentially violent incidents without the use of other interventions.
- Staff and service user perspectives on de-escalation techniques.

7.8.5.1.3 Clinical evidence

One hundred and ten studies were identified in the initial sift. After sifting for relevance and duplicates, 10 full papers were ordered. Seven were opinion pieces, anecdotal reports, or fell outside the inclusion criteria for this review. References were checked and four further studies were identified and ordered. However, only four studies were primary research papers, three of which proved relevant to the research question. No study offered evidence above level III. No additional studies from the RCPsych review were included. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Included studies

A prospective observation study (Jambunathan and Bellaire 1996) attempted to evaluate the effectiveness of crisis prevention (CPI) techniques in preventing the need for mechanical restraint and seclusion. Techniques were assigned levels and these were linked with a stage of escalation (see table below). Ten registered nurses prospectively collected data in four-hour shifts. All were trained in CPI on 12-hour initial training and four-hour refresher course. The study evaluated aggressive incidents including a wide cross-section of psychiatric patients in a state-run in-patient psychiatric facility. The study suggests that CPI techniques allow most conflict situations (84.2 per cent) to be resolved without the need for mechanical

Table 3 Outline of CPI techniques

Escalation level and associated behaviour	LEVEL 1: Anxiety (Change or increase in behaviours such as crying, pacing, rocking, wringing hands, raising voice)	LEVEL 2: Defensive (Begins to loose rationality, becomes verbal, yelling, belligerent, sarcastic, intimidates, uses verbal threats, shakes fists)	LEVEL 3: Acting out (Loses control, physical episode)	LEVEL 4: Tension reduction (Regains control)
CPI techniques used	Supportive, emphatic, active listening, asking questions, discussing thoughts/feelings, reducing stimuli, refocusing tasks, offering medication as needed.	Limit setting, allow verbal release, isolate situation, assemble a team, planning for de-escalation or physical control.	Physically holding patient, escorting patient to safe area, mechanical restraints or seclusion if CPI unsuccessful.	Attempt to regain therapeutic rapport, coping mechanisms, contracting.

(N.B. Most CPI techniques were verbal de-escalation techniques, however physical restraint is included in the third stage as a CPI technique.)

restraint or seclusion. Most service users' behaviour cues (76.6 per cent) and most staff interventions (69.4 per cent) occurred at level 2. However, there appeared to be a lack of intervention at level 1. It was also noted that more than 50 per cent of the incidents occurred on admission units. More medication was administered where staff did not have an in-depth knowledge of the service users.

While the study is reasonably designed, it is a non-experimental pilot study, observers were not blinded to either staff or service users, and staff were informed that observations would be carried out prior to the study. The results also do not allow the different service user groups to be analysed independently. No supporting evidence is offered for selection of antecedents of violence, or for their division into four levels of escalation. Supporting evidence is also lacking with regard to the relationship between levels of escalation and CPI techniques.

A before and after study at a veterans' medical centre, (Richmond et al. 1996) also measured whether the implementation of de-escalation techniques reduced the use of restraint and seclusion – unlike Jambunathan and Bellaire (1996), they did not treat physical restraint as a de-escalation technique. They suggested that training in verbal de-escalation, 'time out', relaxation techniques, medication, diversional activities and decreased stimulation led to a 47 per cent decrease in restraint use and a 31 per cent decrease in the use of seclusion. Whilst these results seem promising, the study design is non-experimental and confounders are not explored.

Staff perspectives

A qualitative study (Johnson and Hauser 2001) used unstructured interviews to elicit nurses' views on how to de-escalate the escalating service user. The author reported that expert nurses were able to develop an awareness of where service users are on the continuum of escalation, noticing early behavioural and verbal signs, which allowed them to successfully implement de-escalation techniques. However, the sample size was very small, and the method non-experimental.

Service user perspectives

A triangulation study using incident forms, questionnaires and interviews, (Duxbury 2002), noted that service users were not aware of staff using de-escalation techniques ($p<0.000$).

The RCPsych review did not include any studies that evaluated de-escalation techniques. Therefore the findings of this review alter those of the RCPsych psychosocial interventions review, although the evidence presented above is limited.

Evidence statement

Level of evidence	Evidence statement
Level 4	The limited evidence suggests that de-escalation techniques decrease rates of disturbed/violent behaviour.

7.8.5.1.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.5.2 Observation

7.8.5.2.1 **Objectives**

Current guideline

Two review questions were identified and used to inform all searches (see Appendix 4 for search strategy, databases searched and search logs).

Review questions:

- Are psychosocial techniques, such as observation, effective in pre-empting and preventing

disturbed/violent behaviour in adult psychiatric in-patient settings?

- What are staff and service users' views about the effectiveness and appropriateness of observation as a means of pre-empting and preventing disturbed/violent and potentially violent situations in adult psychiatric in-patient settings?

7.8.5.2.2 **Selection criteria**

Types of studies

Systematic reviews through to before and after designs. Qualitative studies were also included. (Evidence Levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- The effectiveness of observation techniques at decreasing the number of disturbed/violent incidents and potentially violent incidents, without the use of other interventions.
- Staff and service user perspectives on observation techniques.

Types of outcome excluded

- Observation which pertained to suicide or self-harm.
- Observation in non-psychiatric in-patient care settings.

7.8.5.2.3 **Clinical evidence**

Seventy-five studies were identified in the initial sift. After sifting for relevance and duplicates 22 full papers were ordered. However, 12 were opinion pieces, anecdotal reports, or fell outside the inclusion criteria for this review.

Fourteen studies were primary research, however, only nine studies proved relevant to the research question. No study offers evidence above level III. References were checked for missing articles but no further relevant primary studies were identified. No additional studies from the RCPsych review were included. (Evidence tables of included studies are found in Appendix 5. Evidence tables of excluded tables are found in Appendix 6).

Appraisal of methodological quality

In addition to the quality concerns mentioned above, these studies raised the following methodological concerns:

- Most of the studies (with the exception of Bowles and Dodds 2001; Shugar and Rehaluk 1990) did not address the question of effectiveness.

These studies were included to provide a systematic review of the research that has been conducted on observation in psychiatric in-patient settings. Gaps in the research can be readily identified and low graded evidence statements were presented to assist the GDG in their deliberations.

Included studies

Several statewide surveys to establish the reason why constant observation (CO) was used have been conducted in the US. Torkelson and Dobal (1999) carried out a six-month statewide survey focusing primarily on surgical and medical units and their use of CO. Stratified randomisation was used to select hospitals. Authors found that the decision to initiate and discontinue CO could be made by a wide spectrum of people (clinician, nurse, family member). The most common reason for CO was either danger to self or others. Although 84/89 hospitals agreed to participate, very little information on cost was provided. The results are difficult to analyse from the perspective of violence to others, since this is not differentiated from violence to self. The analysis is also flawed. No firm conclusions of the effectiveness of CO are offered.

Moore et al. (1995) also undertook a statewide survey. Hospitals were selected by stratified randomisation; 19/26 agreed to participate, however only 15 made use of constant observation (CO). Of these, only six were psychiatric hospitals. Again a wide spectrum of people made the decision to initiate CO. Those observing requested more training and information. There was a lack of information on costs. No attempt was made to differentiate between different interpretations of CO. The hospitals that used CO to combat violence are not specified.

Bowers et al. (2000) carried out a random stratified sample survey of constant observation (CO) policies in England and Wales. There was no consistency amongst trusts (see Evidence table for full details). Of 26 policies supplied, only two used the same terminology – constant observation had different meanings in different locations; level 1 meant either high or low levels of observation. Differences also existed between official policy and questionnaire responses. It was noted that this is particularly worrying, as agency staff are often used to carry out CO. The report does not discuss the effectiveness of CO.

Shugar and Rehluk (1990) conducted a retrospective controlled cohort study to consider the effectiveness of close observation (CO). Carried out in a psychiatric teaching unit, this study examined the use of CO in both civil and forensic patients. Various predictors signalling the need for CO were identified. However, most patients had CO supplemented by medication, so that it is difficult to assess the efficacy of CO. The authors acknowledge this and therefore only offer tentative conclusions. The authors suggest that CO should only be used as a short-term measure but offer no evidence. While an interesting study, the design is weak and the conclusions may therefore be limited.

Philips et al. (1977b) used a retrospective/historic two-year cross-sectional survey to assess whether a correlation existed between involvement in constant observation (CO) and absenteeism. A statistically positive correlation ($p<0.05$) was noted. Discrepancies were explained in terms of reduced staffing levels forcing a reduction in CO, and high demand for CO obligating nurses not to take sick leave. There is a lack of essential information in this study. The conclusions drawn should be interpreted with caution.

Philips et al. (1977a) identified the type of service users who usually receive continuous observation (CO). Using a retrospective 10-year cohort study, they found that service users receiving CO were most likely to be female and suffering from either schizophrenia or depression. (CO was used for suicide risk for both types of service users, and for behavioural reasons with service users suffering from schizophrenia). The age range for service users with depression was between 30-50, while for schizophrenia, it was between 15-29 years and 35-40 years. Staff concerns about CO related to the length of time an individual nurse was engaged in CO (entire shift) and the effect of CO on other service users and staff within the ward. Seventy-five percent were in favour of a special unit for CO, with 45 per cent suggesting they would be prepared to work there full-time, 34 per cent sometimes and 21 per cent never. The author stresses that more research is necessary to elicit the therapeutic value of CO – a procedure that is identified as cost effective but time consuming.

Bowles and Dodds (2001) report the effect of dismantling the formal observation policy in a 21-bedded acute ward in Bradford. They argue that formal observation became redundant and, after 18 months, one-to-one observation was not used at all, with five to 10 minute checks used only rarely. The number of suicides did not increase, but the levels of absconding were almost halved, with self-harm falling by two-thirds and violence and aggression by a third. Staff sickness was also reduced by two-thirds. Removal of the policy has also meant a saving of £45,000 over 12 months. They state that service users are now more involved in their care and in ward decisions. The authors argue that the removal of this policy – which they describe as an 'outmoded ritual of mental health nursing' – has freed up nurses' time, allowing activities to be set up and time to be 'gifted' to service users as required. Ninety-five percent of service users now receive daily one-to-one time with a nurse, which the authors argue is the most valuable intervention. While the authors acknowledge that the study is too small for the results to be generalised, they insist that it should bring the practice of formal observation into question. This study does not provide enough information about their previous formal observation policy and so is open to a number of interpretations. The one-to-one interventions implemented, once formal observation was dismantled, could be viewed as a more therapeutic and appropriate form of formal observation.

A three-and-a-half month prospective audit was conducted in a psychiatric intensive care unit (Lehane and Rees 1996). It examined responses to incidents that would have formerly led to seclusion. The author notes that one-to-one nursing was used in 86 per cent of cases but does not offer any information on its effectiveness. The sample size is relatively small.

Service user perspectives

One study examined service user perspectives on observation. Jones et al. (2000) conducted a three-month survey in one mental health trust to assess service users' feelings about and preferences within constant and close observation – the highest level out of four levels employed within the trust. The study revealed that mental health service users – including those who exhibited aggressive behaviour, but particularly those with suicidal tendencies – preferred to be observed and felt safest when observed by either nurses they knew or nurses who talked to them.

Staff perspectives

One study considered staff perspectives on observation. Neilson and Brennan (2001) carried out a retrospective/historic audit to determine staff knowledge of and attitudes toward a new hospital special observation (SO) policy and differences between wards with respect to these two variables. This was assessed by a knowledge questionnaire, semi-structured interviews and a score-schedule of a randomised sample of 144 special observation record sheets (SORS). The hospital policy had four levels of SO – red, amber, blue and green – in order of decreasing urgency. Nurses were purposely selected to ensure a broad mix of trained and untrained staff. All staff demonstrated good knowledge of the policy. However, although 35.29 per cent stated that communication and documentation had improved since its implementation, authorising signatures and reasons for SO were often not stated. Staff also felt that decisions about SO were too

medically driven (94.2 per cent) and that there was poor medical review of SO (32.36 per cent). In addition, 82.4 per cent felt that blue level was used too frequently, without clinical assessment of need. They also stated that it was impossible for staffing levels to meet current demands of SO (73.6 per cent); 29.41 per cent felt that red level could provoke disturbed patients and 23.6 per cent felt that gender needed greater consideration when allocating staff to SO.

Yonge and Stewin (1992) conducted qualitative research using 'ethnography' – a programme for textual analysis. Findings suggested that close observation (CO) is a procedure that nurses find stressful. Nurses felt that they were also on CO and had to find ways of dealing with emotions caused by this encounter. Meal times and bathroom visits were flagged up as particularly stressful for nurses. None of the nurses interviewed accompanied the patient into the bathroom, even where this was in breach of hospital policy. Nurses also supported one another in handover, attempting to limit the repetitive questions for the patient. At the same time, some saw CO as an opportunity to develop a quality relationship with the patient. Nurses expressed different preferences for certain types of CO patients – psychotic, depressed.

The RCPsych review did not include any studies that evaluated observation. Therefore the findings of this review alter the findings of the RCPsych psychosocial interventions review, although the evidence presented above is limited.

Evidence statements

Level of evidence	Evidence statement
Level 4	It is not possible to ascertain the effectiveness of observation on the basis of the available evidence.
Level 4	The limited evidence suggests that service users prefer to be observed by a nurse that they know and that most staff find observation a stressful procedure.

7.8.5.2.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.6 Other interventions

7.8.6.1 Physical interventions and seclusion

7.8.6.1.1 **Objectives**

The original RCPsych guideline evidence base on restraint and seclusion was examined. A list of excluded studies was available in the archived information received from the Royal College of Psychiatrists' Research Institute. The following information was taken from the final report in the RCPsych guideline, which states that these hypotheses were used to inform their search strategies:

RCPsych hypothesis:

- Restraint when skilfully applied by trained and supervised staff, according to monitored protocols and the context of other methods, is an effective and safe means of coping with overtly violent behaviour.
- When properly used and explained, restraint can be acceptable both to users of services and to staff.
- Seclusion is unnecessary if restraint is properly applied in association with other methods of good practice.

After sifting and quality checks, 16 references on restraint and seclusion were included in the RCPsych evidence review.

However, the included studies did not offer generalisable criteria in support of these hypothesis so the RCPsych review concluded that:

No strongly evidence-based conclusions can be drawn from the quantitative evidence.

Current guideline

Three review questions were identified and used to inform all searches (see Appendix 4 for search strategies, databases searched and search logs). Physical intervention includes the use of pain compliance.

Review questions

- Is physical intervention safe and effective for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?
- Is seclusion safe and effective for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?
- What are service users' perspectives on the use of physical intervention and seclusion for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings?

7.8.6.1.2 **Selection criteria**

Types of study

Systematic reviews through to before and after designs. Qualitative studies were also included. (Evidence levels 1-2).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any

form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Effectiveness and safety of various physical interventions and seclusion when used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
- Staff and service user perspectives on physical interventions and seclusion when used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

7.8.6.1.3 **Clinical evidence**

One hundred and thirty three studies were identified in the initial sift. After sifting for relevance and duplicates 84 full papers were ordered. After quality appraisal, 21 papers were included, seven papers were excluded and 60 were opinion pieces, anecdotal reports, or fell outside the inclusion criteria for this review. References were checked and 14 further studies were identified and ordered. None met the inclusion criteria. In addition, 10 studies from the RCPsych review were included. (Evidence tables of all included studies can be found in Appendix 5. Evidence tables of all excluded tables can be found in Appendix 6).

Quantitative evidence

A Cochrane review undertaken by Salias and Fenton (2001) focused on the effectiveness of restraint or seclusion or strategies designed to reduce the need for restraint or seclusion in the treatment of mental illness. It found no trials that met the minimum criteria. It concluded:

> In the absence of any controlled trials in those with serious mental illness, no recommendation can be made about the effectiveness, benefit or harmfulness of seclusion or restraint. In view of data from non-randomised studies, use should be minimised for ethical reasons.

This Cochrane systematic review is currently being updated. Contact with the author suggests that the conclusions are unlikely to change.

Four studies in the RCPsych review considered the role of the seclusion room in a psychiatric in-patient setting (Brooks et al. 1994; Craig et al. 1989; Hafner et al. 1989; Kingdon and Bakewell 1988). Two of these studies suggest that use of seclusion rooms reduce violent incidents. However, one study (Kingdon and Bakewell 1988) suggests that violent incidents are better reduced by improved staffing patterns, education and management participation. The fourth study (Brooks et al. 1994) suggests that both levels of restraint and seclusion are increased by overcrowding.

No studies examined the use of pain compliance in physical interventions.

Evidence statements

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine the effectiveness and safety of either physical interventions or seclusion for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.
Level 4	There is insufficient evidence to determine the effectiveness or acceptability of pain compliance as a technique for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings.

Sudden death

Evidence from published case series that link physical interventions to adverse reactions was collated (see Evidence tables of included studies, Appendix 5). It was not possible to determine whether there was a relationship between physical interventions and an increased likelihood of sudden death.

Three studies were conducted in attempt to show the relationship between restraint and positional asphyxia. Parkes (2000), Schmidt and Snowden (1999) and Chan et al. (1997) conducted experimental studies on healthy subjects. All suggest that restraint in the prone position does not result in effects likely to cause death and that other factors need to be in situ.

This issue was not specifically addressed in the RCPsych review.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine the relationship between physical interventions and sudden death.

Staff and service user perspectives

Six studies examined staff perspectives on physical intervention and seclusion:

One study focused on staff decision-making processes. A sample of 64 nurses – a response rate of 77 per cent – were

asked about knowledge and experience gained, as well as values and concerns with regard to the practice of seclusion. Key themes emerged around safety and the abuse of seclusion. However, in a further study, nurses stated that seclusion had a place in real world practice (Alty 1997).

Muir-Cochrane (1996) found that, in a sample of seven nurses, the core underlying themes relating to the use of seclusion were control, and that staff saw themselves as gatekeepers who maintain control.

Mason (1997) took a random sample of 25 nurses in a forensic hospital and found decision-making around the use of physical interventions and seclusion to be based upon the need to stick to an original decision. They found that a feeling of being under the gaze of others in authority led to the need to balance the responsibility of an untoward incident, against care of the individual. Furthermore, they found that nurses felt a need to justify their actions to those in authority and therefore tended to adopt positions of safety.

Marangos-Frost and Wells (2000), in an ethnographic study, interviewed six nurses on an unlocked psychiatric ward. They found themes consistent with other studies presented here, in particular concerning the decision-making dilemma of choosing between risking harm to the patient and others, or restraining – both equally unwelcome options. However, the findings were based on those that self-harmed, as well as those that harmed others, and the nurses were very experienced, therefore not representative of the usual ward staff team.

Holzworth and Wills (1999) found a sample of nine nurses in a short-term psychiatric hospital had a preference for seclusion over restraint. However, they noted that overall, there was inconsistency between nursing staff in selecting seclusion, restraint or observation. Lemonidou (2002) conducted a descriptive survey of nurses' attitudes and choice of restrictive intervention. The study involved 190 nurses in adult psychiatric inpatients in five hospitals in Greece. The findings suggest that nurses prefer seclusion to restraint. It was also noted that nearly half of the service users continue to be aggressive after restraints were removed. However, this study focused on the use of mechanical restraints.

The RCPsych review also contained two further studies (Tooke and Brown 1992; Soliday 1985), which compared staff and service user perceptions of seclusion. Service users who had been secluded had less favourable attitudes towards seclusion than either staff or service users who had not been secluded. Some service users saw seclusion as punitive. However, other service users saw a need for seclusion. In one of the studies, staff stated that they could not see how they could cope without access to a seclusion room.

Four studies examined service user perspectives on physical intervention and seclusion:

A relatively recent UK-based study carried out by Sequeria and Halstead (2002) with a sample of 14 in-patients who had been interviewed 12 hours after being restrained, found emergent themes of anger with a sense of injustice, and that service users felt that the intervention was unwarranted. The researchers also noted that anxiety continued long after the incident, along with mental upset. Contrary to this, the study also found that female patients restrained by female staff welcomed the safe feeling of containment, which even led to them seeking restraint.

A study by Gallop et al. (1999) highlighted concerns raised about the effects of restraint on those who may have previously suffered sexual abuse. They found that service users reported negative experiences of being rendered powerless and being degraded. In this study, six out of the 10 participants were restrained for self-harm. Therefore, care is required whilst extrapolating to this review. Nevertheless the study highlights the need to be aware of previous history when considering this intervention.

Bonner et al. (2002) conducted a pilot study in the UK, where he interviewed two members of staff and a service user involved for each incident that resulted in physical restraint. Initial findings suggested that failed communication is an antecedent of restraint. The study further suggested that restraint was used as a last resort to contain and support the patient. The study also suggests that both patient and staff can suffer trauma and distress after the incident and that support, post incident, is important to both groups.

Using a questionnaire survey (Mann et al. 1993), suggested a range of attitudes towards the seclusion room, with only a minority of service users suggesting that there should be no such room. The authors noted that many service users reported that the room was helpful. They noted that these tended to be service users who had no history of substance abuse ($p<0.05$). Conversely, service users with no history of substance abuse more often reported that the room was like a padded cell ($p<0.05$). Service users who used the room for the first time were more likely to report that it was stuffy ($p<0.05$) and to describe it as torture ($p<0.05$). Non-compliers were less likely to label the room safe and secure ($p<0.05$). Service users with disorders other than depressive disorders were more likely to report that once in the seclusion room, it is difficult to get out ($p<0.05$).

Three further studies in the RCPsych review (Wise et al. 1988; Hammill et al. 1986; Binder and McCoy 1983) surveyed service users who had experienced seclusion. Another study (Eriksson and Westrin 1995) surveyed service users about seclusion, rapid tranquillisation and restraint. These studies found a mixed response to these

measures. Whilst service users sometimes saw a need for them, on many occasions they felt that they had been used unnecessarily.

None of these studies significantly change the findings of the RCPsych review.

Evidence statements

Level of evidence	Evidence statement
Level 4	The available evidence suggests that staff may find using seclusion and physical interventions traumatic, but also consider that these interventions serve a necessary function.
Level 4	The limited evidence suggests that service users may find seclusion and restraint degrading, although some service users believe that measures, such as seclusion and physical intervention, are sometimes justified.

7.8.6.1.4 **Economic evidence**

No studies containing relevant economic data were found (see Appendix 9).

7.8.6.2 Rapid tranquillisation

7.8.6.2.1 **Objectives**

The aim of this review is to examine the evidence on the efficacy and safety of medications currently used for rapid tranquillisation (i/v, i/m, oral (any form) in psychiatric in-patient settings). It builds on the original RCPsych guideline, the NICE schizophrenia guideline (2002) and a recent New Zealand health technology appraisal (2001) all of which also examined this intervention.

I Original RCPsych guideline

The original RCPsych evidence review on rapid tranquillisation was examined. Their searches were undertaken based on the following review questions and hypotheses:

RCPsych review aim

- To produce a systematic review of the use of medication in managing violent incidents in clinical settings in which mental health care is provided.

RCPsych hypotheses and sub-hypotheses

- Is medication effective and safe in preventing and managing violent incidents?
- What are the contra-indications to using medication to manage disturbed/violent behaviour?
- Is the effectiveness of medication related to general sedation or to specific therapeutic effect on an underlying disorder?
- Is medication effective in the management of disturbed/violent behaviour irrespective of the aetiology of disturbed/violent behaviour?

The RCPsych review inclusion criteria:

Any controlled or non-controlled (including qualitative) research studies.

The RCPsych outcome measures:

- The reduction of disturbed/violent behaviour
- An increase of safety to patients and staff
- Measure of therapeutic effectiveness
- Measure of harmful effects of medication
- Measure of the threshold of the use of medication.

Searches were made from 1986-1996 on Medline, Cinahl, Embase and Psychlit.

After sifting and quality checks, 15 references relating to rapid tranquillisation were included by the RCPsych reviewer. Of these, only six were controlled studies that were judged to be fair to good.

The reviewer indicated that no evidence had been found on which evidence-based recommendations could be made.

The review of the literature has shown that using strictly evidence-based criteria, no individual or combined psycho-pharmacological agent (s) is the definitive intervention during or just prior to an act of violence [...] It is clear that more research needs to be carried out if the questions posed in our hypotheses are to be satisfactorily answered.

II Schizophrenia guideline

The systematic review for the NICE schizophrenia guideline (2002) drew on Broadstock (2001) and the Cochrane review of zuclopenthixol acetate (Fenton M et al. 2001). They identified six phase III randomised controlled trials that addressed the issue of rapid tranquillisation in relation to schizophrenia. These have been added to the evidence review for this guideline.

III New Zealand health technology appraisal (HTA) (M Broadstock 2001)

This systematic review identified 12 phase III randomised controlled trials that addressed the issue of rapid tranquillisation. These have been added to the evidence review for this guideline. One of these studies (Thomas et al. 1992) was excluded from the current review, as most of the participants had a primary diagnosis of intoxication and therefore falls outside the population considered in

this guideline. Another study (Salzman et al. 1991) was excluded, as it did not appear to be a randomised controlled trial.

Current guideline

The current guideline focuses on the efficacy of rapid tranquillisation as an intervention for the short-term management of disturbed/violent behaviour. However, unlike the RCPsych review, dual diagnosis is not included in the scope. This has meant that some papers included by the RCPsych and the New Zealand HTA are excluded from this review. The inclusion criteria are also more stringent, as only systematic reviews to phase III randomised controlled trials are included, as noted below, which has led to further exclusions from the RCPsych review.

The following questions were identified and used to inform the search strategy of the current review (see Appendix 4 for search strategy, databases searched and search logs).

Review questions:

- What is the effectiveness of brief or fast acting pharmacological interventions for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings?
- How safe are the pharmacological agents that are used for rapid tranquillisation and what are the side effects?
- What are staff and service users' views/perceptions about the effectiveness and appropriateness of pharmacological interventions as a means of intervening in a disturbed/violent or imminently violent situation?
- How safe and effective is PRN medication for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings?

7.8.6.2.2 **Selection criteria**

Types of study

Systematic reviews through to phase III randomised controlled trials (evidence level 1). Qualitative studies and surveys were also included to obtain information on staff and service user views to answer review question 3.

Interventions

Rapid tranquillisation i/v, i/m, and oral (any form).

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All adult in-patient mental health settings, excluding learning disability.

Types of outcome

- Decrease in hostility/aggression
- Tranquillisation
- Sedation/somnolence
- Side effects and adverse reactions
- Satisfaction with care
- Economic outcomes (considered in separate economic review – see Appendix 9).

7.8.6.2.3 **Search strategy**

In addition to the searches covering 1985-2003, searches were also conducted covering 1969-1985 on all databases to ensure that no research papers were missed in the RCPsych review.

7.8.6.2.4 **Clinical evidence**

Eighty-three studies were identified in the initial sift. After sifting for relevance and duplicates 71 full papers were ordered. A further paper was identified through the stakeholder consultation process.

Medication

Twenty-three papers were opinion pieces, anecdotal reports, letters, or fell outside the inclusion criteria for this review. References were checked and one further study was identified.

Eight papers were systematic reviews, seven of which proved relevant to the research question. However, one systematic review was a duplicate, so only six systematic reviews were included. Eleven randomised controlled trials were retrieved; one was excluded because it was already included in an included systematic review. Ten further randomised controlled trials that were not mentioned in any of these systematic reviews were located, all of which proved relevant to the research question. All trials were phase III as advised by NICE. All evidence is level 1.

The rapid tranquillisation search strategy was broad enough to have found any articles on PRN that related to the short-term management of disturbed/violent behaviour. One systematic review (Whicher et al.2002) was found and five further studies were identified.

Service user and staff perceptions

Seven surveys and qualitative studies examined staff and service user perceptions and preferences in relation to rapid tranquillisation and PRN medication. These studies were included, as they address the acceptability of this

intervention to staff and service users, and doctors' preferences concerning rapid tranquillisation medications, and therefore supplement the evidence base from randomised controlled trials. All evidence is level 3.

Sudden death

Although sudden death was not searched for specifically, one case study on sudden death was retrieved by the searches. Three further studies were located in references to studies ordered for this review. No study presented evidence above level 2.

Additional search

In addition to the search from 1985-2003, a further search was conducted from 1969-1985 to ensure that no research papers were missed by the RCPsych review. Seventy papers were identified in this search. After sifting for relevance and duplicates, 30 full papers were ordered. A further seven papers were included, 19 papers were excluded and 13 papers were opinion pieces, anecdotal reports, letters, or fell outside the inclusion criteria for this review. References were checked, but no further studies were identified.

Of the seven included papers, three were randomised controlled studies that examined drugs used for rapid tranquillisation. Three were cross-sectional surveys, which examined the use of PRN medication in various relevant settings, and one was a cross-sectional study of service users' attitudes to an incidence of forcible medication.

(Evidence tables of all included studies can be found in Appendix 5. Evidence tables of all excluded tables can be found in Appendix 6).

Appraisal of methodological quality

Common methodological shortcomings were:

- inappropriately small sample sizes (number needed to treat (NNT) not always stated or sufficient)
- participants not always sufficiently agitated to require rapid tranquillisation
- outcome measures not always sufficiently defined
- intention to treat analysis not always clearly described
- statistical measures (OR, RR, CI) not clearly reported.

Included studies

I Systematic reviews

Six systematic reviews were used to inform this review.

Efficacy of medication

Four of these reviews looked at the efficacy of a particular medication. Three reviews were all of very high quality (Cure and Carpenter 2001; Fenton et al. 2001; Carpenter and Berk 2000); a further review was of a lesser quality, but the quality was not overly compromised (Aleman and Kahn 2001). These reviews were used as part of the evidence base for assessing the efficacy of the medications droperidol, zuclopenthixol acetate, clotiapine and risperidone. Three of these reviews examined the efficacy of these medications specifically with reference to rapid tranquillisation (Carpenter and Berk 2002; Fenton et al. 2002; Cure and Carpenter 2001). These three reviews looked at the efficacy of droperidol, clotiapine and zuclopenthixol acetate respectively. All three reviews concluded that the use of these medications in emergency psychiatry was currently only justified in terms of clinical (that is, expert opinion), rather than research evidence. Clotiapine is off patent and currently unavailable in the UK since the manufacturers, Novartis, found the production off patent costs prohibitive. Droperidol was voluntarily withdrawn by the manufacturer, Janssen-Cilag Ltd, from the end of March 2001, amid concerns over the medication's safety as an oral treatment for chronic conditions. Cost effectiveness of production resulted in other forms of the medication also being withdrawn.

The reviewers suggest that further research is needed into the efficacy of droperidol for the purposes of rapid tranquillisation, for which it seemed to be safe, although the evidence underlying the medication's safety is also clinical rather than research-based. Likewise authors of the review on clotiapine also stressed that whilst they did not want to discourage the use of this medication for rapid tranquillisation, more research is needed to establish its efficacy and safety in relation to other medications used for this intervention. Similar conclusions were reached about zuclopenthixol acetate, with the reviewers stressing that there was no evidence to suggest that this medication was either safer or more effective than other medications currently used for rapid tranquillisation. Furthermore zuclopenthixol acetate is slow acting and therefore is normally no longer recommended for rapid tranquillisation. This evidence is graded at level 1.

The evidence from these reviews indicates that none of these medications emerges as a gold standard medication for use in rapid tranquillisation. Zuclopethixol acetate is slow acting and not normally used for rapid tranquillisation and both droperidol and clotiapine are unavailable in the UK for rapid tranquillisation. The evidence tables and meta-analyses relating to these medications are given in Appendix 8.

Evidence statement

Level of evidence	Evidence statement
Level 1+	The available evidence suggests that zuclopenthixol acetate should not normally be used for rapid tranquillisation.

Risperidone

The other systematic review which was included as part of the evidence base for this guideline examined risperidone (Aleman and Kahn 2001), an atypical antipsychotic. This study did not focus on the issue of rapid tranquillisation. However, it was included because it informed the review about the action of this agent and its various side effects. (All meta-analyses from this systematic review are included in Appendix 8).

The review of risperidone (Aleman and Kahn 2001) considered this medication's function for the management of aggression, but excluded a study because it looked specifically at violence, although there were additional quality issues underlying this exclusion. Some attempt was made to counter the heterogeneity of the studies, by carrying out analyses of only double-blinded randomised studies and those with similar doses, in order to assess the significance of various methodological differences between the studies. The reviewers argue that there was a clear superiority of risperidone over conventional antipsychotics (mostly haloperidol). However, the authors acknowledge that the service users in the included studies did not have chronic aggressive behaviour, which limits the generalisability of the result in relation to rapid tranquillisation. The reviewers also note that risperidone is not available as an intramuscular preparation, which further limits its suitability for an emergency situation. The authors' conclusions on the efficacy and appropriateness of risperidone appear to be overly optimistic in relation to the evidence base and should, therefore, be interpreted with caution.

All the papers included in the above reviews are not included separately in the evidence tables. The literature was trawled for further studies that would add to the evidence base of these reviews, but no additional studies were located.

Systematic reviews assessing the safety and efficacy of rapid tranquillisation

Two further systematic reviews were included in this evidence review, but were considered principally in terms of background information. Both reviews had a similar aim to the current review – that is to assess the efficacy and safety of rapid tranquillisation as an intervention for the short-term management of violence (NICE schizophrenia guideline 2002; Broadstock 2001). Both of these reviews stressed the dearth of the evidence base. Neither suggested that one medication emerged as the gold standard medication for use in rapid tranquillisation. The schizophrenia guideline undertook limited meta-analysis while Broadstock did not. Both studies identified medications that they believed were safe and efficacious for rapid tranquillisation on the basis of very limited research evidence. The NICE schizophrenia guideline closely followed the Broadstock review, which is being used as a base for this current review. In addition, many of the recommendations from the schizophrenia guideline were drawn verbatim from the RCPsych review. In addition to recommending the use of intramuscular haloperidol (a conventional antipsychotic) and intramuscular lorazepam (a benzodiazepine), they also suggested that intramuscular olanzapine (an atypical antipsychotic) should be considered for use in rapid tranquillisation for service users with schizophrenia. They suggested that a combination of haloperidol and lorazepam should be used only in exceptional circumstances and also that the BNF limits should not be exceeded, except within exceptional circumstances. They recommended the use of intravenous medications, as the original RCPsych guideline had done, for exceptional circumstances. They also recommended that i/m diazepam and i/m chlorpromazine should not be used for rapid tranquillisation.

The New Zealand health technology appraisal, undertaken by Marita Broadstock, (2001) suggested that benzodiazepines and antipsychotics seemed to be reasonably safe and effective for rapid tranquillisation and that no significant differences in terms of effectiveness were noted between them or between single and combination regimes. The review argued that there was some evidence to suggest that droperidol may be faster acting that other antipsychotics, but equally safe and effective. They found no studies that appraised the effectiveness of valproate or atypicals and therefore did not comment on their efficacy or safety for use in rapid tranquillisation. They also noted that there was some evidence to suggest that there were less extrapyramidal symptoms (EPS) associated with benzodiazepines (lorazepam), or benzodiazepines and antipsychotics (lorazepam and haloperidol) in combination, than when antipsychotics were used alone (haloperidol, clotiapine). Broadstock (2001) notes that the conclusions arrived at are broadly consistent with those found in the RCPsych guideline.

Conclusion

The current guideline is not considering studies where the primary diagnosis is alcoholism or substance abuse. Therefore studies included in these reviews were included or excluded from this guideline review, on the basis of the inclusion criteria outlined above. One study (Thomas et al. 1992), included in both Broadstock (2001) and the RCPsych guideline was excluded in this guideline's review because the study population did not necessary or primarily have a psychiatric illness, and because most of the participants were intoxicated. This trial was also excluded from the Cure and Carpenter (2001) systematic review on these grounds. All other randomised controlled

trials included in these reviews were included in the current review and are assessed below, in conjunction with several additional randomised controlled trials identified in the searches.

II Randomised controlled trials

Nineteen randomised controlled trials, not included in the systematic reviews by Cure and Carpenter 2001; Fenton M et al. 2001; Carpenter and Berk 2000 are included in this review. One of these studies reported on two different trials (Garza-Trevino et al. 1989). Eleven of these studies were conducted in the USA. One took place in Israel, one took place in Brazil, one took place in India, one took place in Denmark and the other three were multi-country studies. Unless otherwise stated, all studies compared intramuscular loading (i/m) of various medications. Some studies switched to oral loading after the first 24hours. Where this occurs, it is indicated in the evidence tables.

Haloperidol vs. lorazepam (vs. haloperidol and lorazepam)

Four studies compared the benzodiazepine (i/m) lorazepam and the conventional anti-psychotic (i/m) haloperidol. (Foster et al. 1999; Bieniek et al. 1998; Battaglia et al. 1997; Garza-Trevino et al. – study I, 1989). Two of the studies (Foster et al. 1999; Battaglia et al. 1997) evaluated the efficacy and safety of these two medications against each other. Foster et al. (1999) noted no significant difference between the agitation scores for lorazepam and haloperidol at one hour on the BPRS (p=0.39, WMD=3.26 [-4.16, 10.68] 95% CI), but did note a significant difference in favour of lorazepam at one hour on the CGI (p=0.002, WMD=0.67 [0.25, 1.09] 95% CI). Battaglia et al. (1997) noted no significant difference between haloperidol and lorazepam at one hour, based on mean ABS score (p=0.27, WMD=-1.92 [-5.31, 1.47] 95% CI). Two of the studies (Battaglia et al.; 1997; Garza-Trevino et al. – study I, 1989) considered the efficacy and safety of these two medications against a combination of haloperidol and lorazepam. Battaglia et al. (1997) noted a significant difference between haloperidol and combination at one hour, based on ABS score (p=0.03, WMD=3.85 [0.46, 7.24] 95% CI) and between lorazepam and the combination at one hour based on ABS score (p=0.005, WMD=-5.77 [-9.76, -1.78] 95% CI). However, it is unclear if the combination would have been superior if the dose of the single agents had been equivalent to that of the combination. Garza-Trevino et al., study I, 1989 found that the combination was more likely to lead to tranquillisation in 30 minutes. These findings were replicated in ANOVAS. However, the authors suggest that it is unclear whether the combination would have been superior if the dose of the single agents had been equivalent to that of the combination.

One study (Bieniek et al. 1998) only considered the efficacy and safety of haloperidol against that of a combination of haloperidol and lorazepam. No differences were noted between the two groups with ANOVAS, but non-parametric tests indicated that a greater percentage of participants improved after 60 minutes in the combined group.

Whilst two of the studies compared the same single doses, and two of the studies compared the same combined doses, there were many methodological problems with these studies. These problems included: relatively small sample sizes, short follow-up periods, side effects not being recorded, many comparisons performed with no adjustment for p-value, baseline and information not recorded. The studies were also heterogeneous. One study (Garza-Trevino et al. 1989) was not double-blinded, one study (Battaglia et al. 1997) considered sleep as a desirable endpoint, (the other studies did not), and combination doses were not equivalent to single medication doses. With such heterogeneity, meta-analysis was not appropriate.

In terms of efficacy, no study found the antipsychotic to differ from the benzodiazepine. However, given the side effects caused by haloperidol (for example, dystonia), all authors suggested that lorazepam may be the preferred course of treatment. All three studies (Foster et al. 1999; Bienien et al. 1997; Garza-Trevino et al. – study I, 1989) that compared combination against a single medication or medications suggested the superiority of the combination in terms of efficacy. However, two studies note that, since the single dose was not equivalent to the combined dose, it remains unclear whether the combined doses were more effective simply because of the strength of dose. The study (Battaglia et al. 1997) that did not comment on this, regarded sleep as a desirable endpoint and therefore viewed effectiveness in terms of a different outcome. One study (Foster et al. 1999) noted that there is need for more dose response studies.

Conclusion

The studies suggest that the medications (i/m) haloperidol and (i/m) lorazepam are equally effective. It is also suggested that the combination of haloperidol (i/m) with lorazepam (i/m) is also effective. Although there are many methodological problems with the studies, the body of evidence suggests that, either as single agents or in combination, these medications are efficacious. However the dose response comparisons between the combination or the medications as single agents is unclear on the evidence of these trials. Whilst more extrapyramidal side effects (EPS) are recorded with haloperidol, the chosen medication should be dictated by individual service user histories.

Evidence statement

Level of evidence	Evidence statement
Level 1+ to 1-	The available evidence suggests that (i/m) haloperidol and (i/m) lorazepam are equally effective. However, there is no firm evidence for either the efficacy or safety of haloperidol or lorazepam as single agents, or in combination. Haloperidol has been found to result in an increased likelihood of more extrapyramidal effects.

Olanzapine vs. haloperidol vs. placebo

Two trials (Brier et al. 2002; Wright et al.2001) evaluated (i/m) olanzapine against (i/m) haloperidol and against (i/m) placebo. Both studies were large multi-site, multi-country studies. However, they included participants with schizophrenia (571 participants in total). Both authors were involved in both studies and both work for Eli Lilly who sponsored both studies.

It is unclear whether the participants actually required rapid tranquillisation, since all gave consent before being included in the study. Objective measures of behaviour were used in both studies at baseline (PANSS – positive and negative syndrome scale). There was no long-term follow up with either study. Both olanzapine and haloperidol were significantly more effective than placebo in reducing agitation at two and 24 hours in both studies. At 30 minutes, a dose of 5.0mg, 7.5mg or 10mg were significantly more effective than the placebo. Olanzapine was significantly more effective than haloperidol in reducing agitation at 15, 30 and 45 minutes (Wright et al. 2001). In Brier et al. (2002), group sizes did not allow comparison with placebo. Acute dystonia was not associated with olanzapine, but was found in 7 per cent of the haloperidol group. (Wright et al. 2001) Brier et al. (2002) also found that olanzapine was not associated with dystonia. There were no differences between olanzapine, haloperidol and placebo in terms of hypotension and clinically relevant changes in the QTc interval (Brier et al. 2002). On this basis, Brier et al. (2002) suggests that olanzapine has a safer profile than haloperidol. The schizophrenia guideline examined both of these studies and undertook a meta-analysis that slightly favoured olanzapine (see Appendix 8 for results).

Conclusion

Olanzapine (i/m) would appear to be both effective and safe for use in rapid tranquillisation for service users with schizophrenia. It would also appear to have fewer side effects than (i/m) haloperidol and more rapid onset of action. However, in these two trials the populations were only suffering from moderate disturbance where rapid tranquillisation was not necessarily required. Therefore further RCTs with appropriate populations are needed to verify the findings from these trials for use of olanzapine in those who are disturbed/violent. (Level 1 and level 2.)

It has subsequently been noted that a warning has been issued by the manufacturers advising against the use of olanzapine outside the SPC recommended dose, as adverse effects have been recorded.

Evidence statement

Level of evidence	Evidence statement
Level 1+ to 2	The evidence suggests that olanzapine (i/m) is safe and effective for rapid tranquillisation for service users with schizophrenia. However the study population did not necessarily require rapid tranquillisation. The evidence suggests olanzapine (i/m) has fewer side effects and is more rapid in onset than (i/m) haloperidol.

Ziprasidone (vs. haloperidol)

Three studies considered the efficacy and safety of (i/m) ziprasidone (Daniel et al. 2001; Lesem et al. 2001; Brook et al. 2000). Two considered this medication only (Lesem 2001; Daniel et al. 2001), measuring the effectiveness and safety of different doses (2mg vs. 10mg and 2mg vs. 20mg). The other study (Brook et al. 2000) compared (i/m) ziprasidone with (i/m) haloperidol.

Brook et al. (2000) found significant reductions in agitation from baseline at day three that favoured ziprasidone. (BPRS total WMD=-3.06 [-5.68, -0.44]95% CI; BPRS agitation score WMD=-1.13 [-2.23,0.03] 95% CI;CGI-S WMD=-0.34 [-0.55,-0.13]. However, the paper contained insufficient data to calculate the relative reductions in agitation at earlier time periods.

The other two studies, Daniel et al. (2001) and Lesem et al. (2001), employed the same methodology; both were sponsored by Pfizer. It was not clear whether either of the studies dealt with truly agitated participants, since all gave consent. Both 10mg and 20mg were noted to be significantly more effective than 2mgs. A reduction of two or more on BARS scale at two hours after initial injection showed the following significant result for 10mgs (p=0.003, OR=0.32 [0.15, 068] 95% CI), and the following for 20mgs (p<0.00001, OR0.04 [0.01,0.16] 95% CI). Lesem et al. (2001) argues that 10mg is a therapeutic dose but probably at the lower end of the spectrum, especially given the agitation levels of the participants in the study. There was no significant difference in side effects with any of the doses. Most side effects were moderate, suggesting the reasonable safety of this atypical antipsychotic. The study Brook et al. (2000), comparing haloperidol with ziprasidone, did not consider rapid tranquillisation, but the management of acute psychosis. In this context,

compared to haloperidol, ziprasidone was significantly more effective in managing aggression by day seven. However, no firm conclusions about the relative effectiveness of ziprasidone compared to haloperidol as an agent for rapid tranquillisation can be arrived at on the basis of this study.

Conclusion

It would seem that (i/m) ziprasidone 20mg is relative safe for use in rapid tranquillisation. Its effectiveness needs further testing with more highly agitated participants. Whilst meta-analysis of these two studies would have been possible, the value of doing so appears limited, given that the participants did not necessarily require rapid tranquillisation and no comparison with other medications was made (level 1). The relative effectiveness and safety of (i/m) ziprasidone compared to (i/m) haloperidol as an agent for rapid tranquillisation cannot be established on the basis of this evidence (level 2). Ziprasidone received a black box warning in 2002 in relation to its QTc prolonging potential, which may be increased in situations of high arousal.

Evidence statements

Level of evidence	Evidence statement
Level 1-	The evidence suggests ziprasidone (i/m) is safe for use in rapid tranquillisation, however its effectiveness with highly agitated service users is not known.
Level 2	The relative effectiveness and safety of (i/m) ziprasidone compared to (i/m) haloperidol as an agent for rapid tranquillisation cannot be established on the basis of this evidence.

Loxapine vs. haloperidol (vs. thiothixene)

Four studies examined the use of (i/m) loxapine. Three compared it to haloperidol (IM) (Tuason 1986; Fruensgaard et al. 1977; Paprocki and Versiani 1977) and the other to (i/m) thiothixene (Dubin and Weiss 1986). Neither Tuason 1986 nor Dubin and Weiss 1986 were double-blinded and in one of these studies (Dubin and Weiss 1986), it is unclear whether participants required rapid tranquillisation. However, the other two studies (Fruensgaard et al.1977; Paprocki and Versiani 1977) were double blinded. All medications achieved significant improvement from baseline and there were no significant difference in numbers of adverse reactions between groups, except in one study (Fruensgaard et al. 1977) where (i/m) loxapine 50mgs produced more pronounced sedation ($p<0.025$). Haloperidol 5mg did not differ in median time to rapid tranquillisation from loxapine 25mg (Tuason 1986) (at two hours OR=0.32 [0.09,1.22] 95% CI based on CGI ratings for global improvement. The same is also true of the mean BPRS scores at two hours WMD =1.10 [0.78, 1,42]). Nor did haloperidol 5mg differ in median time to rapid tranquillisation from loxapine 50mgs (Fruensgaard et. al. 1977; Paprocki and Versiani, 1977). There is insufficient data to calculate 95 per cent CI for these two studies. However, thiothixene 10mgs (Dubin and Weiss 1986) was significantly less tranquillising in the initial phase of treatment than loxapine 25mgs (60min vs. 95min) p=0.0008 OR=9.00 [2.49,32.57] 95% CI.

Conclusion

The studies had various limitations which make it difficult to formulate firm conclusions about the relative effectiveness and safety of (i/m) loxapine compared to either (i/m) haloperidol or (i/m) thiothixene for use in rapid tranquillisation. However, at the doses prescribed, loxapine would appear to provide a more rapid tranquillising effect than thiothixene (level 1).

Evidence statement

Level of evidence	Evidence statement
Level 1-	The evidence is not conclusive for the effectiveness or safety of (i/m) loxapine compared with either (i/m) haloperidol or (i/m) thiothixine.

Thiothixene and lorazepam vs. haloperidol and phenobarbital

A further study also considered the use of (i/m) thiothixene in combination with (i/m) lorazepam against (i/m) haloperidol in combination with (i/m) phenobarbital (Garza-Trevino et al. 1989 – study II). This study was not double-blinded, there was a very short follow-up period (24 hours) and the side effects were not described, although the authors claim that there were few indications of over-sedation or dystonic reactions. There appeared to be no difference in effectiveness between the two groups. The authors argue therefore that a combination of antipsychotic and a hypnosedative is a useful intervention for the management of agitated behaviour.

Conclusions

It is difficult to generalise concerning the effectiveness and safety of these medication combinations on the basis of only one study, given the various limitations noted above.

Evidence statement

Level of evidence	Evidence statement
Level 1-	The evidence for thiothixene and lorazepam vs. haloperidol and phenobarbital combinations is inconclusive.

Haloperidol (vs. flunitrazepam, vs. molidone, vs. midazolam and sodium amytal vs. midazolam, vs. chlorpromazine)

Four trials (Binder and McNiel 1999; Dorevitch et al. 1999; Wyant et al. 1990; Reschke 1974) evaluated the efficacy and safety of five further medications against (i/m) haloperidol; (i/m) flunitrazepam, (i/m) molindone, and (i/m) midazolam, (i/m) sodium amytal, and (i/m) chlorpromazine. Neither of the first two studies showed a significant difference between haloperidol and the other medication in terms of effectiveness. Flunitrazepam showed a slightly quicker reduction in aggression at 30 minutes, but this did not reach significance at 90 minutes on the OAS scale (p=0.37 OR=3.00 [0.27, 33.08]). Molidone showed slightly less reduction in symptoms at three hours. Erythema at injection site was slightly more common for molidone than haloperidol. This side effect is not discussed in relation to (i/m) flunitrazepam. Both studies had small sample sizes and neither used objective measures to evaluate behaviour at baseline. In the study of molidone there was no adjustment to the p value to account for the many comparisons and outcomes (outcomes were not restricted to rapid tranquillisation). It was also difficult to assess whether side effects resulted from the oral phase of the intervention.

The study of (i/m) haloperidol vs. (i/m) midazolam or (i/m) sodium amytal (Wyant et al. 1990) randomly assigned participants to either (i/m) haloperidol 10mg, (i/m) midazolam 5mg or (i/m) sodium amytal 250mg. Over two hours, (i/m) sodium amytal and (i/m) midazolam proved significantly more effective than haloperidol in terms of mean global ratings for motor agitation (p< or =0.05), but there was no significant difference in hostility rating (p<0.10). This study has several limitations, not least being a very small sample size. It is also only single blinded. In addition, there is insufficient data in the paper to calculate 95 per cent CI. Side effects are not mentioned. On both these counts it could have been excluded, but is reported here to illustrate the available research on these medication combinations. The authors recognise the need for a large-scale future study comparing midazolam with lorazepam.

In the study of (i/m) haloperidol vs. (i/m) chlorpromazine aggression was significantly more effectively controlled with (i/m) haloperidol 5mgs and 2mgs (p<0.05) compared to (i/m) haloperidol 1mg, (i/m) chlorpromazine 25mgs or (i/m) placebo. More adverse reactions were noted with haloperidol (transient hypertension, drowsiness (awake), dry mouth and mild EPS) than chlorpromazine, although there was greater somnolence with chloropromazine. The study had a very small sample size. Most participants in this study were women.

Conclusions

Given the limitations of the studies, no firm conclusion can be reached about the relative superiority of these medications compared to haloperidol, although both flunitrazepam and molindone appear to be reasonably safe and effective within these trials. The study of midazolam and sodium amytal did not mention side effects. These trials' limitations mean that no firm conclusions about these medications can be drawn. The study of midazolam used sleep as a desirable endpoint, making comparisons with other studies difficult. Chlorpromazine (i/m) was slower acting than haloperidol, although it had fewer side effects. Chlorpromazine (i/m) is no longer considered a suitable medication for rapid tranquillisation, since it is a local irritant if given intramuscularly; carries a risk of cardiovascular complications; causes hypotension due to ·-adrenergic receptor blocking effects, especially in the doses required for rapid tranquillisation; and is erratically absorbed. Its effect on QTc intervals also suggests that it is unsuitable for use in rapid tranquillisation.

Evidence statement

Level of evidence	Evidence statement
Level 2-	The evidence for haloperidol (vs. flunitrazepam, vs. molidone, vs. midazolam and sodium amytal vs. midazolam, vs. chlorpromazine) is inconclusive.

Haloperidol plus promethazine (vs. lorazepam vs. midazolam)

One study (Trec 2003) compared (i/m) halperidol-promethazine with (i/m) midazolam. Clinicians decided doses within a range of 7.5-15mgs of (i/m) midazolam and 5mgs of (i/m) halperidol plus 25-50mgs (i/m) promethazine. More somnolence was noted in the midazolam group. One man suffered respiratory depression with (i/m) midazolam 15mgs and recovered after being given (i/v) flumazenil 0.25mgs. One woman with epilepsy suffered a grande mal seizure with (i/m) haloperidol 5mgs and (i/m) promethazine 50mgs. When ratios of those either asleep or tranquil at one hour were considered, the study favours midazolam (OR=0.49 [0.22, 1.09] 95% CI, NNT=12.5 [6.4, 77.7] 95% CI). However, a larger percentage of these patients were asleep in the midazolam group than in the haloperidol + promethazine group (93 per cent compared to 87 per cent). If only those patients who were tranquil at one hour are considered, the treatment favours haloperidol + promethazine (OR=2.91 [1.64, 5.18] 95% CI). No definitions are provided for tranquil or asleep. The preferred outcome in the UK context is considered to be tranquil (calm) and conscious.

The other study (Alexander 2004), compared (i/m)

haloperidol and promethazine combined with (i/m) lorazepam. Doses were (i/m) haloperidol 10mgs plus (i/m) promethazine 25-50mgs or (i/m) lorazepam 4mgs. (i/m) Haloperidol plus (i/m) promethazine was significantly more likely to induce sleep for all time periods (p=0.00). (i/m) Haloperidol plus (i/m) promethazine also resulted in quicker onset of tranquillisation (p=0.0001)/sleep (p=0.0000). Four people in the lorazepam group were never tranquil; one person in the haloperidol plus promethazine group was never tranquil. No adverse reactions were noted with haloperidol plus promethazine. One person in the lorazepam group with history of bronchial asthma complained of moderate worsening of respiratory difficulty; one person reported nausea and dizziness. There was no dystonia. Sleep was considered the desirable endpoint. When ratios of those either asleep or tranquil at one hour are considered, the study favours haloperidol (OR=5.44 [1.16, 25.52] 95% CI). However, a larger percentage of these patients were asleep in the haloperidol + promethazine group than in the lorazepam group (98 per cent compared to 90 per cent). If only those patients who were tranquil at one hour are considered, the treatment favours lorazepam (OR=0.33 [1.18, 0.58] 95% CI).

Conclusions

Unlike most of the other studies in this review, both were large studies of a high methodological quality. Despite this, after consultation with two independent methodological advisers, it was decided that meta-analysis would not be appropriate for the following reasons. Firstly, it is not clear that the two benzodiazepines (midazolam and lorazepam) are sufficiently similar clinically to be treated as a single class, nor is it clear that the two benzodiazepine doses are equivalent, which could make the effect size vary. Secondly, the primary outcome was four hours in TREC (2003) but 15 minutes in Alexander (2004). These were rated by blinded assessors (Alexander 2004). While TREC (2003) did take measurements at 20 minutes, these were not made by blinded raters. There is also a danger of masking differences in effect when combining different time points.

One of these trials (Alexander 2004) considered sleep the primary desirable outcome. However, the study did detail numbers asleep and numbers tranquil at each endpoint (as did Huf 2003). Alexander (2004) argues that sleep is a safer option for staff however, no significant difference in injury rates were noted with lorazepam, which was less sleep inducing. Neither study mentioned whether monitoring procedures – for example, observation, ECG, etc. – were put in place once participants were classified as asleep. There is disagreement between the studies as to whether haloperidol plus promethazine is actually more likely to induce sleep than a benzodiazepine. As sleep is not normally considered a desirable endpoint for rapid tranquillisation, the studies suggest that haloperidol plus promethazine may be effective in rapid tranquillisation when sleep is a desirable outcome, which has been suggested as being a safer option for staff. However, if tranquil (calm) is the desirable endpoint, lorazepam alone is favoured.

Few patients treated with (i/m) haloperidol plus (i/m) promethazine suffered dystonic reactions, since promethazine has anti-cholingeric properties.

Evidence statement

Level of evidence	Evidence statement
Level 1+	The available evidence suggests that haloperidol with promethazine i/m is effective in rapid tranquillisation by inducing sleep. The evidence suggests lorazepam i/m is effective in rapid tranquillisation by calming the service user.

Heterogeneity

The included studies had many heterogeneous aspects/deficiencies in reporting, such as differing settings, and insufficient time to allow NNT to be calculated. Furthermore, some studies did not contain sufficient data to allow the OR to be calculated. The studies also had different comparator medications, doses and outcomes (for example, sleep as the endpoint and sleep as an adverse effect). In addition, the term sleep is often loosely defined in these studies, which further complicated any comparison. Follow-up periods also differed across studies. After methodological advice, it was considered that in the face of such heterogeneity, meta-analysis would be inappropriate.

Appraisal of methodological quality

There were also many methodological quality issues – for instance, most studies did not report their method of randomisation nor how they ensured blinding/lack of bias. It was felt that meta-analysing studies of low quality might therefore be misleading. Furthermore the outcome measurements were not comparable or always clearly defined. Actual dosages given in the studies also make comparisons within and between studies difficult.

Evidence statements

Level of evidence	Evidence statement
Level 1+ to 1-	A gold standard medication for rapid tranquillisation has not yet been established
Level 1+ to 1-	There appear to be no conclusive benefits in terms of effectiveness of one antipsychotic over another; of antipsychotics over benzodiazepines; or of combination medications over single medication regimes for rapid tranquillisation.
Level 1+ to 1-	The body of evidence suggests rapid tranquillisation as an intervention for the short-term management of disturbed/violent behaviour is both reasonably effective and reasonably safe. This evidence suggests that both benzodiazepines and antipsychotics appear to be effective and reasonably safe for use in rapid tranquillisation.
Level 4	It is not possible to determine the safety or effectiveness of medications other than antipsychotics and benzodiazepines for rapid tranquillisation.

III Studies other than randomised controlled trials

Most of the non-randomised studies which examined rapid tranquillisation that were identified investigated medications which were considered in the randomised controlled trials or systematic reviews discussed above. One study discussed a medication not considered elsewhere. This study (Lee et al. 1992) was a prospective cohort study (n =10) that considered the use of lithium citrate. There were considerable limitations to this study noted by the authors, such as a lack of a wash out period and the lack of a double-blind control. They suggest that this medication may be an alternative treatment to neuroleptics or benzodiazepines, particularly for service users who demonstrate persistently agitated behaviour, despite treatment with neuroleptics, benzodiazepines, barbiturates and/or antihistamines. However, they recognised the need for a randomised controlled trial.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence of the safety or effectiveness of lithium citrate for use in rapid tranquillisation for those who demonstrate persistently agitated behaviour.

IV Sudden death and rapid tranquillisation

No randomised controlled trials had death as an adverse event. However, four case studies were identified in which death was linked to medication.

One case study reported in a letter, noted that a young adult who was given (i/v) diazepam 20mg and (i/v) haloperidol 20mgs by a GP and psychiatrist at home suffered a fatal cardiac arrest (Quesnstedt et al. 1992). One other case of sudden death (Dolan et al.1995) occurred after rapid tranquillisation. In this case, post-mortem examination revealed some congestion of the pulmonary parenchyma. The author expressed concern that the autopsy had partially attributed the cause of death to medication, when sudden death in similar circumstances, without the presence of medication, is known to occur.

In another study (Lynch and Kotsos 2001), a white female was found at home with a fatal dose of benzatropine. It is unclear whether a suicide attempt was made.

In the final study (Kumar 1997) an aggressive service user was restrained and stopped breathing before rapid tranquillisation took place, but a toxic level of chlorpromazine was found in his blood after treatment with chlorpromazine, zuclopenthixol acetate and zuclopenthixol decanoate in the weeks preceding his death. One study did not specify the ethnicity of the deceased; the other three studies all noted that the deceased were Caucasian; three service users were male, the other was female.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine whether there is an association between sudden death and the pharmacological interventions used for the short-term management of disturbed/violent behaviour.

V Qualitative studies and surveys

Our searches identified seven qualitative studies which were deemed to be of reasonable quality to merit inclusion in this review. Three were conducted in the UK, one in the USA, one in Israel and one in Sweden.

Two of studies set in the UK did not specifically ask staff and service users about their feelings and beliefs about rapid tranquillisation.

The first study (Hyde et al.1998) compared user dissatisfaction scores with incidents of rapid tranquillisation and found that there was no correlation between a service user satisfaction score and their experience of this intervention. However, as the questionnaire did not ask service users to score their satisfaction/dissatisfaction with this intervention, there are many other confounders that could obscure this correlation. It is unclear what the aims of the questionnaire were. The other UK study (Duxbury 2002) asked staff,

service users and medical staff for their views on the approaches used to manage violence. Again, there was no specific reference to rapid tranquillisation, but a disparity was noted between actual violence reported in incident forms and the use of rapid tranquillisation. The authors suggest that this is a worrying trend. They note that both staff and service users agreed that there was a need for greater alternatives to restraint, seclusion and rapid tranquillisation.

The third study (Burgess 1997) reviewed doctors' medication preferences for rapid tranquillisation. The study took the form of two cross-sectional surveys conducted in Oxfordshire – the first in 1990 and the second in 1994-5 – to assess the effect of guidance issues by the Royal College of Psychiatrists. The following outcome measures were considered: drug of choice; route of choice; other drugs used if situation not rapidly resolved by drug of choice; mean dose (second study only); desired endpoint (second study only); time to desired endpoint (second study only). Doctors were asked to rate the same scenario of a psychotic patient. Study 1 showed the following results: 56 per cent response rate (sent to consultants only). The drug of choice was chlorpromazine. The route of choice was intramuscular (93 per cent) against intravenous (7 per cent). Forty-two other drugs were used if the situation was not rapidly resolved by drug of choice, suggesting no consensus. These included neuroleptics, benzodiazepines, anticonvulsants and paraldehyde.

Study 2 showed the following results: 77 per cent response rate from registrars, junior doctors and consultants – 69 per cent response rate from consultants. The drug of choice was chlorpromazine (25 per cent), with haloperidol + lorazepam (22 per cent) and haloperidol alone (16 per cent). Junior doctors were more likely than consultants to use a short acting antipsychotic and a benzodiazepine as first line treatment ($p<0.05$). The route of choice was intramuscular/oral (93 per cent) against intravenous (7 per cent). Mean dose: chlorpromazine 103.4mg, haloperidol alone 9.6 mg, haloperidol + lorazepam 9.2mgs of haloperidol. Other drugs used if the situation was not rapidly resolved by drug of choice included increasing the dose of neuroleptic medication, adding benzodiazepine and adding clopixol acuphase. 14 per cent would use clopixol acuphase as first line treatment either alone or with other drugs; 62 per cent would consider clopixol acuphase at some point in the first 24 hours. The desired endpoint was: patient non-sedated but calm, 59 per cent; patient sedated but mobile, 31 per cent; patient asleep, 10 per cent. Time to desired endpoint was: within one hour, 21 per cent; within 6 hours, 43 per cent; within 12 hours, 16%; within 24 hours, 10%; more than 24 hours, 6 per cent.

The authors noted that by 1990, only 7 per cent of doctors used a short acting antipsychotic + a benzodiazepine, with 35 per cent in 1994 ($p<0.001$). However only consultants were surveyed in 1990 and the study showed that significantly more junior doctors than consultants would choose this drug combination in 1994 ($p<0.05$). The authors also noted that: a) haloperidol continued to be prescribed at a higher dosage equivalent than chlorpromazine, even when used in combination with a benzodiazepine; b) i/v administration is unpopular despite reports that diazepam plus haloperidol is the most rapid effect method of rapid tranquillisation; c) that while the preferred endpoint is non-sedated but calm, most advocated highly sedative drugs, i.e. benzodiazepines. The authors posited that the introduction of local protocols, in line with RCPsych guidance, many have further altered doctors' choices and suggested that an additional survey is required to monitor this.

The other four studies surveyed service users, with the aim of discovering their views about forcible medication. One study (Haglund et al. 2003), also interviewed staff. In the study, service user and nurse perceptions of forced medication differed. Nurses focused more on positive effects of medications, while service users stressed the negatives. Less service users retrospectively approved of forced medication than anticipated by nurses. Nurses mentioned no alternatives to rapid tranquillisation.

However, all service users mentioned at least one alternative (dialogue, more explanation of ill-health, coaxing, waiting, no medication, no injection). Nurses perceived these measures necessary to improve health. The authors noted that service users were more likely to accept forced medication from a nurse they knew.

Another study (Schmeid and Ernst 1983) asked service users to rate the retrospective acceptability of both seclusion and rapid tranquillisation. Service users were asked immediately after the intervention and also once psychosis passed. Service users found rapid tranquillisation more unacceptable than seclusion or restraint ($p=0.01$; for men only $p=0.001$). However, many service users were unclear on their feelings about these interventions and did not know which staff member had instigated the intervention. The authors note that this was particularly true for male service users, many of whom had alcohol related problems. This is now an old study and although rapid tranquillisation was the least acceptable of these interventions, it is not possible to generalise whether service users in the UK also prefer seclusion to rapid tranquillisation. The author suggests that it is beneficial for service users to discuss their feelings after the use of one of these interventions.

Greenberg et al. (1996) conducted structured telephone

interviews with service users two weeks after discharge. There was a 50 per cent loss to follow-up. The authors noted that 60 per cent of service users interviewed retrospectively agreed that rapid tranquillisation had been beneficial, while 43 per cent felt that they should be coerced in similar situations in the future. However, the authors acknowledge that the responses of those lost to follow-up might have been more negative.

In another study, where semi-structured interviews were conducted on the ward, a far more negative response to rapid tranquillisation was noted. Only 4/11 service users retrospectively approved of rapid tranquillisation and one of these did so only in the most vague of terms. The rest all disapproved. However staff believed that 7/11 service users had retrospectively approved of the use of this intervention.

Schwartz et al. (1988), in a small study in one hospital setting, assessed service users' mental state both before and after forcible medication (service users with organic brain disorder were excluded). They argued that those who retrospectively disagreed with the treatment did not recognise that they had an illness that had required hospitalisation; did not agree that the hospitalisation was necessary; or that it had been helpful ($p<0.01$). They also noted significant differences between those who did and those who did not retrospectively agree with forcible medication on the BPRS scales for thought disturbances and hostile suspiciousness. At discharge, the following eight items were significant for those who did not retrospectively agree with the forcible medication: conceptual disorganisation ($p<0.05$); mannerisms and posturing ($p<0.01$); grandiosity; hostility; suspiciousness; unco-operativeness; unusual thought content ($p<0.001$). In the light of these findings, the authors argue that judicial review of forcible medication is seldom required.

Evidence statement

Level of evidence	Evidence statement
Level 4	The evidence suggests that service users' retrospective responses to rapid tranquillisation are variable. Both staff and service users agree that, where possible and appropriate, alternatives to restraint, seclusion and rapid tranquillisation are preferable.

VI PRN medication

Although only rapid tranquillisation is mentioned directly in the scope, pro re nata (PRN) – as needed – medication is also sometimes used in a similar way to rapid tranquillisation in psychiatric in-patient settings. For this reason, a review of the use of PRN medication in this context was undertaken.

Effectiveness

One systematic review (Whicher et al. 2002) was found that examined the efficacy of PRN for the short-term management of aggressive behaviour. No randomised trials were found which met the inclusion criteria for this review.

Whicher et al. (2002) conclude that:

> This common current practice has no support from randomised trials. Current practice is based on clinical experience and habit rather than high quality evidence. Current practice, therefore, outside of a well designed, conducted and reported randomised trial, is therefore difficult to justify.

No further studies were identified which examined the effectiveness of PRN medication as a pharmacological intervention for the short-term management of disturbed/violent behaviour.

Staff perspectives

A study by Geffin et al. (2002a) examined the beliefs of doctors and nurses in in-patient psychiatric units about PRN medication for psychiatric disorders. They concluded that nurses and doctors have different views about the effectiveness of antipsychotics and benzodiazepines. They noted that some of these views are at odds with the known properties of these medications. They argue therefore that doctors should always specify the usage when writing PRN prescriptions. They argue that further education is needed to achieve best practice in PRN medication.

A second survey by Geffin et al. (2002b) examined the uses of PRN medication in two large psychiatric units. The authors noted that while a maximum daily dose was normally specified (87 per cent), indications for use were only specified in 6 per cent of cases. Staff noted medication-related morbidity in 37 per cent of service users taking PRN medication, compared to 3 per cent on only regular scheduled medication. Forty-nine percent of PRN medication was given for agitation. However, administration records frequently failed to specify a reason for use in 48 per cent of cases. Nearly two-thirds of administrations (64 per cent) had no recorded outcome. Of the remaining 26 per cent, 76 per cent were reported as being partially or completely effective, with the remainder recorded as ineffective. Higher daily doses of PRN medication were given to manic patients, males, younger patients and those with substance abuse disorders. Co-prescription of typical antipsychotics PRN with atypical antipsychotics was common (64 per cent).

Three further studies were found which also examined the

use of PRN medication. One was set in Canada (Craven et al. 1987); two were set in the USA (Walker 1991; Craig and Bracken 1995). A finding of two of these studies (Craven et al. 1987; Walker 1991) was that indications were not always included in the prescriptions. Where an indication was given, only one was specified, although the prescriptions was often used for a number of indications. Minimum intervals between doses were not always stated and maximum daily doses were also not always specified. In addition very few of the prescriptions specified an end-date.

The other study (Craig and Bracken 1995), noted a difference between the use of PRN medication with service users who had a discrete period of disruptive behaviour and those who had intermittent periods throughout their stay. The following results were significant: half of the intermittent vs. more than 90 per cent of those with discrete episodes had an increase in their medication or had their medication changed during the study month (p=0.03). The authors noted that 12/27 service users who had antipsychotic medication serum levels drawn either before or after the study were found to be in a sub-therapeutic range, with two-thirds below detection. They suggest the importance of checking serum levels to ensure that these are adequate, in order to reduce the need for PRN medication.

Evidence statement

Level of evidence	Evidence statement
Level 4	The evidence suggests that the use of PRN medication for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings is inconsistent and may not be appropriately administered or monitored. Health care professionals require education on the appropriate use of PRN medication

7.8.6.2.5 **Economic evidence**

There are two papers that are economic analyses of rapid tranquillisation. One is a UK-based cost minimisation study (Hyde et al. 1998) and the other is a cost consequence analysis, based in Canada (Laurier et al. 1997). Both compare zuclopenthixol acetate with haloperidol. The two papers are in disagreement regarding which of the two medications is more cost effective and thus the literature is inconclusive. Zuclopenthixol acetate is no longer recommended for RT due to a long onset of action. See discussion above. (For details of the health economics review, see Appendix 9).

7.8.7 Emergency departments

7.8.7.1 Objectives

No specific searches into the short-term management of disturbed/violent behaviour in emergency departments were undertaken in the RCPsych guideline.

Two review questions were identified and used to inform all searches (See Appendix 4 for search strategies, databases searched and search logs)

Review questions

- How is disturbed/violent behaviour by psychiatric patients best managed in the short-term in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?
- What are the views of staff and service users about the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

These questions were addressed in relation to the various interventions and related topics covered in this guideline and specific review questions were devised (see below).

7.8.7.2 Selection criteria

Types of studies

Systematic reviews to before and after studies (levels 1-2). Qualitative studies were also included.

Types of participants

Adult psychiatric service users <16 years, excluding people with a primary diagnosis of substance abuse, older persons with an organic mental disorder (for example, any form of dementia) or a progressive neurological disease (for example, Parkinson's disease).

Types of setting

All emergency departments.

Types of outcome

- Appropriateness, effectiveness and safety of interventions and related concerns for the short-term management of disturbed/violent behaviour of psychiatric patients presenting to emergency departments.
- Staff and service user perspectives on the appropriateness, effectiveness and safety of interventions and related concerns for the short-term management of disturbed/violent behaviour in emergency departments.

7.8.7.3 Clinical evidence

Eighty-one papers were identified in the initial sift. After sifting for relevance and duplicates, 50 full papers were ordered; 18 met the inclusion criteria; 12 were excluded. All the other papers were opinion pieces, anecdotal reports

or fell outside the inclusion criteria for this review. References were checked but no further studies were identified. (Evidence tables of included studies can be found in Appendix 5. Evidence tables of excluded studies can be found in Appendix 6).

Appraisal of methodological quality

In addition to the quality concerns raised above, these studies had the following methodological problems:

- confounders not considered or taken into account
- inappropriate sample size
- much anecdotal 'evidence' based on author's experience and reflection rather than on primary research.

I Prevention

Seventeen studies addressed issues around prevention of disturbed/violent behaviour in emergency departments.

I.i Environment

I.i.a Review question: how does the environment and organisation impact on disturbed/violent behaviour by psychiatric patients in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?

No studies addressed this review question.

I.i.b Review question: what are the views of staff and service users about how the environment and organisation impacts on the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

Lillywhite et al. (1995) audited the interview rooms and surveyed the staff of a mental health service to assess the safety of interview rooms in a general hospital outpatients' department, general hospital emergency department and a psychiatric hospital, according to 10 safety criteria, and to assess medical staff's ratings of the relative importance of these 10 criteria. Emergency department rooms scored least well in terms of suitability for interviewing potentially aggressive patients, scoring poorly on every criteria other than 'alarm bell.' This was due to: a) the isolated position from other staff, especially at night when most psychiatric assessments take place b) cubicles used are cramped, with inadequate seating and a lack of privacy c) the emergency department is where junior doctors are most likely to assess disturbed and potentially violent patients, and unlikely to have the support of psychiatric trained nurses or access to their notes prior to assessment. Features felt to be most important with agitated/potentially violent patients were space, access, layout, weapons, alarm and ease of exit. The study indicated a large disparity between the features of the ideal interviewing situation and those actually available. The authors recommend safety features should be incorporated, and that violent incidents should be monitored and logged, reviewed and acted upon. The numbers of staff surveyed were low (22) and of those only three were emergency department staff which, divided between three sites, provides a weak basis for generalisation.

Burns and Harm (1993) conducted a questionnaire and interview study of 682 emergency nurses. Interviewees reported feeling that there was a lack of concern for their personal safety. Emergency nurses found debriefings helpful. It was suggested that critical incident stress debriefing teams should formulate strategies for involving nurses in the debriefing process and that nurse peers should play a significant role in the debriefings.

Cembrowicz and Shepherd (1992) conducted a survey of staff in a UK emergency department, which concluded that fitted furniture and padded seating should be installed, and that potential weapons should be stored out of sight. They suggest that CCTV may deter casual hooliganism, but will be ignored by the highly intoxicated. In their view, security officers tend to be under-trained. They suggest that the use of uniforms may aggravate a violent situation.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to determine how the environment and organisation impacts on the incidence of disturbed/violent behaviour by psychiatric patients in an emergency department. The limited evidence suggests that staff feel that the environment in emergency departments often puts them at risk of disturbed/violent behaviour.

I.ii Prediction: antecedents, warning signs and risk factors

I.ii.a Review question: how is disturbed/violent behaviour by psychiatric patients best predicted in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting, and what are the key risk factors?

In a survey of staff and records in the violent incident book of the A&E department of a UK general hospital, Cembrowicz and Shepherd (1992) reported that in four of the last 20 incidents recorded, the violent patient was known to have a psychiatric illness. They found nursing staff and male doctors were most frequently assaulted;

receptionists least frequently. The recording of information by staff was haphazard, sometimes due to time pressures, because they hadn't been injured themselves or because they wanted to avoid being blamed if they made frequent reports. If an assailant used a weapon, it was most likely to be any implement that happened to be ready-to-hand. The study concluded that staff need to be aware of body language which signals an angry outburst (flared nostrils, staring eyes, aggressive stance, pointing and pacing) and the risks of violent behaviour associated with intoxication.

Beck et al. (1991) conducted a case-control study using record review of 99 patients identified over six months as violent (evidence of assault or battery) or potentially violent (verbal threat or staff impression of poor control and anger or agitation); 95 control patients, judged not to be violent or potentially violent; and staff interviews. They found that women were more often violent, and men were more often potentially violent, made threats or were a source of concern to staff ($p<0.03$). Study patients were, on average, four years younger than control patients ($p<0.005$), more often brought in by police, and subsequently hospitalised (62 per cent vs. 29 per cent).

Cooper (1988) undertook a retrospective survey of patients referred by a general emergency department to a psychiatric unit. He analysed the antecedents and mapped the course of violent behaviour. Thirty percent had physically attacked another person immediately prior to presentation in the emergency department. Most of this violence was perpetrated by non-psychotic individuals in the throws of an interpersonal crisis. Twenty-five percent were found to be acutely intoxicated with alcohol, but intoxication may have gone undetected in many more. The majority of patients referred from an emergency department to a psychiatric ward were judged to be non-psychotic, presenting with situational crises and personality disorders rather than a major mental illness.

In a cross-sectional survey of all 130 qualified staff in the emergency departments of two hospitals, Lee et al. (2001) found that greater self-efficacy (judgements of what one can accomplish, rather than skills one possesses) was observed in higher grade staff who had experienced higher levels of aggression. The author notes that the nature of the association between self-efficacy and levels of violent behaviour encountered is not illuminated by this study. This study did not differentiate between violence committed by people with psychiatric illness and people without psychiatric illness.

Evidence statement

Level of evidence	Evidence statement
Level 4	Limited evidence suggests that heightened arousal, depressive symptoms and alcohol intoxication are antecedents of disturbed/violent behaviour in emergency departments.

I.ii.b Review question: what are the views of staff and service users about prediction of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence on risk factors for disturbed/violent behaviour in emergency departments from the perspective of staff and service users.

II Training

II.a Review question: how effective is training in the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments immediately prior to admission to an adult psychiatric in-patient setting?

No studies addressed this review question.

II.b Review question: What are the views of staff and service users about training in the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence to determine the effectiveness of training in the short-term management of disturbed/violent behaviour in emergency departments, nor staff views on such training.

III Minority ethnic groups, gender and other special concerns

III.i.a Review question: how do ethnicity, gender or other special concerns impact on the short-term management of disturbed/violent behaviour by psychiatric patients in A&E settings, immediately prior to admission to an adult psychiatric in-patient setting?

No studies addressed this review question.

III.i.b Review question: what are the views of staff and service users about the impact of ethnicity, gender or other special concerns on the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence to ascertain whether: ethnicity, gender or special concerns (for example, disability) impact on or influence the approach to short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments. There is no evidence to determine staff or service user perspectives on whether ethnicity, gender or other special concerns influence or have an impact on the short-term management of disturbed/violent behaviour in emergency departments.

IV Psychosocial techniques

IV.i De-escalation techniques

IV.i.a Review question: are de-escalation techniques an effective tool for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?

Lee et al. (2001) found that nurses' aggression management training did not appear to equip them with the skills required to manage violent behaviour in emergency departments. He recommends that aggression management training should encourage nurses to examine their beliefs about violence and should focus on diffusion and de-escalation of violence, rather than control and restraint techniques.

Lane (1986) reports case studies of three patients admitted to the emergency department. He describes how techniques employing empathy (a combination of the suspension of judgement and sympathetic and creative imagination) were used to manage violence where more severe measures (restraint and medical management) might otherwise have been used. Generalisability is very limited.

IV.i.b Review question: what are the views of staff and service users about the use of de-escalation techniques for the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence to suggest that de-escalation techniques are an effective tool for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments.

IV.ii Observation

IV.ii.a Review question: is observation an effective tool for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?

No studies addressed this review question.

IV.ii.b Review question: what are the views of staff and service users about the use of observation for the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence on whether observation is an effective tool for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments.

V Other Interventions

V.i Pharmacological interventions: rapid tranquillisation and PRN medication

V.i.a Review question: are pharmacological interventions effective and safe for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?

Roberts and Geeting (2001) describe the use of ketamine to tranquillise a dangerous and violent patient on admission to the emergency department. Within two to three minutes of intramuscular administration of 480mg ketamine (5mg/kg), violent activity had completely ceased. Mild sinus tachycardia and transient hypertension were observed 10 minutes after initial sedation, but all vital signs were normal 50 minutes after ketamine

administration. Ketamine effects dissipated within two hours, however additional aliquots of lorazepam were required to control agitation over the next 12 hours. No immediate complications from ketamine or emergence phenomena were observed.

The authors argue that given ketamine's wide safety profile, potent anaesthetic effects, rapid onset, ease of intramuscular administration, absence of respiratory depression and short duration of action, it is considered useful for immediate tranquillisation of selected, undifferentiated, uncontrollable adults, who are in a life-threatening situation that requires immediate medical intervention. Concomitant use of benzodiazepines and selected use of atropine are suggested to ameliorate emergence phenomena, and to dry excessive oral secretions. The authors stress that, after use, close monitoring of cardiovascular parameters is essential. This is a case study of a single patient, so it is not possible to generalise.

V.i.b Review question: what are the views of staff and service users about the use of pharmacological interventions for the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

Binder and McNiel (1999) conducted a cross-sectional survey of 20 medical directors of psychiatric emergency departments. The aim was to assess how acutely violent patients were managed in psychiatric emergency rooms, to examine medical directors' practices and to investigate emergency department characteristics. Fourteen reported that acutely violent patients are usually put in restraints and medicated intramuscularly or intravenously and given a medical assessment only after they were less agitated. Thirteen used the same acute medication regimen for all violent patients, regardless of eventual diagnosis. Eleven used haloperidol plus lorazepam, with or without benzatropine. Five used droperidol, in one case alongside lorazepam and diphenhydramine. Fifteen stated that the intramuscular route was the most common, two preferred the intravenous route whenever possible. All 20 felt that their preferred medication regimen was effective for calming the violent patient, usually after one dose and always after one to two repeated doses. Only three stated that agitated patients will usually take medications orally and that mechanical restraints are rarely used. Factors cited as allowing them to use less coercive techniques included: a system where most contacts were with people who were known to the system or who had case management protocols; a computerised system where information on patients is available within 30 to 60 seconds; a less violent patient population; and the availability of nurse clinicians who know the population. Results suggest that the strategies most frequently advocated in recent review articles for the assessment and management of violent patients are not generally applied by those responsible for the emergency management of acutely violent patients. Clinicians appeared to place the highest priority on prevention of patient and staff injuries, by rapidly reducing violent behaviour through restraints and intramuscular medications – typically a combination of neuroleptics and benzodiazepines – irrespective of diagnosis. The authors suggest that one could argue that these practices involve risks of excessive coercion, overmedicating patients, and exacerbating underlying medical conditions. On the other hand, the clinical experience of practitioners suggests that these strategies rapidly ameliorate acute violence and thereby reduce the risk of injury.

No studies were found on the use of PRN in emergency departments.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is no evidence to suggest that different medication regimes are either more effective or safe for rapid tranquillisation in emergency departments than medication regimes commonly used for the short-term management of disturbed/violent behaviour in psychiatric in-patient settings. The limited evidence suggests that staff in emergency departments may use inappropriate strategies for dealing with the short-term management of disturbed/violent behaviour in service users.

V.ii Physical interventions

V.ii.a Review question: are physical interventions effective and safe for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments, immediately prior to admission to an adult psychiatric in-patient setting?

In Beck et al. (1991), a study in a psychiatric emergency service, psychotic patients who were restrained were 6.36 times more likely to be hospitalised than were psychotic patients who were not restrained ($p<0.05$). Non-psychotic patients who were restrained were 5.36 times more likely to be hospitalised than non-psychotic patients who were not restrained ($p<0.03$). Patients brought in by police were more likely to be put into restraints than patients brought in by others, and more likely than patients who came in unaccompanied.

V.ii.b Review question: what are the views of staff and service users about the use of physical interventions for the short-term management of disturbed/violent

behaviour by psychiatric patients in an emergency department?

Foust and Rhee (1993) conducted a prospective descriptive questionnaire study of all staff in an emergency department over nine months, to determine the incidence of battery (wilful and unlawful use of force or violence on the person of another) against emergency department medical staff by patients or visitors. Over the course of the study period, 19 instances of battery occurred. In eight cases, battery occurred when the patient was restrained, and four when the patient was restrained, but restraint was being modified.

The department's unusual restraint policies were described, whereby all patients placed on psychiatric or substance abuse 'holds' (requiring that they are a danger to themselves, to others or gravely disabled) be restrained with a loosely applied cloth belt that encircles the abdomen. Four of the incidents occurred when the patient was in abdominal restraint only, and eight other incidents when in abdominal and extremity restraint. The restraint procedures were not described. It was noted that 79 per cent of battery was carried out by patients with psychiatric problems or who were intoxicated. Consistent with other studies, incidents were significantly under-reported. In only four cases were hospital incident forms filled in. Authors recommend that strategies to prevent or control violence should be concentrated on evening and nightshifts.

Evidence statement

Level of evidence	Evidence statement
Level 4	There is insufficient evidence to assess whether physical interventions are either effective or safe for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments, on the basis of the available literature.

V.iii Seclusion

V.iii.a Review question: is seclusion effective and safe for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency, immediately prior to admission to an adult psychiatric in-patient setting?

No studies addressed this review question.

V.iii.b Review question: what are the views of staff and service users about the use of seclusion for the short-term management of disturbed/violent behaviour by psychiatric patients in an emergency department?

No studies addressed this review question.

Evidence statements

Level of evidence	Evidence statement
Level 4	There is an absence of evidence to determine whether seclusion is either effective or safe for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments. There is an absence of evidence to determine staff or service user views on the use of seclusion for the short-term management of disturbed/violent behaviour by psychiatric patients in emergency departments.

7.8.7.4 Economic evidence

No studies containing relevant economic data were found (see Appendix 9).

8 Recommendations and good practice points

All recommendations derive from the available evidence, GDG input and formal consensus processes, all of which are detailed in previous sections. The grading of the recommendations is explained in Section 7.4.

8.1 Guidance

** Please note that the numbering of the recommendations and good practice points within this section remains consistent with the numbering included in the NICE version of the guideline. The NICE version of the guideline is available via the NICE website at the following address: www.nice.org.uk/page.aspx?o=244477*

1.1 Environment (in-patient psychiatric settings)

The physical and therapeutic environment can have a strong, mitigating effect on the short-term management of disturbed/violent behaviour. The following recommendations are the minimum requirements that should be expected within in-patient psychiatric settings.

*See evidence statement page 36, para 7.8.2.1.3.

1.1.1 Safety and security

1.1.1.1 When staff are engaged in the short-term management of disturbed/violent behaviour, every effort should be made to manage the service user in an open care setting. **[D]**

1.1.1.2 All services should provide a designated area or room that staff may consider using, with the service user's agreement, specifically for the purpose of reducing arousal and/or agitation. In services where seclusion is practised, this area should be in addition to a seclusion room (see recommendation 1.1.1.3). **[D]**

1.1.1.3 In services in which seclusion is practised, there should be a designated seclusion room fit for purpose. This room should allow clear observation, be well insulated and ventilated, have access to toilet/washing facilities and be able to withstand attack/damage. **[D]**

1.1.1.4 Secure, lockable access to a service user's room, bathroom and toilet area is required, with external staff override. **[D(GPP)]**

1.1.1.5 The internal design of the ward should be arranged to facilitate observation, and sight lines should be unimpeded (for example, not obstructed by the opening of doors). Measures should be taken to address blind spots within the facility, including consideration of the use of CCTV and parabolic mirrors. **[D]**

1.1.1.6 Facilities should ensure routes of safe entry and exit in the event of an emergency related to disturbed/violent behaviour. **[D]**

1.1.1.7 There should be a separate area to receive service users with police escorts. **[D(GPP)]**

1.1.2 Activities and external areas

1.1.2.1 The environment should take into account the service user's needs.

- Services should be able accommodate service users' needs for engaging in activities and individual choice – there should be an activity room and a dayroom with a television, as boredom can lead to disturbed/violent behaviour.
- Service users should have single sex toilets, washing facilities, day areas and sleeping accommodation.
- There should be a space set aside for prayer and quiet reflection. **[D]**

1.1.2.2 There should be daily opportunities for service users to engage in physical exercise, group interaction, therapy and recreation. **[D(GPP)]**

1.1.2.3 There should be access to the day room at night for service users who cannot sleep. **[D(GPP)]**

1.1.2.4 Service users should be able to have easy access to fresh air and natural daylight. **[D(GPP)]**

1.1.2.5 Where practicable, access to an external area should be via the unit and where necessary, appropriate standards of fencing should be provided. **[D]**

1.1.3 Service user concerns

1.1.3.1 The environment should take into account service user needs for:

- safety
- privacy
- dignity
- gender – and cultural-sensitivity
- sufficient physical space

- ✦ social and spiritual expression. **[D]**

1.1.3.2 Where possible, service users should have privacy when making phone calls, receiving guests, and talking to a staff member. **[D(GPP)]**

1.1.3.3 Facilities should have adequate means of controlling light, temperature, ventilation and noise. **[D(GPP)]**

1.1.3.4 Internal smoking areas/rooms should have powerful ventilation and be fitted with a smoke-stop door(s). **[D(GPP)]**

1.1.3.5 All areas should look and smell clean. **[D(GPP)]**

1.1.3.6 Suitable access facilities are needed for people who have problems with mobility, orientation, visual or hearing impairment or other special needs. **[D(GPP)]**

1.1.4 Alarms

*See evidence statement page 37, para. 7.8.2.2.3.

1.1.4.1 Each service should have a local policy on alarms and determine the need for alarms according to a comprehensive risk assessment of the clinical environment, service users and staff. The policy should be disseminated, and staff made familiar with its contents. **[D]**

1.1.4.2 Comprehensive risk assessment of the clinical environment should be used to determine whether supplementary personal alarms should be issued to individual staff members and vulnerable service users. **[D(GPP)]**

1.1.4.3 Collective responses to alarm calls should be agreed before incidents occur. These should be consistently applied and rehearsed. **[D(GPP)]**

1.1.4.4 Furniture should be arranged so that alarms can be reached and doors are not obstructed. **[D(GPP)]**

1.1.4.5 Alarms should be accessible in interview rooms, reception areas and other areas where one service user and one staff member work together. **[D(GPP)]**

1.1.4.6 All alarms (for example, panic buttons and personal alarms) should be well maintained and checked regularly. **[D(GPP)]**

1.1.5 Clinical environment

1.1.5.1 There should be a regular and comprehensive general risk assessment to ensure the safety of the clinical environment. **[D(GPP)]**

1.1.5.2 Bed occupancy should be decided at a local level and this level should not be exceeded, because overcrowding leads to tension, frustration and overstretched staff. **[D(GPP)]**

1.1.5.3 There should be a stable and consistent in-patient team, as high staff turnover and overuse of short-term bank, locum and agency health care staff may create an unsafe environment. **[D(GPP)]**

1.1.6 Interagency working

1.1.6.1 Local protocols should be developed to ensure that the police and staff are aware of the procedures and ascribed roles in an emergency, in order to prevent misunderstanding between different agencies. Such policies should set out what constitutes an emergency requiring police intervention. **[D(GPP)]**

1.2 Prediction

Disturbed/violent behaviour can never be predicted with 100 per cent accuracy. However, this does not mean that risk assessment should not be carried out.

1.2.1 Policy

1.2.1.1 Measures to reduce disturbed/violent behaviour need to be based on comprehensive risk assessment and risk management. Therefore, mental health service providers should ensure that there is a full risk management strategy for all their services. **[D]**

1.2.2 Risk assessment

1.2.2.1 Risk assessment should include a structured and sensitive interview with the service user and, where appropriate, carers. Efforts should be made to ascertain the service user's own views about their trigger factors, early warning signs of disturbed/violent behaviour and other vulnerabilities, and the management of these. Sensitive and timely feedback should complete this process. **[D(GPP)]**

1.2.2.2 Risk assessment should be used to establish whether a care plan should include specific interventions for the short-term management of disturbed/violent behaviour. **[D(GPP)]**

1.2.2.3 When assessing for risk of disturbed/violent behaviour, care needs to be taken not to make negative assumptions based on ethnicity. Staff members should be aware that cultural mores may manifest as unfamiliar behaviour that could be misinterpreted as being aggressive. The assessment of risk should be objective, with consideration being given to the degree to which the perceived risk can be verified. **[D(GPP)]**

1.2.2.4 All staff should be aware of the following factors that may provoke disturbed/violent behaviour:

- ✦ attitudinal
- ✦ situational
- ✦ organisational

- environmental. **[D(GPP)]**

1.2.2.5 Actuarial tools and structured clinical judgement should be used in a consistent way to assist in risk assessment, although no 'gold standard' tool can be recommended. **[D]**

1.2.2.6 Since the components of risk are dynamic and may change according to circumstance, risk assessment (of the environment and the service user) should be ongoing and care plans based on an accurate and thorough risk assessment. **[D]**

1.2.2.7 The approach to risk assessment should be multidisciplinary and reflective of the care setting in which it is undertaken. The findings of the risk assessment should be communicated across relevant agencies and care settings, in accordance with the law relating to patient confidentiality. **[D]**

Commentary

Further details of the law relating to patient confidentiality can be found on the General Medical Council website (http://www.gmc-uk.org) and from the Department of Health website (http://www.dh.gov.uk).

1.2.3 Antecedents and warning signs

*See evidence statement page 39, para.7.8.2.3.3.

1.2.3.1 Certain features can serve as warning signs to indicate that a service user may be escalating towards physically violent behaviour. The following list is not intended to be exhaustive and these warning signs should be considered on an individual basis.

- Facial expressions tense and angry.
- Increased or prolonged restlessness, body tension, pacing.
- General over-arousal of body systems (increased breathing and heart rate, muscle twitching, dilating pupils).
- Increased volume of speech, erratic movements.
- Prolonged eye contact.
- Discontentment, refusal to communicate, withdrawal, fear, irritation.
- Thought processes unclear, poor concentration.
- Delusions or hallucinations with violent content.
- Verbal threats or gestures.
- Replicating, or behaviour similar to that which preceded earlier disturbed/violent episodes.
- Reporting anger or violent feelings.
- Blocking escape routes. **[D(GPP)]**

1.2.4 Risk factors

*see evidence statement page 40, para. 7.8.2.3.3.

Certain factors can indicate an increase risk of physically violent behaviour. The following lists are not intended to be exhaustive and these risk factors should be considered on an individual basis.

1.2.4.1 Demographic or personal history should be taken into account when assessing the risk of disturbed/violent behaviour, including the following features.

- History of disturbed/violent behaviour.
- History of misuse of substances or alcohol.
- Carers reporting service user's previous anger or violent feelings.
- Previous expression of intent to harm others.
- Evidence of rootlessness or 'social restlessness'.
- Previous use of weapons.
- Previous dangerous impulsive acts.
- Denial of previous established dangerous acts.
- Severity of previous acts.
- Known personal trigger factors.
- Verbal threat of violence.
- Evidence of recent severe stress, particularly loss event or the threat of loss.
- One or more of the above in combination with any of the following:
  - cruelty to animals
  - reckless driving
  - history of bed-wetting
  - loss of a parent before the age of eight years.

  [D(GPP)]

1.2.4.2 Clinical variables should be taken into account when assessing the risk of disturbed/violent behaviour, including the following features.

- Misuse of substances and/or alcohol.
- Drug effects (disinhibition, akathisia).
- Active symptoms of schizophrenia or mania, in particular
  - delusions or hallucinations focused on a particular person
  - command hallucinations
  - preoccupation with violent fantasy
  - delusions of control (especially with violent theme)
  - agitation, excitement, overt hostility or suspiciousness.
- Poor collaboration with suggested treatments.

- Antisocial, explosive or impulsive personality traits or disorder.
- Organic dysfunction. **[D(GPP)]**

* See evidence statements pages 46 and 47, para 7.8.2.3.3. v, vi, vii.

1.2.4.3 Situational variables should be taken into account when assessing the risk of disturbed/violent behaviour, including the following features.

- Extent of social support.
- Immediate availability of a potential weapon.
- Relationship to potential victim (for example, difficulties in relationship are known).
- Access to potential victim.
- Limit setting (for example, staff members setting parameters for activities, choices etc.).
- Staff attitudes. **[D(GPP)]**

1.3. Training

Staff need to have the appropriate skills to manage disturbed/violent behaviour in psychiatric in-patient settings. Training in the interventions used for the short-term management of disturbed/violent behaviour safeguards both staff and service users. Training that highlights awareness of racial, cultural, social and religious/spiritual needs, and gender differences, along with other special concerns, also mitigates against disturbed/violent behaviour. Such training should be properly audited to ensure its effectiveness.

* See evidence statements on page 50, para. 7.8.3.3 Ia, and on page 51, para. 7.8.3.3 Ib

1.3.1 Policy

1.3.1.1 All service providers should have a policy for training employees and staff-in-training, in relation to the short-term management of disturbed/violent behaviour. This policy should specify who will receive what level of training (based on risk assessment), how often they will be trained, and also outline the techniques in which they will be trained. **[D]**

1.3.1.2 All service providers should specify who the training provider is and ensure consistency in terms of training and refresher courses. **[D]**

1.3.1.3 Training relating to the management of disturbed/violent behaviour should be subject to approved national standards. **[D]***

1.3.1.4 If participants on training courses demonstrate inappropriate attitudes then trainers should pass this information onto the relevant line manager for appropriate action. **[D]**

** The NHS security management service (SMS) is developing a training curriculum for the management of violence. The National Institute for Mental Health in England (NIMHE) is drawing up an accreditation scheme for trainers. The work is due for completion in 2005.*

1.3.2 Specific staff training needs

1.3.2.1 There should be an ongoing programme of training for all staff in racial, cultural, spiritual, social and special needs issues to ensure that staff are aware of and know how to work with diverse populations and do not perpetuate stereotypes. Such courses should also cover any special populations – such as migrant populations and asylum seekers – that are relevant to the locality. **[D]**

1.3.2.2 All staff whose need is determined by risk assessment should receive ongoing competency training to recognise anger, potential aggression, antecedents and risk factors of disturbed/violent behaviour and to monitor their own verbal and non-verbal behaviour. Training should include methods of anticipating, de-escalating or coping with disturbed/violent behaviour. **[D]**

1.3.2.3 Staff members responsible for carrying out observation and engagement should receive ongoing competency training in observation, so that they are equipped with the skills and confidence to engage with service users. **[D]**

1.3.2.4 All staff involved in administering or prescribing rapid tranquillisation, or monitoring service users to whom parenteral rapid tranquillisation has been administered, should receive ongoing competency training to a minimum of immediate life support (ILS – Resuscitation Council UK) (covers airway, cardio-pulmonary resuscitation [CPR] and use of defibrillators). **[D]**

1.3.2.5 Staff who employ physical intervention or seclusion should as a minimum be trained to basic life support (BLS – Resuscitation Council UK). **[D]**

1.3.2.6 All staff whose level of need is determined by risk assessment should receive training to ensure current competency in the use of physical intervention, which should adhere to approved national standards. **[D]**

1.3.2.7 Service providers should ensure that staff's capability to undertake physical intervention and physical intervention training courses is assessed. **[D]**

1.3.2.8 All staff whose level of need is determined by risk assessment should receive ongoing competency training in the use of seclusion. Training should include appropriate monitoring arrangements for service users placed in seclusion. **[D]**

1.3.2.9 All staff involved in rapid tranquillisation should

be trained in the use of pulse oximeters. **[D]**

1.3.2.10 Prescribers and those who administer medicines should be familiar with and have received training in rapid tranquillisation, including:

- the properties of benzodiazepines; their antagonist, flumazenil; antipsychotics; antimuscarinics; and antihistamines
- the risks associated with rapid tranquillisation, including cardio-respiratory effects of the acute administration of these drugs, particularly when the service user is highly aroused and may have been misusing drugs; is dehydrated or possibly physically ill
- the need to titrate doses to effect. **[D]**

1.3.2.11 All staff involved in undertaking of searches should receive appropriate instruction, which is repeated and regularly updated. **[D]**

1.3.3 Incident recording

1.3.3.1 Training should be given to all appropriate staff to ensure that they are aware of how to correctly record any incident, using the appropriate local templates. **[D]**

1.3.4 Refresher courses

1.3.4.1 Services should review their training strategy annually to identify those staff groups that require ongoing professional training in the recognition, prevention and de-escalation of disturbed/violent behaviour and in physical intervention to manage disturbed/violent behaviour. **[D]**

*See evidence statement page 53, para. 7.8.3.3. Ib

1.3.5 Evaluating training

1.3.5.1 All training should be evaluated, including training in racial, cultural, religious/spiritual and gender issues, along with training that focuses on other special service user concerns. **[D]**

1.3.5.2 Independent bodies/service user groups should, if possible, be involved in evaluating the effectiveness of training. **[D]**

* See evidence statements on page 50, para. 7.8.3.3 Ia, and page 53, para. 7.8.3.3 II.

1.3.6 Service user training/involvement in training

1.3.6.1 Service users and/or service user groups should have the opportunity to become actively involved in training and setting the training agenda, for example groups with potential vulnerabilities such as:

- service users with a sensory impairment
- black and minority ethnic service users
- service users with a physical impairment
- service users with a cognitive impairment
- female service users
- service users with communication difficulties. **[D]**

1.4 Working with service users

There is a growing acceptance that service users in adult psychiatric in-patient settings ought to be involved in their care, as far as possible. This extends to the short-term management of disturbed/violent behaviour, where service user input can be made through measures such as advance directives. Listening to service users' views and taking them seriously is now also regarded as an important factor in the short-term management of disturbed/violent behaviour. Service users may also have physical needs that need to be taken into account, when using the interventions discussed in this guideline.

The recommendations and good practice points that follow also address the needs that arise from diversity (cultural, social, religious/spiritual and gender-related needs) and physical needs in the context of the short-term management of disturbed/violent behaviour. It is important that service users should not be treated less favourably on the basis of their culture, gender, diagnosis, sexual orientation, disability, ethnicity or religious/spiritual beliefs.

*See evidence statement on page 57, para. 7.8.4.1.4 Ic, and on page 58, para. 7.8.4.2.1 Ia.

1.4.1 Creating a feeling of safety and understanding

Preventing disturbed/violent behaviour is a priority. Providing relevant information so that service users feel safe and understand what may happen to them in the event that they become disturbed/violent will help prevent unnecessary aggravation.

1.4.1.1 All service users, regardless of culture, gender, diagnosis, sexual orientation, disability, ethnicity or religious/spiritual beliefs should be treated with dignity and respect. **[D]**

1.4.1.2 Service users should have access to information about the following in a suitable format:

- which staff member has been assigned to them and how and when they can be contacted
- why they have been admitted (and if detained, the reason for detention, the powers used and their extent, and rights of appeal)
- what their rights are with regard to consent to treatments, complaints procedures, and access to independent help and advocacy
- what may happen if they become disturbed/violent.

This information needs to be provided at each admission, repeated as necessary and recorded in the notes. **[D]**

Commentary

Although no studies were identified that specifically addressed the issue of information provision for service users, the Guideline Development Group viewed this as an important issue requiring guidance. The Group maintain it is the legal right that detained service users are given this information and that this information should be viewed as a right for all service users. (See also the legal preface on page 20, para. 6.1.1)

1.4.1.3 An effective and fair complaints procedure should be put in place. **[D(GPP)]**

1.4.1.4 Where at all possible, service users should have a choice of key worker. **[D(GPP)]**

1.4.1.5 Service users identified to be at risk of disturbed/violent behaviour should be given the opportunity to have their needs and wishes recorded in the form of an advance directive. This should fit within the context of their overall care and should clearly state what intervention(s) they would and would not wish to receive. This document should be subject to periodic review. **[D]**

Commentary

Although no studies were identified that specifically addressed the issue of advance directives, the Guideline Development Group (in particular those with personal experience of the issue) felt that it was important for service users to be able to have input into their care. The Group did not consider that discussing these issues with appropriate service users would cause unnecessary anxiety. The Group used formal consensus techniques to develop this recommendation.

1.4.1.6 During the staff/service user risk assessment interview, where a risk of disturbed/violent behaviour is discussed or identified as a possibility, intervention and management strategies (and the service user's preferences regarding these) should be recorded in the service user's care plan and health care record. Efforts should be made to ascertain the service user's own views about their trigger factors, early warning signs of disturbed/violent behaviour and other vulnerabilities, and the management of these. The service user should be given a copy of the care plan and, subject to their agreement, a copy should be given to their carer. **[D(GPP)]**

1.4.1.7 The physical needs of the service user should be assessed on admission or as soon as possible thereafter and then regularly reassessed. The care plan should reflect the service user's physical needs. **[D(GPP)]**

1.4.1.8 Following any intervention for the short-term management of disturbed/violent behaviour, every opportunity should be taken to establish whether the service user understands why this has happened. Where possible, this should be carried out by a staff member not directly involved in the intervention. This should be documented in the service user's notes. **[D]**

1.4.1.9 Staff should take time to listen to service users, including those from diverse backgrounds, (taking into account that this may take longer when using interpreters), so that therapeutic relationships can be established. **[D(GPP)]**

1.4.1.10 All services should have a policy for preventing and dealing with all forms of harassment and abuse. Notification of this policy should be disseminated to all staff and displayed prominently in all clinical and public areas. **[D]**

1.4.1.11 In the event of any form of alleged abuse, the matter should be dealt with by staff as soon as is practicable, in accordance with relevant policies of the service. **[D(GPP)]**

1.4.1.12 During the administration or supply of medicines to service users, confidentiality should be ensured. **[D(GPP)]**

1.4.1.13 Prescribers should be available for and responsive to requests from the service user for medication review. **[D(GPP)]**

1.4.1.14 Staff should be encouraged to talk to service users from diverse backgrounds, including those with special needs, about their experiences and to offer them support and understanding, especially if their experience has been negative. **[D]**

1.4.2 Pregnant women

1.4.2.1 Special provision should be made for pregnant women, in the event that interventions for the short-term management of disturbed/violent behaviour are needed. These should be recorded in the service user's care plan. **[D(GPP)]**

1.4.3 Black and minority ethnic service users

See also recommendation 1.2.2.3.

*See evidence statements on pages 58 and 59, paras. 7.8.4.2.3 Ia, Ib, IIb, IIIa

1.4.3.1 Services must identify a board member to take specific responsibility for all matters relating to equality and diversity. Responsibilities must include the nature and adequacy of service provision in relation to the short-term management of disturbed/violent behaviour, training on all matters relating to equality and diversity, monitoring

service usage by ethnicity and consultation with local black and minority ethnic groups. **[D]**

1.4.4 Service users with disabilities

*See evidence statement page 61, para. 7.8.4.4.4.

1.4.4.1 Each service should have a policy that outlines the procedures for dealing with service users who have disabilities, including those with physical or sensory impairment and/or other communication difficulties. **[D(GPP)]**

1.4.4.2 Individual care plans should detail staff responsibilities for de-escalation, rapid tranquillisation, physical intervention and seclusion of service users who have disabilities, including those with physical or sensory impairment and/or other communication difficulties. **[D(GPP)]**

1.4.5 Managing the risk of HIV or other infectious diseases

Policy

1.4.5.1 Services should have policies in place, developed in conjunction with the trust infection control officer or relevant officer in the service, that outline the reasonable steps that can be taken to safeguard staff and other service users if a service user who has HIV, hepatitis or other infectious or contagious diseases is acting in a manner that may endanger others. **[D(GPP)]**

1.4.5.2 If staff are aware that a service user has HIV, hepatitis or other infectious or contagious diseases, the advice of the trust infection control officer or relevant officer in the service should be sought. **[D(GPP)]**

Confidentiality issues

1.4.5.3 Service users are owed important obligations of confidentiality, but these are not absolute. In certain circumstances they may be breached to safeguard others. This is particularly relevant where a service user has HIV, hepatitis or other infectious or contagious diseases, and is acting in a manner that puts others at risk. Legal and ethical advice should be sought in these circumstances. **[D(GPP)]**

1.4.5.4 If any service user or staff member has sustained any injury during the management of disturbed/violent behaviour where blood has been spilt or the skin has been broken, or there has been direct contact with bodily fluids (all bodily fluids should be treated as potentially infectious), the local infection control policy should be followed. **[D(GPP)]**

1.5 Searching

The undertaking of necessary and lawful searches of both service users and visitors can make an important contribution to the effective management of disturbed/violent behaviour in psychiatric in-patient settings. Unlawful, insensitive and unnecessary searches can also exacerbate disturbed/violent behaviour. Searches should be undertaken by appropriately trained staff.

See also recommendation 1.3.2.11 (Training).

1.5.1 Policy

1.5.1.1 All facilities should have an operational policy on the searching of service users, their belongings and the environment in which they are accommodated, and also the searching of visitors. Where necessary, the policy should refer to related policies, such as those for substance misuse and police liaison. The searching policy should be in place in order to ensure the creation and maintenance of a safe and therapeutic environment for service users, staff and visitors. **[D]**

1.5.1.2 The searching policy should address all aspects of personal through to environmental searching – from the decision to initiate a search through to the storage, return or other disposal (including the lawful disposal of any items such as firearms and illicit drugs) of items found. **[D]**

1.5.1.3 Post search support for all those involved should be provided. **[D]**

1.5.1.4 The searching policy should set out, in terms that can easily be understood by all those with responsibilities under the policy, the legal grounds for undertaking searches in the absence of consent. **[D]**

1.5.1.5 The searching policy should specifically address the searching of service users detained under the Mental Health Act; informal service users without capacity to consent at the time of the search; informal service users with capacity to do so; and staff and visitors. **[D]**

1.5.1.6 The searching policy should also extend to the routine and random searching of detained service users, where it is proposed to do so because there is a pressing social need to do so (for example, there is a chronic substance abuse problem on the ward) and undertaking such searches is a proportionate response to that need. **[D]**

1.5.2 Carrying out searches

1.5.2.1 The level of intrusiveness of any personal search undertaken must be a reasonable and proportionate response to the reason for the search. Ordinarily rub down or personal searching should be provided for in the policy, together with procedures for their authorisation in the absence of consent. **[D]**

1.5.2.2 All searches should be undertaken with due regard to the service user's dignity and privacy and by a member(s) of staff of the same sex. **[D]**

1.5.2.3 The searching policy should provide for the circumstances in which a service user physically resists being searched. In this event a multidisciplinary decision should be made as to the need to carry out a search using physical intervention. If a decision is made not to proceed, then the searching policy should set out the options available to deal with the situation. **[D]**

1.5.2.4 The searching policy should make provision for the following:

- service users, staff and visitors should be informed that there is a policy on searching
- the consent of the person it is proposed to search should always be sought
- the person being searched should be kept informed of what is happening and why
- a comprehensive record of every search should be made, including its justification
- any consequent risk assessment and risk management should be placed in the appropriate records. **[D]**

1.5.2.5 Following every search undertaken where consent has been withheld, there should be a post-incident review that includes an advocacy service or hospital managers visiting the service user who has been searched. **[D]**

1.5.2.6 The exercise of powers of search should be audited regularly and the outcomes reported regularly to the trust board or appropriate body. **[D]**

1.6 De-escalation techniques

De-escalation involves the use of techniques that calm down an escalating situation or service user; therefore, action plans should stress that de-escalation should be employed early on in any escalating situation. Action plans should be developed at a local level, detailing how to call for help in an emergency.

* See evidence statement page 63, para.7.8.5.1.3.

See also recommendation 1.1.1.2 (Environment) and recommendation 1.3.2.2 (Training).

1.6.1 General

1.6.1.1 A service user's anger needs to be treated with an appropriate, measured and reasonable response. De-escalation techniques should be employed prior to other interventions being used. **[D(GPP)]**

1.6.1.2 Staff should accept that in a crisis situation they are responsible for avoiding provocation. It is not realistic to expect the person exhibiting disturbed/violent behaviour to simply calm down. **[D(GPP)]**

1.6.1.3 Staff should learn to recognise what generally and specifically upsets and calms people. This will involve listening to individual service users and carer's reports of what upsets the service user, and this should be reflected in the service user's care plan. **[D(GPP)]**

1.6.1.4 Staff should be aware of, and learn to monitor and control, their own verbal and non-verbal behaviour, such as body posture and eye contact etc. **[D(GPP)]**

1.6.1.5 Where possible and appropriate, service users should be encouraged to recognise their own trigger factors, early warning signs of disturbed/violent behaviour, and other vulnerabilities. This information should be included in care plans and a copy given to the service user. Service users should also be encouraged to discuss and negotiate their wishes should they become agitated. **[D(GPP)]**

1.6.1.6 Where de-escalation techniques fail to sufficiently calm a situation or service user, staff should remember that verbal de-escalation is an ongoing element of the management of an escalating individual. Verbal de-escalation is supported but not replaced by appropriate physical intervention. **[D(GPP)]**

1.6.2 De-escalation techniques

1.6.2.1 One staff member should assume control of a potentially disturbed/violent situation. **[D(GPP)]**

1.6.2.2 The staff member who has taken control should:

- consider which de-escalation techniques are appropriate for the situation
- manage others in the environment, for example removing other service users from the area, enlisting the help of colleagues and creating space
- explain to the service user and others in the immediate vicinity what they intend to do
- give clear, brief, assertive instructions
- move towards a safe place and avoid being trapped in a corner. **[D(GPP)]**

1.6.2.3 The staff member who has taken control should ask for facts about the problem and encourage reasoning. This will involve:

- attempting to establish a rapport and emphasising co-operation
- offering and negotiating realistic options and avoiding threats
- asking open questions and inquiring about the reason for the service user's anger, for example 'What has caused you to feel upset/angry?'

- showing concern and attentiveness through non-verbal and verbal responses
- listening carefully and showing empathy, acknowledging any grievances, concerns or frustrations, and not being patronising or minimising service user concerns. **[D(GPP)]**

1.6.2.4 The staff member who has taken control should ensure that their own non-verbal communication is non-threatening and not provocative. This will involve:

- paying attention to non-verbal cues, such as eye contact and allowing greater body space than normal
- adopting a non-threatening but safe posture
- appearing calm, self-controlled and confident without being dismissive or over-bearing. **[D(GPP)]**

1.6.2.5 Where there are potential weapons, the disturbed/violent person should be relocated to a safer environment, where at all possible. **[D(GPP)]**

1.6.2.6 Where weapons are involved, a staff member should ask for the weapon to be placed in a neutral location rather than handed over. **[D(GPP)]**

1.6.2.7 Staff should consider asking the service user to make use of the designated area or room specifically for the purpose of reducing arousal and/or agitation to help them calm down. In services where seclusion is practised, the seclusion room should not routinely be used for this purpose (see recommendation 1.1.1.2). **[D(GPP)]**

1.7 Observation and engagement

The primary aim of observation should be to engage positively with the service user. This involves a two-way relationship, established between a service user and a staff member, which is meaningful, grounded in trust, and therapeutic for the service user. Observation is an intervention that is used both for the short-term management of disturbed/violent behaviour and to prevent self-harm. The recommendations and good practice points below are specifically directed towards the use of observation as an intervention for the short-term management of disturbed/violent behaviour. However, many are also applicable where observation is used to prevent self-harm. The terminology covers both uses of observation.

*See evidence statement page 66, para. 7.8.5.2.3.

See also recommendation 1.3.2.3 (Training).

1.7.1 Policy

1.7.1.1 Each service should have a policy on observation and engagement that adheres to contemporary NICE terminology and definitions. This policy should include:

- who can instigate observation above a general level
- who can increase or decrease the level of observation
- who should review the level of observation
- when reviews should take place (at least every shift)
- how service users' perspectives will be taken into account
- a process through which a review by a full clinical team will take place if observation above a general level continues for more than one week. **[D]**

1.7.2 Definitions of levels of observation

1.7.2.1 The observation terminology used in this guideline should be adopted across England and Wales to ensure consistency of use. **[D]**

1.7.2.2 *General observation* is the minimum acceptable level of observation for all in-patients. The location of all service users should be known to staff, but not all service users need to be kept within sight. At least once a shift a nurse should set aside dedicated time to assess the mental state of the service user and engage positively with the service user. The aim of this should be to develop a positive, caring and therapeutic relationship with the service user. This assessment should always include an evaluation of the service user's moods and behaviours associated with risks of disturbed/violent behaviour, and these should be recorded in the notes. **[D]**

1.7.2.3 *Intermittent observation* means that the service user's location should be checked every 15 to 30 minutes (exact times to be specified in the notes). Checks need to be carried out sensitively in order to cause as little intrusion as possible. However, this check should also be seen in terms of positive engagement with the service user. This level is appropriate when service users are potentially, but not immediately, at risk of disturbed/violent behaviour. Service users who have previously been at risk of harming themselves or others, but who are in a process of recovery, require intermittent observation. **[D]**

1.7.2.4 *Within eyesight* means the service user should be kept within eyesight and accessible at all times, by day and by night and, if deemed necessary, any tools or instruments that could be used to harm themselves or others should be removed. It is required when the service user could, at any time, make an attempt to harm themselves or others. It may be necessary to search the service user and their belongings, while having due regard for the service user's legal rights and conducting the search in a sensitive way. Positive engagement with the service user is an essential aspect of this level of observation. **[D]**

1.7.2.5 *Within arms length* is needed for service users at the highest levels of risk of harming themselves or others, who may need to be supervised in close proximity. On

specified occasions, more than one member of staff may be necessary. Issues of privacy, dignity and the consideration of gender in allocating staff, and the environmental dangers need to be discussed and incorporated into the care plan. Positive engagement with the service user is an essential aspect of this level of observation. **[D]**

1.7.3 Possible antecedents or warning signs that observation is required

1.7.3.1 In addition to the antecedents that indicate disturbed/violent behaviour (see recommendation 1.2.3.1), observation above a general level should be considered if any of the following are present:

- history of previous suicide attempts, self-harm or attacks on others
- hallucinations, particularly voices suggesting harm to self or others
- paranoid ideas where the service user believes that other people pose a threat
- thoughts or ideas that the service user has about harming themselves or others
- threat control override symptoms
- past or current problems with drugs or alcohol
- recent loss
- poor adherence to medication programmes or non-compliance with medication programmes
- marked changes in behaviour or medication
- known risk indicators. **[D(GPP)]**

1.7.4 Carrying out observation

1.7.4.1 Designated levels of observation should only be implemented after positive engagement with the service user has failed to dissipate the potential for disturbed/violent behaviour. **[D(GPP)]**

1.7.4.2 The least intrusive level of observation that is appropriate to the situation should always be adopted, so that due sensitivity is given to a service user's dignity and privacy, whilst maintaining the safety of those around them. **[D(GPP)]**

1.7.4.3 Decisions about observation levels should be recorded by both medical and nursing entries in the service user's notes. The reasons for using observation should be clearly specified. **[D(GPP)]**

1.7.4.4 All decisions about the specific level of observation should take into account:

- the service user's current mental state
- any prescribed medications and their effects
- the current assessment of risk
- the views of the service user as far as possible. **[D(GPP)]**

1.7.4.5 When making decisions about observation levels, clear directions should be recorded that specify:

- the name/title of the persons who will be responsible for carrying out the review
- the timing of the review. **[D(GPP)]**

1.7.4.6 Observation skills should be used to recognise, prevent and therapeutically manage disturbed/violent behaviour. Specific observation tasks should be undertaken by registered nurses, who may delegate to competent persons. **[D]**

1.7.4.7 Nurses and other staff undertaking observation:

- should take an active role in engaging positively with the service user
- should be appropriately briefed about the service user's history, background, specific risk factors and particular needs
- should be familiar with the ward, the ward policy for emergency procedures and potential risks in the environment
- should be able to increase or decrease the level of engagement with the service user, as the level of observation changes
- should be approachable, listen to the service user, know when self-disclosure and the therapeutic use of silence are appropriate and be able to convey to the service user that they are valued. **[D(GPP)]**

1.7.4.8 An individual staff member should not undertake a continuous period of observation above the general level for longer than two hours. **[D]**

1.7.4.9 The service user's psychiatrist/on-call doctor should be informed of any decisions concerning observation above the general level as soon as possible. **[D(GPP)]**

1.7.4.10 A nominated hospital manager should be made aware when observation above the general level is implemented, so that adequate numbers and grades of staff can be made available for future shifts. **[D(GPP)]**

1.7.4.11 Staff members should be aware that service users sometimes find observation provocative, and that it can lead to feelings of isolation and even dehumanisation. **[D(GPP)]**

1.7.5 Service user needs

1.7.5.1 The service user should be provided with information about why they are under observation, the aims of observation and how long it is likely to be maintained. **[D(GPP)]**

1.7.5.2 The aims and level of observation should, where appropriate, be communicated with the service user's approval to the nearest relative, friend or carer. **[D(GPP)]**

1.7.5.3 Although difficult, where possible, the handover from one nurse or staff member to another should involve the service user so that they are aware of what is being said about them. **[D(GPP)]**

1.8 Other interventions

Where de-escalation techniques have failed to calm a service user, it may be necessary to make use of additional interventions, such as physical intervention, rapid tranquillisation and seclusion to manage the incident. All such interventions should only be considered once de-escalation techniques have been tried and have not succeeded in calming the service user.

The choice of intervention(s) will depend on a number of factors, but should be guided primarily by:

- service user preference (if known)
- the clinical needs of, and risks to, the service user
- obligations to other service users affected by the disturbed/violent behaviour
- the protection of staff, service users and visitors
- the facilities available within the particular setting.

The intervention selected must amount to a proportionate and reasonable response to the risk posed. This section should be read alongside the Mental Health Act Code of Practice (www.dh.gov.uk/assetRoot/04/07/49/61/04074961.pdf).

1.8.1 Overarching recommendations

See also recommendations 1.3.2.4 and 1.3.2.5 (Training); 1.9.1.1 and 1.9.1.2 (Incident reporting).

1.8.1.1 Rapid tranquillisation, physical intervention and seclusion should only be considered once de-escalation and other strategies have failed to calm the service user. These interventions are management strategies and are not regarded as primary treatment techniques. When determining which interventions to employ, clinical need, safety of service users and others, and, where possible, advance directives should be taken into account. The intervention selected must be a reasonable and proportionate response to the risk posed by the service user. **[D]**

Commentary

There is a lack of evidence relating to the effectiveness of these three interventions, particularly for physical intervention and seclusion. The Guideline Development Group therefore felt the need to stress caution when implementing these interventions, and used formal consensus techniques to derive this recommendation. (See also the legal preface on page 20, para. 6.1.1).

Equipment

1.8.1.2 A crash bag (including an automatic external defibrillator, a bag valve mask, oxygen, cannulas, fluids, suction and first-line resuscitation medications) should be available within three minutes in health care settings where rapid tranquillisation, physical intervention and seclusion might be used. This equipment should be maintained and checked weekly. **[D]**

Personnel

1.8.1.3 At all times, a doctor should be quickly available to attend an alert by staff members when rapid tranquillisation, physical intervention and/or seclusion are implemented. **[D]**

Commentary

There is limited evidence in this area. However, a number of high profile inquiries, most recently, the inquiry into the death of David Bennett, have stressed the need for a doctor to be available to attend an alert by staff members when rapid tranquillisation, physical interventions and/or seclusion have been implemented. The inquiry into the death of David Bennett recommended that a doctor should be available within 20 minutes of such an alert. Some mental health services currently rely on emergency services in the event of such an incident. The GDG believes that dialing for emergency services in the event of an alert is not sufficient in itself. After much discussion, the GDG felt that half-an-hour is a reasonable amount of time in which to expect a doctor to be present. Formal consensus techniques were used to derive this recommendation.

Legal concerns

1.8.1.4 All staff need to be aware of the legal framework that authorises the use of rapid tranquillisation, physical intervention and seclusion. The guidance of the Mental Health Act Code of Practice (chapter 19) should be followed, with any departures from that guidance clearly recorded and justified as being in the service user's best interest. **[D(GPP)]**

Service user concerns

1.8.1.5 When using interventions such as rapid tranquillisation, physical intervention or seclusion, steps should be taken to try to ensure that the service user does not feel humiliated (such as respecting a service user's need for dignity and privacy commensurate with the needs of administering the intervention). **[D(GPP)]**

1.8.1.6 The reasons for using rapid tranquillisation,

physical intervention or seclusion should be explained to the service user at the earliest opportunity. **[D(GPP)]**

1.8.1.7 After the use of rapid tranquillisation, physical intervention or seclusion, the service user's care plan should be reassessed and the service user should be helped to reintegrate into the ward milieu at the earliest safe opportunity. **[D(GPP)]**

1.8.1.8 Service users should be given the opportunity to document their account of the intervention in their notes. **[D(GPP)]**

1.8.2 Physical intervention

*See evidence statements on pages 67 and 69, para. 7.8.6.1.3.

See also recommendation 1.3.2.6 (Training).

Carrying out physical intervention

1.8.2.1 During physical intervention, staff should continue to employ de-escalation techniques. **[D]**

1.8.2.2 There are real dangers with continuous physical intervention in any position. Physical intervention should be avoided if at all possible, should not be used for prolonged periods, and should be brought to an end at the earliest opportunity. To avoid prolonged physical intervention, an alternative strategy, such as rapid tranquillisation or seclusion (where available), should be considered. **[D]**

Commentary

There is limited evidence in this area. However, a number of high profile inquiries, most recently, the inquiry into the death of David Bennett, have stressed the dangers of prolonged restraint. The GDG was aware that the inquiry into the death of David Bennett recommended that a three-minute limit be placed on any period of restraint. However, this recommendation was not evidenced-based. Furthermore the three-minute limit is not used by other services, the prison service and the police service, which advocate different limits. The GDG discussed this issue at length and consulted with experts. It was noted that a time limit might endanger staff and other service users. Given the lack of evidence for a time limit, the GDG therefore decided that a time limit should not be set on physical interventions, but that the dangers of prolonged restraint should be highlighted, and the use of restraint discouraged. A recommendation was therefore made which advocates that any use of physical interventions should be brought to an end at the earliest opportunity, and periods of prolonged restraint should be avoided. Formal consensus techniques were used to draw up this recommendation. The David Bennett Inquiry makes particular reference to the use of the prone position. However, the evidence base surrounding the dangers of positional restraint is weak. Furthermore, the GDG believes that there are dangers related to restraint in any position and therefore decided not to highlight one position as safer than another, but to discourage restraint for prolonged periods in any position.

1.8.2.3 During physical intervention, one team member should be responsible for protecting and supporting the head and neck, where required. The team member who is responsible for supporting the head and neck should take responsibility for leading the team through the physical intervention process, and for ensuring that the airway and breathing are not compromised and that vital signs are monitored. **[D]**

Commentary

There is limited evidence in this area. However, a number of high profile inquiries, most recently, the inquiry into the death of David Bennett, have stressed the need for staff to protect a service user's head and airway during the restraint process. The inquiry suggests that failure to do so, and the application of pressure to certain parts of the body, may endanger the life of the service user. The focus groups conducted for the guideline also heard reports from participants who described finding it difficult to breathe during restraint, due to their head not being sufficiently supported. Although the National Institute of Mental Health In England (NIHME) and the NHS Security Management Service (SMS) are currently developing a curriculum for training that will cover this area, the GDG felt that this was an area of particular concern. After consultation with experts, including trainers, the GDG therefore decided to use formal consensus techniques to develop recommendations in this area. The GDG considers the protection of the head when appropriate to constitute a duty of care. See also the legal preface on page 20, para. 6.1.1

1.8.2.4 During physical intervention, under no circumstances should direct pressure be applied to the neck, thorax, abdomen, back or pelvic area. The overall physical and psychological well being of the service user should be continuously monitored throughout the process. **[D]**

1.8.2.5 A number of physical skills may be used in the management of a disturbed/violent incident.

- The level of force applied must be justifiable, appropriate, reasonable and proportionate to a specific situation and should be applied for the minimum possible amount of time.
- Every effort should be made to utilise skills and techniques that do not use the deliberate application of pain.

- The deliberate application of pain has no therapeutic value and could only be justified for the immediate rescue of staff, service users and/or others. **[D]**

Commentary

There is limited evidence in this area and the GDG was aware that the application of pain to help manage a violent/disturbed situation is a sensitive topic. However, currently around 50 per cent of training courses in England and Wales teach the use of pain as a technique that can be applied as part of a physical intervention. The GDG therefore felt that it was necessary to make a recommendation on this issue. A great deal of discussion took place in the course of the development of the guideline concerning this issue. To ensure a balanced representation at guideline development meetings, experts holding differing perspectives were invited to give presentations. Using formal consensus techniques the GDG finally derived a recommendation that restricts the use of pain to the immediate rescue of staff, service users or others.

1.8.2.6 Mechanical restraints are not a first-line response or standard means of managing disturbed/violent behaviour in acute mental health care settings. In the event that they are used, it must be a justifiable, reasonable and proportionate response to the risk posed by the service user, and only after a multidisciplinary review has taken place. Legal, independent expert medical and ethical advice should be sought and documented. **[D]**

Commentary

There is limited evidence in this area and the GDG was aware that the use of mechanical restraints is a sensitive issue. However, such restraints are used in very exceptional circumstances, usually in high secure hospitals. The GDG therefore felt that it was necessary to make a recommendation in this area. This stresses that mechanical restraints can only be used in such exceptional circumstances and only after a multidisciplinary review has taken place. Formal consensus techniques were used to draw up this recommendation.

1.8.3 Seclusion

*See evidence statements on pages 67 and 69, para. 7.8.6.1.3.

See also recommendations 1.1.1.3 (Environment) and 1.3.2.8 (Training).

Carrying out seclusion

1.8.3.1 The use of seclusion should be recorded in accordance with the guidance in the Mental Health Act Code of Practice. **[D]**

1.8.3.2 Seclusion should be for the shortest time possible and should be reviewed at least every two hours and in accordance with the guidance in the Mental Health Act Code of Practice. The service user should be made aware that reviews will take place at least every two hours. **[D]**

1.8.3.3 If seclusion is used, an observation schedule should be specified. **[D(GPP)]**

1.8.3.4 A service user in seclusion should retain their clothing, as long as it does not compromise their safety and the safety of others. **[D(GPP)]**

1.8.3.5 Service users in seclusion should be allowed to keep personal items, including those of religious or cultural significance (such as some items of jewellery), as long as they do not compromise their safety or the safety of others. **[D(GPP)]**

Rapid tranquillisation and seclusion

1.8.3.6 The use of seclusion with rapid tranquillisation is not absolutely contraindicated. However, the following advice should be carefully considered and followed.

- If the service user is secluded, the potential complications of rapid tranquillisation should be taken particularly seriously.
- The service user should be monitored by 'within eyesight' observation by an appropriately trained individual.
- Once rapid tranquillisation has taken effect, seclusion should be terminated. **[D(GPP)]**

1.8.4 Rapid tranquillisation

*See evidence statement on page 78, para. 7.8.6.2.4 II, and on page 80, para. 7.8.6.2.4 V.

See also recommendations 1.3.2.4, 1.3.2.9 and 1.3.2.10 (Training).

1.8.4.1 Medication for rapid tranquillisation, particularly in the context of physical intervention, should be used with caution, owing to the following risks:

- loss of consciousness instead of tranquillisation
- sedation with loss of alertness
- loss of airway
- cardiovascular and respiratory collapse
- interaction with medicines already prescribed or illicit substances taken (can cause side effects such as akathisia, disinhibition)
- possible damage to patient–staff relationship
- underlying coincidental physical disorders. **[D]**

Policy

1.8.4.2 Local protocols should be produced that cover all aspects of rapid tranquillisation. Such protocols should be

in accordance with legal requirements (especially in respect of detained patients, the consent to treatment, and the emergency treatment powers and duties under the Mental Health Act), and relevant NICE guidance, and should be subject to review. **[D]**

Risks associated with rapid tranquillisation

1.8.4.3 There are specific risks associated with the different classes of medications that are used in rapid tranquillisation. The specific properties of the individual drugs should be taken into consideration. When combinations are used, risks may be compounded. Staff need to be aware of the following.

For benzodiazepines:

- loss of consciousness
- respiratory depression or arrest
- cardiovascular collapse (in service users receiving both clozapine and benzodiazepines).

For antipsychotics:

- loss of consciousness
- cardiovascular and respiratory complications and collapse
- seizures
- subjective experience of restlessness (akathisia)
- acute muscular rigidity (dystonia)
- involuntary movements (dyskinesia)
- neuroleptic malignant syndrome
- excessive sedation.

For antihistamines:

- excessive sedation
- painful injection
- additional antimuscarinic effects. **[D(GPP)]**

Circumstances for special care

1.8.4.4 Extra care should be taken when implementing rapid tranquillisation in the following circumstances:

- the presence of congenital prolonged QTc syndromes
- the concurrent prescription or use of other medication that lengthens QTc intervals, both directly and indirectly
- the presence of certain disorders affecting metabolism, such as hypo- and hyperthermia, stress and extreme emotions, and extreme physical exertion. **[D]**

Carrying out rapid tranquillisation

1.8.4.5 The service user should be able to respond to communication throughout the period of rapid tranquillisation. The aim of rapid tranquillisation is to achieve a state of calm sufficient to minimise the risk posed to the service user or to others. **[D]**

1.8.4.6 When a service user is transferred between units, a full medication history, including the service user's response to medications, any adverse effects, and an advance directive should accompany them. Where possible, the service user's account of their experience of rapid tranquillisation should also be included. On discharge, all such information should be filed in their health care record and be subject to regular review. **[D(GPP)]**

Oral therapy for rapid tranquillisation

1.8.4.7 Oral medication should be offered before parenteral medication as far as possible. **[D]**

*See evidence statement on page 81, para 7.8.6.2.4 VI.

1.8.4.8 All medication given in the short-term management of disturbed/violent behaviour should be considered as part of rapid tranquillisation (including pro re nata [PRN] medication taken from an agreed rapid tranquillisation protocol or as part of an advance directive). **[D]**

1.8.4.9 Oral and intramuscular medications should be prescribed separately and the abbreviation of o/i/m should not be used. **[D]**

1.8.4.10 When the behavioural disturbance occurs in a non-psychotic context, it is preferable to initially use oral lorazepam alone, or intramuscularly if necessary. **[B]**

1.8.4.11 When the behavioural disturbance occurs in the context of psychosis, to achieve early onset of calming/sedation, or to achieve a lower dose of antipsychotic, an oral antipsychotic in combination with oral lorazepam, should be considered in the first instance. (See chart for rapid tranquillisation at end of section.) **[D]**

1.8.4.12 The Medicines and Healthcare products Regulatory Agency (MHRA) has warned against the use of risperidone or olanzapine in the treatment of behavioural symptoms of dementia, due to increased risk of stroke and death. **[B]**

1.8.4.13 Sufficient time should be allowed for clinical response between oral doses of medication for rapid tranquillisation. (See chart for rapid tranquillisation at end of section.) **[B]**

Parenteral therapy for rapid tranquillisation

*See evidence statements on page 74 and 77, para. 7.8.6.2.4 II.

1.8.4.14 If parenteral treatment proves necessary, the intramuscular route (i/m) is preferred over intravenous (i/v) from a safety point of view. The service user should be transferred to oral routes of administration at the earliest opportunity. **[D]**

1.8.4.15 Where rapid tranquillisation through oral therapy is refused, is not indicated by previous clinical response, is not a proportionate response, or is ineffective, a combination of an intramuscular antipsychotic and an intramuscular benzodiazepine (i/m haloperidol and i/m lorazepam) is recommended. **[B]**

1.8.4.16 In the event of moderate disturbance in service users with psychosis, i/m olanzapine* may also be considered. Intramuscular lorazepam should not be given within one hour of i/m olanzapine. Oral lorazepam should be used with caution. **[B]**

** The manufacturer has issued a warning that use outside of the details contained within the Summary of Product Characteristics may increase the risk of fatality.*

1.8.4.17 There is not sufficient evidence that the safety of either combination of i/m haloperidol with i/m promethazine or i/m midazolam alone has been sufficiently demonstrated in the UK. However, it has been shown to be effective and relatively safe elsewhere. The GDG is therefore not able to recommend either for routine psychiatric practice in the UK. **[B]**

Commentary

The GDG were of the opinion that the evidence was not clinically relevant to the UK context because the outcome of the studies had sleep as a primary outcome, whereas in the UK and increasingly elsewhere the primary objective is to calm the service user to enable other psychosocial techniques to be employed.

1.8.4.18 Sufficient time should be allowed for clinical response between intramuscular (i/m) doses of medications for rapid tranquillisation. (See chart for rapid tranquillisation at end of section.) **[B]**

1.8.4.19 The use of two drugs of the same class for the purpose of rapid tranquillisation should not occur. **[D]**

1.8.4.20 Medications should never be mixed in the same syringe. **[D(GPP)]**

1.8.4.21 When using i/m haloperidol as a means of managing disturbed/violent behaviour, an antimuscarinic agent, such as procyclidine or benzatropine, should be immediately available to reduce the risk of dystonia and other extrapyramidal side effects, and should be given intramuscularly or intravenously as per manufacturer's recommendations. **[D]**

1.8.4.22 Intravenous administration of benzodiazepines or haloperidol should not normally be used except in very exceptional circumstances, which should be specified and recorded. This decision should not be made by junior medical staff in isolation. **[D]**

1.8.4.23 If immediate tranquillisation is essential, then intravenous administration may be necessary. If it is used, staff should be appropriately trained to recognise symptoms of respiratory depression, dystonia or cardiovascular compromise (such as palpitations, significant changes in blood pressure, or collapse). **[D]**

1.8.4.24 If intravenous medication is used, the service user should never be left unattended. Intravenous administration should never occur without full access to the full support and resuscitation as outlined in recommendations 1.3.2.4 and 1.8.1.2. **[D]**

1.8.4.25 In very exceptional circumstances, which should be specified and recorded, i/m haloperidol in combination with i/m promethazine, or i/m midazolam alone may be considered as an alternative to intravenous administration of benzodiazepines or haloperidol. This decision should not be made by junior staff without discussion with the senior on-call psychiatrist. **[D]**

Medications not normally used for rapid tranquillisation

1.8.4.26 Zuclopenthixol acetate injection is not recommended for rapid tranquillisation due to long onset and duration of action. However, zuclopenthixol acetate injection may be considered as an option for rapid tranquillisation when:

- it is clearly expected that the service user will be disturbed/violent over an extended period of time
- a service user has a past history of good and timely response to zuclopenthixol acetate injection
- a service user has a past history of repeated parenteral administration
- an advance directive has been made indicating that this is a treatment of choice.

It should never be administered to those without any previous exposure to antipsychotic medication. The British National Formulary (BNF) and manufacturer's summary of product characteristics (SPC) should be consulted regarding its use. **[B]**

Medications not recommended for rapid tranquillisation

1.8.4.27 The following medications are not recommended for rapid tranquillisation.

- Intramuscular or oral chlorpromazine or oral (a local irritant if given intramuscularly; risk of cardiovascular complications; causes hypotension due to ·-adrenergic receptor blocking effects, especially in the doses required for rapid tranquillisation; is erratically absorbed; its effect on QTc intervals suggests that it is unsuitable for use in rapid tranquillisation). **[C]**
- Intramuscular diazepam. **[C]**

- Thioridazine. **[C]**
- Intramuscular depot antipsychotics. **[D]**
- Olanzapine or risperidone should not be used for the management of disturbed/violent behaviour in service users with dementia. **[C]**

Doses for rapid tranquillisation

It is recognised that clinicians may decide that the use of medication outside of the SPC is occasionally justified, bearing in mind the overall risks. However, where the regulatory authorities or manufacturer issues a specific warning that this may result in an increased risk of fatality, the medication should only be used strictly in accordance with the current marketing authorisation.

1.8.4.28 When using rapid tranquillisation there may be certain circumstances in which the current BNF uses and limits and SPC may be knowingly exceeded (for example, for lorazepam). This decision should not be taken lightly and the risks should not be underestimated. A risk–benefit analysis should be recorded in the case notes and a rationale should be recorded in the care plan. Where the risk–benefit is unclear, advice may be sought from clinicians not directly involved in the service user's care. **[D]**

Commentary

The inquiry into the death of David Bennett recommends that BNF limits should not be exceeded when giving rapid tranquillisation. The GDG carefully discussed this issue at length and it was felt that in certain circumstances there are grounds for knowingly exceeding BNF limits and for using medications off licence, where this is recognised clinical practice. However, the GDG stresses that a decision to exceed BNF limits should not be taken lightly and the risk of doing so should be carefully assessed. It also stresses that, where the risk benefit is unclear, it may be desirable to seek advice from staff members who are not directly involved in the service user's care. The GDG also wishes to stress that any decision to exceed BNF limits must be recorded in the case notes and a rationale recorded in the care plan. This recommendation was drawn up using formal consensus techniques.

1.8.4.29 If current BNF or SPC doses are exceeded, it is particularly important that frequent and intensive monitoring of a calmed service user is undertaken, with particular attention to regular checks of airway, level of consciousness, pulse, blood pressure, respiratory effort, temperature and hydration. **[D]**

1.8.4.30 In all circumstances of rapid tranquillisation, the prescriber and medication administrator should pay attention to:

- the total dose of medication prescribed
- arrangements for review
- issues of consent, BNF and SPC requirements and physical and mental status of the service user. **[D]**

1.8.4.31 The dose of antipsychotic medication should be individualised for each service user. This will be dependent on several factors, including the service user's age (older service users generally require lower doses); concomitant physical disorders (such as renal, hepatic, cardiovascular, or neurological); and concurrent medication. **[D(GPP)]**

1.8.4.32 A specialist mental health pharmacist should be a member of the multidisciplinary team in all circumstances where rapid tranquillisation is used. These pharmacists have a responsibility to monitor and ensure safe and appropriate usage of medication. **[D]**

Care after rapid tranquillisation

1.8.4.33 After rapid tranquillisation is administered, vital signs should be monitored and pulse oximeters should be available. Blood pressure, pulse, temperature, respiratory rate and hydration should be recorded regularly, at intervals agreed by a multidisciplinary team, until the service user becomes active again. **[D]**

1.8.4.34 In the following circumstances, more frequent and intensive monitoring by appropriately trained staff is required and should be recorded in the care plan. Particular attention should be paid to the service user's respiratory effort, airway, and level of consciousness:

- if the service user appears to be or is asleep/sedated
- if intravenous administration has taken place
- if the BNF limit or SPC is exceeded
- in high-risk situations
- where the service user has been using illicit substances or alcohol
- where the service user has a relevant medical disorder or concurrently prescribed medication. **[D]**

1.8.4.35 If verbal responsiveness is lost as a consequence of administration of medication, a level of care identical to that needed for general anaesthesia should be given. **[D]**

Chart for rapid tranquillisation

Medication	Time to max plasma concentration	Approx plasma half-life	Licensed indications as at August 2004 (see current summary of product characteristics [SPC])	Notes
Haloperidol injection (SPC)	15–60 min (SPC and http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	10–36h (SPC and http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	Schizophrenia: treatment of symptoms and prevention of relapse. Other psychoses; especially paranoid. Mania and hypomania. Mental or behavioural problems, such as aggression, hyperactivity and self-mutilation in the mentally retarded and in patients with organic brain damage. As an adjunct to short-term management of moderate to severe psychomotor agitation, excitement, violent or dangerously impulsive behaviour. Nausea and vomiting.	
Haloperidol oral solution (SPC)	2–6h http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	10–36h http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	Schizophrenia and other psychoses. Short-term adjunctive management of psychomotor agitation, excitement, violent or dangerously impulsive behaviour, mental or behavioural disorders, especially when associated with hyperactivity and aggression. Short-term adjunctive management of severe anxiety, restlessness and agitation in the elderly, intractable hiccup, nausea and vomiting, Gilles de la Tourette syndrome and severe tics.	
Haloperidol tablets (SPC)	2–6 h (http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	1–36h (http://www.intox.org/databank/documents/pharm/haloperi/ukpid24.htm)	Schizophrenia and other psychoses. Short-term adjunctive management of psychomotor agitation, excitement, violent or dangerously impulsive behaviour, mental or behavioural disorders, especially when associated with hyperactivity and aggression. Short-term adjunctive management of severe anxiety, restlessness and agitation in the elderly, intractable hiccup, nausea and vomiting, Gilles de la Tourette syndrome and severe tics.	
Lorazepam injection (SPC)	60–90 min	12–16h	Pre-operative medication or premedication for uncomfortable or prolonged investigations. The treatment of acute anxiety states, acute excitement or acute mania. The control of status epilepticus.	
Lorazepam tablets (SPC)	2h	12h	Short-term treatment of moderate and severe anxiety. Short-term treatment of anxiety in psychosomatic, organic and psychotic illness. Short-term treatment of insomnia associated with anxiety. Pre-medication before operative dentistry and general surgery.	
Olanzapine dispersable tablets (SPC)	5–8h	32–50h	Treatment of schizophrenia. Maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.	Not approved for the treatment of dementia-related psychosis and/or behavioural disturbances.

Chart for rapid tranquillisation (continued)

Medication	Time to max plasma concentration	Approx plasma half-life	Licensed indications as at August 2004 (see current summary of product characteristics [SPC])	Notes
Olanzapine injection (SPC)	15–45 min	32–50h	Indicated for the rapid control of agitation and disturbed behaviours in patients with schizophrenia or manic episode, when oral therapy is not appropriate. Treatment with olanzapine powder for solution for injection should be discontinued, and the use of oral olanzapine should be initiated, as soon as clinically appropriate.	The manufacturer has issued a warning that use outside of the details contained within the SPC may increase the risk of fatality. i/m olanzapine may produce a five-fold increase in plasma concentration vs. the same dose given by the oral route. Not approved for the treatment of dementia-related psychosis and/or behavioural disturbances.
Olanzapine tablets (SPC)	5–8h	32–50h	Treatment of schizophrenia. Maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder.	Not approved for the treatment of dementia-related psychosis and/or behavioural disturbances.
Risperidone dispersable tablets (SPC)	1–2h	24h	The treatment of acute and chronic schizophrenic psychoses, and other psychotic conditions, in which positive or negative symptoms are prominent. Maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Treatment of mania in bipolar disorder.	Not licensed for the treatment of behavioural symptoms of dementia.
Risperidone liquid (SPC)	1–2h	24h	The treatment of acute and chronic schizophrenic psychoses, and other psychotic conditions, in which positive or negative symptoms are prominent. Maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Treatment of mania in bipolar disorder.	Not licensed for the treatment of behavioural symptoms of dementia.
Risperidone tablets (SPC)	1–2h	24h	The treatment of acute and chronic schizophrenic psychoses, and other psychotic conditions, in which positive or negative symptoms are prominent. Maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Treatment of mania in bipolar disorder.	Not licensed for the treatment of behavioural symptoms of dementia.

1.9 Incident reporting and post incident reviews, following rapid tranquillisation, physical intervention and seclusion

See also recommendation 1.3.3.1 (Training).

1.9.1 Incident reporting

1.9.1.1. Any incident requiring rapid tranquillisation, physical intervention or seclusion should be recorded contemporaneously, using a local template. **[D]**

1.9.1.2 Incidents of physical assault should be reported to the NHS Security Management Service (SMS) as per Secretary of State directives November 2003 (www.cfsms.nhs.uk/files/VAS%20directions%20250204.pdf). **[D]**

1.9.2 Post-incident reviews

1.9.2.1 A post incident review should take place as soon after the incident as possible, but in any event within 72 hours of the incident ending. **[D(GPP)]**

1.9.2.2 Mental health service providers should have systems in place with appropriately skilled staff to ensure that a range of options of post incident support and review mechanisms are available and take place within a culture of learning lessons. The following groups should be considered:

- staff involved in the incident
- service users
- carers and family where appropriate
- other service users who witnessed the incident
- visitors who witnessed the incident
- independent advocates
- local security management specialist (SMS). **[D(GPP)]**

1.9.2.3 The aim of a post incident review should be to seek to learn lessons, support staff and service users, and encourage the therapeutic relationship between staff, service users and their carers. **[D(GPP)]**

1.9.2.4 The post incident review should address what happened during the incident, any trigger factors, each person's role in the incident, how they felt during the incident, how they feel at the time of the review, how they may feel in the near future, and what can be done to address their concerns. If possible, a person not directly involved in the incident should lead the review. **[D(GPP)]**

1.9.2.5 Appropriate support, including ongoing individual post incident review sessions, should be available as required. **[D(GPP)]**

1.9.2.6 One-off post incident review sessions have been shown to be unhelpful and should not be undertaken. **[B]**

1.9.2.7 Consequential sick leave and the return to work should be monitored and positively and carefully managed to ensure that staff are supported. **[D(GPP)]**

1.9.2.8 Consequential sick leave should be audited to identify trends within the organisation to inform future strategy and training in relation to the management of disturbed/violent behaviour. **[D(GPP)]**

1.10 Emergency departments

Service users will often attend and be admitted to psychiatric in-patient services through emergency departments. The following section applies specifically to emergency department staff when caring for service users requiring mental health assessments. Recommendations in sections 1.2, 1.3, 1.4, 1.5, 1.6, 1.8 (except 1.8.3) and 1.9 also apply.

1.10.1 Training

*See evidence statement on page 83, para 7.8.7.3 IIb.

1.10.1.1 In addition to ongoing competency training in the management of disturbed/violent behaviour, appropriate staff groups in emergency departments should receive training in the recognition of acute mental illness and awareness of organic differential diagnoses. Service user involvement should be encouraged. **[D]**

1.10.2 Risk

*See evidence statement page 83, para 7.8.7.3 I.ii.b.

1.10.2.1 Emergency units should have a system in place to alert staff to patients known by the unit to pose a risk of disturbed/violent behaviour, so that steps can be taken to minimise risks to staff and other patients. The system should be reviewed at reasonable intervals to avoid stigmatisation. **[D(GPP)]**

1.10.3 Mental health assessments

1.10.3.1 On making an initial assessment, if staff working in emergency departments decide a mental health assessment is required, they should seek specialist advice from the relevant mental health professional. **[D]**

1.10.4 Environment

*See evidence statements on page 82, para 7.8.7.3 Ii.

1.10.4.1 Every emergency department should have at least one designated interview room for mental health assessments. Larger emergency departments (more than 75,000 attendances a year) may require additional rooms. The room(s) should be close to or part of the main emergency department receiving area. **[D]**

1.10.4.2. The designated interview room(s) should be made available on a priority basis for mental health

assessments. It should be of a sufficient size to comfortably accommodate six seated persons, be fitted with an emergency call system, an outward opening door, and a window for observation, have reasonable ventilation, contain soft furnishings and be clear of potential weapons. **[D]**

1.10.4.3 Staff interviewing a patient in the designated interview room should always inform a senior member of the emergency nursing staff before commencing the interview. **[D(GPP)]**

1.10.4.4 Ordinarily a chaperone should be present, and interviews without chaperones should only proceed after discussion with relevant staff. When a staff member is alone, five-minute checks via the interview room window should occur whilst the interview is taking place. **[D(GPP)]**

1.10.5 Personnel

1.10.5.1 Every emergency department should have access to an identified consultant psychiatrist for liaison with providers of local mental health services. **[D(GPP)]**

1.10.5.2 Appropriate psychiatric assessment should be available within one hour of alert from the emergency department, at all times. **[D]**

1.10.5.3 In addition to a mental health liaison team, there should be at least one registered mental nurse working with every emergency department. Larger emergency departments (more than 75,000 attendances a year) may require more. **[D(GPP)]**

1.10.5.4 Emergency departments should be encouraged to employ registered mental nurses. **[D(GPP)]**

1.10.6 Rapid tranquillisation

*See evidence statement on page 85, para 7.8.7.3. V.i.b.

1.10.6.1 The decision to use rapid tranquillisation in an emergency setting should be taken by a senior medical member of staff, where at all possible. **[D(GPP)]**

1.10.6.2 Mental health staff should be contacted at the first available opportunity, after the administration of rapid tranquillisation. **[D(GPP)]**

1.10.6.3 If rapid tranquillisation is considered necessary, prior to formal diagnosis and where there is any uncertainty about previous medical history (including history of cardiovascular disease, uncertainty regarding current medication, or possibility of current illicit drug/alcohol intoxication), lorazepam should be considered as the first-line drug of choice. Where there is a confirmed history of previous significant antipsychotic exposure, and response, haloperidol in combination with lorazepam is sometimes used. **[D(GPP)]**

1.10.7 Communication provision

1.10.7.1 For patients whose preferred language is not English, interpreting services should be provided. Provision should also be made for patients who have communication difficulties who may need additional support, for example, visual aids, simplified language, or an interpreter who can sign. **[D(GPP)]**

9 Audit criteria

NICE produce audit criteria in their guidelines based on the key priorities for implementation, where these can be easily translated into audit criteria. The audit criteria detailed below related to those key priorities that can be easily audited.

In addition to producing these audit criteria, the NCC-NSC has liaised closely with the audit team at the Royal College of Psychiatrists, which have been devising audit tools and conducting an audit on the short-term management of disturbed/violent behaviour in psychiatric in-patient settings on behalf of the Healthcare Commission. These audit tools cover the main areas discussed in this guideline. These audit tools can be used on at a local level and copies can be freely downloaded from the Royal College of Psychiatrist website at the following URL: http://www.rcpsych.ac.uk/cru/qual.htm

Possible objectives for an audit

- To ensure that the environment is safe and helps prevent disturbed/violent behaviour.

People who could be included in an audit and time period for selection

- Staff who work or have close associations with the ward/unit being audited.
- People who do not have direct links with the ward/unit, for example service user representatives; community health council members in Wales and patient forums in England; staff from other areas involved in the care pathway.

Criterion	Exception	Definition of terms
1. . There is an effective risk assessment and risk management plan to manage risk of disturbed/violent behaviour in the case notes of each service user at high risk. Refer to key priority 1 (recommendation 1.2.1.1)	Nil	
2. Services have a policy for training employees and staff-in-training in the short-term management of disturbed/violent behaviour. Refer to key priorities 2 to 5 (recommendations 1.3.1.1, 1.3.2.2, 1.3.2.4, 1.3.2.5)	Nil	The policy will specify • who will receive what level of training (based on risk assessment) • how often they will be trained • an outline of the techniques in which they will be trained (for example, training in de-escalation techniques) • that staff involved in rapid tranquillisation should receive ongoing competency training to a minimum of immediate life support (ILS) • that staff involved in physical intervention or seclusion should be trained to a minimum of basic life support (BLS).
3. On each admission, it has been recorded that a service user has access to information in a suitable format concerning: • which staff member has been assigned to them and how and when they can be contacted • why they have been admitted (and if detained, the reason, the powers used and their extent, and rights of appeal) • their rights regarding consent to treatments, complaints procedures and access to independent help and advocacy • what may happen to them if they become disturbed/violent. Refers to key priority 6 (recommendation 1.4.1.2)	Nil	A suitable format includes offering the information to the service user in: • their preferred language • in a format which is accessible if they have communication difficulties.
4. The service user's care plan contains an up-to-date advance directive detailing the service users preferred strategies in the event of a disturbed/violent incident. Refers to key priority 7 (recommendation 1.4.1.5)	a) The service user who is not able to give an advance directive and who does not have an advocate or carer. b) The service user who has turned down the opportunity to record an advance directive. c) The service user who is not at any risk of becoming disturbed/violent.	The term 'preferred strategies' refers to the service user's choice of rapid tranquillisation, physical intervention and/or seclusion that may be used without a service user's consent.
5. The record of an incident involving rapid tranquillisation, seclusion and/or physical intervention adequately justifies the use of these interventions and the procedures taken during these interventions and any adverse outcomes. Refers to key priorities 8 and 9 recommendations 1.8.1.1, 1.8.2.3)	Nil	

10 Recommendations for research

The following research recommendations have been identified for this NICE guideline, not as the most important research recommendations, but as those that are most representative of the full range of recommendations. All of the recommendations for research should consider the importance of including study-level variables relating to gender, ethnicity and those with special concerns. These research recommendations have been drawn up by GDG consensus. Further clarification has been added by the NICE technical advisor.

Prospective cohort studies are required to identify antecedents of disturbed/violent behaviour in adult psychiatric in-patient settings.

Before and after studies, surveys, cross-sectional studies and cohort studies should be undertaken to establish the following, in relation to the deliberate application of pain in physical interventions used for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings, and in accident and emergency settings:

- effectiveness
- ethical and legal and safety aspects
- role within range of physical interventions taught to staff
- staff and service user perceptions.

Before and after studies, surveys, cross-sectional studies and cohort studies should be undertaken to investigate the following aspects of mechanical restraints for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings, and in accident and emergency settings:

- effectiveness
- ethical and legal and safety aspects
- role within range of physical interventions taught to staff
- staff and service user perceptions.

Qualitative and survey research is needed to examine service users' – including black and minority ethnic groups' – views on the antecedents and risk factors of disturbed/violent behaviour, and the use of observation, de-escalation techniques, physical interventions and seclusion for the short-term management of disturbed/violent behaviour in adult psychiatric in-patient settings and in accident and emergency settings.

Clinical trials and longitudinal cohort studies should be conducted in large, well-designed randomised controlled studies with adult psychiatric in-patients (including black and minority ethnic groups) that compare the utility, acceptability, safety and desirable endpoints of available medicines and their dosages for rapid tranquillisation and PRN regimes (including atypical and antipsychotics), and assess the long-term side effects.

Controlled before and after studies are needed to evaluate the major training programmes identified by the National Institute for Mental Health in England (NIMHE) and the Counter Fraud and Security Management Service (SMS). These studies must assess the short-term and long-term effectiveness of the training programme in psychiatric in-patient settings and assess the safety of the techniques used in these training packages for both staff and service users.

Prospective cohort studies are needed to develop valid and reliable prediction tools for use in psychiatric in-patient settings appropriate for use in the UK that:

- may predict the imminent onset of disturbed/violent behaviour
- confirm the predictive validity of key risk factors and assist clinical judgement in risk prediction.

Controlled before and after studies that examine whether observation and/or de-escalation techniques minimise the need for seclusion, restraint or rapid tranquillisation are needed.

National audit data collections are required on the incidence of sudden death among psychiatric service users (including ethnicity, age, and gender) receiving rapid tranquillisation and on death/morbidity associated with restraint and seclusion.

Prospective cohort studies, before and after studies and qualitive research is needed to develop restraint techniques, which allow communication between deaf service user and deaf and visually impaired service users and staff, as well as other physically impaired service users, while also ensuring staff and service user safety.

11 Dissemination of the guidelines

- The guideline will be produced in a full and summary format and a version for the public (Information for the public).
- Full copies of the guideline will be available through the NICE website (http://www.nice.org.uk) in PDF format and summary through the National Electronic Library for Health (NeLH (http://www.nelh.nhs.uk/) and National Guideline Clearinghouse (http://www.guidelines.gov).

12 Validation

The guideline was validated through two stakeholder consultation processes. The first and second drafts were submitted to NICE in April and June 2004. NICE obtained and collated stakeholders' comments, which were considered by the GDG.

13 Scheduled review of the guideline

The process of reviewing the evidence is expected to begin four years after the date of issue of this guideline. Reviewing may begin earlier than four years, if significant evidence that affects the guideline recommendations is identified sooner. The updated guideline will be available within two years of the start of the review process.

14 Guidelines and reports consulted

For full reference details on each of these publications, please see the next section.

A safer place to work: protecting NHS hospital and ambulance staff from violence and aggression.

Assessment and clinical management of risk of harm to other people. Royal College of Psychiatrists Special Working Party on Clinical Assessment and Management of Risk.

Breaking the circles of fear – a review of the relationship between mental health services and African and Caribbean communities. A report from the Sainsbury Mental Health Centre.

C&R techniques and deaf people: a *discussion paper.*

Clear expectations, consistent limits. The Centre for Residential Child Care.

Clinical risk management: a clinical tool and practitioners manual. The Sainsbury Centre for Mental Health.

Commission for Racial Equality-Annual Report 2002.

Consensus statement of the use of high dose antipsychotic medication. Royal College of Psychiatrists.

Cross-cultural psychiatry: a practical guide. D Bhugra and K Bhui.

Dealing with violence against nursing staff: an RCN guide for nurses and managers.

Ethnicity and mental health service provision. Academic Unit, Northern Birmingham Mental Health Trust.

Guidance on restrictive physical interventions for people with learning disability and autistic spectrum disorder, in health, education and social care settings. Department of Health.

Guidelines for prevention of workplace violence for health care and social service workers. AM Herman and CN Jeffress.

Guidelines for reducing violence in mental health services. Ministry of Health, New Zealand.

Guidelines for the provision of advice and training in the prevention and management of conflict, aggression and violence – codes of practice. Institute of Conflict Management.

Inside outside – improving mental health services for black and minority ethnic communities in England. Department of Health.

'*Letting through the light' (Odiri) – a training pack on black people and mental health* (1998). Race Equality Unit.

Mainstreaming gender and women's mental health implementation guide.

Management of Imminent Violence: Clinical practice guidelines to support mental health services. Royal College of Psychiatrists.

Mental Health Act 1983 and Department of Health Code of Practice to the Mental Health Act 1983 (3rd edn.).

Mental health nursing: addressing acute concerns. Report by the Standing Nursing and Midwifery Advisory Committee.

Mental health policy and implementation guide: national minimum standards for general adult services in psychiatric intensive care units (PICU) and low secure environments. Department of Health.

Mental health policy implementation guide: adult acute in-patient care provision. Department of Health.

Mental health policy implementation guide: adult acute in-patient care provision. Department of Health.

Modern standards and modern services: mental health, National Service Framework.

National visit 2: improving care for detained patients from black and minority ethnic communities preliminary report. The Sainsbury Centre for Mental Health.

Not just bricks and mortar: report of the Royal College of Psychiatrists working party on the size, staffing, structure, siting and security of new acute adult psychiatric in-patient Units. Royal College of Psychiatrists.

Nursing in secure environments United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting.

Physical interventions – a policy framework. British Institute of Learning Disabilities.

Physical restraint – practice, legal, medical and technical, considerations. Practice Paper No.2. The Centre for Residential Childcare.

Position statement on the use of seclusion and restraint. American Psychiatric Nurses Association.

Practice guidance: safe and supportive observation of patients at risk: m*ental health nursing: addressing acute concerns.* Standing Nursing and Midwifery Advisory Committee.

Procedural guidelines for physical restraint and seclusion mental health policy. Mental Health Section, Ministry of Health, New Zealand.

Psychiatric services to accident and emergency department: r*eport of a joint working party of the Royal College of Psychiatrists and the British Medical Association for Accident and Emergency Medicine.*

Psychiatric services to accident and emergency departments. Royal College of Psychiatrists.

Racism and mental health – prejudice and suffering. Editor K Bhui.

Raised voices – African-Caribbean and African users' views and experiences of mental health services in England and Wales. MIND Publication.

Rapid tranquillisation: a questionnaire survey of practice. *Psychiatric Bulletin*.

Recommendations on the use of restraints and isolation – clinical practice guidelines. Collége des Médecins du Québec.

Report of the review of security at high security hospitals. Department of Health.

Review paper for the national task force: violence against social care staff. National Institute for Social Work Research Unit.

Safer working in the community: a guide for NHS managers and staff on reducing the risks for violence and aggression. Royal College of Nursing.

Safety for trainees in psychiatry: report of the collegiate trainees' committee working party on the safety of trainees. Royal College of Psychiatrists.

Safety, privacy and dignity in mental health units: guidance on mixed sex accommodation for mental health services. Department of Health.

Schizophrenia: core interventions in the treatment and management of schizophrenia in primary and secondary care, clinical guideline. National Collaborating Centre for Mental Health.

Seclusion and restraint practice standards: a review and analysis. National Mental Health Association.

Seclusion, control and restraint. Royal College of Nursing.

Secure futures for women: making a difference, women's mental health strategy. Department of Health.

Sexual abuse and harassment in psychiatric settings. Royal College of Psychiatrists.

Social division and difference: black and ethnic minorities. NHS National Programme on Forensic Mental Health Research and Development.

Standards of places of safety under Section 136 of the Mental Health Act (1983). Royal College of Psychiatrists.

Strategies for the management of disturbed and violent patients in psychiatric units. Royal College of Psychiatrists.

The association between antipsychotic drugs and sudden death: r*eport of the working group of the Royal College of Psychiatrists' Psychopharmacology Sub-Group.* Royal College of Psychiatrists.

The prevention and management of aggression: a good practice statement. Clinical Resource and Audit Group, Working Group on Mental Illness, The Scottish Office.

The recognition, prevention and therapeutic management of violence in acute in-patient psychiatry: *A literature review and evidence-based recommendations for good practice.* Prepared for the United Kingdom Central Council for Nursing, Midwifery and Health Visiting.

The recognition, prevention and therapeutic management of violence in mental health care. United Kingdom Central Council for Nursing, Midwifery and Mental Health Visiting.

Violence and aggression to staff in health services: guidance on assessment and management. Health and Safety Commission.

Women and secure psychiatric services: *A literature review.*

Women in context: good practice in mental health services for women. Good Practices in Mental Health.

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CLINICAL PRACTICE GUIDELINES

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Ownership:	**Dr Tony Stevens, Medical Director**			
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1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

The use of psychotropic medication in acute psychiatric emergencies is with the aim of controlling agitation, aggression or excitement. As there are no drugs that produce an immediate antipsychotic effect, the principal aim is immediate sedation and tranquillisation – hence, this is often known as 'rapid tranquillisation'. Antipsychotic (neuroleptic) drugs can be used for this purpose and may then be continued for their antipsychotic effect, which may take two or three weeks to develop.

The use of antipsychotics in acute psychiatric emergencies has been linked to sudden death, the cause of which is not entirely clear. During violent struggles an injection may be inadvertently injected intravascularly or the normally clinically insignificant prolongation of QTc interval associated with some antipsychotics might be potentiated by the arrhythmogenic effect of catecholamines released during violent struggles. Monitor closely when IM antipsychotics have to been used in patients prescribed other medicines that might prolong QTc interval.

1.2 Purpose

To ensure a consistent approach to Rapid Tranquillisation for the management of disturbed and violent behaviour in order to minimise risk..

2.0 DEFINITIONS/SCOPE OF THE POLICY

This Guideline document describes the recommended pharmacological management options that may be used to manage disturbed and violent behaviour in adolescents and adult patients cared for in the Belfast Health And Social Care Trust. The physical observations and monitoring required after the use injectable medication are described.

It is expected that this Guideline will be used Primarily in Mental Health settings but it may be applicable for the acute management of known or apparently disturbed mental states in other settings. In these situations, clinicians may wish to seek further advice on management from a psychiatrist.

However, it is important to recognise that this is NOT applicable for the primary management of acute alcohol withdrawal.

2.0 ROLES/RESPONSIBILITIES

All staff involved in the Rapid Tranquillisation of patients with disturbed and violent behaviour should follow this guideline.

Clinicians should use their own clinical judgement in each case and if they decide that a different management approach is clinically indicated then the reasons for this should be clearly documented.

4.0 KEY POLICY PRINCIPLES

Key Policy Statement

4.1 Policy Principles

4.1.1 Rapid Tranquillisation should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques and should only be considered when de-escalation approaches have failed.

4.1.2 Patients should only be treated with the medicines described in this guideline only after it is established that the risk of not doing so is greater than the risk of rapid tranquillisation.

4.1.3 This guideline applies to the management of acutely disturbed behaviour and not to the management of delirium.

4.1.4 Staff should be trained, to a level appropriate to their role, in how to assess and manage potential and actual violence using de-escalation techniques, restraint and the pharmacological treatment. Staff should also be trained to use Intermediate Life Support when appropriate.

4.1.5 If the patient has expressed a preference for a particular antipsychotic in an Advance Decision consider prescribing this, if appropriate to the clinical circumstances.

4.1.6 Before an intramuscular medication is administered, the patient must be given the opportunity to take oral medication if it is thought this would be effective and appropriate in the clinical circumstances.

4.1.7 In all cases the likely minimum effective dose of medication should be used.

4.1.8 Staff involved in rapid tranquillisation should be aware of the licensed indications and maximum doses of medicines (see BNF or Summary of Product Characteristics, SPC) and should endeavour to keep within these limits. In some cases current BNF and SPC dose may be knowingly exceeded (e.g. lorazepam >4mg/day), bearing in mind the overall risks. This decision should not be taken lightly or the risks underestimated. Record a risk-benefit decision and rationale in the case notes. Junior doctors must consult a more senior colleague in these cases.

4.1.9 All staff need to be aware of the legal framework that authorises the use of these interventions

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This Guideline is applicable in all Mental Health inpatient units within the Belfast Trust. All medical and nursing staff working in mental health inpatient units should be aware of this Guideline. Further Consultation is required before this Guideline is fully implemented outside mental health units

5.2 Resources

A training needs analysis is included in Appendix F. It is the responsibility of the Associate Medical Director and the Director of Nursing for Mental Health services to ensure training is in place

Training on Rapid Tranquillisation forms part of the Induction Training for Medical Staff on rotational training placements.
Training on Rapid Tranquillisation is part of the MAPA 5 day training for Staff working in Mental Health Inpatient units

5.3 Exceptions

Further Consultation is required before this Guideline is fully implemented outside Mental Health units

6.0 MONITORING

Compliance with this Guideline will be monitored by reviewing either

- Case notes of patients who undergo rapid tranquillisation
- Incident forms completed after rapid tranquillisation
- Physical Intervention monitoring forms completed after episodes of restraint

7.0 EVIDENCE BASE / REFERENCES

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SPc Olanzapine tablets and Injection, Electronic Medicines Compendium, www.medicines.org.uk accessed 30/10/2010

SPc Risperidone tablets, Electronic Medicines Compendium, www.medicines.org.uk accessed 30/10/2010

SPc Lorazepam Tablets and Injection Electronic Medicines Compendium, www.medicines.org.uk accessed 30/10/2010

8.0 CONSULTATION PROCESS

Draft Guideline circulated for consultation to all Consultant psychiatrists in Adult Mental Health, Psychiatry of Old Age, Child and Adolescent Services and Learning Disability Services.

9.0 APPENDICES / ATTACHMENTS

Appendix A, Medication in Acute Psychiatric Emergencies

Appendix B, Flow chart for Pharmacological management of violent and aggressive behaviour (FOR ADULTS OVER 18 YEARS)

Appendix C, Flow Chart for Pharmacological management of violent and aggressive behaviour (FOR ADOLESCENTS from 13 to 17 years inclusive)

Appendix D, Post Rapid Tranquillisation Monitoring Guidelines

Appendix E, Dose Information for medicines used in Rapid Tranquillisation

Appendix F, Rapid Tranquillisation Training Needs Analysis

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact. ☐

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Stephen Guy

_____ **Date: _____July 2012_____**

Name
Title

_____ **Date: _____July 2012_____**

Name
Title

Appendix A

Medication in Acute Psychiatric Emergencies

1.0 General Prescribing Principles

The aim of rapid tranquillisation is to achieve a state of calm sufficient to minimise the risk posed to the patient and others. Patients should be able to respond throughout. With this is mind, it is important to individualise the dose and type of medication for each service user. This will depend on several factors including previous response to medication, age, physical problems (renal, hepatic, cardiovascular or neurological disease) other prescribed medication and possible use of drugs of abuse.

- Check that the patient has not had previous allergy or severe idiosyncratic reaction to the drugs to be used.
- Check there is no recent history of Neuroleptic Malignant Syndrome or hyperthermia.
- Simultaneous administration of IM antipsychotics and IM benzodiazepines (lorazepam) may be associated with excessive sedation and cardio respiratory depression. If this combination is deemed necessary then patients must be monitored for excessive sedation and for postural hypotension.
- Patients taking clozapine and olanzapine require care when giving benzodiazepines as potentially fatal orthostatic and cardio-respiratory dysregulation have been reported. If this combination is considered necessary it is essential to undertake frequent monitoring of the patient.
- If the patient has expressed a preference for a particular antipsychotic in an Advance Decision consider prescribing this if warranted by clinical circumstances.
- Avoid unnecessary polypharmacy. This may necessitate careful choice of drug in relation to either current treatment or expected maintenance treatment.
- Carefully consider the number of active PRN prescriptions operative at any one time in relation to the risk of inadvertent overdose.
- Prescribe oral and IM doses separately – do not use PO/IM abbreviation.
- Don't mix medications in the same syringe.
- Patients entering LEVEL 2 on the protocol must have details of all medicines administered, rational of use and an assessment of effectiveness recorded in the clinical notes. All current PRN prescriptions on the kardex should be discontinued and reviewed in 6-12 hours after which they may be re-prescribed if necessary.

1.1 Maximum Doses

Staff involved in rapid tranquillisation should be aware of the licensed indications and maximum doses of medicines (see BNF or Summary of Product Characteristics, SPC) and should endeavour to keep within these limits. In some cases current BNF and SPC dose may be knowingly exceeded (e.g. lorazepam >4mg/day), bearing in mind the overall risks. This decision should not be taken lightly or the risks underestimated. Record a risk-benefit decision and rationale in the case notes. Junior doctors must consult a more senior colleague in these cases. If BNF doses are exceeded, it is particularly important to undertake frequent and intensive monitoring of a calmed patient. Pay particular attention to regular check of airway and intensive monitoring of level of consciousness, pulse, blood pressure, respiratory effort, temperature and hydration. (Appendix D).

Cardiovascular Safety

Antipsychotics as a group are probably associated with an increased risk of QTc prolongation. Normal limits of QTc are less than 440 ms in men and less than 470 ms in women. The risk of arrhythmia increases exponentially beyond normal limits, with strong evidence that QTc greater than 500 ms is clearly linked to an increased risk of arrhythmia. The risk is dose related and the risk for individual drugs is probably additive when they are used in combination.

The table below summarises the risk for common antipsychotics

Low Effect	Moderate Effect	High Effect
Aripiprazole Amisulpride Clozapine Flupentixol Fluphenazine Olanzapine Risperidone Sulpiride	Chlorpromazine Quetiapine	Haloperidol Pimozide Sertindole

The SPC for haloperidol recommends a baseline ECG before commencing treatment with haloperidol and the NICE guideline for Schizophrenia (CG82) recommends an ECG before starting an antipsychotic if a patient is admitted as an inpatient.

A number of medications are associated with prolonged QTc including erythromycin, quinine, amiodarone, ciclosporin, diphendyramine and tamoxifen. Diuretics can cause electrolyte disturbance which is also a risk factor. Consult the BNF for further examples of drugs that prolong QTc.

1.3 Drug Selection

See Appendix E for a summary of recommended drugs, their onset of action and doses for different age groups.

A benzodiazepine may be the safest and best tolerated drug with which to effect 'rapid tranquillisation' of the patient. Once the patient has been calmed, either by de-escalation techniques or by a benzodiazepine, an antipsychotic drug may be best for maintenance of the situation. Remember that repeated use of a benzodiazepine may result in tolerance to the effect and this will probably become evident by 7 to 10 days.

There is limited clinical experience of aripiprazole IM within the Trust. It is included in this policy as a 3rd line option to provide an alternative whenever haloperidol or olanzapine are contraindicated or have failed to produce and adequate response. Aripiprazole is not recommend as an option in Adolescents aged between 13 and 18 years

1.4 For Adults Over 18 years

The flow chart in Appendix B outlines a stepped approach to rapid tranquillisation for Adults over 18 years of age.

If you are unsure about initial pharmacological management then always call a more senior doctor. If you are a junior doctor and your initial drug treatment does not work then you should consider discussion with someone more senior. If you are a Consultant and have tried two or three approaches without success then it may be wise to seek a second opinion from a colleague. If the incident is outside a mental health unit, clinicians may wish to consult a psychiatrist for further advice.

1.5 For Adolescents aged between 13 and less than 18 years

The flow chart in Appendix C outlines a stepped approach to rapid tranquillisation for Adolescents between 13 and less than 18 years of age.

If you are unsure about initial pharmacological management then always call a more senior doctor. If you are a junior doctor and your initial drug treatment does not work then you should consider discussion with someone more senior. If you are a Consultant and have tried two or three approaches without success then it may be wise to seek a second opinion from a colleague. If the incident is outside an adolescent mental health setting, clinicians may wish to consult a child and adolescent psychiatrist for further advice.

1.6 For Older People (65+) (see appendix E)

This guideline applies to the management of acutely disturbed behaviour and not to the management of delirium.

There is evidence that antipsychotics are associated with increased mortality (probably by increasing the risk of cerebrovascular adverse events) even in people without dementia. A cautious approach is recommended.

- Oral medication should always be offered whenever possible.
- Lorazepam, starting at a low dose, is the preferred first line treatment.
- If there is confirmed history of previous antipsychotic use then oral haloperidol or olanzapine may be considered.
- If a patient requires IM medication, lorazepam should be used first line.
- IM haloperidol or IM olanzapine may be used if there is confirmed history of previous antipsychotic use.
- If previous use of antipsychotics can't be confirmed and lorazepam fails to control the situation, low dose olanzapine may be considered. In such cases it may be appropriate to consult a doctor experienced in the management of older people.

1.7 For people with dementia. (see appendix E)

Non-pharmacological options should be considered as first line management. If this is ineffective, then lorazepam may be considered. Risperidone is licensed for short-term use for persistent aggression in people with moderate to severe Alzheimer's dementia. The starting dose is 0.25mg twice daily increased to 0.5mg twice daily. If ongoing use of risperidone is considered necessary then the advice of a doctor experienced in the management of dementia should be sought.

In very exceptional circumstances, when oral treatment is impossible, low dose haloperidol IM may be used. In these cases, consider consulting a doctor with experience in managing disturbed behaviour in people with dementia.

1.8 Monitoring after Use of Intramuscular medication

Appendix D outlines the monitoring required after the use of intramuscular medication.
If patients refuse monitoring of vital signs or of they remain too behaviourally disturbed to be approached, this must be documented in the patients notes at each time monitoring would have been due. The patient should be observed for sign/symptoms of pyrexia, hypotension, over sedation and general physical well-being and documented accordingly

1.9 Drugs NOT recommended for rapid tranquillisation

The following drugs are NOT recommended for rapid tranquillisation:

- Oral and IM chlorpromazine – IM chlorpromazine is painful and can cause severe hypotension. Chlorpromazine must never be given intravenously.
- IM diazepam – absorption is erratic.
- IM depot antipsychotics.
- Olanzapine in dementia related disturbance.
- Zuclopenthixol acetate is not recommend for routine use in rapid tranquillisation due to its slow onset of action. It may however be recommended by a senior doctor or consultant when:
    - The patient is disturbed/violent over an extended time period
    - Past history of good/timely response
    - Past history of repeated parenteral administration required
    - Cited in an advance decision

1.10 Actions after Rapid Tranquillisation

A doctor should be available to quickly attend an alert by staff members when Rapid Tranquillisation has been implemented, for an appropriate period of time to ensure the treatment has been effective and that undue adverse effects are no longer likely to occur.

A report of use of Rapid Tranquillisation should be made on a Trust Incident Form. A post-incident review may be held within 72 hours.

Appendix B

Pharmacological management of violent and aggressive behaviour (FOR ADULTS OVER 18 YEARS)

See Appendix D for management of older people and people with dementia

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques.
If de-escalation techniques are unsuccessful or inappropriate, consider pharmacological management.

LEVEL 1
Disturbed but accepting oral medication

- Ongoing verbal de-escalation.
- Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response.

Appropriate oral medicines and doses are listed below. Consider combination of lorazepam with an antipsychotic if indicated by clinical circumstances.
DO NOT USE OLANZAPINE IN DEMENTIA.

Lorazepam 1 – 2mg **(Max 4mg/24hrs)**

Haloperidol 5 – 10mg (Max 30mg /24hrs)

Olanzapine 10mg (Max 20mg/24hrs)

Review the situation after 45 minutes. If response is inadequate consider repeating oral therapy or moving to LEVEL 2.

NOTES

- **Consider oral risperidone in people with** Alzheimer's dementia – see Appendix E
- Oral lorazepam alone may be preferable where there is uncertainty about previous history:
  - Including history of cardio-vascular disease
  - Uncertainty regarding current medication
  - Possibility of current illicit drug/alcohol intoxication
- Oral antipsychotics may be preferable in patient with
  - Current regular benzodiazepine use
  - A history of respiratory depression

If unsuccessful or inappropriate

LEVEL 2
Disturbed but refusing oral medication or risk of harm to self or others

- Review all medication administered within the last 24hrs – be aware of BNF maximum doses.
- Ensure resuscitation equipment and emergency drugs are available within 3 minutes.

Consider:
IM treatment with lorazepam, haloperidol or olanzapine as single agents. Consider aripiprazole if haloperidol or olanzapine are contraindicated or have failed to produce an adequate response
OR
Lorazepam in combination with an antipsychotic

Lorazepam 1-2mg IM (Max 4mg/24hrs)

Olanzapine 5-10mg (Max 20mg/24hrs)

Haloperidol 5-10mg IM (Max 18mg/24hrs)

Aripiprazole 5.25-9.75mg IM (Max 30mg/24hrs)

Review the situation after 45 minutes. If there is continued concern seek advice from a more senior doctor before proceeding further

Don't use IM lorazepam within one hour of IM olanzapine. Use oral lorazepam with caution

NOTES

- For aripiprazole and olanzapine, leave at least 2hrs between injections. Max of three injections in 24hrs
- Dilute lorazepam 1:1 with saline or water for injection prior to administration.
- Flumazenil must be available if IM lorazepam is used.
- If IM haloperidol is used, monitor for emergence of EPSEs, especially dystonia and give procyclidine 5mg orally or IM according to severity of symptoms.

If unsuccessful or inappropriate

LEVEL 3
Situation rapidly deteriorating or failure to respond to LEVEL 2 Interventions

- Review current treatment to date.
- Seek advice from a more senior doctor, or a Consultant before proceeding.

Options to consider at this stage include:

- Repeat IM injections as per LEVEL 2.
- Zuclopenthixol acetate (See Guideline notes)
- Promethazine 50mg IM, useful in benzodiazepine intolerant patients. Onset of action is slow. Allow 1-2 hours to assess response before repeating to maximum of 100mg in 24 hrs.

Appendix C

Pharmacological management of violent and aggressive behaviour (FOR ADOLESCENTS from 13 to 17 years inclusive)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques.
If de-escalation techniques are unsuccessful or inappropriate, consider pharmacological management.

LEVEL 1
Disturbed but accepting oral medication

- Ongoing verbal de-escalation.
- Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response.

Appropriate oral medicines and doses are listed below. Consider combination of lorazepam with an antipsychotic if indicated by clinical circumstances. DO NOT USE OLANZAPINE IN DEMENTIA.

Lorazepam 0.5 - 2mg (Max 4mg/24hrs)

Haloperidol 1 – 5mg (Max 15mg /24hrs)

Olanzapine 10mg (Max 20mg/24hrs)

Review the situation after 45 minutes. If response is inadequate consider repeating oral therapy or moving to LEVEL 2.

NOTES
- Consider oral risperidone in people with Alzheimer's dementia – see Appendix D
- Oral lorazepam alone may be preferable where there is uncertainty about previous history:
  - Including history of cardio-vascular disease
  - Uncertainty regarding current medication
  - Possibility of current illicit drug/alcohol intoxication
- Oral antipsychotics may be preferable in patient with
  - Current regular benzodiazepine use
  - A history of respiratory depression

If unsuccessful or inappropriate

LEVEL 2
Disturbed but refusing oral medication or risk of harm to self or others

- Consult a CAMHS doctor before proceeding.
- Review all medication administered within the last 24hrs – be aware of BNF maximum doses.
- Ensure resuscitation equipment and emergency drugs are available within 3 minutes

Consider:
IM treatment with lorazepam, olanzapine or haloperidol as single agents
OR
Lorazepam in combination with an antipsychotic

Lorazepam 0.5-2mg IM (Max 4mg/24hrs

Haloperidol 2-5mg IM (Max 15mg/24hrs)

Olanzapine 5-10mg (Max 20mg/24hrs)

Review the situation after 45 minutes. If there is continued concern about the patient, seek advice from a more senior colleague before proceeding further.

Don't use IM lorazepam within one hour of IM olanzapine. Use oral lorazepam with caution

NOTES
- The dose of haloperidol will be guided by the patient's weight.
- For olanzapine, leave at least 2hrs between injections. Max of three injections in 24hrs
- Dilute lorazepam 1:1 with saline or water for injection prior to administration.
- Flumazenil must be available if IM lorazepam is used.
- If IM haloperidol is used, monitor for emergence of EPSEs, especially dystonia and give procyclidine 5mg orally or IM according to severity of symptoms.

If unsuccessful or inappropriate

LEVEL 3
Situation rapidly deteriorating or failure to respond to LEVEL 2 Interventions

- Review current treatment to date.
- Consider appropriatness of current placement.
- Seek advice from a more senior doctor, or a Consultant with experience in Child and Adolescent Psychiatry before proceeding.

Options to consider at this stage include
- Repeat IM injections as per LEVEL 2 to maximum daily doses.

Rap
adol

Appendix D

Post Rapid Tranquillisation Monitoring Guidelines

Rapid tranquillisation - Monitoring

After any parenteral drug administration for RT, or where clinically necessary with oral medication, patients require to be monitored as below. (Where the patient's mental state or behaviour makes this impossible this must be documented. Observe for, and record, any signs of over sedation, pyrexia, hypotension or general malaise.)

Use the Trust Standard Observation Chart (SOC) to monitor:

- **Level of consciousness**
- **Temperature**
- **Pulse**
- **Blood pressure**
- **Respiratory Rate**

- **Monitoring should be every 10 minutes for one hour, then half-hourly until the patient is ambulatory.**
- **The Early Warning Score should be calculated from the SOC each time and further action taken if indicated by this.**
- **If necessary, a doctor should be called and transfer to an acute medical facility may sometimes be required.**
- **Remember that protection of the airway is paramount and it is important to maintain good hydration.**
- **If the patient is asleep or unconscious, the use of pulse oximetry to continuously measure oxygen saturation is recommended.**

- Pay particular attention to level of consciousness and blood pressure when IM antipsychotics and IM benzodiazepines are used in combination.
- An ECG is recommended when parenteral antipsychotics are given, especially when higher doses are used. Staff should be sufficiently well trained to interpret ECG traces (including calculation of QT/QTc interval). If an ECG shows any cause for concern then a physician must be asked for advice on patient management.
- **NOTE: An ECG is essential if IM antipsychotics are used in adolescents.**

Management of problems occurring during Rapid Tranquillisation	
Problem	Remedial Measures
Acute Dystonia (including oculogyric crises)	Give **procyclidine 5 - 10mg Orally or IM**
Reduced respiratory rate <10/minute or oxygen saturation <92%	Give oxygen; ensure patient is not lying face down. Give **flumazenil** if benzodiazepine induced. Give flumazenil 200microgram IV over 15 seconds. If desired level of consciousness is not obtained within 60 seconds, a further 100microgram can be injected and repeated at 60 second intervals to a maximum total dose of 1mg (1000microgram) in 24 hours (initial + 8 additional doses). Monitor respiration rate continuously until it returns to baseline level. N.B. Effect of flumazenil may wear-off & respiratory depression return – monitoring must continue beyond initial recovery of respiration. If induced by any other agent the patient will require mechanical ventilation.
Irregular or slow pulse <50 beats/min	**Refer to specialist medical care immediately.**
Fall in blood pressure > 30mmHg drop in systolic BP on standing or diastolic BP <50mmHg	Lie patient flat, raise legs if possible. Monitor closely and seek further medical advice if necessary.
Increased temperature	**Withhold antipsychotics –**risk of NMS or perhaps arrhythmias. Monitor closely, cool the patient, and check muscle creatinine kinase**.** **Refer to specialist medical care** if continued or other signs of NMS present e.g. sweating, hypertension or fluctuating BP, tachycardia, incontinence (retention or obstruction), muscular rigidity (may be confined to head and neck), confusion, agitation or loss of consciousness.

Appendix E
Dose Information for medicines used in Rapid Tranquillisation

Medication	Time to Peak Plasma concentration	Adolescents (13 – 17)	Adults (18 – 65)	Older People (65+)	People with Dementia
Lorazepam tablets and IM injection	50 – 90 minutes (Sedation within 30-45 minutes)	By Mouth OR by IM injection 0.5mg - 2mg Maximum 4mg/24hrs	By Mouth Or by IM injection 1mg - 2mg Maximum 4mg/24 hours	By Mouth Or by IM injection 0.5mg - 1mg Maximum 4mg/24 hours	By Mouth Or by IM injection 0.5mg - 1mg Maximum 4mg/24 hours
Aripiprazole IM injection	1 –3 hours	Not Applicable	By IM injection 9.75mg (1.3ml) – Consider lower dose (5.25mg) on basis of clinical status Effective range 5.25 –15mg Max dose 30mg/24hrs by any route	Effectiveness in over 65's not established. Consider lower doses on basis of clinical status	**Not Recommended**
Risperidone tablets oral solution		Not applicable	Not applicable	Not applicable	By mouth in Alzheimer's dementia 0.25 – 0.5mg twice daily.
Olanzapine tablets and Orodispersible tablets	5 – 8 hours	By mouth in psychosis 5mg – 10mg Maximum 10mg/2hrs	By mouth 10mg Maximum 20mg/24 hours	As a second line option By mouth 5-10mg Maximum 20mg/4hrs	**DO NOT USE OLANZAPINE IN PEOPLE WITH DEMENTIA**
Olanzapine IM injection	15 – 45 minutes (peak levels up to 5 times that of oral dose)	By IM injection 2.5mg – 10mg/2hrs Maximum of 3 injections in 24 hours with at least 2 hours between injections. When used for Rapid tranquillisation, Maximum of 20mg/24 hours by ALL routes must NOT be exceeded	By IM injection 5-10mg Maximum of 3 injections in 24 hours with at least 2 hours between injections When used for Rapid tranquillisation, Maximum of 20mg/24 hours by ALL routes must NOT be exceeded	By IM injection >60 yrs 2.5mg – 5mg Maximum of 3 injections in 24 hours with at least 2 hours between injections When used for Rapid tranquillisation, Maximum of 20mg/24 hours by ALL routes must NOT be exceeded	**DO NOT USE OLANZAPINE IN PEOPLE WITH DEMENTIA**
Haloperidol injection	15 – 60 minutes (Sedation in 30 – 45 minutes)	By IM injection 1mg – 5mg Maximum 10mg/24hrs	By IM injection 5mg – 10mg Maximum 18mg/24 hours	Only use first line if there is confirmed history of previous exposure to typical antipsychotics. Start with lower doses than the 18-65 age group	Use only in very exceptional circumstances. Consider consulting a doctor with experience in dementia. **Do not use in dementia with Lewy Bodies**
Haloperidol Oral solution and tablets	2 – 6 hours (Sedation usually within 30-45 minutes)	By Mouth in psychosis 2mg - 5mg Maximum 15mg/24hrs	By Mouth 5mg - 10mg Maximum 30mg/24 hours	Only use first line if there is confirmed Hx of previous exposure to typical antipsychotics. Start with lower doses than the 18-65 age group	**Consider oral risperidone as an alternative**

NOTES:

- Remember, 0.5mg lorazepam is equivalent to 5mg diazepam.
- Haloperidol 5mg IM is equivalent to approx 8mg – 10mg orally.
- Orodispersible tablets offer no advantage in speed of onset but are harder to spit out or conceal.
- Olanzapine injection is not licensed for use beyond 3 days.
- Olanzapine IM and lorazepam IM should not be used within one hour of each other and then only after careful consideration with strict post-injection monitoring.
- There is probably an increased risk of cerbro-vascular events in older patients with all antipsychotics.

Appendix F

Rapid Tranquillisation Training Needs Analysis

Set out below is the training needs analysis for all staff groups indentifying which groups of staff require training and the level and frequency required.

The aim of training is to ensure that all staff are aware of their duties, role and responsibilities to enable them to implement the Rapid Tranquillisation guideline.

Staff Group	RT training including flow chart and monitoring	Medication used in RT	Basic Life Support	Intermediate Life Support	Automated external defibrillator	Pulse oximetry
Frequency	Annual	Annual	Annual	Annual	Annual	Annual
Medical Staff						
Consultant	√	√		√	√	√
Specialist Trainees	√	√		√	√	√
Core Trainees	√	√		√	√	√
Staff Grade	√	√		√	√	√
F1/F2 Trainee	√	√		√	√	√
Staff Based in Acute inpatient units						
Registered nurses	√	√	√	√ (in high risk areas)	√	√
Healthcare assistants	√ (overview)	√ (overview)	√			

NICE National Institute for Health and Care Excellence

NICE guideline

Violence and aggression: short-term management in mental health, health and community settings

NICE guideline

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www.nice.org.uk/guidance/ng10

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline replaces CG25 and ESUOM28.

This guideline is the basis of QS154.

Overview

This guideline covers the short-term management of violence and aggression in adults (aged 18 and over), young people (aged 13 to 17) and children (aged 12 and under). It is relevant for mental health, health and community settings. The guideline aims to safeguard both staff and people who use services by helping to prevent violent situations and providing guidance to manage them safely when they occur.

Who is it for?

- Healthcare professionals
- Adults, young people and children with a mental health problem who use services in mental health, health and community settings, and their families and carers

Introduction

Violence and aggression refer to a range of behaviours or actions that can result in harm, hurt or injury to another person, regardless of whether the violence or aggression is physically or verbally expressed, physical harm is sustained or the intention is clear.

Violence and aggression are relatively common and serious occurrences in health and social care settings. Between 2013 and 2014 there were 68,683 assaults reported against NHS staff in England: 69% in mental health or learning disability settings, 27% against ambulance staff, 25% involving primary care staff and 26% involving acute hospital staff. Violence and aggression in mental health settings occur most frequently in inpatient psychiatric units and most acute hospital assaults take place in emergency departments.

The manifestation of violence and aggression depends on a combination of intrinsic factors, such as personality characteristics and intense mental distress, and extrinsic factors, such as the attitudes and behaviours of surrounding staff and service users, the physical setting and any restrictions that limit the service user's freedom. The impact of violence and aggression is significant and diverse, adversely affecting the health and safety of the service user, other service users in the vicinity, carers and staff. Violence and aggression can also affect public opinion about services and service users and result in a strong negative impact on the overall experience of care. Although the guideline contains recommendations on intervening before violence and aggression occur, it is not always possible to avoid violence. Therefore a graded set of interventions is needed to prevent minor violence from escalating into severe violence.

Since the publication of the previous guideline in 2005 (NICE guideline CG25) there have been some important advances in our knowledge of the management of violence and aggression, including service users' views on the use of physical intervention and seclusion, and the effectiveness, acceptability and safety of drugs and their dosages for rapid tranquillisation. The previous guideline was restricted to people aged 16 and over in adult psychiatric settings and emergency departments; this update has been expanded to include some of the previously excluded populations and settings. All areas of NICE guideline CG25 have been updated and this guideline replaces it in full.

This guideline covers the short-term management of violence and physically threatening behaviour in mental health, health and community settings. This includes inpatient psychiatric care, emergency and urgent care, secondary mental health care (such as care

provided by assertive community teams, community mental health teams, early intervention teams and crisis resolution and home treatment teams), community healthcare, primary care, social care and care provided in people's homes. The guideline covers anticipating and reducing the risk of violence and aggression, prevention methods (such as searching, de-escalation and pharmacological strategies, including p.r.n. medication), restrictive interventions (for example, restraint, rapid tranquillisation and seclusion), staff training, and post-incident debrief and review.

This guideline includes adults (aged 18 and over), children (aged 12 and under) and young people (aged 13 to 17) with a mental health problem who are currently service users within mental health, health and community settings. It also covers carers of service users with mental health problems in these settings.

This guideline does not cover but may be relevant to practice regarding people who do not have mental health problems, those who are not carers of people with mental health problems, people in whom the primary behaviour is self-harm and people with a primary diagnosis of learning disability.

Safeguarding children

Remember that child maltreatment:

- is common
- can present anywhere, such as emergency departments and primary care or on home visits.

Be aware of or suspect abuse as a contributory factor to or cause of the symptoms or signs of violence or aggression in children. Abuse may also coexist with violence or aggression. See the NICE guideline on child maltreatment for clinical features that may be associated with maltreatment.

This section has been agreed with the Royal College of Paediatrics and Child Health.

Medicines

The guideline assumes that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual service users.

This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of consultation, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The service user (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are indicated in the recommendations.

Person-centred care

This guideline offers best practice advice on the care of service users with mental health problems whose behaviour is violent or aggressive.

Service users and healthcare professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Service users should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the service user is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the Department of Health's advice on consent. If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in the NICE guideline on patient experience in adult NHS services.

NICE has also produced guidance on the components of good service user experience. All healthcare professionals and social care practitioners working with people using adult NHS mental health services should follow the recommendations in the NICE guideline on service user experience in adult mental health.

If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's Transition: getting it right for young people.

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people with mental health problems whose behaviour is violent or aggressive. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in section 1.

See implementation: getting started for information about putting the recommendations on manual restraint, rapid tranquillisation and formal external post-incident reviews into practice.

Anticipating and reducing the risk of violence and aggression

Reducing the use of restrictive interventions

Staff training

- Health and social care provider organisations should train staff who work in services in which restrictive interventions may be used in psychosocial methods to avoid or minimise restrictive interventions. This training should enable staff to develop:
  - a person-centred, values-based approach to care, in which personal relationships, continuity of care and a positive approach to promoting health underpin the therapeutic relationship
  - an understanding of the relationship between mental health problems and the risk of violence and aggression
  - skills to assess why behaviour is likely to become violent or aggressive, including personal, constitutional, mental, physical, environmental, social, communicational, functional and behavioural factors
  - skills, methods and techniques to reduce or avert imminent violence and defuse aggression when it arises (for example, verbal de-escalation)
  - skills, methods and techniques to undertake restrictive interventions safely when these are required
  - skills to undertake an immediate post-incident debrief (see recommendations 1.4.55 to 1.4.61)
  - skills to undertake a formal external post-incident review in collaboration with experienced service users who are not currently using the service (see recommendations 1.4.62 to 1.4.63).

A framework for anticipating and reducing violence and aggression in inpatient psychiatric wards

- Use the following framework to anticipate violence and aggression in inpatient psychiatric wards, exploring each domain to identify ways to reduce violence and aggression and the use of restrictive interventions.
  - Ensure that the staff work as a therapeutic team by using a positive and encouraging approach, maintaining staff emotional regulation and self-management (see recommendation 1.3.19) and encouraging good leadership.
  - Ensure that service users are offered appropriate psychological therapies, physical activities, leisure pursuits such as film clubs and reading or writing groups, and support for communication difficulties.
  - Recognise possible teasing, bullying, unwanted physical or sexual contact or miscommunication between service users.
  - Recognise how each service user's mental health problem might affect their behaviour (for example, their diagnosis, severity of illness, current symptoms and past history of violence or aggression).
  - Anticipate the impact of the regulatory process on each service user (for example, being formally detained, having leave refused, having a failed detention appeal or being in a very restricted environment such as a low-, medium- or high-secure hospital).
  - Improve or optimise the physical environment (for example, use unlocked doors whenever possible, enhance the décor, simplify the ward layout and ensure easy access to outside spaces and privacy).
  - Anticipate that restricting a service user's liberty and freedom of movement (for example, not allowing service users to leave the building) can be a trigger for violence and aggression.
  - Anticipate and manage any personal factors occurring outside the hospital (for example, family disputes or financial difficulties) that may affect a service user's behaviour.

Preventing violence and aggression

Using p.r.n. medication

- When prescribing p.r.n. medication as part of a strategy to de-escalate or prevent situations that may lead to violence and aggression:
  - do not prescribe p.r.n. medication routinely or automatically on admission
  - tailor p.r.n. medication to individual need and include discussion with the service user if possible
  - ensure there is clarity about the rationale and circumstances in which p.r.n. medication may be used and that these are included in the care plan
  - ensure that the maximum daily dose is specified and does not inadvertently exceed the maximum daily dose stated in the British national formulary (BNF) when combined with the person's standard dose or their dose for rapid tranquillisation
  - only exceed the BNF maximum daily dose (including p.r.n. dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented and carried out under the direction of a senior doctor
  - ensure that the interval between p.r.n. doses is specified.

De-escalation

Staff training

- Health and social care provider organisations should give staff training in de-escalation that enables them to:
  - recognise the early signs of agitation, irritation, anger and aggression
  - understand the likely causes of aggression or violence, both generally and for each service user
  - use techniques for distraction and calming, and ways to encourage relaxation
  - recognise the importance of personal space
  - respond to a service user's anger in an appropriate, measured and reasonable way and avoid provocation.

General principles

- Establish a close working relationship with service users at the earliest opportunity and sensitively monitor changes in their mood or composure that may lead to aggression or violence.

Using restrictive interventions in inpatient psychiatric settings

Using restrictive interventions

- Do not use restrictive interventions to punish, inflict pain, suffering or humiliation, or establish dominance.

Rapid tranquillisation

- If there is evidence of cardiovascular disease, including a prolonged QT interval, or no electrocardiogram has been carried out, avoid intramuscular haloperidol combined with intramuscular promethazine and use intramuscular lorazepam instead.

Post-incident debrief and review

Formal external post-incident review

- The service user experience monitoring unit or equivalent service user group should undertake a formal external post-incident review as soon as possible and no later than 72 hours after the incident. The unit or group should ensure that the formal external post-incident review:
  - is led by a service user and includes staff from outside the ward where the incident took place, all of whom are trained to undertake investigations that aim to help staff learn and improve rather than assign blame
  - uses the information recorded in the immediate post-incident debrief and the service user's notes relating to the incident
  - includes interviews with staff, the service user involved and any witnesses if further information is needed
  - uses the framework in recommendation 1.2.7 to:
    - evaluate the physical and emotional impact on everyone involved, including witnesses
    - help service users and staff to identify what led to the incident and what could have been done differently
    - determine whether alternatives, including less restrictive interventions, were discussed
    - determine whether service barriers or constraints make it difficult to avoid the same course of actions in future
    - recommend changes to the service's philosophy, policies, care environment, treatment approaches, staff education and training, if appropriate
    - avoid a similar incident happening in future, if possible.

Managing violence and aggression in emergency departments

- If a service user with a mental health problem becomes aggressive or violent, do not exclude them from the emergency department. Manage the violence or aggression in line with recommendations 1.4.1 to 1.4.45 and do not use seclusion. Regard the situation as a psychiatric emergency and refer the service user to mental health services urgently for a psychiatric assessment within 1 hour.

Managing violence and aggression in community and primary care settings

- Health and social care provider organisations, including ambulance trusts, should consider training staff working in community and primary care settings in methods of avoiding violence, including anticipation, prevention, de-escalation and breakaway techniques, depending on the frequency of violence and aggression in each setting and the extent to which staff move between settings.

Managing violence and aggression in children and young people

Staff training

- Child and adolescent mental health services (CAMHS) should ensure that staff are trained in the management of violence and aggression using a training programme designed specifically for staff working with children and young people. Training programmes should include the use of psychosocial methods to avoid or minimise restrictive interventions whenever possible. Staff who might undertake restrictive interventions should be trained:
  - in the use of these interventions in these age groups
  - to adapt the manual restraint techniques for adults in recommendations 1.4.23 to 1.4.33, adjusting them according to the child or young person's height, weight and physical strength
  - in the use of resuscitation equipment (see recommendation 1.4.3) in children and young people.

Managing violence and aggression

- Manage violence and aggression in children and young people in line with the recommendations for adults in sections 1.1 to 1.6, taking into account:
  - the child or young person's level of physical, intellectual, emotional and psychological maturity
  - the recommendations for children and young people in this section
  - that the Mental Capacity Act 2005 applies to young people aged 16 and over.

Assessment and initial management

Identify any history of aggression or aggression trigger factors, including experience of abuse or trauma and previous response to management of violence or aggression.

1 Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

Terms used in this guideline

Advance decision A written statement made by a person aged 18 or over that is legally binding and conveys a person's decision to refuse specific treatments and interventions in the future.

Advance statement A written statement that conveys a person's preferences, wishes, beliefs and values about their future treatment and care. An advance statement is not legally binding.

Advocate A person who represents someone's interests independently of any organisation, and helps them to get the care and support they need.

Breakaway techniques A set of physical skills to help separate or break away from an aggressor in a safe manner. They do not involve the use of restraint.

Carer A person who provides unpaid support to a partner, family member, friend or neighbour who is ill, struggling or disabled.

Children People aged 12 years or under.

De-escalation The use of techniques (including verbal and non-verbal communication skills) aimed at defusing anger and averting aggression. P.r.n. medication can be used as part of a de-escalation strategy but p.r.n. medication used alone is not de-escalation.

Incident Any event that involves the use of a restrictive intervention – restraint, rapid tranquillisation or seclusion (but not observation) – to manage violence or aggression.

Manual restraint A skilled, hands-on method of physical restraint used by trained healthcare professionals to prevent service users from harming themselves, endangering others or compromising the therapeutic environment. Its purpose is to safely immobilise the service user.

Mechanical restraint A method of physical intervention involving the use of authorised equipment, for example handcuffs or restraining belts, applied in a skilled manner by designated healthcare professionals. Its purpose is to safely immobilise or restrict movement of part(s) of the body of the service user.

Observation A minimally restrictive intervention of varying intensity in which a member of the healthcare staff observes and maintains contact with a service user to ensure the service user's safety and the safety of others. There are different levels of observation, as defined in recommendation 1.4.11.

Positive engagement An intervention that aims to empower service users to actively participate in their care. Rather than 'having things done to' them, service users negotiate the level of engagement that will be most therapeutic.

p.r.n. (pro re nata) When needed. In this guideline, p.r.n. refers to the use of medication as part of a strategy to de-escalate or prevent situations that may lead to violence or aggression; it does not refer to p.r.n. medication used on its own for rapid tranquillisation during an episode of violence of aggression

Rapid tranquillisation Use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral medication is not possible or appropriate and urgent sedation with medication is needed.

Restrictive interventions Interventions that may infringe a person's human rights and freedom of movement, including observation, seclusion, manual restraint, mechanical restraint and rapid tranquillisation.

Seclusion Defined in accordance with the Mental Health Act 1983 Code of Practice: 'the supervised confinement of a patient in a room, which may be locked. Its sole aim is to contain severely disturbed behaviour that is likely to cause harm to others'.

Violence and aggression A range of behaviours or actions that can result in harm, hurt or injury to another person, regardless of whether the violence or aggression is physically or verbally expressed, physical harm is sustained or the intention is clear.

Young people People aged between 13 and 17 years.

1.1 Principles for managing violence and aggression

Improving service user experience

1.1.1 Use this guideline in conjunction with NICE's guideline on service user experience in adult mental health and:

- work in partnership with service users and their carers
- adopt approaches to care that respect service users' independence, choice and human rights
- increase social inclusion by decreasing exclusionary practices, such as the use of seclusion and the Mental Health Act 1983.

1.1.2 Ensure that the safety and dignity of service users and the safety of staff are priorities when anticipating or managing violence and aggression.

1.1.3 Use of restrictive interventions must be undertaken in a manner that complies with the Human Rights Act 1998 and the relevant rights in the European Convention on Human Rights.

1.1.4 Unless a service user is detained under the Mental Health Act 1983 or subject to a deprivation of liberty authorisation or order under the Mental Capacity Act 2005, health and social care provider organisations must ensure that the use of restrictive interventions does not impose restrictions that amount to a deprivation of liberty.

Staff training

1.1.5 In any setting in which restrictive interventions could be used, health and

social care provider organisations should train staff to understand and apply the Human Rights Act 1998, the Mental Capacity Act 2005 and the Mental Health Act 1983.

Involving service users in decision-making

1.1.6 Involve service users in all decisions about their care and treatment, and develop care and risk management plans jointly with them. If a service user is unable or unwilling to participate, offer them the opportunity to review and revise the plans as soon as they are able or willing and, if they agree, involve their carer.

1.1.7 Check whether service users have made advance decisions or advance statements about the use of restrictive interventions, and whether a decision-maker has been appointed for them, as soon as possible (for example, during admission to an inpatient psychiatric unit) and take this information into account when making decisions about care.

1.1.8 If a service user has not made any advance decisions or statements about the use of restrictive interventions, encourage them to do so as soon as possible (for example, during admission to an inpatient psychiatric unit). Ensure that service users understand the main side-effect profiles of the medications recommended in this guideline for rapid tranquillisation (see recommendation 1.4.37) so that they can make an informed choice.

1.1.9 Ensure that service users understand that during any restrictive intervention their human rights will be respected and the least restrictive intervention will be used to enable them to exercise their rights (for example, their right to follow religious or cultural practices during restrictive interventions) as much as possible. Identify and reduce any barriers to a service user exercising their rights and, if this is not possible, record the reasons in their notes.

1.1.10 Ensure that carers are involved in decision-making whenever possible, if the service user agrees, and that carers are involved in decision-making for all service users who lack mental capacity, in accordance with the Mental Capacity Act 2005.

Preventing violations of service users' rights

1.1.11 Evaluate, together with the service user, whether adjustments to services are needed to ensure that their rights and those of their carers (including rights related to protected characteristics as defined by the Equality Act 2010) are respected, and make any adjustments that are needed. Adjustments might include providing a particular type of support, modifying the way services are delivered or the approach to interaction with the service user, or making changes to facilities. Record this in the service user's care plan.

1.1.12 Health and social care provider organisations should train staff in cultural awareness and in the organisation's duties under the Equality Act 2010.

Working with the police

1.1.13 Health and social care provider organisations should work with the police, and local service user groups if possible, to develop policies for joint working and locally agreed operating protocols that cover:

- when and how police enter health or social care settings (including psychiatric and forensic inpatients, emergency departments, general health inpatients, GP surgeries, social care and community settings and 136 place-of-safety suites)
- when and how health and social care professionals enter police cells
- transferring service users between settings.

Review the operating protocols regularly to ensure compliance with the policies and update the policies in light of operational experience.

1.2 Anticipating and reducing the risk of violence and aggression

Reducing the use of restrictive interventions

Staff training

1.2.1 Health and social care provider organisations should train staff who work in services in which restrictive interventions may be used in psychosocial methods to avoid or minimise restrictive interventions. This training should enable staff to develop:

- a person-centred, values-based approach to care, in which personal relationships, continuity of care and a positive approach to promoting health underpin the therapeutic relationship
- an understanding of the relationship between mental health problems and the risk of violence and aggression
- skills to assess why behaviour is likely to become violent or aggressive, including personal, constitutional, mental, physical, environmental, social, communicational, functional and behavioural factors
- skills, methods and techniques to reduce or avert imminent violence and defuse aggression when it arises (for example, verbal de-escalation)
- skills, methods and techniques to undertake restrictive interventions safely when these are required
- skills to undertake an immediate post-incident debrief (see recommendations 1.4.55 to 1.4.61)
- skills to undertake a formal external post-incident review in collaboration with experienced service users who are not currently using the service (see recommendations 1.4.62 and 1.4.63).

Restrictive intervention reduction programme

1.2.2 Health and social care provider organisations should ensure that all

services that use restrictive interventions have a restrictive intervention reduction programme (see recommendation 1.2.3) to reduce the incidence of violence and aggression and the use of restrictive interventions.

1.2.3 Restrictive intervention reduction programmes should:

- ensure effective service leadership
- address environmental factors likely to increase or decrease the need for restrictive interventions (see recommendation 1.2.7)
- involve and empower service users and their carers
- include leisure activities that are personally meaningful and physical exercise for service users
- use clear and simple care pathways
- use de-escalation
- use crisis and risk management plans and strategies to reduce the need for restrictive interventions
- include post-incident debrief and review (see recommendations 1.4.55 to 1.4.61)
- explore the current and potential use of technology in reporting, monitoring and improving the use of restrictive interventions
- have routine outcome monitoring, including quality of life and service user experience
- be based on outcome measures (safety, effectiveness and service user experience) to support quality improvement programmes
- include regular staff training in line with recommendation 1.2.1.

1.2.4 Health and social care provider organisations should collate, analyse and synthesise all data about violent events and the use of restrictive interventions, and involve service users in the process. The information should:

- be shared with the teams and services involved
- be shared with the trust board or equivalent organisational governing body
- be linked to the standards set in safeguarding procedures.

1.2.5 Health and social care provider organisations should develop a service user experience monitoring unit, or equivalent service user group, led by service users and including staff, to report and analyse data on violence and aggression and the use of restrictive interventions.

1.2.6 Health and social care provider organisations should publish board reports on their public websites that include data about incidents of violence and aggression and use of restrictive interventions within each team, ward and service, and include reasons for the similarities and differences between services.

A framework for anticipating and reducing violence and aggression in inpatient psychiatric wards

1.2.7 Use the following framework to anticipate violence and aggression in inpatient psychiatric wards, exploring each domain to identify ways to reduce violence and aggression and the use of restrictive interventions.

- Ensure that the staff work as a therapeutic team by using a positive and encouraging approach, maintaining staff emotional regulation and self-management (see recommendation 1.3.19) and encouraging good leadership.
- Ensure that service users are offered appropriate psychological therapies, physical activities, leisure pursuits such as film clubs and reading or writing groups, and support for communication difficulties.
- Recognise possible teasing, bullying, unwanted physical or sexual contact, or miscommunication between service users.
- Recognise how each service user's mental health problem might affect their behaviour (for example, their diagnosis, severity of illness, current symptoms and past history of violence or aggression).

- Anticipate the impact of the regulatory process on each service user, for example, being formally detained, having leave refused, having a failed detention appeal or being in a very restricted environment such as a low-, medium- or high-secure hospital.
- Improve or optimise the physical environment (for example, use unlocked doors whenever possible, enhance the décor, simplify the ward layout and ensure easy access to outside spaces and privacy).
- Anticipate that restricting a service user's liberty and freedom of movement (for example, not allowing service users to leave the building) can be a trigger for violence and aggression.
- Anticipate and manage any personal factors occurring outside the hospital (for example, family disputes or financial difficulties) that may affect a service user's behaviour.

Assessing and managing the risk of violence and aggression

1.2.8 When assessing and managing the risk of violence and aggression use a multidisciplinary approach that reflects the care setting.

1.2.9 Before assessing the risk of violence or aggression:

- Take into account previous violent or aggressive episodes because these are associated with an increased risk of future violence and aggression.
- Do not make negative assumptions based on culture, religion or ethnicity.
- Recognise that unfamiliar cultural practices and customs could be misinterpreted as being aggressive.
- Ensure that the risk assessment will be objective and take into account the degree to which the perceived risk can be verified.

1.2.10 Carry out the risk assessment with the service user and, if they agree, their carer. If this finds that the service user could become violent or aggressive, set out approaches that address:

- service user-related domains in the framework (see recommendation 1.2.7)

- contexts in which violence and aggression tend to occur
- usual manifestations and factors likely to be associated with the development of violence and aggression
- primary prevention strategies that focus on improving quality of life and meeting the service user's needs
- symptoms or feelings that may lead to violence and aggression, such as anxiety, agitation, disappointment, jealousy and anger, and secondary prevention strategies focusing on these symptoms or feelings
- de-escalation techniques that have worked effectively in the past
- restrictive interventions that have worked effectively in the past, when they are most likely to be necessary and how potential harm or discomfort can be minimised.

1.2.11 Consider using an actuarial prediction instrument such as the BVC (Brøset Violence Checklist) or the DASA-IV (Dynamic Appraisal of Situational Aggression – Inpatient Version), rather than unstructured clinical judgement alone, to monitor and reduce incidents of violence and aggression and to help develop a risk management plan in inpatient psychiatric settings.

1.2.12 Consider offering service users with a history of violence or aggression psychological help to develop greater self-control and techniques for self-soothing.

1.2.13 Regularly review risk assessments and risk management plans, addressing the service user and environmental domains listed in recommendation 1.2.7 and following recommendations 1.2.9 and 1.2.10. The regularity of the review should depend on the assessment of the level of risk. Base the care plan on accurate and thorough risk assessments.

1.2.14 If service users are transferring to another agency or care setting, or being discharged, share the content of the risk assessment with staff in the relevant agencies or care settings, and with carers.

An individualised pharmacological strategy to reduce the risk of violence and aggression

1.2.15 A multidisciplinary team that includes a psychiatrist and a specialist pharmacist should develop and document an individualised pharmacological strategy for using routine and p.r.n. medication to calm, relax, tranquillise or sedate service users who are at risk of violence and aggression as soon as possible after admission to an inpatient psychiatric unit.

1.2.16 The multidisciplinary team should review the pharmacological strategy and the use of medication at least once a week and more frequently if events are escalating and restrictive interventions are being planned or used. The review should be recorded and include:

- clarification of target symptoms
- the likely timescale for response to medication
- the total daily dose of medication, prescribed and administered, including p.r.n. medication
- the number of and reason for any missed doses
- therapeutic response
- the emergence of unwanted effects.

If rapid tranquillisation is being used, a senior doctor should review all medication at least once a day.

1.3 Preventing violence and aggression

Searching

Developing a policy on searching

1.3.1 Health and social care provider organisations should have an operational policy on the searching of service users, their belongings and the

environment in which they are accommodated, and the searching of carers and visitors. The policy should address:

- the reasons for carrying out a search, ensuring that the decision to search is proportionate to the risks
- the searching of service users detained under the Mental Health Act 1983 who lack mental capacity
- the rationale for repeated searching of service users, carers or visitors, for example those who misuse drugs or alcohol
- the legal grounds for, and the methods used when, undertaking a search without consent, including when the person physically resists searching
- which staff members are allowed to undertake searching and in which contexts
- who and what can be searched, including persons, clothing, possessions and environments
- the storage, return and disposal of drugs or alcohol
- how to manage any firearms or other weapons carried by service users, including when to call the police
- links to other related policies such as those on drugs and alcohol, and on police liaison.

1.3.2 Develop and share a clear and easily understandable summary of the policy on searching, for use across the organisation for all service users, carers or visitors who may be searched.

Carrying out searches

1.3.3 Health and social care provider organisations should ensure that searches are undertaken by 2 members of staff, at least 1 of whom should be the same sex as the person being searched.

1.3.4 When a decision has been made to undertake a search:

- provide the person who is to be searched with the summary of the organisation's policy on searching
- seek consent to undertake the search
- explain what is being done and why throughout the search
- ensure the person's dignity and privacy are respected during the search
- record what was searched, why and how it was searched, and the disposal of any items found.

1.3.5 If a service user refuses to be searched, carry out a multidisciplinary review of the need to perform a search using physical force and explore any consequences in advance. Use physical force only as a last resort.

1.3.6 If consent for a search has not been given, a multidisciplinary review has been conducted and physical force has been used, conduct an immediate post-incident debrief (see recommendations 1.4.55 to 1.4.61) and a formal external post-incident review (see recommendations 1.4.62 and 1.4.63) with the service user that includes a visit from an advocacy service or hospital manager.

1.3.7 If a service user is carrying a weapon, ask them to place it in a neutral location rather than handing it over.

1.3.8 If a service user who is at risk of becoming violent or aggressive is in a room or area where there are objects that could be used as weapons, remove the objects or relocate the service user.

1.3.9 Audit the exercise of powers of search and report the outcomes to the trust board or equivalent governing body at least twice a year.

Using p.r.n. medication

1.3.10 When prescribing p.r.n. medication as part of a strategy to de-escalate or prevent situations that may lead to violence and aggression:

- do not prescribe p.r.n. medication routinely or automatically on admission

- tailor p.r.n. medication to individual need and include discussion with the service user if possible
- ensure there is clarity about the rationale and circumstances in which p.r.n. medication may be used and that these are included in the care plan
- ensure that the maximum daily dose is specified and does not inadvertently exceed the maximum daily dose stated in the British national formulary (BNF) when combined with the person's standard dose or their dose for rapid tranquillisation
- only exceed the BNF maximum daily dose (including p.r.n. dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented, and carried out under the direction of a senior doctor
- ensure that the interval between p.r.n. doses is specified.

1.3.11 The multidisciplinary team should review p.r.n. medication at least once a week and, if p.r.n. medication is to be continued, the rationale for its continuation should be included in the review. If p.r.n. medication has not been used since the last review, consider stopping it.

De-escalation

Staff training

1.3.12 Health and social care provider organisations should give staff training in de-escalation that enables them to:

- recognise the early signs of agitation, irritation, anger and aggression
- understand the likely causes of aggression or violence, both generally and for each service user
- use techniques for distraction and calming, and ways to encourage relaxation
- recognise the importance of personal space
- respond to a service user's anger in an appropriate, measured and reasonable way and avoid provocation.

General principles

1.3.13 Establish a close working relationship with service users at the earliest opportunity and sensitively monitor changes in their mood or composure that may lead to aggression or violence.

1.3.14 Separate agitated service users from others (using quiet areas of the ward, bedrooms, comfort rooms, gardens or other available spaces) to aid de-escalation, ensuring that staff do not become isolated.

1.3.15 Use a wide range of verbal and non-verbal skills and interactional techniques to avoid or manage known 'flashpoint' situations (such as refusing a service user's request, asking them to stop doing something they wish to do or asking that they do something they don't wish to do) without provoking aggression.

1.3.16 Encourage service users to recognise their own triggers and early warning signs of violence and aggression and other vulnerabilities, and to discuss and negotiate their wishes should they become agitated. Include this information in care plans and advance statements and give a copy to the service user.

1.3.17 Communicate respect for and empathy with the service user at all stages of de-escalation.

De-escalation techniques

1.3.18 If a service user becomes agitated or angry, 1 staff member should take the primary role in communicating with them. That staff member should assess the situation for safety, seek clarification with the service user and negotiate to resolve the situation in a non-confrontational manner.

1.3.19 Use emotional regulation and self-management techniques to control verbal and non-verbal expressions of anxiety or frustration (for example, body posture and eye contact) when carrying out de-escalation.

1.3.20 Use a designated area or room to reduce emotional arousal or agitation and support the service user to become calm. In services where seclusion is practised, do not routinely use the seclusion room for this

purpose because the service user may perceive this as threatening.

1.4 Using restrictive interventions in inpatient psychiatric settings

Restrictive interventions are most likely to be used in inpatient psychiatric settings, but may be used in emergency departments, outpatient services and child and adolescent mental health services (CAMHS).

See implementation: getting started for information about putting the recommendations on manual restraint, rapid tranquillisation and formal external post-incident reviews into practice.

Staff training

1.4.1 Health and social care provider organisations should train staff working in inpatient psychiatric settings to undertake restrictive interventions and understand the risks involved in their use, including the side-effect profiles of the medication recommended for rapid tranquillisation in this guideline, and to communicate these risks to service users.

Staffing and equipment

1.4.2 Health and social care provider organisations should:

- define staff:patient ratios for each inpatient psychiatric ward and the numbers of staff required to undertake restrictive interventions
- ensure that restrictive interventions are used only if there are sufficient numbers of trained staff available
- ensure the safety of staff during the use of restrictive interventions, including techniques to avoid injuries from needles during rapid tranquillisation.

1.4.3 Health and social care provider organisations should ensure that resuscitation equipment is immediately available if restrictive interventions might be used and:

- include an automatic external defibrillator, a bag valve mask, oxygen, cannulas, intravenous fluids, suction and first-line resuscitation medications
- maintain equipment and check it every week.

1.4.4 Staff trained in immediate life support and a doctor trained to use resuscitation equipment should be immediately available to attend an emergency if restrictive interventions might be used.

Using restrictive interventions

1.4.5 Use a restrictive intervention only if de-escalation and other preventive strategies, including p.r.n. medication, have failed and there is potential for harm to the service user or other people if no action is taken. Continue to attempt de-escalation throughout a restrictive intervention.

1.4.6 Do not use restrictive interventions to punish, inflict pain, suffering or humiliation, or establish dominance.

1.4.7 Ensure that the techniques and methods used to restrict a service user:

- are proportionate to the risk and potential seriousness of harm
- are the least restrictive option to meet the need
- are used for no longer than necessary
- take account of the service user's preferences, if known and it is possible to do so
- take account of the service user's physical health, degree of frailty and developmental age.

Observation

General principles

1.4.8 Staff should be aware of the location of all service users for whom they are responsible, but not all service users need to be kept within sight.

1.4.9 At least once during each shift a nurse should set aside dedicated time to assess the mental state of, and engage positively with, the service user. As part of the assessment, the nurse should evaluate the impact of the service user's mental state on the risk of violence and aggression, and record any risk in the notes.

Developing a policy on observation

1.4.10 Health and social care provider organisations should have a policy on observation and positive engagement that includes:

- definitions of levels of observation in line with recommendation 1.4.11
- who can instigate, increase, decrease and review observation
- when an observer should be male or female
- how often reviews should take place
- how service users' experience of observation will be taken into account
- how to ensure that observation is underpinned by continuous attempts to engage therapeutically
- the levels of observation necessary during the use of other restrictive interventions (for example, seclusion)
- the need for multidisciplinary review when observation continues for 1 week or more.

Levels of observation

1.4.11 Staff in inpatient psychiatric wards (including general adult wards, older adult wards, psychiatric intensive care units and forensic wards) should use the following definitions for levels of observation, unless a locally agreed policy states otherwise.

- Low-level intermittent observation: the baseline level of observation in a specified psychiatric setting. The frequency of observation is once every 30 to 60 minutes.

- High-level intermittent observation: usually used if a service user is at risk of becoming violent or aggressive but does not represent an immediate risk. The frequency of observation is once every 15 to 30 minutes.
- Continuous observation: usually used when a service user presents an immediate threat and needs to be kept within eyesight or at arm's length of a designated one-to-one nurse, with immediate access to other members of staff if needed.
- Multiprofessional continuous observation: usually used when a service user is at the highest risk of harming themselves or others and needs to be kept within eyesight of 2 or 3 staff members and at arm's length of at least 1 staff member.

Using observation

1.4.12 Use observation only after positive engagement with the service user has failed to dissipate the risk of violence and aggression.

1.4.13 Recognise that service users sometimes find observation provocative, and that it can lead to feelings of isolation and dehumanisation.

1.4.14 Use the least intrusive level of observation necessary, balancing the service user's safety, dignity and privacy with the need to maintain the safety of those around them.

1.4.15 Give the service user information about why they are under observation, the aims of observation, how long it is likely to last and what needs to be achieved for it to be stopped. If the service user agrees, tell their carer about the aims and level of observation.

1.4.16 Record decisions about observation levels in the service user's notes and clearly specify the reasons for the observation.

1.4.17 When deciding on levels of observation take into account:

- the service user's current mental state
- any prescribed and non-prescribed medications and their effects
- the current assessment of risk

- the views of the service user, as far as possible.

1.4.18 Record clearly the names and titles of the staff responsible for carrying out a review of observation levels (see recommendation 1.4.11) and when the review should take place.

1.4.19 Staff undertaking observation should:

- take an active role in engaging positively with the service user
- be appropriately briefed about the service user's history, background, specific risk factors and particular needs
- be familiar with the ward, the ward policy for emergency procedures and potential risks in the environment
- be approachable, listen to the service user and be able to convey to the service user that they are valued.

1.4.20 Ensure that an individual staff member does not undertake a continuous period of observation above the general level for longer than 2 hours. If observation is needed for longer than 2 hours, ensure the staff member has regular breaks.

1.4.21 When handing over to another staff member during a period of observation, include the service user in any discussions during the handover if possible.

1.4.22 Tell the service user's psychiatrist or on-call doctor as soon as possible if observation above the general level is carried out (see recommendation 1.4.11).

Manual restraint

1.4.23 Health and social care provider organisations should ensure that manual restraint is undertaken by staff who work closely together as a team, understand each other's roles and have a clearly defined lead.

1.4.24 When using manual restraint, avoid taking the service user to the floor, but if this becomes necessary:

- use the supine (face up) position if possible **or**
- if the prone (face down) position is necessary, use it for as short a time as possible.

1.4.25 Do not use manual restraint in a way that interferes with the service user's airway, breathing or circulation, for example by applying pressure to the rib cage, neck or abdomen, or obstructing the mouth or nose.

1.4.26 Do not use manual restraint in a way that interferes with the service user's ability to communicate, for example by obstructing the eyes, ears or mouth.

1.4.27 Undertake manual restraint with extra care if the service user is physically unwell, disabled, pregnant or obese.

1.4.28 Aim to preserve the service user's dignity and safety as far as possible during manual restraint.

1.4.29 Do not routinely use manual restraint for more than 10 minutes.

1.4.30 Consider rapid tranquillisation or seclusion as alternatives to prolonged manual restraint (longer than 10 minutes).

1.4.31 Ensure that the level of force applied during manual restraint is justifiable, appropriate, reasonable, proportionate to the situation and applied for the shortest time possible.

1.4.32 One staff member should lead throughout the use of manual restraint. This person should ensure that other staff members are:

- able to protect and support the service user's head and neck, if needed
- able to check that the service user's airway and breathing are not compromised
- able to monitor vital signs
- supported throughout the process.

1.4.33 Monitor the service user's physical and psychological health for as long as clinically necessary after using manual restraint.

Mechanical restraint

1.4.34 Health and social care provider organisations should ensure that mechanical restraint in adults is used only in high-secure settings (except when transferring service users between medium- and high-secure settings as in recommendation 1.4.36) and its use is reported to the trust board.

1.4.35 Use mechanical restraint only as a last resort and for the purpose of:

- managing extreme violence directed at other people **or**
- limiting self-injurious behaviour of extremely high frequency or intensity.

1.4.36 Consider mechanical restraint, such as handcuffs, when transferring service users who are at high risk of violence and aggression between medium- and high-secure settings. In this context, restraint should be clearly planned as part of overall risk management.

Rapid tranquillisation

Rapid tranquillisation in this guideline refers to the use of medication by the parenteral route (usually intramuscular or, exceptionally, intravenous) if oral medication is not possible or appropriate and urgent sedation with medication is needed.

1.4.37 Use either intramuscular lorazepam on its own or intramuscular haloperidol combined with intramuscular promethazine for rapid tranquillisation in adults. When deciding which medication to use, take into account:

- the service user's preferences or advance statements and decisions
- pre-existing physical health problems or pregnancy
- possible intoxication
- previous response to these medications, including adverse effects

- potential for interactions with other medications
- the total daily dose of medications prescribed and administered.

1.4.38 If there is insufficient information to guide the choice of medication for rapid tranquillisation, or the service user has not taken antipsychotic medication before, use intramuscular lorazepam.

1.4.39 If there is evidence of cardiovascular disease, including a prolonged QT interval, or no electrocardiogram has been carried out, avoid intramuscular haloperidol combined with intramuscular promethazine and use intramuscular lorazepam instead.

1.4.40 If there is a partial response to intramuscular lorazepam, consider a further dose.

1.4.41 If there is no response to intramuscular lorazepam, consider intramuscular haloperidol combined with intramuscular promethazine.

1.4.42 If there is a partial response to intramuscular haloperidol combined with intramuscular promethazine, consider a further dose.

1.4.43 If there is no response to intramuscular haloperidol combined with intramuscular promethazine, consider intramuscular lorazepam if this hasn't been used already during this episode. If intramuscular lorazepam has already been used, arrange an urgent team meeting to carry out a review and seek a second opinion if needed.

1.4.44 When prescribing medication for use in rapid tranquillisation, write the initial prescription as a single dose, and do not repeat it until the effect of the initial dose has been reviewed.

1.4.45 After rapid tranquillisation, monitor side effects and the service user's pulse, blood pressure, respiratory rate, temperature, level of hydration and level of consciousness at least every hour until there are no further concerns about their physical health status. Monitor every 15 minutes if the BNF maximum dose has been exceeded or the service user:

- appears to be asleep or sedated

- has taken illicit drugs or alcohol
- has a pre-existing physical health problem
- has experienced any harm as a result of any restrictive intervention.

Seclusion

1.4.46 Use seclusion in adults only if the service user is detained in accordance with the Mental Health Act 1983. If a service user not detained under the Mental Health Act 1983 is secluded in an emergency, arrange a mental health assessment under the Mental Health Act 1983 immediately.

1.4.47 Services that use seclusion should have a designated seclusion room that:

- allows staff to clearly observe and communicate with the service user
- is well insulated and ventilated, with temperature controls outside the room
- has access to toilet and washing facilities
- has furniture, windows and doors that can withstand damage.

Carrying out seclusion

1.4.48 Record the use of seclusion in accordance with the Mental Health Act 1983 Code of Practice.

1.4.49 Ensure that seclusion lasts for the shortest time possible. Review the need for seclusion at least every 2 hours and tell the service user that these reviews will take place.

1.4.50 Set out an observation schedule for service users in seclusion. Allocate a suitably trained member of staff to carry out the observation, which should be within eyesight as a minimum.

1.4.51 Ensure that a service user in seclusion keeps their clothing and, if they wish, any personal items, including those of personal, religious or cultural significance, unless doing so compromises their safety or the safety of

others.

Rapid tranquillisation during seclusion

1.4.52 If rapid tranquillisation is needed while a service user is secluded, undertake with caution following recommendations 1.4.37 to 1.4.45 and:

- be aware of and prepared to address any complications associated with rapid tranquillisation
- ensure the service user is observed within eyesight by a trained staff member
- undertake a risk assessment and consider ending the seclusion when rapid tranquillisation has taken effect.

Post-incident debrief and formal review

In this guideline an incident is defined as any event that involves the use of a restrictive intervention – restraint, rapid tranquillisation or seclusion (but not observation) – to manage violence or aggression.

1.4.53 Health and social care provider organisations should ensure that wards have sufficient staff with a mix of skills and seniority levels that enable them to:

- conduct an immediate post-incident debrief (see recommendations 1.4.55 to 1.4.61)
- monitor and respond to ongoing risks, and contribute to formal external post-incident reviews (see recommendations 1.4.62 to 1.4.63).

1.4.54 The trust board or equivalent governing body should ensure that it receives regular reports from each ward about violent incidents, the use of restrictive interventions, service users' experience of those interventions and the learning gained.

Immediate post-incident debrief

1.4.55 After using a restrictive intervention, and when the risks of harm have

been contained, conduct an immediate post-incident debrief, including a nurse and a doctor, to identify and address physical harm to service users or staff, ongoing risks and the emotional impact on service users and staff, including witnesses.

1.4.56 Use the framework outlined in recommendation 1.2.7 to determine the factors that contributed to an incident that led to a restrictive intervention, identify any factors that can be addressed quickly to reduce the likelihood of a further incident and amend risk and care plans accordingly.

1.4.57 Advise the service user experience monitoring unit, or equivalent service user group, to start a formal external post-incident review.

1.4.58 Ensure that the service user involved has the opportunity to discuss the incident in a supportive environment with a member of staff or an advocate or carer. Offer the service user the opportunity to write their perspective of the event in the notes.

1.4.59 Ensure that any other service users who may have seen or heard the incident are given the opportunity to discuss it so that they can understand what has happened.

1.4.60 Ensure that all staff involved in the incident have the opportunity to discuss their experience with staff who were not involved.

1.4.61 Discuss the incident with service users, witnesses and staff involved only after they have recovered their composure and aim to:

- acknowledge the emotional responses to the incident and assess whether there is a need for emotional support for any trauma experienced
- promote relaxation and feelings of safety
- support a return to normal patterns of activity

- ensure that everyone involved in the service user's care, including their carers, has been informed of the event, if the service user agrees.

  Ensure that the necessary documentation has been completed.

Formal external post-incident review

1.4.62 The service user experience monitoring unit or equivalent service user group should undertake a formal external post-incident review as soon as possible and no later than 72 hours after the incident. The unit or group should ensure that the formal external post-incident review:

- is led by a service user and includes staff from outside the ward where the incident took place, all of whom are trained to undertake investigations that aim to help staff learn and improve rather than assign blame
- uses the information recorded in the immediate post-incident debrief and the service user's notes relating to the incident
- includes interviews with staff, the service user involved and any witnesses if further information is needed
- uses the framework in recommendation 1.2.7 to:
  - evaluate the physical and emotional impact on everyone involved, including witnesses
  - help service users and staff to identify what led to the incident and what could have been done differently
  - determine whether alternatives, including less restrictive interventions, were discussed
  - determine whether service barriers or constraints make it difficult to avoid the same course of actions in future
  - recommend changes to the service's philosophy, policies, care environment, treatment approaches, staff education and training, if appropriate
  - avoid a similar incident happening in future, if possible.

1.4.63 The service user experience monitoring unit or equivalent service user group should give a report to the ward that is based on the formal external post-incident review.

1.5 Managing violence and aggression in emergency departments

For guidance on manual restraint and rapid tranquillisation, which may be used in emergency departments, see recommendations 1.4.23 to 1.4.33 and recommendations 1.4.37 to 1.4.45 respectively. Emergency department staff may also be involved in immediate post-incident debriefs (see recommendations 1.4.55 to 1.4.61).

Liaison mental health

1.5.1 Healthcare provider organisations and commissioners should ensure that every emergency department has routine and urgent access to a multidisciplinary liaison team that includes consultant psychiatrists and registered psychiatric nurses who are able to work with children, young people, adults and older adults.

1.5.2 Healthcare provider organisations should ensure that a full mental health assessment is available within 1 hour of alert from the emergency department at all times.

Staff training

1.5.3 Healthcare provider organisations should train staff in emergency departments in methods and techniques to reduce the risk of violence and aggression, including anticipation, prevention and de-escalation.

1.5.4 Healthcare provider organisations should train staff in emergency departments in mental health triage.

1.5.5 Healthcare provider organisations should train staff in emergency departments to distinguish between excited delirium states (acute organic brain syndrome), acute brain injury and excited psychiatric states (such as mania and other psychoses).

Staffing

1.5.6 Healthcare provider organisations should ensure that, at all times, there are sufficient numbers of staff on duty in emergency departments who have training in the management of violence and aggression in line with this guideline.

Preventing violence and aggression

1.5.7 Undertake mental health triage for all service users on entry to emergency departments, alongside physical health triage.

1.5.8 Healthcare provider organisations should ensure that emergency departments have at least 1 designated interview room for mental health assessment that:

- is close to or part of the main emergency department receiving area
- is made available for mental health assessments as a priority
- can comfortably seat 6 people
- is fitted with an emergency call system, an outward opening door and a window for observation
- contains soft furnishings and is well ventilated
- contains no potential weapons.

1.5.9 Staff interviewing a person in the designated interview room should:

- inform a senior member of the emergency nursing staff before starting the interview
- make sure another staff member is present.

Managing violence and aggression

1.5.10 If a service user with a mental health problem becomes aggressive or violent, do not exclude them from the emergency department. Manage

the violence or aggression in line with recommendations 1.4.1 to 1.4.45 and do not use seclusion. Regard the situation as a psychiatric emergency and refer the service user to mental health services urgently for a psychiatric assessment within 1 hour.

1.6 Managing violence and aggression in community and primary care settings

For guidance on manual restraint, which may be used by ambulance staff, see recommendations 1.4.23 to 1.4.33. Ambulance staff may also be involved in immediate post-incident debriefs (see recommendations 1.4.55 to 1.4.61).

Developing policies

1.6.1 Health and social care provider organisations, including ambulance trusts, should ensure that they have up-to-date policies on the management of violence and aggression in people with mental health problems, and on lone working, in community and primary care settings, in line with this guideline.

Staff training

1.6.2 Health and social care provider organisations, including ambulance trusts, should consider training staff working in community and primary care settings in methods of avoiding violence, including anticipation, prevention, de-escalation and breakaway techniques, depending on the frequency of violence and aggression in each setting and the extent to which staff move between settings.

1.6.3 Health and social care provider organisations, including ambulance trusts, should ensure that staff working in community and primary care settings are able to undertake a risk assessment for violence and aggression in collaboration with service users known to be at risk and their carers if possible. The risk assessment should be available for case supervision and in community teams it should be subject to multidisciplinary review.

Managing violence and aggression

1.6.4 After a risk assessment has been carried out, staff working in community and primary care settings should:

- share the risk assessment with other health and social care services and partner agencies (including the police and probation service) who may be involved in the person's care and treatment, and with carers if there are risks to them
- be aware of professional responsibilities in relation to limits of confidentiality and the need to share information about risks.

1.6.5 In community settings, carry out Mental Health Act 1983 assessments with a minimum of 2 people, for example a doctor and a social worker.

1.6.6 Community mental health teams should not use manual restraint in community settings. In situations of medium risk, staff should consider using breakaway techniques and de-escalation. In situations of high risk, staff should remove themselves from the situation and, if there is immediate risk to life, contact the police.

1.7 Managing violence and aggression in children and young people

Staff training

1.7.1 Child and adolescent mental health services (CAMHS) should ensure that staff are trained in the management of violence and aggression using a training programme designed specifically for staff working with children and young people. Training programmes should include the use of psychosocial methods to avoid or minimise restrictive interventions whenever possible. Staff who might undertake restrictive interventions should be trained:

- in the use of these interventions in these age groups

- to adapt the manual restraint techniques for adults in recommendations 1.4.23 to 1.4.33, adjusting them according to the child or young person's height, weight and physical strength
- in the use of resuscitation equipment (see recommendation 1.4.3) in children and young people.

1.7.2 CAMHS should have a clear and consistently enforced policy about managing antisocial behaviour and ensure that staff are trained in psychosocial and behavioural techniques for managing the behaviour.

1.7.3 CAMHS staff should be familiar with the Children Act 1989 and 2004 and the Mental Health Act 1983, as well as the Mental Capacity Act 2005 and the Human Rights Act 1998. They should also be aware of the United Nations Convention on the Rights of the Child.

Managing violence and aggression

1.7.4 Manage violence and aggression in children and young people in line with the recommendations for adults in sections 1.1 to 1.6, taking into account:

- the child or young person's level of physical, intellectual, emotional and psychological maturity
- the recommendations for children and young people in this section
- that the Mental Capacity Act 2005 applies to young people aged 16 and over.

1.7.5 Collaborate with those who have parental responsibility when managing violence and aggression in children and young people.

1.7.6 Use safeguarding procedures to ensure the child or young person's safety.

1.7.7 Involve the child or young person in making decisions about their care whenever possible.

Assessment and initial management

1.7.8 Assess and treat any underlying mental health problems in line with relevant NICE guidelines, including the NICE guidelines on antisocial behaviour and conduct disorders in children and young people, attention deficit hyperactivity disorder, psychosis and schizophrenia in children and young people, autism diagnosis in children and young people and autism.

1.7.9 Identify any history of aggression or aggression trigger factors, including experience of abuse or trauma and previous response to management of violence or aggression.

1.7.10 Identify cognitive, language, communication and cultural factors that may increase the risk of violence or aggression in a child or young person.

1.7.11 Consider offering children and young people with a history of violence or aggression psychological help to develop greater self-control and techniques for self-soothing.

1.7.12 Offer support and age-appropriate interventions (including parent training programmes) in line with the NICE guideline on antisocial behaviour and conduct disorders in children and young people to parents of children and young people whose behaviour is violent or aggressive.

De-escalation

1.7.13 Use de-escalation in line with recommendations 1.3.12 to 1.3.20 for adults, modified for children and young people, and:

- use calming techniques and distraction
- offer the child or young person the opportunity to move away from the situation in which the violence or aggression is occurring, for example to a quiet room or area
- aim to build emotional bridges and maintain a therapeutic relationship.

Restrictive interventions

1.7.14 Use restrictive interventions only if all attempts to defuse the situation have failed and the child or young person becomes aggressive or violent.

1.7.15 When restrictive interventions are used, monitor the child or young person's wellbeing closely and continuously, and ensure their physical and emotional comfort.

1.7.16 Do not use punishments, such as removing contact with parents or carers or access to social interaction, withholding nutrition or fluids, or corporal punishment, to force compliance.

Manual restraint

1.7.17 If possible, allocate a staff member who is the same sex as the child or young person to carry out manual restraint.

Mechanical restraint

1.7.18 Do not use mechanical restraint in children.

1.7.19 Healthcare provider organisations should ensure that, except when transferring young people between medium- and high-secure settings (as in recommendation 1.7.20), mechanical restraint in young people is used only in high-secure settings (on those occasions when young people are being treated in adult high-secure settings), in accordance with the Mental Health Act 1983 and with support and agreement from a multidisciplinary team that includes a consultant psychiatrist in CAMHS.

1.7.20 Consider using mechanical restraint, such as handcuffs, when transferring young people who are at high risk of violence or aggression between medium- and high-secure settings, and remove the restraint at the earliest opportunity.

Rapid tranquillisation

1.7.21 Use intramuscular lorazepam for rapid tranquillisation in a child or young

person and adjust the dose according to their age and weight.

In May 2015, lorazepam was off label in children and young people for this indication.

1.7.22 If there is only a partial response to intramuscular lorazepam, check the dose again according to the child or young person's age and weight and consider a further dose.

1.7.23 Monitor physical health and emotional impact continuously when undertaking rapid tranquillisation in a child or young person.

Seclusion

1.7.24 Decisions about whether to seclude a child or young person should be approved by a senior doctor and reviewed by a multidisciplinary team at the earliest opportunity.

1.7.25 Report all uses of seclusion to the trust board or equivalent governing body.

1.7.26 Do not seclude a child in a locked room, including their own bedroom.

2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.

2.1 Medication for promoting de-escalation

Which medication is effective in promoting de-escalation in people who are identified as likely to demonstrate significant violence?

Why this is important

Although there are studies that demonstrate the value of medication in the management of violence and aggression, there is little information on management before violence becomes overt. Often p.r.n. medication is given at this point but there is little evidence of efficacy. It is clearly preferable to avoid violence whenever possible.

This question should be addressed by a randomised controlled trial in which people at risk of becoming violent are randomised, with their consent, to 1 or more of the medications commonly used to effect rapid tranquillisation or other medication not normally used for this purpose. Outcomes should include measures of violence, degree of sedation, acceptability of the medication and adverse effects, all recorded over a suitable timescale to match the pharmacokinetic properties of the drugs.

2.2 Violence related to drug or alcohol misuse

What is the best environment in which to contain violence in people who have misused drugs or alcohol?

Why this is important

There are major problems in managing drug- and alcohol-related violence. The risk of severe violence can last for many hours in people who have misused drugs and alcohol

and most settings in which violence takes place (such as emergency departments) do not have the facilities needed to contain people for several hours with an adequate level of supervision. As a consequence many people are taken, often inappropriately, to police cells. It is likely that there are less expensive and more effective environments available for this purpose.

Data about the size of this problem and an epidemiological survey of its frequency and duration, as well as current methods of managing drug- and alcohol-related violence, are needed to start answering this question.

2.3 Advance statements and decisions

What forms of management of violence and aggression do service users prefer and do advance statements and decisions have an important role in management and prevention?

Why this is important

There are widely differing opinions among service users about the best way of managing violence and decisions are often made according to personal preference. Advance statements and decisions are not widely used, although they might have an important role in management and prevention.

The question could be answered by randomising people who are at risk of becoming violent or who have demonstrated repeated violence into 2 groups: a control group with no advance statements and decisions, and a group who make advance statements and decisions indicating the forms of management they prefer and those they do not want. The subsequent frequency of violent episodes and their outcomes could then be compared.

2.4 Content and nature of effective de-escalation

What is the content and nature of effective de-escalatory actions, interactions and activities used by mental health nurses, including the most effective and efficient means of training nurses to use them in a timely and appropriate way?

Why this is important

Although it is regularly recommended, there has been little research on the nature and efficacy of verbal and non-verbal de-escalation for adults with mental health problems who become agitated. Research is needed to systematically describe current techniques for de-escalation and develop and test these techniques with adults who have cognitive impairment or psychosis. In addition, research should be carried out to develop methods of training staff and test the outcomes of these methods.

There is a similar lack of research on the nature and efficacy of verbal and non-verbal de-escalation of seriously agitated children and young people with mental health problems. These techniques need to take account of and be adapted to the specific background, developmental/cognitive and psychiatric characteristics of this age group. Additional research should therefore be commissioned on the lines recommended for adults. The research should systematically describe expert practice in adults, develop and test those techniques in aroused children and young people with mental health problems, and develop and test different methods of training staff working with children and young people with mental health problems.

2.5 Long duration or very frequent manual restraint

In what circumstances and how often are long-duration or repeated manual restraint used, and what alternatives are there that are safer and more effective?

Why this is important

Adults who are agitated and violent sometimes continue to struggle and fight during manual restraint and rapid tranquillisation may fail. This results in long periods of restraint and further doses of medication. These occurrences are used as justifications for seclusion and, very rarely, for the use of mechanical restraint if repeat episodes occur. Yet there is no information about the frequency of such events or the demography and symptomatology of the adults who are subject to such measures. Exploratory survey work should be commissioned as a matter of urgency to assess the scope of this problem and potential measures for prevention or alternative management that minimise excessive, severe and risky containment methods.

The reasons why children and young people with mental health problems need long-duration or very frequent manual restraint may be expected to vary from those in adults but have similarly been little investigated. Exploratory survey work should therefore specifically address the scope of this problem as it affects children and young people and assess potential measures for prevention or alternative management that minimise any existing excessive, severe or risky containment methods.

Implementation: getting started

While developing this guideline, the Guideline Development Group identified 13 recommendations in 6 areas as key priorities for implementation. With input from stakeholders, experts and health professionals, 3 areas were identified as having a big impact on practice and being challenging to implement. This section highlights some important changes to practice that may result from implementing the guideline. However, other changes to practice may be needed to fully implement the guideline.

Staff working in inpatient mental health and emergency care settings may be particularly affected by these changes.

Manual restraint

Recommendations 1.4.4 to 1.4.6 and recommendations 1.4.24 and 1.4.29.

Potential impact of implementation

This guideline recommends that taking service users to the floor during manual restraint should be avoided, but that if it is necessary, the supine (face up) position should be used in preference to the prone (face down) position. The Winterbourne View Hospital: Department of Health review and response reported that restraint was being used to abuse service users. Mind's Mental health crisis care: physical restraint in crisis found that restrictive interventions were being used for too long, often not as a last resort, and sometimes purposely to inflict pain, humiliate or punish. Mind also reported that in 2011/12 the prone position was being used, in some trusts as many as 2 to 3 times a day. This position can, and has, caused death after as little as 10 minutes, by causing a cardiac event. Consistent implementation of these recommendations will save lives, improve safety and minimise distress for all involved.

Challenges for implementation

- Higher staffing levels will be needed in some settings to successfully implement these recommendations, particularly ensuring that a doctor trained to use emergency equipment is immediately available if manual restraint might be used.

- Training will be needed in psychosocial interventions to avoid or minimise the use of restrictive interventions, and about why manual restraint, when used, should last no longer than 10 minutes.

Support for implementation

- Section 1.2 of this guideline outlines how to reduce the use of restrictive interventions, including manual restraint, and other methods that can be used to reduce the risk of violence and aggression. It includes a framework for anticipating and reducing violence and aggression in inpatient psychiatric wards.
- The Department of Health's Positive and safe programme promotes a reduction in the use of restrictive interventions. Department of Health's Positive and proactive care: reducing the need for restrictive interventions and Department of Health, Skills for Care and Skills for Health's A positive and proactive workforce provide a framework to help staff working in health and social care settings to change their culture, leadership and professional practice to deliver care and support that keeps people safe and promotes recovery.
- The Mental Health Act 1983 Code of Practice provides guidance for professionals as well as guidance about for service users, their families and carers about their rights.

Return to recommendations

Rapid tranquillisation

Recommendations 1.4.37 to 1.4.45

Potential impact of implementation

Rapid tranquillisation is defined in this guideline as the administration of sedative medication by injection, and although a number of effective agents are available for sedation, there is no evidence showing clear superiority for any one agent. Therefore individualised treatment needs to be emphasised, taking into account the service user's view, pre-existing physical health problems, previous response to medications including adverse effects, the potential for interactions with other medications, and the total daily dose of medications prescribed and administered. Intramuscular lorazepam is recommended for service users who have not taken antipsychotic medication before

because it is an effective intervention that is likely to be acceptable to the majority of service users. Prescribing the initial dose of rapid tranquillisation as a single dose will ensure that any subsequent treatment options can be individualised, taking account of both response and any emergent adverse effects of the initial treatment choice.

Challenges for implementation

- During development of the guideline it became known that the manufacturer of intramuscular olanzapine had decided to withdraw the product from the UK market, and so the Guideline Development Group would not be able to make recommendations for its use. However, it remains a licensed product in the European Union (EU) and some organisations import the product from elsewhere in the EU.
- Local rapid tranquillisation policies and protocols will need revision and healthcare professionals will need educating in how these differ from previous versions. It may also be necessary to emphasise the need to tailor the choice of medication for rapid tranquillisation to the individual. Where rapid tranquillisation is used, adequate numbers of skilled staff should be available to monitor the outcome of the intervention in order to make an individualised decision about subsequent choice of medication and dose frequency.

Support for implementation

- The rationale for the recommendations is described in section 6.5.1 of the full guideline.
- The cost difference between medication options is not large and the most cost-effective strategy is likely to be one that tailors treatment to the individual, taking into account their preferences, current medication and medication history.
- The use of intramuscular lorazepam for service users who have not taken antipsychotic medication before is supported because of its favourable benefit:harm profile.
- Although it is possible to import intramuscular olanzapine into the UK as an EU-licensed product, the Guideline Development Group was unable to comment on the use of this preparation because the manufacturer had withdrawn it from the UK market.

- These recommendations do not preclude the use of alternative treatment options. However, their use should be tailored to the individual in line with the recommendations for rapid tranquillisation.
- The summary of product characteristics for haloperidol recommends a baseline electrocardiogram (ECG). If an ECG is not available the prescriber should consider the risks and benefits of using this treatment and be able to justify their prescribing decision, because it may be considered an off-label use.

Return to recommendations

Formal external post-incident reviews

Recommendations 1.4.53 to 1.4.63

Potential impact of implementation

Formal external post-incident reviews are an important aid in identifying the causes and effects of violence if restraint is needed to contain a situation, and the impact of this on all involved. Full recording of incidents of violence and aggression is currently variable and therefore it is difficult to get a clear picture nationally. Mind's Mental health crisis care: physical restraint in crisis reported responses from freedom of information requests made to all 54 mental health trusts in England in 2013 about the use of prone restraint. Of these, 27 trusts did not record this information.

The information gathered during a review can inform future service delivery and, on an individual level, any further work with the service user involved to make it less likely that a similar event will happen again. Use of formal external post-incident reviews could lead to safety improvements for staff and service users, and save costs to the service long-term if, as a result of the review, positive changes are made to avoid such situations in the future.

Challenges for implementation

- In organisations where formal external post-incident reviews are not carried out routinely, new policies and processes will need to be developed; staff will need to be trained to carry out the reviews and service users will need to be supported to take part in this process.

- Additional training and guidance will be needed about when and how to approach service users to include them in the process in ways that meet their needs.
- Getting all of the necessary staff, including a doctor, in addition to volunteers and service users to participate in the review process may have an impact on current workload and service capacity.
- In some settings there can be many incidents in a short time. In such circumstances implementing the 72-hour follow-up may be more challenging.

Support for implementation

- The framework outlined in recommendation 1.2.7 can be used to determine the factors that contributed to an incident that involved using a restrictive intervention.
- No economic evidence was found on post-incident management strategies. Clear costs are incurred when considering the staff time needed to deliver comprehensive post-incident reviews. These costs may be recouped by the potential for improved relationships and better understanding of events, allowing safer and more adaptive practice in the future.

Return to recommendations

Finding more information and committee details

You can see everything NICE says on this topic in the NICE Pathway on violence and aggression.

To find NICE guidance on related topics, including guidance in development, see the NICE webpage on mental health services.

For full details of the evidence and the guideline committee's discussions, see the full guideline. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting our guidelines into practice, see resources to help you put NICE guidance into practice.

Update information

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Author(s)	Stephen Guy, Lead Mental Health Pharmacist			
Ownership:	Dr Cathy Jack, Medical Director			
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14/11/2009	0.2	S Guy S Cooper	Incorporation of comments on consultation.
11/6/2010	0.3	S Guy	Update in light of changes in Maudsley Guidelines. Aripiprazole IM added
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2/6/2011	0.6	S Guy Chris Kelly	Changes from D&T committee meeting 14/1/2011
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7/6/2016	1.2	S Guy	Comments from Medical Staff consultations
16/11/2016	1.3	S Guy	Acceptance that policy applies within Emergency Departments

1.0 INTRODUCTION / PURPOSE OF POLICY

1.1 Background

Violence and aggression refer to a range of behaviours or actions that can result in harm, hurt or injury to another person. The violence or aggression can be physical or verbal. Rapid tranquillisation is the use of medication by the Intramuscular route if oral medication is not possible or appropriate and urgent sedation with medication is needed.

1.2 Purpose

The purpose of this Guideline is to ensure a consistent approach to Rapid Tranquillisation or the acute management of violent and aggressive behaviour in order to minimise risk

This Guideline should be read alongside the Policy on the Use of Restrictive Practices in Adults and Children's Services (S&G 15/09)

2.0 SCOPE OF THE POLICY

2.1 This guideline describes intramuscular (IM) medication treatment options that may be used to manage violence and aggressive behaviour in adults, older adults, children and young people when oral medication is not possible or appropriate and urgent sedation is needed. This is commonly called Rapid Tranquillisation (RT)

2.2 The policy applies to adult mental health inpatient units, child and adolescent mental health inpatient units, learning disability inpatient units and to people with violence and aggression associated with mental illness in Emergency Departments

2.2 In addition this guideline outlines the use of "as required" or PRN oral medication that may be considered as part of a strategy to de-escalate or prevent situations that may lead to violence and aggression

2.3 The Trust Policy Use of Restrictive Interventions for Adult & Children's Services (S&G 15/09) sets out the circumstances where restrictive practices may be used and the interventions in this Guideline must be used within the framework of the restrictive interventions policy

2.4 This guideline describes the physical observations and monitoring required after Rapid Tranquillisation has been administered. This guideline is not aimed at the management of violence and aggression encountered on general medical wards however, it might offer useful guidance for staff in these environments. In these situations, clinicians may wish to seek further advice on management from a psychiatrist

2.0 ROLES/RESPONSIBILITIES

This Guideline should be implemented on all mental health, learning disability, child and adolescent mental health inpatient wards and Emergency Departments

3.1 It is the responsibility of the Medical Director to ensure implementation of this guideline.

3.2 All staff involved in the Rapid Tranquillisation of patients presenting with aggressive or violent behaviour should be aware of this guideline and follow it when it is appropriate to do so.

3.3 Clinicians should use their own clinical judgement in each case and if they decide that a different management approach is clinically indicated then the reasons for this should be clearly documented. This is particularly important in Level 3 interventions as there is less evidence to guide practice. Some of the recommendations in Level 3 are not mentioned in the NICE Violence (NG10) Guideline. The NICE guideline does clearly state that its recommendations do not preclude the use of alternative treatments provided their use is tailored to the individual's clinical circumstances. It is the prescriber's responsibility to clearly document the rational for their treatment choice in these circumstances.

4.0 KEY POLICY PRINCIPLES

Definitions

- *Rapid Tranquillisation* - The use of medication by the intramuscular route if oral medication is not possible or appropriate and urgent sedation with medication is needed.

- *Adult* - A person over the age of 18yrs

- *Child* – A person aged 12 years and under

- *Young Person* –A person aged between 13 and 17 years

- *Violence and Aggression* - a range of behaviours or actions that can result in harm, hurt or injury to another person. The violence or aggression can be physical or verbal.

Key Policy Statement(s)

Policy Principles

4.1.1 This guideline does not apply to the management of delirium or acute alcohol withdrawal.

4.1.2 Rapid Tranquillisation should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques and should

only be considered when de-escalation, including oral PRN, have failed to produce a satisfactory response

4.1.3 Staff should be trained, to a level appropriate to their role, in how to assess and manage potential and actual violence or aggression using de-escalation techniques, restraint and pharmacological management. Staff should also be trained to use Immediate Life Support when appropriate.

4.1.4 If the patient has expressed a preference for a particular antipsychotic in an Advance Decision consider prescribing this if appropriate to the clinical circumstances.

4.1.5 Before administering an intramuscular medication, the patient must be given the opportunity to take oral medication if it is thought this would be effective and appropriate in the clinical circumstances. If oral medication is given in these cases staff should consider if initiating the post RT monitoring in Appendix E might be appropriate.

4.1.6 Only exceed the BNF maximum daily dose (including PRN. dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented, and carried out under the direction of a senior doctor. Consider lower maximum doses in older adults or the physically frail.

4.1.7 An Incident Form (IR1) must be completed after each instance of RT. NOTE an IR1 is not an automatic requirement after use of oral PRN medication given as part of a de-escalation strategy unless warranted by other events.

4.1.8 If Rapid Tranquillisation is being used, a senior doctor should review all medication at least once a day.

4.1.8 All staff should be aware of the legal framework that authorises the use of these interventions. If repeated interventions are required, give consideration to use of the Mental Health Order NI (1986)

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

This Guideline is relevant to the following staff groups

5.1.1 Medical staff working in adult, child and adolescent mental health wards, learning disability wards and Emergency Departments

5.1.2 Nursing staff working in adult, child and adolescent mental health wards, learning disability wards and Emergency Departments

5.1.3 Pharmacists working in adult, child and adolescent mental health wards, learning disability wards and Emergency Departments

5.1.4 This guideline should be implemented by relevant services within 3 months of approval. If this timescale can't be met then the Co-Director for Mental Health should be notified

5.2 **Resources**

A training needs analysis is included in Appendix F. It is the responsibility of the Co-Director and the Associate Medical Director for mental health to ensure training is in place.

Training on Rapid Tranquillisation forms part of the Induction Training for Medical Staff on rotational training placements.

Training on Rapid Tranquillisation is part of the MAPA 5 day training for Staff working in Mental Health Inpatient units

5.3 **Exceptions**

There are no exceptions.

6.0 MONITORING

Compliance with this Guideline will be monitored by reviewing either

- Case notes of patients who undergo rapid tranquillisation
- Incident forms completed after rapid tranquillisation
- Physical Intervention monitoring forms completed after episodes of restraint

This monitoring should include any section 75 implications of implementing the policy.

7.0 EVIDENCE BASE / REFERENCES

Maudsley Prescribing Guidelines 12th Edition, Taylor, D, Paton C, Kapur S, Wiley Blackwell, London 2015

NICE: NG10, Violence and aggression: short-term management in mental health, health and community settings: May 2015.

NICE: CG178, Psychosis and schizophrenia in adults: prevention and management: February 2014

SPc Haloperidol tablets and Injection (Mercury Pharmaceuticals), Electronic Medicines Compendium, www.medicines.org.uk accessed 6/6/2016

SPc Aripiprazole Injection 7.5mg/ml Electronic Medicines Compendium, www.medicines.org.uk accessed 6/6/2016

SPc Olanzapine tablets and Injection, Electronic Medicines Compendium, www.medicines.org.uk accessed 6/6/2016

SPc Risperidone tablets, Electronic Medicines Compendium, www.medicines.org.uk accessed 6/6/2016

SPc Lorazepam Tablets and Injection Electronic Medicines Compendium, www.medicines.org.uk accessed 6/6/2016

8.0 CONSULTATION PROCESS

The following were consulted and asked for comments on draft versions of this policy

- Consultant medical staff working in Adult Mental Health services
- Consultant medical staff working in child and adolescent mental health services (CAMHS) and CAMHS learning disability services
- Consultant medical staff working in Adult Learning Disability Services
- Senior Mental health nurse managers

9.0 APPENDICES / ATTACHMENTS

Appendix A - Medication in Acute Psychiatric Emergencies
Appendix B - Dose Information for medicines used in Rapid Tranquillisation
(Refer to flow charts for place in RT)
Appendix C - Pharmacological management of violent and aggressive behaviour (FOR ADULTS OVER 18 YEARS)
Appendix D - Pharmacological management of violent and aggressive behaviour (for Children and Young People under 18 YEARS)
Appendix E - Rapid Tranquillisation - Monitoring
Appendix F - Rapid Tranquillisation Training Needs Analysis

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out. The outcome of the Equality screening for this policy is:

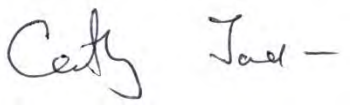
Major impact ☐

Minor impact ☐

No impact. X

SIGNATORIES
(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

_____ **Date: ___February 2017____**
Author



_____ **Date: ___February 2017____**
Director

(Appendix A)

Medication in Acute Psychiatric Emergencies

Introduction

This guideline is based around NICE NG10 Violence and aggression: short term management in mental health, health and community settings (2015). All staff should familiarise themselves with the NICE Violence and Aggression pathway which serves as a useful summary of the full NICE guideline. The Pathway also offers guidance on prevention and de-escalation strategies which are not described in this medicine related guideline.

Level 1 describes oral "as required" (PRN) management options that may be offered as part of a strategy in order to de-escalate or prevent situations that might lead to violence and aggression. The NICE guideline clearly states that PRN medication on its own is not de-escalation.

Level 2 describes Intramuscular (IM) management options which should only be considered when there is actual or clear risk of violence or aggression and de-escalation and other preventative strategies including PRN have failed. It is common practice for patients to be prescribed the same PRN medicine to be administered orally or if indicated intramuscularly. Administration of the PRN medication intramuscularly would not be de-escalation and must be considered Rapid Tranquillisation (RT). De-escalation attempts should continue up to the administration of IM medication, if in these circumstances the person then accepts oral medication instead of IM, consider if initiating the post RT monitoring in Appendix E might be appropriate.

Level 3 describes interventions to consider if Level 2 interventions have failed to produce a sufficient response. Level 3 interventions should only be used by or after consultation with a senior doctor. Level 3 interventions include

- Repeating the same Level 2 intervention
- Alternative approaches in Level 2 that were not offered
- Different strategies including medicines or combinations not included in NICE NG10. These must be tailored to the individual and might be guided by previous response in similar circumstances. The rationale and outcome must be clearly recorded

1.0 General Prescribing Principles

When prescribing PRN medication as part of a de-escalation strategy or medication for rapid tranquillisation it is important to individualise the dose and type of medication for each service user. This will depend on several factors including previous response to medication, age, allergies, physical problems (renal, hepatic, cardiovascular or neurological disease) other prescribed medication and possible use of drugs of abuse. Consider the following points when prescribing

- Check that the patient has not had previous allergy or severe idiosyncratic reaction to the drugs to be used.

- Check there is no recent history of Neuroleptic Malignant Syndrome or hyperthermia.
- Simultaneous administration of IM antipsychotics and IM benzodiazepines (lorazepam) may be associated with excessive sedation and cardio respiratory depression. If this combination is deemed necessary, then patients must be monitored for excessive sedation and for postural hypotension. (Note this is a Level 3 intervention)
- Patients taking clozapine and olanzapine require care when giving benzodiazepines, in particular parenterally, as potentially fatal orthostatic and cardio-respiratory dysregulation have been reported. If this combination is considered necessary, it is essential to undertake frequent monitoring of the patient especially after the use of IM preparations.
- If the patient has expressed a preference for a particular antipsychotic in an Advance Decision, consider prescribing this if warranted by clinical circumstances.
- Avoid unnecessary polypharmacy. This may necessitate careful choice of drug in relation to either current treatment or expected maintenance treatment.
- Carefully consider the number of active PRN prescriptions operative at any one time in relation to the risk of inadvertent overdose. Check if the patient is prescribed the same or similar medicine as a regular and PRN.
- Prescribe oral and IM doses separately – do not use PO/IM abbreviation.
- When administering more than one IM medicine don't mix medications in the same syringe.
- When prescribing haloperidol in combination with promethazine, do not pre-emptively administer procyclidine to reduce risk of EPSE. The rationale for haloperidol combined with promethazine is improved tolerability (lower incidence of EPSE), Prescribing promethazine and procyclidine together is likely to increase anticholinergic side effects.
- Patients entering LEVEL 2 on the protocol must have details of all medicines administered, rational of use and an assessment of effectiveness recorded in the clinical notes. All current PRN prescriptions on the kardex should be discontinued and reviewed in 6-12 hours after which they may be re-prescribed if necessary.

1.1 Maximum Doses

Only exceed the BNF maximum daily dose (calculate total dose including PRN dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented, and carried out under the direction of a senior doctor. If BNF doses are exceeded in Rapid Tranquillisation, undertake frequent and intensive monitoring post incident. Monitor level of consciousness, pulse, blood pressure, respiratory effort, temperature and hydration. (Appendix E).

1.2 Prescribing PRN medication

As required (PRN) medication may be prescribed as part of a de-escalation strategy to prevent situations that might lead to violence and aggression or during the rapid tranquillisation process. When prescribing PRN medication take the following points into consideration.

- Do not prescribe PRN medication routinely or automatically on admission
- Individualise PRN medication and discuss with the patient if possible
- State the rationale for prescribing PRN e.g. “for agitation” and ensure this is recorded in the care plan.
- If more than one PRN medication is prescribed for the same indication the prescription should state which is first line and which is second line for the indication.
- State the maximum dose of PRN that can be administered in a 24 hour period.
- State the minimum interval between PRN doses.
- When possible avoid variable doses of PRN e.g. lorazepam 1–2mg as this leads to higher doses being administered without review.
- Check that prescribing PRN medication does not inadvertently lead to exceeding the maximum BNF dose when combined with the patient’s regular medication.
- Only exceed the BNF maximum daily dose (calculate total dose including PRN dose, the standard dose and dose for rapid tranquillisation) if this is planned to achieve an agreed therapeutic goal, documented, and carried out under the direction of a senior doctor.

1.3 Cardiovascular Safety

Antipsychotics as a group are probably associated with an increased risk of QTc prolongation. Normal limits of QTc are less than 440 ms in men and less than 470 ms in women. Limited evidence suggests the risk of arrhythmia increases exponentially beyond normal limits, with strong evidence that QTc greater than 500ms is clearly linked to an increased risk of arrhythmia. The risk is dose related and the risks for individual drugs are probably additive when they are used in combination.

Table 1 summarises the risk for common antipsychotics

Table 1

Low Effect **No or average increase <10msec at clinical doses or severe effect only reported following overdose**	**Moderate Effect** **Average increase >10msec at clinical doses or ECG officially recommended**	**High Effect** **Average increase >20msec**
Aripiprazole Asenapine Clozapine Flupentixol Fluphenazine Lurasidone Olanzapine Paliperidone Risperidone Sulpiride	Amisulpride* Chlorpromazine Haloperidol Levomepromazine Quetiapine	Any intravenous antipsychotic Pimozide Sertindole Any antipsychotic or combination of antipsychotics used in doses exceeding BNF maximum dose

*Torsades de pointes common in overdose with Amisulpride
Table adapted from the Maudsley Guideline 12th edition, 2015

The NICE Guideline CG 178 Psychosis and schizophrenia in adults: prevention and management recommends that before starting an antipsychotic, an ECG should be offered if the person is admitted as an inpatient. In particular, the Summary of Product Characteristics for haloperidol recommends a baseline ECG. If an ECG is not available the prescriber should consider the risks and benefits of using intramuscular haloperidol and be able to justify their prescribing decision, because it may be considered an off-label use

A number of non-psychotropic medications are associated with prolonged QTc. These are shown in Table 2

Table 2

Antibiotics	Antimalarials	Antiarrhytmics	Others
Erythromycin	Chloroquine	Quinidine	Amantadine
Clarithromycin	Mefloquine	Disopyramide	Ciclosporin
Ampicillin	Quinine	Procainamide	Diphenhydramine
Co-trimoxazole		Sotalol	Hydroxyzine
Ciprofloxacin		Amiodarone	Methadone
Levofloxacin		Bretylium	Nicardipine
Moxifloxacin			Tamoxifen

Table adapted from the Maudsley Guidelines 12th edition, 2015

1.4 Drug Selection

See Appendix B for a summary of recommended drugs and recommended doses for different age groups.

A benzodiazepine may be the safest and best tolerated drug with which to effect 'rapid tranquillisation' of the patient. Once the patient has been calmed, either by de-escalation techniques or by a benzodiazepine, an antipsychotic drug may be best for maintenance of the situation. Remember that repeated use of a benzodiazepine may result in tolerance to the effect and this will probably become evident by 7 to 10 days.

2.0 Rapid tranquillisation For Adults over 18 years

The flow chart in Appendix C outlines a stepped approach to rapid tranquillisation for Adults over 18 years of age.
If you are unsure about initial pharmacological management then always call a more senior doctor. If you are a junior doctor and your initial drug treatment does not work then you should consider discussion with someone more senior. If you are a Consultant and have tried two or three approaches without success, then it may be wise to seek a second opinion from a colleague. If the incident is outside a mental health unit, clinicians may wish to consult a psychiatrist for further advice.

3.0 For Children and Young People under 18yrs of age

The NICE Guideline on Violence and Aggression states that restrictive interventions (which includes Rapid Tranquillisation) should only be used if all attempts to defuse the situation have failed and the child or young person becomes aggressive or violent.

Staff must be familiar with and use the de-escalation techniques outlined in the NICE guideline to avoid having to use a restrictive intervention

3.1 General Prescribing Principles in Children and Young People

The general prescribing principles for adults outlined in Section 1.0 apply when prescribing for children and young people.

3.2 Consent

Medication can be given against a child's will with parental consent i.e. permission from a person with Parental Responsibility under The Children's Act NI and or common law. If repeated medication is required, the Mental Health Order NI (1986) should be considered. Children and young people should be informed that a medication is going to be given and always given the opportunity to accept oral medication.

3.3 Rapid Tranquillisation for Children and Young People

The flow chart in Appendix D outlines a stepped approach to rapid tranquillisation for Children and Young People aged between 6 and 18 years of age.
If you are unsure about initial pharmacological management then always call a more senior doctor. If you are a junior doctor and your initial drug treatment does not work then you should consider discussion with someone more senior. If you are a Consultant and have tried two or three approaches without success then it may be wise to seek a second opinion from a colleague. If the incident is outside an adolescent mental health setting, clinicians may wish to consult a child and adolescent psychiatrist for further advice.

4.0 For Older Adults (65+) Without Dementia

This guideline applies to the management of acutely disturbed behaviour and <u>not</u> to the management of delirium.

Follow the flow chart for Adults over 18 after considering the information below and the specific dose information for Older Adults without Dementia in Appendix B

There is evidence that antipsychotics are associated with increased mortality (probably by increasing the risk of cerebrovascular adverse events) even in people without dementia. A cautious approach is recommended.

- Oral medication should always be offered whenever possible.
- Lorazepam, starting at a low dose, is the preferred first line treatment.
- If there is confirmed history of previous antipsychotic use then oral haloperidol or olanzapine may be considered.

- If a patient requires IM medication, lorazepam should be used first line.
- IM haloperidol or IM olanzapine may be used if there is confirmed history of previous antipsychotic use.
- When using haloperidol in older adults consideration should be given to the appropriateness of combining with promethazine due to the increased risk of additive anticholinergic side effects and increased confusion.
- If previous use of antipsychotics can't be confirmed and lorazepam fails to control the situation, low dose olanzapine or haloperidol may be considered. In such cases it may be appropriate to consult a doctor experienced in the management of older people.

5.0 For people with dementia

Follow the flow chart for Adults over 18 after considering the information below and the specific dose information for People with Dementia in Appendix B

Non-pharmacological options should be considered as first line management. If this is ineffective, then lorazepam may be considered. Risperidone is licensed for short-term use for persistent aggression in people with moderate to severe Alzheimer's dementia. The starting dose is 0.25mg twice daily increased to 0.5mg twice daily. If ongoing use of risperidone is considered necessary then the advice of a doctor experienced in the management of dementia should be sought.

In very exceptional circumstances, when oral treatment is impossible, low dose haloperidol IM may be used. In these cases, consider consulting a doctor with experience in managing disturbed behaviour in people with dementia.

6.0 Physical Health and Side Effect Monitoring after Use of Intramuscular medication

Appendix E summarises the monitoring required after rapid tranquillisation (i.e. IM administration of medicines)

Physical health and side effect monitoring is essential after an episode of rapid tranquillisation. Note routine monitoring is not automatically required after oral medication unless it is clinically indicated by the patient's condition.

The following observations should commence 15 minutes after each episode of rapid tranquillisation and be documented on the Trust Standard Observation form

- Respiratory rate
- Sa02 if clinically indicated or if patient is asleep
- Pulse
- Blood Pressure
- Temperature
- Level of Consciousness

In addition observe for side effects of medication and maintain good hydration. When possible, obtain an ECG after administration of an IM antipsychotic. An ECG is essential after administration of an antipsychotic to a young person. Staff should be sufficiently trained to interpret ECG traces (including calculation of QT/QTc interval). If an ECG shows any cause for concern then contact a physician for advice on patient management. Record these observations and any actions in the clinical notes.

6.1 Frequency of monitoring
After rapid tranquillisation carry out the required observations every 15 minutes for the first hour.

After one hour, continue observations at least every hour until there are no further concerns about physical health status.

Consider extended or more frequent monitoring in the following circumstances

- The BNF maximum dose of a prescribed medicine has been exceeded
- The patient appears to be asleep or sedated
- Concerns about possible illicit drug or substances or alcohol use
- Pre-existing physical health problem
- The patient experienced any harm as a result of a restrictive intervention

6.2 Documentation of side effect and physical health monitoring
Checks for side effects after rapid tranquillisation should be recorded in the clinical notes. Physiological observations must be recorded on the Standard Observation Chart and EWS scores calculated in accordance with the Trust Policy on Measuring and Recording Physiological Observations

6.2 Refusal to co-operate with side effect and physical health monitoring
If patients refuse physiological observation or of they remain too behaviourally disturbed to be approached, this must be documented in the patients notes at each time monitoring would have been due. The patient should be observed for sign/symptoms of pyrexia, hypotension, over sedation and general physical well-being and documented accordingly

7.0 Drugs NOT recommended for rapid tranquillisation

The following drugs are NOT recommended for rapid tranquillisation:

- Oral and IM chlorpromazine – IM chlorpromazine is painful and can cause severe hypotension. Chlorpromazine must never be given intravenously.
- IM diazepam – absorption is erratic.
- IM depot antipsychotics.
- Olanzapine in dementia related disturbance.
- Zuclopenthixol acetate is <u>not</u> recommended for routine use in rapid tranquillisation due to its slow onset of action. It may however be

recommended as a LEVEL 3 intervention by a senior doctor or consultant when:

- The patient is disturbed/violent over an extended time period
- Past history of good/timely response
- Past history of repeated parenteral administration required
- Cited in an advance decision

8.0 Actions after Rapid Tranquillisation

A doctor should be available to quickly attend an alert by staff members when Rapid Tranquillisation has been implemented, for an appropriate period of time to ensure the treatment has been effective and that undue adverse effects are no longer likely to occur.

A report of use of Rapid Tranquillisation should be made on a Trust Incident Form. A post-incident review may be held within 72 hours.

Dose Information for medicines used in Rapid Tranquillisation (Refer to flow charts for place in RT) (Appendix B)

Medication	Child (6- 12 years)	Adolescents (13 – 17)	Adults (18 – 65)	Older People (65+)	People with Dementia
Lorazepam tablets and IM injection	By Mouth or by IM injection 0.5 – 1mg Maximum 4mg/24hrs	By Mouth OR by IM injection 0.5mg - 2mg Maximum 4mg/24hrs	By Mouth Or by IM injection 1mg - 2mg Maximum 4mg/24 hours	By Mouth Or by IM injection 0.5mg - 1mg Maximum 4mg/24 hours	By Mouth Or by IM injection 0.5mg - 1mg Maximum 4mg/24 hours
Aripiprazole IM injection	NOT APPLICABLE	NOT APPLICABLE	By IM injection 9.75mg (1.3ml) – Consider lower dose (5.25mg) on basis of clinical status Effective range 5.25 –15mg Max dose 30mg/24hrs by any route	Effectiveness in over 65's not established. Consider lower doses on basis of clinical status	**Not Recommended**
Risperidone tablets and oral solution	<50kg 0.5mg once daily >50kg 1mg once daily	<50kg 0.5mg once daily >50kg 1mg once daily	NOT APPLICABLE	NOT APPLICABLE	By mouth in Alzheimer's dementia 0.25 – 0.5mg twice daily.
Olanzapine tablets and Orodispersible tablets	NOT APPLICABLE	NOT APPLICABLE	By mouth 10mg Maximum 20mg/24 hours	As a second line option By mouth 5 - 10mg Maximum 20mg/24hrs	**DO NOT USE OLANZAPINE IN PEOPLE WITH DEMENTIA**
Olanzapine IM injection	NOT APPLICABLE	By IM injection 2.5mg – 10mg Maximum of 3 injections in 24 hours with at least 2 hours between injections. When used for RT, Maximum of 20mg/24 hrs by all routes.	By IM injection 5 – 10mg Maximum of 3 injections in 24 hours with at least 2 hours between injection. When used for RT, Maximum of 20mg/24 hrs by all routes.	By IM injection >60 yrs 2.5mg – 5mg Maximum of 3 injections in 24 hours with at least 2 hours between injections When used for RT, Maximum of 20mg/24 hrs by all routes.	**DO NOT USE OLANZAPINE IN PEOPLE WITH DEMENTIA**
Haloperidol injection	NOT APPLICABLE	**If no recent ECG, consider risk/benefits as use may be unlicensed.** By IM injection 1mg – 5mg Maximum 10mg/24hrs	**If no recent ECG, consider risk/benefits as use may be unlicensed.** By IM injection 5mg Maximum 18mg/24 hours	**If no recent ECG, consider risk/benefits as use may be unlicensed.** Only use first line only with a confirmed history of previous tolerability to typical antipsychotics. Start with lower doses than the 18-65 age group	Use only in very exceptional circumstances. Consider consulting a doctor with experience in dementia. **Do not use in dementia with Lewy Bodies**
Haloperidol Oral solution and tablets	NOT APPLICABLE	By Mouth in psychosis 1mg - 5mg Maximum 10mg/24hrs	By Mouth 5mg - 10mg Maximum 20mg/24 hours	Only use first line only with a confirmed history of previous tolerability to typical antipsychotics. Start with lower doses than the 18-65 age group	**Consider oral risperidone as an alternative**
Promethazine	NOT APPLICABLE	NOT APPLICABLE	By IM injection 25 – 50mg Maximum 100mg/24hrs	Consider appropriateness if confusion is a concern. Consider lower doses than 18-65yrs group	**Not Recommended**

NOTES:

- Remember, 0.5mg lorazepam is equivalent to 5mg diazepam.
- Haloperidol 5mg IM is equivalent to approx. 8mg – 10mg orally.
- Orodispersible tablets offer no advantage in speed of onset but are harder to spit out or conceal.
- Olanzapine IM and lorazepam IM should not be used within one hour of each other and then only after careful consideration with strict post-injection monitoring.
- There is probably an increased risk of cerbro-vascular events in older patients with all antipsychotics.
- Lorazepam is unlicensed for control of aggression in under 12's. Risperidone is only licensed <12yrs for aggression associated with Conduct Disorder

Pharmacological management of violent and aggressive behaviour (FOR ADULTS OVER 18 YEARS) (Appendix C)

See Appendix B for additional information on the management of older people and people with dementia

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques

LEVEL 1

Accepting oral meds and as part of de-escalation strategy

- Continue de-escalation strategy
- Consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances
- Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response

Suggested oral medication

Lorazepam 1 - 2mg
(Max 4mg/24hrs)
OR
Haloperidol 3 - 5mg
(max 20mg/24hrs)
OR
Olanzapine 10mg
Do not use in Dementia
(Max 20mg/24hrs)

Continue de-escalation strategy.
If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

When deciding which medication to use, consider

- Oral risperidone in people with Alzheimer's dementia (Appendix B)
- Oral lorazepam is preferred with
  - an uncertain history
  - presence of cardiovascular disease
  - Current illicit drug/alcohol intoxication
- Oral antipsychotics preferred with
  - Current regular benzodiazepine use
  - History of respiratory depression

LEVEL 2

Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate

- Review all medication administered in the last 24 hours – be aware of BNF max doses
- Ensure resuscitation equipment and emergency bag is available within 3 minutes

Suggested IM medication

Lorazepam IM 1 - 2mg
(Max 4mg/24hrs)
(IV flumazenil must be available)
OR
Haloperidol IM 5mg
(Max 18mg/24hrs)
Combined with
Promethazine IM 25 - 50mg
(Max 100mg/24hrs)

If there is continued concern seek advice from a more senior doctor before proceeding further

When deciding which medication to use, consider

- Lorazepam as first line if history is unclear or antipsychotic naive
- Pre-existing physical health problems or pregnancy
- Avoiding haloperidol in cardiovascular disease or if there has been no recent ECG
- Previous response, including adverse effects
- Potential for interactions with other medicine
- Possible intoxication
- Promethazine is contraindicated in CNS depression
- Promethazine may be unsuitable in older adults with confusion due to its anticholinergic effects.

LEVEL 3

Situation rapidly deteriorating or failure to respond to LEVEL 2 interventions

If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor must review all treatment and response every 24 hours.
If one round of LEVEL 2 interventions have had insufficient effect a senior doctor should review treatment and consider the following

- The appropriateness of current placement
- Age and physical presentation
- Check sufficient time has been allowed for response
- If there has been a partial response to a LEVEL 2 intervention, consider repeating that intervention
- If a LEVEL 2 intervention has had insufficient effect consider offering the alternative LEVEL 2 intervention

If LEVEL 2 interventions have had insufficient effect

- Carry out a full review of treatment to date and seek a second opinion if needed.

Options to consider as part of an individualised care plan include

- Further repeats of LEVEL 2 interventions
- Haloperidol IM combined with Lorazepam IM
- Olanzapine IM 10mg (Max 20mg by all routes). Do not combine with IM lorazepam and use with caution if IM lorazepam has been given within 1 hour.
- Aripiprazole IM 9.5mg (Max 30mg)
- Clopixol Accuphase (see guideline notes)

Pharmacological management of violent and aggressive behaviour (for Children and Young People under 18 YEARS)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques (Appendix D)

LEVEL 1
Accepting oral meds and as part of de-escalation strategy

- Continue de-escalation strategy
- Consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances
- Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response

Children 6-12 yrs Suggested Oral Medication

Lorazepam 0.5 – 1mg (Max 4mg/24hrs)	Continue de-escalation strategy. If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

Young People 13-18yrs Suggested Oral Medication

Lorazepam 0.5 - 2mg (Max 4mg/24hrs) **OR** **Haloperidol 1 – 5 mg** (max 10mg/24hrs) **OR** **Risperidone <50kg 0.5mg, >50kg 1mg** (Max 3mg/24hrs)	Continue de-escalation strategy. If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

See Adult flow chart for things to consider when choosing which medication to use

LEVEL 2
Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate

- Consult a CAMHS doctor before using IM medication in a child under 12yrs of age
- Consult a CAMHS doctor before using IM medication in a young person (13-18yrs) unless IM medication is already included in the young person's care plan.
- Check if an individual care plan recommends an approach not covered in this guideline
- Review all medication administered in the last 24 hours – be aware of BNF max doses
- Ensure resuscitation equipment and emergency bag is available within 3 minutes

Children 6-12yrs Suggested IM Medication

Lorazepam IM 0.5 - 1mg (Max 4mg/24hrs)	If there is continued concern seek advice from a more senior doctor before proceeding further

Young People 13 -18 yrs Suggested IM Medication

Lorazepam IM 0.5 -2mg (Max 4mg/24hrs)	If there is continued concern seek advice from a more senior doctor before proceeding further

See Adult flow chart for things to consider when choosing which medication to use

LEVEL 3
Situation rapidly deteriorating or failure to respond to Level 2 interventions

If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor must review all treatment and response every 24 hours.
If one round of LEVEL 2 interventions have had insufficient effect a senior doctor should review treatment and consider the following options

- The appropriateness of current placement
- Check sufficient time has been allowed for response
- If there has been a partial response to lorazepam consider repeating the dose

If there has been insufficient response to lorazepam

- Carry out a full review and seek a second opinion if needed.

Options to consider at this stage include

- Further repeats of IM lorazepam
- ≥13yrs, Haloperidol IM 1 - 5mg (Max 10mg)
- ≥13yrs, Haloperidol IM combined with Lorazepam IM
- ≥13yrs, Olanzapine 2.5 - 10mg (Max 20mg by all routes). Do not combine with IM lorazepam and use with caution if IM lorazepam has been given within 1 hour.

(Appendix E)

Rapid tranquillisation - Monitoring

Following any IM drug administered for RT, or where considered clinically necessary after oral medication, monitor and record as shown below. Document and record on the Trust Standard Observation Chart (SOC) or clinical notes as appropriate.

The Early Warning Score should be calculated from the SOC each time and further action taken if indicated

Observations	Monitoring Frequency	General Comments
• Respiratory Rate • SaO2 (if appropriate) • Pulse • Blood Pressure • Temperature • Level of Consciousness • Assess for Side effects • Monitor level of hydration	Every 15 minutes for first hour. After one hour, continue observations at least hourly until there are no further concerns about physical health status. **Action when Observations are not possible** Record if the patient's mental state or behaviour prevents observations. Complete and record any observations possible, in particular signs of over sedation, pyrexia, hypotension or general malaise	• Arrange medical review of the patient after administration of IM medication • Protection of the airway is paramount • Ensure adequate levels of hydration are maintained • Consider urgent transfer to an Emergency Department if condition warrants • Pay particular attention to level of consciousness and blood pressure when IM antipsychotics and IM benzodiazepines are used in combination. • An ECG is recommended when IM antipsychotics, in particular when haloperidol or higher doses are given. • An ECG is essential after IM antipsychotics are administered to Young People.

Management of problems occurring during Rapid Tranquillisation

Problem	Remedial Measures
Acute Dystonia (including oculogyric crises)	Give **procyclidine 5 - 10mg Orally or IM** **NOTE** Do not pre-emptively administer procyclidine when IM haloperidol is combined with IM promethazine as the risk of extrapyramidal side effects (EPSE) is significantly reduced by the promethazine. If EPSE do occur after the IM haloperidol/promethazine combination, administer additional procyclidine with caution. Monitor for increased anticholinergic side effects.
Reduced respiratory rate <10/minute or oxygen saturation <92%	Give oxygen; ensure patient is not lying face down. If induced by any agent other than a benzodiazepine the patient will require transfer for mechanical ventilation. If benzodiazepine induced, give flumazenil 200microgram IV over 15 seconds. If desired level of consciousness is not obtained within 60 seconds, a further 100microgram can be injected and repeated at 60 second intervals to a maximum total dose of 1mg (1000microgram) in 24 hours (initial + 8 additional doses). Monitor respiration rate continuously until it returns to baseline level. N.B. Effect of flumazenil may wear-off & respiratory depression return – monitoring must continue beyond initial recovery of respiration
Irregular or slow pulse <50 beats/min	**Refer to specialist medical care immediately.**
Fall in blood pressure > 30mmHg drop in systolic BP on standing or diastolic BP <50mmHg	Lie patient flat, raise legs if possible. Monitor closely and seek further medical advice if necessary.
Increased temperature	**Withhold antipsychotics** –risk of NMS or perhaps arrhythmias. Monitor closely, cool the patient, and check muscle creatinine kinase. **Refer to specialist medical care** if continued or other signs of NMS present e.g. sweating, hypertension or fluctuating BP, tachycardia, incontinence (retention/obstruction), muscular rigidity (may be confined to head and neck), confusion, agitation or loss of consciousness.

(Appendix F)

Rapid Tranquillisation Training Needs Analysis

Set out below is the training needs analysis for all staff groups identifying which groups of staff require training and the level and frequency required The aim of training is to ensure that all staff are aware of their duties, role and responsibilities to enable them to implement the Rapid Tranquillisation guideline.

Staff Group	RT training including flow charts and monitoring	Medication used in RT	Basic Life Support	Immediate Life Support	Automated external defibrillator	Pulse oximetry
	Annual	Annual	Annual	Annual	Annual	Annual
Medical Staff						
Consultant	✓	✓		✓	✓	✓
Specialist Trainees	✓	✓		✓	✓	✓
Core Trainees	✓	✓		✓	✓	✓
Staff Grade	✓	✓		✓	✓	✓
F1/F2 Trainee	✓	✓		✓	✓	✓
Staff Base in Acute Inpatient Units	✓	✓		✓	✓	✓
Registered Nurse	✓	✓	✓	✓(in high risk areas)	✓	✓
Healthcare Assistant	✓(Overview)	✓(Overview)	✓			

Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation

Authors:	RT Subcommittee of the Minimising Restrictive Practice Regional Group
Authors Position:	
Responsible Director /Ownership:	Mental Health Directorate
Target Audience, i.e., specific staff groups: or Directors/Divisions policy to be issued to:	This Guideline is directed to all staff within the adult mental health, psychiatry of old age and intellectual disability inpatient settings, all acute hospital inpatient settings including emergency departments, dementia inpatient services and CAMHS inpatient settings.
Related policies, procedures and guidance	This guideline should be considered in conjunction with other relevant local and regional HSC Trust policies, procedures, guidelines, and legislation.
Approved by:	
Operational Date:	
Review Date:	

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1. Introduction

The recommendations in this regional guideline are based on the NICE NG10 Violence and aggression: short term management in mental health, health and community settings (2015). The guidance also offers guidance on prevention and de-escalation strategies which are not described in NICE NG10 which have been at arrived at after careful consideration of the evidence available. When exercising their clinical decision for the pharmacological management of acute behavioural disturbance, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients. It is not mandatory to apply the recommendations contained herein, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

This guideline adopts the definition in the British Association for Psychopharmacology / National Association of Psychiatric Intensive Care Units (BAP/NAPICU) guidelines of acute behavioural disturbance being reflective of an acute mental state associated with an underlying mental or physical disorder, symptoms of which range from agitation and distress (which may or may not lead to aggression or violence) to actual aggression or violence that causes harm or injury to another person or damage to property. The violence or aggression can be physical or verbal. Management of acute behavioural disturbance is multifaceted and in addition to medication should incorporate de-escalation techniques and non-pharmacological measures.

All staff should familiarise themselves with the NICE NG10 pathway which serves as a useful summary of the full NICE guideline and outlines other approaches to management of acute behavioural disturbance.

The focus of this guideline is on the pharmacological management in de-escalation and rapid tranquillisation (RT) only; and describes the recommended pharmacological management options that may be used to manage acute behavioural disturbance in patients cared for in Health and Social Care Trusts hospitals across Northern Ireland.

2. Purpose

The purpose of this regional guideline is to ensure a consistent approach to the management of acute behavioural disturbance, whilst maintaining patient safety and minimising risk. The safety and dignity of patients and staff are a priority.

This regional guideline sets out the standards of care that are expected by clinical team members when prescribing medication for the management of acute behavioural disturbance.

3. Scope

This guideline DOES NOT apply to the management of delirium or acute alcohol (including psychoactive substances) withdrawal. The appropriate pathways should be followed.

This guideline is concerned with the prescribing, administration and monitoring of oral PRN, intramuscular and intravenous medication and is intended to support the delivery of appropriate, safe and effective pharmacological de-escalation and RT. The guidance represents expected practice for hospital settings and replaces all previous local RT related guidance or procedures.

This guideline does not provide advice on non-pharmacological strategies for de-escalation and staff should refer to the NICE NG10 guideline for this information.

4. Definitions

Acute behavioural disturbance (ABD) is defined by British association of Psychopharmacology (BAP) as a composite term to include the concepts of ‘agitation’, ‘aggression’ and ‘violence’ in the context of an acute mental state associated with an underlying mental and/or physical disorder.

De-escalation is defined by NICE as the use of techniques (including verbal and non-verbal communication skills) aimed at diffusing anger and averting aggression. PRN medication, given orally, can be used as part of a de-escalation strategy accompanied by non- pharmacological techniques.

Oral PRN (pro re nata) is defined as when needed. In this guideline, PRN. refers to the use of medication as part of a strategy to de-escalate or prevent situations that may lead to violence or aggression; it does not refer to PRN medication used on its own for rapid tranquillisation during an episode of violence of aggression.

Rapid tranquillisation (RT) is defined by NICE as the use of medication by the parenteral route (usually intramuscular (IM) or, exceptionally, intravenous (IV)) if oral medication is not possible or appropriate and urgent sedation with medication is needed.

Violence and aggression is defined as a range of behaviours or actions that can result in harm, hurt or injury to another person. The violence or aggression can be physical or verbal.

For the purposes of this policy and to guide safe prescribing the following are recognised:
Child is defined as a person aged between 6 and 12 years.
Young person is defined as a person aged between 13 and 17 years.
Adult is defined as a person 18 years and older.
Older adults are defined as persons 65 years and over.

Parkinsonian syndrome is defined as including those patients with idiopathic Parkinson's disease, Parkinson's disease dementia and Dementia with Lewy Bodies).

SPC is defined as Summary of Product Characteristics

Senior Doctor is defined a ST4 and above, specialty and associate specialist doctors or consultant, all with experience in the pharmacological management of ABD.

5. Roles and responsibilities

5.1 The Trusts will:

- Ensure that governance arrangements are in place and will include audit procedures that relate to training needs and provision, and the review of untoward incidents.
- Ensure that when the guideline is reviewed and updated that this is supported by local governance arrangements.
- Learn and react appropriately to any untoward incidents and events related to RT.
- Respond or react to any resource implications related to RT.

5.2 It is the responsibility of the relevant service area Directors and Medical Director to ensure implementation of this guidance.

5.3 All staff involved in the RT of patients presenting with ABD should be familiar with the content of this guideline and follow it when it is appropriate to do so.

5.4 Clinicians should use their own clinical judgement in each case and if they decide that a different management approach is clinically indicated then the reasons for this should be clearly documented.

6. Training

6.1 Staff should be trained, to a level appropriate to their role, in how to assess and manage potential and actual violence or aggression using de-escalation techniques, restraint and pharmacological management.

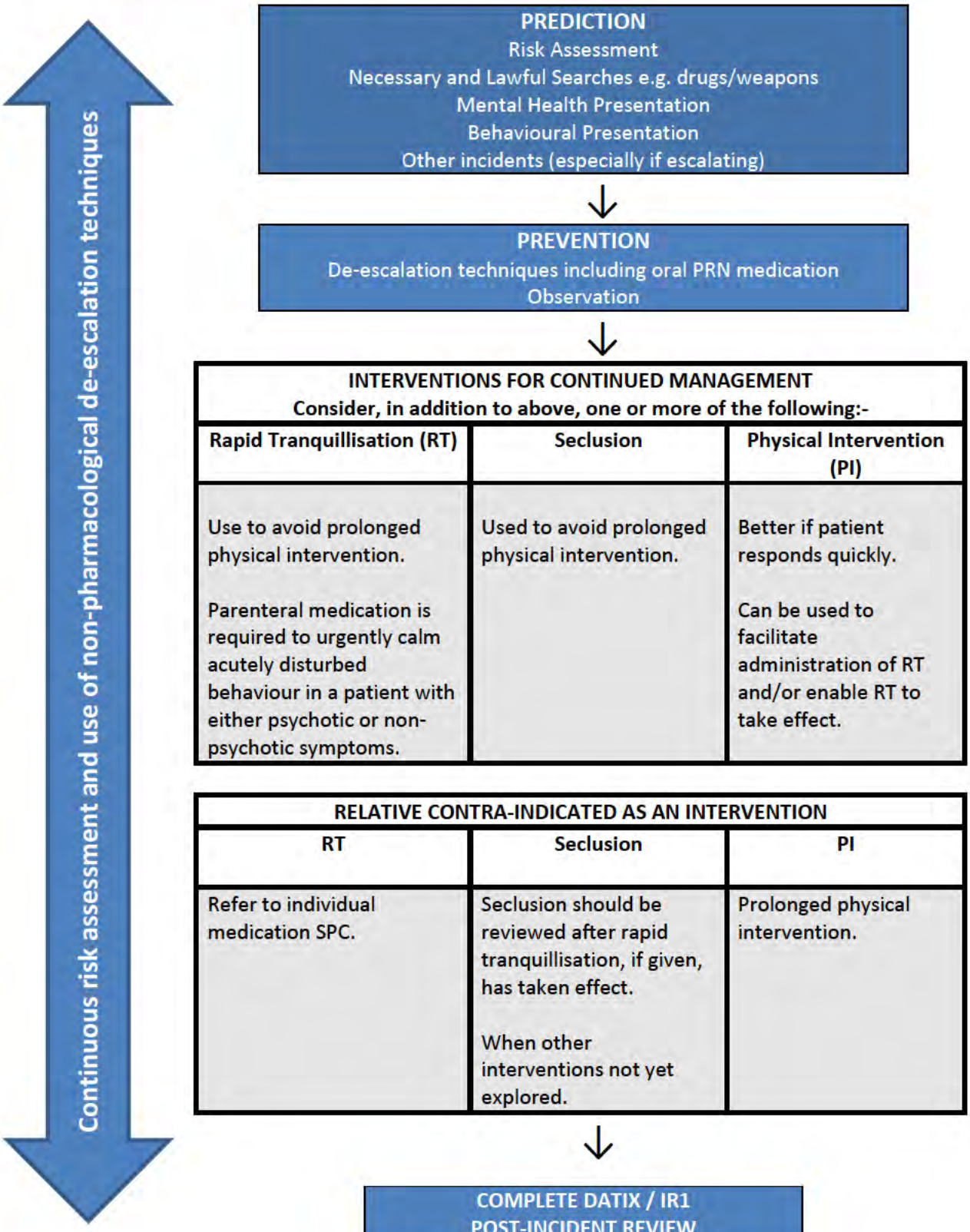
6.2 Appropriate staff should also be trained to Immediate Life Support (ILS) in the maintenance of patient's airways, cardio-pulmonary resuscitation (CPR), the use of defibrillators and the use of pulse oximeters.

6.3 Prescribers and those who administer medicines should be familiar with and have received training in rapid tranquillisation, including: the properties of benzodiazepines; antipsychotics; antimuscarinics and antihistamines, associated risks, including cardio-respiratory effects of the acute administration of the drugs.

6.4 The responsibility to ensure adequate training is undertaken lies with the service area Directors and Medical Director and should extend to include locum, agency and bank staff.

6.5 In addition for members of the Royal College of Psychiatrists, an e-learning module 'rapid tranquillisation of the acutely disturbed patient' may be for available.

7. Overview of the short-term management of ABD



8. Key Principles

8.1 Staff should adopt approaches to care that respect patients; independence, choice and human rights.

8.2 A multidisciplinary approach is required to manage harmful or potentially harmful behaviour and should involve the patient and their carers. The focus is towards prediction and prevention of potentially harmful events.

8.3 All staff involved in an incident requiring the use of restrictive practice should be aware of the potential for damage to the patient / professional relationship and ensure that everything possible is done to reduce the impact

8.4 All staff involved in RT need to be aware of the legal framework that authorises this intervention and this should be in line with the guidance contained within the RQIA Guidelines on the use of the Mental Health (Northern Ireland) Order 1986, the Mental Health (Northern Ireland) Order 1986 Code of Practice and the Mental Capacity Act (Northern Ireland) 2016 and its supporting Deprivation of Liberty Safeguards Code of Practice. Any departure from that guidance should be clearly recorded and clinically justified.

8.5 Documentation in patient's notes must demonstrate that administration of a particular medication for RT was justified, reasonable, proportionate and the least restrictive option to meet the need. Any incident requiring restrictive practice (e.g. physical intervention, seclusion or parenteral RT medication) **must** be recorded on the Datix Incident Reporting System.

8.6 Level 1 refers to the use of oral medication. This is indicated for patients where non-pharmacological de-escalation techniques were not adequate to diffuse anger or avert aggression, the patient is accepting of oral medication and there is not an immediate risk of violence or aggression. The NICE guideline clearly states that oral PRN medication on its own is not de-escalation.

8.7 Level 2 refers to rapid tranquillisation. It should only be considered when there is actual or clear risk of imminent violence or aggression where de-escalation and other preventative strategies including oral PRN have been unsuccessful. It is common practice for patients to be prescribed the same PRN medicine to be administered orally or if indicated intramuscularly. If the medication is administered by IM/IV injection this is not de-escalation and must be considered RT.

8.8 Level 3 describes interventions to consider if Level 2 interventions have failed to produce a sufficient response. Level 3 interventions should only be used by or after consultation with a senior doctor.

8.9 Any preference that the patient has expressed when they are well, concerning future treatment should be taken into consideration. These may include preferred treatment choices documented in the multidisciplinary team treatment and care plan known to the patients care coordinator or keyworker e.g. Wellness and Recovery Action Plan (WRAP), advance directives or behaviour support plan. WRAP plans, advance directives and behaviour support plans must be accessible and up to date.

8.10 The patient must be informed about the medications that are prescribed and administered in an emergency, as soon as possible following the administration of the medication. Where consent to share information has been previously given, the family member/carer must be informed about the medications prescribed and administered in an emergency as soon as possible following the administration of a medication.

8.11 Specific to children and adolescent services. All patients must be informed that medication is to be given and given the opportunity at any stage to accept oral medication voluntarily. In children / young people who are not Gillick competent, parent(s)/carer(s) should be informed of the situation and consent sought for treatment, in advance if at all possible. Consideration should be given to inform the child/adolescent and parent(s)/carer(s) that rapid tranquillisation has been necessary.

8.12 Specific to Intellectual disability (ID) Services. All patients must be informed (in a way that best facilitates their understanding) that medication is to be given and given the opportunity to accept oral medication.

8.13 A post-incident de-brief should take place as soon as possible after the incident and, where possible, a post-incident review should take place within 72 hours of an incident ending. (see section 15.1.2)

8.14 Resuscitation facilities must be available within three minutes in all healthcare settings where RT might be used. Suitable equipment must be available and maintained as per local resuscitation guidance.

8.15 Staff must follow local infection control policies relevant to the area at that time.

9. Specific risks of medications in combination with other physical practice interventions

9.1 Patients may occasionally require physical intervention to prevent violence to themselves or others. There are increased risks associated with medications used in combination with physical restraint. Effective drug treatment may be needed to allow assessment and management. Medication should be prescribed following attempts to de-escalate using non-pharmacological approaches and the least restrictive practice that is appropriate to manage any evolving incident.

9.2 Medication for RT, particularly in the context of physical intervention, should be used with caution owing to the following risks:

- loss of consciousness
- sedation with loss of alertness
- loss of airway
- cardiovascular and respiratory collapse
- interaction with medicines already prescribed or illicit substances taken
- possible damage to patient-staff relationship
- underlying coincidental physical disorder

10. Prescribing Principles

The following should be considered when choosing which treatment is appropriate for use, and documented in the patient's clinical notes/ management plan, according to local policy:

- The patients' preferences or advance statements and best interest decisions, where possible.
- Pre-existing physical health conditions.
- Previous response to medication, including adverse effects.
- Potential for interaction with other medications.
- The total daily dose of medication prescribed and administered.
- Whether there is a chance the patient may be pregnant, and whether this has been tested.

10.01 The aim of pharmacological de-escalation/RT is not sedation, but to achieve a state of calm so that there is minimal risk to the patient, staff and others.

10.02 When RT is being administered, a doctor should be available for advice. A junior doctor must be able to contact a senior doctor for advice if required. .

10.03 Medical notes should be reviewed, if available, to see if the patient's response and tolerability to previous medications is known. In addition current and historical physical co-morbidities that may affect drug absorption /distribution /elimination should be considered as well as recent observations and ECG (The NICE Guideline CG 178 Psychosis and schizophrenia in adults: prevention and management recommends that before starting an antipsychotic, an ECG should be offered). Any other relevant information should be taken into consideration when prescribing e.g. exclusion of substance intoxication, organic brain states or injuries, allergy status, history of severe idiosyncratic reaction to the medication or Neuroleptic Malignant Syndrome (NMS) and medication adherence if relevant, and consider any reasons for medication non-adherence or refusal.

10.04 Avoid unnecessary polypharmacy. This may necessitate careful choice of drug in relation to either current treatment or expected maintenance treatment.

10.05 When prescribing oral PRN medication for pharmacological de-escalation or medication for RT, then prescribing should be as per the medicines code, in addition:

- The indication for use MUST be clearly indicated.
- The order in which these are to be used if more than one medication is prescribed for the same indication.
- If two medicines are intended to be given at the same time this should be clearly stated.
- Frequency of administration / minimum interval between doses.
- Maximum dose in 24 hours.

10.06 The inpatient Kardexes MUST be reviewed at least once weekly by the Multidisciplinary team if pharmacological de-escalation or RT is prescribed.

10.07 If RT is being administered, a senior doctor should discuss or review all prescribed medications, at least once a day (this can be done remotely), as part of continuous risk assessment; to ensure changes in the patient's mental and physical state over time are reflected.

10.08 If an inpatient is being transferred between or within another clinical area or Trust, a full medical history, including the patient's response to medications, any adverse effects, should accompany them along with any Wellness and Recovery Action Plan (WRAP), advance directives or behaviour support plan.

10.1. Advice on doses

10.1.1. Prescribe the minimum effective dose and consider tolerability and previous response. For prescribing information for the drugs used in management of ABD, (see Appendix A). Consider lower maximum doses in older adults or the physically frail.

10.1.2. Frequent small doses are safer and more effective than single large doses, but this may lead to a risk of accumulation. Therefore, the medication used should have a short duration of action and the prescriber should bear in mind the pharmacokinetics of the agents used.

10.1.3. Avoid variable doses of oral PRN e.g. lorazepam 1–2mg as this leads to higher doses being administered without review.

10.1.4. Allow sufficient time following administration for therapeutic response before doses are repeated.

10.1.5. In some cases current BNF and SPC dose may be knowingly exceeded under the advice of a senior doctor (e.g. lorazepam >4mg/day), bearing in mind the overall risks.

10.1.6. Promethazine should not be used in patients suffering from CNS depression of any cause or within 14 days of administration of a monoamine oxidase inhibitor.

10.1.7. **High Dose Antipsychotic Monitoring** must be conducted if a patient is receiving more than 100% BNF maximum daily dose of antipsychotics (monotherapy or poly-therapy). Undertake frequent and intensive monitoring post incident including level of consciousness, pulse, blood pressure, respiratory rate, temperature and hydration. The rationale for prescribing high dose antipsychotics **must** be documented in the patents notes.

10.2. Level 1 Oral pharmacological de-escalation

10.2.1. When prescribing oral PRN medication for pharmacological de-escalation take the following points into consideration:

- Do not prescribe oral PRN medication for de-escalation routinely or automatically on admission.
- Individualise oral PRN medication and discuss with the patient if possible.

10.2.2. Lorazepam alone is encouraged as the drug of first choice, particularly in elderly and frail individuals. There is normally a delayed onset of action particularly if the patient has recently ingested food. Once the patient has been calmed, either by de-escalation techniques or use of lorazepam an alternative medication such as an antipsychotic drug may be required for maintenance of the situation. Remember that repeated use of a benzodiazepine may result in tolerance to the effect and this will probably become evident within 7 to 10 days.

10.2.3. If lorazepam is not clinically appropriate for the management of ABD and:

- If a patient is prescribed a regular antipsychotic, consider promethazine. Promethazine has anticholinergic side effects such as dry mouth, blurred vision, urinary retention and constipation. Prescription of promethazine is not recommended in individuals who are cognitively impaired or who are at risk of cognitive impairment, e.g. older and/or frail individuals and patients with dementia or delirium/history of delirium. Promethazine may also prolong the QT interval.
- If a patient is not already taking regular oral or depot antipsychotic oral haloperidol or olanzapine may be used.

10.2.4. When necessary, and in certain clinical circumstances, alternative Level 1 options such as oral risperidone or quetiapine may be considered. For dosing see Appendix A

10.3. Level 2 Rapid Tranquillisation

10.3.1. Intramuscular (IM) administration is recommended and should be used within mental health settings in the vast majority of cases, however intravenous (IV) administration may be considered in the non-mental health settings in certain clinical circumstances but should be avoided in elderly and frail whenever possible.

10.3.2. The recommendations below do not preclude the use of alternative treatment options. However, their use should be tailored to the individual in line with the recommendations for RT.

10.3.3. When prescribing medication for use as RT.

- Do not prescribe for ongoing use
- Prescribe oral and parenteral doses separately – do not use PO/IM abbreviation as these routes are indicated for different reasons.
- Prescribe defined doses as opposed to a dosing range where possible.
- When administering more than one parenteral medicine do not mix medications in the same syringe

10.3.4. The use of parenteral lorazepam alone is supported as the first line option in patients where there is no clear psychotic component to the presentation or where there is insufficient information to guide the choice of medication. Intramuscular (IM) formulations can take in excess of an hour before achieving full effect. Staff should take such delays into account before administering follow-up doses.

10.3.5. If there is a partial response to parenteral lorazepam, consider a further dose.

10.3.6. If there is no response to parenteral lorazepam, consider IM haloperidol combined with IM promethazine. There is some evidence to suggest that promethazine reduces the risk of movement-related side effects associated with haloperidol. If parenteral haloperidol is used, monitor for emergence of EPSEs, especially dystonia and ensure procyclidine is available.

10.3.7. If there is a partial response to IM haloperidol combined with IM promethazine, the full effect of haloperidol may not be apparent for more than 1hour and more than 2hours for promethazine. Consider repeating parenteral haloperidol WITHOUT promethazine if it is less than 2hours since the last injection.

10.3.8. The SPC for haloperidol recommends all patients must have an ECG prior to administration. If an ECG is not available, or there is evidence of cardiovascular disease, the prescriber should consider the risks and benefits of using parenteral haloperidol and be able to justify their prescribing decision, as it is considered an off-label use.

10.3.9. Simultaneous administration of parenteral antipsychotics and parenteral lorazepam may be associated with excessive sedation and cardio respiratory depression. If this combination is deemed necessary then patients must be monitored for excessive sedation and postural hypotension.

10.3.10. Patients taking regular clozapine or olanzapine require care when giving benzodiazepines especially parenteral route as potentially fatal orthostatic and cardio-respiratory dysregulation have been reported. If this combination is considered necessary, it is essential to undertake frequent monitoring of the patient.

10.4. Level 3: Failure to respond to Level 2 RT

10.4.1. Different strategies including medicines or combinations not included in NICE NG10. These must be tailored to the individual and might be guided by previous response in similar circumstances. The rationale and outcome must be clearly recorded.

10.5. Alternative options for RT outside of guidance for Emergency Departments (ED)

10.5.1. ED will be expected to use these guidelines for the majority of individuals with acute behavioural disturbance secondary to psychiatric states (e.g. psychosis and mania). However it is recognised that within ED only, a cohort of individuals will present with acute behavioural disturbance, secondary to an underlying medical condition, and may need to be treated as per The Royal College of Emergency Medicine (RCEM) guideline – Management of Excited Delirium/Acute Behavioural Disturbance.

10.5.2. Documentation in patient's notes must demonstrate that administration of a particular medication outside the regional guideline for the management of acutely disturbed behaviour though the use of pharmacological de-escalation and rapid tranquillisation was justified, reasonable, proportionate and the least restrictive option to meet the need.

10.5.3. ED staff should be involved in immediate post-incident debrief and NICE recommend that a full mental health assessment should be available within 1 hour of alert from the ED, or as soon as is appropriate.

10.6. Alternative options for RT outside of guidance for all other acute and mental health settings

10.6.1. All other areas will be expected to use these guidelines for the majority of individuals. However it is recognised that a small cohort of individuals may need to be treated where IM lorazepam or IM haloperidol + IM promethazine are not considered clinically appropriate, the following may be considered. See Appendix A for dosing.

- Olanzapine IM**. Olanzapine IM MUST NOT be administered within one hour of IM lorazepam**. It is not licensed for use beyond three days
- Aripiprazole IM causes less hypotension than olanzapine, but some sources suggest that it may be less effective.
- Promethazine IM alone: useful for benzodiazepine-tolerant patients.

- In very exceptional circumstances there may be indication to give medication intravenously (IV). The decision to use IV route must only be used following discussion with the consultant or senior doctor who has previous experience of using intravenous (IV) interventions for ADB. Administration may only be undertaken by a practitioner who is fully trained in IV administration, can manage medical emergencies and where resuscitation equipment is available.
- ECT may also be considered, if clinically appropriate.

10.6.2. Documentation in patient's notes must demonstrate that administration of a particular medication outside the regional guideline for the management of acutely disturbed behaviour though the use of pharmacological de-escalation and rapid tranquillisation was justified, reasonable, proportionate and the least restrictive option to meet the need.

11. Drugs NOT recommended for rapid tranquillisation

11.1. The following drugs are **NOT** recommended for rapid tranquillisation:

- Oral and IM chlorpromazine – IM chlorpromazine is painful and can cause severe hypotension. Chlorpromazine **MUST NEVER** be given intravenously.
- IM diazepam – absorption is erratic.
- IM depot antipsychotics- they are not fast acting.
- Zuclopenthixol acetate (Clopixol Acuphase ®) is **not** recommended for routine use in RT due to its slow onset of action.

11.2. Zuclopenthixol acetate (Clopixol Acuphase ®) may be recommended by a consultant Psychiatrist in certain circumstances for behavioural disturbance occurring over an extended time period. This MUST include a multidisciplinary review, including conducting a comprehensive case review, reviewing the appropriateness of the clinical setting for the patient and their treatment. In addition there MUST be at least one of the following:

- Past history of good/timely response.
- An advance directive indicates that it is the treatment of choice and it forms part of the patients overall management plan.
- Past history of repeated parenteral administration required.

11.3. Zuclopenthixol acetate (Clopixol Acuphase ®) **MUST NOT BE USED** on individuals who:

- Are antipsychotic (neuroleptic) naïve i.e. patients without any previous exposure to antipsychotic medication.
- Are sensitive to extrapyramidal side effects.
- Have cardiac disease, hepatic or renal impairment or are pregnant.

12. Precautions for rapid tranquillisation and prescribing in specific patient groups (See Appendices A,B,C,D & E)

12.1. General precautions for prescribing

12.1.1 The dose of medication prescribed should be adjusted and lowered according to bodyweight, and any other co-morbid medical conditions including but not limited to:

- patients with eating disorders
- physical frailty
- any disorders that affect metabolism, including hypothermia, stress, extreme emotional response and post extreme physical exertion
- organic disease
- hepatic or renal impairment

12.1.2 Antipsychotic medication (in particular haloperidol) should be avoided where possible in patients with a parkinsonian syndrome.

12.1.3 Compromised respiratory function – in general avoid benzodiazepines. Where benzodiazepines need to be considered seek advice from senior doctor.

12.1.4 History of epilepsy or at risk of seizures; caution when using antipsychotics – due to risk of lowering of seizure threshold.

12.1.5 Potential interaction with other mediations

12.2 Cardiovascular Safety

12.2.1 The cardiovascular health and risk factors for each patient should be assessed prior to the prescribing of medications for de-escalation and RT.

12.2.2 Antipsychotics as a group are probably associated with an increased risk of QTc prolongation. Normal limits of QTc are less than 440 ms in men and less than 470 ms in women. The risk is dose related and the risks for individual drugs are probably additive when used in combination. Therefore avoid antipsychotic medication if there is known QT / QTc prolongation or conduction abnormalities to avoid potentiation of ventricular arrhythmia or cardiac arrest. Consider risk factors for prolonged QTc interval, such as congenital long QT syndrome, family history of cardiac conduction abnormalities and previous occurrences of medication-mediated QTc prolongation. (see table 1 and 2)

Table 1: Summary of the risk for QTc prolongation for common antipsychotics.

(Adapted from the Maudsley Guideline 13th edition, 2018)

No effect	Low Effect No or average increase <10msec at clinical doses or severe effect only reported following overdose	Moderate Effect Average increase >10msec at clinical doses or ECG officially recommended	High Effect Average increase >20msec	Unknown effect
Brexpiprazole* Cariprazine* Lurasidone	Aripiprazole+ Asenapine Clozapine Flupentixol Fluphenazine Loxapine Perphenazine Prochlorperazine Olanzapine++ Paliperidone Risperidone Sulpiride	Amisulpride** Chlorpromazine Haloperidol Iloperidone Levomepromazine Melperone Quetiapine Ziprasidone	Any intravenous antipsychotic Pimozide Sertindole Any antipsychotic or combination of antipsychotics used in doses exceeding BNF maximum dose	Pipotiazine Trifluoperazine Zuclopenthixol (including Clopicol Acuphase®)

**Limited clinical experience (association with QT prolongation may emerge)*

+ One case of torsades de pointes (TDP) reported; 2 cases of QT prolongation and an association with TDP found in database study. Recent data suggest aripiprazole causes QTc prolongation of around 8ms; it may increase QT dispersion

++Isolated cases of QTc prolongation and has effects on cardiac ion channel, I_{K1}, other data suggest no effect on QTc.

***Torsades de pointes common in overdose, strong association with TDP in clinical doses with Amisulpride*

Table 2: Other psychotropic and non-psychotropic medications associated with prolonged QTc.

(A*dapted from the Maudsley Guideline 13th edition, 2018 and crediblemeds)*

Antibiotics	Antimalarials	Antiarrthymics	Others
Erythromycin Clarthromycin Ampicillin Co-trimoxazole Ciprofloxacin Levofloxacin Moxifloxacin	Chloroquine Mefloquine Quinine	Quinidine Disopyramide Procainamide Sotalol Amiodarone Bretylium	Citalopram Tricyclic antidepressants Trazodone Lithium Promethazine Methadone Amantadine Cyclosporin Diphenydramine Hydroxyzine Nicardipine Tamoxifen

Refer to www.crediblemeds.org for latest and more detailed information.

12.2.3 Haloperidol is contraindicated in clinically significant cardiac disorders. A clinical risk assessment must be carried out before prescribing haloperidol. The SPC for haloperidol recommends that a baseline ECG is performed prior to treatment for all patients and also avoiding the use of concomitant antipsychotics. This may not always be possible in ABD. In such a situation, the prescribing doctor will have to balance the cardiac risks against those arising from the patient's behaviour.

12.2.4 Consider, when applicable:

- The use of lorazepam alone
- To avoid antipsychotics (particularly the use of parenteral haloperidol with IM promethazine).
- The use of any concomitant medication, which may prolong QTc interval.

12.3 **Intellectual Disability (ID)** (See Appendix B and Appendix A)

12.3.1 Patients will be managed as per Appendix B but staff must be familiar with the NICE guidelines for managing challenging behaviour in ID.

12.3.2 The choice between using physical intervention and RT as a method of managing violent behaviour in those with an ID should be part of an overall care plan. RT for patients lacking capacity should be undertaken in adherence with best interest protocol/ guidelines.

12.3.3 People with severe learning and communication difficulties may not be able to express discomfort or pain in usual ways.

12.3.4 Sensory impairments must be detected and remedied to minimise the consequent disability, and a specialised and sensitive approach is usually needed.

12.3.5 Caution should be exhibited for patients with ID particularly if they have conditions like epilepsy, severe ID, genetic disorders or dementia.

12.3.6 If possible avoid using parenteral RT for patients with severe ID or severe autism particularly if it is in the context of non-psychotic challenging behaviour. Benzodiazepines may be preferable to antipsychotics for challenging behaviour wherever possible.

12.4 **Pregnancy and Perinatal Period** (See Appendix B and Appendix A)

12.4.1 Extra care should be taken in prescribing in pregnancy and perinatal period. Pregnant women should be managed in accordance with Appendix B except that:

12.4.2 Specialist advice must be sought on the management of pregnant and perinatal women requiring emergency sedation. Over-sedation has particular risks for these women, particularly if they resume care of their infant. Effects on the foetus through the placenta or to the infant in breastmilk must be considered and appropriate precautions taken.

12.4.3 Pregnant women who are at known risk of relapse and behavioural disturbance should have a clear plan in their notes which should be shared with all relevant statutory professionals and services involved in the female's care.

12.4.4 When choosing a drug for RT, an antipsychotic or a benzodiazepine with a short half-life should be considered: if an antipsychotic is used, it should be at the minimum effective dose because of the potential for neonatal extra pyramidal symptoms: if a benzodiazepine is used, the risks of floppy baby syndrome should be taken into account. Up to date advice on the appropriateness of individual agent must always be sought from pharmacy and using appropriate sources of information such as the British Association for psychopharmacology guidelines www.bap.org.uk . The National Poisons Information Service (NPIS) can also be contacted by telephone: 0344 892 0111 for advice.

12.4.5 Intramuscular injections for RT may be administered in to the gluteal muscle or lateral thigh.

12.4.6 During the perinatal period, the woman's care should be managed in close collaboration with a psychiatrist, a paediatrician, an anaesthetist and a midwife.

12.4.7 A pregnant woman should never be secluded or left alone post rapid tranquillisation.

12.4.8 There should be particular emphasis on keeping the mother hydrated and on the regular monitoring and documentation of temperature, pulse, BP, respiratory rate and oximetry.

12.4.9 Anticholinergics for extrapyramidal side effects of antipsychotics should not be prescribed except for short term use. Instead, adjust the dose and timing of the antipsychotic or switch to another to avoid such side effects.

12.5 **Children and young people under 18 years of age** (See Appendix C and Appendix A)

12.5.1 The NICE Guideline NG10 on violence and aggression states that restrictive interventions (which includes RT) should only be used if all attempts to defuse the situation have failed and the child or young person becomes aggressive or violent. Staff must be familiar with and use the de-escalation techniques outlined in the NICE guideline to avoid having to use a restrictive intervention.

12.5.2 Medication can be given against a children or young persons will, with parental consent i.e. permission from a person with parenteral responsibility under The Children's Act NI and or common law. If repeated medication is required the Mental Health Order NI (1986) should be considered. Children and young people should be informed that a medication is going to be given and always given the opportunity to accept oral medication. Please note that Restraint is defined in the Mental Capacity Act (NI) 2016 Deprivation of Liberty Code of Practice as short, time-bound and reactive to an immediate event, and this may include provision of medication. For any young person requiring high or unusual levels of restraint should seek further advice from Department of Legal Services.

12.5.3 Parents or carers may have the right to stay with the child and young person before, during and after RT takes place. If the parent or carer is adversely affecting the safety and/or the efficacy of the situation, they may however be asked to leave for the benefit of the child or young person – this must be a clinical decision.

12.5.4 Junior doctors should not prescribe RT to children and young people without consultation with a senior doctor/consultant with experience in managing ABD in children and young people, unless *in exceptional circumstances*, where they must discuss directly after with a more senior doctor and record reasons for this occurring.

12.5.5 If initial drug treatment does not work then junior doctors should consider discussion with someone more senior. If a consultant has tried two or three approaches without success then it may be wise to seek a second opinion from a colleague or consult with a psychiatrist who works within the Child and Adolescent Mental Health Service (CAMHS).

12.6 **Older adults or physically frail without dementia** (See Appendix D or Appendix B and Appendix A)

12.6.1 When non-pharmacological measures are insufficient and medication is required, oral medication should always be offered whenever possible. Oral lorazepam, starting at a low dose, is the preferred first line treatment

12.6.2 If lorazepam alone gives an insufficient response or is inappropriate, then a low dose oral antipsychotic may be considered. There is evidence that antipsychotics are associated with increased mortality (probably by increasing the risk of cerebrovascular adverse events) even in people without dementia. A cautious approach is recommended. (See Appendix A). However, agents such as haloperidol, olanzapine, risperidone or quetiapine may be considered. Haloperidol should be avoided if the patient is antipsychotic naive, has a significant cardiac history, has had no recent ECG, or has parkinsonian syndrome. Oral promethazine may not be suitable and is usually not recommended where confusion is a concern.

12.6.3 If oral medication has failed or not possible and a patient requires parenteral medication, lorazepam should be used first line. Parenteral haloperidol may be used if there is confirmed history of previous antipsychotic use, however note contraindications detailed above. This may be in combination with parenteral promethazine, although caution should be taken due to potential for adding to the anticholinergic burden and should be avoided if confusion is present. If previous use of antipsychotics can't be confirmed and lorazepam fails to control the situation, low dose parenteral olanzapine may be given (but not within 1 hour of parenteral lorazepam). Other alternatives include parenteral aripiprazole but this should be after consultation with a senior doctor. (See Appendix A)

12.6.4 In all cases where an antipsychotic or promethazine is felt to be required (either orally or parenteral) it should be under the advice of a senior doctor experienced in the management of ABD in older people/physically frail.

12.7 **People with dementia** (See Appendix E)

12.7.1 Patients with dementia who present with acute behavioural disturbance should be carefully assessed for delirium and treated appropriately. This guideline does not apply to the management of behavioural disturbance in the context of delirium. If delirium is suspected or identified then the appropriate clinical guideline should be followed.

12.7.2 Non-pharmacological interventions should be offered as first-line management unless the patient is severely distressed or there is an

immediate risk of harm to the patient and/or others. Always assess for pain, using a standardised pain scale e.g. Bolton Pain Scale and review the use of analgesics before considering other options. A trial of paracetamol prescribed regularly should be considered for all patients with non-cognitive symptoms of dementia, even when there are no overt symptoms of pain.

12.7.3 If non-pharmacological interventions are ineffective, then lorazepam may be considered. Risperidone is licensed for short-term use for persistent aggression in people with moderate to severe Alzheimer's dementia. If risperidone is not appropriate, and another antipsychotic is required, oral olanzapine may be considered. If on-going use of risperidone or oral olanzapine is considered necessary then the advice of a doctor experienced in the management of dementia should be sought. Oral haloperidol is not recommended, and should only be prescribed in exceptional circumstances under the supervision of a dementia specialist.

12.7.4 Covert administration of oral medication may be suitable in cases where an individual lacks the mental capacity to consent to treatment (see individual Trust guidance regarding same).

12.7.5 People with Alzheimer's disease, vascular dementia or mixed dementias with mild-to-moderate non-cognitive symptoms should not routinely be prescribed antipsychotic drugs because of the possible increased risk of cerebrovascular adverse events and death.

12.7.6 People with Dementia with Lewy Bodies (DLB) with mild-to-moderate non-cognitive symptoms, should not be prescribed antipsychotic drugs, because those with DLB are at particular risk of severe adverse reactions. If an antipsychotic is required for oral de-escalation, low dose oral quetiapine may be useful (outside of product license) due to its low propensity to cause extra-pyramidal side effects. Prescription of antipsychotics in such patients should only be done under the supervision of a senior doctor with experience in DLB.

12.7.7 When parenteral treatment is necessary, parenteral lorazepam or parenteral olanzapine may be used with caution. Only in very exceptional circumstances, when other treatment is impossible, low dose parenteral haloperidol may be used. In these cases, a senior doctor with experience in managing disturbed behaviour in people with dementia should be consulted.

13. Physical Health Monitoring, Side Effect Monitoring and Follow Up after RT (See Appendix F)

13.1 Medical and Nursing Support

13.1.1 When RT has been administrated, nursing staff will contact a doctor to attend the treatment setting as soon as possible when necessary.

13.1.2 If there is deterioration in the patient's physical health or clinical observations, as indicted by a change in the standard observation chart score, then the patient should be escalated for medical review.

13.1.3 The nursing staff and or doctor must also assess the patient's mental state and review the level of psychiatric observations during the post RT period.

13.2 Criteria for monitoring

13.2.1 Physical health and side effect monitoring is essential after an episode of RT (parenteral route).

13.2.2 Routine monitoring is not automatically required after all oral medication, but may be required in certain circumstances, such as:

- It is clinically indicated by the patient's condition.
- The patient was at the point of being administered parenteral rapid tranquillisation but accepted oral medication (individual assessment).
- BNF maximum daily dose of a drug is exceeded in RT.

13.3 Monitoring parameters and frequency of monitoring

13.3.1 Following each episode of RT, or in the circumstances described above for oral medication, the following physical observations should be commenced and recorded on the Trust Standard Observation chart (SOC)/NEWS 2 and the clinical notes:

- Respiratory rate
- SpO_2
- Temperature
- Blood pressure
- Heart rate
- Level of consciousness

13.3.2 After RT, or when clinically necessary with oral medications, carry out the required observations every 15 minutes for the first hour. After one hour, continue observations at least every hour until there are no concerns about the physical health status.

13.3.3 Consider extended or more frequent monitoring in the following circumstances:

- The BNF maximum dose of a medicine has been exceeded.
- The patient appears to be asleep or sedated.
- Concerns about possible illicit drug (including novel substances) or alcohol use.
- Pre-existing physical health problem.
- The patient experienced any harm as a result of a restrictive intervention.

13.4 **Situations where full monitoring and assessment cannot be completed** (See Appendix G)

13.4.1 There may be circumstances when taking a full set of observations according to standard observation charts (SOC) is not possible e.g. patient refuses physiological observation or if they remain too behaviourally disturbed to be approached. In these cases the Non-Contact Physical Health Observations Guidance and Assessment tool should be used to access the patients ABCDE status instead of the Trust standard observation chart. In addition to completing the Non-Contact Physical Health Observations Chart nursing staff should record the following on the Trust SOC chart:

- Respiratory rate.
- Level of consciousness.
- Temperature (using non touch thermometer).
- Pulse oximetry (may be possible if the patient is asleep/ unconscious).

13.4.2 It should be clearly documented on the Trust SOC and in the patient's notes that these are non-contact observations and the reasons for doing so documented in the notes each time they have been carried out. The use of Trust SOC, and calculation of scores, should recommence at the earliest opportunity.

13.4.3 If there is any concern regarding the patient's physical wellbeing such as indicated by a RED status in the Non-Contact Physical Health Observations Guidance and Assessment tool, then the patient MUST be escalated to a doctor and a group of staff who are MAPA trained must enter the room and check the patient's physiological observations. The patient **MUST NOT be left alone.**

13.5 Side Effect Monitoring

13.5.1 For detailed information on the management of complications and side effects associated with RT. (See Appendix F)

13.5.2 RT can be associated with risks to the patient's physical health;

- Inadequate sedation can risk patient exhaustion, dehydration and increases the risk of violence.
- Over sedation can lead to loss of consciousness or reduced alertness.
- Minor injuries and bruising may be present, especially if restraint has been used.
- Prominent side effects of medication can occur; these can be distressing and, unpleasant and include akathisia, dystonia, parkinsonian and hypotension. However side effects may be serious or life threatening and include lowered seizure threshold, respiratory depression or arrest, cardiac arrhythmias and neuroleptic malignant syndrome.

13.5.3 Respiratory depression can be a complication of administration of benzodiazepines. Treatment is with flumazenil, a benzodiazepine antagonist that must be given intravenously. If Flumazenil is being considered on a psychiatric ward, it should be used with input from general physicians whilst transfer of the patient to a medical ward is being sought. See Appendix E for more information on indications for administering flumazenil. Risk of respiratory depression is increased by:

- Underlying respiratory disease.
- Existing compromised respiratory function.
- Co-administration with other medications known to suppress respiratory function e.g. opiates.
- Administration via the parenteral route.
- Administration of higher doses.
- Physical restraint.

13.5.4 Checks for side effects after RT should be recorded in the patient's clinical notes each time they are carried out along with any actions taken to manage these.

13.6 Overall management of patient Electrocardiogram (ECG)

13.6.1 An ECG must be obtained after administration of a parenteral antipsychotic or dosing exceeds BNF maximum daily dose, where possible.

13.6.2 However an ECG is ESSENTIAL after administration of an antipsychotic to a child or young person.

13.6.3 The SPC for Haloperidol injection advise continuous ECG monitoring for repeated intramuscular doses.

13.6.4 Calculate QTc and if an ECG shows any cause for concern then a doctor must be contacted for advice on patient management. Record these observations and any actions in the patient's clinical notes.

14. Recording

14.1 Following administration of oral de-escalation medication

14.1.1 When oral medicines are administered for the management of acutely disturbed behaviour (either as oral PRN in anticipation of the acute disturbed behaviour or upon a prescription written at the time of the event) the following will be recorded in patient's case notes and patient's recovery care plan (where appropriate):

14.1.1.1 The nature of the acutely disturbed behaviour

14.1.1.2 The time course of events from:

- The onset of the behaviour until the offering of oral medicines
- The impact of non-drug strategies
- The acceptance or refusal of oral medicines
- The impact of the administration of oral medicines

14.2 Following administrating of RT

14.2.1 Following administration of RT, in addition to the points mentioned above, the following, should be undertaken and recorded in the patient's case notes and patient's recovery care plan, (where appropriate):

- Physical monitoring completed and documented.
- Prescription chart reviewed re: regular medication.
- Team debrief (see section 15.1.2).
- Handover to clinical team (if out of hours)
- Update risk assessment
- Reassure patient debrief which will include discussion on how to manage further similar incidents.
- Have a member of staff designated to record the course of events.
- Communication with carer.
- A post-incident review may be held within 72 hours.

- Datix is completed after each instance of restrictive practice i.e. rapid tranquillisation.

15. Ongoing Support and Learning

Post incident support and learning has benefits for both patients and staff as they may help minimise the negative impact of an event and help maintain a positive user-staff relationship especially in relation to minimising conflict and crisis events which are likely to lead to the use of restrictive interventions.

15.1 Post incident de-brief

15.1.1 As soon as reasonably practicable, within a supportive environment, provide the opportunity for those involved to debrief and discuss the event, preferably guided by the team leader/incident manager.

- Include involvement of patient and (where agreed by the patient) peer supports and or advocate services and significant others such as family/carer.

15.1.2 During the de-brief process opportunity should be given for:

- The patient to talk about the event from their point of view, when possible.
- Acknowledge the emotional responses to the incident and assess whether there is a need for on-going emotional support including access to counselling services for any trauma experienced.
- Consider any contributing factors to identify any elements that can be addressed quickly to reduce the likelihood of further incidents.
- Staff to reflect on what went well and didn't go so well and what could be done differently.
- Staff to improve primary and secondary preventive approaches including preferences expressed by the patient in how they would like to be managed in future crisis events (advanced statements/directives).
- Support a return to normal patterns of activity.
- Ensure that everyone involved in the patients care, including their carers has been informed of the event, if the patient agrees.
- Complete documentation including DATIX; review and amend risk and care plans accordingly.
- Share any learning with other units as appropriate and address any training needs identified.
- Any concerns or complaints expressed by the patient must be dealt with at the point of service delivery in the first instance immediately and

directly in an attempt to resolve the matter informally, speedily and appropriately in accordance with the Trust's Policy for The Management of Complaints.

15.2 Post incident review

15.2.1 A formal external post-incident review should be undertaken as soon as possible and no later than 72 hours after the incident.

15.2.2 This uses the information from the post-incident debrief, the patients notes and interviews with staff, where relevant, to develop a report which will

- evaluate the physical and emotional impact on everyone involved, including witnesses
- help patients and staff to identify what led to the incident and what could have been done differently
- determine whether alternatives, including less restrictive interventions, were discussed
- determine whether service barriers or constraints make it difficult to avoid the same course of actions in future
- recommend changes to the service's philosophy, policies, care environment, treatment approaches, staff education and training, if appropriate

16. Monitoring and audit

Monitoring and audits will be carried out against the standards set by this guidance as per Table 3. The outcomes of which will be used in conjunction with the local, regional or national learning or feedback. This guidance needs to be reviewed every three years or in the event of a Serious Adverse Incident (SAI).

Table 3 Overview of monitoring and audit

Aspect of compliance or effectiveness being monitored	Method of monitoring	Professional responsible for monitoring	Monitoring frequency	Group or committee who receive findings of reports	Group or individual responsible for completing any actions
Compliance with NICE guidance	Monitoring reports	Medical director	Annually	DTC	Medical director
Prescribing with regard to RT	Audit of kardex for pa ients receiving RT. POMH-UK audit tool where available	MRP lead (*) POMH lead (*)	Annually As per POMH	Governance fora Chief Executive POMH-Lead	Medical director POMH lead
How physical health observations are recorded, when patients have received RT	Audit of documentation of post RT monitoring	MRP Lead (*)	Annually	Governance fora	Mental Health Director Medical director
Staff have completed training associated with this guidance in line with Trust requirements e.g. MAPA, ILS, NEWS2	Certification of completion of e-learning Or Attendance certificate at Trust learning	Training will monitored in line with Trust statutory and mandatory Training			Relevant director of service

DTC= Drugs & Therapeutics Committee MRP = Minimising Restrictive Practice (*) Mental Health only

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18. Acknownledgements

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Appendix A - Dose information for specific populations (Not applicable to delirium)

Dose ranges highlighted as a guide only: remember to avoid variable dosing on kardex.

Medication	Time to Peak Plasma concentration	Child (6-12 years)	Young person (13 – 17)	Adults (18 +)	Older and Frail People	People with Dementia
Haloperidol oral solution and tablets **If no recent ECG, consider risk/benefits as use may be unlicensed.**	2 – 6 hours (Sedation usually within 30-45 mins)	***Not Applicable***	*Consider risk of acute dystonia especially in the antipsychotic naïve* PO 1mg up to 5mg Max 10mg/24hrs	PO 5mg Max 20mg/24 hours	*Only use first line if there is confirmed history of previous exposure to typical antipsychotics. Start with lower doses:* PO 0.5mg up to 2.5mg (Usual Max 5mg/24hrs.)	***Not recommended.*** *Use only in very exceptional circumstances and under advice of senior doctors with experience in dementia. Consider licensed oral risperidone as an alternative* PO 0.5mg (Max 2mg/24hrs)
Haloperidol injection **If no recent ECG, consider risk/benefits as use may be unlicensed.**	IM 15 – 60 mins (Sedation usually within 30 – 45 mins) IV: 10 mins	***Not Applicable***	*Unlicensed: Only use as part of an individualised care plan.* *Consider risk of acute dystonia especially in the antipsychotic naïve* IM injection 1mg up to 5mg Max 10mg/24hrs	By IM/IV injection 5mg Max 20mg/24 hours	*Only use first line if there is confirmed history of previous exposure to typical antipsychotics. Start with lower doses* IM 0.5mg up to 2.5mg (Max 5mg/24hrs)	***Not recommended.*** *Use only in very exceptional circumstances and under advice of senior doctors with experience in dementia. Consider licensed oral risperidone as an alternative* IM 0.5mg (Max 2mg/24hrs)
Lorazepam tablets and IM/IV injection	PO/IM 50-90 mins (Sedation usually within 30-45 mins) IV:2-5mins	*Unlicensed but may be justified in some cases* PO or by IM injection 0.5 or 1mg Max:2mg/24hrs	PO or IM injection 0.5mg, 1mg or 2mg Max 4mg/24hrs	PO or IM/IV injection 1mg or 2mg Max 4mg/24 hours	PO or IM injection 0.5mg Max 2mg/24 hours (IV route NOT recommended)	PO or IM injection 0.5mg Max 2mg/24 hours (IV route NOT recommended)
Olanzapine tablets/ orodispersible tablets *(NB orodispersible tablets have no advantage in speed of onset but are harder to spit out/conceal)*	5 – 8 hours	***Not Applicable***	***Not Applicable***	Initially 5mg or 10mg PO Max 20mg/24 hours	*Consider as a second line option.* 2.5mg PO Max 10mg/24hrs.	*Unlicensed but may be justified in some cases.* 2.5mg PO Maximum 5mg//24hours
Promethazine oral solution, tablets & IM injection	Oral 2-3 hours IM 1-2 hours ***IV:NOT recommended***	***Not Applicable***	*Unlicensed: Only use as part of an individualised care plan* PO or IM injection 10mg to 25mg Max 50mg/24hrs	PO 25mg or 50mg Max 100mg/24 hrs	*Consider appropriateness, if confusion is a concern* PO or IM injection 2.5mg. Max 50mg/24hrs	***Not recommended.*** *Use may be considered in those with compromised respiratory function or sensitive/tolerant to benzodiazepines.* PO or IM injection 12.5mg or 25mg. Max 50mg/ 24hrs

Appendix A - Dose information for specific populations (not applicable to delirium)

Dose ranges highlighted as a guide only: remember to avoid variable dosing on kardex.

Medication	Time to Peak Plasma concentration	Child (6-12 years)	Young person (13 – 17)	Adults (18 +)	Older and Frail People	People with Dementia
Aripiprazole IM injection	1 –3 hours	***Not Applicable***	***Not Applicable***	9.75mg (1.3ml) – Consider lower dose (5.25mg) on basis of clinical status Effective range 5.25 –15mg Max dose 30mg/24hrs by any route	*Effectiveness in over 65's not established. Consider lower doses on basis of clinical status.* Consider starting dose 5.25mg Max of TWO injection in 24 hours.	***Not Recommended***
Olanzapine IM injection	15-45 minutes (peak levels up to 5 times that of oral doses)	***Not Applicable***	*Unlicensed but may be justified in some cases under consultant direction.* 2.5mg, 5mg or 10mg IM repeated after 2 hours if needed. Max IM dose is 10mg daily. Max total daily dose by all routes of 20mg not to be exceeded. Max of 3 injections/ 24hrs for 3 days	5 or 10mg IM repeated after 2 hours if needed. Max combined oral/IM dose is 20mg daily NOT to be exceeded. Max of 3 injections/24hrs for 3 days.	*Use may be justified in some cases under consultant direction.* 2.5mg IM repeated after 2 hours if needed. Max combined oral/IM dose is 10mg daily NOT to be exceeded. Max of 3 injections/24hrs for 3 days	***Not recommended.*** *Use only in very exceptional circumstances and under advice of senior doctors with experience in dementia. Consider licensed oral risperidone as an alternative* 2.5mg IM repeated after 2 hours if needed. Max combined oral/IM dose is 5mg daily NOT to be exceeded. Max of 2 injections/24hrs for 3 days
Quetiapine Oral tablets/Solution	1-2 hours	***Not Applicable***	***Not Applicable***	*Unlicensed but may be justified in some cases.* PO 50-100mg (suggested max 200mg/24hours)	*Unlicensed but may be justified in some cases.* PO 12.5mg or 25mg (suggested Max 50mg/24hrs)	*Unlicensed but may be justified in some cases such as Lewy Body Dementia* PO 12.5mg or 25mg (suggested max 50mg/24hrs)
Risperidone tablets / orodispersible tablets/ oral solution	1 -2 hours	***Not Applicable***	20-45kg 0.5mg, Very slow increase to Max 2.5mg >45kg 0.5mg. Very slow increase to Max 3mg	*Unlicensed but may be justified in some cases.* Suggested dose PO 1-2mg BD PRN Max 4mg/24hours	*Consider as a second line option. Unlicensed but may be justified in some cases.* Suggested dose PO 0.25mg once or twice daily PRN. Max 2mg/24hours	In *Alzheimer's Disease* Suggested dose *PO* 0.25mg once or twice daily PRN. Max 2mg/24 hours

Appendix B - Pharmacological management of acute behavioural disturbance (FOR ADULTS 18 YEARS AND OVER)

(Not applicable to delirium, also consider using Appendix D for older adults and frail)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques

LEVEL 1
Accepting oral meds and as part of de-escalation strategy

Consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances.
Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response.

Consider lower doses in older adults or frail (Appendix A & D)

Suggested Oral Medication

Lorazepam 1 or 2mg
(Max 4mg/24hrs)
OR

Promethazine 25 or 50mg
(Max100mg/24hrs)
OR

Haloperidol 5mg
(max 20mg/24hrs)
OR

Olanzapine 10mg♦ (♦ Available as an orodisperible product)
(Max 20mg/24hr

Continue de-escalation strategy.

If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

LEVEL 2
Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate

Review all medication administered in the last 24 hours – be aware of BNF max doses.
Ensure resuscitation equipment and emergency response is readily available within 3 minutes.

Suggested Medication

Lorazepam IM (or IV)[a] 1 or 2mg [b, c]
(Max 4mg/24hrs)

OR

Haloperidol IM 5mg
(Max 20mg/24hrs)
Combined with Promethazine IM 25 or 50mg
(Max 100mg/24hrs)

If there is continued concern seek advice from a more senior doctor before proceeding further

NOTES
*a. **IV in certain clinical settings. NOT recommended in elderly and frail and in mental health settings***
b. IM Lorazepam and IM Olanzapine must not be administered within 1 hour of each other
c. IV flumazenil must be readily available

LEVEL 3
Situation rapidly deteriorating or failure to respond to LEVEL 2 interventions

If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor must review all treatment and response every 24 hours.

If one round of LEVEL 2 interventions have had insufficient effect a senior doctor should review treatment and consider the following:

- The appropriateness of current placement
- Age and physical presentation
- Check sufficient time has been allowed for response
- If there has been a partial response to a LEVEL 2 intervention, consider repeating that intervention
- If a LEVEL 2 intervention has had insufficient effect consider offering the alternative LEVEL 2 intervention
- Carry out a full review of treatment to date and seek a second opinion if needed.

If LEVEL 2 interventions have had insufficient effect:

Consider as part of an individualised care plan include:

- Further repeats of LEVEL 2 interventions (do not repeat promethazine if it is < 2hrs since the last injection)
- Haloperidol IM combined with Lorazepam IM
- Alternative medications (see Section 10)
- Zuclopenthixol acetate (Clopixol Acuphase®) (see Section 11)

When deciding which medication to use, consider:	Additional Considerations

• **Oral or parenteral lorazepam is preferred first line if:**
  ○ Patient is an older adult or physically frail
  ○ There is an uncertain history
  ○ Presence of cardiovascular disease
  ○ Current illicit drug/alcohol intoxication
  ○ Antipsychotic naïve
• Antipsychotics and/or promethazine preferred with:
  ○ Current regular benzodiazepine use
  ○ History of respiratory depression
	• Avoid antipsychotics, where possible, in patients with a parkinsonian syndrome (including idiopathic Parkinson's disease Parkinson's disease dementia and Dementia with Lewy Bodies)
	• Avoid haloperidol in cardiovascular disease or if there has been no recent ECG.
	• Pre-existing physical health problems (e.g. extra care in patients with eating disorders, physical frailty or comorbidity of any disorders that affect metabolism, including hypothermia, stress, extreme emotional response and post extreme physical exertion) or pregnancy.
	• Previous response, including adverse effects
	• Potential for interactions with other medicine
	• Possible Intoxication
	• Promethazine is contraindicated in CNS depression and those prescribed a monoamine oxidase inhibitor within the last 14 days. Promethazine may be unsuitable in older adults with confusion due to its anticholinergic effects.

Appendix C Pharmacological management of acute behavioural disturbance (for Children and Young People age 6 to 17 years) (Not applicable to delirium)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques

LEVEL 1
Accepting oral meds and as part of de-escalation strategy

Consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances.
Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response.

Suggested Oral Medication

Children 6-12 years
Lorazepam 0.5 or 1mg
(Max 2mg/24hrs)

Young People 13-17years
Lorazepam 0.5mg, 1mg or 2mg
(Max 4mg/24hrs)
OR
Haloperidol 1mg up to 5 mg★
(max 10mg/24hrs)
OR
Promethazine 10mg to 25mg
(max 50mg/24hrs)
OR
Risperidone♦
20kg-45kg 0.5mg(Slowly increase to Max 2.5mg/24hrs)
>45kg 0.5mg (Slowly increase to Max3mg/24 hrs)

♦ Available as an orodisperible product.

For both age groups:
Continue de-escalation strategy.
If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

LEVEL 2
Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate

Consult a senior doctor/consultant before using IM medication in a child under 12 years of age.
Consult a senior doctor/consultant before using IM medication in a young person (13-17 years) unless IM medication is already included in the young person's care plan.
Check if an individual care plan recommends an approach not covered in this guideline.
Review all medication administered in the last 24 hours – be aware of BNF max doses.
Ensure resuscitation equipment and emergency bag is available within 3 minutes.

Suggested IM Medication

Children 6-12 years
Lorazepam IM 0.5 or 1mg
(Max 2mg/24hrs)

Young People 13 -17 years
Lorazepam IM 0.5mg, 1mg or 2mg
(Max 4mg/24hrs)

For both age groups:
If there is continued concern, seek advice from a more senior doctor/consultant before proceeding

LEVEL 3
Situation rapidly deteriorating or failure to respond to Level 2 interventions

If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor/consultant must review all treatment and response every 24 hours.

If one round of LEVEL 2 interventions have had insufficient effect a senior doctor/consultant should review treatment and consider the following options:
- The appropriateness of current placement
- Check sufficient time has been allowed for response
- If there has been a partial response to lorazepam consider repeating the dose
- Carry out a full review and seek a second opinion if needed.

If there has been insufficient response to IM lorazepam:

Consider as part of an individualised care plan include (in no particular order)
- Further repeats of IM lorazepam
- ≥13yrs, Haloperidol IM 1 - 5mg★ (Max 10mg/24hrs)
- ≥13yrs, Haloperidol IM combined with lorazepam IM
- ≥13yrs, Promethazine IM (10 to 25mg, Max 50mg/24hrs)
- ≥13yrs, Olanzapine 2.5mg, 5mg or 10mg (Max 10mg/24hrs IM). **Do not combine** with IM lorazepam and use with caution if IM lorazepam has been given within 1 hour.

When deciding which medication to use, consider:	Additional Considerations
• Oral or parenteral lorazepam is preferred first line if: o There is an uncertain history o Presence of cardiovascular disease o Current illicit drug/alcohol intoxication o Antipsychotic naïve • Antipsychotics may be preferred with: o Current regular benzodiazepine use o History of respiratory depression	• Avoid haloperidol in cardiovascular disease or if there has been no recent ECG. • Pre-existing physical health problems (e.g. extra care in patients with eating disorders, physical frailty or comorbidity of any disorders that affect metabolism, including hypothermia, stress, extreme emotional response and post extreme physical exertion) or pregnancy • Previous response, including adverse effects • Potential for interactions with other medicine • Possible Intoxication • Promethazine is contraindicated in CNS depression. ★Dosing for haloperidol should be a fixed dose in the range from 1mg to a max of 5mg. Please consider the available strengths of oral haloperidol 0.5mg, 1.5mg or 5mg to facilitate ease of administration; e.g. 1.5mg is easier to administer than 2mg.

Appendix D - Pharmacological management of acute behavioural disturbance (FOR OLDER and FRAIL ADULTS)
(Not applicable to delirium, please also consider using Appendix B)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques

LEVEL 1 Accepting oral meds and as part of de-escalation strategy	LEVEL 2 Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate	LEVEL 3 Situation rapidly deteriorating or failure to respond to LEVEL 2 interventions
Consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances. Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response. **Suggested Oral medications:** ***1st line:*** **Lorazepam 0.5mg** (Max 2mg/24hrs) ***2nd line:*** **Haloperidol 0.5mg-2.5mg★** (Usual Max 5mg/24 hrs) **OR** **Olanzapine 2.5mg** (Max 10mg/24hrs) **OR** **Risperidone 0.25mg** (Max 2mg/24hrs) **OR** **Quetiapine 12.5mg or 25mg** (Max 50mg/24hrs) **OR** **Promethazine 25mg** (Max 50mg/24hrs) Continue de-escalation strategy. If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2	Review all medication administered in the last 24 hours – be aware of BNF max doses. Ensure resuscitation equipment and emergency response is readily available within 3 minutes. **Suggested Medication** ***1st line:*** **Lorazepam IM (or IV)[a] 0.5mg** (Max 2mg/24hrs) [b, c] ***2nd line:*** **Haloperidol IM 0.5mg-2.5mg★** (Max 5mg/24 hours) **Plus or minus** **Promethazine IM 25mg** (Max 50mg/24hours) **OR** **Olanzapine IM 2.5mg [b]** Max 10mg/24hrs [d] (Leave at least 2hrs between injections.) Max of three injections in 24hrs. If there is continued concern seek advice from a more senior doctor before proceeding further ***NOTES*** *a. **IV in certain clinical settings. NOT recommended for elderly and frail and in mental health settings*** *b. Lorazepam and IM Olanzapine must not be administered within 1 hour of each other* *c. IV flumazenil must be readily available* *d. Maximum of 10mg in 24 hours from PO and IM routes combined.*	If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor must review all treatment and response every 24 hours. If one round of LEVEL 2 interventions have had insufficient effect a senior doctor should review treatment and consider the following: • The appropriateness of current placement • Age and physical presentation • Check sufficient time has been allowed for response • If there has been a partial response to a LEVEL 2 intervention, consider repeating that intervention • If a LEVEL 2 intervention has had insufficient effect consider offering the alternative LEVEL 2 intervention • Carry out a full review of treatment to date and seek a second opinion if needed. **If LEVEL 2 interventions have had insufficient effect:** **Consider as part of an individualised care plan include:** • Further repeats of LEVEL 2 interventions • Alternative medications e.g. **Aripiprazole** (see Section 10 & 12.6)

When deciding which medication to use, consider:	Additional Considerations

• **Oral or parenteral lorazepam is preferred first line if:**
  ○ There is an uncertain history
  ○ Presence of cardiovascular disease
  ○ Current illicit drug/alcohol intoxication
  ○ Antipsychotic naïve
• Antipsychotics are associated with increased mortality
  ○ Olanzapine, risperidone and quetiapine all unlicensed but use may be justified in some circumstances
  ○ IM aripiprazole effectiveness in over 65 not established
• Promethazine may increase risk of confusion
	• Avoid antipsychotics, where possible, in patients with a parkinsonian syndrome (including idiopathic Parkinson's disease Parkinson's disease dementia and Dementia with Lewy Bodies)
	• Avoid haloperidol in cardiovascular disease or if there has been no recent ECG
	• Pre-existing physical health problems (e.g. extra care in patients with eating disorders, physical frailty or comorbidity of any disorders that affect metabolism, including hypothermia, stress, extreme emotional response and post extreme physical exertion) or pregnancy.
	• Previous response, including adverse effects and increased risk of falls
	• Potential for interactions with other medicine
	• Possible Intoxication
	★Dosing for haloperidol should be a fixed dose in the range from 1mg to a max of 2.5mg. Please consider the available strengths of oral haloperidol tablets/caps 0.5mg 1.5mg to facilitate ease of administration; e.g. 1.5mg is easier to administer than 2mg.

Appendix E Pharmacological management of acute behavioural disturbance (for PATIENTS WITH DEMENTIA) (Not applicable to delirium)

Pharmacological management should be part of an overall management plan that includes appropriate nursing care and de-escalation techniques

LEVEL 1
Accepting oral meds and as part of de-escalation strategy

Only consider combination of oral lorazepam with an oral antipsychotic if indicated by clinical circumstances. Ensure all risks and benefits are fully considered before prescribing antipsychotic drugs.
Avoid antipsychotics in patients who have parkinsonian syndrome (including idiopathic Parkinson's disease Parkinson's disease dementia and Dementia with Lewy Bodies)
Consider moving to LEVEL 2 if oral therapy is refused or is not indicated by previous clinical response or is not a proportionate response.

Suggested Oral medications:

1st line:
Lorazepam 0.5mg
(Max 2mg/24hrs)

2nd line:
Risperidone 0.25mg ♦
(Max 2mg/24hrs)
Oral risperidone licensed for treatment of aggression in Alzheimer's dementia
OR
Olanzapine 2.5mg ♦
(Max 5mg/24hrs)
Olanzapine licensed for agitation and disturbed behaviour in schizophrenia and mania ONLY.

Continue de-escalation strategy. If response is inadequate after 45 minutes, consider repeating oral therapy or moving to LEVEL 2

♦ Available as an orodisperible product.

LEVEL 2
Actual or clear risk of violence or aggression. De-escalation including oral PRN not possible or appropriate

Check if an individual care plan recommends an approach not covered in this guideline.
Review all medication administered within the last 24hrs – be aware of BNF maximum doses.
Ensure resuscitation equipment and emergency response is readily available within 3 minutes.

Suggested IM medications:

1st line:
Lorazepam 0.5mg IM
(Max 2mg/24hrs)
(IV flumazenil must be readily available)

OR

Olanzapine*
2.5mg IM
(Max 5mg/24hrs)
*(*Unlicensed, use ONLY in certain clinical circumstances)*
For Olanzapine, leave at least 2hrs between injections. Max of two injections in 24hrs.

If there is continued concern, seek advice from a more senior doctor before proceeding further.

CAUTION
- **IM lorazepam and IM olanzapine must not be administered within 1 hour of each other.**

LEVEL 3
Situation rapidly deteriorating or failure to respond to Level 2 interventions

If Rapid Tranquillisation (LEVEL 2) is being used, a senior doctor must review all treatment and response every 24 hours

If one round of LEVEL 2 interventions have had insufficient effect a senior doctor should review treatment and consider the following options:
- The appropriateness of current placement
- Check sufficient time has been allowed for response
- Carry out a full review and seek a second opinion if needed.

If LEVEL 2 interventions have had insufficient effect:

Consider as part of an individualised care plan include:
- Repeat IM injections as per LEVEL 2.
- Use alternative medications not yet tried **in exceptional circumstances only**
  - Haloperidol 0.5mg IM with caution due to known increased risk of cerebrovascular adverse events. Allow sufficient time for response before repeating to maximum of 2mg/24 hrs
  - Promethazine 25mg IM with caution, useful in benzodiazepine tolerant patients or if there has been a known or suspected previous paradoxical reaction to benzodiazepines. Onset of action is slow. Allow 1-2 hours to assess response before repeating to maximum of 50mg/24hrs

When deciding which medication to use, consider:	Additional Considerations
• **Oral or parenteral lorazepam is preferred first line:** • In all cases where an antipsychotic is felt to be required (either orally or parenteral) it should be under the advice of a senior doctor experienced in the management of ABD in dementia and consider antipsychotics only when benefits outweigh risks.	• Avoid antipsychotics, where possible, in patients with a parkinsonian syndrome (including idiopathic Parkinson's disease Parkinson's disease dementia and Dementia with Lewy Bodies) • Avoid haloperidol in cardiovascular disease or if there has been no recent ECG. • Pre-existing physical health problems (e.g. extra care in patients with physical frailty or comorbidity of any disorders that affect metabolism, including hypothermia, stress, extreme emotional response and post extreme physical exertion) • Potential for interactions with other medicine • Possible intoxication • Increased risk of falls • Access pain using a standardised pain scale e.g. Bolton Pain Scale and consider regular analgesia prior to sedative medication

Appendix F	Rapid tranquillisation Monitoring

Following any IM/IV drug administered for RT, or where considered clinically necessary after oral medication, monitor and record as shown below.
Document and record on the Trust Standard Observation Chart (SOC) e.g. NEWS 2 or clinical notes as appropriate.

The Early Warning Score should be calculated from the Trust Standard Observations Chart e.g. NEWS 2 each time and further action taken if indicated

Observations	Monitoring Frequency	General Comments
• Respiratory Rate • SaO2 (if appropriate) • Pulse • Blood Pressure • Temperature • Level of Consciousness • Assess for Side effects • Monitor level of hydration	Every 15 minutes for first hour. After one hour, continue observations at least hourly until there are no further concerns about physical health status. **Action when Observations are not possible** The Non-Contact Physical Health Observations Guidance and Assessment tool (Appendix F) should be used. Record if the patient's mental state or behaviour prevents observations. Complete and record any observations possible, in Trust Standard Observational Chart e.g. NEWS 2.	• Arrange medical review of the patient after administration of IM medication • Protection of the airway is paramount • Ensure adequate levels of hydration are maintained • Consider urgent transfer to an Emergency Department if not already in ED, if condition warrants • Pay particular attention to level of consciousness and blood pressure when IM antipsychotics and IM benzodiazepines are used in combination. • An ECG is recommended when antipsychotics, in particular when haloperidol or higher doses are given. • An ECG is essential after IM antipsychotics are administered to Young People.

Management of side effects and problems that can occur during and after rapid tranquillisation (RT) (and occasionally during and after oral pharmacological de-escalation)

Problem	Remedial Measures
Acute Dystonia (including oculogyric crises, torticollis) *NB. 10% prevalence, more common in young males, neuroleptic naïve, high potency drugs e.g. haloperidol*	Give **procyclidine 5 - 10mg Orally or IM (IV in ED Departments only)** **NOTE** Do not pre-emptively administer procyclidine when IM haloperidol is combined with IM promethazine as the risk of extrapyramidal side effects (EPSE) is significantly reduced by the promethazine. If EPSE do occur after the IM haloperidol/promethazine combination, administer additional procyclidine with caution. Monitor for increased anticholinergic side effects.
Reduced respiratory rate • <10/minute or • Oxygen saturation <92% (Note: COPD patients may have a lower baseline SPO_2)	Give oxygen; ensure patient is not lying face down. If induced by any agent other than a benzodiazepine the patient will require transfer for mechanical ventilation ***If benzodiazepine induced:*** Give flumazenil 200microgram IV over 15 seconds. If desired level of consciousness is not obtained within 60 seconds, a further 100microgram can be injected and repeated at 60 second intervals to a maximum total dose of 1mg (1000microgram) in 24 hours (initial + 8 additional doses). Monitor respiration rate continuously until it returns to baseline level. The effect of flumazenil may wear-off & respiratory depression return – monitoring must continue beyond initial recovery of respiration. Clinicians should be familiar with the use of flumazenil or if being considered on a psychiatric ward, it should be used with input from general clinicians. Additional information is available from Medusa (see local Trust for details), on the treatment of benzodiazepine poisoning and flumazenil should be administered in this context. *Do not use flumazenil if the patient has a history of epilepsy; co-ingested pro-convulsants including tricyclic antidepressant; or in benzodiazepine dependent patients. These patients will require transfer for mechanical ventilation, maintain airway management until transfer .*
Irregular or slow pulse <50 beats/min	**Refer to specialist medical care immediately.**
Fall in blood pressure > 30mmHg drop in systolic BP on standing or diastolic BP <50mmHg	Lie patient flat, raise legs if possible. Monitor closely and seek further medical advice if necessary.
Increased temperature	**Withhold antipsychotics** –risk of NMS or perhaps arrhythmias. Monitor closely, cool the patient, maintain hydration and check muscle creatinine kinase. **Refer to specialist medical care** if continued or other signs of NMS present e.g. sweating, hypertension or fluctuating BP, tachycardia, incontinence (retention/obstruction), muscular rigidity (may be confined to head and neck), confusion, agitation or loss of consciousness.
Akathisia	Review antipsychotic choice, consider propranolol 30-80mg/day prn in 2-3 divided doses (caution with asthma, bradycardia hypotension) or benzodiazepines e.g. diazepam 5-15mg/day prn in divided doses

Appendix G	Non-Contact Physical Health Observation Guidance and Assessment tool (adapted from Southern Health NHS Foundation Trust)

Health and Social Care in Northern Ireland

Use addressograph or write in CAPITAL LETTERS

Surname: ……

First names: ……

H&C number: ……

DOB: …….. Check Identity

Circumstances when use of Trust Standard Observations Chart (SOC) is not possible:

When taking a full set of physical observations is ***NOT*** possible or considered to pose significant risk to the patient and/or staff. For example:

- It is not safe to approach the patient
- Approaching the patient may cause significant distress or antagonise the situation
- The patient declines physical observations (the rationale for taking physical observations must be explained to the patient if appropriate)

The use of the non-contact observations assessment tool must be documented on the SOC and a summary for the rationale of this made in the patients progress notes or clinical system

If it is not possible to undertake a full set of physical observations using Trust SOC you should still:

- Record respiratory rate if possible on Trust SOC
- Record Conscious level on Trust SOC
- Note on Trust SOC chart that Non-Contact physical observation assessment tool is being used
- Record in the patients progress notes or in the clinical system, the reason that the Non-Contact physical observation is being used

Use the assessment tool overleaf to record the Non-Contact observations following the ABCDE structure

If any red box statements are true, the patient MUST be escalated to a doctor and a full ABCDE assessment should be undertaken based upon clinical judgement. Medical team/999 must be contacted if required.

Differentiating between unconsciousness and sleep:

- Being asleep is not the same as being unconscious
- If someone is asleep we would expect then to occasionally change position while sleeping and to have a normal complexion for them
- If you are concerned the patient is not sleeping and may be unconscious refer to the Nurse in charge and/or medical team and undertake a full Glasgow Coma Scale (GCS) assessment of conscious level

Non-Contact ABCDE Assessment Tool

Ensure that observations are repeated every 15mins for 1 hours post intramuscular injections

Utilise the ABCDE guidance below to assess the patient and document in the table below

If any RED box statements are true the patient MUST be escalated to an doctor and a full ABCDE assessment should be undertaken.

Medical team/999 MUST be contacted if required.
DO NOT leave the patient.

Use addressograph or write in CAPITAL LETTERS

Surname: .....

First names: .....

H&C number: .....

DOB: ..... Check Identity

Airway	Talking (not just moan and groans) Airway clear- including when asleep
Breathing	Breathing is quiet and regular Respiratory rate 12-10 breaths per minute
Circulation	Mobility normal for the patient Presenting as normal If asleep, monitor movement Warm skin, normal colour for patient Comfortable presentation
Disability	Alert Drinking and eating as normal Active
Exposure	No signs of injury, bruising, bleeding or rashes.

Airway	Airway obstructed? Silence? Coughing? Swelling? Gurgling? If awake can they speak(not just moans and groans) Risk of vomiting? Consider moving onto their side and carry out constant observations to prevent choking/aspiration if there is a risk of vomiting
Breathing	Noisy or difficult breathing even with open airway Respiratory rate less than 12 or more than 20 breaths per minute Shallow rapid breathing pattern Struggling to breath (using additional muscles and working hard) Abnormal breathing sounds? Stridor? Wheeze? Gurgling? **Consider asthma, COPD, intoxication and has rapid tranquillisation been used?**
Circulation	Change in ability to mobilise Flushed? Pale? Sweaty? Clammy? Mottled? (purplish discolouration to skin) Central cyanosis (blue tinge to lips, tip of nose or ear lobes) Ashen (grey discolouration to skin) Trauma/significant bleeding
Disability	Unresponsive Unexpected sleepiness, drowsiness, confusion or fitting Responsive to voice, pain or unresponsive **Consider diabetes or epilepsy**
Exposure	Abnormal shuffling or unsteady gait Muscle rigidity **THINK NMS** Signs of dehydration: dry cracked lips not passing urine. Signs of physical injury/bleeding/rash Signs of infection: **THINK SEPSIS**

Record of Non-contact Physical Health Observations

Date / Time	All green statements (circle if true)	A	B	C	D	E	If any RED statements are triggered tick relevant ABCDE box below. Document your concerns in the larger box provided (include when and who the patient was escalated to, what support was started, alterations to monitoring and outcomes of review).	Name, Signature and role
Date Time	All green statements (circle if true)	A	B	C	D	E		
Date Time	All green statements (circle if true)	A	B	C	D	E		
Date Time	All green statements (circle if true)	A	B	C	D	E		
Date Time	All green statements (circle if true)	A	B	C	D	E		

Belfast Health and Social Care Trust
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Guideline Code: BHSCT/ASPC/MH (12) 2022

Title:	**Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation**		
Trust Contact	Dr Ruth Barr, Clinical Lead for Recovery Services in ASPC Tel: 028 950 45196 Ruth.Barr@belfasttrust.hscni.net Stephen Guy, Lead Mental Health Pharmacist Tel: 028 950 46321 Stephen.Guy@belfasttrust.hscni.net		
Policy Author(s)	Regional Mental Health Pharmacists Group		
Responsible Director:	Moira Kearney, Co-Director, Adult Social and Primary Care		
Policy Type: (tick as appropriate)	*Directorate Specific ☐	Clinical Trust Wide ☒	Non Clinical Trust Wide ☐
If policy type is confirmed as ***Directorate Specific** please list the name and date of the local Committee/Group that policy was **approved**			
Approval process:	Drugs and Therapeutics Committee Standards and Guidelines Committee Executive Team Meeting	**Approval date:**	05/09/2021 05/04/2022 13/04/2022
Operational Date:	April 2022	**Review Date:**	April 2027
Version No.	3	**Supercedes**	V2 - February 2017 – February 2022
Key Words:	Violence, aggression, rapid tranquillisation, restrictive practices		
Links to other policies	BHSCT/PtCtCare (06) 2021 Restrictive Practices Policy for Adults and Children BHSCT Policy for measuring and recording physiological observations (2010) SG 07/09		

1.0 INTRODUCTION / SUMMARY OF POLICY

See section 1, Appendix A

2.0 SCOPE OF THE POLICY

See section 3, Appendix A

3.0 ROLES AND RESPONSIBILITIES

See section 5-5.4, Appendix A

4.0 CONSULTATION

Regional Consultation

- Pharmacy Leads in all NI Trusts with direction to forward to stakeholders in their Trust
- Service user/carer advocates (CAUSE)
- Trust Towards Zero Suicide Service improvement mangers
- Trust Directors of Nursing, Medical Directors with specific direction to include medical wards and Emergency Departments

Belfast Trust Specific Consultation

- All Consultant Psychiatrists in Adult Mental Health, Intellectual Disability services and Psychiatry of Old Age
- Lead Pharmacist for Emergency Department
- Consultant lead for CAMHS inpatient services

5.0 POLICY STATEMENT/IMPLEMENTATION

See Appendix A: sections 7 to 15

5.1 Dissemination

This Guideline is directed to all staff within the adult mental health, psychiatry of old age and intellectual disability inpatient settings, all acute hospital inpatient settings including emergency departments, dementia inpatient services and CAMHS inpatient settings.

Once approved by the relevant committees, this guideline will be available on the Trust intranet site.

5.2 Resources

See section 6 Appendix A

5.3 Exceptions

This guideline DOES NOT apply to

- Management of delirium or
- Acute alcohol (including psychoactive substances) withdrawal.
- Children under 6 years of age

The appropriate pathways should be followed.

6.0 MONITORING AND REVIEW

See section 16, Appendix A

7.0 EVIDENCE BASE/REFERENCES

See section 17 Appendix A

8.0 APPENDICES

Appendix A: Regional Guideline for the Management of Acutely Disturbed Behaviour.

9.0 NURSING AND MIDWIFERY STUDENTS

Nursing and/or Midwifery students on pre-registration education programmes, approved under relevant 2018/2019 NMC education standards, must be given the opportunity to have experience of and become proficient in the **Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation**, where required by the student's programme. This experience must be under the appropriate supervision of a registered nurse, registered midwife or registered health and social care professional who is adequately experienced in this skill and who will be accountable for determining the required level of direct or indirect supervision and responsible for signing/countersigning documentation.

Direct and indirect supervision

- Direct supervision means that the supervising registered nurse, registered midwife or registered health and social care professional is actually present and works alongside the student when they are undertaking a delegated role or activity.
- Indirect supervision occurs when the registered nurse, registered midwife or registered health and social care professional does not directly observe the student undertaking a delegated role or activity. (NIPEC, 2020)

This policy has been developed in accordance with the above statement.

Wording within this section must not be removed.

10.0 EQUALITY IMPACT ASSESSMENT

The Trust has legal responsibilities in terms of equality (Section 75 of the Northern Ireland Act 1998), disability discrimination and human rights to undertake a screening exercise to ascertain if the policy has potential impact and if it must be subject to a full impact assessment. The process is the responsibility of the Policy Author. The template to be complete by the Policy Author and guidance are available on the Trust Intranet or via this **link**.

All policies (apart from those regionally adopted) must complete the template and submit with a copy of the policy to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the equality screening for the policy is:

Major impact ☐
Minor impact ☐
No impact ☐

Wording within this section must not be removed

11.0 DATA PROTECTION IMPACT ASSESSMENT

New activities involving collecting and using personal data can result in privacy risks. In line with requirements of the General Data Protection Regulation and the Data Protection Act 2018 the Trust considers the impact on the privacy of individuals and ways to militate against any risks. A screening exercise must be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this **link**.

If a full impact assessment is required, the Policy Author must carry out the process. They can contact colleagues in the Information Governance Department for advice on Tel: 028 950 46576

Completed Data Protection Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net

The outcome of the Data Protection Impact Assessment screening for the policy is:

Not necessary – no personal data involved ☐
A full data protection impact assessment is required ☐

A full data protection impact assessment is not required ☐
Wording within this section must not be removed.

12.0 RURAL NEEDS IMPACT ASSESSMENT

The Trust has a legal responsibility to have due regard to rural needs when developing, adopting, implementing or revising policies, and when designing and delivering public services. A screening exercise should be carried out by the Policy Author to ascertain if the policy must be subject to a full assessment. Guidance is available on the Trust Intranet or via this **link.**

If a full assessment is required the Policy Author must complete the shortened rural needs assessment template on the Trust Intranet. Each Directorate has a Rural Needs Champion who can provide support/assistance.

Completed Rural Impact Assessment forms must be returned to the Equality & Planning Team via the generic email address equalityscreenings@belfasttrust.hscni.net
Wording within this section must not be removed.

13.0 REASONABLE ADJUSTMENT ASSESSMENT

Under the Disability Discrimination Act 1995 (as amended) (DDA), all staff/ service providers have a duty to make Reasonable Adjustments to any barrier a person with a disability faces when accessing or using goods, facilities and services, in order to remove or reduce such barriers. E.g. physical access, communicating with people who have a disability, producing information such as leaflets or letters in accessible alternative formats. E.g. easy read, braille, or audio or being flexible regarding appointments. This is a non-delegable duty.

The policy has been developed in accordance with the Trust's legal duty to consider the need to make reasonable adjustments under the DDA.
Wording within this section must not be removed.

SIGNATORIES
(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

Stephen Guy

05/04/2022

_____ **Date:** _____
Policy Author

Moira Kearney.

05/04/2022

_____ **Date:** _____
Director

Appendix A

Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation

Derbyshire NHS
Mental Health Services NHS Trust

GUIDELINES FOR THE DRUG MANAGEMENT OF THE ACUTELY DISTURBED PATIENT (previously called Rapid Tranquillisation)

1. Introduction

a. What is the aim of using drugs to manage acutely disturbed behaviour?

i. The administration of drugs is one of a number of strategies used to manage a high risk of imminent violence. The aim is tranquillisation which means calming without sedating and to achieve calming as quickly as is safely possible. This drug strategy to manage acutely disturbed behaviour is sometimes called rapid tranquillisation

b. Why is the term 'rapid tranquillisation' not used in this guidelines

i. The reasons for this are**:**

1. Many staff regard the term 'rapid tranquillisation' to be synonymous with the use of IM injections
2. Drugs are commonly used to manage acutely disturbed behaviour but the mechanism is through the use of prn medicines already prescribed rather than through new prescribing specifically at the time of the event.
3. Anticipatory prescribing using prns should be seen in the same way as prescribing when the event occurs

c. When should drugs be used to manage acutely disturbed behaviour?

i. There are a variety of other approaches for managing a high risk of imminent violence. These include de-escalation, distraction techniques, consideration of placement, physical restraint and seclusion. All of these strategies should be considered in each case as alternatives to the administration of drugs. Drugs are likely to be appropriate only when some of these have been tried and have failed. Even when drugs are used, the other strategies should continue to be used alongside as each is likely to augment the effect of the others. Particular caution is necessary if combining drug use with seclusion. Patients who are sedated should not be secluded.

ii. When patients are intoxicated general supportive measures are usually indicated rather than the administration of drugs

d. When should enhanced physical monitoring be in place

i. Particular monitoring is required when intramuscular injections are used, when the patient is naive to either antipsychotics or benzodiazepines and when multiple drugs are administered.

e. **Planning for the use of drugs to manage acutely disturbed behaviour**

i. For many patients acutely disturbed behaviour is expected, particularly at the beginning of the admission. Medicines are prescribed in anticipation of the event as 'prn' medicines. **Anticipatory prescribing using prns should be seen in the same way as prescribing when the event occurs. Before the prescribing of medicines for anticipatory use, similar precautions and testing should be in place.**

ii. For many patients acutely disturbed behaviour is both predictable and has occurred before. Care plans for the management of individual patients should be made in advance of the episode of acutely disturbed behaviour. These care plans should both indicate:

1. At what stage drugs should be used
2. If more than one drug is prescribed in what order.
3. At what stage medical involvement is required.

iii. The plans developed should be on the basis of past experience of the response of the patient to the drugs used and should include any advance statements agreed with the patient.

iv. In such circumstances it is common for the prescribing of drugs to be on a prn or 'as required' basis empowering nursing staff to undertake initial stages of the plan without need to involve medical staff. Medical and nursing staff should read the guidance in the DMHST Medicines Code (chapter 4) on PRN prescribing.

v. For some patients the likely response to the drugs prescribed is unknown. In such circumstances medical staff should limit the prescribing of prn drugs (particularly parenteral) before medical staff are involved.

vi. For some patients the initial plans to control acutely disturbed behaviour may prove ineffective. In such circumstances medical staff should be called to review the drugs prescribed and administered and if need be, seek assistance from senior medical staff or a mental health clinical pharmacist.

vii. If parenteral (IM) injections are to be used additional physical monitoring should be available.

2. **<u>Practice Guidelines</u>**

a. **Principles of drug use to manage acutely disturbed behaviour**

i. The aim of using drugs to manage acutely disturbed behaviour is to safely and quickly achieve calming of the patient without sedation, reducing the risk of imminent violence. In occasional extreme situations sedation will be unavoidable, but this is not an optimal result.

ii. The aim of drug use to manage acutely disturbed behaviour is not to treat the underlying cause of aggression or violence. Treatment of any underlying condition must proceed alongside drug use but is distinct from it.

iii. The underlying condition does not necessarily predict response to drugs or preclude them. Violence need not be associated with psychosis for drug treatment to be an appropriate therapy. Similarly, violence that is associated with psychosis may respond to non-pharmacological intervention.

iv. Using drugs to manage acutely disturbed behaviour should not be carried out without an assessment of the physical health of the patient and a consideration of concurrent medication.

b. **When drugs are prescribed in anticipation of acutely disturbed behaviour there is the expectation that:**

i. The prescriber has taken into account the physical health of the patient when the prescribing the prn drug including, if antipsychotics are to be used an ECG.

ii. The nurse has taken into account the current physical health of the patient. If the nurse has concerns about the physical health of the patient or feels that the physical health has deteriorated since the prn was originally prescribed medical advice should be sought.

iii. Staff involved in administering, prescribing and monitoring of a patient receiving IM injections to manage acutely disturbed behaviour must be adequately trained in:
    1. Management of imminent violence
    2. Knowledge of common drugs used, their side effects and risks
    3. The Derbyshire Early Warning System (DEWS) procedure
    4. Immediate Life Support skills and the administration of flumazenil

iv. Managers responsible for units and wards where drugs are used to manage acutely disturbed patients must:
    1. Ensure that all medical staff who prescribe drugs for such circumstances have read this guideline, and undertaken the associated e learning training module
    2. Ensure that all nursing staff who administer drugs in such circumstances have read this guideline, and undertaken the associated e learning training module
    3. Maintain evidence of completion of the e training module by such staff

v. Policies for the use of physical restraint, the use of drugs to manage acutely disturbed behaviour and seclusion should be consistent. A patient who is sedated (or intoxicated) should not be secluded.

vi. Parenteral (IM) therapy should only be considered when non-drug measures and oral drug therapy have been ineffective or refused.

3. **<u>Drugs used to manage acutely disturbed behaviour</u>**

a. Suitable drugs for the management of acutely disturbed behaviour need to have a rapid onset of action. Frequent small doses are safer and more effective than single large doses, but this may lead to a risk of accumulation. Therefore the

drugs used should have a short duration of action and the prescriber should bear in mind the pharmacokinetics of the agents used. The previous medication taken by the patient must be considered in this regard.

b. No drug currently meets the criteria as ideal for the management of acutely disturbed behaviour. Oral medicines are commonly delayed in onset, particularly if the patient has recently ingested food and even if they are provided in a liquid or rapid dissolving formulation. Oral olanzapine may take a few hours before achieving maximum effect. Also IM formulations of benzodiazepines (lorazepam and diazepam) can take in excess of an hour before achieving full effect. Staff should take such delays into account before administering follow-up doses

c. Benzodiazepines are commonly used for the management of acutely disturbed behaviour and have important advantages over antipsychotics in terms of side effects and toxicity. Increasingly benzodiazepines are the recommended choice (Lorazepam oral/im and Diazepam oral only). DMHST is keen to encourage the use of lorazepam alone as the first drug of choice.

d. Traditionally antipsychotics have been used for the management of acutely disturbed behaviour in psychiatry, because violence is commonly associated with psychosis. However, the aim of drug management in this situation is to control behaviour. It is distinct from treatment of mental illness. Increasingly antipsychotics are seen as second line choices.

e. It is common for combinations of benzodiazepines and antipsychotics to be used. In patients where antipsychotics are considered necessary this practice is thought to be beneficial because it reduces the dose of the antipsychotic that is required. It has been suggested that the two classes of drug have a synergistic action and that benzodiazepines may counteract the lowering of seizure threshold by antipsychotics. However this practice has the following problems:
    i. The evidence base to support this practice is weak.
    ii. For many patients the use of one class of drug may be sufficient.
    iii. Increasing concern about the propensity of I/M haloperidol to cause dystonic reactions in acute use has resulted in a lowering of the recommended doses
    iv. Olanzapine injection is not to be given at the same time as Lorazepam. If benzodiazepines need to be given after IM Olanzapine wait at least one hour.

f. **Key practice points for use of Olanzapine injection:**

    i. IM injections should only be used when oral is not appropriate
    ii. Olanzapine injection is not to be given at the same time as Lorazepam. If benzodiazepines have already been given it is important to evaluate clinically for sedation and cardio-respiratory depression before giving IM Olanzapine.
    iii. The maximum initial dose of Olanzapine IM is 10mg (5mg for older adults and in renal or hepatic impairment).
    iv. A minimum of 2 hours should elapse between first and second injections
    v. The maximum licensed dose for Olanzapine by any route is 20mg a day. When prescribing/administering IM Olanzapine DO NOT EXCEED 20mg total in 24 hours- check oral & IM prescriptions before giving.

vi. Olanzapine injection rapidly reaches peak blood levels, but has a relatively long half life, therefore drug accumulation is possible with repeated doses. Do not give more than 3 injections in 24 hours (up to a maximum of 20mg in 24 hours – 15mg in the elderly). Do not give for more than 3 consecutive days
vii. Monitor carefully after administration (see policy). Cardio-respiratory depression, hypotension and bradycardia have been reported amongst the cases of adverse events.
viii. For further advice contact your mental health trust clinical pharmacist.

g. Sedative drugs such as Promethazine are available and may be useful when other agents have failed.

h. Zuclopenthixol acetate (acuphase) is not an appropriate drug for use for the rapid management of disturbed behaviour. It has a significantly delayed onset of action and a relatively long duration of action. It may have a role in the *ongoing management* of a risk of violence once tranquillisation has been satisfactorily achieved. However it is important to consider the pharmacokinetics of other drugs when prescribing it. For example, caution is necessary in a patient who has recently received a dose of depot antipsychotic which has not yet reached peak levels.

KEY MESSAGES

Avoid benzodiazepines in patients with compromised respiratory function

Avoid antipsychotics in those who have compromised cardiovascular function.

If antipsychotics are considered necessary, consider olanzapine in those who are antipsychotic naive or who have a history of extrapyramidal side effects.

When IM injections are used additional monitoring should be in place

Zuclopenthixol acetate (acuphase) is not an appropriate drug for use for the rapid management of acutely disturbed behaviour

Table 1 – drugs used for the management of acutely disturbed behaviour, their properties and side effects

Drug	route	Pharmacokinetics	Major side effects/risks	Notes
Benzodiazepines				
Lorazepam	Po/im	Onset 10-30 mins Peak 60-90 mins. T½ 12-16 hours	Respiratory depression disinhibition	Benzodiazepines have a wide therapeutic index and respiratory depression is readily reversed with the specific antagonist flumazenil. There is conflicting evidence about disinhibition, which may be more likely in the elderly, adolescents and those with organic brain disease or learning disabilities.
Diazepam	Po	Peak 30-90 minutes T½ 20-100 hours		
Short acting antipsychotics				
Haloperidol Tablets/liquid injection	Po im	Onset 1-2 hours peak at 4 hours peak at 20 minutes T½ 21 hours	EPSEs hypotension Cardiac arrest NMS sudden death increased QT_c & arrhythmias seizures	Not recommended for iv use because of the increased risk of arrhrythmias NB Lower doses now recommended – see chart
Risperidone Tablets, liquid or orodispersible	po	Peak 1 hour T½ 24 hours (longer in the elderly)	Hypotension	Care with postural hypotension Monitor for increased anxiety or agitation Rate of absorption and onset of effect is the same for liquid and orodispersible as plain tablets
Olanzapine Tablets or orodispersible injection	Po im	Peak at 5-8 hours T½ 34 hours (elderly 50 hours) Peak at 15-45 minutes T½ 30 hours	Drowsiness Hypotension Bradycardia Syncope	Im administration results in maximum plasma concentration 5× higher than same oral dose Caution with the elderly, females and non-smokers, who may experience higher levels- consider reduced dose, especially if second injection needed. Do not use in dementia or in individuals with cerebrovascular risk factors for stroke.
Antihistamines				
Promethazine	im	Onset 1-2 hours T½ 7-15 hours	Prolonged sedation Seizures Cardiorespiratory depression	Has a relatively slow onset of action but is reported to be useful where other agents have failed
Longer acting antipsychotics				
Zuclopenthixol acetate [acuphase]	im	Onset 2-8hours (very variable) Peak 24-36 hours T½ 60 hours	EPSEs sudden death cardiac arrest arrythmias	**This is not an appropriate drug for use in RT. It should not be used in those who are neuroleptic-naive, who are struggling, who are sensitive to EPSE, who are comatose or those with cardiac disease, hepatic or renal impairment or in pregnancy**
Antimuscarinics				
Procyclidine	Po/im	T½ 12 hours	Blurred vision Urinary retention Dry mouth	Quicker onset of action occurs with im use. In sensitive individuals or with high doses confusion, anxiety and agitation may occur.

Note: The pharmacokinetics of lorazepam are the same whether given orally or parenterally. Therefore the only reason to give lorazepam parenterally is if the patient refuses oral.

4 Physical monitoring before and during the administration of drugs for the management of acutely disturbed behaviour

a. *Before the prescribing of drugs either in anticipation or at the time of their use to manage acutely disturbed behaviour the prescribing doctor should:*

- **i.** Consider the possibility of a physical examination
- **ii.** Review the patients notes with regard to his/her general medical history
- **iii.** Check for recent ECG, U&E & urine drug screen results, a previous history of severe extrapyramidal effects, previous response to drugs or other methods of managing imminent violence
- **iv.** Review current prescribed medication, taking note of administrations of prn prescriptions.
- **v.** Review consent issues
- **vi.** Review any drug advance statements

b. *When administering drugs prescribed in anticipation of acutely disturbed behaviour the nurse should:*

- **i.** Consider whether there are physical health issues or a physical examination is necessary
- **ii.** Review consent issues (particularly if detained under the Mental Health Act 1983)
- **iii.** Review any drug advance statements
- **iv.** Consider and take into account the possibility of illicit drug or alcohol use

c. *During the use of drugs to manage acutely disturbed behaviour :*

- **i.** Close monitoring by nursing staff is necessary to ensure prompt recognition of the serious complications. The frequency must be agreed with the clinical team and will vary according to the clinical state of the patient. Some observations may be difficult if a patient remains agitated or aggressive. Problems in this regard should be clearly documented and discussed with the prescriber or the clinical team. **Observations should be particularly frequent when a patient is sedated and if IM injections have been administered .** Table 2 gives suggested scheme when IM injections are used

Table 2 – scheme for physical monitoring after administration of IM drugs to manage acutely disturbed behaviour:

For the 1st hour after drug administration:		
	• **Alertness**	Every 5 minutes
	• **Pulse** • **Respiratory rate** • **Blood pressure** • **Temperature**	Every 10 minutes
After the first hour and until the patient is ambulatory:		
	• **Alertness** • **Pulse** • **Respiratory rate** • **Blood pressure** • **Temperature**	Every 30 minutes
Once the patient is ambulatory:		

	• Continue to monitor alertness, mental state and behaviour. • Restart physical observations if any concerns.

d. If physical complications arise access the Derbyshire Early Warning System (DEWS) Score Chart

Whilst Awaiting Help

Monitor: Conscious level, Respiratory rate Pulse rate, Blood pressure, Temperature, SPO2
Oxygen: What are the service user's oxygen saturations? Give oxygen at 10 – 15 ltr/min unless COPD
Vein: Assess venous access and if trained and score is greater than 3 cannulate
ECG: Have 12 lead ECG machine available and if trained carry out the ECG

- In addition **fluid balance and electrolyte balance** should be monitored as clinically indicated.

- **An ECG** is recommended at the earliest opportunity and particularly when parenteral antipsychotics have been given in high doses. It should be considered when multiple drugs have been used, there is a past history of cardiovascular problems, patient is antipsychotic drug naïve or where there is a history of recent substance misuse.

- If a patient is unconscious **continuous pulse oximetry** is recommended.

5. Management of side effects & complications

Table 3 – common or serious side effects and management

Complication	Symptoms/signs	Management
Acute dystonia	Severe painful muscular stiffness	Procyclidine 5-10 mgs im
Hypotension	Fall in blood pressure (orthostatic or <50mmHg diastolic)	Lie patient flat and raise legs Monitor closely
Neuroleptic malignant syndrome	Increasing temperature, fluctuating blood pressure, muscular rigidity, confusion/altered consciousness	Withhold antipsychotics Monitor closely, consider CPK level Liaise with general medical team immediately
Arrhythmias	Slow (<50/minute) or irregular pulse	Monitor closely and liaise with general medical team immediately

Respiratory depression	Reducing respiratory rate, reducing consciousness	If respiratory rate drops below 10/minute in a patient who has received benzodiazepines, give flumazenil (caution in epilepsy): 1. 200microgram i.v. over 15 seconds 2. if consciousness not resumed within 60 seconds give 100microgram over 10 seconds 3. repeat at 60 second intervals. Maximum dose 1mg/24 hours N.B Elderly doses are the same. Liase with general medical team. Continue to monitor after respiratory rate returns to normal. Flumazenil has a shorter duration of action than many benzodiazepines therefore there is a risk that patients may become resedated. Further doses of Flumazenil may be required. Patients may become agitated or anxious on wakening

6. After the use of drugs for the management of acutely disturbed behaviour

1. All patients should be offered the opportunity to discuss their experiences and should be provided with a clear explanation of the decision to use drugs for the management of acutely disturbed behaviour. They should be given an opportunity to write their account of their experience in the notes.

2. Similarly, staff and other patients should have the opportunity to discuss the incident.

3. The outcome of the use of drugs for the management of acutely disturbed behaviour should inform the steps to be taken and the drugs to be used in the future.

4. Drugs used for the management of acutely disturbed behaviour provide a short term strategy for managing a risk of imminent violence. Medium and longer term measures should be considered at an early stage with the aim of avoiding repeated use of this procedure.

5. The diagnosis and its relationship to violence should be considered. Regular treatment should be reviewed.

7. Training Requirements

1. Nursing staff should understand the principles of drugs used for the management of acutely disturbed behaviour and feel confident about administering drugs and carrying out physical monitoring.

2. Doctors should understand the principles of drugs used for the management of acutely disturbed behaviour, be aware of the pharmacokinetics of the agents used and feel confident about prescribing them.

3. All nursing and medical staff should have read and be aware of these guidelines.

4. An e-learning package has been developed to support the implementation of the rapid tranquillisation policy. Ward managers of adult inpatient areas should insure

their staff complete the e-learning module before participating in the administration of drugs to manage acutely disturbed behaviour.

8. Entries into clinical notes

8.1 The medical notes

1. When medicines are first prescribed for the management of acutely disturbed behaviour (either as prn in anticipation of the acute disturbed behaviour or at the time of the event) the medical notes should make reference to:

    1. Review of general medical history
    2. Review of ECG, physical investigations
    3. Physical examination or why this was not possible?
    4. Previous response to drugs used for the management of acutely disturbed behaviour/adverse effect
    5. Assessment of potential for illicit drug/alcohol use
    6. Review of current prescribed medicines
    7. The frequency of monitoring agreed with nursing/clinical team
    8. Whether the choice of medicines is coved by an advance statement

2. When parenteral (IM) medicines are prescribed for the management of acutely disturbed behaviour the medical notes should make reference to:

    - The circumstances necessary for the appropriate use of parenteral medicines eg whether the patient is refusing oral medicines
    - The reasons for the decision to give parenteral treatment for the management of acutely disturbed behaviour rather than oral medicines
    - The frequency of monitoring agreed with nursing/clinical team
    - Review of drug management plan

8.2 The nursing notes

- When medicines are administered for the management of acutely disturbed behaviour (either as prn in anticipation of the acute disturbed behaviour or upon a prescription written at the time of the event) the nursing notes should make reference to:

    - The nature of the acutely disturbed behaviour
    - The timecourse of events from:
        - The onset of the behaviour until the offering of oral medicines
        - The impact of non-drug strategies
        - The acceptance or refusal of oral medicines
        - The impact of the administration of oral medicines

- When parenteral medicines are administered for the management of acutely disturbed behaviour the nursing notes should make reference to:

In the first hour after each injection	▪ checking for alertness every 5 minutes ▪ checking of respiration every 10minutes or reasons why this was not possible? ▪ checking of BP every 10 minutes or reasons why this was not possible?

- checking of temperature every 10minutes or reasons why this was not possible
- evidence as to whether the patient is ambulant
- evidence of on going physical monitoring

8. 3 DMHST is keen to discourage the use of Zuclopenthixol acetate (acuphase) for rapid tranquillisation. Nursing staff should in addition to the above record:

- Those strategies used prior to the administration of Zuclopenthixol acetate (acuphase)
- The reasons for the selection of Zuclopenthixol acetate (acuphase)

It is anticipated that wards will review their use of Zuclopenthixol acetate (acuphase) at 3 monthly intervals

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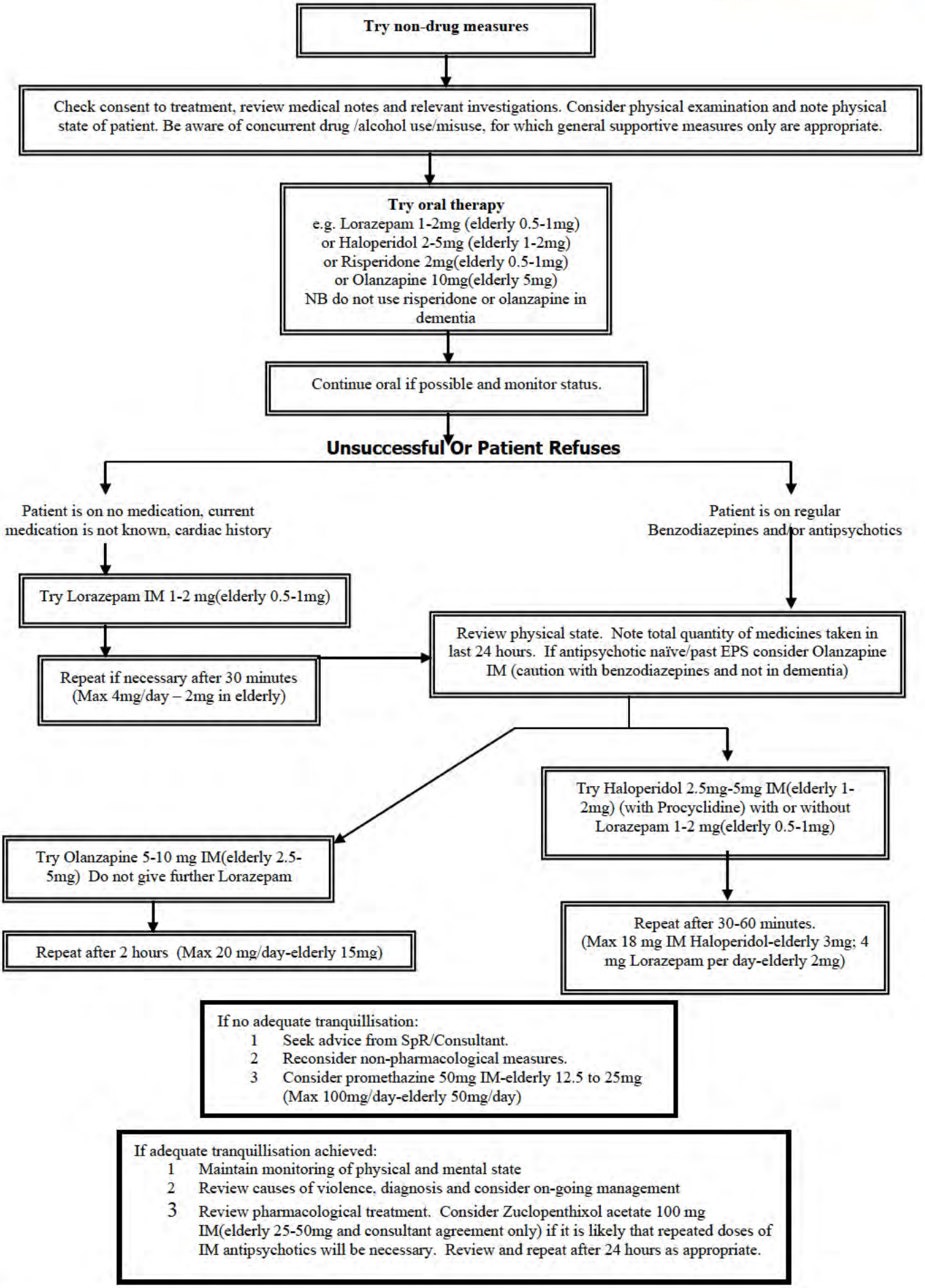
An Algorithm for the drug control of **ACUTE DISTURBED OR VIOLENT BEHAVIOUR**
(Adapted from the Maudsley Guideline 2008)

Derbyshire NHS
Mental Health Services NHS Trust



CNWL MH NHS Trust
GUIDELINES FOR RAPID CONTROL OF ACUTELY DISTURBED PATIENTS (Adults)

1. AIM

The aim of rapidly tranquillising a patient is to quickly calm the severely agitated patient, in order to reduce the risk of imminent and serious violence to self or others, rather than treat the underlying psychiatric condition. The aim is not to induce sleep or unconsciousness, the patient should be sedated but still able to participate in further assessment and treatment, however there may be occasions when sedation is an appropriate goal.

2. PRINCIPLES

2.1 Patients should only be treated with the following medicines after an assessment of risk and when it has been established that the risk of not doing so is greater than the risk of acute pharmacological treatment.

2.2 Staff should be trained in how to assess and manage potential and actual violence using de-escalation techniques, restraint, seclusion and rapid tranquillisation. Staff should also be trained to use and maintain the techniques and equipment required to undertake cardiopulmonary resuscitation.

2.3 Intervention should take the form of talking to the patient in a calm manner and by being seen by the patient to be listening to their grievances. If this fails, secluding the patient may be of some benefit (therefore this document should be read in conjunction with the Trust's seclusion policy).

2.4 Other non-pharmacological interventions should, where possible, also be explored, for example increasing the level of observations of the patient, increasing the level of staffing, changing the patients setting, this may include transfer to a Psychiatric ICU.

2.5 If a patient is acutely disturbed, then the patients' doctor or duty psychiatrist must be called to attend immediately. It is vital that the attending psychiatrist obtains as much history as possible from the patient and other sources before medication is given, as the opportunity to make a diagnosis may be lost if the patient is sedated before an understanding of their mental state is reached. However the immediate safety of the patient and staff is of prime concern. Due consideration should be paid to potential non-psychiatric causes for the disturbed behaviour (e.g. organic, psychological, intoxication or withdrawal states).

2.6 In all cases the patient must be informed that medication is going to be given and must be given the opportunity at any stage to accept oral medication voluntarily. The patient with schizophrenia should be given the opportunity to make an informed choice where at all possible. If a patient is unable to give informed decision an atypical should be prescribed for regular treatment.

2.7 In all cases the minimum effective dose of medication should be used, BNF maximum doses should only be exceeded in extreme circumstances.

3. PHARMACOLGICAL TREATMENTS

3.1 Polypharmacy within a class of medication (e.g. antipsychotics) should, where at all possible, be avoided.

3.2 Consideration should be given to any co-existing medical illnesses, and any regularly prescribed oral/depot medication, this may impact on dose requirements and potential side effects.

3.3 Where there is documented in the patients' care plans their preference in medication to be used in the event of an acute episode of illness (an advance directive), this preference should be adhered to if clinically appropriate. The CPA co-ordinator must ensure that the individuals' advance directive is notified to the prescribers during the acute phase of illness.

3.4 Oral medication should be offered before parenteral treatment is administered, although IM medication has a faster onset of action. If there is a valid prn prescription for this, this may then be given by nursing staff.

3.3 <u>The following steps are recommended as oral medication regimes</u>:

3.3.1 ***Lorazepam*** 1-4mg

OR

3.3.2 ***Lorazepam*** 1-4mg and ***haloperidol*** 5-10mg

OR

3.3.3 ***Olanzapine*** 10mg

Caution if using a typical antipsychotic in an unknown or antipsychotic naïve patient.

3.4 Oral atypicals are considered first line choices in patients newly diagnosed with schizophrenia, see the Trusts Atypical Antipsychotic Prescribing Guidelines for preferred agent.

3.5 If oral medication is repetitively refused, the decision to forcibly medicate a patient (IM) will be taken jointly by medical and nursing staff. Once the decision has been made to forcibly medicate, the patient must be isolated from other patients on the ward and placed in a side room. Nursing and medical staff involved in physically restraining the patient should be proficient in "Control & Restraint" techniques and should have adequate immunisation against hepatitis B.

3.6 <u>The following steps are recommended as parenteral medication regimes</u> for patients who have not been adequately settled by non-drug measures or oral medication, or who are refusing oral medication:

3.6.1 ***Lorazepam*** 2mg, given IM.
Repeat after 30 mins if necessary, or step 3.6.2

OR

3.6.2 ***Haloperidol*** 5-10mg and ***Lorazepam*** 2mg, both given IM.
Repeat after 30mins if necessary.

3.6.3 ***Haloperidol*** 5-10mg and ***Diazemuls***® (diazepam) 10mg by slow IV injection over at least 2-3 mins each. Repeat after a minimum of 5-10 mins if clinically required.

In view of the safety considerations the IM route is preferable to the IV route. IV administration should only be used when other methods have failed, in exceptional circumstances, with expressed consultant authority.

3.6.4 With either regimen (3.6.2) or (3.6.3) a maximum of 18mg haloperidol and 60mg of diazepam may be given in twenty four hours.

3.6.5 The maximum BNF dose of IM lorazepam is 4mg/d in adults, at times doses higher than this may be required, in such circumstances advice should be sought from senior colleagues.

3.6.6 Lorazepam should be mixed in a 1:1 ratio with water for injections before administration.

3.6.7 If parenteral haloperidol is used ***anticholinergics*** (e.g. Procyclidine 5-10mg IM/IV or benzatropine mesylate 1-2mg IM/IV) should also be given to reduce the risk of dystonia and other extrapyramidal symptoms.

3.6.8 NEVER mix drugs in the same syringe.

3.6.9 Advice of a senior colleague/consultant may be appropriate.

3.7 ***Flumazenil*** should be given if respiratory rate drops below 10/min due to benzodiazepine administration. Repeated doses may be required as it is short acting, see current BNF for further dosing details. Flumazenil is best avoided in epileptic patients – start mechanical ventilation instead.

3.8 ***Zuclopenthixol Acetate*** (Clopixol Acuphase®) 50-150mg IM should only be considered if a patient responds to other short acting parenteral antipsychotics, if it is anticipated that the patient will require further frequent doses of IM typical antipsychotics. Do not give to an actively struggling patient. Do not administer to antipsychotic naïve patients.
The pharmacokinetics of this formulation should be borne in mind, refer to the Trust's prescribing guidelines on Zuclopenthixol acetate (Clopixol Acuphase®).

3.9 ***Amylobarbitone*** and ***paraldehyde*** are not recommended for administration and should be considered only whenever other treatment strategies have failed. The decision to use such agents should be made only by a consultant and pharmacy should be contacted for further advice and guidance on administration and monitoring requirements.

3.10 ***Diazepam*** should not be administered IM due to its erratic pattern of absorption.

3.11 Do NOT use ***chlorpromazine*** parentally. Administration via the IV route is unlicensed in the UK and carries the risk of prolonged unconsciousness. It must not be given IM as the injection is extremely painful and severe hypotension is common.

3.12 When an IM atypical antipsychotic becomes available this may be a more appropriate choice of antipsychotic medication, particularly in patients with a history of severe dystonic reactions, and in those whose history is unknown or are neuroleptic naïve.

4. MONITORING REQUIREMENTS

4.1 Constant visual observation of the patient should be maintained.

4.2 Blood pressure, pulse, temperature, respiratory rate, blood oxygen saturation (using pulse oximeters) and level of consciousness should be ***monitored*** every 15 mins after IM injections, and every 5 mins after IV infusions for the first hour, then hourly for 4 hours or until the patient becomes active again. Measurements should be documented on the patients' notes. If staff are unable to monitor any of these parameters the reasons for such omissions must also be documented in the patients' notes.

4.3 Resuscitation equipment and medication, including flumazenil, must be available and easily accessible, staff should be familiar with their use.

4.4 Ensure adequate physical restraint before attempting parenteral administration in a struggling patient.

5. SPECIAL POPULATIONS

5.1 Avoid ***benzodiazepines*** in patients who are physically unwell, delirious or who have significant respiratory impairment. Use benzodiazepines in preference to antipsychotics in patients with cardiac disease, as these are safer, but beware of accumulation.

5.2 Older Adults

Similar principles as for adult patients should be applied. Particular care should be given to co-existing medical states and prescribed medication, the risk of accumulation of sedatives and the possibility of delirium. For acute behavioural disturbances in the elderly lorazepam 0.5-1mg po/im bd-tds should be used.
The use of typical antipsychotics should be avoided (e.g. haloperidol) due to the high incidence of extrapyramidal symptoms. Regular atypical antipsychotics can be used orally (prn use is not licensed), however prn IM haloperidol may still be required if oral medication is repetitively refused. Advice should be sought from senior colleagues if two or more parenteral doses are required or ≥2mg lorazepam.

5.3 Ethnic Origin

There is conflicting evidence as to whether the patients' race gives rise to any differences in response to antipsychotic medication, each case should be dealt with on an individual basis.

6. FEEDBACK

6.1 The reason for prescribing any medication for the acutely disturbed patient should be documented in the medical notes, as well as the working diagnosis.

6.2 Any medication administered and the patients' response should be recorded.

6.3 Nursing and medical staff should always have a short feedback session following emergency restraint and sedation.

6.4 After the treatment of an acute disturbance patient should be debriefed, this should be documented in their notes, and they should be offered the opportunity to write an account in their notes.

This document should be read in conjunction with the Trusts' Medicines Policy

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