Muckamore Abbey Hospital Inquiry

Module 3 – Policy and Procedure

MODULE 3 WITNESS STATEMENT –
ON BEHALF OF BELFAST HEALTH AND SOCIAL CARE TRUST
RELATING TO PRN MEDICATION

I, Brona Shaw, of the Belfast Health and Social Care Trust (the "Belfast Trust"), and I, Stephen Guy of the Belfast Trust (formerly Lead Mental Health Pharmacist), make the following statement for the purposes of the Muckamore Abbey Hospital Inquiry (the "MAH Inquiry"):

1. By letter of 2 May 2023 the MAH Inquiry asked the Belfast Trust to address the:

   "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."

2. This statement endeavours to address what is a complex subject. It is also part of a much wider area or continuum relating to the management of disturbed behaviour. It inevitably spans nursing, medicine and pharmacy. For that reason, we have collaborated and provided a joint statement, in order to best assist the MAH Inquiry.

3. Within this statement, we cross-refer to certain matters addressed within the Belfast Trust Module 3 witness statement of 20 March 2023 ("the 20 March 2023 Module 3 Statement") signed by Mr Hagan, and also the Belfast Trust Module 3

addendum witness statement signed by Mr Hagan of 17 April 2023 ("the 17 April 2023 Module 3 Addendum Statement").

4. Given the breadth and multidisciplinary nature of the matters which we address, we make this statement having had the assistance of the following individuals:

   a. Claire Erki, Interim Lead Mental Health Pharmacist, Belfast Trust;

   b. Deirdre Murray, Clinical Pharmacist at Muckamore Abbey Hospital (MAH);

   c. Dr Damien Hughes, formerly a Consultant Psychiatrist at MAH from 2006 until 2018 (Cranfield ward). Dr Hughes also trained at MAH in 1998;

   d. Billie Hughes, Co-Director, Intellectual Disability Services, and former Divisional Nurse at MAH;

   e. Dr Paul Devine, Consultant in Forensic Psychiatry; Clinical Director, Forensic and Secure Mental Health; Interim Clinical Director, Intellectual Disability Services, Belfast Trust;

   f. Karen Devenney, Senior Nurse Manager, Safety and Quality;

   g. Roisin McMahon, Divisional Nurse, Learning Disability, Belfast Trust;

   h. Sam Warren, Safety Intervention Trust Advisor/Trainer, Safety Intervention Team, Belfast Trust (currently on secondment as a Senior Nurse Manager at MAH);

   i. Neil Walsh, Safety Intervention Trust Advisor/Trainer, Safety Intervention Team, Belfast Trust;

   j. Jenni Armstrong, former Resource Nurse at MAH; and

k. Dr Lisa Montgomery, ST5, Child and Adolescent Psychiatry.

5. In making this statement, we endeavour to provide an overview in relation to the use of PRN medication from the formation of the Belfast Trust, including in respect of each of the sub-topics identified in the MAH Inquiry's letter of 2 May 2023. In doing so, given the objective of the current phase of evidence stated in the MAH Inquiry evidence request letter dated 9 December 2022, we focus on identifying the policies, procedures and other guidelines that were applicable during the timeframe which the MAH Inquiry is considering, together with the framework of surrounding structures and regulation. We do not seek to address the adequacy and effectiveness of that provision; we understand that this is a matter which the MAH Inquiry will consider, as necessary, in due course.

6. The documents that we refer to in this statement can be found in the exhibit bundle attached to this statement marked "BS2". The MAHI letter of 2 May 2023 can be found behind Tab 1 in the exhibit bundle.

Context in respect of "PRN"

7. "*PRN*" is an abbreviation of the Latin term "*pro re nata*", which means "*when needed*".

8. The acronym is used in relation a wide range of prescribed medication that is to be taken or administered when needed.

9. It is not confined to medications that may be administered to a patient by intramuscular injection. It also encompasses oral medications.

10. The "PRN" acronym is used to refer to a type, or basis, of prescription, rather than to any particular medication. There are many different prescribed medications that may form part of the class or group referred to as "PRN" medication.

11. "PRN" medication is used in a very wide variety of contexts across the health and social care system (primary, secondary and community care). It is not confined to use in a learning disability hospital, or for the management of acute disturbed behaviour. For example, a GP may prescribe "PRN" pain relief medication, or certain forms of inhaler to relieve breathing difficulties. Similarly, in acute hospital settings such as emergency departments, "PRN" medication is commonly prescribed for pain relief, muscle relaxation or to alleviate distress.

12. In the context of mental health and learning disability care, the term "PRN" is commonly used in the context of the management of acute behavioural disturbance. In this context, the use of PRN medication is generally part of a strategy to de-escalate or prevent situations of patient agitation, aggression and violence. It is a pharmacological strategy which may be used as part of a continuum of interventions, including non-pharmacological techniques, to manage instances of acute behavioural disturbance (symptoms of which may range from agitation and distress to actual aggression or violence).

13. In the context of mental health and learning disability care the use of "PRN" can refer to the use of oral medication utilised as part of a de-escalation strategy (we will refer to this as "oral PRN de-escalation"), through to intramuscular, or IM, medication administered to achieve "Rapid Tranquilisation" during an episode of violence or aggression.

14. As we describe in more detail below, all PRN medication at MAH is prescribed by a qualified prescriber who is generally a doctor, though, for completeness, we also describe below the position in relation to the "Non-Medical Prescriber". PRN medication is prescribed on a patient's Medicine Prescription and Administration Record, commonly known as a "Kardex". The doctor will determine the type of medication, frequency of use, and the dose to be administered. At MAH the administration of the prescribed PRN medication is carried out by a nurse only. The nature of the original prescription can allow some discretion to the

administering nurse, in terms of the amount to be given within the capped time period and amount, beyond which a further consultation with a doctor is necessary.

15. In its letter of 2 May 2023, the MAH Inquiry asked the Belfast Trust to address "*policies relating to the administration of PRN sedation*". We are not aware of the phrase "PRN sedation" being a medical term per se, nor of it having any technical or specific meaning. It is not a specific concept or definition used within the Belfast Trust. Nonetheless, we assume that the MAH Inquiry Panel wishes to understand the framework within which PRN medication intended to have effect in the management of disturbed behaviour has been prescribed and administered at MAH.

16. At the outset, and as identified in summary above, it is important to distinguish oral PRN de-escalation medication from what is known as "*Rapid Tranquilisation*" medication. Rapid Tranquilisation medication is that administered by the parenteral (non-oral) route if oral medication is not possible or appropriate and urgent sedation with medication is needed. Generally, this involves intramuscular administration. It may, exceptionally, involve intravenous administration, although we are not aware of such administration having been utilised in an inpatient mental health setting. For clarity, within this statement, we refer to this as "*intramuscular Rapid Tranquilisation*". The administration of oral PRN de-escalation medication is not considered to form part of "Rapid Tranquilisation".

17. Intramuscular Rapid Tranquilisation is considered a form of restrictive intervention alongside, for example, physical restraint and seclusion. It is classed as a pharmacological/chemical restraint or intervention and is therefore referred to within the Regional and Belfast Trust Restrictive Practices policies. These were identified at paragraphs 38 and 39 of the 20 March 2023 Module 3 Statement and at paragraph 34 of the 17 April 2023 Module 3 Addendum Statement.

18. There are some links between oral PRN de-escalation medication and intramuscular Rapid Tranquilisation medication. First, each is a pharmacological response which may be used to manage acute behavioural disturbance. Second, in many cases, oral PRN de-escalation may be the preferred, less invasive alternative to intramuscular Rapid Tranquilisation. Even for individuals for whom intramuscular Rapid Tranquilisation has been prescribed, such medication is generally to be administered only where de-escalation and other preventative strategies, including oral PRN de-escalation, have been, or would be expected to be, unsuccessful. In practice, this generally involves a patient being offered oral PRN de-escalation unless the treating team considers that the risks are disproportionate. Accordingly, oral PRN de-escalation is sometimes referred to as "*pre-rapid tranquilisation*". Third, oral PRN de-escalation and intramuscular Rapid Tranquilisation are often addressed within the same or related policies and other provisions, including those which we address in this statement.

19. The prescription and administration of medications in the management of disturbed behaviour is part of a continuum of treatment designed to prevent harm to the patient or others. It can range from the prescription and administration of low levels of oral PRN de-escalation to alleviate low levels of agitation right through to the urgent prescription and administration of intramuscular Rapid Tranquilisation in response to an otherwise uncontrollable incident in which an individual is presenting a serious risk to themselves or to others.

20. As indicated earlier, this spectrum of PRN medication options used in the likes of MAH is not limited to mental health and learning disability; it may be used to manage disturbed behaviour across a range of care settings including older adult, dementia and CAMHS inpatient settings and <u>all</u> acute hospital inpatient settings including emergency departments. Each of the policy provisions to which we refer within this statement has applied, or been relevant, within those areas also.

21. We wish to emphasise at the outset that, even in the mental health and learning disability context, in the case of most individuals for whom oral PRN de-escalation is prescribed and/or administered, it is only a form of oral PRN de-escalation that is prescribed and/or ever required to be administered. The use of intramuscular Rapid Tranquilisation is comparatively rare. That has been the position at MAH also.

22. To assist the MAH Inquiry, within this statement we address both oral PRN de-escalation and intramuscular Rapid Tranquilisation.

Policies relating to PRN medication

23. The documents that are likely to be of most assistance to the MAH Inquiry and which bear on the prescription and administration of oral PRN de-escalation and/or intramuscular Rapid Tranquilisation during the primary date range of the Terms of Reference of the MAH Inquiry, are as follows:

    a. February 2005 NICE Clinical Practice Guidelines "*Violence: The short-term management of disturbed/violent behaviour in in-patient psychiatric setting and emergency departments*" (CG25);

    b. 2012 Belfast Trust "*Rapid Tranquilisation Guideline for the immediate pharmacological management of violent and aggressive behaviour in adults and adolescent patients in the Belfast Health and Social Care Trust*" (version 1);

    c. May 2015 NICE Guideline 10 "*Violence and aggression: short-term management in mental health, health and community settings*" (NG10); and

    d. February 2017 Belfast Trust "*Rapid Tranquilisation Guideline for the Pharmacological Management of Violent and Aggressive Behaviour in Adults, Children and Young People in Inpatient Units*" (SG 44/12) (version 2).

24. Copies of each document are provided behind Tab 2 of the exhibit bundle.

25. Each of the above documents were identified in paragraphs 38 to 40 of the 20 March 2023 Module 3 Statement in addressing restraint and seclusion in the broader context of restrictive interventions. This broader context is important in relation to intramuscular Rapid Tranquilisation. As the regional and Belfast Trust Restrictive Practices policies are referred to at paragraphs 38-39 of the 20 March 2023 Module 3 Statement and at paragraphs 24 of the 17 April 2023 Module 3 Addendum Statement, we do not repeat that content here, or seek to address those documents further; however, the attention of the MAH Inquiry is drawn to them in the context of PRN medication.

26. Although outside the primary time period which the MAH Inquiry is considering, and as identified at paragraphs 38pp and 45 of the 20 March 2023 Module 3 Statement, the following documents, copies of which are provided behind Tab 2 of the exhibit bundle, have since also been issued:

    a. 2022 HSCNI "*Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation*". This is the first ever regional guidance on the subject; and

    b. April 2022 Belfast Trust "*Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation*" (BHSCT/ASPC/MH (12) 2022) (version 3).

27. In broad overview, the 2012 Belfast Trust Rapid Tranquilisation Guideline referred to at paragraph 23.b above was the first Belfast Trust policy in this area. It superseded any policies from this area of the Legacy Trusts that merged to form the Belfast Trust. A first draft of the 2012 policy was produced in May 2009. Unfortunately, we are unable, up to this point, to provide details as to the local policy position before the Belfast Trust became operational in 2007. However, we can say that important general and clinical guidance, including the Maudsley

Prescribing Guidelines to which we refer below, were in existence prior to 2007. They were also in use by clinicians within the Belfast Trust before the new policy became operational in 2012.

28. The 2012 Belfast Trust Rapid Tranquilisation Guideline was based on the February 2005 NICE Guidelines (CG25) and the October 2009 Maudsley Prescribing Guidelines (10th Edition). The February 2005 NICE Guidelines (CG25) were the first NICE Guidelines in this area.

29. It is necessary to highlight an important change in the use of terminology.

30. Unusually, the February 2005 NICE Guidelines (CG25) uses the term "*Rapid Tranquilisation*" in a broad sense, to comprise both the use of oral PRN de-escalation and intramuscular Rapid Tranquilisation medication. The relevant definitions are set out at page 12 of that document. They are:

    a. "*PRN (Pro re nata): medication that may be used as the occasion arises; when necessary*"; and

    b. "*Rapid tranquilisation: 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…*"

31. The 2012 Belfast Trust Rapid Tranquilisation Guideline implemented and reflected the February 2005 NICE Guidelines (CG25) in using the term "*Rapid Tranquilisation*" in that broad sense, although the detailed provisions of the 2012 Belfast Trust policy do delineate between the use of "*oral medication*" and "*intramuscular medication*".

32. We do not know at this remove why the February 2005 NICE Guidelines (CG25) adopted the above definition. Our understanding is that both oral PRN de-escalation and intramuscular Rapid Tranquilisation were used as, and were understood to be, separate and distinct pharmacological responses long before February 2005. The prevailing view was that the broad definition of "*Rapid Tranquilisation*" which the February 2005 NICE Guidelines adopted was not reflective of established practice, where the term was used strictly to refer only to injectable intramuscular medication.

33. Accordingly, the May 2015 NICE Guideline 10 (NG10), which superseded the February 2005 version, included clear and updated definitions on which all subsequent guidance has been based. It contained a clear distinction between oral PRN de-escalation medication, and that used for intramuscular Rapid Tranquilisation. For completeness, the revised definitions are set out at page 19 of the May 2015 NICE Guideline 10, and include:

    a. "*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*"; and

    b. "*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.*"

34. The February 2017 Belfast Trust Rapid Tranquilisation Guideline was developed to implement the May 2015 Nice Guideline 10 (NG10) and adopted the above definitions, which distinguishes between the two forms of medication.

35. The 2022 HSCNI "*Regional Guideline for the Management of Acutely Disturbed Behaviour (ADB) through the use of Pharmacological De-escalation and Rapid Tranquillisation*" was the first regional policy contribution in this area. It was

developed by the Rapid Tranquilisation Subcommittee of the Minimising Restrictive Practice Regional Group. The Group's membership comprised representatives (mainly mental health pharmacy leads) from each of the five HSC Trusts, including Mr Guy and Ms Erki.

36. The new 2022 Regional Guideline is also based on the May 2015 NICE Guideline 10 (NG10), as well as on further learning and development in this area. It is an amalgamation of the various HSC Trust guidelines which were in place at that time. Although in the absence of regional policy direction, each individual HSC Trust had developed its own policy in this area, and there were necessarily some differences in format, we can say that there was a large degree of commonality between them.

37. This would appear to be for two reasons. First, all generally shared the common basis of the prevailing national documents and clinical guidance, such as NICE Guidelines and the Maudsley Prescribing Guidelines. Such documents are detailed in nature and clear in their direction; they do not allow for a large degree of variation. The second reason is that there was considerable collaboration and sharing of work between the different HSC Trusts on this issue. We are informed and believe that previous iterations of the Belfast Trust Guidelines were shared with colleagues in the other HSC Trusts.

38. Within the Belfast Trust, the pharmacy team also had sight of, and regard to, the equivalent policies developed by health trusts in England and Wales. This may have been, for example, as a result of sharing by the relevant author, or through a professional network, such as the mental health pharmacy special interest group formerly known as the UK Psychiatric Pharmacists Group (and, since 2010, the College of Mental Health Pharmacy). By way of example only, behind Tab 2 of the exhibit bundle are copies of the following policies that Mr Guy had retained and has been able to retrieve to assist the MAH Inquiry:

a. Derbyshire Healthcare NHS Foundation Trust Mental Health Services "*Guidelines for the Drug Management of the Acutely Disturbed Patient*". Please note that this copy is marked as "final Draft" and is undated. In passing, we note that this document does not use the term "Rapid Tranquilisation". This is explained at section 1(b) on the first page and includes, as we have already described, that many staff, even at that time, regarded the term as synonymous with the use of intramuscular injections; and

b. The 2003 Central and North West London NHS Foundation Trust "*Guidelines for Rapid Control of Acutely Disturbed Patients (Adults)*".

39. Accordingly, the MAH Inquiry may note substantial similarities between the 2017 Belfast Trust Rapid Tranquilisation Guideline and the 2022 HSCNI Regional Guideline – see, by way of example, the "*flow charts*" which are appended to each document. Part of the intention in bringing together the individual HSC Trust policies into a new regional policy was to simplify and streamline the transfer of relevant HSC staff between the Trusts. For example, the knowledge and skills received from training undertaken in one HSC Trust in this area would be more easily transferable.

40. The MAH Inquiry has asked the Belfast Trust to address those policies relating to "*the administration of PRN sedation*". The "*administration*" of PRN medication, whether oral PRN de-escalation or intramuscular Rapid Tranquilisation, is only one stage in the use of such medication. In order to provide a more comprehensive picture of the policy framework and regulation in relation to the use of medication in the management of disturbed behaviour, we address, in turn:

a. The prescription of medication;

b. The dispensing of medication;

c. The administration of medication; and

d. The monitoring required following the administration of medication.

41. In the limited time available, we are able to address the key aspects of each stage by way of overview only.

Prescription of medication

42. In the case of both oral PRN de-escalation and intramuscular Rapid Tranquilisation, medication may be prescribed only by a qualified prescriber. Generally, this means a doctor. However, it could also mean other non-medical professionals approved and registered within the Belfast Trust as a "Non-Medical Prescriber" (NMP). We address the framework in this area at paragraphs 61 to 67 below. Currently, there is one nurse registered as a NMP at MAH. That individual has been registered since 28 February 2020. However, we are advised by colleagues that this individual is not actively prescribing, and so there is no NMP function at MAH currently. To the best of our knowledge, there have not previously been any active NMPs prescribing at MAH.

43. Prescribing is a central part of the clinical education and training of doctors working in mental health and learning disability. It is not possible, in the limited time available, to address this aspect in detail. However, clinical training in psychiatry also involves placements in facilities including psychiatrist intensive care wards and secure inpatient units. The general and specialist training undertaken by doctors equip them with the breadth and depth of knowledge and practice-developed skills which form the basis of their work thereafter. Further, medical staff must maintain and develop knowledge and skills that are relevant to their role and practice and are bound by all regulatory and professional guidance, including in relation to the prescribing of medicines.

44. Specific guidelines relevant to the prescribing of medication for oral PRN de-escalation and intramuscular Rapid Tranquilisation include:

a. The Maudsley Prescribing Guidelines in Psychiatry (the "Maudsley Guidelines"). This is the leading reference guide on the safe and effective prescribing of psychotropic agents. The Maudsley Guidelines originated as a local pamphlet produced by and for Bethlem Royal Hospital and Maudsley Hospital in London in 1994. The first edition to be published commercially was the fifth edition, in 1999, although the Maudsley Guidelines were in circulation within the profession before that time. The Maudsley Guidelines are now in their 14th edition and are published internationally. Due to the size of the publication we have exhibited behind Tab 3 of the exhibit bundle extracts from the below listed editions which comprise the cover, the initial pages and contents pages, and those pages which specifically address "*Acutely disturbed or violent behaviour*":

    i. 9th Edition, published in 2007;

    ii. 10th Edition, published in 2009;

    iii. 11th Edition, published in 2012;

    iv. 12th Edition, published in 2015;

    v. 13th Edition, published in 2018; and

    vi. 14th Edition, published in 2021; and

b. The British Association of Psychopharmacology ("BAP") publications including the 2018 Joint BAP and National Association of Psychiatric Intensive Care and Low Secure Units ("NAPICU") Guidelines entitled "*Evidence-based consensus guideline for the clinical management of acute disturbance: De-escalation and rapid tranquilisation*". This is the first version of this guideline. It follows,

and refers throughout, to the May 2015 NICE Guideline 10 (NG10) and the prevailing Maudsley Prescribing Guidelines (then the 12th edition, published in 2015). A copy of this document is also provided behind Tab 3 of the exhibit bundle.

45. Each of the 2012 and 2017 Belfast Trust Rapid Tranquilisation Guidelines included a number of "*General Prescribing Principles*" (see Appendix A to each set of Guidelines) as well as detailed guidance in relation to drug selection and dosage. Such guidance generally reflected a synthesis of the prevailing clinical and professional guidance and was an important source of reference for medical staff engaged in the prescription of oral PRN de-escalation or intramuscular Rapid Tranquilisation.

46. However, it is important to highlight that the general management approach suggested in policies or other guidelines does not displace the proper exercise of clinical judgment by the prescriber. All policy and other guidance in this area, over time, has emphasised the need for a highly individualised approach tailored to the particular clinical circumstances which present in each case; there can be no "one size fits all". If a clinician considers that a different management approach is clinically indicated, that course should be followed and the reasons for it clearly documented.

47. Further, within the Belfast Trust, all prescribing must be in accordance with the general requirements of the Hospital Medicines Code and the "*Medicines Code Policy*" (SG 09/11). This document was addressed at paragraph 83 of the 20 March 2023 Module 3 Statement.

48. As to the form of prescription, all medication must be prescribed on a Kardex that relates to each patient. The Kardex relating to the individual patient then forms part of the patient material. The prescription of oral PRN de-escalation or intramuscular Rapid Tranquilisation is recorded on the page entitled "*As required*

medication", with the prescribing clinician completing information in the left column and the prescription start date. Also behind Tab 3 of the exhibit bundle is a sample Kardex written up for intramuscular Rapid Tranquilisation and used as part of the Rapid Tranquilisation training which we address further below.

49. It is important to explain that this section of a Kardex concerns "*as required medication*" generally – i.e. PRN medication in the broad sense we described in paragraph 8 above. Accordingly, alongside medication prescribed for oral PRN de-escalation and/or intramuscular Rapid Tranquilisation to assist in the management of disturbed behaviour, in the context of MAH, it is commonplace to see recorded in this section paracetamol for pain relief, Piriton or other antihistamine medication for hay fever and laxatives for constipation.

50. The relevant Belfast Trust policies have imposed certain general requirements in relation to the prescription of oral PRN de-escalation and intramuscular Rapid Tranquilisation. These have reflected the prevailing NICE Guidelines and include:

    a. The rationale for prescribing PRN must be recorded in the patient care plan and the indication stated on the Kardex. This might include, for example, "*agitation*" or "*aggression*";

    b. Medication for Oral PRN de-escalation and intramuscular Rapid Tranquilisation should be prescribed separately;

    c. 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 (i.e. the order in which each medication is to be used);

    d. The maximum dose that can be administered in a 24-hour period must be stated, as must be minimum intervals between doses;

    e. Variable doses (such as "*1-2mg*") should be avoided; and

f. The prescribed dosage may only exceed the British National Formulary ("BNF") maximum daily dose, calculated as including all prescribed medication, where planned to achieve an agreed therapeutic goal and properly documented as described in the policies.

51. As to the timing of the prescribing decision, all national and local guidance, including the Belfast Trust policies, has cautioned that PRN medication should not be prescribed routinely or automatically on admission. However, by its nature, PRN medication is generally prescribed well in advance of the time that it may be needed.

52. In the context of learning disability, this often means it being detailed as part of an individual's care plan. The prescribing clinician will individualise the dose and type of medication having regard to a range of factors including the individual's previous response to medication, age, physical condition and other prescribed medication. It is of obvious importance that staff observe and report service user behaviour as accurately as possible in order to assist prescribers when making prescribing decisions.

53. It is also important to emphasise that, in this context, the decision to prescribe medication (and if so, what medication) is a holistic one and cannot be viewed in isolation. It is taken having regard to all other aspects of the care plan and proposed responses for the management of behavioural disturbance.

54. In the context of MAH, although the prescribing clinician ultimately must make the prescribing decision, this is done within a framework of regular multidisciplinary team ("MDT") meetings and review. By way of example, we are informed by Dr Hughes that, during his tenure, a weekly MDT meeting took place in relation to each patient. This process continues. These are focused and robust meetings, for which records will form part of the Belfast Trust's disclosure to the

MAH Inquiry. Each MDT meeting involves a review of the individual's care plan and drug Kardex by at least one or all of a Consultant Psychiatrist, Senior House Officer (SHO, i.e. the ward doctor) and (from 2018) the Clinical Pharmacist. This includes review of all prescribed medication and all medication that has been administered in the preceding week (including both oral PRN de-escalation and intramuscular Rapid Tranquilisation). We address this process further below, as this scrutiny by a range of relevant professionals served as an important check on both the prescribing decision and its administration. For now, we wish to explain that the frequency of MDT review meant that the prescribing decision in relation to PRN was not a static one; once made, it was subject to review each week and could be subject to adjustment.

55. The medication options available, and the recommended types of medication, for both oral PRN de-escalation and intramuscular Rapid Tranquilisation, have changed relatively little over time. However, the generally recommended dosage has reduced considerably. This is reflected in the iterations of the Belfast Trust Rapid Tranquilisation Guidelines. This reduction is partly due to the increased emphasis on, and the improved training of staff in relation to, non-pharmacological prevention and de-escalation methods.

56. It is also important to highlight that not all medication prescribed for the management of behaviour by oral PRN de-escalation is sedation medication. We are aware that there are patients at MAH for whom the "*first line*" medication prescribed for "*agitation*" is paracetamol. This may be because such patients often complain of, or indicate, pain. Further, and for the avoidance of doubt, where sedating medications or potentially sedating medications are used, the aim of oral PRN de-escalation and intramuscular Rapid Tranquilisation is not to achieve a state of "*sedation*", but to achieve a state of sufficient calm so that there is minimal risk to the individual patient, staff members and others where the patient is displaying acutely disturbed behaviour.

57. A number of the medicines used in this area are available in both oral and intramuscular injectable form. For instance, we are informed by Dr Hughes that his experience of working on a ward at MAH was that the administration of intramuscular Rapid Tranquilisation was comparatively rare, and, where it was prescribed, that prescription was often for the same type and dose of medication as the oral PRN de-escalation medication. The reason for this is that often, in this context, individual patients may reach a heightened state of agitation in which oral medication is refused and the alternative means of administration is required.

58. Outside of the regular framework of MDT review, there are also times where, in response to behavioural presentation, such as an escalating incident, it is the opinion of ward nursing staff that there may be a need to consider the prescription of further PRN medication in order to manage the incident. That scenario could lead to a consultation with a doctor for a decision to be made as to whether it is safe and necessary to prescribe further medication. A prescription may thereby be issued "live" as a stat dose. This would be written up on the individual's Kardex as a one-off prescription to be administered immediately.

59. Further, where intramuscular Rapid Tranquilisation is used, the Belfast Trust policies over time have provided that a senior doctor must review all prescribed medication every 24 hours, and so the prescribing decision is also revisited in those circumstances.

60. Finally, there is necessarily an interplay between an initial prescription of oral PRN de-escalation or intramuscular Rapid Tranquilisation, and the need for, and frequency of, its administration. The management of an individual's medication in the context of a learning disability inpatient facility such as MAH is an evolving matter which is subject to continuous review in the way described. For example, based on proper administration of prescribed medication, a high frequency of

prescribed PRN administration by either method could indicate the need for changes to be made to an individual's regular medication.

61. For completeness, we briefly address the specific framework governing non-medical prescribing within the Belfast Trust.

62. "*Non-Medical Prescriber*" (or "NMP") is a status which may be acquired by members of certain professional groups of non-medical staff through successful completion of a recognised prescribing course, registration with the appropriate professional body as a prescriber of medicines and (following review of their formal application) approval and registration as a NMP on the Belfast Trust NMP Register. The relevant professional groups of non-medical staff who could attain NMP status are registered nurses, midwives, specialist community public health nurses, pharmacists, optometrists, and certain allied health professionals. NMP status entitles such individuals to prescribe medication within the Belfast Trust as either an "independent" or "supplementary" prescriber.

63. The framework for the development and implementation of non-medical prescribing of medicines within the Belfast Trust is set out in the dedicated Belfast Trust policy identified at paragraph 88 of the 20 March 2023 Module 3 Statement. The first three iterations of the Belfast Trust "*Non-Medical Prescribing of Medicines*" (SG 14/13) policy were provided with the 20 March 2023 Module 3 Statement. For completeness, behind Tab 3 of the exhibit bundle is a copy of the current version (version 4), which became operational in June 2021.

64. We do not here seek to repeat the detail of the provisions of that policy, and it is beyond the scope of this statement to address the broader professional and statutory guidance relevant to each professional group to which it refers. However, the policy applies across all clinical areas within the Belfast Trust, to all of the professional groups we have referred to above, and establishes a centralised framework for NMP. It is intended to:

a. Ensure professional and statutory obligations are met;

b. Contribute to the provision of holistic care;

c. Provide robust standards for non-medical prescribing of medicines;

d. Clarify accountability and responsibility;

e. Provide a framework under which potential applicants could determine eligibility to undertake an approved prescribing programme; and

f. To maintain a live register of NMPs within the Belfast Trust with an agreed annual renewal process.

65. The NMP Register is a central, live, electronic document that is maintained by the Pharmacy Central Administration Team (specifically, the Head of Pharmacy and Medicines Management) and is located on the Belfast Trust Intranet site. It was established around 2010. The NMP Register records core details including the name, professional designation, professional registration number, staff location, date of registration as a NMP, any renewals of the registration and current status. As the NMP Register is updated annually (each April), it serves as a database of those non-medical staff members who are currently approved and authorised to prescribe as part of their role.

66. As described above, registration follows a formal application for inclusion on the NMP Register. A template application form is appended to the Belfast Trust policy. The application involves the agreement of parameters of prescribing with the staff member's line manager/professional lead. The Non-Medical Prescriber must then work within their authorised parameters unless these are subsequently expanded. The annual renewal process involves certain review mechanisms, including the requirement that the line manager must review and verify that the Non-Medical

Prescriber is working within their authorised parameters of prescribing. The parameters of prescribing are reviewed as part of the staff member's annual appraisal process.

67. The broader framework governing non-medical prescribing within the Belfast Trust is overseen by a multi-disciplinary group known as the Non-Medical Prescribing Group (the "NMP Group"). The NMP Group meets three times per year and was established by (and reports to) the Medicines Optimisation Committee, which is part of the Belfast Trust Integrated Governance and Assurance Framework. The purpose of the NMP Group in relation to non-medical prescribing is to ensure the appropriate policy development and maintenance and the operation of the framework including the professional approval process and the maintenance of the live NMP Register. By way of further information, behind Tab 3 of the exhibit bundle is a copy of the Terms of Reference for both the Non-Medical Prescribing Group and the Medicines Optimisation Committee.

Dispensing of medication

68. To the best of our knowledge, there has been no on-site pharmacy at MAH since at least 2010. Following the closure of the on-site pharmacy, MAH was served by the Belfast Trust pharmacy service based at Knockbracken Healthcare Park. Since around 2018, in relation to inpatient medication, the position has been that wards typically hold an agreed stock list for medication, which is replenished by the pharmacy service on a weekly basis. We are advised by colleagues that most of the PRN medication addressed within this statement would tend to feature on a ward stock list. Following the prescription of new non-stock medication for a patient, the ward nursing staff are responsible for completing and sending a requisition to the pharmacy service based at Belfast City Hospital, from which the non-stock items are dispensed and transported to MAH. In the case of routinely required medication, a supply is maintained securely in a clinical room. All medication

must be stored securely in clinical areas in accordance with the Belfast Trust Hospital Medicines Code, to which we have already referred.

69. As to the dispensing of medication for discharge or home leave, prescriptions for discharge or home leave medicines are ordered by a doctor using the Trust prescription template within the PARIS system. A full list of medicines should be provided on the prescription, including those medicines where a supply at discharge is not required. The number of days required must be specified. For medicines prescribed as "PRN", the prescriber must indicate the quantity to be supplied. The role of the clinical pharmacist in facilitating the supply of discharge medication includes checking the prescription against the patient's inpatient Kardex for accuracy and appropriateness. This must be done in accordance with professional standards as well as Belfast Trust policy. Paragraph 87 of the 20 March 2023 Module 3 Statement provided the various iterations of the "*Northern Ireland Clinical Pharmacy Standards*" (SG 27/10) as implemented within the Belfast Trust.

Administration of medication

70. Within the Belfast Trust, in a hospital setting, medication must be administered by a registered nurse. Whilst there may be some medical wards in the Belfast Trust where doctors also administer medication, this is rare in the mental health and learning disability context. Health care assistants and other ward staff may not administer medication.

71. The above position applies equally to both oral PRN de-escalation and intramuscular Rapid Tranquilisation. In practical terms, oral medication may be taken personally by an individual patient or service user. However, the decision as to its administration at a particular time, is a clinical decision which must be made by the registered nurse. The nature of a PRN prescription, whether for oral de-escalation or intramuscular Rapid Tranquilisation, is that its administration is

at the discretion of the nurse. Its very purpose is to ensure that there is, within appropriate bounds, flexibility based on patient need.

72. The decision to administer oral PRN de-escalation or intramuscular Rapid Tranquilisation cannot be viewed, or taken, in isolation. It is part of the broader management of the individual's behaviour, which includes appropriate nursing care and the use of continued de-escalation techniques including verbal, paraverbal and non-verbal communication (for example, "talking down") and other non-pharmacological options.

73. The appropriate response, or range of responses, is highly fact-specific and will vary according to the individual circumstances. Even for a single individual, the appropriate responses may vary with each scenario that presents itself. Paragraphs 44 to 46 of the 17 April 2023 Module 3 Addendum Statement explained that such matters, including decision-making, risk assessment and management techniques to achieve de-escalation, are core aspects of the MAPA/Safety Intervention training used within the Belfast Trust.

74. For that reason, the Module 3 Addendum Statement (see paragraph 46) also highlighted the degree of overlap between the contents of the MAPA/Safety Intervention training and other forms of training received by staff working within learning disability, such as positive behaviour support and the specific training in relation to Rapid Tranquillisation (which we address further below). An example of this overlap is the fact that, following a recent Quality Improvement ("QI") project concerning PRN medication at MAH, involving an audit and other change initiatives, since 2023 "CALM" cards now feature on each patient Kardex at MAH. These cards highlight alternatives to the use of medication derived from Positive Behaviour Support plans, and serve as an aide memoire for registered nurses in considering alternative strategies for a particular patient prior to the administration of any PRN medication.

75. Module 7 of the Safety Intervention training addresses "Decision Making". It introduces a decision making "matrix", which is a tool for assessing risk behaviour and assists staff to determine the safety intervention which meets the criteria of reasonable, proportionate to the risk, and the least restrictive intervention. Further, the "Emergency" content of the course also covers a specific holding skill for the administration of intramuscular Rapid Tranquilisation as well as well as the considerations to be taken into account prior to administration and in relation to post-administration monitoring.

76. The Belfast Trust Rapid Tranquilisation Guidelines have reflected the NICE Guidelines in stating clearly that the administration of oral PRN de-escalation is not, on its own, de-escalation. Rather, they provided for a "*stepped approach*" in considering any pharmacological response. This stepped approach for different patient groups (children and young people age 6-17 years, adults over 18 years, older and frail adults and people with dementia) is summarised in the "flow charts" appended to the 2012 and 2017 Belfast Trust Rapid Tranquilisation Guidelines. The general "flow chart" relevant to adults over 18 is found at Appendix B of the 2012 policy and Appendix C of the 2017 policy. This flow chart is broadly replicated in the flow chart found at Appendix B of the new 2022 HSCNI Regional Guideline.

77. The flow charts delineate three "*levels*" of response:

    a. "*Level 1*", marked in green, is the administration of oral PRN de-escalation. Pharmacological management in the form of oral PRN may be offered as part of a strategy to de-escalate and prevent situations that may lead to violence and aggression. This may include where non-pharmacological de-escalation techniques have failed or are inappropriate. Where oral PRN is administered, other de-escalation techniques should be continued;

b. "*Level 2*", marked in amber, is the administration of intramuscular Rapid Tranquilisation. This should be considered only when there is an actual or clear risk of violence or aggression and de-escalation and other preventative strategies, including oral PRN, are not possible or are inappropriate. De-escalation attempts should continue up to the administration of intramuscular medication; these may lead to the individual accepting oral medication and obviate the need for the administration of intramuscular Rapid Tranquilisation; and

c. "*Level 3*", marked in red, refers to a further level of intervention required where intramuscular Rapid Tranquilisation (at "Level 2") has failed to produce a sufficient response. This generally involves an approach highly tailored to the individual circumstances and requires the involvement of a senior doctor.

78. The above framework seeks to ensure that the least restrictive option, and the option consistent with the level of risk posed, is used at all times, and provides for allowing at least 45 minutes before moving from oral PRN de-escalation to intramuscular Rapid Tranquilisation.

79. The 2012 and 2017 Belfast Trust Rapid Tranquilisation Guidelines also contained some practical guidance in relation to the administration of medication. For example, the guidance at Appendix A of each version provides that when administering more than one intramuscular medicine, medications should not be mixed in the same syringe.

80. More broadly, all registered nurses are trained to administer medication and to assess for effects or side effects. Further, in administering both oral PRN de-escalation and intramuscular Rapid Tranquilisation, as in managing medicines more generally, the registered nurse must adhere to the Belfast Trust Hospital Medicines Code and relevant regulatory and professional guidance, including that issued by the NMC. This includes, for example, relevant guidelines issued by the

Nursing and Midwifery Council ("*NMC*"), as identified at paragraph 38 of the 20 March 2023 Module 3 Statement. This includes:

a. 2004 NMC "*Guidelines for the administration of medicines*"; and

b. 2007 NMC "*Standards for Medicines Management*"(withdrawn following publication of the Royal Pharmaceutical Society and Royal College of Nursing "*Professional Guidance on the Administration of Medicines*").

81. Paragraph 85 of the 20 March 2023 Module 3 Statement also identified (and provided a copy of) the February 2017 Belfast Trust "*Injectable Medicines Code Policy*" (SG 71/16) (version 1), which, from its operational date, applied in the case of the administration of intramuscular medicines.

82. As referred to above, the Kardex records the administration of all medication as well as its prescription. To the right of the prescription column, there is an administration chart to be completed by the nurse by applying their signature to record each administration of medication and the date, time, dose and route (i.e. oral by another route).

83. Since the summer of 2022, as part of the recent audit and Quality Improvement project referred to above, an additional process has been introduced within MAH for the completion by two registered nurses of a specific form recording that PRN medication has been given after discussing other agreed alternatives including that de-escalation techniques have been unsuccessful. This requirement essentially instigates a "critical conversation" between the two registrants prior to the administration of PRN medication and acts as an additional safeguard in relation to the decision to do so. To give effect to this process, a template form was drawn up for each ward. By way of example, behind Tab 4 of the exhibit bundle is a copy of the template form currently used in Killead and Donegore wards. Among other details, the agreed rationale for the administration must be stated.

Post-administration monitoring

84. Each of the 2012 and 2017 Belfast Trust Rapid Tranquilisation Guidelines also contain certain requirements as to the physical observations and monitoring required following the administration of PRN medicines. These are summarised in the "*Monitoring*" table found at Appendix D of the 2012 Guideline and at Appendix E of the 2017 Guideline.

85. Different requirements have applied following the administration of oral PRN de-escalation and intramuscular Rapid Tranquilisation. Namely:

    a. Physical health and side effect monitoring is mandatory following the administration of intramuscular Rapid Tranquilisation;

    b. Physical health and side effect monitoring is not automatically required following the administration of oral PRN de-escalation. It is required in certain specific circumstances: if clinically indicated by the patient's condition or if the BNF maximum daily dose is exceeded. Post-administration monitoring must also be considered in those circumstances where a patient was at the point of being administered intramuscular Rapid Tranquilisation but, in the event, accepted oral medication.

86. The particular checks and observations to be undertaken are detailed within the policy. They include the individual's respiratory rate, pulse, blood pressure, temperature, level of consciousness, level of hydration and any other side effects. The 2012 policy required observations to be carried out every 10 minutes for the first hour, and thereafter every half an hour until the individual is ambulatory. The 2017 policy required observations to be carried out every 15 minutes for the first hour, and thereafter every hour until there are no further concerns.

87. The Belfast Trust policies have required all checks for side effects to be recorded in the individual's clinical notes and all physiological observations to be recorded on

the Trust "*Standard Observation*" Chart. As described within the policies, the Standard Observation form is used to calculate an "Early Warning Score" on each occasion of monitoring. This score is calculated in accordance with the Belfast Trust "*Policy on Measuring and Recording Physiological Observations*" (SG 07/09). The iterations of this policy are provided behind Tab 5 of the exhibit bundle.

88. The 2017 policy also addressed the action required in those circumstances where an individual refuses physiological observation or remains too behaviourally disturbed to be approached. If this were the case, it was required to be documented in the individual's notes at each time monitoring would have been due, with the patient observed for sign/symptoms of pyrexia, hypotension, over sedation and general physical well-being (and these observations then documented).

89. Finally, each of the Belfast Trust Rapid Tranquilisation Guidelines has included guidance as to the remedial measures which may be available in the case of presentation of particular physical responses. These include to seek medical advice.

Staff competency to make decisions about using PRN

90. The MAH Inquiry has asked the Belfast Trust to address the specific matter of "*how staff were assessed as competent to make decisions about using PRN*".

91. There is no specific policy or procedure which provides for a specific assessment of the competency of staff to make decisions about using PRN medication – either as to the prescription or the administration of such medication. Nor are we aware of such a policy or procedure existing within any of the other Northern Ireland HSC Trusts or elsewhere.

92. There are, however, a range of structures and processes which have sought to ensure the general competency of medical and nursing staff in the area in which they work. These include, for example:

a. Their education and professional training, including supervision processes and training within the specialism of psychiatry/mental health and learning disability. There are also the requirements of, and oversight by, their regulatory and professional bodies. These matters were addressed as part of the Belfast Trust's Module 4 witness statement;

b. Appraisal processes. A specific process of Medical Appraisal governs the annual appraisal of medical and dental staff within the Belfast Trust. The Belfast Trust appraisal process known as Staff Development Review applies to registered nurses. These were referred to in paragraph 342 of the 20 March 2023 Module 3 Statement. It is important to emphasise that the appraisal process is not a generic process; it involves the review and scrutiny of the particular work of the doctor/nurse within their particular speciality and within the particular role and environment within that speciality. In a context such as MAH, this will generally include matters concerning the prescription and administration of medication; and

c. The service-level assurance mechanisms including the observation of junior staff by more senior professionals, the line management structure, leadership walk arounds, peer review processes and clinical and social care audit.

93. In addition, certain Belfast Trust staff training processes have sought to ensure the competency of staff specifically to make decisions about the management of disturbed behaviour and, within that, to make decisions about prescribing and administering oral PRN de-escalation and intramuscular Rapid Tranquilisation. In addition to the Belfast Trust induction training in Medicines Management, these include:

a. Specific Belfast Trust induction training on Rapid Tranquilisation; and

b. MAPA, now Safety Intervention, training, to which we have already referred at paragraphs 74 and 75 above.

94. We briefly address each in turn. Training on "*Prescribing and Medication in Psychiatry*" forms part of the psychiatry induction training for junior doctors on rotational training placements. A copy of the current presentation slides used to deliver the psychiatry induction training is provided behind Tab 6 of the exhibit bundle. This presentation is intended to provide an overview of the key guidelines in this area, the main pharmacological options that may be considered, and risks and guidance arising from particular medication or combinations. Training dates are arranged and overseen by the medical workforce co-ordinator. The training itself is maintained and delivered by the pharmacy team – generally, the lead pharmacist for mental health. Over time, there have been some changes and updates to the contents of this training to reflect the review of the policy. By way of example, behind Tab 6 of the exhibit bundle we have also provided a previous version of the training presentation slides dated September 2021.

95. As we have already described, and as was explained when addressing this training at paragraphs 44 to 69 of the 17 April 2023 Module 3 Addendum Statement, the MAPA/Safety Intervention programmes concern the management of challenging and disturbed behaviour more generally. They include, but are not limited to, training in physical intervention techniques. Rather, the focus of such training is on prevention, and thereafter, de-escalation. A considerable portion of the training involves training in decision-making and risk assessment, as well as the range of prevention and de-escalation techniques including communication strategies to ensure the most proportionate and least restrictive intervention. Accordingly, this is of central importance to the decision whether to administer prescribed PRN medication in combination with other non-pharmacological management.

96. Further, specific training on "Rapid Tranquilisation" has also been delivered by a Mental Health Pharmacist as an enhancement to the 5-day MAPA/ Safety

Intervention course delivered at Knockbracken (sometimes attended by MAH staff). This takes the form of the same PowerPoint presentation that we have identified at paragraph 94 above in relation to medical staff inductions. This "Rapid Tranquilisation" course has not been delivered as part of the MAPA/SI course delivered at MAH. As explained at paragraphs 48 to 50 of the 17 April 2023 Module 3 Addendum Statement, Knockbracken and MAH have historically been separate accredited training centres, albeit with a degree of collaboration and overlap. However, work is currently ongoing to standardise the SI courses delivered at the Knockbracken and MAH sites. To date, the MAH site has introduced the "Lived Experience" element and formalised sessions from the PBS team and the Adult Safeguarding team. It is anticipated that a next step would be to include the introduction of the specific "Rapid Tranquilisation" session that has been delivered by the Pharmacy team at Knockbracken. More broadly, work is ongoing to progress a business proposal in respect of the merger of the two training centres. All of this work has been assisted by Mr Warren's secondment to MAH from his substantive role within the Knockbracken SI Team.

97. The MAPA/Safety Intervention training programmes include an assessment aspect. This was addressed at paragraph 65 of the 17 April 2023 Module 3 Addendum Statement

Processes in place for assurance in relation to the use of PRN medication

98. Finally, the MAH Inquiry has asked the Belfast Trust to address "*the processes in place for assurance that PRN was being used properly*".

99. In addition to the satisfactory completion and oversight of staff education and training, and the professional competence of individual staff, a number of different processes, both internal and external, have provided assurance in relation to the prescription and administration of oral PRN de-escalation and intramuscular

Rapid Tranquilisation during the time period which the MAH Inquiry is considering. We address these in turn.

100. As to internal processes, first, there is the review of the medication administered and the post-administration monitoring required as part of the use of intramuscular Rapid Tranquilisation and, less often, oral PRN de-escalation, which has already been described.

101. Second, there is the ongoing review of a patient's case notes and the scrutiny of Kardexes as part of the weekly MDT process to which we have already referred at paragraph 54 above.

102. This process is an important check on both the prescribing decision and the exercise of the discretion to administer prescribed medication. Where the Kardex shows that oral PRN de-escalation or intramuscular Rapid Tranquilisation has been administered, the MDT meeting will include discussion as to the circumstances of the administration, the rationale for the use of PRN medication and its efficacy. Relevant background is offered by the nursing member as to the need for, and effect of, the medication. This process enables scrutiny of the clinical decision by other senior professionals. More recently, the reflective practice PRN administration form identified at paragraph 83 above has also been considered as part of the MDT review.

103. Another aspect of the weekly MDT review is review of any incidents involving the individual patient, including in relation to the use of restrictive interventions. Each of the 2012 and 2017 Belfast Trust Rapid Tranquilisation Guidelines required a Trust Incident Form to be completed after each administration of intramuscular Rapid Tranquilisation, and provided that a post-incident review may be held within 72 hours. A Datix incident form is also completed where there has been an incident of acutely disturbed behaviour and this has been managed with oral PRN sedation. By contrast, a Datix report is not completed where PRN sedation is

administered to a patient other than in the course of an incident of acutely disturbed behaviour or psychological escalation.

104. Since 2018, the MDT meetings have also involved Ms Murray, the ward-based clinical pharmacist based at MAH. Her work has been a valuable addition to the MDT structure in relation to the use of medication, but it is a limited resource. Since 2020, the role has been funded as 0.8 Whole Time Equivalent (or WTE). Ms Murray works across the operative wards at MAH. We should add that it is not typical, within mental health and learning disability in Northern Ireland, to have a clinical pharmacist on each inpatient ward. Unlike in acute settings, there is more limited scope for patient/pharmacist contact. Further, pharmacy resources for mental health and learning disability in Northern Ireland have been comparatively very limited.

105. Within the MDT meeting, Ms Murray's role as clinical pharmacist includes review of the Kardex to ensure that all medications prescribed are legible, appropriate, compliant with national and local guidelines and safe, within legal limits. It also includes providing advice to the prescribing clinician in relation to the particular medication, doses or form prescribed. By way of example, although the relevant policy framework enables a prescription for oral PRN de-escalation to be issued in excess of the BNF maximum daily dose, where doing so is considered clinically mandated, clinical pharmacy input might include highlighting the level of prescription and the applicable guidance. This may lead to the prescribing decision being revisited after the meeting.

106. A third internal assurance mechanism is that Ms Murray has been responsible, alongside Dr Michael Kingsley (a GP), for co-facilitating a review of all patient Kardexes at MAH every six months. This is part of a review of physical health monitoring to comply with physical health monitoring guidelines. Further, at least once per year, Ms Murray meets with the ward manager to undertake a review of the agreed stock holding of medications kept on the ward.

107. A fourth assurance mechanism is the governance structures within MAH and the Belfast Trust and the reporting lines that such structure establishes. For example, the administration of oral PRN de-escalation and intramuscular Rapid Tranquilisation is tracked weekly per patient and per ward, forming part of the weekly "Live Governance" for the ward that is considered at weekly Live Governance calls and reviewed as part of individual ward rounds based on the Purposeful Inpatient Admission (or "PIpA") model. Further, as already described, Datix incident forms are completed in the case of each administration of medication as part of an incident of acutely disturbed behaviour, and these are also reviewed as part of these processes.

108. The data collected and reported is also collated and trends are identifiable through the graphs prepared on a ward basis, which in turn feed into a monthly "safety dashboard" for the MAH site as a whole. By way of example, behind Tab 7 of the exhibit bundle is a recent example of the datasets prepared for weekly Clinical Improvement Meetings, as well as a copy of a 2023 "Safety dashboard" monthly report to MDAG.

109. Audits also provide an assurance process in relation to the prescription and administration of medication for behavioural management. The policy framework governing clinical audits both regionally and within the Belfast Trust was addressed at paragraphs 314 and 315 of the 20 March 2023 Module 3 Statement. Paragraphs 399 to 410 of the Belfast Trust's Module 4 witness statement provided further detail as to the structure and governance arrangements relating to the service level audits undertaken at MAH from 2008 onwards.

110. At paragraph 401 of the Belfast Trust's Module 4 witness statement, Ms Shaw referred to "Care Plan Audits" and provided an example of an internal Care Plan Audit. The matters reviewed as part of such an audit would include all aspects of the management of the patient's behaviour including all prescribed medication and its administration.

111. Behind Tab 7 of the exhibit bundle we have provided a list of service level audits carried out at MAH through the Mental Health & Learning Disability Audit Lead Committee, and that were registered with the Belfast Trust Standards, Quality and Audit ("SQA") Department, from 2008 to date. This refers to:

a. An audit registered in July 2009 entitled "*Rapid Tranquilisation for Patients with Learning Disabilities*";

b. An audit registered in October 2009 entitled "*Antipsychotic Monitoring*";

c. An audit registered in January 2012 entitled "*Audit of Benzodiazepine use in Kilead ward*";

d. An audit registered in May 2013 entitled "*Prescribing high dose & combination antipsychotics in adult wards*";

e. An audit registered in October 2016 entitled "*Audit of PRN Benzodiazepine*"; and

f. An audit registered in October 2016 entitled "*Kardex Audit*".

112. It is important to highlight that the list provided reflects the audits completed under the Mental Health & Learning Disability SQA Department. It is likely that there were further reviews and projects which are not reflected in that central register, and details of which will need to be obtained. For example, we are informed by Dr Hughes that, during his time working at MAH, there was a regular flow of audit projects led by non-permanent staff, including trainee doctors and students. He recalls that such projects were presented at monthly medical audit meetings until in or around 2012/2013, and at monthly academic meetings for medical staff, which are continuing. Such projects may not be reflected in the central list which has been provided. By way of example, behind Tab 7 of the

exhibit bundle are copies of the presentations delivered in relation to Kardex audits in each of 2015 and 2016.

113. We are also informed by Ms Murray that she undertook a "baseline audit" of drug Kardexes at MAH in 2020. Behind Tab 7 of the exhibit bundle are copies of those documents retained by Ms Murray in relation to that audit, which comprise the raw data as collated by Ms Murray.

114. In addition, over time, a number of "*POMH audits*" were undertaken. These were audits undertaken for the purposes of a national multi-centre approach to reviewing and comparing prescribing habits across the United Kingdom, organised through the Prescribing Observatory for Mental Health (or "POMH"). By way of example, behind Tab 7 of the exhibit bundle is some explanatory correspondence and enclosed documents from the POMH Central Project Team, which provides background to a 2010 audit concerning the use of antipsychotic medication in people with learning disabilities.

115. More recently, since July 2022, the current MAH management team has overseen a QI project concerning PRN medication at MAH, involving an audit and other change initiatives. This has been intended to review and further improve current practice. The audit, led by Dr Devine, is entitled "*Safer Prescribing: Pro Re Nata (PRN) pre Rapid Tranquilisation (RT) Audit Muckamore Abbey Hospital*". Dr Devine has recently written up a summary of that audit. A copy of that document, which includes the basis for, findings of, and actions arising from the audit, is provided behind Tab 7 of the exhibit bundle. The audit confirmed good practice and, as we have already described in relation to the introduction of "CALM" cards on patient Kardexes and the "critical conversation" between two registered nurses before the administration of any medication, a number of improvement actions identified as part of the audit are now in place at MAH.

116. Other general sources of assurance in relation to the use of PRN medication are those which were identified in paragraph 305 of the 20 March 2023 Module 3

Statement in addressing Module 3(l) (Procedures to provide assurance regarding adherence to policies), such as the Belfast Trust's investigation, monitoring, review and analysis of incidents/Serious Adverse Incidents, complaints, claims, inquests and patient/service user feedback through the various "Patient Experience" mechanisms.

117. External processes have also provide a degree of assurance as to the use of PRN at MAH.

118. First, there is a three-month review of the treatment plan of every detained patient at MAH. This included a review of all prescribed medication, both regular and PRN. Until 2015, this was completed by another doctor within the hospital, known as a Responsible Medical Officer or "RMO". From in or around 2015, the RQIA became more closely involved in this process. RQIA appointed a visiting psychiatrist to provide this review and second opinion of the individual's treatment plan.

119. Second, there is the review processes arising from the Mental Health Review Tribunal. Patient treatment plans were comprehensively reviewed by the MHRT psychiatrist every two years and/or upon the application of the patient. This necessarily included the review of all prescribed medication.

120. Third, there is the review inherent in the movement of patients between wards at MAH, and between MAH and other hospitals and/or the community. This movement meant that prescribing decisions undertaken by a particular doctor at MAH in relation to both oral PRN de-escalation and intramuscular Rapid Tranquilisation, and records of the administration of such medication, were reviewed by other professionals, including other psychiatrists. Similarly, upon discharge, a patient's discharge letter, which will include details of medication prescribed at that time, such as oral PRN de-escalation, is provided to their GP.

121. Fourth, the RQIA undertook both announced and unannounced visits to MAH. Psychiatrists were often part of the RQIA visiting team and a number of these visits would have involved review and scrutiny of the treatment plans of individual patients. This provided a further layer of review of prescribed medication and its administration.

Conclusion

122. We hope that the information provided in this statement, and the documents exhibited to it, will be of assistance in respect of this important and complex subject.

Declaration of Truth

123. The contents of this witness statement are true to the best of our knowledge and belief. We have either exhibited or referred to the further documents which, collectively, the contributors to this statement believe are necessary to address the matters on which the MAHI Panel has requested the Belfast Trust to give evidence.

Signed: **Brona Shaw**
Stephen Guy

Dated: **7 June 2023**

Belfast Trust Module 3 PRN Statement Exhibit Bundle – "BS2"

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