Witness Name: **Andrea Sutcliffe**

Statement No.: **1**

Exhibits: **Exhibit AS/1 - AS/102**

Dated: 2 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF ANDREA SUTCLIFFE

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 31 October 2023. I am authorised by The Nursing and Midwifery Council ('the NMC') of 23 Portland Place, London, W1B 1PZ to provide this witness statement.

I, Andrea Sutcliffe of the NMC will say as follows:

Background

1. I am the Chief Executive and Registrar of the NMC. I have held this role since 14 January 2019.

2. I welcome the opportunity to provide evidence to the Inquiry. As Chief Executive and Registrar I hold the most senior executive role at the NMC and am responsible for leading and managing the organisation's professional, business and financial affairs.

3. As Registrar, a role prescribed in the NMC's Order and Rules, my main responsibility is to maintain and uphold the register of people eligible to practise as nurses, midwives throughout the UK and nursing associates in England. This includes overseeing the registration process, making decisions on individuals regarding their entry onto the Register and their suitability for remaining on the Register.

4. As the Chief Executive, I determine the way the strategy, set by the Council, is delivered and ensure that the NMC acts in accordance with its corporate governance

framework. I also ensure that the NMC complies with legislation (EU and UK) along with its legal and charitable status.

5. Having a baby is one of the most important moments of any parent's life. Having that baby's life intentionally taken away or knowing that an individual attempted to take that life away is a truly devastating experience that should never happen. The impact on the parents and families who have lost babies or those who now have children with lifelong injuries involved is heartbreaking and my thoughts and sympathies and those of everyone at the NMC continue to be with them and all those impacted by the terrible crimes committed by Lucy Letby (LL).

6. This statement is divided into six sections. In the first section I will set out our role and governance and management structures. Section two provides an overview of our core regulatory functions. This includes how we consider fitness to practise concerns about professionals raised by employers, patients, families and the public, and what support we provide to those going through or impacted by our fitness to practise processes.

7. The third section covers LL's regulatory journey and focuses on the fitness to practise investigation into LL's conduct. This section covers the decisions we made and actions we took. It also explains when and why we made those decisions or took the actions that we did at the particular time. The fourth section covers the fitness to practise investigation into Alison Kelly (AK) who was the Director of Nursing (DoN) at the Countess of Chester hospital (CoCH) at the relevant time.

8. The fifth section covers other issues the Inquiry asked us to include in our statement including the press statements we issued, other concerns raised and how we work with others. The final section provides our current views on management, governance and leadership accountability as well as the lessons we have learnt to date.

Section one: Our role

9. The NMC is the regulatory body for nursing and midwifery professionals in the UK. We are a statutory body, established and governed by the Nursing and Midwifery Order 2001 ('the Order'), in accordance with s60 and s62(4) Health Act 1999. We hold a register of 808,488[1] nurses and midwives in the UK and nursing associates in England.

10. Our statutory obligations and powers are set out within the Order, which provides that our principal functions are to establish standards of education, training, conduct and performance for nurses, midwives and nursing associates, and to ensure the

[1] Data correct on 30 September 2023, published on 30 November 2023

maintenance of those standards[2]. Rules made under the Order regulate the performance of these statutory functions.

11. Our over-arching objective is the protection of the public[3]. Our Order provides for us to pursue this objective in three ways[4]:

    a. Protect, promote and maintain the health, safety and wellbeing of the public.

    b. Promote and maintain public confidence in the nursing and midwifery professions.

    c. Promote and maintain proper professional standards and conduct for members of the nursing and midwifery professions.

12. These objectives are central to everything that we do, and we want to make sure every nurse, midwife and nursing associate can provide good and safe care.

13. Our core role is to regulate. We set and promote high professional standards for nurses and midwives across the United Kingdom (UK), and nursing associates in England. We maintain the register of professionals eligible to practise, and we investigate concerns about nurses, midwives and nursing associates.

14. To regulate well, we support both the public and our professions. We create resources and guidance that are useful throughout the career of our professionals, helping them to apply our standards in their day-to-day practice and to use their professional judgement and decision making when addressing new challenges. We support both the public and our professions when they are involved in our fitness to practise investigations.

15. Regulating well and supporting people who use health and care services and our professions allow us to influence health and social care. We share intelligence from our regulatory activities and work with our partners to support workforce planning and sector-wide decision making. We use our voice and evidence base to speak up for issues affecting our professions and public safety.

Governance

16. The Council is our governing body. It sets our strategic direction and budget, monitors performance and holds the Executive to account. The Council's constitution is set out in the Nursing and Midwifery (Constitution) Order 2008. Since May 2013 the Council has

[2] Article 3(2) of the Order
[3] Article 3(4) of the Order
[4] Article 3(4A) of the Order

been made up of twelve members, six lay people and six nurses or midwives. The Council must include at least one member from each of England, Northern Ireland, Scotland and Wales. Council members are all appointed by the Privy Council.

17. Between January 2009 and April 2013, the Council was made up of fourteen members including seven lay people and seven registrant members. Following the publication of the Dickson Report in 2008 and the Command Paper published by Government in 2011, the Council for Healthcare Regulatory Excellence (now the Professional Standards Authority) was commissioned to review the constitution of health and care regulators' Councils. That review recommended that Councils should have between eight and 12 members. The Department of Health (DHSC) consulted on changes to the constitution of Councils and as a result the Nursing and Midwifery (Constitution) Amendment Order 2012[5] was laid on 5 November 2012 and came into force 1 May 2013, reducing the Council's membership from 14 to 12.

18. The Nursing and Midwifery Council Standing Orders[6] (**Exhibit AS/1)** set out the procedures by which Council can conduct its business. They cover membership and remit of the Committees of Council, the procedures the Council and its committees use when they conduct their business. INQ0002413

19. The Council is supported in conducting its business by the following Committees:

    a. Appointments Board – composed of independent members and advises Council on the appointment of panel members and legal assessors to the Practice Committee and the appointment of registration appeal panel members to the Registration Appeals Committee.
    b. Audit Committee – supports the Council and management by reviewing the assurances on governance, risk management, the control environment and integrity of financial statements and the annual report.
    c. Remuneration Committee – ensures there are appropriate systems in place for remuneration and succession planning and reviews significant changes to and progress of our People Plan.
    d. Investment Committee – implements the investment strategy and is responsible for operational investment decision making.
    e. Accommodation Committee – oversees implementation of the Council's accommodation plan.

[5] Article 2(a) of the Nursing and Midwifery (Constitution) Amendment Order 2012 made changes to Article 2 of the Nursing and Midwifery (Constitution) Order 2008 ("Constitution Order"). Article 2 previously referred to requirement for seven registrant and seven lay members of Council. The Amendment Order changed this to six each, reducing Council total membership from 14 to 12.
[6] Made by the Council under Article 12, Schedule 1 of the Nursing and Midwifery Order 2001

20. The Standing Orders contain our scheme of delegation[7], which specifies the decisions which should be made by the Council, the Chair of Council, the Chief Executive and Registrar and which should be made by the constituted committees of Council. They also specify how Registrar decisions are delegated.

21. Previously there was a statutory requirement for the Council to have a Midwifery Committee. This statutory requirement was removed in 2017. Since 2015 we have convened a Midwifery Panel comprising senior midwifery leaders and people speaking on behalf of women and families using maternity services. The Midwifery Panel is not a formal governance mechanism, but it ensures we receive advice and insight specific to midwifery services and has published terms of reference (**Exhibit AS/100**). INQ0002576

Management

22. The Executive team implements the strategic direction set by Council and ensures our policies and processes are of a high standard. The team is led by me, and I am accountable to the Council for leading and managing our professional, business and financial affairs.

23. I appoint a team of Executive Directors who have responsibility for overseeing the work of their Directorates. The Directorates and their responsibilities are:

    a. Strategy and Insight – formulating our strategy and regulatory policy and generating evidence and insight to inform our work.
    b. Communications and Engagement – leading our internal and external communications and stakeholder engagement.
    c. People and Organisational Effectiveness – ensuring our people and processes are effective and continually improving.
    d. Resources and Technology – ensuring our technology is fit for purpose and our resources are managed effectively.
    e. Professional Regulation – responsible for regulatory decisions about those joining, or already on, our register which covers registration and fitness to practise.
    f. Professional Practice – responsible for maintaining and promoting our professional and educational standards, quality assurance of education programmes and our employer link service.

[7] Appendix 1 of the Standing Orders

24. There are several Deputy Directors, Assistant Directors and Heads of Department in each Directorate who support the Executive Directors. There are multidisciplinary teams that sit within each of those Directorates to manage our work effectively.

25. The structure of our organisation has changed over time and in 2011 when LL applied for registration, we had these Directorates:
    a. Human Resources and Organisational Development
    b. Policy and Standards
    c. External Affairs
    d. Resources
    e. Governance
    f. Registration
    g. Education
    h. Fitness to practise

Section two – Our core regulatory functions

Education, training and standards

26. Our core regulatory function is to establish standards of education, training, conduct and performance for nurses and midwives in the UK and nursing associates in England, and ensure these are maintained. We do not regulate the conduct of students but we are required to assure ourselves of the quality of their education and training.

27. We set the standards of proficiency necessary to join the register for each of the professions we regulate[8]. These standards represent the skills, knowledge and attributes all registered nursing and midwifery professionals must demonstrate.

28. We set the standards of education and training necessary to achieve the standards of proficiency[9]. Together, these are used by the approved education institutions (AEIs) to shape the content and design of both the theory and practice programme curricula delivered by AEIs. Through our quality assurance (QA) process we approve education institutions and programmes that meet our standards of education and training, we monitor these programmes to ensure they continue to meet our standards, and we seek assurance that the quality of practice learning placements for students is managed through effective partnerships between AEIs and their practice learning partners. This ensures that nurses, midwives and nursing associates are consistently educated to a high standard and can deliver safe and effective care at the point of entry to the

[8] Article 5(2)(a) of the Order
[9] Article 15 (1)(a)

register. Where we have concerns that our standards of education and training are not, or will not, be met, we can refuse to approve, or withdraw approval from, a programme or AEI.

29. To support our QA function , we appoint visitors who attend AEIs to assess whether our standards are being, or will be, met. Our current contract provider for QA is Mott MacDonald. The QA visitor reviews and scrutinises the curricula and programme specification and module specifications alongside the university approval panel members which include external examiners appointed by the university. In December 2022 we also introduced student listening events as further evidence to support our decision making. The QA visitors then provide a report with their recommendations to inform our decision whether or not to approve a programme or AEI or consider whether action needs to be taken in respect of existing programmes. These decisions are ratified our QA Board.

30. To qualify as a nurse or midwife in the UK, or a nursing associate in England, individuals must complete an approved qualification provided by an AEI. The recruitment and admission of students and the design and delivery of curricula are undertaken by the AEIs and practice partners in line with our standards. Once qualified, individuals need to meet our registration requirements to join the register and these are outlined below.

Education and training requirements

31. The standards that applied to the programme that LL studied on were the 'Standards of proficiency for pre-registration nursing education (2004)' (**Exhibit AS/2**). This publication provided the standards of proficiency and standards of education required for all UK pre-registration nursing education programmes[10]. INQ0002414

32. These standards of proficiency replaced all previous requirements for pre-registration nursing programmes of education issued by us or previously the United Kingdom Central Council (UKCC) and the four National Boards for Nursing, Midwifery and Health Visiting for England, Northern Ireland, Scotland and Wales (National Boards).

33. The University of Chester School of Health and Social Care (UOC) in conjunction with placement partners sought approval of a BSc (Hons) and DipHE – Child Branch (together with Adult, Learning Disabilities and Mental Health branches) on 3 May 2007.

[10] The Nursing and Midwifery Council (Education, Registration and Registration Appeals) Rules 2004 (the Registration Rules) provide the powers to develop these standards.

34. The programme was recommended for approval by QA visitors acting on behalf of the NMC subject to some minor conditions which were met. We formally approved the programme with effect from 27 June 2007 for a period of five years (**Exhibit AS/3**). Re-approval was due on 27 June 2012. INQ0002415

35. Between 2008 and 2011, AEIs were granted 'earned autonomy' and asked to self-monitor for one year and we would conduct a monitoring visit the following year. In April 2011 the children's nursing programme at UOC was subject to self-assessment monitoring. In the self-assessment programme monitoring report completed by UOC, they reported that the quality of provision continued to be well supported (**Exhibit AS/4**). INQ0002416

36. We published new Standards for pre-registration nursing education in September 2010 (**Exhibit AS/5**) which introduced graduate only entry to nursing for the first time. INQ0002417

37. UOC sought approval of their new undergraduate nursing degree and Masters of Nursing: Children's Nursing on 24 November 2011. Formal approval was granted on 19 January 2012 for a period of five years with a reapproval date of 19 December 2016.

38. In 2018, following our commitment to undertake a strategic programme of change for education we reviewed and updated new education and training standards, including:

    a. Standards framework for nursing and midwifery education

    b. Standards for student supervision and assessment

    c. Standards for pre-registration nursing programmes

    d. Standards of proficiency for registered nurses.

39. Some specific updates to the standards for pre-registration nursing programmes were published in March 2023 to reflect certain changes now the UK is no longer in the European Union. This included changes to general education requirements and the use of up to 600 hours of simulation for practice learning.

40. The UOC gained approval in line with the new 2018 standards on 31 July 2020 with effect from 16 June 2020.

Children's nursing

41. To be registered as a 'Registered nurse – children's nursing', individuals must have completed an NMC approved course which results in a children's nursing qualification.

42. For students who started their course in 2008, in the first year to 18 months of the pre-registration nursing programme they undertook a 'common foundation of learning' that included shared learning with students in the three other fields of practice. Students had experience of each 'designated area of practice' (adult, child, learning disabilities and mental health branches).

43. The latter half of the programme then focused on a student's intended field of practice. For children's nursing this part of the programme provided learning opportunities to enable students to become proficient in the practice of children's nursing. Preserving patient safety, professionalism and trust are referenced throughout the standards and Code.

44. Within the 'Standards of proficiency for pre-registration nursing education 2004' (**Exhibit AS/2**) the section on children's nursing states (page 24): INQ0002414

    'The philosophy of children's nursing is based upon the principle of family centred care and the belief that children should be cared for by people they know and, wherever possible, within their home environment. Children's nurses understand the complex relationships between personal, socio-economic and cultural influences upon child health and child rearing practices. They develop nursing and technological competence through the application of professional knowledge, skills, values and attitudes in order to empower children and families in health decisions, promoting and providing safe, effective and informed care. Children's nurses work in a variety of settings, across and beyond traditional boundaries, and within a multi-disciplinary and multi-agency team. In particular they contribute to child protection, in collaboration with other key professionals, respecting and promoting the rights of the child.

45. Those standards also include a domain that focuses on care management (pages 32-33) which includes patient safety. This domain makes clear that the outcomes students need to achieve for entry to the register include being able to identify actual and potential risks to patients, participating in measures to promote and ensure health and safety, communicating safety concerns to a relevant authority and the appropriate management of risk. The professional and ethical practice domain also states that the AEI's curriculum should commit to the principle that the primary purpose of the registered nurse is 'to protect and serve society'.

46. The 2018 standards (Exhibit AS/5) also make clear the need to understand and act in accordance with the Code (1.1), recognising and assessing risk and taking prompt action to safeguard those who are vulnerable (3.9) as well as complying with local and national frameworks to assess, manage and report risks (6.3). INQ0002417

Safeguarding

47. Safeguarding is part of the Code and Standards as detailed below.

48. Our Code (Exhibit AS/7) refers to safeguarding by stating that those on our register must: INQ0002419

    a. Raise and, if necessary, escalate any concerns they may have about patient or public safety, of the level of care people are receiving in their workplace or any other health and care setting and use the channels available to them in line with our guidance and their own working practices (16.1).

    b. Take reasonable steps to protect people who are vulnerable or at risk from harm, neglect or abuse (17.1)

    c. Share information if they believe someone may be at risk of harm, in line with the laws relating to the disclosure of information (17.2).

    d. Have knowledge of and keep to the relevant laws and policies about protecting and caring for vulnerable people (17.3).

49. In the 2004 Standards of proficiency (Exhibit AS/2), safeguarding was referred to as child protection and we made clear that: INQ0002414

    a. The curriculum should provide opportunities to gain contemporary knowledge and skills within the changing context of health care delivery. It needs to prepare students for future practice roles and responsibilities, providing foundation knowledge and skills that will enable further development through lifelong learning, such as foundation knowledge for nurse prescribing and child protection (page 18).

50. The 2010 Standards for pre-registration nursing education (Exhibit AS/5) state AEIs together with their practice partners need to: INQ0002417

    2.8 ensure that field-specific content in relation to the law, safeguarding, consent, pharmacology and medicines administration and optimisation is included for entry to the register in one or more fields of nursing practice

51. We set high level outcome focused principles in our standards, and AEIs and their practice learning partners are responsible for the development, delivery, and day to day management of their pre-registration nursing programmes.

52. We expect safeguarding to be part of the curriculum in order to meet the outcome focused principles in our standards. Prior to practice placement learning AEIs prepare students for the placement, including any relevant polices that they would need to be aware of locally. As evidence and policy changes, it is the responsibility of the AEI and its partners to update the teaching and learning in line with those changes. During the approval process for our programmes, we scrutinise how safeguarding is formally taught in the curriculum and we check that it is taught in a field specific way. Our QA visitors also have to include a written narrative in our QA approval reports which sets out the evidence the QA visitors have seen on how safeguarding is taught.

53. As the regulator, we do not provide safeguarding training ourselves, this is provided during pre-registration education programmes. Once professionals are registered, employers are responsible for having appropriate safeguarding policies in place and for ensuring that staff are appropriately trained on those policies. As outlined in paragraph 48, our Code also requires those on our register to comply with local safeguarding policies and guidance.

The Allitt Inquiry[11]

54. When independent inquiries and reviews such as the Allitt Inquiry publish their reports, we review the recommendations against our standards, Code and regulatory processes to consider what changes we may need to make.

55. The report was published in 1994 when the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) was responsible for regulating nursing and midwifery professionals. We do not have any contemporaneous information about how the report's recommendations were implemented at the time. Recommendations 1,4,5 and 6 from that report focused on health and character of individuals applying for nursing programmes. Our 2004 Standards of proficiency for pre-registration nursing education which were in place at the time that LL was training stated that:

    a. Applicants must demonstrate that they have good health and character, sufficient for safe and effective practice as a nurse, on entry to, and for continued participation in, programmes leading to registration with the NMC.

[11] The Allitt Inquiry: Independent Inquiry relating to deaths and injuries on the children's ward at Grantham and Kesteven General Hospital during the period February to April 1991 by Cecil Clothier.

b. Approved educational institutions shall obtain evidence of the applicant's good health and good character as part of their selection, admission and ongoing monitoring processes (pages 9-10).

56. Our 2018 standards state that in order to confirm entry to a programme AEIs need to:

1.1 Confirm on entry to the programme that students:

1.1.1 Meet the entry criteria for the programme as set out by the AEI and are suitable for their intended field of nursing practice: adult, mental health, learning and disabilities and children's nursing.

1.2 Ensure students' health and character are sufficient to enable safe and effective practice on entering the programme, throughout the programme and when submitting the supporting declaration of health and character in line with the NMC's health and character decision-making guidance. This includes satisfactory occupational health assessment and criminal record checks.

57. It is for the AEI and its partners to develop the detail of their pre-registration nursing programmes including the content of individual modules. Although we do not specifically require AEIs to refer to the Allitt report or other reports in their curricula, our standards framework for nursing and midwifery education state that curricula need to remain relevant in respect of contemporary health and social care (5.2). Throughout our standards for proficiency 2018 we also make clear that we expect nursing practise to be evidence based, which includes understanding and applying relevant legal, regulatory and governance requirements, policies and ethical frameworks, including any mandatory reporting duties (1.2) in respect of the contemporary health and social care agenda.

Post registration qualifications

58. The NMC does not set standards or approve programmes that lead to any qualifications as a Neonatal Nurse Practitioner or Advanced Neonatal Nurse practitioner.

59. We are currently exploring whether additional regulation of 'advanced practice' is needed. Advanced practice is where experienced nurses and midwives take on complex, autonomous and expert roles. This work is ongoing and is due to complete in 2025.

60. We currently only set standards and approve programmes for certain post registration and specialist practice qualifications. These are:

a. Prescribing standards

b. Standards of proficiency for Specialist Community Public Health Nurses

c. Standards of proficiency for community nursing specialist practice qualifications

d. Associated post-registration programme standards.

Our Code

61. In addition to our education and training standards, the Order also requires us to set the standards of conduct, performance and ethics expected of registrants and prospective registrants[12]. We do this through our publication of 'the Code', which sets out the professional standards that nurses, midwives and nursing associates must uphold as registered professionals.

62. The 2008 version of the Code (**Exhibit AS/6**) was laid out under the following themes: INQ0002418

a. The people in your care must be able to trust you with their health and wellbeing.

b. Make the care of people your first concern, treating them as individuals and respecting their dignity.

c. Work with others to protect and promote the health and wellbeing of those in your care, their families and carers, and the wider community.

d. Provide a high standard of practice and care at all times.

e. Be open and honest, act with integrity and uphold the reputation of your profession.

f. Have appropriate arrangements in place for patients to seek compensation if they have suffered harm.

63. The Code was updated in January 2015 (**Exhibit AS/7**), and there was a minor update in 2018 in response to the inclusion of nursing associates in England on the register. Since 2015 The Code is structured around four themes: INQ0002419

a. prioritise people

[12] Article 3(2) and Article 21(1)(a) of the Order

b. practise effectively

c. preserve safety

d. promote professionalism and trust.

64. The Code contains a series of statements that signify what good practice looks like – it puts patients and service users first, ensures safe and effective practice and promotes trust through professionalism.

65. We do not set specific training on the Code but we have developed supporting information and animations to support the use of the Code in day-to-day professional practice All students learn about the Code in line with our standards and how this is achieved is the responsibility of individuals AEIs.

Monitoring compliance

66. We do not actively monitor compliance with the Code and standards of proficiency by individual registered professionals. We monitor how the AEIs provide training on the Code via our QA process. Instead professionals must demonstrate their continued ability to practise in line with our Code and standards through revalidation. We can also take action through our fitness to practise process where we receive concerns that professionals may have failed to meet our Code and standards. Both these processes are explained in more detail below.

Registration

67. We maintain the register of professionals eligible to practise in the UK and we process registration applications from individuals who were educated both in the UK and internationally. Applicants are entitled to join the register where they meet our registration requirements[13], and demonstrate they are capable of safe and effective practice. In 2011 our UK registration process was as follows:

    a. When an individual completed their undergraduate university course, the University uploaded the student's information to us through a secure portal. This included the student's name and title, date of birth, postal address, gender, nationality, qualification type, programme start and end dates.

    b. This upload process created the registration application in our database and generated an application pack for the student which was posted to them.

[13] Article 9(2) of the Order sets out the statutory conditions for registration in a part of the Register.

c. The application required a declaration of good health and character from the designated signatory for the University at the University, and a completed application form and the registration fee from the applicant.

d. Once all the requirements were met, we checked the application form was completed correctly and the good health and good character declaration had been signed by the designated signatory for the University.

e. If everything was correct, we accepted the application and the student was added to the register.

68. We publish guidance on health and character which sets out what needs to be declared. It also provides the general principles we apply and the factors considered by us when assessing whether an applicant's health and character makes them capable of safe and effective practice.

69. Prior to 2015, we provided guidance to AEIs on health and character (**Exhibit AS/8**) to INQ0002420 support them in applying our health and character requirements, and ensure students met requirements for undertaking NMC approved qualifications and entry to the register. We did not publish public facing guidance on health and character at that time. In December 2014 our Council approved an updated registration policy and recommended that we also develop additional guidance on health and character to support decision makers. The first version of our public facing health and character guidance was published in October 2015 (**Exhibit AS/9**). INQ0002421

70. This guidance consolidated and clarified the existing requirements in our legislation as well as the guidance we had previously issues for AEIs. When we updated this guidance in 2019 (**Exhibit AS/10**) we included separate sections on: INQ0002422

a. How decisions on registration applications are made.

b. Temporary injury or health conditions.

c. Long term health conditions.

d. Mental health conditions.

e. Information for students and AEIs.

f. Details of the health and character declarations required.

g. Absolute discharges, an admonition in Scotland and conduct that would breach the requirements of the Code.

h. Working without registration.

i. Cautions and convictions, including information for students.

j. Drug and alcohol offences.

71. The updated Guidance also:

a. Emphasises that professionals should inform us about convictions and cautions immediately and outlined the role of others (such as employers) in managing health conditions or disabilities.

b. Makes clear that we only want to know about health issues in relation to whether a professional can practise safely and effectively – we do not need to know about health conditions and/or disabilities that are not relevant to protecting the public.

c. Has removed the phrase 'practice without restriction[14]' when considering whether a professional is capable of safe and effective practice.

72. To coincide with the publication of the revised health and character guidance in 2019 we also changed the registration process and asked students to make additional declarations about their health and character and professional indemnity[15] arrangements. The process has been managed entirely electronically through our NMC Online secure system since November 2015. Health and character declarations are made through the secure portal rather than being paper based.

73. We consider all applications on a case-by-case basis, considering all relevant information and circumstances before deciding whether to admit an individual onto the register.

74. We do not regulate student nurses, student midwives or student nursing associates so we require AEIs to assess the character and health of students and prospective students according to their own regulations, policies and processes and equality legislation. When a student completes a pre-registration programme successfully, AEIs are required to sign a declaration of health and character for their students in line with the pre-registration standards.

Revalidation

[14] Conditional registration is available under Article 10 (3) of the Order but we do not use this power so we removed this wording for clarity as we do not register individuals with restrictions

[15] Professionals on our register must ensure they have appropriate indemnity cover in place so that someone who suffered harm through the negligent action of a nurse, midwife or nursing associate are able to claim any compensation to which they are entitled.

75. All those on our register are required to renew their registration every three years. Since April 2016 this has been done through our revalidation process. Revalidation was introduced to strengthen practice by ensuring that in addition to undertaking continuing professional development and practice hours, professionals also needed to take part in reflective practice. Revalidation ensures that those on our register continually reflect and develop their practice in line with our Code and standards of proficiency. Our revalidation requirements are set out in our Revalidation guidance[16] (**Exhibit AS/87).** To meet our revalidation requirements, since April 2016 every three years those on our register must declare that they have completed: INQ0002560

    a. 450 practice hours, or 900 hours if renewing two registrations (for example as both a nurse and a midwife)

    b. 35 hours of CPD including 20 hours of participatory learning

    c. Five pieces of practice-related feedback

    d. Five written reflective accounts

    e. Reflective discussion

76. When a professional revalidates, they also must sign a health and character declaration, confirm their professional indemnity arrangements and have a confirmer validate their submission.

77. Revalidation is about promoting good practice and strengthening confidence in the nursing and midwifery professions, it is not an assessment of fitness to practise. Our revalidation guidance makes clear that individuals who are going through the fitness to practise process must revalidate:

    'If you are subject to an NMC investigation, condition(s) of practice order or a caution, you are still required to apply to renew your registration as long as you fulfil all the requirements at renewal'.

78. If a professional subject to fitness to practise proceedings does not revalidate, our legislation prevents their registration from lapsing automatically. Their registration will be held effective until the conclusion of the fitness to practise investigation, after which they will automatically lapse from the register. If a professional has been struck off the register, they are not able to revalidate.

[16] Our revalidation guidance "How to revalidate" sets out the requirements for renewing registration in addition to containing our standards for post-registration continuing professional development under Article 19(1) of the Order.

79. Revalidation is not intended to create a new way of raising a fitness to practise concern about a nurse, midwife or nursing associate. The purpose of the confirmation stage of revalidation is for confirmers to verify that the professional has met the revalidation requirements. It is not the confirmer's role to make a judgement about whether or not a professional is capable of safe and effective practice (**Exhibit AS/87 (paragraph 189)).** INQ0002560 If at any point a confirmer did have concerns about a professional's fitness to practise, they would be expected to raise it promptly through our fitness to practise process.

80. Prior to April 2016, professionals on our register had to complete a 'notice of practice' form. The Prep Handbook (**Exhibit AS/70**) sets out the continuing professional development framework for registrants. Those on our register had to self-declare: INQ0002515

    a. They had worked in some capacity using their nursing or midwifery qualification during the previous three years for a minimum of 450 hours.

    b. They had undertaken 35 hours of continuing professional development and recorded this over three years prior to the renewal of their registration.

    c. Health and character.

    d. Indemnity (from July 2014).

Employer Link Service (ELS)

81. Our ELS was set up in response to a recommendation of the Mid Staffordshire NHS Foundation Trust Public Inquiry Report[17]. The team was established to provide advice and support to employers who have concerns about professionals on our register. The team was first established September 2015 as a pilot. During the pilot the team was led by a Head of Service Delivery with two Regulation Advisers (RAs) and it sat in our Fitness to Practise Directorate.

82. Following the successful pilot, in April 2016 we started to recruit an additional four RAs to join the team as well as an Assistant Director. In 2020 the team moved to our Strategy and Insight Directorate. In February 2021 we expanded the team and strengthened the management structure. There is now an Assistant Director, a Head of Delivery, two Principal Regulation Advisers, twelve RAs, three Employer Link Officers and a team coordinator. There is a RA responsible for each of the English NHS regions and one for each of the devolved administrations. Following a restructure in 2023, the ELS team was moved to our Professional Practice Directorate.

[17] Recommendation 232: 'The Nursing and Midwifery Council could consider a concept of employment liaison officers, similar to that of the General Medical Council, to provide support to directors of nursing. If this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap'.

83. ELS aims to encourage robust local investigation where there are concerns relating to nurses and midwives, and to ensure that where these relate to fitness to practise, appropriate and timely referrals are made. ELS does not get involved in local investigations but we do produce guidance for employers on how to conduct local investigations.

84. The five main areas of the work of the ELS are to:

    a. Support local employers with the management of and proportionate responses to practice concerns.

    b. Share key messages and understand context and intelligence.

    c. Deliver learning and support sessions to employers.

    d. Operate an employer advice line to support queries.

    e. Liaise with key regional local partners and regulators.

85. The ELS advice line operates between 09:00 - 17:00 Monday to Friday. Regulatory Advisers (RAs) provide advice to employers who call with fitness to practise concerns, advising on whether the employer should make a fitness to practise referral. The RA does not ask for evidence or documentation about any individual case and the advice provided is informed by what they are told by the employer at the time.

86. The notes of discussions and reasons for the advice provided are stored on our case management system and since 2017 we have assurance measures in place to ensure that the advice we provide is consistent. These include:

    a. Monthly peer to peer review where advice is reviewed by another RA and complex cases are discussed.

    b. Monthly peer review meetings between the RAs and clinical advisors where complex cases or cases with differing views are discussed and referred to the monthly benchmarking meeting if necessary.

    c. Monthly benchmarking meeting where RAs, clinical advisors and colleagues from the Screening team review cases and agree next steps.

Fitness to practise

87. When a concern is raised about a professional on our register's conduct, health, or competence we investigate through our fitness to practise process. We take regulatory

action where needed to protect people who use health and social care services and to ensure public trust and confidence in the professions is maintained.

88. Our fitness to practise process is set out in the Order[18] and the Nursing and Midwifery Council (Fitness to practise) Rules 2004 (SI2004/1761). The Order sets out that we can take action where a nurse, midwife or nursing associate's fitness to practise is impaired by reason of misconduct, lack of competence, criminal conviction or caution, physical or mental health or not having the necessary knowledge of English[19].

89. On 31 August 2018 we introduced 12 overarching principles for fitness to practise that were updated in April 2021 (**Exhibit AS/11**). These principles help guide whether we need to take regulatory action. Since August 2018 we have also issued guidance that sets out how we determine seriousness and the most recent version was published in August 2023 (**Exhibit AS/12**). INQ0002423 INQ0002424

90. Our guidance on seriousness states:

    a. When assessing whether a concern is serious, we look at what risks are likely to arise if the nurse, midwife or nursing associate does not remedy or put this concern right. This could be risks to patients or service users or, in some cases, to the public's confidence in all nurses and midwives.

    b. By focusing on how risks could arise if concerns are not put right, we can see what the nurse or midwife may need to do to remedy the problems in their practice, or what action we may need to take if they do not.

    c. When our decision makers are looking at overall fitness to practise, they will always consider what the nurse or midwife has done to remediate the concerns.

91. The guidance also links to more detailed information on the three broad categories of seriousness we focus on as a regulator:

    a. Serious concerns which are more difficult to put right.

    b. Serious concerns which could result in harm to patients if not put right.

    c. Serious concerns based on the need to promote public confidence in nurses, midwives and nursing associates.

92. The processes outlined below apply to the majority of referrals we receive[20].

[18] The Nursing and Midwifery Order 2001 ('the Order').
[19] Article 22, Nursing and Midwifery Order 2001
[20] We have a process whereby we can refer certain limited matters direct to the FtPC. This is usually in

93. For each of the stages involved in the fitness to practise process we have a Head of function leading the team. They are supported by a multidisciplinary team including decision makers, senior managers, lawyers, investigators, clinical advisors and case officers. All the guidance that supports our fitness to practise process and decision making is available on our website and is known as the 'Fitness to practise library'.

Screening stage

94. Screening is the first stage in our fitness to practise process[21]. If we receive a concern about a nurse, midwife or nursing associate's conduct or practice it is logged on our internal records systems and our screening team complete an initial assessment of the referral, including an assessment of risk based on the information referred. We assess whether a case requires, or may require, an application for an interim order (see paragraph 96 for details). If we decide that an application for an interim order is necessary, we aim to list the application for a hearing to take place within 28 days of receipt of the referral.

95. Between 2016 and May 2021 we had a four-stage test at screening:

    a. Are the concerns serious enough to suggest that the nurse or midwife may not be fit to practise?

    b. Does the case meet our formal requirements?

    c. Will we be able to obtain credible evidence about the concerns?

    d. Can the nurse or midwife show they have already remedied any problems in their practice sufficiently so that we can be confident that any risk to patients, along with risk to public trust in nurses and midwives or professional standards, has already been dealt with?

96. In May 2021 (**Exhibit AS/13**) we moved from four to three questions. This change has given us greater flexibility when considering cases in screening. We consider any of the three questions in any order we consider appropriate to the particular referral in question. INQ0002425

97. The three stages are:

    a. **Step one** – whether we have a written concern about a nurse, midwife or nursing associate on our register.

referrals involving convictions for the most serious of cases of criminal offending, where there has been a conviction at the point of referral.

[21] Rule 2a(4) of the Fitness to Practise Rules.

b. **Step two** – whether there is evidence of a serious concern that could need us to take regulatory action to protect the public.

c. **Step three** – whether there is clear evidence to show that the nurse, midwife or nursing associate is currently fit to practise.

98. Our screening team can:

a. Make enquiries to enable them to make a decision.

b. Decide to refer the matter for investigation.

c. Decide not to investigate at that stage[22].

Investigation

99. Following a decision at the Screening stage to refer a matter for investigation, the investigation team investigates the concerns, including gathering key information, documentation and witness statements. We will also ask the professional to respond to the concerns made against them. This provides them with an opportunity to reflect on the concerns raised and provide context to the case.

100. Once the investigation team have concluded their investigations, the case is passed to case examiners to review and decide the next steps[23].

Case Examiners

101. Our case examiners were introduced in March 2015[24]. Case examiners review the evidence from our investigation and decide[25] if the concerns relating to the nurse, midwife or nursing associate's practice or conduct should be closed or referred to the fitness to practise committee. Case examiners decide whether there is a case to answer in pairs, with one being a registrant and one a lay person.

102. Case examiners must assess on the papers whether there is a realistic prospect that a panel would find the professional's fitness to practise to be currently impaired. This involves considering the possibility that the Fitness to Practise Committee would decide, using the evidence we have gathered so far, that:

a. there is a case to answer on the facts

[22] We also have a process where we can reconsider these decisions.
[23] The process for referring an allegation falls within Article 22(1)(a) and (b) is further expanded in Rule 2A of the FTP Rules
[24] Nursing and Midwifery Council (Fitness to Practise) (Education, Registration and Registration Appeals) (Amendment) Rules Order of Council 2015, SI 2015/52
[25] Rule 6C of the FtP Rules

b. the nurse, midwife or nursing associate's fitness to practise is currently impaired.

103. Case examiners do not decide whether the case against the nurse, midwife or nursing associate is proved, whether or not the incidents in the case happened, or whether or not the nurse, midwife or nursing associate's fitness to practise is actually impaired.

104. Between March 2015 and June 2017, if the case examiners decided that there was no case to answer, they were only able to close the case with no further action. If they decided that there was a case to answer, they could only refer the case to the fitness to practise Committee for determination.

105. Since June 2017, the outcomes at this stage are:

a. **No case to answer** - if case examiners decide there is no case to answer (either on the facts or on the question of impairment), there will be no further action, and the case will be closed. Case examiners may choose to give the registrant advice which will be private and will not be published on the register. They can also choose to give a professional a warning which is published on our register for 12 months.

b. **A case to answer –** if case examiners decide there is a case to answer, they can either refer the matter to the Fitness to Practise Committee for final determination or recommend undertakings. Undertakings are steps a nurse, midwife or nursing associate agrees to take, for example, extra training. Undertakings are reviewed by case examiners to make sure the nurse, midwife or nursing associate has done what they said they would.

106. The current decision-making guidance for case examiners (**Exhibit AS/22**) includes information on: INQ0002434

a. How case examiners decide if there is a case to answer.

b. Available outcomes – advice, warnings, undertakings.

c. Reconsidering closed cases where new concerns are received within three years of a case being closed.

d. Revisiting case to answer decisions.

Investigating Committee

107. Before the introduction of case examiners in March 2015, these case to answer decisions were made by the Investigating Committee. That Committee still exists and meets to consider:

a. The making and reviewing of interim orders.

b. Cases relating to fraudulent or incorrect entry to the registers.

c. Case where the case examiners disagree on what the case to answer decision should be.

Fitness to Practise Committee

108. This is the final stage of our fitness to practise process. If the case is referred to the Fitness to Practise Committee (FTPC)[26], a panel of the FTPC will consider the case at a meeting or hearing. The panel is independent and must make its own decision about a nurse, midwife or nursing associate's fitness to practise. In both meetings and hearings, there will be an independent legal assessor to give legal advice. We issue guidance for our FTPC decision making which includes guidance on impairment and sanctions **(Exhibit AS/23).** INQ0002435

109. The panel must decide on the balance of probabilities whether it finds the facts proved and whether those facts prove the charges in relation to the professional's misconduct or competence. The panel must then decide whether or not the professional's fitness to practise is currently impaired and if so, what sanction if any it is appropriate to impose.

110. At a meeting or hearing, a panel will make a decision about the case. Possible outcomes include:

a. **No sanction** - this is where either the panel has decided there is no current impairment or the person on our register is impaired but no sanction is needed.

b. **Caution** - a caution is like a warning. Cautions can last between one to five years and are published on our register.

c. **Conditions** - if a registrant receives conditions of practice, they are still allowed to work, but there are restrictions to what they can do. For example, they may be supervised during work or be instructed to go on specific training and provide reflections. Conditions last between one to three years.

[26] Part 4 of the FtP Rules

d. **Suspension** – A registrant is not allowed to work during this period. Suspensions can last anywhere between one or 12 months. After this time, it might expire or be looked at again at the end of the suspension period and be extended.

e. **Strike off** – if the panel decide to strike a registrant off the register, they will be taken off the register altogether. During this time, they cannot work or call themselves a registered nurse, midwife or nursing associate but can make an application to re-join our register after five years, which will be considered by the FTPC to determine whether they should be permitted to re-join the register.

Interim orders

Powers

111. Article 31 of the Order gives us the power to seek and impose an interim order. Interim orders temporarily suspend or restrict a nurse, midwife or nursing associate's practice while their case is being investigated and may include cases of lack of competence, misconduct, poor clinical practice and serious convictions or imprisonment. They can be made at any time of the process as information indicating risk becomes available. Our Fitness to Practise Rules 2004 provide additional procedural provisions relating to interim orders.

112. There are two types of interim orders available under Article 31(2):

a. **Interim suspension order** - the panel suspends the nurse, midwife or nursing associate's registration for up to 18 months.

b. **Interim conditions of practice order** - the panel imposes conditions on the nurse, midwife or nursing associate for up to 18 months.

113. We can seek an interim order at any stage of our fitness to practise process[27] before a final decision has been made on the substantive case. Where a final decision is made by our FTPC, an interim order can be made at the same time as a condition of practice, suspension or striking off order[28]. Substantive orders do not come into effect until after the expiry of the appeal period[29] so this provides an important safeguard for this period.

114. The grounds for imposing an interim order are set out under Article 31(2). The Practice Committee must be satisfied:

[27] Article 31(1)(a)
[28] Article 29(5) (a-c)
[29] Article 29 (10)

'that it is necessary for the protection of members of the public or is otherwise in the public interest, or is in the interests of the person concerned, for the registration of that person to be suspended or to be made subject to conditions'.

115. When an interim order is imposed the maximum length of time it can be imposed for is 18 months. If an interim order has been put in place before a final decision has been made there needs to be a review of that interim order every six months[30]. We also must hold an early review of the order at any time '*where new evidence relevant to the order has become available after the making of the order[31]'*.

116. The Committee conducting the review has no power to vary the original length of the interim order but they can[32]:

a. Revoke the order or any condition imposed by the order.

b. Confirm the order.

c. Vary any condition imposed by the order.

d. Change the type of interim order in place.

117. If it becomes necessary to extend an interim order timeframe, we must apply to the High Court in England and Wales, the Court of Session in Scotland, or the High Court of Justice in Northern Ireland, where appropriate, for an extension. There is no limit placed in the Order on the number of times an interim order can be extended by the Court. The Court also has powers to change the type of order in place[33].

118. Our Order also outlines the circumstances where an interim order would cease to have effect[34].

119. Since July 2015, Article 31 of the Order has only been amended once, in 2017[35]. The changes coincided with our transition from separate Health and Conduct and Competence Committees to a single Fitness to Practise Committee. The main changes included:

a. Changing the review period from three to six months after the first review.

b. Increasing the situations where an interim order would cease to have effect to include no case to answer and undertakings.

[30] Article 31(6)
[31] Article 31(6)
[32] Article 31 (7)
[33] Article 31(9)
[34] Article 31(5)
[35] The Nursing and Midwifery (Amendment) Order 2017 (SI2017 no.321)

c. Increasing what the Court could do when we applied for an extension.

120. Once a case has been considered by an Interim Order (IO) panel, whether they impose an order or not, it automatically progresses to investigation from screening.

Guidance

121. There is a specific section of our online fitness to practise guidance library relating to interim orders (**Exhibit AS/14**). This guidance is used by our fitness to practise colleagues and panel members. The fitness to practise library was established in July 2017. There are currently six parts of guidance relating to interim orders: INQ0002426

a. INT 1 – Interim orders, their purpose and when we impose them.

b. INT 2 – Decision making factors for interim orders.

c. INT 2a – Interim orders and fraudulent or incorrect entry allegations.

d. INT 2b – Interim orders and not having the necessary knowledge of English.

e. INT 3 – Applications for interim orders.

f. INT 4 – Interim orders and multiple referrals.

122. An overview of each of the three sections relevant to the Inquiry's request and how they have changed over time is outlined below.

123. As will be seen below, our guidance is reviewed and updated for a number of reasons. This may be in response to feedback from the Professional Standards Authority (PSA), learning from an Inquiry or a fitness to practise case, or a request from operational teams. We may also update our guidance due to a change in legislation or to reflect the outcomes of regulatory case law.

124. When updating guidance, we engage with our operational colleagues and our external representative bodies. We may also engage more widely with groups such as our Public Voice Forum or Professional Strategic Advisory Group or with the PSA.

INT1 - Interim orders, their purpose and when we impose them

125. This section outlines the types of interim orders available. It states the purpose of interim orders is to protect the public from risk while we investigate concerns. It also states that an interim order will be needed in cases where the concerns are so serious that either patient safety would be put at risk or there would be serious damage to the reputation of the professions if the person was allowed to practise without any

restrictions. It covers which Panels can make (or review) interim orders and when in the process this can happen.

126. The first version of our Interim Orders guidance from our fitness to practise library is from 28 July 2017 (**Exhibit AS/15**). We updated the guidance on 12 October 2018 (**Exhibit AS/16**). The principal changes made were: INQ0002427 INQ0002428

a. Specific reference to risk

b. Including an explanation as to why an interim order might be required after a decision at a final hearing resulting in a finding of impaired fitness to practise.

127. We updated *ITN1* again on 13 September 2019 (**Exhibit AS/17**). The principal changes were: INQ0002429

a. Reference to interim orders having a restrictive impact on professionals.

b. The need for good evidence of potential harm to patients or the reputation of the profession.

c. Making clear that the interim order imposed must be proportionate to the risk.

d. Inclusion of new sections focusing on which panels can make and review interim orders.

128. On 2 October 2023 *ITN1* was updated to include reference to how seriously we view deliberate breach of an interim order, which may itself require regulatory action. This amendment was prompted by a development in case law.[36]

129. Some minor amendments were made to that version on 10 October 2023 where a footnote was expanded and that is the most recent version.

INT2 - Decision making factors for interim orders

130. This is currently the key document used by our decision makers when deciding whether to apply for or impose an interim order. It states that a two-stage test should be followed when applying for or imposing an interim order. The first stage is to consider whether there is sufficient evidence of a case against the nurse, midwife or nursing associate, referred to as a 'prima facie case'. *INT2* lists some factors to consider when assessing the strength of the evidence:

36 GMC v Donadio [2021]

a. 'The source of the evidence. Where the evidence comes from may affect whether it's reasonable for us to rely on it when deciding whether to impose an interim order. Evidence which comes directly from an identifiable source is likely to be more reliable than evidence from an indirect or unknown source. If the evidence is disputed, it will rarely be fair to rely on anonymous or multiple hearsay as the only basis for imposing an interim order. Where the police have charged someone with a criminal offence, this may be sufficient for the panel to go on to consider the need for an interim order, even where the underlying material isn't available to us'.

b. 'The accuracy of the information and whether it's sufficiently clear for the registrant to understand the basis for concern. If all of the available evidence is vague or tenuous, the registrant may not be able to respond to it beyond a bare denial and so it may not be fair for us to rely on it.'

c. 'The nature of any evidence which supports / corroborates the concerns being raised. Although the panel can't make a decision on the facts of any disputed allegation, it can discount evidence that's inconsistent with objective or undisputed evidence, or which is clearly unreliable.'

131. Once it is considered that there is sufficient (or "prima facie") evidence, the next step is to consider whether an order is required under one of the three statutory grounds set out in Article 31(2):

a. Necessary to protect the public.

b. Otherwise in the public interest.

c. In the nurse, midwife or nursing associate's own interest.

132. The guidance in place at the relevant time was the previous version of *ITN2,* from 28 July 2017 (**Exhibit AS/71**). INQ0002516

133. In 2017 the guidance was separated into four documents. On 26 November 2018 we amalgamated all four documents into one and removed reference to the reputation of the regulator as a consideration (**Exhibit AS/18**). INQ0002430

134. On 2 October 2019 (**Exhibit AS/19**) we updated *INT2* to make the following changes: INQ0002431

a. To introduce a two-stage process, the first stage being the need for there to be "sufficient" evidence or a "prima facie" case

b. It now included an 'evidence of concerns' section to support decision-makers on their approach to the sufficiency of evidence or whether there is a prima facie case.

135. In October 2019, the changes to *INT2* were made because at the time, we considered that our guidance needed to be strengthened to refer more explicitly to the evidential threshold required for an interim order to be imposed, and to provide more support for decision-makers in considering the sufficiency of evidence. This was informed by a recent case in the High Court in Northern Ireland, in which a judge revoked a number of NMC interim orders due to criticisms of our approach to the underlying evidence of the registrants' wrongdoing. This case and related criminal proceedings are ongoing. The 2017 version of ITN2 did not include any reference to an evidential threshold, unlike a pre-2017 version, endorsed by the Court of Appeal in Perry v NMC[37], which had stated that a prima facie case needed to be established based on the case of George v GMC.

136. *INT2* was updated again on 24 September 2021 (**Exhibit AS/20**). The changes made were: INQ0002432

a. Reference to nursing associates included.

b. Changed 'remediation' to 'strengthened practice' in line with changes to our wording on this issue.

137. On 19 June 2023 (**Exhibit AS/101**) we updated *INT2* to amend the section on 'evidence of concerns' in relation to police charging decisions. We made this change to reflect a case in Scotland where a professional successfully appealed against the imposition of an interim order. The case highlighted the different practices across the four countries in relation to charging decisions and the need for our guidance to apply in all countries. INQ0002577

138. The current version of *INT2* was published on 2 October 2023. The key change made in this version followed a High Court decision concerning the issue of freedom of expression.[38] We clarified the guidance to enable decision-makers to consider where an interim order might have the effect of restricting and individual's freedom of expression and factor this into their decision. Minor corrections were made to that version on 10 October 2023.

INT3- Applications for interim orders

[37] Perry v NMC [2013] EWCA Civ 145
[38] White v GMC [2021] case

139. *INT3* outlines what we do when we conduct risk assessments of fitness to practise cases and consider whether to make a referral to a panel for an interim order consideration. It also outlines our approach if a registrant is already on a substantive order and we receive additional concerns and it also covers the format and procedures for hearings.

140. *INT3* states for risk assessments:

'Our screening team carries out an initial risk assessment on each referral they receive. When we receive new information that an interim order might be necessary, we will carry out a risk assessment. In conducting the risk assessment, we will consider if it is likely that the panel would impose an interim order based on one or more of the three grounds, namely whether it is necessary for the protection of members of the public, is otherwise in the public interest, or is in the nurse, midwife or nursing associate's own interests'.

141. The first available version of *INT3* was published on 28 July 2017 (**Exhibit AS/21**). It was updated to the current version on 14 October 2022. The changes made between the two versions were: INQ0002433

a. The inclusion of nursing associates.

b. The inclusion of a new section on arrangements for interim order hearings.

Role of employers with interim orders

142. Our fitness to practise principles outline the role of the employer in relation to fitness to practise concerns. Principle four states:

'*Employers should act first to deal with concerns about a nurse, midwife or nursing associate's practice, unless the risk to patients or the public is so serious that we need to take immediate action'.*

143. This principle recognises that employers are closest to the source of the risk to patients or members of the public, and so can intervene more directly and quickly to deal with the risk. We say that we only need to become involved early on if the person poses a risk which the employer cannot manage effectively and which means that their right to practise needs to be withdrawn or restricted immediately. We offer advice and support to the employers throughout the process.

144. Principle five states:

We always take regulatory action when there is a risk to patient safety that is not being effectively managed by an employer'.

145. In this principle we explain that we will become involved where employers are unable to put the right controls in place to keep patients or members of the public safe. We explain that could include placing restrictions on an individual's practice.

Patients and members of the public raising concerns

146. Patients, families and members of the public can raise concerns with us and we are required to consider whether those concerns mean that a professional's fitness to practise is impaired. All stages of the fitness to practise process apply to concerns raised by members of the public. We recognise that raising a concern and engaging with the fitness to practise process can be daunting. The process for investigating concerns about individuals on our register raised by patients, families and the public has remained broadly consistent between June 2015 and now.

147. We provide information on how patients, families and the public can raise concerns on our website and we direct them to our helpline (**Exhibit AS/24).** Concerns must be made in writing and members of the public looking to make a referral are directed to the online referral form on our website and we can provide support with this. INQ0002436

148. This form suggests that they raise the concern with the nurse, midwife or nursing associate or their place of work before coming to us and we signpost to the NHS website for details on how to raise concerns locally. We also signpost to organisations that can support people raising concerns with the NHS (Healthwatch and NHS complaints advocacy service) and the Care Quality Commission and Patients Association for service complaints. Patients, families and members of the public can still always decide that they want to raise a concern directly with us and we will consider that referral.

149. Once an individual has decided that they want to make a referral to us, they complete our online referral form. The form asks for:

a. Details of the person they are raising a concern about.

b. A description of what happened.

c. Details of what they have already done to raise their concern.

d. Details of any other people who saw what happened.

150. We also ask people to upload relevant information including medical records, emails or letters they have already sent about their concern. We offer support, including assistance to complete the online referral form and we update them as their case progresses through our fitness to practise process.

151. Our Public Support Service (PSS) was launched in October 2018 and provides support to people who have made or are involved in a fitness to practise referral. This includes patients, carers, families, colleagues and others. The service plays a key role in ensuring that raising a concern with us is accessible for all. The PSS helps to ensure that as an organisation we fully understand the concerns being raised with us and support people's needs to enable them to engage with the fitness to practise process. Colleagues in PSS can help individuals understand who we are and how our investigative process works. We help others to understand our regulatory decisions and the reasons for decisions. We also support people to deal with the impact the process can have on them. Some examples of the help the PSS provides include:

a. carrying out needs assessments to identify adjustments or additional needs;

b. supporting witnesses throughout the process and at hearings;

c. tailored support plans;

d. providing specialist support for those with complex or multiple needs;

e. making referrals to our support advocacy service or communication intermediaries.

152. To improve the experience of members of the public when making referrals to us, we introduced our referrals helpline in December 2022. The helpline does not accept referrals over the phone. Advisors are available on the helpline to explain more about our role, how we can help and what support we can offer. We provide advice on:

a. Whether we are the right regulator to consider their concerns.

b. What information we will need from them.

c. What to expect when making a referral and indicative timeframes.

d. How referrals are progressed through our process.

e. Reasonable adjustments and additional support we can provide.

Employers raising concerns

153. Since February 2021 we have had a dedicated area on our website called 'Managing concerns: a resource for employers'. This contains a suite of resources to support employers to respond to concerns about a nurse, midwife or nursing associate's practice. We collaborated with several stakeholders to identify good practice to help promote a just and learning culture.

154. Employers can engage with us through an ELS Regulation Adviser (RA) allocated to their region (or country) or they can contact the ELS advice line as outlined above. We provide advice on when concerns can and should be managed locally and when a referral should be made to us. We have guidance on our website that sets out employers can work with us when managing concerns (**Exhibit AS/25**). INQ0002437

155. We also have guidance on our website explaining what types of referrals should be made to us (**Exhibit AS/26)**. This guidance outlines the different approaches employers could take given the context and type of concerns. INQ0002438

156. In line with our statutory requirements and fitness to practise principles we make very clear that referrals should be made to us where:

a. Concerns pose a serious risk to people who use services and would be difficult to put right.

b. Local action cannot effectively manage any ongoing risks to people who use services.

c. Concerns require us to take action to protect public confidence in the professions and uphold standards.

157. We encourage employers to raise their concerns through the online form. If the employer is unsure whether a concern meets the threshold for referral the RA can support the decision-making process as outlined above.

158. If the RA considers the concern so significant that the referral should be made without delay and there is not sufficient assurance that the employer will do that, the RA can escalate and submit the referral to our screening team themselves.

Whistleblowers

159. When considering whistleblowing concerns, we always act according to our legal obligations which includes giving careful consideration to a whistleblower's request that their identity should not be disclosed. However, if an issue is serious and requires a fitness to practise investigation, the information we receive and use to assess the

allegations can expose the identities of referrers. Whistleblowing protection is protection in employment but not in our processes. We provide whistleblowing guidance for nurses, midwives, students or other members of staff **(Exhibit AS/27**). That guidance outlines: INQ0002439

a. What whistleblowing is.

b. The criteria set out in law to protect whistleblowers.

c. What whistleblowing concerns should be raised with us.

d. How to raise a whistleblowing concern.

e. What happens when a concern is raised.

f. Sources of advice and support.

160. In the Screening section of our fitness to practise guidance library, we include guidance on referrers that wish to remain anonymous. We make clear that we may need to disclose the referrer's identity to refer a case to the case examiners or Fitness to Practise Committee. If the referral meets our screening requirements, then we have the power to investigate and refer a case ourselves[39] without an external referrer. We offer the same support to whistleblowers that we do to others raising concerns.

161. We have a dedicated email address for workers wanting to raise a whistleblowing concern with us but concerns can also be raised using our fitness to practise referral form.

162. Since April 2017 we have had a legal duty[40] to publish an annual report on the whistleblowing disclosures made to us. We publish a joint report with other health and care professional regulators to show the action that we have taken and how we work together to handle serious concerns raised with us. Our 2023 report covers activity between 1 April 2022 and 31 March 2023 (**Exhibit AS/28**). INQ0002440

163. Where concerns raised are better managed by other organisations, we share that information with them. During the last reporting period we shared information with:

a. Care Inspectorate Scotland

b. Care Quality Commission

c. General Medical Council

[39] Article 22(6) of the Nursing and Midwifery Order and Rule 2(A)(4) of the Fitness to Practise Rules.
[40] The Prescribed Persons (Reports on Disclosures of Information) Regulations 2017

d. Healthcare Safety Investigation Branch

e. Health and Safety Executive

f. Healthcare Inspectorate Wales

g. Mental Welfare Commission for Scotland

h. Office for Standards in Education, Children's Services and Skills

i. Regulation and Quality Improvement Authority.

Identifying concerns

164. We have two internal oversight groups where colleagues from across our organisation come together to share and consider emerging issues or concerns. The Intelligence Coordination Group (ICG) was initially established in 2017 and the Intelligence Sharing Hub (ISH) was established in 2022. The ICG acts as the governance and decision-making group for managing regulatory risk. It coordinates and considers risk from across the organisation and considers the implications on patient safety and nursing and midwifery practice. The ISH is the forum for sharing potential regulatory risks.

165. These groups focus on concerns relating to patient safety which are identified from a variety of sources including our regulatory intelligence work, education assurance activity and concerns identified through external inquiries, reviews and media reports.

166. Both groups help us to manage and coordinate our response to regulatory risk and better protect the public by making appropriate interventions based on evidence and sound judgment. They consider opportunities to coordinate our response with other stakeholders including other health and social care regulators. They are also a mechanism for considering what insight and learning can be shared to influence safer care.

167. We have constructive and collaborative working relationships with a broad range of stakeholders. We regularly identify and share concerns around patient safety with others to ensure the appropriate organisation can manage any concerns.

168. We hold memoranda of understanding (MOUs) with other regulators which set out our agreement on how we will work together and share information when we have concerns. These are all available on our website. We also share information with organisations where we do not hold MOUs if we consider it in the public interest to do

so including organisations such as NHS Counter Fraud Authority, National Crime Agency, Home Office and Healthcare Safety Investigation Branch.

169. We are a signatory of the Care Quality Commission's emerging concerns protocol for England. This protocol allows any one of the signatories to initiate a regulatory review panel with other members to share and discuss any concerns that may arise to understand if other members have similar or additional concerns. We have both initiated and attended Regulatory Review Panels (RRP) under this process. We also use The Framework for Sharing Intelligence with Heath and Care Regulators in Scotland and are members of the Healthcare summit in Wales.

170. We are involved in discussions around emerging risks and issues on both a national and regional level in England. We are members of the National Joint Strategic Oversight Group (NJSOG) and the National Perinatal Safety and Surveillance Group (NPSSCG) which are both convened by NHS England. NJSOG is a forum of healthcare regulators that meet to consider national policy and risks and exchange learning, intelligence and information at a national level. The NPSSCG supports the timely identification and escalation of concerns from regional teams and insight from regulators and national bodies to inform actions. ELS colleagues also attend Regional Quality Groups.

Managing third party investigations

171. Our fitness to practise cases can sometimes be subject to investigations by third parties such as the police, NHS Counter Fraud Authority and other regulators. When this happens, we can decide to place a case on hold if there are clear and compelling reasons to do that and it is in the public interest.

172. In August 2014 we issued operational guidance for our colleagues on how to deal with cases that are also subject to a third-party investigation. The aim of the guidance was to help inform decisions about whether our fitness to practise investigation should be put on hold while the third-party investigation takes place.

173. When we launched our fitness to practise guidance library in July 2017, we created several pieces of guidance which covered how we should deal with cases where there was a third-party investigation. In August 2018 we combined the seven pieces of

guidance which explained how we dealt with cases where there is a third-party investigation into a single piece of guidance (**Exhibit AS/97**). INQ0002573

174. In September 2021 we made some changes to the guidance to include reference to nursing associates (**Exhibit AS/98**). INQ0002574

175. In July 2022 we updated our guidance, following a recommendation from the independent investigation into the death of Elizabeth Dixon[41], and introduced a fourth circumstance where a third-party investigation may impact on the progression of our own investigation; 'the outcome of the other investigation is likely to have an impact on our decision on the fitness to practise of the person we are investigating'.

176. We give an example of a separate investigation taking place into systematic failings at an organisation which are relevant to the concerns that we are investigating in relation to the individual. We also emphasised that we will do as much as we can to progress our own case, and that we will be proactive in seeking updates and assessing risk when our case is delayed (**Exhibit AS/99**). This is the current guidance that is published on the website. INQ0002575

Section three: Lucy Letby

Regulatory activities

177. Lucy Letby (LL) started her undergraduate education for registered nurse programme - children's branch of nursing on 22 September 2008 at the University of Chester (UOC).

178. On 20 September 2011 the UOC signed the declaration of good health and character which formed part of the application to join the register. LL's application to join the register was received on 5 October 2011 **(Exhibit AS/29)**. INQ0002442

179. On 11 October we accepted her application and she was admitted to the register as a 'Registered Nurse – Children Nursing (Level 1)' with an effective date of 19 September 2011[42]. Her NMC PIN, which is her unique identifier, is I&S.

[41] Recommendation nine: Professional regulatory and criminal justice systems should contain an inbuilt 'stop' mechanism to be activated when an investigation reveals evidence of systematic or organisational failures, and which will trigger an appropriate investigation into those wider systemic failures.
[42] Backdating the registration date to coincide with the end of the undergraduate course was our standard

180. On 18 September 2014 LL renewed her registration and as part of that renewal she made a series of declarations demonstrating she met our requirements at the time for registration (**Exhibit AS/30**). Those requirements were: INQ0002443

a. 450 hours of registered nurse practise over the last three years

b. 35 hours of continuing professional development

c. Declaring if she had received a police charge, caution or conviction other than one that was protected since 1 August 2004.

d. Declaring that her health and character was sufficiently good to enable safe and effective practice.

181. On 30 August 2017 LL submitted her revalidation application. This was accepted on 14 September 2017 as she complied with all the standard declarations required as part of the revalidation process (**Exhibit AS/31)**. This process is a self-declaration which is signed by a confirmer. We do conduct sample checks of revalidation submissions but as LL's was not included in that sample, she was not required to submit any further information. INQ0002444

182. On 1 September 2020 LL was due to revalidate but no application was received. In order to remain on the register, LL was due to pay her registration renewal fee by 30 September 2020. LL did not pay the fee but she remained effective on the register, as our Order prevents a professional's registration from lapsing where they are the subject of an fitness to practise investigation (see paragraph 63).

Fitness to practise case investigation

183. We received a fitness to practise referral from AK about LL on 5 July 2018. Prior to that, AK had discussed LL with our Employer Link Service. A summary of key dates, activities and exhibits is provided below:

i. **6 July 2016**: Our ELS was informed during a telephone call with AK for the first time about a rise in neonatal mortality rates and potential concerns regarding LL (**Exhibit AS/32**). AK stated that the CoCH Executive team was to meet on 6 July 2016 to decide whether to report LL to the police. ELS advised AK that we needed to know about both the Trust's Board decision whether to report to the police and any subsequent action taken by the police. INQ0002445

practice at the time.

ii. **8 July 2016:** AK emailed ELS and asked for amendments to be made to the meeting note (**Exhibit AS/32**). INQ0002445

iii. **12 July 2016**: ELS emailed AK to confirm the meeting notes from 6 July had been amended (**Exhibit AS/32**). INQ0002445

iv. **15 September 2016**: ELS emailed CoCH to confirm introductory meeting scheduled for 29 November.

v. **24 November 2016**: ELS emailed AK and Sue Hodkinson (Director of HR) with agenda and bundle for meeting on 29 November.

vi. **29 November 2016**: Our ELS had an introductory meeting with AK, Sue Hodkinson (Director of HR). At that meeting the call from 6 July 2016 was discussed and we were informed that due to the rise in neonatal mortality rates the Royal College of Paediatrics and Child Health (RCPCH) was undertaking a review. Our Employer Link Service was informed that there were no immediate risks to patient safety, the reviewers had recommended a more detailed review into a number of identified incidents to be undertaken by an independent consultant, which the Trust had challenged. LL had been moved from the neonatal unit for her own protection. It was agreed there was no grounds for a referral to be made at this stage as the Trust was managing with a view to a phased approach return to the neonatal unit (**Exhibit AS/33**). INQ0002447

vii. **5 January 2017**: ELS called AK to discuss the publication of the RCPCH report. AK confirmed on email that the RPCH report would be published on 8 February 2017. (**Exhibit AS/34**). INQ0002448

viii. **18 May 2017:** We received a CoCH press release that Cheshire police had announced its own investigation into the neonatal deaths at CoCH. ELS spoke to AK who informed ELS that several medical colleagues believed LL could be the common denominator and it was their strong view she was the cause of the deaths. We were informed that this was based on the identification of her being present on most, but not all of the occasions of neonatal deaths and non-fatal collapses. AK advised that LL had been placed on restricted duties, that the police investigation had just begun but LL had not been arrested, charged or named as a suspect at that stage. ELS advised AK to wait for the police investigation to develop and to keep us regularly updated with any meaningful developments (**Exhibit AS/35**). INQ0002449

ix. **15 June 2017**: ELS attended a follow up meeting at CoCH and was advised the police investigation was ongoing, no arrests had been made, and LL remained on restricted duties in a non-clinical role (**Exhibit AS/36).** INQ0002450

x. **9 October 2017**: AK notified us that the police would now start interviewing CoCH employees as witnesses (**Exhibit AS/37).** INQ0002451

xi. **3 July 2018**: We learnt through our regular media monitoring that an individual had been arrested in connection with multiple deaths at CoCH. ELS contacted AK and she advised that a fitness to practise referral would be made within 48 hours (**Exhibit AS/38 (page 1)).** INQ0002453

xii. **4 July 2018**: ELS contacted Cheshire Police to confirm the reasons for describing the individual arrested as a 'healthcare professional' rather than as a registered nurse **(Exhibit AS/39)** INQ0002454

xiii. **5 July 2018**: AK made a fitness to practise referral to us about LL outlining the concerns raised by the paediatricians at CoCH. AK included the RCPCH report. AK said that no clear conclusions could be drawn from the RCPCH report and Cheshire Police were investigating **(Exhibit AS/40).** An interim order risk INQ0002455 assessment was conducted and it was decided not to apply for an interim order at that stage for the following reasons: First, we had limited evidence of involvement by LL available to us given our understanding of the case law was that there needed to be a prima facie case against a registered professional. Second, we did not consider that the fact of arrest alone in these circumstances provided the evidence needed to apply for an interim order. The police had informed us that the arrest was a step taken to gather evidence and interview under caution. The police did not provide any further detail explaining the information they had to form the grounds to arrest LL. Third, the RCPCH report had been disclosed to us and that did not find a definitive link between LL and the deaths. Fourth, the Trust informed us it was the lack of definitive conclusions that prompted the referral to the police as opposed to positive evidence of wrongdoing by LL. Fifth, LL had been identified as being on duty for all deaths, although not necessarily assigned to the baby in question. Finally, we were told that LL's colleagues and supervisors had no concerns with her clinical practice and described her in positive terms, although we were aware that a number of consultants at the CoCH felt strongly that LL was involved and they had a 'gut feeling' about it. We were also aware that LL had been removed from clinical duties. **(Exhibit AS/41, Exhibit AS/57 (pages 1 – 4)).** INQ0002460 INQ0002500

xiv. **6 July 2018:** ELS called AK who advised LL had been released on conditional bail and a condition of the bail restricted LL from working in any healthcare environment. We contacted the police who confirmed LL had been released on bail but the individual we contacted was not aware of the bail conditions. They said there was no timescale for completing the investigations **(Exhibit AS/42).** INQ0002461

xv. **19 July 2018:** We requested bail conditions from the police (**Exhibit AS/43**). INQ0002462

xvi. **20 July 2018:** The police provided brief detail about the bail conditions 'LL is not to work in any healthcare setting or to have unsupervised contact with anyone under the age of 16' (**Exhibit AS/86**). INQ0002580

xvii. **31 July 2018:** We wrote to LL to notify her of the fitness to practise referral made by AK enclosing a copy of the referral (**Exhibit AS/44).** INQ0002465

xviii. **24 October 2018:** We emailed the police for an update. The police acknowledged our email and advised they would respond when the senior investigating officer returned (**Exhibit AS/45).** INQ0002466

xix. **27 November 2018:** We sent a follow up email to the police (**Exhibit AS/46**). INQ0002469

xx. **13 December 2018**: We sent a follow up email to the police and requested an acknowledgement (**Exhibit AS/46**). INQ0002469

xxi. **14 December 2018**: We received a response from the police stating the investigation was still ongoing and there was no timescale for conclusion. Bi-monthly updates were suggested (**Exhibit AS/46**) INQ0002469

xxii. **28 December 2018**: We emailed the Royal College of Nursing (RCN) to ask for LL's current employment status. RCN replied on 8 January 2019 and confirmed that LL is 'excluded' 'from work I&S pending the conclusion of the police investigation. (**Exhibit AS/93**). INQ0002569

xxiii. **6 March 2019:** We emailed the police for an update **(Exhibit AS/47).** INQ0002472

xxiv. **14 March 2019:** Police confirmed the case is ongoing and LL remained on bail **(Exhibit AS/48).** INQ0002475

xxv. **13 May 2019**: We emailed for an update and the police confirmed bail conditions would expire in July 2019 and we would be provided with an update before then (**Exhibit AS/49).** INQ0002478

xxvi. **14 May 2019:** We responded to police seeking information and explained that the expiry of the bail conditions was a material change which affected the risk posed by LL. Police responded to say that they could not disclose full bail conditions but could confirm that the relevant conditions were 'not to gain employment, whether paid or unpaid, with babies or children, either in a healthcare setting or otherwise' **(Exhibit AS/50)**. INQ0002481

xxvii. **24 May 2019:** We were informed on a call with the police that the bail conditions were (1) Not to engage in healthcare services; (2) Not to work with vulnerable people; and (3) Not to have unsupervised contact with anyone under the age of 18. Police also advised that LL would have been on bail with these conditions for 12 months as of 3 July 2019. Police would extend this for a minimum of three months. (**Exhibit AS/51**) INQ0002484

xxviii. **30 May 2019:** A further interim order risk assessment was completed and a decision made not to apply for an interim order. This was on the basis that we did not consider that the more detailed information in relation to LL's bail conditions was new information; we knew the bail conditions would be extended; the police had informed us that they had not put the matter to the CPS for a charging decision to be made; the investigation was ongoing and they could not say how long it would last. The evidential position was unchanged **(Exhibit AS/38 (page 25-26), Exhibit AS/57 (pages 5-7).** INQ0002453 INQ0002500

xxix. **3 June 2019:** ELS called AK to inform her we would not be seeking an IO and explained our reasoning **(Exhibit AS/68).** INQ0002513

xxx. **10 June 2019:** Police emailed us to confirm that LL had been re-arrested. We followed up with the police explaining that we needed information in order to assess the risk to patients. Police advised they could not provide any information on the investigation or any information on bail **(Exhibit AS/38 (pages 26-27))** INQ0002453

xxxi. **11 and 13 June 2019:** Police emailed to confirm relevant part of LL's new bail conditions 'she not gain employment (paid or otherwise) with babies or children under 18, in a healthcare setting (or otherwise)'. A third interim order risk assessment was then conducted, prompted by LL's re-arrest. A decision was made not to apply for an interim order as the re-arrest by itself did not change the evidential basis for an interim order, the bail conditions remained the same and the police had informed us that there had not been any significant

development in their investigation prompting the arrest other than it has been 11 months since LL was first arrested and the investigation had reached a level of maturity which required the police to make further enquiries. The decision to arrest was not due to an acute episode or particular piece of evidence. The police were unable to provide further detail. **(Exhibit AS/57 (pages 7-14), AS/38 (pages 34 - 36)).** INQ0002500 INQ0002453

xxxii. **17 June 2019:** Police advised that a general prohibition on LL practising as a nurse would be disproportionate to managing the risk **(Exhibit AS/38 (pages 38)).** INQ0002453

xxxiii. **24 June 2019:** We wrote to the police requesting full disclosure of LL bail conditions (**Exhibit AS/52**). INQ0002485

xxxiv. **8 July 2019:** We received a copy of LL's full bail conditions (subject to some redactions of sensitive information) (**Exhibit AS/53**). INQ0002488

xxxv. **18 July 2019**: A further interim order risk assessment was concluded and a decision made not to apply on the basis that the only evidence we had was a link staff had made between the registrant and the deaths and the police were not giving us any further information (**Exhibit AS/57 14 – 17, Exhibit AS/38 44 – 57**). INQ0002500 INQ0002453

xxxvi. **23 July 2019**: We emailed the RCN and CoCH to ask whether LL still employed (**Exhibit AS/94).** CoCH confirmed on 30 July that LL is employed by the Trust but not currently working, nor living in Cheshire (**Exhibit AS/95).** RCN confirmed on 31 July that LL continued to be employed by the Trust, suspended I&S and has no other employment. INQ0002570 INQ0002571

xxxvii. **4 August 2019:** AK emailed to confirm CoCH was unable to share any information with us due to the police investigation **(Exhibit AS/102).** INQ0002578

xxxviii. **11 September 2019:** Police confirmed that LL bail conditions had been extended until 10 March 2020 (**Exhibit AS/54).** INQ0002491

xxxix. **9 January 2020:** Police advised no material change (**Exhibit AS/55**). INQ0002494

xl. **20-23 July 2020**: We requested an update from the police (**Exhibit AS/56**). INQ0002497

xli. **1 October 2020**: We emailed the RCN to ask whether LL remained employed (albeit suspended) by CoCH and to notify us if the position changes and LL secures employment elsewhere **(Exhibit 96).** INQ0002572

xlii. **15 October 2020:** AK confirmed that LL is still suspended from Trust and I&S I&S **(Exhibit AS/57 page 28).** INQ0002500

xliii. **11 November 2020:** Police advised that LL rearrested. Further interim order risk assessment conducted, no application to be made as the re-arrest does not change our risk assessment **(Exhibit 57 (pages 32-33), Exhibit AS/38 (pages 68-69)).** INQ0002500 INQ0002453

xliv. **12 November 2020**: LL was charged with eight counts of murder and ten of attempted murder. A decision was made to apply for an interim order on the basis that we now had the evidence needed to apply for an order **(Exhibit 57 (pages 33-45)) Exhibit AS/38 72 – 76**). We notified LL **(Exhibit AS/58).** INQ0002453 INQ0002453 INQ0002501

xlv. **20 November 2020**: IC panel imposed interim order suspension for 18 months (**Exhibit AS/59**). INQ0002502

xlvi. **6 May 2021**: Investigating Committee reviews LL interim order and order is confirmed **(Exhibit AS/60).** INQ0002504

xlvii. **12 October 2021:** Investigating Committee reviewed LL interim order and order was confirmed (**Exhibit AS/61**). INQ0002505

xlviii. **30 March 2022:** Investigating Committee reviewed LL interim order and order was confirmed (**Exhibit AS/62**). INQ0002506

xlix. **12 May 2022:** High Court extended LL interim order until 18 May 2023 (**Exhibit AS/63).** INQ0002507

l. **21 September 2022:** Investigating Committee reviewed LL interim order and order was confirmed (**Exhibit AS/64**). INQ0002508

li. **13 March 2023:** Investigating Committee reviewed LL interim order and order was confirmed (**Exhibit AS/65**). INQ0002509

lii. **3 May 2023:** High Court extended LL interim order until 17 May 2024 (**Exhibit AS/66**). INQ0002510

liii. **18 August 2023:** LL found guilty.

liv. **21 August 2023:** LL sentenced to whole life order.

lv. **22 August 2023:** We notified LL that her substantive case would be sent to the Case Examiners for consideration (**Exhibit AS/67).** INQ0002512

lvi. **19 September 2023**: We received LL's certificate of conviction.

lvii. **21 September 2023**: Case Examiners considered substantive case, decided there was a case to answer and referred the case to the Fitness to practise Committee.

lviii. **26 October 2023**: We wrote to LL to advise that Fitness to practise Committee would consider her case from 12-13 December 2023 **(Exhibit AS/69)** We also engaged with affected families through the police family liaison team and notified them of the hearing date. INQ0002514

lix. **12 December 2023:** Our Fitness to practise Committee will consider LL's substantive case. We will be asking the panel to strike LL off our register in light of her conviction.

184. The key contact at the CoCH for the LL case was Alison Kelly (AK) until 19 May 2021 when CoCH asked us to send all emails to Susan Gilby as AK had left the trust. On 29 March 2023, CoCH asked us to send any future correspondence to Acting Chief Executive Jane Tomkinson. In May 2023 we were advised to use Claire Raggett, the Operation Hummingbird liaison as the key contact and from August 2023 we have been asked to send all communications through Nicola Price the Chief People Officer at CoCH.

Interim order consideration

185. As set out in the chronology above, the first interim order risk assessment on LL's fitness to practise case was conducted on 5 July 2018, on the same day the referral was received. Risk assessing a case and considering whether to apply for an interim order is done periodically throughout the duration of a case. Detailed risk assessments and consideration of the interim order position were made on and around 5 July 2018, 30 May 2019, 11 to 13 June 2019, 18 July 2019, 11 November 2020 and 12 November 2020 as set out in the chronology above.

186. An interim order was imposed on 20 November 2020, seven days after LL was charged.

187. Due to the seriousness of the allegations against LL and the public interest in the case, in-house lawyers conducting the interim order risk assessments escalated the matter to the Executive Director for Fitness to Practise and Deputy Director for Fitness to Practise who had oversight of the interim order risk assessments and accountability for all case work.

188. It is clear from our records that we engaged regularly with CoCH and the police and fitness to practise colleagues undertook regular interim order risk assessments of the case. On each occasion, a decision was made not to apply for an interim order for the reasons detailed in the chronology above. These decisions aligned with our understanding, derived from the caselaw, of the evidence needed for an interim order to be imposed.

Section four: Alison Kelly

Fitness to practise investigation

189. This investigation is ongoing and currently is at our screening stage so the information provided is correct as of 11 December 2023.

190. The Inquiry has asked whether we provided any training to employers about investigating and managing concerns and whether that training was provided to AK. ELS offer learning sessions to organisations including sessions about fitness to practise and managing concerns. The RA offered a learning session at the meeting we had with AK on 15 June 2017 and this offer was followed up with an email on 26 June 2017. We made a further offer to provide a learning session by email on 15 January 2019 and we did not receive a response. Fitness to practise referral discussions about LL took place between ELS and AK from July 2016.

191. A summary of key dates, activities and exhibits is provided below.

i. **20 May 2020:** We received a fitness to practise referral for Alison Kelly on 20 May 2020. The referral was made by Irrelevant & Sensitive Irrelevant & Sensitive Irrelevant & Sensitive. The referral related to how AK had dealt with the concerns they had raised about the conduct of LL. Claire Raggett is the current contact at CoCH for this case **(Exhibit AS/72)** INQ0002517

ii. **21 May 2020:** We acknowledged the referrals and provided information about our fitness to practise process **(Exhibit AS/73)** INQ0002518

iii. **2-10 June 2020:** We discussed the case with the GMC's Employer Liaison Adviser **(Exhibit AS/74).** INQ0002524

iv. **14 September 2020:** We wrote to the referrers to seek confirmation that the referral would not be treated as a whistleblowing referral. (**Exhibit AS/75).** We followed up on 1 October and 20 October 2020. INQ0002525

v. **22-27 January 2021**: Referrers confirmed they would like referral to be treated as whistleblower referral (**Exhibit AS/76**). INQ0002532

vi. **20-27 January 2021**: We emailed the police to discuss AK referral and potential impact on criminal case (**Exhibit AS/77**) INQ0002533

vii. **15 February 2021**: The police advised that our investigation into AK should be delayed until after the trial **(Exhibit AS/78).** INQ0002534

viii. **19 February 2021**: We advised referrers and the Trust that the case was on hold as enquiries would prejudice the criminal investigation **(Exhibit AS/79)** INQ0002535

ix. **6 July 2023:** Following discussions with the police around progressing the case, we signed an information sharing agreement (**Exhibit AS/80).** INQ0002542

x. **18-23 August 2023**: We received fitness to practise referrals about AK from four members of the public **(Exhibits AS/88, AS/89 and AS/90).** INQ0002561, INQ0002562 & INQ0002566

xi. **21 August 2023**: Following the end of the criminal trial, we requested disclosure of information from CoCH to progress case the fitness to practise case against AK (**Exhibit AS/81).** INQ0002543

xii. **22 August 2023:** We sent a second disclosure request to CoCH **(Exhibit AS/82)** and we followed this up with an email to CoCH's CEO on 24 August 2023. INQ0002546

xiii. **31 August 2023:** We were advised by CoCH's CEO that they were awaiting instructions from the Inquiry team before disclosing information.

xiv. **5 September 2023:** Following a meeting with Claire Raggett at CoCH on 4 September we contact CoCH who advised that they would be able to share relevant information with us within the next three to four weeks (**Exhibit AS/83**) INQ0002552

xv. **9 October 2023**: We received disclosure of a large volume of documents from CoCH. We are continuing to review this information in line with our screening process.

Section five: Other matters

Other concerns or complaints

192. The Inquiry has asked whether there were any other concerns or complaints made to us about any other nurse who worked at the CoCH between June 2015 and June 2016. All fitness to practise concerns are logged on our case management system. Since 2017 we have logged allegation type and employer information for each case.

Between 2014 and 2017 our data was structured in a different way and the data we have on employers was backfilled into the system so the data is less reliable. As with all data, the reliability in the reporting is dependent on consistent user input.

193. We conducted a search of our data from June 2015 to June 2016 using CoCH as an employer and we found five cases concerning nurses at CoCH during that period. These referrals did not relate to the provision of neonatal care. Irrelevant & Sensitive

Irrelevant & Sensitive

Irrelevant & Sensitive

. We have reviewed the detail of each of those five cases and according to the information on our case files, none of the nurses worked in the neonatal unit at CoCH.

194. During the reporting of the criminal trial, three individuals

three individuals

were also named. There were no allegations raised with us, but we considered that we needed to make preliminary inquiries to establish whether information contained in the reports may amount to fitness to practise concerns. We asked CoCH for information to enable us to confirm the registration status of the three individuals and from this were able to verify that they were no longer on our register. As they are no longer on our register, we do not have the legal power to consider allegations made against them. We do have an alert system in place for all three individuals so if they want to return to our register, we are able to consider any allegations at that stage.

195. There was widespread reporting during and after the trial that related to these three individuals. I&S

I&S

196. There was one other nurse mentioned in the post-trial coverage I&S

I&S

I&S

. She is on our register but this reporting did not raise any issues that resulted in a need to make preliminary enquiries and we have not received any allegations about her fitness to practise.

197. We do not have sufficient evidence to comment on whether the culture at CoCH contributed to any lack of reporting of criminal activity by LL at this stage. The referral **I&S** made allegations about the culture at CoCH but we are yet to investigate these in any detail for the reasons set out in section four above. It is part of our fitness to practise process to consider context which means looking beyond the actions of an individual and understanding the role of other people, the culture and environment they were working in. When conducting our investigation into AK, we will consider whether the context in which she was working, including the culture of the organisation was a factor but this will not be the primary focus of our investigation. We will also consider whether she contributed to a culture that failed to protect patient safety.

Press statements and public comments

198. Any statements we make about fitness to practise proceedings are guided by two documents, our Fitness to practise information handling guidance and Guidance on publication of fitness to practise and registration appeal outcomes.

199. Our information handling guidance states, for example, that the fact a nurse, midwife or nursing associate is under investigation is generally treated as confidential until our Case Examiners decide there is a case to answer or issue a warning. Before this point, whenever we communicate with a third party about a case, we will explain to them that our investigation is confidential.

200. Our statements on LL's fitness to practise investigation followed this approach. When a registered professional is subject to an interim suspension order, it is in the public domain because it appears against their entry on the public facing register.

201. When it came to disclosing the fact that we hold a referral for AK in August 2023, we exercised our discretion under the guidance to disclose this in the public interest. By confirming that we had a referral about AK, our aim was to maintain public trust and confidence in the professional regulation of nursing, by reassuring the public that we were looking into serious concerns about a senior professional on our register, who had oversight at the time of these unprecedented serious and tragic events.

202. On 13 November 2020, we published a statement on our website titled, 'NMC comment on nurse charged with murder' (**Exhibit AS/84**). This followed news that LL had been charged with murder and attempted murder. **INQ0002555**

203. The statement included a comment, in the name of our Executive Director of Professional Regulation at the time which confirmed that we would take regulatory action in light of the charging decision. We later updated the statement to confirm that on Friday 20 November 2020 an independent fitness to practise panel imposed an 18-month interim suspension order on LL's registration. The statement included some answers to anticipated questions.

204. On 18 August 2023, we published a statement titled, 'NMC responds to verdict in Lucy Letby trial'. This followed news of LL's conviction for murder and attempted murder (**Exhibit AS/85**). This included a comment, in my name, confirming we would move forward with further regulatory action, seeking to strike LL off the register in light of her conviction. INQ0002556

205. On 21 August 2023, in response to an enquiry from PA Media about whether we would be taking action against any staff who worked at the Countess of Chester Hospital at the time of the events in question, we said:

'We can confirm that Alison Kelly has been referred to our fitness to practise process. At the request of the police we had paused this referral pending the outcome of the criminal trial of Lucy Letby. Now there's a verdict, we'll move forward and look at the concerns raised with us very carefully and take regulatory action if we need to. This is an ongoing case, so we're unable to discuss it further at this time.'

206. This was given to the journalist as background information, not as a comment. We gave the same information to other outlets including The Independent, Nursing in Practice and BBC News.

207. On 24 August 2023, we responded to an enquiry from the Daily Mail about why LL remained on the NMC register. We provided some background information about the legislation and rules underpinning our fitness to practise process, plus a comment in the name of our Executive Director of Professional Regulation:

'We've restarted our fitness to practise processes in relation to Lucy Letby, to enable us to put a case forward to an independent panel where we will be seeking to strike her off the NMC register. We're committed to progressing these actions, in line with our regulatory responsibilities, as quickly as possible.'

208. On 24 August 2023 we responded to an enquiry from Nursing Standard, about whether the press should stop referring to LL as a nurse when she is removed from the register, and whether there was any specific timeframe for when she would be removed from the register.

209. We provided a comment in the name of our Executive Director of Professional Regulation:

'We've restarted our fitness to practise processes in relation to Lucy Letby, to enable us to put a case forward to an independent panel where we will be seeking to strike her off the NMC register. We're committed to progressing these actions, in line with our regulatory responsibilities, as quickly as possible. If the independent panel agrees our recommendation that Ms Letby should be removed from the register, she will no longer be a registered nurse and it wouldn't be right to describe her as one.'

210. On 1 September 2023, we responded to an enquiry from The Sunday Times about why there was a gap between LL's arrest and her interim suspension from our register. We provided the following comment in my name but the article has not yet been published:

'After Lucy Letby's initial arrest in 2018, we remained in close contact with the police. We carefully considered whether we had the necessary evidence to apply to an independent panel to restrict her practice. While the police continued with their criminal investigation, they were understandably extremely limited in the evidence they could share with us. This meant that in line with our published guidance, we did not have the evidence to seek to restrict her practice. In the meantime, the police had already imposed bail conditions preventing Ms Letby from working with children and babies. As soon as she was charged, we moved quickly to suspend her from the register. It's right that we now carefully review the approach we took to this case, to learn anything we can for the future.'

Working with others

General Medical Council

211. We have well established working relationships with the General Medical Council (GMC). Colleagues across both organisations meet to discuss issues affecting our regulatory functions and we collaborate on work where we can. I meet the Chief Executive of the GMC on a regular basis to discuss joint issues. Some examples of our collaborative working include:

a. In 2011/2012 we launched a joint initiative with the Royal College of Physicians, the British Medical Association and the GMC to make GP practices aware that they must check the registration status of practice nurses.

b. In August 2012 we issued a joint statement with the General Medical Council on professional values.

c. In 2016/2017 we held a joint event for patients and public groups.

d. We signed a joint statement with the GMC and other health and care regulators on being a reflective practitioner.

e. In March 2020, along with the GMC and other health organisations, we published a guide to ensure that medicines and treatment that people get online are safe and right for them.

f. In March 2020 we issued a statement with the other regulators of health and social care professionals including the GMC which set out how we were continuing to regulate during the pandemic. This was reissued in January 2021 and December 2021.

g. In April 2020 we issued a joint statement with the GMC on advance care planning including do not attempt cardiopulmonary resuscitation (DNACPR).

h. Together with the NHS Race and Health Observatory, the GMC and CQC we issued an open statement in May 2021 on tackling racism.

i. One of our Council members sat on the advisory forum for the GMC's review of Good Medical Practice, published in 2023 and a member of our Standards team was seconded to support this work.

j. In 2023 we held a joint NMC/GMC Council and Executive teams meeting, where collaboration and regulatory reform were the particular focus.

k. We have current joint guidance for doctors, nurses, midwives and nursing associates on the Professional Duty of Candour, published June 2015 (**Exhibit AS/92**). INQ0002568

l. We have collaborated to help members of the public involved in NMC or GMC fitness to practise cases.

m. We work together with the GMC and the CQC, on maternity issues, including a pilot where we will share data, and on joint training sessions within trusts. We hope to soon launch a joint campaign about multi-disciplinary working.

n. Ongoing collaboration on international registration and policy matters. We are a member of the Alliance of UK Health Regulators on Europe (AURE), which GMC convenes and which now has both an EU and international focus.

o. Both we and GMC are represented on the joint regulators' forums in Northern Ireland, Scotland and Wales as well as meeting monthly with the Chief Executives of Regulatory Bodies (CEORB).

212. ELS works with the GMC on a national and regional level. Our outreach teams meet annually to discuss areas of alignment, mutual challenges, and work programmes. This includes sharing information, some joint learning session delivery and joint delivery of the Professional Behaviours and Patient Safety programme for maternity services.

213. In England there is an RA attached to each of the seven regions. They liaise regularly with the counterpart teams at the CQC, GMC and other professional regulators. RAs regularly attend quality and risk regional meetings with other regulators and providers.

214. The NMC has also worked closely with the GMC, CQC and other regulators as part of the working group for the Emerging Concerns Protocol since 2017.

Care Quality Commission

215. We have well-established working relationships with the Care Quality Commission (CQC) at different levels within the organisation. My previous job was as the Chief Inspector, Adult Social Care. I regularly meet the Chief Executive of the CQC to discuss areas of collaboration. We also have regular meetings between us, the GMC and the CQC where we discuss common issues, for example, the role of regulation in NHS England's Long Term Workforce Plan and the CQC's new role to regulate integrated care systems.

216. Our ELS RAs liaise regularly with their counterparts at the CQC and other system regulators. They provide the CQC with pre-inspection information when requested and attend NHS England Regional Quality Groups with the CQC and others. An RA attends the Controlled Drugs National Group Forum convened by the CQC and together with the GMC, ELS have recently met with the National Guardian's Office to consider how we can work more closely together and support the Freedom to Speak Up Guardians.

217. A memorandum of understanding with the CQC sets out the framework to support the working relationship between the two regulators. It outlines particular areas of co-operation including the cross-referral of concerns, joint working and the exchange of information. This year[43], we have already shared information or intelligence with the CQC on 124 occasions.

[43] Data correct on 5 December 2023

218. Both we and the CQC are signatories to the Emerging Concerns Protocol. The protocol sets a mechanisms for organisations to share information that may indicate risks to people or the public and escalate information of concern. We initiated the protocol earlier this year in response to concerns about the education of midwives at Canterbury Christ Church University, where the results of the CQC's latest inspection formed part of the evidence we considered when we made the decision to withdraw approval of the university's midwifery programme.

219. We have secured CQC agreement to make it a condition of GP practice registration to have satisfactory processes in place for checking the qualifications and registration status of practice nurses.

220. The CQC regularly publishes reports, for example in its annual State of Care report and its annual maternity survey. We respond to these reports and the insight they provide feeds into our strategic considerations. For example, findings from the maternity survey have helped to shape an upcoming campaign on multidisciplinary work – a campaign to be run jointly by us and the GMC.

221. We work with the GMC and the CQC on maternity issues, sharing of data and conducting joint analysis relating to regulatory risk. We also run joint training sessions within trusts.

Employers

222. Our relationships with employers have developed significantly since 2011. In 2011 our Head of External Liaison engaged directly with employers and advised Directors of Nursing and Local Supervising Authority midwifery officers through a dedicated helpline.

223. During 2012 and 2013 we published updated advice and information for employers of nurses and midwives, which contained an overview of our fitness to practise processes and highlighted employers' responsibilities for managing concerns. In that same period, we held two events with NHS Employers for senior nurses, midwives, and HR professionals, which looked at how to make more effective referrals to the NMC.

224. During 2014 and 2015 we established a professional strategic advisory group, which brought together senior nurses and midwives from a variety of practice settings across the UK. This group continues to meet four times a year and is involved in all key aspects of our work, as well as reflecting the realities of practice back to us.

225. Our engagement with employers increased ahead of the introduction of revalidation in April 2016. We increased our face-to-face engagement with employers and organisations representing employers, we established a strategic advisory forum to help shape the model of revalidation and this included several employers across the UK. There was a revalidation programme board established in each of the four countries to support employers to adopt revalidation. A key purpose of that group was to use pre-existing relationships and structures within each nation to cascade information to employers. This approach was mirrored with the introduction of new standards for nurses (2018) and midwives (2019).

226. As we have outlined above the ELS was established in 2016 primarily to engage with employers. ELS has regular planned and reactive meetings with trusts and health boards across the UK and has close working relationships with employers in all four UK nations.

227. We also have midwifery-specific relationships. Until 2017 there was a statutory requirement for us to have a Midwifery Committee, which advised our Council on midwifery matters, including policy issues that affect midwifery practice, education or supervision. Before our legislation changed, we introduced a non-statutory strategic advisory group, called the Midwifery Panel in 2015. This eventually replaced the statutory panel and continues to meet four times a year.

228. We have established relationships at a senior level with key employers and/or those who represent them, including NHS England, NHS Employers and the key social care associations. I meet the Chief Executive of NHS England together with the Chief Executive of the GMC and I also meet all four of the UK Chief Nursing Officers and Chief Midwifery Officers monthly.

229. We collaborate with employers on specific pieces of work, for example, before we welcomed nursing associates onto our register, we worked closely with a pilot group of employers to test how the new, regulated role would work in practice.

230. Our employer confirmation service allows employers to check the registration status of registered employees. Our employer newsletter goes out four times a year to around 15,000 subscribers.

Patient groups

231. In 2012/2013 we established a Patient and Public Engagement Forum. The forum met three to four times a year and was made up of more than a hundred patient groups,

patient advocates and health charities. This was a means of reaching patients and the public to raise awareness about our role and informed various aspects of our work including our revalidation model, and public involvement in the quality assurance of education. This group's last meeting was in December 2015 and it then evolved into the Patient and Public Advisory Group.

232. Our approach to public support and engagement changed in 2018. That year, we established a Public Support Steering Group (PSSG) to shape the development of our Public Support Service which launched that year. The PSSG brought together patient groups alongside members of the public with experience of our fitness to practise processes, other stakeholders and colleagues. The group worked to design and develop the new service, and later engaged with us on other policy issues.

233. When the PSSG concluded its term in 2021, a new Public Voice Forum (PVF) was established. This forum brings together members of the public with lived experience of health and social care. It meets four times a year and has a wider remit as a strategic advisory group to shape and inform our work.

234. Since 2021, we have invested in fostering more consistent and purposeful engagement with patient groups and organisations advocating for people who use health and care services. This involves ongoing interaction with relevant stakeholder groups on matters of shared interest. We also actively partner with the PVF and patient and public groups on policy and service development. This has included shaping changes to our legislation, a campaign aimed at building pregnant women's understanding of what to expect from their midwives and informing improvements to our fitness to practise processes and support for people.

Section six: Learning lessons

235. We established an internal working group at the end of 2022 to prepare for the end of LL's criminal trial and to consider what lessons we could learn. We have started to scrutinise each of our regulatory processes and actions and through that process have already identified four key areas of learning. We will continue to learn lessons, including those identified by the Inquiry, and will consider how to incorporate this learning into our future approach to make any necessary improvements.

Education

236. We have taken steps to seek assurances from UOC regarding their education provision at CoCH. This included in February 2017, seeking and receiving assurances

following the internal investigation at CoCH by RCPCH and the Royal College of Nursing. UOC's response also addressed the findings of a 2016 Care Quality Commission (CQC) report which identified low staffing in the children's unit.

237. In July 2018, after LL had been arrested as part of our education assurance mechanism, we reported UOC and specifically the CoCH as a critical concern as there were public safety concerns. We considered students may be exposed to poor care, and they may not have the necessary support and be under undue pressure due to lack of resources. We identified that there were four AEI practice placement partners for UOC; University of Chester, Glyndwr University, Liverpool John Moores University and Edge Hill University. These AEIs all informed us that they had no students placed at CoCH. UOC also provided a risk assessment and stated that students had been withdrawn from the neonatal unit.

238. In February 2023 we met with the Vice Chancellor and Dean of Health at UOC to discuss their records in relation to LL which they had shared with police. We were informed that UOC had not identified any obvious concerns from their review of LL's educational experience. LL completed her programme with a BSc (Hons (2:2)). She failed her final practice placement at the first attempt and the areas for improvement were underdeveloped leadership skills, low confidence and not seeking help when needed. Following detailed feedback and support she passed on the second attempt. There were no disciplinary or fitness to practise concerns regarding LL on file. Although occupational health records had not been retained there was nothing on LL's main student record to suggest any health concerns.

239. UOC was satisfied that appropriate governance mechanisms, including whistleblowing procedures were in place at the time. LL was well regarded and was invited back as a guest speaker for students in training during 2013/2014.

Registration and revalidation

240. We reviewed LL's registration and revalidation records. There were no concerns about LL's registration application in 2011, all the necessary declarations were made and the UOC declaration of good character was signed by the course tutor I&S

I&S I&S

I&S

241. There were no concerns with LL's registration renewal application in September 2014, all the necessary declarations were made (**Exhibit AS/31**). There were also no concerns with her revalidation application in September 2017. Her revalidation confirmer, Yvonne Farmer, was employed at CoCH at the time but was not her line manager. I&S I&S

242. We were made aware by CoCH on 29 November 2016 that LL had been moved from the neonatal unit for her own protection (Exhibit AS/33) and were advised on 18 May 2017 that LL was still working at CoCH. CoCH told us LL had been moved to a different area in a non-clinical role to enable her to work in a different area outside of the pressure of the clinical environment and to protect her from the stress of being under suspicion by the medical team (Exhibit AS/35). The police investigation began in May 2017, LL revalidated in September 2017 and police interviews with CoCH staff began in October 2017.

243. Revalidation is not about assessing fitness to practise; it is a means to promote good practice in line with our Code and standards and is based on a system of reflection and self-declaration supported by a confirmer.

244. We have carefully reviewed LL's revalidation process and are satisfied that she revalidated in line with our guidance. No system based on self-declaration is likely to detect allegations of misconduct or criminality and that is not the purpose of revalidation.

245. A review of our revalidation process is planned to start in 2025/26 as part of our regular reviews of policy and procedures and we will explore options for strengthening our approach to revalidation. We will explore whether there is any evidence that choosing a confirmer who is not a line manager results in a different risk profile for that individual. We will take into consideration during this review any relevant findings or recommendations from this Inquiry if they are available.

ELS

246. AK contacted the ELS advice line on 6 July 2016 regarding increased neonatal mortality, prior to having an introductory meeting with ELS. Our records indicate there was contact between ELS and AK from July 2016 onwards and there are many examples of us engaging CoCH for updates on the employer's investigation and, later, the police investigation. However, we have recognised that during that period our

record keeping could have been better and there are some gaps in communication (which may reflect either a lack of communication or poor record keeping). For example:

a. AK advised ELS on 6 July 2016 that CoCH was due to decide that day whether to refer LL to the police. ELS advised that we would need to be informed of CoCH's decision and any subsequent police action through the advice line. There is no record of that call taking place. We emailed CoCH on 15 September 2016 to confirm an introductory meeting with ELS on 29 November 2016 and the referral is discussed then.

b. AK advised ELS on 9 October 2017 that the police investigation had progressed to interviewing employees as witnesses. There is no record of ELS engagement with the CoCH after that until 3 July 2018.

247. ELS advised AK on several occasions in 2016 and 2017 to continue with local actions and not to make a referral to us. Given the information provided to ELS by AK, that advice was in line with our approach.

248. On one occasion (18 May 2017), on the evidence of the call notes, ELS advice may have given the impression that a referral would only be required in the event of 'findings [of] deliberate endangerment', which is too high a bar. This is unlikely to have posed any material risk to safety because, at that point, the police investigation had just started and a fitness to practise investigation would have been highly unlikely to be able to proceed concurrently.

249. The appropriateness of ELS advice is dependent on the quality of information on which it is based. In this case, the primary source of information was AK. With hindsight, our ELS advisers could have provided greater critical scrutiny than is recorded in the notes and we could have done more to support AK and CoCH to raise the concerns with the police sooner. We now have a more robust process in place for the quality review of advice line calls through benchmarking and peer review and calls like the AK one to ELS are discussed at these meetings. We are also continuing to reflect on our approach to clinical and safeguarding advice being sought at appropriate times during our regulatory processes.

250. As soon as NMC was notified LL had been arrested on 3 July 2018, ELS correctly advised that an immediate referral was required to be made within 48 hours. The referral was received on 5 July 2018.

Fitness to practise

251. We have reviewed all of our case information and reflected on our approach to managing LL's fitness to practise investigation. The case file shows there was an early misunderstanding about LL's bail conditions. After LL's arrest, AK informed us 6 July 2018 that LL's bail conditions prevented her from working in any healthcare setting and the police advised the same.

252. We requested the bail conditions from the police on 19 July 2018. On 20 July 2018 we were informed LL's bail conditions were not to work in any healthcare setting or to have unsupervised contact with anyone under the age of 16. On 24 May 2019 we spoke to the police and were informed over the phone that the bail conditions were (1) Not to engage in healthcare services; (2) Not to work with vulnerable people; and (3) Not to have unsupervised contact with anyone under the age of 18. We conducted our second interim order risk assessment after receiving that information. Following further correspondence with the police, we wrote to request full disclosure of LL's bail conditions on 25 June 2019[44]. On 8 July 2019 we received a copy of LL's full bail conditions (subject to some redactions of sensitive information).

253. In hindsight, we should have formally requested the bail sheet sooner, rather than relying on more general information provided by the police and AK and we have identified that this is an area where we need to provide further training and guidance to colleagues. However, whilst the bail conditions were a factor in our decision not to apply for an IO before charges were made against LL, they were not the key issue. Our decision not to apply for an IO before charges were made against LL was principally because we considered we had insufficient evidence to do so.

254. Our guidance on interim orders aligned with our understanding of relevant case law at the time the guidance was introduced. Paragraphs 121 to 141 above explain the relevant changes to our interim order guidance since 2017. At the time of LL being referred to us, our guidance did not include express reference to an evidential threshold in respect of interim orders, although the practice of decision makers was influenced by our interpretation of case law at the time that prima facie evidence was required for an interim order application. On 2 October 2019, updated guidance was published expressly stating that there was a need for 'prima facie' evidence. This was in line with wording from previous NMC guidance that had been endorsed by the Court of Appeal in 2013 in *Perry v NMC*. It was reintroduced into the guidance following a successful challenge against a number of interim orders in the High Court in Northern Ireland, as detailed in paragraph 135. Our reasons for not applying for an interim order prior to LL

[44] Under Article 45 of the Order

being charged with criminal offences are detailed at paragraphs 183 xiii, xxviii, xxxv, xliii, xliv and 185 to 188 above. At the point of charge, we were confident that we could rely on the charges as sufficient evidence to apply for an interim order, whereas the fact of arrest had not been sufficient. However, we are currently considering whether we need to make further amendments to clarify the approach that decision-makers should take to evidence at the interim stage. If we make changes, we expect to do that by Spring 2024 and we would be happy to provide the Inquiry with a supplementary witness statement outlining any changes we make together with the rationale for those changes.

255. We are also reflecting on the structure of our decision making for interim order risk assessments and whether our current arrangements are appropriate. We have made some changes and our current approach, in complex or sensitive cases, would be to have a case conference bringing together expertise from across the organisation, including, where applicable, lawyers, clinical advisors and our safeguarding lead. We also have greater appetite to seek external, independent legal advice in complex or sensitive matters. However, we are considering how we can further strengthen our approach.

Governance, management and accountability of senior management and professional regulation

256. Recent inquiries and reviews into major failings in care have highlighted the often-devastating impact that poor leadership and governance and management structures can have on patient safety and care. As the regulator for nursing and midwifery professionals as individuals, we are limited in our ability to comment on the effectiveness of hospital governance and management structures in keeping babies safe and ensuring the quality of care.

257. We believe all NMC-registered professionals, regardless of their role or level of seniority, have a leadership role to play and a requirement to speak up according to our duty of candour guidance **(Exhibit AS/92**) We make this explicit in our Code where we state, 'throughout their career, all our registrants will have opportunities to demonstrate leadership qualities, regardless of whether or not they occupy formal leadership positions'. INQ0002568

258. Leadership involves skilled communication and our standards and Code reflect the need for our registrants to prioritise people, to treat them as individuals and uphold their dignity while listening and responding to their preferences and concerns. We expect our

professionals to treat people with kindness, respect and compassion; both the people they care for as well as their interdisciplinary and multiagency teams and colleagues in all settings.

259. We define what knowledge, skills and attributes all our professions must be able to demonstrate before joining our register through our standards of proficiency for registered nurses (Future Nurse) and our standards of proficiency for midwives (Future Midwife). These are new standards which were published in 2018 and 2019 respectively. These standards have been implemented into the nursing and midwifery pre-registration education programmes and work is ongoing to support their implementation into practice. Following wide consultation with the sector, professionals and the public, we included specific sections in these documents on leadership and we decoupled leadership from management.

260. In the standards of proficiency for registered nurses, platform one focuses on 'being an accountable professional'. In the standards of proficiency for registered midwives, domain one focuses on 'being an accountable, autonomous professional midwife'. Leadership is also a theme in our new post-registration standards for community and public health nursing.

261. We launched a new leadership campaign 'Good leadership means better care' on 5 December 2023 to support nursing and midwifery leaders and their teams to deliver the safe high-quality care that people using services have the right to expect. In this campaign we share stories and best practice resources around the importance of good leadership in helping teams to provide the best, safe care for people and communities.

262. We also share insights from our data through our new Spotlight on Nursing and Midwifery publication to help influence and effect change within health and social care. This was published in August 2023 and included the insights from the detailed analysis we conducted on maternity safety. We found common themes around midwives not always speaking up and poor communication with teams and people. We highlighted the need for managers and leaders to do more to foster cultures in which every midwife feels confident to speak up and we encouraged our stakeholders to reflect on the findings from that report.

263. Our professions, like other health and care professionals, have a responsibility to be candid, to be honest when mistakes happen and to speak up when things go wrong and we issue guidance on duty of candour **(Exhibit AS/92)**. We issue guidance on raising concerns (**Exhibit AS/91**) which recognises the important role that clinical INQ0002568 INQ0002567

leaders play in promoting an open culture in which staff are accountable and encouraged to raise concerns to ensure the public are protected.

264. Any proposed changes to the current structure of professional regulation will need to be carefully considered to ensure that they are properly scoped to address an identified risk and do not duplicate existing regulatory controls. Any changes to the structure would also need to work across England, Wales, Scotland, and Northern Ireland.

Regulatory reforms

265. We are working with Government on planned reform to our legislation. This will bring significant changes to the way in which we progress fitness to practise concerns which will benefit patient safety.

266. After this reform, we will be able to act faster to remove professionals convicted of certain very serious criminal offences. Where a professional is convicted of offences specified in the legislation, I as Registrar, will be able to remove them from the register instead of having to proceed through the current fitness to practise process as is the case now. The specified offences include convictions for murder, rape, sexual offences involving children, human trafficking and exploitation as well as convictions for blackmail, extortion and sexual assault when a custodial sentence (whether immediate or suspended) is imposed. The professional has a right to appeal the decision to the High Court or Court of Session in Scotland. This process, known as "automatic removal" mirrors the powers given to Social Work England under their 2018 regulations.

267. In the future this would mean that if a case like LL were ever to occur again, we would be able to remove the professional from the register much quicker which brings clear public protection benefits.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 2 February 2024