Witness Name: Professor Jonathan Benger
Statement No. 1
Exhibits: 32
Dated: 26 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF PROFESSOR JONATHAN BENGER CBE

I, Professor Jonathan Benger CBE, will say as follows: -

1. I make this witness statement further to receipt of the Rule 9 letter from the Thirlwall Inquiry addressed to the Chief Executive of the National Institute for Health and Care Excellence ["NICE"] dated 20 November 2023. I have prepared this witness statement to assist the Thirlwall Inquiry in its understanding of NICE and its work in relation to hospital based maternity services, with particular reference to the care and safety of neonates. As requested, this statement will focus on the period between 4 January 2012 and 19 October 2023 ["the relevant period"].

2. On behalf of everybody at NICE, I would like to start by expressing my heartfelt condolences to all those affected by the dreadful events at the Countess of Chester Hospital ["COCH"]. NICE as an organisation very much welcomes the work of the Thirlwall Inquiry and will work with the Inquiry in an open and transparent manner.

3. I am currently the Chief Medical Officer ["CMO"] and Interim Director of the Centre for Guidelines ["CfG"] at NICE. I joined NICE on 1 January 2023 as CMO and became Interim Director of CfG in March 2023 and I report directly to the Chief Executive. I am a member of the Executive Team ["ET"] and the Guidance Executive ["GE"] and I sit on the Board as an Executive Director. I am also NICE's Caldicott Guardian. The Caldicott Guardian is responsible for protecting the confidentiality of people's health and care information and making sure it is used properly.

4. As the CMO, I lead the Clinical Directorate that was established in April 2023. Its role is to provide end-to-end clinical oversight and support to all areas of NICE's work. A key aspect of the directorate's work is topic prioritisation. From April 2024, I will chair the NICE Prioritisation Board that will lead on the NICE topic prioritisation process, driven by

systematic intelligence gathering. The Directorate is also responsible for NICE's patient safety function and provides management support for NICE's Patient Safety Oversight Group ["PSOG"], of which I am a member, and which is chaired by Dr Peter Barry, a Consultant Clinical Adviser for CfG. Further detail about the PSOG is provided later in this statement.

5. The CfG is responsible for developing guidelines on the promotion of good health, the prevention of ill health, the appropriate treatment and care for people with specific diseases and conditions, and social care and service delivery. The Directorate also develops quality standards and indicators for health, public health and social care.

Personal background and experience

6. In addition to my role as the CMO for NICE, I am also a Professor of Emergency Care at the University of the West of England (since April 2008) and Consultant in Emergency Medicine at University Hospitals Bristol NHS Foundation Trust (since December 2003).

7. Prior to joining NICE in January 2023, I held the following positions:

    - NHS England's ["NHSE"] Interim Chief Clinical Information Officer between June 2022 and December 2022.
    - Chief Medical Officer at NHS Digital between November 2019 and May 2022.
    - NHSE's National Clinical Director for Urgent and Emergency Care between May 2013 and July 2019.
    - Prior to May 2013, I was the Medical Director, Air Operations and Critical Care for Great Western Ambulance Service NHS Trust.

8. I qualified as a Doctor in 1990 and became a Doctor of Medicine in 2002. I also hold a Diploma in Immediate Medical Care (Royal College of Surgeons of Edinburgh) (2002), Diploma in Child Health (Royal College of Physicians) (1997) and Diploma in Anaesthetics (Royal College of Anaesthetists) (1996). My medical practice has primarily focused on emergency medicine.

9. I am an internationally recognised expert in emergency airway management, cardiac arrest and resuscitation in pre-hospital and in-hospital settings. I have participated in expert reviews of practice, including the Fourth National Audit Project of the Royal College of Anaesthetists and Difficult Airway Society, reviewing over 100 in-hospital events leading to death and serious harm, and co-authoring an extensive report and several supporting

papers arising from this. I have also participated in internal and external case reviews and acted as an expert witness, advising the English Coroner's Court on positional asphyxia, cardiac arrest and resuscitation in several high profile and complex cases, particularly in relation to death in custody and mental health units.

10. I hold full registration with the General Medical Council. I am also a fellow of the Royal College of Emergency Medicine and a fellow of the Royal College of Surgeons of England.

NICE role, function and legislative basis

11. NICE, originally known as the National Institute for Clinical Excellence, was set up by the Government in 1999 as a Special Health Authority. It was then re-established as a non-departmental public body under the Health and Social Care Act 2012 ["HSC Act 2012"] and is now known as the National Institute for Health and Care Excellence, to reflect a role that encompasses health care, social care and public health.

12. NICE is an arm's length body of the Department of Health and Social Care ["DHSC"]. Arm's-length bodies are a specific category of central government public bodies that are administratively classified by the Cabinet Office. NICE was established to help ensure that people have equal access to clinically and cost-effective treatments, wherever they live. NICE helps practitioners and commissioners get the best care to patients, fast, while ensuring value for the taxpayer. NICE does this by:

    - Producing useful and usable guidance for health and care practitioners.
    - Providing rigorous, independent assessment of complex evidence for new health technologies.
    - Developing recommendations that focus on what matters most and drive innovation into the hands of health and care practitioners.
    - Encouraging the uptake of best practice to improve outcomes for everyone.

13. A Framework Agreement exists between NICE and DHSC which sets out the parameters in which NICE operates and discharges its responsibilities, including the relationship between NICE and DHSC. A copy of the agreement is exhibited as **Exhibit JB-01** INQ0010538 As can be seen in the agreement, NICE's role is to provide guidance and support to providers and commissioners, to help them improve outcomes for people using the NHS, public health and social care services. NICE supports the health and care system by describing what good quality care looks like in the NHS, public health and social care

sectors and helps promote the integration of health and social care. NICE does this by producing robust evidence-based guidance and advice, developing quality standards and providing information services for commissioners, practitioners and managers across the spectrum of health and social care.

14. NICE's statutory role and responsibilities are set out within the HSC Act 2012 and its supporting regulations (The National Institute of Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013). In its present incarnation, NICE was established by section 232 of the HSC Act 2012 and its functions are set out in Part 8 and Schedule 16 of the HSC Act 2012. In exercising its functions, in accordance with section 233(1), NICE must have regard to:

> *(1)a) The broad balance between the benefits and costs of the provision of health services or of social care in England,*
>
> a. *The degree of need of persons for health services or social care in England, and*
>
> b. *The desirability of promoting innovation in the provision of health services or of social care in England.*
>
> *(2) Nice must exercise its functions effectively, efficiently and economically.*

15. The Secretary of State for Health and Social Care is accountable to Parliament for the health system, including NICE, with support from the DHSC. The DHSC Permanent Secretary is the Principal Accounting Officer and is accountable to Parliament for the issue of any Parliamentary funding to NICE and for matters such as monitoring NICE's activities.

16. Although NICE is established as an English public body, it has agreements in place with the devolved administrations in Wales, Northern Ireland and Scotland, to enable these nations to utilise aspects of NICE guidance.

NICE core principles

17. A set of Core Principles underpin NICE's work. There is a structured approach to guidance development based on clearly defined processes and methods, which are published on

the website, regularly reviewed and consulted upon in line with the requirements in the HSC Act 2012.

18. These Core Principles, are as follows:
    1) Prepare guidance and standards on topics that reflect national priorities for health and care, as identified by the DHSC and NHSE;
    2) Describe our approach in process and methods manuals and review these regularly;
    3) Use independent advisory committees to develop recommendations;
    4) Take into account the advice and experience of people using services and their carers or advocates, health and social care professionals, commissioners, providers and the public;
    5) Offer people interested in a topic the opportunity to comment on and influence recommendations;
    6) Use evidence that is relevant, reliable and robust;
    7) Base our recommendations on an assessment of population benefits and value for money;
    8) Support innovation in the provision and organisation of health and social care services;
    9) Aim to reduce health inequalities;
    10) Consider whether it is appropriate to make different recommendations for different groups of people;
    11) Propose new research questions and data collection to resolve uncertainties in the evidence;
    12) Publish and disseminate our recommendations and provide support to encourage their adoption; and
    13) Assess the need to update our recommendations in line with new evidence.

19. Guidance development is informed by the experience, expertise and views of the people who will be affected. This includes patients, carers and members of the public, as well as professionals, representatives of NHS organisations, the life sciences industry and local government.

20. Guidance is developed by independent advisory committees that include experts such as clinicians, health economists, patients and carers. Consultation processes enable individuals and organisations to comment on draft recommendations.

21. NICE guidance aims to support strategies that improve population health as a whole, while offering particular benefit to the most disadvantaged. In addition to the protected characteristics in the Equality Act 2010, NICE also takes into account inequalities away from socioeconomic factors and the circumstances of certain groups of people, such as looked-after children and people who are homeless. NICE guidance aims to reduce and not increase identified health inequalities.

NICE governance and management

22. NICE is led by a unitary board comprising of a Non-Executive Chairman and Non-Executive Directors ["NED's"] appointed by the Secretary of State for Health and Social Care, and Executive Directors appointed by the NED's. A high-level overview of NICE's governance structure as of October 2023 is exhibited as **Exhibit JB-02** INQ0010539 The Board, accountable to the DHSC, ensures that the ET is held to account for the performance of the organisation and that NICE meets the highest possible standards in its conduct. The Board exercises its duties via its formal board meetings (which are usually held in public), the two board committees and informal non-decision-making Board seminars.

23. The DHSC Permanent Secretary has appointed a Senior Departmental Sponsor ["SDS"] who acts as NICE's designated, consistent point of contact within DHSC and a link between NICE and departmental senior officials and Ministers. The SDS is supported by a DHSC Sponsor Team, which carries out the principal day-to-day liaison between DHSC and NICE. The DHSC Sponsor Team is the primary contact for NICE and they support the SDS in advising the responsible minister on the discharge of his or her responsibilities in respect of NICE. The current responsible minister is The Rt Hon Andrew Stephenson CBE MP.

24. NICE's Senior Leadership Organogram is exhibited as **Exhibit JB-03** INQ0010540 It details the Senior Leadership Team and the direct reports to ET members, as at October 2023. It also details Chief Executives and key directors of CfG and the Centre for Health Technology Evaluation ["CHTE"] within NICE since 2015.

25. Dr Sam Roberts is the Chief Executive of NICE. Dr Roberts commenced this role on 1 February 2022 following the retirement of the previous Chief Executive, Professor Gillian Leng CBE. Prior to becoming Chief Executive, Professor Leng was NICE's deputy Chief Executive and Director of the Health and Social Care ["HSC"] Directorate (now known as the Implementation and Partnerships Directorate ["IPD"]). Professor Leng joined NICE in 2001 and was appointed as Chief Executive on 1 April 2020, following the retirement of Sir Andrew Dillon CBE on 31 March 2020. Sir Andrew had been Chief Executive since NICE's formation in 1999.

26. As well as chairing the ET, formerly called the Senior Management Team ["SMT"], Dr Roberts also chairs the GE, which meets weekly and comprises a number of members of the ET and other senior managers. Its main role is to approve, on behalf of the Board, NICE guidance that has been developed by the independent advisory committees, plus other key products. The GE ensures that the published development processes and methods have been followed; the recommendations or key statements address the remit of the product and are comprehensible and internally consistent; and the product is presented in the correct format. They also seek to ensure that any matters that may compromise the implementation or impact of the product are addressed.

27. NICE is organised into a number of centres and directorates. An overview of NICE's centres and directorates as at October 2023 can be found at **Exhibit JB-04** INQ0010541 The Clinical Directorate and CfG are the directorates that are primarily relevant to the Scope of the Thirlwall Inquiry. The Clinical Directorate is responsible for NICE's patient safety function. The responsibility for NICE's patient safety function prior to the establishment of the Clinical Directorate in 2023 is explained in paragraphs 32 – 37 below. The CfG produces guidelines and quality standards relevant to hospital based maternity services and supports the publication of the British National Formulary ["BNF"] on the NICE website.

28. NICE guidelines are evidence-based recommendations for health and care in England. They set out the care and services suitable for most people with a specific condition or need, as well as people in particular circumstances or settings. The guidelines help health and social care professionals to:
    - prevent ill health.
    - promote and protect good health.
    - improve the quality of care and services.
    - adapt and provide health and social care services.

29. Healthcare guideline topics are commissioned by NHSE, with updates prepared by NICE based on surveillance activity identifying matters such as new evidence or national strategies.

30. NICE quality standards set out priority areas for quality improvement in health, public health and social care. They highlight areas with identified variations in current practice. Each quality standard includes a set of statements to help improve quality and information on how to measure progress. They can be used:
    - For quality improvement (for example to identify areas for improvement and when writing improvement and action plans).
    - For quality assurance and monitoring (for example when developing frameworks for quality assurance and identifying gaps in services, benchmarking and monitoring changes).
    - To influence commissioning (for example identifying support or changes needed to improve services).

    The quality standards can be used by anyone (such as commissioners, service providers and practitioners), looking to improve the quality of health, public health and social care.

31. In addition, the CHTE, whose role it is to develop health technology evaluations, has produced outputs that relate to the treatment of neonates in a hospital setting, as identified in paragraph 98 and **Table 4** below. These evaluations are designed to provide recommendations, in the form of NICE guidance and advice, on the clinical and cost effectiveness of new and existing medicines, health technologies and treatments in the NHS. In the case of Interventional Procedures, recommendations are provided on the safety and efficacy of procedures.

NICE Patient Safety Oversight Group

32. NICE has a statutory duty to produce guidance that covers the three dimensions of quality described in the HSC Act 2012: effectiveness, patient experience and safety. As such, NICE's responsibilities for patient safety were and are included within its delivery of advice and guidance regarding good quality health and social care interventions, as part of a system responsible for delivering such services.

33. On 14 May 2019, the SMT approved the creation and assignment of a Senior Responsible Officer ["SRO"] for patient safety. This was informed by an information gathering exercise that explored NICE's role and response to patient safety systems in England. Although the exercise found that patient safety was an integral part of NICE's delivery of advice and guidance and there were already well established and effective mechanisms for dealing with and responding to patient safety enquiries, there was no single or centralised process. Patient safety responsibilities were dispersed across the organisation, including within the CfG and CHTE directorates. It also noted a rapidly evolving system safety landscape, with the creation of new national bodies / NHS committees with responsibility for safety and who expect or require responses from NICE (for example, the Healthcare Safety Investigation Branch ["HSIB"] which was created in 2018). It also noted a subjective impression that patient safety enquiries to NICE had progressively increased in volume over the past few years. For example, the increase in Regulation 28 letters from HM Coroners received by NICE and engagement in HSIB investigations. The SMT paper detailing the exercise findings and recommendations is exhibited at **Exhibit JB-05** **INQ0010542**

34. In September 2019, Professor Kevin Harris (Director of NICE Interventional Procedures Programme) was appointed as the SRO for patient safety, with Dr Hannah Patrick (Consultant Clinical Advisor in the Managed Access Team) as deputy SRO for patient safety. The purpose of the new role was to strengthen the leadership structure for patient safety issues across NICE, with more explicit management of patient safety implications across teams internally and co-ordinated partnerships with external organisations with key patient safety roles. The SRO decided that the optimal approach in the short term was to support the existing processes and strengthen their governance by providing oversight, rather than implement a new central patient safety monitoring and response system.

35. In practice, the SRO role involved:
    - Identifying and developing oversight of patient safety enquiries to NICE from external bodies, including those from HM Coroner [Regulation 28 letters], the HSIB, DHSC and the Medicines and Healthcare products Regulatory Agency ["MHRA"].
    - Working collaboratively with colleagues across the Centres and Directorates at NICE who held the primary responsibility for the issues being raised, to support them in responding to external agencies.
    - Becoming a permanent member of NICE's GE to allow oversight of potential patient safety issues relating to guidance prior to publication.

- Representing NICE on a number of key national system committees, which have oversight of safety, such as the NHSE National Quality Board and the National Patient Safety Committee, established in 2021.

36. On 18 November 2020, the NICE Board supported the establishment of a Patient Safety Task and Finish Group with cross-directorate membership to ensure that the group was inclusive of each directorate's interests and could facilitate a pan-organisational approach and oversight to patient safety. In addition, the group was tasked with conducting a review of patient safety activity at NICE and recommending a sustainable model for managing patient safety issues in a structured and systematic way, as well as the potential resources required to support such changes.

37. The outcome of this review was that in September 2021 the NICE Board supported the introduction of a cross-Institute patient safety function led by the SRO for patient safety. This included the formal establishment of PSOG. In February 2023, Dr Peter Barry replaced Professor Kevin Harris as the SRO. The SRO reports to the CMO and ET; and on an annual basis report to the Board. The Patient Safety Annual Reports to the Board for 2021 and 2023 are exhibited as **Exhibit JB-06** INQ0010543 **and Exhibit JB-07** INQ0010544 respectively. There was no formal report to the Board in 2022 as it was replaced by a NICE Patient Safety Strategy, which is exhibited as **Exhibit JB-08** INQ0010545. The 2023 Annual Report discussed the role of HSIB and refers to a number of reviews of maternity services and national recommendations underpinned by NICE guidance.

38. The ultimate responsibility for patient safety matters affecting NICE remains with the Chief Executive. When necessary, the SRO will also escalate issues to the CMO, relevant Programme Directors, ET, or directly to the Chief Executive. **Figure 1** below outlines NICE's Patient Safety governance structure.

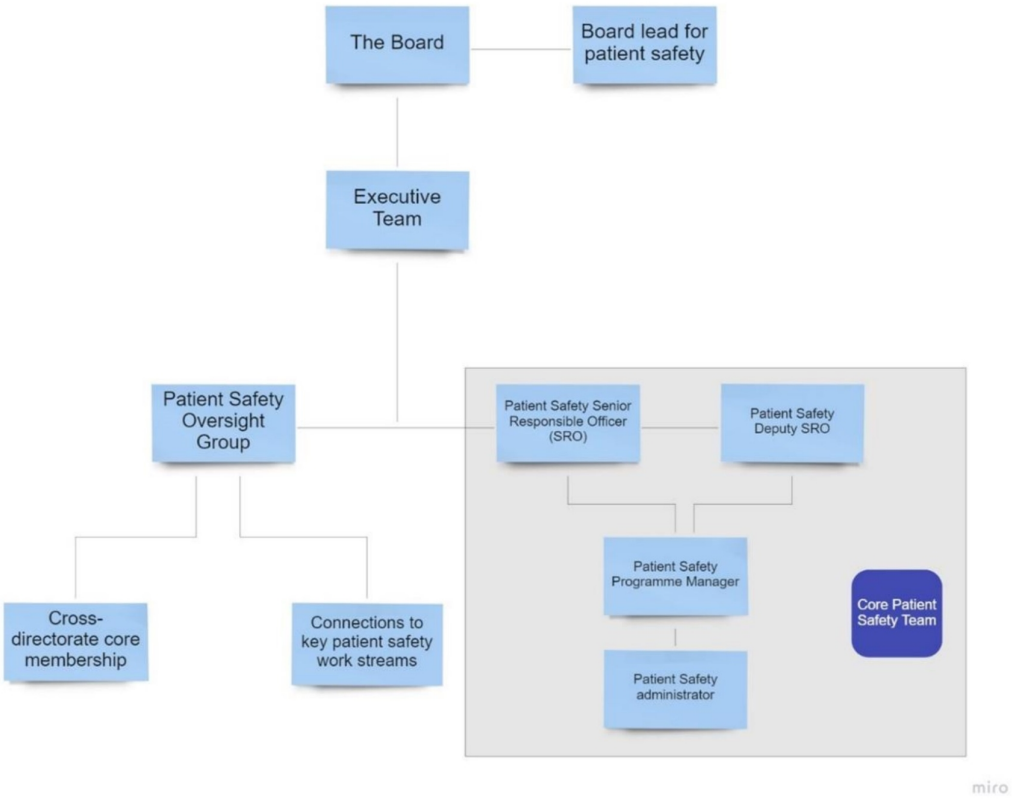

Figure 1: NICE patient safety organogram September 2021

39. The SRO chairs the PSOG, whose membership includes representation from key directorates across NICE including the CfG, CHTE, IPD, Science, Evidence and Analytics directorate and Communications directorate. The terms of reference of the PSOG are produced as **Exhibit JB-09** INQ0010546

40. The role of the PSOG is to provide oversight of and, where required, coordination to patient safety related matters within NICE. This oversight enables the group to identify existing work streams within NICE which relate to patient safety, identify connection points with key external stakeholders and, where possible, promote synergies across work streams both internally and with key external partners.

41. The group provides strategic leadership to NICE's patient safety approach to ensure procedures are explicit across the organisation. It works with internal communications to raise awareness of the PSOG and its work and to highlight the importance of patient safety to all programmes at NICE. The work of the oversight group includes, but is not limited to:

- Supporting the development of NICE guidance to ensure that safety considerations are appropriately considered and integrated across the work of the Institute.
- Providing specialist advice on safety matters to inform the response to arising safety issues and liaising with relevant internal teams to consider the implications of these for published NICE guidance or guidance in development.
- Ensuring that NICE is part of a learning healthcare system by considering how new developments such as real-world evidence, data access and artificial intelligence should be utilised to enhance patient safety through NICE guidance and related activities.
- Responding to formal safety recommendations from the Health Services Safety Investigation Body ["HSSIB"], HM Coroner and other relevant bodies such as the MHRA and others including formal inquiries such as the Independent Medicines and Medical Devices Safety Review ["IMMDS"] led by Baroness Cumberlege.
- Internal signposting of actions required as set out in NICE's response to Regulation 28 "Prevention of Future Death" reports from HM Coroners to relevant teams, such as the CfG or implementation support teams to follow up, and periodically reviewing progress against these by internal teams. (Prior to the inception of PSOG, this process was coordinated by the Associate Director – Corporate Office, in conjunction with the enquiry handling team).

In relation to responding to formal safety recommendations from HM Coroner, NICE's 'Regulation 28 reports safety team standard operating procedure' ["SOP"] is exhibited as Exhibit **JB-10** INQ0010547 NICE's engagement in Regulation 28 reports is set out in a Regulation 28 Action Log, exhibited as **Exhibit JB-11** INQ0010558 From this Action Log, NICE has highlighted NICE reference EH313700, on the closed tab, row 43 (highlighted in yellow), as potentially relevant to the Inquiry. Further details of work with the HSSIB and its predecessor, can be found below.

42. NICE's patient safety model aims to support a system that (i) prevents errors, (ii) learns from the errors that do occur and (iii) builds a culture of safety through collaboration between healthcare professionals, organisations and patients. The activities delivered by PSOG are detailed in **Figure 2** below.

Figure 2: Key activities of PSOG, September 2021

Status of NICE guidance

43. Different types of NICE guidance have a different status within the NHS, public health and social care services. Integrated care boards, NHSE and local authorities are required to fund and resource technologies (predominantly medicines and treatments) recommended through the Technology Appraisal ["TA"] and Highly Specialised Technologies ["HST"] programmes within the NHS.

44. The legal status of this mandatory funding is set out in the NHS Constitution and the HSC Act 2012. The NHS Constitution states that patients have the right to medicines and treatments that have been recommended by NICE for use in the NHS, if the Doctor responsible for the patient's care says they are clinically appropriate. When NICE recommends a treatment 'as an option' through the TA or HST guidance, the NHS must make sure it is available within 3 months (unless otherwise specified) of the guidance publication.

45. The HSC Act 2012 also states that the Secretary of State and the NHS Commissioning Board (now NHSE) should have regard to the quality standards prepared by NICE as part of their duty to secure continuous improvement in the quality of services.

46. The introduction of other selected technologies (devices, diagnostics and digital), which NICE recommends through its Medical Technologies Evaluation Programme, can also be accompanied by an NHS funding mandate (the Medtech Funding Mandate), but this is agreed by NHSE and not mandated in legislation.

47. In relation to all other NICE guidance, including the guidelines and quality standards produced by CfG, it is expected that health and social care professionals will have regard to the recommendations to help them deliver the highest quality care. The recommendations are intended to support the professional expertise and clinical judgement of health professionals, as they discuss treatment options with their patients.

Engagement with health care system partners

48. NICE works closely with a range of key health care system partners and in some instances, had formal agreements in place. A summary of key health care system partners is set out in **Table 1** below.

Organisation	Nature of Relationship
NHS England	NHSE are legally required to fund and resource medicines and treatments recommended through NICE's TA and HST programmes. NHSE is also required to have regard to quality standards produced by NICE. While the majority of NICE's funding comes from the DHSC, NHSE also commission work from NICE including: • Guidelines. • Support for Managed Access Agreements to enable patients to access promising new drugs via the Cancer Drugs Fund and Innovative Medicines Fund. • Medtech Innovation Briefings-to provide briefings to the NHS on promising new technologies and work with stakeholders to identify new topic areas. (this work has now ceased) • Providing technical support to the Accelerated Access Collaborative; and • HealthTech Scan- to support innovative activities in identifying and tracking emerging medical technologies via a secure shared database. This is in the process of being decommissioned.

Medicines and Healthcare products Regulatory Agency (MHRA)	NICE is responsible for considering whether technologies approved by the MHRA should be recommended for use in health and care services based on their clinical and cost effectiveness. NICE and MHRA therefore have related interests in the safe and appropriate use of medicines and medical devices. They work together to ensure information about safety and effectiveness is shared, as appropriate to facilitate decision making. They also work closely to support innovation including through initiatives such as the Innovative Licensing and Access Pathway and Innovative Devices Access Pathway.
Office for Health Improvement & Disparities (OHID) and UK Health Security Agency (UKHSA) (formerly Public Health England)	NICE provides public health guidance and advice to support health, public health and social care commissioners, providers and others to make sure that the care and preventative services provided are of the best possible quality and offers the best value for money. The public health guidance makes recommendations for populations and individuals on activities and strategies that can help prevent disease or improve health.
Care Quality Commission (CQC)	The CQC will use NICE's guidance and quality standards as a reference when inspecting health and care providers.
NHS Digital (formerly HSCIC) – now part of NHSE	NICE and NHS Digital worked together to share data to improve quality of care across health and social care, including increasing availability of real-world data in development of guidance. NICE worked with NHS Digital to develop, publish and maintain a database of quality assured indicators – the national library of quality indicators. In addition, as outlined in the Health and Social Care Act 2012, as a principal body, NICE could request NHS Digital to establish and operate a system for the collection or analysis of information of a description specified in the request.
Health Education England (HEE) – now part of NHSE	NICE and HEE worked together to help assist the spread of innovation across the NHS so that the health care workforce has the right skills, behaviours and training to support the delivery of high-quality services. NICE is commissioned to procure content (journals and databases) on behalf of all NHS professionals.

Table 1 – Key health care system partners

Care Quality Commission ["CQC"]

49. NICE provides support to the CQC to fulfil its role in the regulation of health and social care services. NICE guidance, quality standards and associated measures inform the CQC's methodology and assessment of providers, i.e., CQC inspection frameworks. A

Memorandum of Understanding was agreed between NICE and CQC in October 2014, as can be seen in **Exhibit JB-12** INQ0010569 It was updated in September 2018, as exhibited at **Exhibit JB-13** INQ0010580 and again in April 2021, as exhibited at **Exhibit JB-14** INQ0010591, to reflect changing joint priorities.

50. Since 2014, the responsibility for the relationship between NICE and CQC sat with the NICE Director of the IPD, formerly called the HSC Directorate (which can be seen in the NICE senior leadership organogram, exhibit **JB-03** INQ0010540. The day-to-day responsibility for the relationship with the CQC was normally delegated to an HSC / IPD Programme Director. In October 2015, a regular strategic meeting commenced between NICE and CQC to review plans and address any themes or issues arising from each organisation. This meeting was initially biannual and changed to bi-monthly in 2021. Between 2015 and 2019, Professor Gillian Leng, the then Director of HSC, chaired the meeting. In 2020, Dr Judith Richardson (Acting Director of HSC) took over as Chair and from 2023, Clare Morgan (Director of IPD) was chair. On occasions, CQC chaired some of the meetings.

51. The name of these strategic meetings has changed since inception, from NICE/CQC Oversight Group to NICE/CQC Strategic meeting. However, their focus has been on providing updates on each organisations' work plan, considering how the CQC can continue to use NICE's guidance and quality standards as a reference when inspecting health and care providers and how NICE can support the CQC to do so, with engagement on the basis of themes and issues and rather than specific organisations. The meetings also included a patient safety focus, which was historically focused on the NICE interventional procedures, with the lead for this programme attending meetings. In September 2019, a formal link was made with NICE's overall patient safety work, by the attendance of the NICE patient safety SRO.

52. On 28 July 2022 the strategic meeting discussed maternity safety and in particular the Ockenden Report. It was noted that within the national recommendations sections of the Ockenden report, there is specific reference to NICE guidance, as the underpinning of the Ockenden recommendations and therefore these could be useful to the CQC, to cross reference with the new CQC maternity inspection framework. The minutes of this meeting are exhibited at **Exhibit JB-15** **INQ0010592**

53. In addition to the regular strategic engagement meetings, NICE is currently in the process of establishing a new regular line of communication with a dedicated lead for safety in the CQC. Specifically in relation to safety within a maternity setting, the team recently held an

introductory meeting to outline NICE's PSOG's role and explore opportunities for collaboration with the Associate Director of the new Maternity and Newborn Safety Investigations team, hosted by the CQC. The teams have agreed to meet on a quarterly basis from 2024.

Medicines and Healthcare products Regulatory Agency

54. In addition to the above, NICE works with the MHRA to ensure all NICE guidance is informed by MHRA safety warnings. The MHRA produces a monthly drug safety update ["DSU"] newsletter. This advises healthcare professionals about new safety advice for licensed medicines. This may include new safety warnings, including about the balance of risks and benefits, product withdrawals and other important changes to the marketing authorisation.

55. Since October 2017, NICE reviews DSU content monthly to assess if new MHRA advice may impact on existing NICE guidance. This is documented in a log, including the action taken. If the MHRA advice may have an impact on existing NICE guidance, NICE completes a quality assurance process 'MHRA safety alerts requiring action'. Following the quality assurance process, relevant NICE guidance is updated in response to the DSU if required. No updates to NICE guidance have been required in response to any DSU advice relating to Insulin.

Health Service Safety Investigations Body

56. HSSIB is a fully independent arm's length body of the DHSC, which came into operation in October 2023. HSSIB investigates patient safety concerns across the NHS in England and in independent healthcare settings where safety learning could also help to improve NHS care. Members of the PSOG team (specifically the SRO, Deputy SRO and Patient Safety Programme Manager) routinely engage with the HSSIB on their national investigations programme. Prior to October 2023, the PSOG's engagement was with HSSIB's predecessor, the HSIB, which followed a similar model of engagement. The NICE safety team meets quarterly with the Chief Investigator of HSSIB to discuss strategic-level safety issues in the system and points of collaboration between the two organisations. Prior to inception of the PSOG in 2021, the relationship between NICE and HSIB was managed by the SRO for patient safety, Professor Kevin Harris, following his appointment in September 2019 and prior to that by NICE's Director of the CfG, Dr Paul Chrisp.

57. NICE routinely engages with HSSIB where they identify relevant NICE guidance within the scope of a topic under their national investigation programme. NICE's SOP for responding to HSSIB investigations is exhibited as **Exhibit JB-16** INQ0010593 This SOP was the same for the HSIB. HSSIB will approach NICE where it identifies that any relevant NICE guidance is within the scope of any topic under its national investigation programme and members of PSOG, with input from the relevant guidance-producing teams within NICE, have an exploratory discussion with HSSIB to understand the scope and terms of the investigation and consider which NICE guidance may be potentially relevant. Where HSSIB indicates that as an outcome of the investigation they will issue a formal safety recommendation to NICE, PSOG will assist them in reviewing the wording of the recommendation at a draft stage and additionally, PSOG will review NICE's formal response to the recommendation before it is signed off by the Chief Executive. This response also includes indicative timescales for when the actions set out in it will be completed.

58. Internally, the PSOG team will signpost the actions required in response to the HSSIB recommendation (primarily but not limited to NICE's guideline surveillance team), where they may need to review underpinning evidence on a guideline topic. If the outcome of that review is a decision to update the guideline, this will be scheduled into the CfG work programme. The PSOG team provides an update to HSSIB on the outcome of the surveillance review in response to their action. The PSOG team also provides feedback on behalf of NICE against draft HSSIB publications, which they share for consultation. These may not necessarily issue a recommendation to NICE, yet still reference its guidance.

59. The NICE HSIB Investigations Log is exhibited at **Exhibit JB-17** INQ0010594 The investigation tab contains the details of any HSIB investigation that NICE has engaged with since March 2021. The report tab contains the details of any HSIB reports that NICE reviewed since April 2021 – with entries coded in green if they are concluded and amber if still ongoing. Any entry considered to be relevant to the Inquiry is highlighted in yellow. NICE has highlighted in yellow, row 12 on the investigation tab and row 30 on the report tab, as potentially relevant to the Inquiry. Row 12 relates to an HSIB investigation into the delayed diagnosis of neonatal jaundice in 2022. In relation to tab 30, CfG reviewed a draft report into the Management of preterm labour and birth and suggested wording to inform a safety action. The NICE HSIB Recommendations Action Log is exhibited at **Exhibit JB-18** INQ0010595 This contains details of any HSIB investigations that have led to any changes to NICE guidance between January 2019 and June 2023. As above, entries are coded in green if they are concluded and amber if still ongoing. There is one entry, highlighted in yellow at

row 12, that NICE has identified as potentially relevant to the Inquiry. This relates to the detection of jaundice in newborn babies. Following a recommendation from HSIB to review and update its guidance, NICE undertook a review and published updated guidance in 2023. In addition, for completeness, the NICE HSSIB Engagement Log is exhibited at **Exhibit JB-19** INQ0010596 This contains details of HSSIB investigations that have involved NICE since HSSIB inception and entries are colour coded as above. NICE does not consider that any entries in the Engagement Log are relevant to the Inquiry.

60. To further enhance NICE's collaboration with HSSIB, in Summer 2023 the Patient Safety Programme Manager for NICE undertook a 3-month part-time placement with what was then HSIB's national investigations team. This was to better understand their internal processes for topic identification, investigation methods, quality assurance and recommendation development. NICE will reciprocate this arrangement by hosting a member of HSSIB within NICE's clinical directorate, based with the patient safety team, in early 2024. They will spend time on NICE's patient safety oversight and response activities as well as spending time with the guideline development teams.

Other patient safety partnership working

61. NICE is represented by its CMO on the National Patient Safety Committee at NHSE, which is chaired by the NHS National Clinical Director for Patient Safety. The National Patient Safety Committee was established in 2021, bringing key national healthcare organisations together to address complex patient safety issues that require cross-organisation effort and input to make care safer within the NHS. Additionally, NICE is involved with other key stakeholders through safety-related forums such as the Interim Devices Working Group convened by the MHRA, and NHSE chaired groups such as the Digital Clinical Safety Advisory Group and Patient Safety Inequalities Group.

62. NICE is also a member of the Arm's Length Bodies Safety Recommendations Collaboration Group, which is a cross-healthcare system group convened to optimise the development and implementation of safety-focused recommendations at a system level. The group is chaired by the Chief Investigator of HSSIB, and its membership includes other NHS arm's length bodies including the MHRA and NHS Resolution. It is attended by the National Clinical Director for Patient Safety at NHSE.

Promotion and reinforcement of NICE guidance

63. In addition to the work with key health care system partners referred to above, NICE undertakes a range of additional activities to promote and reinforce the use of NICE guidance, including:
    - All NICE guidance and advice are published on the NICE website.
    - The communications team considers each product and decides whether to issue media releases, media interviews and/or publish news stories on the website, newsletters to stakeholders, podcasts and social media.
    - Responding to public, stakeholder and parliamentary queries through its enquiry handling function.

64. In addition, NICE's Field Team also supports the implementation of NICE guidance in the health and care system by working with local and regional health and care organisations to encourage, inform and facilitate implementation activities. They gather feedback to underpin all aspects of NICE's work, including examples of good practice to share with other organisations and promote the wide range of resources that NICE provides to help put guidance into practice, such as baseline assessment tools, quality standards and service improvement tools.

65. To promote the use of quality standards in the system, NICE works with key national organisations, such as relevant Royal Colleges and national patient groups, to 'support' quality standards. Organisations that agree to formally support the quality standard undertake activities to increase awareness of the quality standard and encourage those commissioning, providing and using services to adopt it. This may include activities such as:

    - producing print or online articles for the organisation's websites or newsletters.
    - using the organisation's social media channels to promote the quality standard.
    - using conferences and other speaking opportunities to present information on the quality standard.
    - running workshops to help other organisations understand how using the quality standard can add value.

    All national supporting organisations are listed on the NICE website for the relevant quality standard. It is important to note that there is a requirement that the organisation is national, therefore NHS trusts are not eligible.

66. In relation to reinforcing the use of medicines related guidance, NICE has supported and managed a network of around 100 medicines and prescribing associates for over 10 years. Associates are professionals including pharmacists, GPs and nurses working in various senior roles and sectors across the UK. The Associates work with NICE to create a national community of practice for medicines optimisation. NICE trains and supports the network on NICE guidance through educational webinars and face-to-face training days. NICE produces slide sets and educational materials for the webinars, including versions which associates can use with their own networks and affiliates (see below). NICE associates share learning and good practice in relation to the implementation of NICE guidance through 1:1s, small group meetings and a closed email forum. The following documents are examples of promotional materials highlighting the programme:

- Medicines and Prescribing Associate Programme flyer 2023 - **Exhibit JB-20** INQ0010597
- The role of a Medicines Prescribing Associate 2023 - **Exhibit JB-21** INQ0010598
- The role of a Medicines Prescribing Affiliate 2023 - **Exhibit JB-22** INQ0010599

67. NICE also works with the Royal Pharmaceutical Society to deliver educational webinars on NICE guidance. Since 2021, NICE has delivered 10 events covering topics such as depression, hypertension, diabetes and shared decision-making.

NICE Guidelines and Quality Standards

68. The full details of all NICE guidelines and quality standards, produced by CfG, that NICE considers are potentially relevant to the Thirlwall Inquiry are contained within the spreadsheet, exhibited as **Exhibit JB-23** INQ0010600 By way of explanation, the chronology tab of the spreadsheet provides a chronology of the key guidelines and quality standards in relation to issues outlined in the Inquiry Scope. It highlights the publication dates, relevant matters addressed and the intended audience. The spreadsheet contains products from 2006 that would have been relevant as of January 2012 and also contains 'minor updates', for information. The 'Column H-K' provides an overview of the advice relevant to the issues outlined in the Scope and identifies which guidelines contain reference to a neonate, the storage of drugs, safe staffing or safeguarding.

The guidelines within the spreadsheet that are potentially relevant to the Thirlwall Inquiry are set out in **Table 2** below.

NICE Guideline Reference	Publication Date	Guideline Title
CG37	23/07/2006	Postnatal care up to 8 weeks after birth
CG47	23/05/2007	Feverish illness in children
CG55	26/09/2007	Intrapartum care
PH11	26/03/2008	Maternal and Child Nutrition
CG63	26/03/2008	Diabetes in pregnancy: Management of diabetes and its complications from pre-conception to the postnatal period
CG89	22/07/2009	Child maltreatment: when to suspect maltreatment in under 18s.
CG98	19/05/2010	Jaundice in newborn babies under 28 days
CG102	23/06/2010	Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management
CH102 (update)	08/09/2010	Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management
CG129	26/09/2011	Multiple pregnancy: antenatal care for twin and triplet pregnancies
CG132	23/11/2011	Caesarean section
CG149	22/08/2012	Neonatal infection (early onset): antibiotics for prevention and treatment
CG160 (replaced CG47)	22/05/2013	Fever in under 5s: assessment and initial management
CG89 (update)	09/01/2014	Child maltreatment: when to suspect maltreatment in under 18s.
SC1	14/03/2014	Managing medicines in care homes
SG1	15/07/2014	Safe staffing for nursing in adult inpatient wards in acute hospitals
PH11 (update)	01/11/2014	Maternal and Child Nutrition
CG190 (replaced CG55)	03/12/2014	Intrapartum care for healthy women and babies
NG1	14/01/2015	Gastro-oesophageal reflux disease in children and young people: diagnosis and management
NG3 (replaced CG63)	25/02/2015	Diabetes in pregnancy: management from preconception to the postnatal period
NG4	27/02/2015	Safe midwifery staffing for maternity settings
NG5	04/03/2015	Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes.
NG9	01/06/2015	Bronchiolitis in children: diagnosis and management
NG3 (update)	16/08/2015	Diabetes in pregnancy: management from preconception to the postnatal period
NG17	26/08/2015	Type 1 diabetes in adults: diagnosis and management
NG25	20/11/2015	Preterm labour and birth

NG28	02/12/2015	Type 2 diabetes in adults: management
NG29	09/12/2015	Intravenous fluid therapy in children and young people in hospital
CG89 (update)	22/02/2016	Child maltreatment: when to suspect maltreatment in under 18s.
NG46	12/04/2016	Controlled drugs: safe use and management
NG51	13/07/2016	Sepsis: recognition, diagnosis and early management
CG98 (update)	26/10/2016	Jaundice in newborn babies under 28 days
NG61	07/12/2016	End of life care for infants, children and young people with life-limiting conditions: planning and management
NG62	25/01/2017	Cerebral palsy in under 25s: assessment and management
NG67	30/03/2017	Managing medicines for adults receiving social care in the community
NG72	09/08/2017	Developmental follow-up of children and young people born preterm
NG51 (update)	13/09/2017	Sepsis: recognition, diagnosis and early management
NG75	27/09/2017	Faltering growth: recognition and management of faltering growth in children
CG89 (update)	09/10/2017	Child maltreatment: when to suspect maltreatment in under 18s.
NG76	09/10/2017	Child abuse and neglect
NG121	06/03/2019	Intrapartum care for women with existing medical conditions or obstetric complications and their babies
NG51 (update)	01/04/2019	Sepsis: recognition, diagnosis and early management
NG124	03/04/2019	Specialist neonatal respiratory care for babies born preterm.
NG121 (update)	25/04/2019	Intrapartum care for women with existing medical conditions or obstetric complications and their babies
NG61 (update)	25/07/2019	End of life care for infants, children and young people
NG25 (update)	02/08/2019	Preterm labour and birth
NG137 (replaced CG129)	04/09/2019	Twin and triplet pregnancy
NG1 (update)	09/10/2019	Gastro-oesphageal reflux disease in children and young people: diagnosis and management
NG143 (replaced CG160)	07/11/2019	Fever in under 5s: assessment and initial management
NG154	26/02/2020	Neonatal parenteral nutrition
NG3 (update)	16/12/2020	Diabetes in pregnancy: management from preconception to the postnatal period
NG17 (update)	16/12/2020	Type 1 diabetes in adults: diagnosis and management' guideline
NG28 (update)	16/12/2020	Type 2 diabetes in adults: diagnosis and management
NG192 (replaced CG192)	31/03/2021	Caesarean birth
NG195 (replaced CG	20/04/2021	Neonatal infection: antibiotics for prevention and treatment

159)		
NG194	20/04/2021	Postnatal Care
NG17 (update)	21/07/2021	Type 1 diabetes in adults: diagnosis and management
NG9 (update)	09/08/2021	Bronchiolitis in children: diagnosis and management
NG204	25/08/2021	Babies, children and young people's experience of healthcare
NG75 (update)	20/10/2021	Faltering growth: recognition and management of faltering growth in children
NG28 (update)	24/11/2021	Type 2 diabetes in adults: management
NG28 (update)	15/02/2022	Type 2 diabetes in adults: management
NG17 (update)	31/03/2022	Type 1 diabetes in adults: diagnosis and management' guideline
NG28 (update)	31/03/2022	Type 2 diabetes in adults: management
CG89 (update)	11/04/2022	Child maltreatment: when to suspect maltreatment in under 18s.
NG25 (update)	10/06/2022	Preterm labour and birth
NG17 (update)	29/06/2022	Type 1 diabetes in adults: diagnosis and management' guideline
NG28 (update)	29/06/2022	Type 2 diabetes in adults: management
CG102 (update)	21/10/2022	Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management
NG29 (update)	21/10/2022	Intravenous fluid therapy in children and young people in hospital
NG192 (update)	21/06/2023	Caesarean birth
NG192 (update)	23/08/2023	Caesarean birth
NG192 (update)	06/09/2023	Caesarean birth
NG235 (replaces CG190)	29/09/2023	Intrapartum care
CG98 (update)	31/10/2023	Jaundice in newborn babies under 28 days
NG17 (update)	21/11/2023	Type 1 diabetes in adults: diagnosis and management' guideline

Table 2: NICE guidelines potentially relevant to Thirlwall inquiry

69. The COCH was a registered stakeholder for the following guidelines:

a. Jaundice in newborn babies under 28 days (published May 2010 / Last updated October 2023)
b. Bronchiolitis in children: diagnosis and management (published June 2015 / Last updated August 2021)
c. Caesarean birth (published March 21 / Last updated September 2023)
d. Diabetes (type 1 and type 2) in children and young people: diagnosis and management

(published August 2015 / Last updated May 2023)

e. Intravenous fluid therapy in children and young people in hospital (published December 2015 / Last updated June 2020)

f. Postnatal care (published April 2021)

70. For completeness (albeit outside of the relevant period), the COCH was a registered stakeholder on the guideline 'Jaundice in newborn babies' in 2009 and NICE did receive comments from the COCH on this guideline. Comments were not received in relation to any of the other guidelines mentioned above, to which COCH was a registered stakeholder.

71. The Quality Standards, produced by CfG that NICE considers to be potentially relevant to the Thirlwall Inquiry are set out in **Table 3** below:

NICE Quality Standard Reference	Publication date	Quality Standard Title
QS4	07/10/2010	Neonatal Specialist care
QS19	27/06/2012	Meningitis (bacterial) and meningococcal septicaemia in children and young people
QS32	11/06/2013	Caesarean birth
QS46	18/09/2013	Multiple pregnancy: twin and triplet pregnancies
QS57	06/03/2014	Jaundice in newborn babies under 28 days
QS64	24/07/2014	Fever in under 5s
QS75	18/12/2014	Neonatal infection
QS98	01/07/2015	Nutrition: improving maternal and child nutrition
QS105	10/12/2015	Intrapartum care
QS112	28/01/2016	Gastro-oesophageal reflux in children and young people
QS120	24/03/2016	Medicines optimisation
QS128	11/08/2016	Early years: promoting health and wellbeing in under 5s.
QS131	21/09/2016	IV fluid therapy in children and young people in hospital
QS135	19/10/2016	Preterm labour and birth
QS105 (update)	28/02/2017	Intrapartum care
QS160	12/09/2017	End of life care for infants, children and young people
QS161	13/09/2017	Sepsis

QS169	18/05/2018	Developmental follow-up of children and young people born preterm
QS179	12/02/2019	Child abuse and neglect
QS135 (update)	02/08/2019	Preterm labour and birth
QS46 (update)	04/09/2019	Multiple pregnancy: twin and triplet pregnancies
QS192	28/02/2020	Intrapartum care- existing medical conditions and obstetric complications
QS161 (update)	18/06/2020	Sepsis
QS193	15/07/2020	Specialist neonatal respiratory care for babies preterm
QS197	28/08/2020	Faltering growth
QS32 (update)	31/03/2021	Caesarean birth
QS205	22/03/2022	Neonatal parenteral nutrition
QS64 (update)	08/03/2023	Fever in under 5s

Table 3: NICE quality standards potentially relevant to Thirlwall inquiry

Safe staffing for maternity settings including neonatal units.

72. The **Exhibit JB-23** INQ0010600 includes details of all CfG guidance relevant to safe staffing. The 'Safe midwifery staffing for maternity settings' guideline (NG4), exhibited as **Exhibit JB-24** INQ0010601 was published on 27 February 2015. This guideline covers all midwifery care for the mother and neonate, including pre-conception and ante-natal care, care during labour and postnatal care up to 6 weeks. Settings may include the home, community, obstetric units and units led by midwives. The only other safe staffing guideline is 'Safe staffing for nursing in adult inpatient wards in acute hospitals (SG1), published on 17 July 2014. The guideline is concerned only with adult wards in acute hospitals.

73. NICE's safe staffing guidance programme was discontinued by NHSE in June 2015 and from that point in time, NHSE developed safe staffing improvement resources for specific settings, including neonatal care. In June 2018, NHSE published a resource 'Safe sustainable and productive staffing: an improvement resource for neonatal care'. For information, this NHSE resource does refer to the NICE 'Specialist neonatal care' quality standard (QS4), published 7 October 2010, and the quality statement: "*Specialist neonatal services have a sufficient, skilled and competent multidisciplinary workforce"*. QS4 was withdrawn on 15 July 2020 and replaced by 'Specialist neonatal respiratory care for babies born preterm' (QS193). QS193 does not cover safe staffing, but covers neonatal respiratory support in hospitals for babies born preterm (before 37 weeks of pregnancy).

Safeguarding babies and neonates in hospital

74. **Exhibit JB-23** INQ0010600 includes details of all CfG guidance relevant to safeguarding babies and neonates in hospital. The 'Child maltreatment: when to suspect maltreatment in under 18s' guideline (CG89)', exhibited as **Exhibit JB-25** INQ0010602, was published on 22 July 2009. It had minor updates in December 2009, January 2014, February 2016 and July 2019. Although it does not specifically mention neonatal settings, it does relate to all children and neonatal hospital settings. This guideline covers the signs of possible child maltreatment in children and young people aged under 18 years. It aims to raise awareness and help health professionals who are not child protection specialists, to identify the features of physical, sexual and emotional abuse, neglect and fabricated or induced illness.

75. NICE also published a related guideline on 'Child abuse and neglect' (NG76) on 9 October 2017, which is exhibited as **Exhibit JB-26** INQ0010603 It had minor updates in November 2018 and July 2020. Again, although there is no specific mention of neonates or neonatal settings, the guideline covers recognising and responding to abuse and neglect in children and young people aged under 18 and neonatal hospital settings does fall under the settings covered. It relates to physical, sexual and emotional abuse, and neglect.

76. In addition, the 'Babies, children and young people's experience of health care' guideline (NG204) was published on 25 August 2021 and is exhibited as **Exhibit JB-27** **INQ0010604** This guideline describes good patient experience for babies, children and young people and makes recommendations on how it can be delivered. The guideline aims to make sure that all babies, children and young people using NHS services have the best possible experience of care. It is recognised that parents and carers play a key role, and where appropriate, NICE took their views into account when developing the recommendations. The guideline is intended for all healthcare professionals, commissioners and providers of NHS or local authority healthcare services.

77. One of the key principles within NG204, section 1.1.1, is safeguarding. It states '*Adhere to all relevant legislation and follow all national and local safeguarding policies and professional guidelines when implementing these recommendations and when planning and delivering healthcare services for all babies, children and young people, in any setting. See further guidance in the NICE advice on safeguarding and the Children's Act 1989 (and*

subsequent updates).' It also makes recommendations in relation to the healthcare environment (section 1.8).

78. NICE has not been commissioned to produce guidance on the use of CCTV in neonatal settings. The only reference to CCTV in the NICE guideline catalogue relates to suicide prevention in community and custodial settings.

The safe use and management of controlled drugs (including Insulin)

79. The **Exhibit JB-23** INQ0010600 includes details of all CfG guidance potentially relevant to the safe use and management of controlled drugs. The 'Controlled Drugs: Safe Use and Management guideline' (NG46) was published on 12 April 2016. This is exhibited as **Exhibit JB-28** INQ0010605 here was no NICE guidance on this topic prior to that date. NG46 relates to systems and processes for using and managing controlled drugs safely in all NHS settings, except care homes. It aims to improve working practices to comply with legislation and have robust governance arrangements. It also aims to reduce the safety risks associated with controlled drugs.

80. This guideline's recommendations are relevant to safe practices with controlled drugs and includes the following recommendations:
    - for organisations - on developing systems and processes, including governance arrangements, storage, stock checks, transportation and destruction and disposal.
    - for organisations - on record keeping, risk assessment, and reporting controlled drug-related incidents.
    - for health professionals - on prescribing, obtaining and supplying, administering and handling controlled drugs.
    - for health professionals - on monitoring use, including governance and systems for reporting concerns and incidents.

    These recommendations were developed using UK controlled drugs legislation and regulations, as amended and updated up to the end of 2015.

81. The guideline is intended for:
    - health professionals providing care for people being treated with controlled drugs
    - social care practitioners
    - commissioners of services using controlled drugs
    - providers of services where controlled drugs are used

- people being treated with controlled drugs, their families or carers and the public.

82. The 'Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes guideline' (NG5) was published on 4 March 2015. There was no NICE guidance on this topic prior to this date. It was updated in September 2019, June 2021 and October 2021. This guideline covers safe and effective use of medicines in health and social care for people taking 1 or more medicines. It aims to ensure that medicines provide the greatest possible benefit to people by encouraging medicines reconciliation, medication review, and the use of patient decision aids. It is for healthcare professionals, social care practitioners, commissioners and providers and people taking 1 or more medicines and their families and carers. This guideline may be relevant to the inquiry as it contains recommendations on systems for identifying, reporting and learning from medicines-related to patient safety incidents recommendations 1.1.1 to 1.1.11.

83. NICE produced two further guidelines relating to the use and management of medicines:

- 'Managing medicines for adults receiving social care in the community' (NG67), published on 30 March 2017. This guideline covers medicines support for adults (aged 18 and over) who are receiving social care in the community.
- 'Managing medicines in care homes' guideline (SC1) was published 14 March 2014. It was updated in January 2018, May 2020 and July 2022. This guideline covers good practice for managing medicines in care homes. These guidelines have been included for completeness but are unlikely to be relevant to the Scope of the Inquiry.

84. NICE has produced the following guidelines relating to the use of Insulin: 'Type 1 diabetes in adults: diagnosis and management' guideline (NG17), which was published on 26 August 2015 and the 'Type 2 diabetes in adults: management 'guideline (NG28), published on 2 December 2015. In 2021, both guidelines were updated to include a recommendation relating to risk minimisation of Insulin therapy, which may be potentially relevant to the inquiry.

85. Recommendation 1.7.6 states '*Ensure the risk of medication errors with insulins is minimised by following Medicines and Healthcare products Regulatory Agency (MHRA) guidance on minimising the risk of medication error with high strength, fixed combination and biosimilar insulin products, which includes advice for healthcare professionals when starting treatment with a biosimilar'.*

86. NICE has not published any other guidelines in relation to the safe use and management of Insulin.

NICE Impact Reports- maternity related

87. Between 2018 and 2021, NICE published a number of 'Impact Reports'. Impact Reports used publicly available data and intelligence to review the uptake and impact of NICE guidance and quality standards in priority areas for health and care safety. The Impact Reports each covered a specific theme and on two occasions, the reports covered the subject of maternity. The reports were reviewed at a NICE public board meeting and then published on the NICE website. In addition, the reports were supported with communications to relevant professional bodies and patient groups, highlighting the areas of high, low and variable uptake identified within the reports.

88. On 5 May 2018, NICE published an Impact Report titled "NICE impact: maternity". This report reviewed the impact and uptake of selected recommendations from NICE guidance on topics including smoking in pregnancy, multiple pregnancy, diabetes in pregnancy, birth setting and maternal choice, and prenatal testing for blood type. The report is exhibited as **Exhibit JB-29** **INQ0010606**

89. On 9 September 2019, NICE published an Impact Report titled "NICE impact: maternity and neonatal care". This report reviewed the impact and uptake of selected recommendations from NICE guidance on multiple pregnancy, prenatal testing for blood type, smoking in pregnancy, perinatal mental health, neonatal specialist care, and valproate prescribing and considered how NICE's evidence-based guidance might contribute to improvements in the safety and personalisation of maternity care. The report is exhibited as **Exhibit JB-30** **INQ0010607**

90. Both reports drew on previously published data from sources such as the National Maternity and Perinatal Audit, the CQC Maternity Survey and the National Neonatal Audit Programme. The 2019 report identifies that NICE's guidance covers the full pathway from admission to specialist care and follow up, as well as acknowledging the importance of the NICE quality standard on neonatal specialist care.

91. NICE did not publish any other Impact Reports relating to maternity or neonatal care during the relevant period.

British National Formulary

92. The BNF is a joint publication of the British Medical Association and the Royal Pharmaceutical Society. The BNF for Children is also a joint publication by the same organisations and should be consulted for detailed information on the use of medicines in children. The BNF is editorially independent and NICE is not responsible for its content or its management. NICE holds the licence to make this resource electronically available on its website to health professionals working in the UK. During the relevant period, NICE printed and disseminated hard copy versions. Currently, NICE only holds an electronic version of the current content.

93. NICE is aware that the current BNF for children does contain some relevant content. For example, 'intravenous infusions for neonatal intensive care'. However, if the Inquiry requires historic information and current and/or historic hard copy exhibits of any relevant sections, it will need to approach the BNF directly.

Other NICE related products related products

94. The NICE Medicines Optimisation Team produced a key therapeutic topic ["KTT"] on 'safer insulin prescribing' in September 2019, including options for local implementation. This was available on the NICE website until February 2022 (when all KTTs were withdrawn). This KTT, exhibited as **Exhibit JB-31** INQ0010608 summarises the evidence base on the topic that has been identified to support medicines optimisation and provides safer insulin prescribing advice in relation to children and adults. It is NICE advice rather than formal NICE guidance.

95. The details of additional NICE guidance and advice, produced by CHTE between January 2012 and October 2023, that NICE considers as potentially relevant to the scope of the Thirlwall Inquiry are contained within the spreadsheet exhibited as **Exhibit JB-32** **INQ0010609** By way of explanation, the chronology tab of the spreadsheet provides a chronology of the key guidance in relation to issues outlined in the Inquiry Scope. It highlights the publication dates and type of product and identifies the matters addressed within the products and the intended audience.

96. The CHTE guidance and advice that NICE considers is potentially relevant (as the treatments and medications are relevant to young children) to the Scope of the Thirlwall inquiry are set out in **Table 4** below:

NICE Guidance Reference	Guideline Title
TA408	Pegaspargase for treating acute lymphoblastic leukaemia.
MIB155	Neon EEG electrode for EEG monitoring in newborns
MIB163	Servo-n with Neurally Adjusted Ventilatory Assist (NAVA) for babies and children.
TA588	Nusinersen for treating spinal muscular atrophy (SMA)
TA729	Sapropterin for treating hyperphenylalaninaemia in phenylketonuria.
TA755	Risdiplam for treating spinal muscular atrophy (SMA)
TA821	Avalglucosidase alfa for treating Pompe disease.
HTE6	Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies: early value assessment.

Table 4: CHTE guidance potentially relevant to Thirlwall inquiry

NICE guidance and advice - planned updates

97. In relation to any established procedures, standards or guidelines that NICE has identified as in need of review or update regarding the quality of care and safety of babies in hospital, **Table 5** below identifies the guidelines considered to be relevant to the Scope of the Inquiry.

Name of guideline	Reason for update	Planned date of publication
Caesarean birth (NG192)	To address new evidence relating to the diagnosis and management of placenta accreta spectrum (formerly morbidly adherent placenta).	30 January 2024
Sepsis: recognition, diagnosis and early management (NG51)	Response to a report from the Academy of Medical Royal Colleges on the initial risk stratification and antimicrobial management of patients with sepsis. To help stratify the risk of deterioration in adults with suspected sepsis the report recommends the use of the UK's National Early Warning System 2 (NEWS2) scale. NEWS2 is a track and trigger early warning score system that is used to	31 January 2024

	identify and respond to patients at risk of acute deterioration.	
Twin and Triplet Pregnancy – Progesterone for preventing preterm birth (NG137)	To address new evidence relating to progesterone for preventing preterm birth. Also relates to cervical length screening.	28 March 2024
Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management (CG102)	Diagnosis in secondary care Procalcitonin - New systematic review and observational evidence supports the use of both serum and cerebrospinal fluid (CSF) procalcitonin (PCT) in the diagnosis of bacterial meningitis, including differential diagnosis between bacterial and viral meningitis. Age-specific reference values - Topic expert feedback and new evidence indicates that up to date age-specific reference values, including those published by Public Health England (PHE), are available. Long-term management - new intelligence indicates a potential impact on recommendations 1.5.8–1.5.10, to take account of the MenB vaccine that has been introduced since publication of NICE guideline CG102.	March 2024. Please note the associated Quality Standard (QS19) will also be updated and published October 2024
Maternal and Child Nutrition (PH11)	Changes to policy and practice as a result of the following publications: • Scientific Advisory Committee on Nutrition (SACN) working group review of the dietary reference values for vitamin D intake. • NICE public health guideline on vitamin D. • The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) report on assessing the health benefits and risks of the introduction of peanut and hen's egg into the infant diet before six months of age in the UK. • SACN sub-group on Maternal and Child Nutrition (SMCN) report on feeding in the first year of life.	November 2024
Child maltreatment: when to suspect maltreatment in under 18s (CG89)	New evidence in relation to bruising in non-mobile infants in response to a national panel review report.	2024
Intrapartum Care – Planning place of birth (NG235)	To address new evidence relating to planning a place of birth.	TBC

Table 5: NICE planned potentially relevant guidance updates

Concluding Comments

98. NICE has built a reputation as a world leader in providing robust, independent, and trusted guidance and advice to the health and care system. NICE welcomes this Inquiry and is keen to learn any lessons that might improve its contribution to the health and care system and ensure that patient safety is prioritised. I would like to repeat my condolences to all those affected by the events at the COCH and to assure the Inquiry that NICE will continue to work with it in an open and transparent manner.

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: 26th February 2024