Witness Name: Paul Chrisp

Statement No.: One

Exhibits: 55

Dated: 15 March 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PAUL CHRISP

I, Dr Paul Chrisp, will say as follows: -

1. I make this witness statement further to receipt of the Rule 9 letter from the Public Inquiry addressed to the Chief Executive of the National Institute for Health and Care Excellence ["NICE"] dated 02 June 2023. I have prepared this witness statement to assist the UK COVID-19 Public Inquiry in its understanding of NICE and NICE's response to the pandemic. As requested, this statement will focus on the period between 1 March 2020 and 28 June 2022 ["the relevant period"] and should be read in conjunction with the witness statement provided by NICE colleague Helen Knight (Director of Medicines Evaluation in the Centre for Health Technology Evaluation ["CHTE"] and the witness statement provided by the current Chief Executive, Dr Samantha Roberts.

2. On behalf of everybody at NICE, I would like to start by expressing my deepest sympathy to all those who lost loved ones during the COVID-19 pandemic and those affected in many other ways, including those that continue to be affected.

3. I am currently the Head of Publishing and Products at NICE. During the relevant period, I was the Director for the Centre for Guidelines ["CfG"], a role that I commenced in September 2018. I joined NICE in 2009, to set up NICE's accreditation programme for guideline developers, which evaluated the quality of processes used by organisations that developed guidelines and awarded an accreditation mark to those achieving the required standard, with the aim of raising the quality of guideline production.

4. I then became the Programme Director of the Medicines and Prescribing Programme and of the Clinical Guideline Updates Programme in April 2013, before

becoming the Programme Director of the Medicines and Technologies Programme and the Deputy Director of Health and Social Care at NICE in October 2016.

5. As I did during the pandemic, I report directly to the Chief Executive. I am also a member of the Executive Team ["ET"], which until January 2021 was known as the Senior Management Team ["SMT"], as well as a member of the Guidance Executive ["GE"]. The ET is responsible for providing leadership to the organisation within the authority delegated by the Board. The GE comprises members of the ET and other senior managers and considers and approves NICE's guidance and advice on behalf of the Board. During the pandemic, I also sat on the Board as an Executive Director and in my current role, I attend Board meetings in a non-voting capacity.

6. In response to the pandemic, NICE SMT established a Gold group, which took responsibility for the COVID-19 response, both internally and externally. I, like all members of SMT, was part of the Gold group.

Personal background and experience

7. Prior to joining NICE in 2009, I spent over 20 years in international medical publishing and communications, focusing on evidence to aid healthcare decision-making and therapeutics.

8. I qualified as a pharmacist in 1984, completed my PhD in 1987 and attained a postgraduate diploma in publishing studies in 1999. I no longer practice as a pharmacist, so I am not a member of the regulatory body, the General Pharmaceutical Council anymore, however I am a member of the Royal Pharmaceutical Society, which is the professional body.

Centre for Guidelines - Role and Function during the pandemic.

9. NICE is an arm's length body of the Department of Health and Social Care ["DHSC"]. NICE was established to help ensure that people had 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. The CfG was one of the eight (now ten) directorates at NICE and is responsible for overseeing the production of guidelines. The primary

objective of the CfG is to develop and maintain high quality, timely, evidence based, cost effective guidance and advice on the prevention, treatment and care of people, for practitioners and commissioners of services.

10. NICE operates in an environment that by its very nature has high stakes. It already had robust and transparent methods and processes to provide the necessary reassurance as to guideline and advice quality and resilience. When COVID-19 became a national health and care emergency, there was a need to quickly adapt ways of working and revise the approach to meet the health care system's needs for speedy and trusted guidance and advice.

11. On the 11 March 2020, James Palmer, National Director Specialised Services at NHS England ["NHSE"], approached NICE to produce guidelines on COVID-19 topics, at pace. The initial email from James asked whether NICE would be able to produce three guidelines on COVID-19 within a week. These guidelines became known as 'COVID-19 rapid Guidelines' and were co-badged with NHSE.

12. After a number of meetings and discussions with Sir Andrew Dillon (NICE's Chief Executive at the time), the following morning, NICE confirmed it was able to help and formulate a plan as to how these challenging deadlines could be met.

13. On the 13 March 2020, NICE received the first commission for rapid guidelines topics from NHSE (critical care, dialysis service delivery, delivery of systemic anti-cancer treatments), followed thereafter by regular commissions. The first wave guidelines were published on 20 March 2020. In response, NICE set up the COVID-19 rapid guideline programme (see details below).

14. On the 17 March 2020, following a further request from NHSE for NICE to reprioritise its work programme, SMT decided to only publish work on topics that were therapeutically critical, such as cancer, and/or address COVID-19 diagnostic or therapeutic interventions. NHSE's request was supported by NICE's sponsor team at the DHSC. SMT agreed prioritisation criteria and the CfG work programme was reviewed in line with the following:

    a. Guidelines that are therapeutically critical.

    b. Guidelines that address COVID-19 diagnostic or therapeutic interventions.

c. Guidelines that are post consultation and could be completed by developers without engagement of stakeholders and/or committee members.

d. Topics which do not fall into any of the above categories, but where staff, if available, can work without engaging stakeholders and/or committee members, for example in carrying out evidence reviews.

15. The purpose at the time was to avoid distracting the NHS when it was facing unprecedented pressure; releasing frontline health care staff who might otherwise have been engaged in guideline committees and as consultees on draft guidelines, and to focus NICE resources on those guideline topics that are either both a) therapeutically critical or b) address COVID-19 diagnostic or therapeutic interventions. This included the COVID-19 rapid guidelines.

16. All guideline topics that were in development at the start of the pandemic or were due to be started in the 3 months from March 2020, were assessed and reviewed against the criteria above. A summary of the guidelines in development and of surveillance reviews in progress or planned for 2020/21 can be found within appendix 1 and appendix 2 of the GE report for the 20 March 2020 meeting, exhibited as **Exhibit PC/01- INQ000252480**.

17. At its meeting on the 20 March 2020, the GE considered the three topics that had been through consultation and could be finished without engagement of stakeholders and/or committee members. It approved the 'Venous thromboembolic diseases: diagnosis, management and thrombophilia testing (update) ["VTD"]' for publication. The GE decided to defer publication of the 'Perioperative care in adults' and 'Joint replacement (primary): hip, knee and shoulder' guidelines. This decision was based on the rationale that the VTD guideline was assessed as therapeutically critical (as COVID-19 might cause as increase in VTD cases through forced inactivity, particularly in the elderly and those who were ill). The topic was published on the NICE website on 26 March 2020.

18. GE also approved that the development work would continue on the remaining guidelines insofar as was possible without engagement with committees or consultees. Of these, the following guidelines had a degree of priority:

- Depression in adults: treatment and management (updates);
- Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management (update);
- Acne vulgaris: management;
- Tobacco: preventing uptake, promoting quitting and treatment dependence (update);
- Diabetes in pregnancy (update);
- Integrated health and care for people who are homeless through being roofless; and
- Low back pain (update).

This was based on a variety of rationales including committee and patient community expectations, phase of committee engagement, government priorities and, in the case of acne vulgaris, a safety alert from the Medicines and Healthcare products Regulatory Agency ["MHRA"].

19. With regard to resources allocated to surveillance reviews, the GE approved the recommendation to finish any outstanding work on those topics within appendix 2 of **Exhibit PC/01 – INQ000252480**. GE also requested clear communications with stakeholders and patient groups to clarify NICE's decision and reasons for prioritising topics across programmes.

20. NICE did not make the prioritisation decisions in isolation. It reached out to the Royal College of Physicians ["RCP"] to communicate and validate the principles of prioritisation of work programmes to avoid distracting clinicians with non-COVID-19 topics at that time. As the RCP is the national professional membership body dedicated to improving the practice of medicine across all specialisms, NICE asked

whether there were any guidelines or areas in which it could continue to engage relevant specialists. RCP confirmed that there were a few who would be less involved in COVID-19, who NICE could continue to consult with on non-COVID-19 topics.

21. By April 2020, NICE had published its third set of rapid COVID-19 guidelines. These covered the management of patients with severe asthma, pneumonia, rheumatological autoimmune, inflammatory and metabolic bone disorders and the management of COVID-19 symptoms in the community. As the year progressed, NICE continued to add to this portfolio, including the rapid guideline on managing the long-term effects of COVID-19, the first of its kind and much needed by the health system. This guideline recommended standards for people experiencing long-term effects, addressed some of the uncertainties and doubts people may have and enable people to understand their symptoms and recognise when to seek help.

22. In June 2020, as the health care system began rebuilding capacity in non-COVID-19 services, NICE began a phased restart of its non-COVID-19 guidelines. Advisory committees were re-established virtually, building on the experiences of running meetings with video-conferencing technology, which had proved successful and provided the organisation with greater flexibility.

Additional COVID-19 related products

23. In addition to the COVID-19 rapid guidelines, the CfG also produced the following during the pandemic:

    a. **Managing COVID-19: treatments visual summary** – A graphic created for clinicians when diagnosing and treating people with COVID-19, which was available online during the pandemic. The graphic detailed exactly which treatments were recommended and at which stage of COVID to use them, either on their own or in combination with other treatments

    b. **Rapid evidence summaries** – Provided an evidence summary, underpinned by a detailed evidence review for:

        - New medicines and significant licence extensions;

- Off-label use of licensed medicines; and
- Unlicensed medicines.

They were produced between March 2020 and January 2021 to advise national and local decision makers on the best evidence available for therapeutics for COVID-19 as it emerged during the early stage of the pandemic.

The summaries were not formal NICE guidance. They were withdrawn when formal recommendations were made on these therapeutics as part of COVID-19 rapid guidelines. Rapid evidence summaries withdrawn in this way were Vitamin D for COVID-19, Remdesivir for treating hospitalized patients with suspected or confirmed COVID-19, Tocilizumab for COVID-19 and Sarilumab for COVID-19.

c. **Medicine prescribing briefing** – A briefing was produced on corticosteroids to respond to the DHSC, NHS and MHRA Central Alerting System ["CAS"] alert on corticosteroids in COVID-19. It provided high-level information about the medicine, along with a summary of the best available evidence to advise clinicians in their decision making with people. It was not formal NICE guidance.

d. **Medicine evidence commentary ["MEC"]** - An advice summary critique of new and relevant information about medicines and prescribing was provided. They were produced within 10 working days to offer a prompt response to the publication of important new evidence, to support health care professionals to inform decision-making. They were not formal NICE guidance.

e. **Clinical knowledge summary ["CKS"]** – Provided concise, accessible summaries of then current evidence for the COVID-19 assessment, diagnosis and management. The summary was updated as evidence emerged. They were to support primary care professionals, focusing on the most common and significant presentations in primary care, to support safe decision-making and improved standards of patient care. CKS topics are

developed by Clarity Informatics Ltd but commissioned and funded by NICE. CKS are not equivalent to NICE guidance as they have not been produced using a NICE process, nor are they signed off by NICE's GE.

f. **Specialty guides** – In the first 6 months of the COVID-19 pandemic, since March 2020, guidance and advice was developed by other organisations including NHSE specialty guidance. In November 2020, at the request of NHSE, NICE launched a new, single point of access to advice on the clinical management of COVID-19. NHSE COVID-19 specialty guides were transferred onto the NICE website. Prior to uploading, NICE reviewed each guide to ensure alignment with COVID-19 rapid guideline advice. Consequently, creating a single, easy-to-access resource for clinicians seeking advice on the management of COVID-19.

Formulating Guidelines

24. The standard process for formulating NICE guidelines is set out in the 'Developing NICE guidelines: the manual' ["the manual"]. The manual explains in detail the process and methods used to develop and update NICE guidelines, covering topics across clinical care (in primary, secondary and community care settings), social care and public health. A copy of the most recent iteration of the manual dated January 2022 is exhibited as **Exhibit PC/02 - INQ000252481**.

25. For new guideline topics, a formal referral is received by NICE from DHSC or NHSE. Each commissioned topic is initially assigned a 'standard (142 week)', 'accelerated (86 week)', or 'short (44 week)' timeline, depending on the expected size of the work required. Following a detailed scoping stage, the time taken to develop the guideline is then typically adjusted through assessment and agreement at NICE.

26. NICE develops guidelines in accordance with the following core principles:

- The guideline is based on the best available evidence of what works and what it costs;
- The guideline is developed by independent and unbiased committees of

experts, from across a range of health and social care professions;

- Committees include at least two lay members (people with personal experience of using health or care services, including carers, or from a community affected by the guideline);

- Consultation allows organisations and individuals to comment at several stages of guideline development, including on the recommendations;

- All guidelines and updates are signed off by NICE's Guidance Executive and approved for publication; and

- Once published, all NICE guidelines are regularly checked and updated in the light of new evidence or intelligence, if necessary.

27. Topic specialists, expert groups, patient groups and other key registered stakeholders are involved throughout the development process, notably through scope consultation, participation in committee activity and consultation on the draft guideline. Stakeholders can register to be involved in guideline development at any time. A summary of the standard guideline development process steps, including stakeholder involvement, is summarised in **figure 1**.

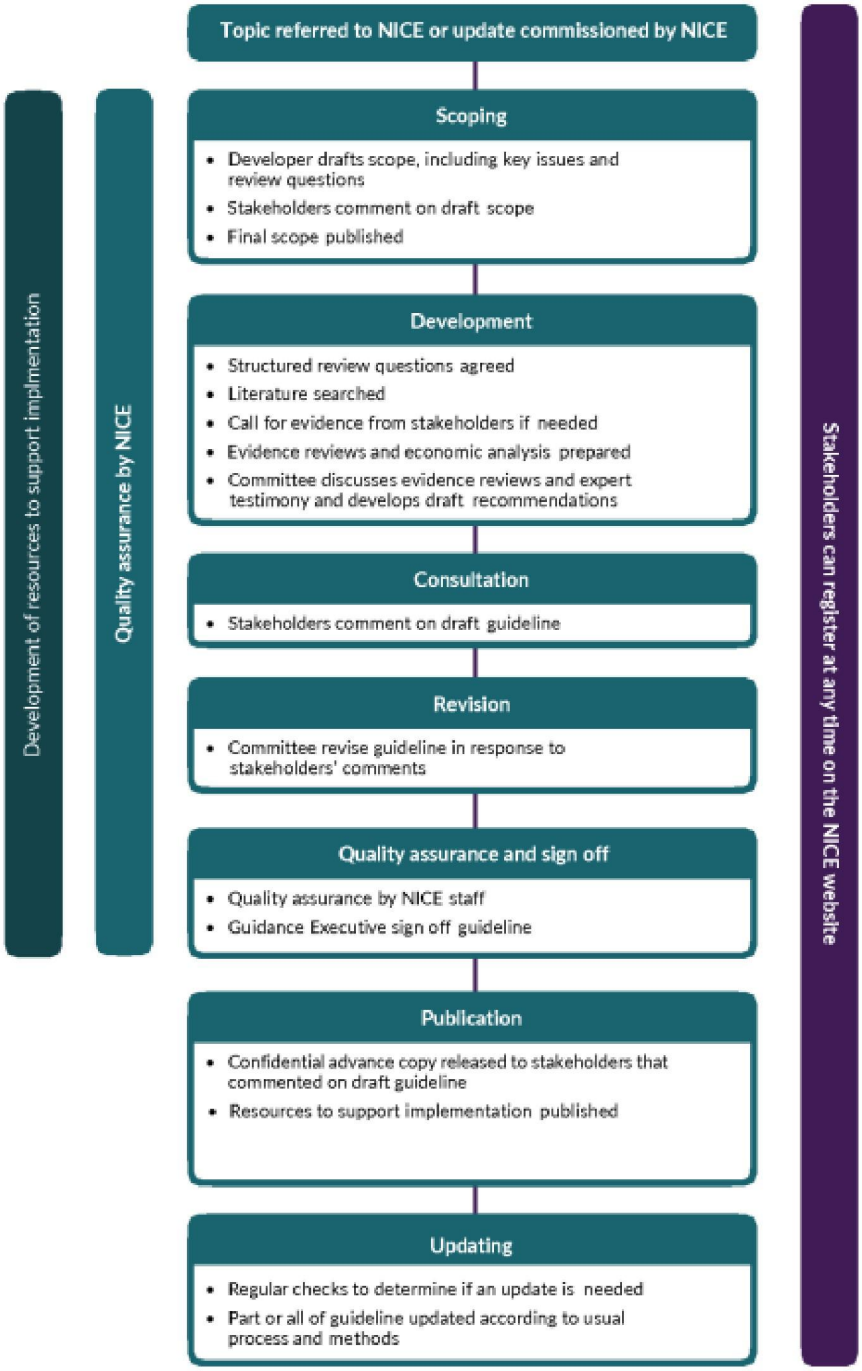

Figure 1 – NICE guideline development process steps

Stakeholder selection process

28. Stakeholders are selected for NICE guidelines via both centre-wide and guidelines-specific activities.

Centre wide activities

29. Periodically a call for stakeholders is sent out via email, approximately every 2-3 months, detailing upcoming guideline or surveillance topics about to commence development and inviting recipient organisations to register as a stakeholder. This email is sent out to all organisations listed within the CfG contacts database, regardless of the topic of the guideline – this is approximately 13,000 recipients. The email contains a link for recipients to access the stakeholder registration page on the NICE website, containing information on the registration process, the stakeholder eligibility criteria and an online registration form. Registrations received are processed and checked by NICE staff and once approved, each guideline's stakeholder list is automatically updated with the newly registered stakeholder organisation. Organisations can also, at any point during guideline development, register to be a stakeholder. The stakeholder registration page is clearly signposted on the main landing page of the NICE website, under the 'Get Involved' heading. Ad hoc registrations received via this route are processed in the same way.

Guideline-specific activities

30. There is a 'standing stakeholder' list, made up of key national organisations that routinely have an interest in NICE guidelines and regularly submit comments on draft scopes and draft guidelines at consultation, to ensure they are always selected as stakeholders, whilst removing the administrative burden of repeatedly registering for each guideline.

31. If the guideline is an update of an existing guideline, the most recent list of stakeholders used by any NICE guidelines team (for example, the stakeholders for the most recent update of the guideline, or the stakeholders for the surveillance review that triggered the update) is imported, to ensure that the most up-to-date organisations and contacts are selected.

32. During a guideline's development, the stakeholder list is regularly reviewed and any gaps or omissions identified are addressed by contacting suggested organisations and inviting them to register. This review of stakeholders happens throughout development. Key points at which this is formally undertaken are listed below:

- Scoping meeting 1 & 3 – (internal meeting) NICE staff, committee chair and topic adviser/s are asked to identify organisations to invite to register as a stakeholder.
- Scoping meeting 2 – (external meeting) NICE staff, committee chair, topic adviser/s and stakeholders (those that have registered to attend) are ask to identify organisations to invite to register as a stakeholder.
- In the run up to consultation on the draft guideline – the guideline committee members are asked to identify organisations to invite to register as stakeholders.
- NICE Public Involvement Programme review the stakeholder list specifically with a view to identifying the appropriate third sector organisations and contacts.

Equality Impact Assessments

33. The impact on people with characteristics protected under the Equality Act 2010 is considered during the development of NICE guidelines. An equality impact assessment ["EIA"] is completed and quality assured by NICE staff before submission of the draft guideline to NICE's GE. The EIA is available with the guideline at the point of publication.

Dissemination of guidelines

34. All guidelines are published on the NICE website. The communications team would consider each guideline and decide whether to issue media releases, media interviews and/or publish news stories on the website. In addition, NICE also responded to public, system and parliamentary queries through its enquiry handling function.

35. NICE's 'field team' works 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.

Changes to process for formulating guidelines during the pandemic

36. Although the guideline methods and process was compressed and changed to meet the requirements of the pandemic, the core principles outlined in paragraph 26 were retained as much as possible. The main differences to development of recommendations during the relevant period compared to the process prior to the COVID-19 pandemic were:

- Much compressed development process (initially 5-10 days rather than 12-24 months);
- Some of the guideline stages were conducted iteratively or in parallel;
- Guideline consultation processes were shortened and targeted. There was no time to undertake public consultation on the scope, extensive consultation on the draft recommendations or write extensive rationales for the recommendations or information for the public;
- Patient experts were not involved in drafting the guidance, so NICE ensured good patient group feedback was provided on the draft recommendations; and
- The rapid guidelines were developed and co-badged with NHSE and were implemented by NHSE as part of the national response to the COVID-19 pandemic.

37. As the pandemic progressed, the rapid guideline methods and processes developed to match the increasing availability of evidence, complexity of the subject and the different waves of the pandemic.

38. Developing guidance on COVID-19 created unique challenges. There was less evidence available than usual as this was a completely new disease. NICE tackled this by setting up and leading a data and analytics taskforce. The group worked

with external partners to detect areas of uncertainty in its COVID-19 guidelines and identify suitable sources of data to address them. In July 2020, the taskforce published an interim framework to assess the quality of wider sources of data and evidence used to inform its COVID-19 work. By December 2020, the framework had received over 600 views from across 50 different countries.

Early guideline methods and processes

39. The COVID-19 rapid guidelines programme objectives were:

    a. To develop joint NICE/NHSE guidance for the NHS and front-line health and care services in specific topic areas to rapid timescale;

    b. To work with NHSE and NICE identified experts in the topic areas to develop recommendations based on the available evidence;

    c. To rapidly review and update guidance in line with national policy, emerging evidence and user feedback; and

    d. To develop evidence summaries to support NHSE decision making and policy development.

40. The clear early direction from NHSE was that guidance should be produced quickly due to the urgency of the situation. The initial request was for publication within 7 calendar days of referral. This urgency was to take priority over the use of standard methods and processes given the imminent wave of infection that was being seen and planned for. Another key consideration was for a single national set of recommendations in any given topic area due to the need to provide consistent national advice to the NHS corporately and to the front-line health care professionals. This was resolved by having guidelines jointly signed off by NICE and NHSE and having the dual NICE/NHS branded guidelines.

41. An interim methods and process guide (PMG35) was developed to provide a framework for developing recommendations in a very short development timeframe. A copy of PMG35 is exhibited as **Exhibit PC/03 - INQ000315809.** On the 20 March 2020, PMG35 was approved by the GE. To prioritise development speed, PMG35 did not include detail on scoping, methods of evidence assessment

and synthesis, composition of guideline decision-making group or process for decision-making, or processes for considering potential conflicts of interests. PMG35 provided no detail on how or when the rapid COVID-19 guidelines would be updated. However, NHSE did confirm that health economic evaluations would not be required for recommendations developed using the rapid guidelines process.

42. The operational approach to developing the early COVID-19 rapid guidelines was based on incident management principles. This included a series of small independent 'cells' that worked with identified experts to scope and draft guidelines to the interim methods and processes. Each guideline development cell consisted of a topic lead with experienced guideline developers, NICE clinical advisers, project and editorial staff to work with identified experts to scope the topic, review evidence (and other relevant guidelines) and to draft recommendations.

43. Each cell reported to the Programme Director who in turn reported to the Director, Centre for Guidelines. Operationally, most issues were addressed within the guideline production cells. There were regular (daily but sometimes more often) meetings between the topic leads and Programme Director to discuss issues of concern (e.g. resource issues within the team, conflicting advice from clinical experts or from different organisations who responded to consultations). An example of this was in the development of the haematopoietic stem cell transplantation rapid guideline (NG164) where there was a difference in opinion between the clinical experts involved in developing the guideline and the national guidance on staff who tested positive or had symptoms of COVID-19. The escalation process worked with NHSE and wider system partners to agree that the rapid guideline recommendation on staffing these units could be included in the guideline. Similar escalations took place for NG178 (renal transplantation) which required discussions between senior NICE, NHS Blood and Transplant and NHSE colleagues to resolve recommendations on the appropriate course of action in the event that a potential transplant patient had not had a COVID-19 test.

44. The rapid guideline development process was very intense and required very long working hours for all of those involved, with some individuals working up to 16 hours a day to complete the work to quality and time. It was recognised that

individuals needed time to rest at the end of each development cycle, so the cells were stood down and new cells stood up for each development process.

45. Initially, daily searches for COVID-19 related evidence were undertaken to identify newly emerging evidence that might be relevant to and inform the COVID-19 rapid guidelines recommendations. This continuous surveillance approach differed to the surveillance approach used for guidelines prior to the COVID-19 pandemic, where guidelines were checked at defined time points post-publication to determine if they needed to be updated (further information can be found in paragraph 79).

Early guideline stakeholder selection process (March-September 2020)

46. An open call for stakeholders – as per the standard pre-pandemic process – for COVID-19 rapid guidelines was not undertaken. Rather, a limited number of stakeholders were identified and invited to become stakeholders.

47. To enable the accelerated development of the early COVID-19 guidelines, the period for stakeholder review of the draft guideline was reduced from 4-6 weeks (standard pre-pandemic process) to less than one working day, normally 09:00hrs to 16:00hrs the same day. To facilitate this, specific organisations were targeted to invite to be stakeholders, so that the number of comments received were manageable for the guidelines team (NICE staff and external experts) to review and make changes to the guideline within the very short turnaround time.

48. Similar to the standard pre-pandemic process, a central 'master' stakeholder list was developed and was used as the basis for all subsequent COVID-19 rapid guidelines during the early phase of the pandemic. The senior NICE team reviewed committee panel memberships from related NICE guidelines and sought input from the NHSE clinical leads and NICE Public Involvement Programme to identify organisations and contacts relevant to the early rapid guideline for inclusion on the central master stakeholder list to ensure the following key areas were represented:

    a. National health providers responsible for responding to system needs, e.g. NHSE, PHE, NHS Scotland and NHS Wales Health Collaborative;

    b. Key respiratory organisations e.g. British Thoracic Society;

c. Key royal colleges e.g. Royal College of Physicians; and

d. Key charity groups e.g. Richmond Group of Charities and Charity Medicines Access Coalition.

49. All organisations that agreed to join as stakeholders were required to sign a confidentiality undertaking. At the scoping stage for each early rapid guideline, the guideline team would review this central stakeholder list and if any topic-specific additions were required, the NICE team would contact them directly to invite them to join as a stakeholder.

Consolidation of interim methods and process

50. By July 2020, NICE SMT had approved an 'interim process and methods for guideline development in response to health and social care emergencies' – appendix L to the manual. This updated PMG35 and was published on the 07 July 2020. The updated version was based on lessons learned and expanded to include all public health emergencies and covered the development of rapid guidance, surveillance and updates to rapid guidance. It provided detail on methods and processes for scoping, convening independent expert panels, undertaking evidence reviews, capturing rationale for decision-making, consultation, minimum reporting standards, recording declarations of interest and equality impact assessments. The first iteration of appendix L, dated July 2020, is exhibited as **Exhibit PC/04 - INQ000252483.**

51. To build resilience in case of future emergencies, the process and methods for the development of guidelines in response to health and social care emergencies is now integral to the guideline's manual.

52. Once the initial waves of guidance had been developed, a COVID-19 guidelines team was established in September 2020 to consolidate rapid guideline maintenance and production. The team's purpose was:

a. To provide easily accessible guidance that helps people make the right healthcare decisions during the pandemic.

b. To develop, test and share efficient and innovative processes and methods for guideline development and maintenance (surveillance and updating) that enables timely advice for healthcare.

c. To integrate COVID-19 content to remove unnecessary duplication and create a single hub of COVID-19 guidance to enhance user experience.

53. The COVID-19 team followed the Interim methods and process set out above. By the team incorporating all aspects of COVID-19 guideline development, surveillance and updating functions, it was able to efficiently and rapidly undertake all aspects of the methods and process guideline lifecycle. Prior to pandemic, these functions were carried out by separate teams.

54. The July 2020 interim methods and processes resulted in some differences compared with the early rapid guideline topics and standard NICE guidelines, as follows:

- The development process was extended depending on the topic and its complexity and was typically around 5-6 weeks (compared with 5-10 days for the early rapid guidelines and 12-24 months for a standard NICE guideline).

- As the evidence base for COVID-19 became more comprehensive and the outputs of key trials emerged, it was possible to begin to review the evidence for some key questions using risk of bias assessments, formal statistical analyses (such as meta-analysis) and use of GRADE to assess the certainty of evidence by outcomes. GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.

- Similar to the early rapid guidelines, health economics was not routinely considered.

- International collaborations were established to share data analyses or study characteristics information to help expedite the development time (see paragraph 90).

- An independent advisory expert panel was convened for the guidelines to agree the scope, consider the evidence, develop recommendations (new and updated), and consider stakeholder feedback on the draft recommendations. Instead of a full public consultation, a targeted peer review approach was used to consult key stakeholders. A range of stakeholders was invited to take part, including relevant national professional and patient or carer groups. The length of the consultation depended on the urgency and complexity of the guideline and ranged from 1 day to 2 weeks. Thematic responses to the targeted peer review were published on the NICE website rather than providing responses to individual stakeholders' comments, as is the process for standard NICE guidelines.

- Compared with the early rapid guidelines, more dedicated patient involvement was included in the process as there were lay representatives on the advisory expert panel. This was more similar to standard NICE guidelines.

- The guidelines were published and updated using MAGICapp, an online authoring tool. Update information was listed on the NICE website to provide clarity on changes since previous versions of the guideline. Subscribers to MAGICapp would receive notifications of a new version of the guideline publishing.

55. The voluntary and community sector stakeholders were particularly hard hit by the pandemic. Many patient support organisations faced increased workloads whilst seeing a reduction in their funding streams. Despite this, NICE's patient-facing stakeholder organisations responded to COVID-19 with enthusiasm. They provided helpful and insightful comments, often at short notice, to ensure the rapid COVID-19 guidance reflected the views of patients, carers and the public. They also provided feedback on the rapid guidance itself, helping NICE establish a continuous quality improvement process as the portfolio developed.

56. As the pandemic progressed, NICE continued to recruit lay members and patient experts to the expert advisory panels, supporting people with reasonable adjustments. The standard involvement methods were adapted to fit with the move to virtual meetings. This included providing a virtual working guide, Zoom training,

laptop loans to those without and increased supportive check-ins with lay members. Pre-meets were introduced with the technical team and peer support offered with experienced lay members. Virtual engagement improved access to meetings for anyone unable to travel, such as those with disabilities. Diversity was an important consideration for managing the long-term effects of COVID-19 expert panel lay membership. The panel included five lay members (two role-shared), made up of one carer and the rest were people with lived experience, including two from ethnic minority backgrounds.

57. Key stakeholders, including organisations representing specific groups within society, were invited to get involved, in line with standard practice. For each COVID-19 rapid guideline, two key patient organisation networks were approached to participate (Richmond Group of Charities and Charity Medicines Access Coalition). In addition, NICE proactively engaged key equality organisations, for example the Race Equality Foundation (Managing the long-term effects of COVID-19 guideline) and Race on the Agenda ["ROTA"] (Thromboembolism guideline). For the guideline on Managing the long-term effects of COVID-19, NICE had virtual meetings with key patient groups, including ethnic minority membership, to ensure they understood how they could influence the guidance. For further details on the guideline's stakeholder process see below.

58. NICE COVID-19 rapid guideline recommendations were agreed by an independent advisory expert panel using a formal decision-making framework which included discussion of:

- The overall quality of the evidence or confidence in the expert opinion;
- The trade-off between benefit and harms;
- The impact on equity and equality;
- The feasibility of implementation (for example resources, capacity, settings and acceptability); and
- Consideration of efficacy, resources, equity, feasibility, acceptability and people's preferences and values.

59. A pragmatic and flexible approach was used for updating rapid guideline recommendations. This allowed for rapid changes in response to emerging evidence. At the beginning of the pandemic, working at speed and in areas where the evidence was limited meant initial recommendations sometimes needed to be modified quickly as further information emerged. As the pandemic progressed, recommendations were updated to reflect changes in the evidence base, clinical or healthcare practice, policy and living surveillance using a multifactorial approach to identify 'triggers' for update.

60. NICE conducted frequent update searches of literature, research and guidance (NICE's and other organisations') - called surveillance. The frequency of searching was reviewed over time, depending on the amount of new evidence being published. This surveillance process developed over time and in the development of a 'living guideline' approach, where guideline recommendations were continuously updated to respond to emerging evidence (see below).

Guideline stakeholder selection process (September 2020 – March 2023)

61. When the COVID rapid guidelines team was formalised in September 2020, the principles of targeted review by a limited number of selected stakeholder organisations were carried over. A list of 'peer review organisations' was determined by the NICE team, including the clinical advisers, building on the master stakeholder list used in the early rapid guidelines programme.

62. As with the rapid guidelines and the standard pre-pandemic process, the central list was reviewed by the NICE team and any co-developers at the beginning of development for each guideline / topic and input was sought from the topic advisers for those topics that were individually scoped. If any topic-specific additions were required, the NICE team would contact them directly to invite them to join as a stakeholder.

Stakeholder eligibility Criteria

63. The following stakeholder eligibility criteria is used for all NICE guidelines. The only difference between standard, pre-pandemic selection of stakeholders and that of the COVID rapid guidelines is that the number of stakeholders / peer review

organisations was limited. This was in order to make it more manageable in relation to the quick turnaround times in the accelerated development process.

- National organisations for people using services, carers and the public:
    - national charities, national patient, user or carer groups;
    - local or regional organisations when there is no national organisation that represents the group's specific interests; and
    - overseas organisations where there is no national UK organisation that represents their interests.
- National organisations representing practitioners:
    - health and social care practitioners;
    - professionals whose practice may be affected by the guideline; and
    - professionals who can influence the uptake of guideline recommendations, for example: Royal Colleges, medical associations, public health and social care professional associations.
- Public sector providers and commissioners (including public sector providers and commissioners of care or services). For example:
    - NHS trusts;
    - integrated care boards (ICBs);
    - primary care networks (PCNs);
    - local authorities; and
    - local Health-watch organisations.

- Organisations that fund or carry out research, including organisations that fund or undertake peer reviewed research. For example:
    - funding councils; and
    - universities based within the UK;
    - private, not-for-profit, voluntary providers of care or services, including:
        - private providers;
        - not-for-profit providers;
        - the voluntary sector; and
        - providers of care.
    - other independent providers, for example:
        - private hospitals;
        - hospices; and
        - care homes .
- Manufacturers and commercial industries, including companies that manufacture:
        - Medicines;
        - devices;
        - equipment or adaptations; and
        - commercial industries relevant to public health.

    This does not include the tobacco industry.

- Government departments and national statutory agencies, for example:
        - Department of Health and Social Care; and

- Public Health England.

- Overseas agencies with a remit covering the UK whose work is directly relevant to the UK population, e.g. The World Health Organisation ["WHO"].

Relationship with RAPID C-19

64. RAPID C-19 was a multi-agency initiative aimed at ensuring safe and timely patient access to treatments that showed evidence of benefit in preventing and treating COVID-19. The RAPID C-19 Oversight Group role was to provide advice to the Chief Medical Officer ["CMO"] on potential COVID-19 medicines in development (that could be expedited for patient access in the NHS), the strength of their clinical effectiveness for treating COVID-19 and suggested next steps. (Further information on RAPID C-19 is provided in Helen Knight's statement).

65. The relationship between RAPID C-19 and the COVID guidelines is illustrated in the therapeutics for COVID-19 process map, which is exhibited as **Exhibit PC/05** **INQ000316255** Where the RAPID C-19 Oversight Group identified a potential therapeutic for COVID-19, the COVID-19 guideline programme assessed it against the criteria set out in **figure 2** below and developed recommendations on its use, where appropriate.

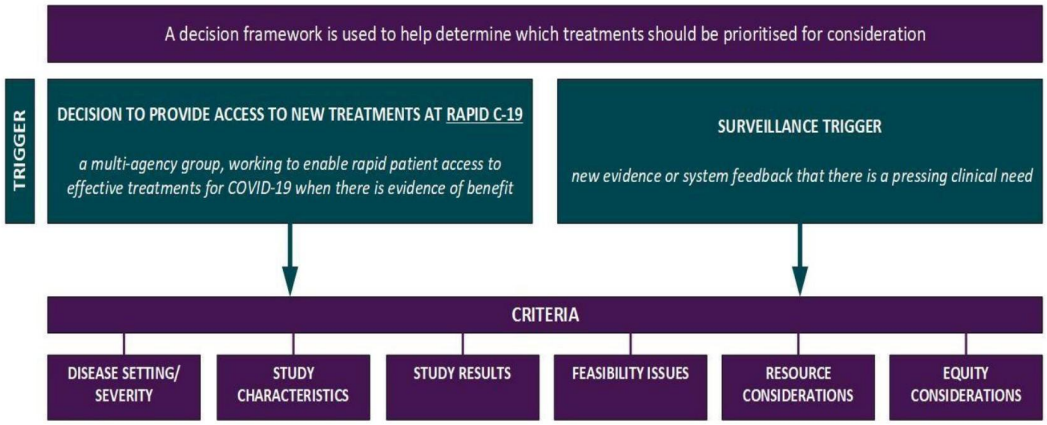

Figure 2: COVID guidelines prioritization criteria for COVID-19 therapeutics

Equality and Health Inequalities

66. Health inequalities are defined by NHSE as 'avoidable, unfair and systematic differences in health between different groups of people'. Health inequalities arise because of the conditions in which we are born, grow, live, work and age.

67. The Health and Social Care Act (2012) stipulates that policy makers and commissioners must 'have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service'. In reflection of this duty, NICE's principles, which guide the development of guidance and standards, include a specific aim to reduce health inequalities.

68. The impact on people with characteristics protected under the Equality Act 2010 was considered during development of COVID-19 rapid guidelines. An EIA was completed, and quality assured by NICE staff before submission of the draft guideline to NICE's GE. This process also took account of inequalities arising from socioeconomic factors and the circumstances of certain groups of people, such as parents, carers, and people who are homeless.

69. The EIA for NG191 Managing COVID-19 outlined that people who live in more socially deprived areas may be more likely to live in overcrowded housing and have occupations that might make them more at risk of exposure to COVID-19. In addition, some people may not have access to the equipment needed to take part in digital consultations and depending on where a person lives, they may not have access to home delivery services (for example, if they live in a rural area).

70. The Guideline Panel noted that for people whose first language is not English, there may be communication difficulties, especially for effective shared decision-making and minimising risk of infection. They also recognised that people who are homeless, refugees, asylum seekers and migrant workers may be living in deprived areas (including overcrowded accommodation), which may mean they are more likely to be exposed to COVID-19 and therefore, people from these groups may also be less likely to be able to access services.

71. To address these issues, the guideline recommended, in the section on communication and shared decision-making, that in the community, the risks and

benefits of face-to-face and remote care should be considered for each person. This would also allow issues such as an individual's ability to access remote care to be considered. With regards to people having difficulty accessing home delivery services depending on where they live (for example in rural areas), the guideline recommends optimising remote care where appropriate, such as pharmacy deliveries, postal services, NHS volunteers and introducing drive-through pick-up points for medicines. Providing a range of potential options may support access in different geographical areas. The guideline also covered the use of necessary medicines at the end of life. It was noted by the panel that if there are fewer health and care staff, differing formulations may be prescribed and family members may be able to support administration of medications if they wish and have been provided with appropriate training.

72. The Guideline Panel for NG188 Managing the long-term effects of COVID-19, acknowledged that particular issues may make it more difficult for certain groups to access services, for example due to mobility issues, carer responsibilities or location. Throughout the guideline, the importance of options for contact with services, including remote or face to face, was emphasised. The guideline also encouraged healthcare services to support access for people in underserved or vulnerable groups and set out a number of suggested proactive actions to reduce barriers and improve awareness and contact, including providing extra time or additional support in consultations and working with community leaders or organisations to raise awareness about the condition. In taking account of socioeconomic factors, the guideline recommended that advice on self-management should include how to get support from other services, including social care, housing and employment, and advice about financial support. The guideline also included research recommendations about how the effectiveness of interventions for post COVID-19 syndrome varies in different population groups, including socioeconomic groups.

Living guidelines

73. The learning from producing rapid guidelines informed a new guideline production model, called 'living guidelines'. This meant that guidelines could be continuously reviewed and updated in response to emerging evidence. The main stages of

guideline development were the same as for standard NICE guidelines and included scoping, reviewing the evidence, drafting recommendations and consulting stakeholders. However, as **figure 3** illustrates, the living guideline approach used to develop COVID-19 content was a continuous cycle of reviewing the evidence and rapid publication and updating as and when 'triggers' necessitate a change to recommendations. Moreover, to ensure development was responsive and maintained currency of guidance, some of the development stages would be undertaken iteratively or in parallel, or data from other organisations may be reused.

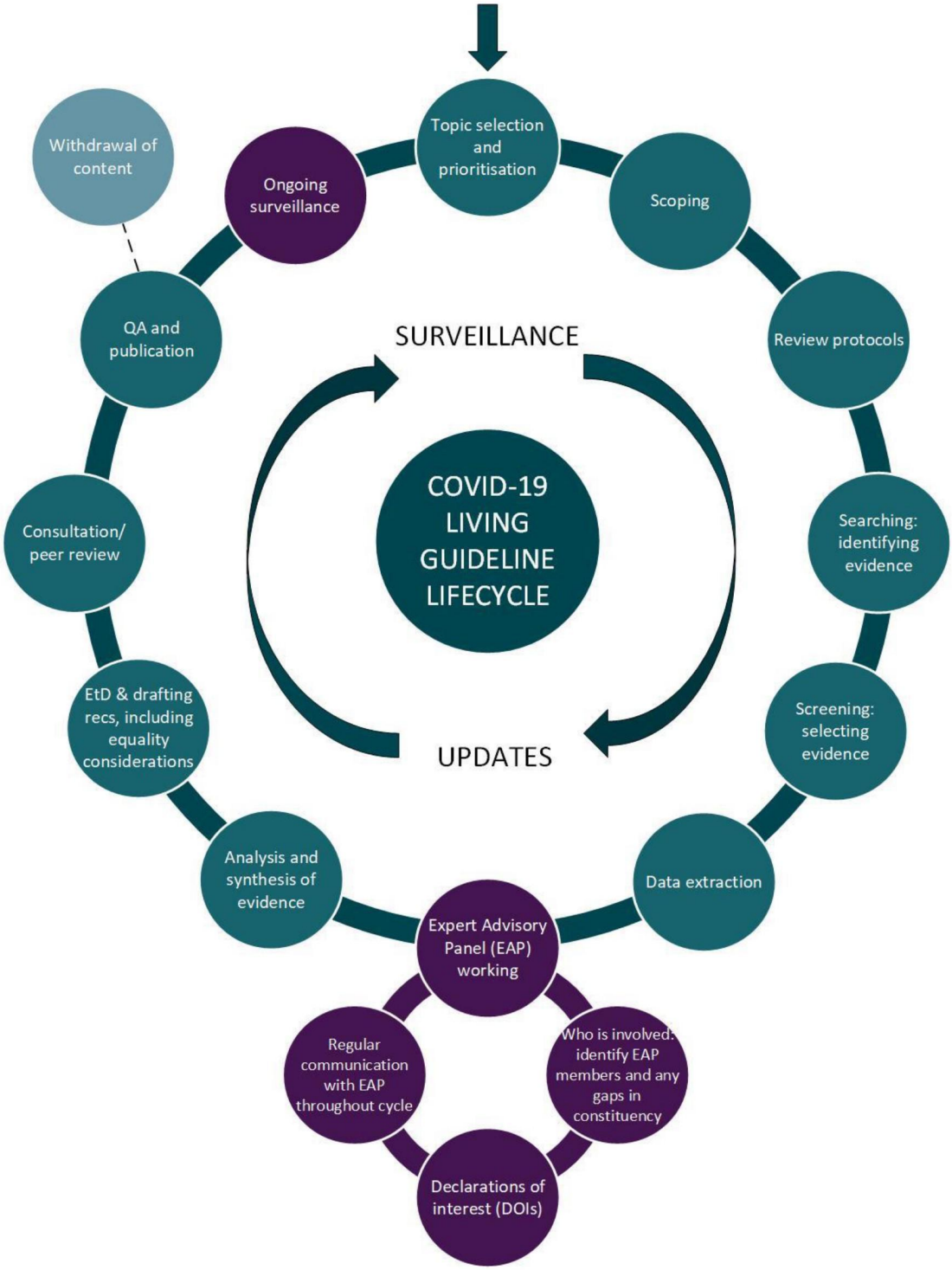

Figure 3: COVID-19 Living Guidelines Lifecycle

74. On 23 March 2021 NICE published the first 'living guideline', on the management of COVID-19 (NG191). The managing COVID-19 guideline included a section on

therapeutics for COVID-19 and consolidated the following early rapid COVID guidelines which were then withdrawn:

- NG159 Critical care in adults;
- NG163 Managing symptoms (including at the end of life) in the community;
- NG165 Managing suspected or confirmed pneumonia in adults in the community;
- NG171 Acute myocardial injury;
- NG173 Antibiotics for pneumonia in adults in hospital;
- NG175 Acute kidney injury in hospital; and
- NG186 Reducing the risk of venous thromboembolism in over 16s with COVID-19.

75. As therapeutics emerged as options for treating COVID-19 or complications of COVID-19, they were assessed and NG191 was continually updated to provide advice for healthcare practitioners based on best available evidence and consensus of the advisory expert panel.

76. The guidelines on vaccine-induced immune thrombocytopenia and thrombosis ["VITT"] and managing the long-term effects of COVID-19 also became living guidelines and were subject to continuous surveillance to identify any triggers for update.

Dissemination of guidelines and advice

77. NICE's field team and system engagement programmes adapted their approach, sensitive to NHS frontline needs and pressure. This included transitioning to virtual contacts and networks. The impact team gathered feedback from the system and collected examples of how the COVID-19 guidelines were being implemented, including a COVID-19 implementation survey; to help understand the impact of COVID-19 on the system and how best to support implementation once this could be resumed.

78. NICE's field team worked virtually to communicate information about the portfolio of COVID-19 products via their NICE manager network. This is a geographical network of individuals, most of whom work in NHS trusts, who support governance / assurance processes around the use of NICE guidance, including dissemination, implementation and monitoring. Support was offered to help the network understand how the COVID-19 portfolio aligned with NICE's existing guidance portfolio and how the COVID-19 specific content differed from the existing content, e.g., in frequency of update.

NICE Involvement in commissioning / designing clinical trials / research

Evidence Surveillance approach

79. From 20 March 2020, a search was updated each working day by NICE information specialists to identify newly published evidence that may be relevant to the COVID-19 rapid guidelines. This was changed to a weekly approach from 6 July 2020 to achieve efficiencies while maintaining timely monitoring of new evidence which fed into the COVID-19 guidelines surveillance, monitoring and updating process. This included new published papers, abstracts, comment pieces, preprints, news items and international guideline developments. The sources included Medline, EMbase and Cochrane bibliographic databases and guideline sources such as WHO, Public Health England ["PHE"] MHRA and Royal Colleges. These records were examined by the CfG surveillance and COVID-19 teams to determine whether they had an impact on guideline recommendations. A 2-step surveillance process was used; first a 'triage' sift was carried out to identify records that were potentially relevant to COVID-19 medicines. Potentially relevant records then underwent a second level of sifting and records relevant to the COVID-19 recommendations were identified.

80. Automation was used to accelerate this process using a validated machine learning classifier. During the relevant period, NICE identified and reviewed, either manually or with automation, 322,789 studies on COVID-19 overall. Of these, 3,789 related to randomised controlled trials (RCTs) on medicines for COVID-19, and 1,176 of these were included for further assessment of potential impact on

existing recommendations or the need for new recommendations. Most studies were rejected on the grounds of relevance and/or risk of bias.

Monitoring ongoing research

81. Relevant studies, systematic reviews, polices and data sources were identified throughout guideline development, update and surveillance and were continuously monitored. This information was considered for its impact on the guidelines as it became available and was used to inform the decision on whether to update the recommendations.

82. A dashboard was established that automatically checked for progress of ongoing trials listed on trial registries or likely to report on PubMed (a search engine accessing the MEDLINE database of references and abstracts on life sciences and biomedical topics). For guidelines, the relevance of these studies was assessed using the following criteria:

    a. The study was adequately powered to address a PICO[1] relevant to the guideline (generally not pilot or feasibility studies);

    b. Findings from the study were likely to be applicable to practice in the NHS;

    c. Relevance to the guideline's PICO or addresses a PICO that may have been relevant to an update;

    d. Directly addressed an uncertainty highlighted in a research recommendation; and

    e. For non-trial events, judgement as to the relevance of the event to the guideline was made on a case-by-case basis.

[1] Population Intervention Comparison Outcome. PICO is a way to help structure a research question and then take that question and translate it into search phrases to find clinical information relating to a specific intervention or therapy.

Other intelligence

83. The guidelines team also undertook a pragmatic targeted intelligence gathering approach, based on the evolving system and policy context and emerging evidence base, to gather feedback from the broader health and care systems and NICE stakeholders, including the identification of relevant datasets that could be used to address areas of uncertainty within the guidelines – for example, datasets published alongside peer-reviewed manuscripts, preliminary reports and experiential feedback from front-line workers – and other related NICE guidance.

NICE's response

84. Evidence and information was considered for impact on guideline recommendations when it became available (known as an impact assessment). The outcomes of the impact assessments were:

a. No update to the guideline or recommendations;

b. Refresh the guideline or recommendations (make changes to the guideline without reviewing the evidence);

c. Rapid update of the guideline or recommendations; and

d. Withdraw the guideline or recommendations.

85. Rapid updates to the recommendations could involve consideration of new evidence from trials. I exhibit, as **Exhibit PC/06-INQ000252485,** a spreadsheet summarising NICE's involvement in responding to clinical trials or research concerning medications recommended to treat COVID-19.

Research Recommendations

86. As NICE developed its COVID-19 guidance, gaps and uncertainties in the evidence base were identified which could benefit from further research. The most important unanswered questions were developed into research recommendations. Research recommendations were made if:

a. There was a lack of evidence,

b. The evidence was uncertain,

c. The recommendations were based on the independent advisory expert panel's knowledge and experience, rather than on evidence.

87. All research recommendations developed for the COVID rapid guidelines were listed on the research recommendations database on the NICE website. They were developed using the 'research recommendations methods and process guide 2015' - a copy of which is exhibited as **Exhibit PC/07-INQ000315818**.

88. NICE works closely with the National Institute for Health Research ["NIHR"] Evaluation, Trials and Studies Co-ordinating Centre ["NETSCC"]. NETSCC reviews the recommendations from the database as well as other sources and explores their suitability for funding.

89. For the long-term effects of COVID-19 guideline, further work with the NIHR informed the calls for research on the topic, by making research recommendations to prioritise evidence gaps. This led to numerous NIHR funded research projects. The research recommendations were driven by the high level of importance to patients, the national priority of the long-term effect of COVID-19 and its potential impact on the health care systems.

International Collaboration

90. In addition to making COVID-19 rapid guidelines freely available to health care practitioners around the world without the normal international licensing fees, as the pandemic progressed, several international collaborations were established and utilised for the development and maintenance of the COVID-19 rapid guidelines, as illustrated in **table 1** below and in **Exhibit PC/08 - INQ000252487**.

Country	Project
Global	**The World Health Organisation (WHO).** WHO produced guidance on the clinical management of COVID-19. The guidance included recommendations on diagnosing, assessing and managing COVID-19. It was used to inform the key themes in the scope of the 'Managing COVID-19 rapid guideline (NG191)'.
Global	Following publication of 'Managing the long-term effects of COVID-19 rapid guideline (NG188)', an international collaborative group was convened to share experience, new evidence and intelligence. NICE shared its quarterly surveillance evidence summaries with this group. The group comprised **WHO, Public Health Agency of Canada, Canadian Agency for Drugs and Technologies in Health, National Australian COVID-19 clinical evidence taskforce, and the Agency for healthcare research and quality, Danish Health Authority**. The Public Health Agency of Canada, provided a pre-print for a systematic review on signs, symptoms and prevalence for the update to NG188.
Norway	**Norwegian Institute of Public Health and MAGICapp**. MAGICapp is a digital authoring and publication platform for the evidence ecosystem, by the MAGIC Evidence Ecosystem Foundation. The Head of MAGIC is Per Olav Vandvik, an Associate Professor at the Department of Health Management and Health Economics at the Faculty of Medicine, University of Oslo, Norway. This publishing platform was used to develop, publish and update the following guidelines: • NG191: Managing COVID-19; • NG188: Managing the long-term effects of COVID-19; and • NG200: Vaccine-induced immune thrombocytopenia and thrombosis (VITT).
Australia	**Australian national COVID-19 Clinical Evidence task force.** NICE collaborated with the task force to produce evidence reviews. NICE, reused data from the task force to inform some recommendations in NG191: Managing COVID-19. Data was either used as shared or was supplemented with

	additional trial results that NICE had accessed through evidence searches conducted in-house. Evidence provided by the taskforce was used through the sharing of RevMan files, which the NICE team used to populate the evidence summaries and GRADE profiles for a review. Data extraction and risk of bias was done in line with the 'interim process and methods for guideline developed in response to health and social care emergencies. This work informed the following evidence reviews: • Evidence review on remdesivir (February 2021); • Evidence review on corticosteroids (March 2021); • Evidence review on tocilizumab (March 2021); • Evidence review on sarilumab (March 2021); • Evidence review on colchicine (April 2021); • Evidence review on azithromycin (May 2021); and • Evidence review on ivermectin (October 2021).
Spain	**UpPriority Implementation Working Group** to test a framework for prioritising COVID recommendations for surveillance.
Spain	**Living Evidence** to inform Health Decisions project to test approaches for maintaining living COVID recommendations.
Germany	**German Cochrane Group.** The group had done a recent review of respiratory support strategies in adults in hospital with suspected or confirmed COVID-19 who require escalation of respiratory support from oxygen therapy. NICE used their data and analyses to inform the 'respiratory support strategies in adults in hospital with suspected or confirmed COVID-19 who require escalation of respiratory support from oxygen therapy evidence review (March 2022)'.
Canada, led by	Development of e-COVID recommendations map to share up to date guidance on COVID-19.

McMasters University	**COVID-19 Evidence Network (COVID-END)** coordination group. Aimed to support decision-making to find and use the best evidence and to help reduce duplication in and better coordinate the evidence syntheses, technology assessment and guidelines being produced globally. Adoption framework for guideline developers to share and adopt and adapt others guidance for COVID-19.
Canada	**University of Manitoba.** NICE collaborated to produce the evidence review on heparins (February 2021). A researcher from the University provided expert testimony on their study at the panel meeting.
United States	**National Institute of Health** to share knowledge of COVID-19 guidance.
United States	**FDA** diagnostics and therapeutics evidence accelerator. A platform for data organisations and researchers in the real-world evidence space to gather, quickly design experiments and share their results.
Philippines and Portugal	**Philippines and Portuguese Health Ministries** NICE shared its experience and learning from guideline development and surveillance to assist in developing their guidelines.
European	**Innovative Medicines Initiative (IMI) European Health Data and Evidence Network (EHDEN) project and the IMI Value Dx project.** The EHDEN project launched a COVID-19 data partner call that has resulted in 28 data partners, who all have relevant COVID-19 databases, to be mapped to the common data model. This allowed rapid data analysis on European data from 11 countries, covering more than 150 million patient records. In addition, the EHDEN project also explored how the network can help facilitate research into the impact of COVID-19 on healthcare delivery. Databases from the UK that are being added to the EHDEN network include CPRD and SAIL. NICE a project partner.

Table 1: International Collaborations

91. In May 2020, NICE delivered a webinar for international organisations on NICE's response to COVID-19. The webinar was attended by more than 300 participants from 42 different countries.

Guidelines and advice produced during the relevant period

92. During the relevant period, NICE published 24 COVID-19 rapid guidelines as set out in **table 2** below –which were viewed in excess of 4 million times. In addition, **Exhibit PC/09 - INQ000252488** provides the detail of the matters addressed by each guideline, the development time and the publication date and is exhibited as:

NICE guideline reference	COVID-19 rapid guidelines title	Exhibit number
NG159	Critical care in adults	**Exhibit PC/14 - INQ000315780**
NG160	Dialysis service delivery	**Exhibit PC/15 - INQ000415424**
NG161	Delivery of systemic anti-cancer treatments	**Exhibit PC/16 - INQ000066688**
NG162	Delivery of radiotherapy	**Exhibit PC/17 - INQ000415448**
NG163	Managing symptoms (including at the end of life) in the community	**Exhibit PC/18 - INQ000315781**
NG164	Haematopoietic stem cell transplantation	**Exhibit PC/19 - INQ000315782**
NG165	Managing suspected or confirmed pneumonia in adults in the community	**Exhibit PC/20 - INQ000415428**
NG166	Severe asthma	**Exhibit PC/21 - INQ000415429**
NG167	Rheumatological autoimmune, inflammatory and metabolic bone disorders	**Exhibit PC/22 - INQ000315783**
NG168	Community-based care of patients with chronic obstructive pulmonary disease (COPD)	**Exhibit PC/23 - INQ000415431**
NG169	Dermatological conditions treated with drugs affecting the immune response.	**Exhibit PC/24 - INQ000315784**

NG170	Cystic fibrosis	**Exhibit PC/25 - INQ000415433**
NG171	Acute myocardial injury	**Exhibit PC/26 - INQ000315785**
NG172	Gastrointestinal and liver conditions treated with drugs affecting the immune response	**Exhibit PC/27 - INQ000315786**
NG173	Antibiotics for pneumonia in adults in hospital	**Exhibit PC/28 - INQ000315787**
NG174	Children and young people who are immunocompromised	**Exhibit PC/29 - INQ000415437**
NG175	Acute kidney injury in hospital	**Exhibit PC/30 - INQ000415438**
NG176	Chronic kidney disease	**Exhibit PC/31 - INQ000415439**
NG177	Interstitial lung disease	**Exhibit PC/32 - INQ000415440**
NG178	Renal transplantation	**Exhibit PC/33 - INQ000415441**
NG179	Arranging planned care in hospitals and diagnostic services	**Exhibit PC/34 - INQ000415442**
NG186	Reducing the risk of venous thromboembolism in over 16s with COVID-19	**Exhibit PC/35 - INQ000415443**
NG187	Vitamin D	**Exhibit PC/36 - INQ000315788**
NG188	Managing the long-term effects of COVID-19	**Exhibit PC/37 - INQ000238545**
NG191	Managing COVID-19	**Exhibit PC/38 - INQ000315790**
NG200	Vaccine-induced immune thrombocytopenia and thrombosis (VITT)	**Exhibit PC/39 - INQ000315791**

Table 2: COVID-19 Rapid Guidelines

93. During the relevant period NICE published a range of guidelines and advice relating to the diagnosis, assessment, management or treatment of COVID-19. This included:

- 3 Living guidelines – NG188: Managing the long-term effects of COVID-19; NG191: Managing COVID-19 and NG200: Vaccine induced immune thrombocytopenia and thrombosis.

- 8 Rapid Evidence Summaries – ES23: Acute use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19; ES26: Anakinra for COVID-19 associated secondary haemophagocytic lymphohistiocytosis (sHLH); ES24:Angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) in people with or at risk of COVID-19; ES25: Long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19; ES27: Remdesivir for treating hospitalised patients with suspected or confirmed COVID-19; ES28:Vitamin D for COVID-19; ES33 / ER7: Tocilizumab for COVID-19; and ES34 / ER8 : Sarilumab for COVID-19.

- 1 Clinical Knowledge Summary - Coronavirus: COVID-19 Summary (continually updated).

- 2 Medicine Evidence Commentary - Vitamin D supplementation for preventing intensive care admissions in people with COVID-19 associated pneumonia; Vitamin D levels and severity of COVID-19 illness.

- 1 Prescribing Briefing – Corticosteroids.

94. I exhibit as **Exhibit PC/10 - INQ000252489**, a spreadsheet, which provides a chronological list of all NICE guidelines, advice and other products relating to the diagnosis, assessment, management or treatment of COVID-19 and the impact of COVID-19 on other medical conditions or treatment pathways, during the relevant period. This spreadsheet details the matters addressed in each product, date of publication, date and reason for any updates, who contributed to the guidance development and any international collaborations.

95. I also exhibit as **Exhibit PC/11-INQ000252490**, a spreadsheet of all guidance and advice published by NICE (or to which NICE contributed) during the relevant period, that contained recommendations in relation to:

a. Changes to oxygen guidelines, specifically lowering the target saturation from 94%-98% in response to increased oxygen demand and limited supply;

b. Infection Prevention and Control measures in healthcare settings;

c. Changes to healthcare provision in primary care;

d. Any acute care guidance which contained reference to the Clinical Frailty Scale;

e. Ambulance services and paramedics;

f. 999 and 111 services;

g. Palliative and end of life care for patients with COVID-19;

h. Do Not Attempt Cardiopulmonary Resuscitation ["DNACPR"] notices; and

i. The diagnosis or treatment of the condition known as Long COVID.

96. By way of explanation of **Exhibit PC/11-INQ000252490**:

- The 'Summary Statistics' tab, tab one, provides a chart outlining the number of recommendations given by NICE that pertain to each topic listed above. This includes a tally of recommendations within NICE guidelines, Specialty guides and the Clinical Knowledge Summary. The number of guidelines tackling health inequalities is also shown here.

- In the 'Guidelines Relevant Recommendations' tab, tab two, the relevant recommendations, in COVID-19 rapid guidelines, in relation to (a) to (i) above are identified. This includes the indication of which recommendations address inequality issues. Additionally, the tab provides the initial date of each recommendation's publication and any subsequent updates.

- The 'Guideline Checklist' tab, tab three, lists all of COVID-19 rapid guidelines that contain any relevant recommendations in relation to (a) to (i) above. This tab also provides a summary of matters addressed by each guideline, the intended audience and the professional bodies that were involved in guideline development.

- The tabs labelled 'Specialty Guide Advice ' and 'Specialty Guide Checklist' contain similar information to tabs two and three but focus on the specialty guides.

- Similarly, the tabs labelled 'Clinical Knowledge Summary Advice ' and 'Clinical Knowledge Summary Checklist' contain information similar to that in tabs two and three, but specifically for a Clinical Knowledge Summary.

97. **Table 3** below provides an overview of all the relevant COVID-19 rapid guidelines, the initial publication date and the matters addressed by each guideline provided within **Exhibit PC/11- INQ000252490**. It also identifies which of the topics listed in paragraph 84 above are relevant to each guideline. The full details of the recommendation covered by each guideline can be found in **Exhibit PC/11 INQ000252490**, 'Guidelines Relevant Recommendations' tab. It is important to note that all COVID-19 rapid guidelines were developed using the 'interim process and methods for guidelines developed in response to health and social care emergencies' (Appendix L of the NICE guidelines manual). In addition, all these guidelines were new and produced to respond to the COVID-19 pandemic.

Guideline title and initial date published	**Summary of matters addressed**	**Recommendation topics**
NG159 Critical Care in Adults (20.03.2020)	This guidance aims to increase the safety of patients requiring critical care during the COVID-19 pandemic and protect staff from infection while effectively utilising NHS resources. The guidance recommends actions to adopt or cease during the pandemic,	Infection prevention & control in healthcare settings Clinical Frailty Score DNACPR

	while adhering to the existing professional standards and laws.	
NG160 Dialysis Service Delivery (20.03.2020)	The guideline provides rapid advice for delivering dialysis services during the COVID-19 pandemic. It is designed to maximise patient safety, protect staff from infection, and optimise the use of NHS resources. It includes recommendations for effective communication with patients to alleviate their anxiety about COVID-19 and to ensure they follow necessary precautions. This includes the use of telephone or video consultations and home delivery services for medicines.	Infection prevention & control in healthcare settings Ambulance and Paramedics
NG161 Delivery of systematic anticancer treatments (03.04.2020)	The guideline focuses on delivering systemic anticancer treatments during the COVID-19 pandemic, ensuring patients' safety, optimal utilisation of NHS resources, and staff protection from infection. The guidance draws from existing national and international policies, and specialist advice from across the UK's NHS. The guideline includes an interim table of treatment regimens, and directions on the necessary adjustments to service delivery during the pandemic.	Infection prevention & control in healthcare settings
NG162 Delivery of radiotherapy (28.03.2020)	This rapid guideline focuses on the delivery of radiotherapy during the COVID-19 pandemic with the objective of safeguarding patients needing such treatments and ensuring optimal use of NHS resources. This guideline complements other professional	Infection prevention & control in healthcare settings 999 and 111 services

	guidelines, standards and laws, and is based on expert advice from specialists and on relevant national and international policies.	
NG163 Managing symptoms (including at the end of life) in the community (03.04.2020)	This document is a rapid guideline focusing on the management of COVID-19 symptoms in the community, including at the end of life. The guidance emphasises the need for effective communication with patients, minimising face-to-face contact through methods such as telephone or video consultations, and electronic prescriptions. It further underscores the importance of comprehensive care planning and symptom management, taking into account each patient's underlying health conditions and the potential for rapid deterioration.	Infection prevention & control in healthcare settings 999 and 111 services Palliative and end of life care for people with COVID-19 Changes to healthcare provision in primary care DNACPR
NG164 Haematopoietic stem cell transplantation (01.04.2020)	This COVID-19 rapid guideline is tailored towards ensuring the safety of patients requiring haematopoietic stem cell transplantation (HSCT), while optimising NHS resources and safeguarding staff from infection.	Infection prevention & control in healthcare settings Ambulance & Paramedics
NG165 Managing suspected or confirmed pneumonia in adults in the community (03.04.2020)	The guideline provides detailed instructions for managing adults with suspected or confirmed pneumonia in the community during the COVID-19 pandemic, including how to communicate effectively with patients, minimise infection risk, plan treatment and care, and diagnose and assess patients' condition. It emphasises on remote consultations where possible	Infection prevention & control in healthcare settings Changes to healthcare provision in primary care 999 and 111 services

	and utilises various remote consultation tools and practices. It also outlines the symptoms for severity identification, the application of assessment tools, and the differentiation between viral COVID-19 pneumonia and bacterial pneumonia.	Palliative and end of life care for patients with COVID-19 DNACPR Ambulances and Paramedics
NG166 Severe Asthma (03.04.2020)	This guideline, produced in response to the COVID-19 pandemic, aims to ensure the safety of adults and children with severe asthma whilst protecting healthcare staff from infection. Its purpose is also to enable effective use of NHS resources. The guidance integrates existing national and international guidance and advice from specialists across the UK.	Infection prevention and control in healthcare settings
NG167 Rhuematological autoimmune, inflammatory and metabolic bone disorders (03.04.2020)	The purpose of this guideline is to maximise the safety of children and adults with rheumatological autoimmune, inflammatory and metabolic bone disorders during the COVID-19 pandemic, while protecting staff from infection. It also enables services to make the best use of NHS resources.	Infection prevention and control in healthcare settings 999 and 111 services Ambulance and Paramedics Changes to healthcare provision in primary car
NG168 Community-based care of patients with chronic obstructive pulmonary disease (COPD). (09.04.2020)	The guidance discusses the provision of community-based care for chronic obstructive pulmonary disease (COPD) patients amid the COVID-19 pandemic, ensuring both patient safety and protection for staff. It incorporates a combination of existing national and	Infection prevention and control in healthcare settings Changes to healthcare provision in primary care

	international guidance, specialist advice, and additional measures to address the evolving pandemic.	999 and 111 services Palliative and end of life care for patients with COVID-19 DNACPR
NG169 Dermatological conditions treated with drugs affecting the immune response (09.04.2020)	The guideline was developed in response to the COVID-19 pandemic to ensure safety for individuals with dermatological conditions that are treated with immunosuppressive drugs. It covers aspects from patient communication to drug supply and treatment considerations, specifically catering to patients known to have COVID-19 and those suspected of having it. The guidelines also provide advice for modifications to regular care practices and protective measures for healthcare workers.	Infection prevention and control in healthcare settings Changes to healthcare provision in primary care 999 and 111 services
NG170 Cystic Fibrosis (09.04.2020)	The COVID-19 rapid guideline on cystic fibrosis was developed to maximise patient safety, optimise NHS resources, and protect staff during the pandemic. The guidance focuses on necessary adaptations during COVID-19 and underscores the continuation of usual professional guidelines, standards, and laws. Guidance is also given for shielding patients not known to have COVID-19, as well as treatment advice for patients known or suspected to have the virus. Healthcare workers are guided on how to handle potential COVID-19 cases in	Infection prevention and control in healthcare settings Changes to healthcare provision in primary care 999 and 111 services

	these patients and how to follow infection prevention and control procedures.	
NG171 Acute Myocardial injury (23.04.2020)	The guideline provides specific recommendations for the identification and management of acute myocardial injury and its complications in adult patients with known or suspected COVID-19, but without pre-existing cardiovascular disease. It encompasses aspects of patient communication, risk minimisation for both patients and healthcare workers, and the diagnostic and management procedures specific to acute myocardial injury in the context of COVID-19.	Infection prevention and control in healthcare settings
NG172 Gastrointestinal and liver conditions treated with drugs affecting the immune response (23.04.2020)	The COVID-19 rapid guideline on gastrointestinal and liver conditions treated with drugs affecting the immune response aims to ensure the safety of individuals with such conditions during the pandemic while protecting healthcare staff and optimizing NHS resources. The document provides recommendations for various aspects of care delivery.	Infection prevention and control in healthcare settings 999 and 111 service Changes to healthcare provision in primary care
NG173 Antibiotics for pneumonia in hospital (01.05.2020)	This guideline outlines the management of suspected or confirmed bacterial pneumonia in adults hospitalised during the COVID-19 pandemic. It provides guidance for diagnosing, treating, and reassessing patients, with the overarching goal of ensuring optimal use of NHS	Palliative and end of life care for people with COVID-19 DNACPR

	resources. It encourages discussions with patients and their families about risks, benefits, and possible outcomes of treatment options. It underscores the importance of distinguishing between bacterial pneumonia and COVID-19 pneumonia, given that antibiotics are ineffective for the latter.	
NG174 Children and Young people who are immunocompromised (01.05.2020)	The guideline details the management and treatment of children and young people who are immunocompromised during the COVID-19 pandemic, with the aim of maximising their safety and using NHS resources effectively. It encompasses primary and secondary immunodeficiencies and chronic diseases associated with immune dysfunction. The guideline details protocols to minimise risk and safeguard mental wellbeing, including communication strategies, reassurance tactics, and advice on regular appointments. It offers instructions for safeguarding and planning if parents or carers have COVID-19.	Infection prevention and control in healthcare settings 999 and 111 services
NG175 Acute kidney injury in hospital (06.05.2020)	The guideline provides critical recommendations to help healthcare professionals prevent, detect, and manage acute kidney injury (AKI) in adults in hospital with known or suspected COVID-19. It aims to improve outcomes and reduce the need for renal replacement therapy. The document focuses on adjusting practices during the pandemic whilst	Infection prevention and control in healthcare settings Palliative and end of life care for people with COVID-1 DNACPR

	upholding usual professional guidelines, standards, and laws.	
NG176 Chronic kidney disease (15.05.2020)	This NICE guideline provides crucial guidance for the management of adults with chronic kidney disease (CKD) during the COVID-19 pandemic. The document outlines strategies to protect staff and patients, and make the most efficient use of National Health Service (NHS) resources. The guidance encompasses a variety of recommendations including ensuring communication with patients and supporting their mental wellbeing, minimising risk through telehealth and reducing face-to-face contact, and providing specific advice for patients with high-risk health conditions. The document offers instructions for the management of patients known or suspected to have COVID-19 and provides a framework for modifying usual CKD care to limit patient exposure to COVID-19 while maximising resource use.	Infection prevention and control in healthcare settings 999 and 111 services Palliative and end of life care for people with COVID-19 DNACPR
NG177 Interstitial lung disease (15.05.2020)	The guideline addresses safe practices for adults with interstitial lung diseases like idiopathic pulmonary fibrosis and pulmonary sarcoidosis amid the COVID-19 pandemic. It focuses on patient communication, minimising risk, symptom assessment, referral practices, disease investigations, patient management, treatment adjustments, and medication supply during the crisis. The guideline also	Infection prevention and control in healthcare settings 999 and 111 services Palliative and end of life care for people with COVID-19 DNACPR

	encourages consultation with specialists, multidisciplinary teams, and palliative care teams when required, and refers to various UK and NHS resources and guides for further information.	
NG178 Renal transplantation (19.06.2020)	This guideline covers children, young people and adults who need or who have had a kidney transplant, and people who are donating a kidney (live donors). It also advises transplant and referring centres on how to run their services while keeping them safe for patients, donors and staff during the COVID 19 pandemic.	Infection prevention and control in healthcare settings 999 and 111 services
NG179 Arranging planned care in hospitals and diagnostic services (27.07.2020)	The document provides guidance on arranging planned care, such as elective surgery, interventional procedures, diagnostics, and imaging, in hospitals and diagnostic services amidst the COVID-19 pandemic. The guideline seeks to enable healthcare professionals to deliver efficient planned care while minimising the risk of COVID-19. The guidance also assists patients in making decisions about their planned care.	Infection prevention and control in healthcare settings 999 and 111 services
NG186 Reducing the risk of venous thromboembolism in over 16s with COVID-19 (20.11.2020)	This guideline outlines pharmacological VTE (venous thromboembolism) prophylaxis for patients undergoing treatment for COVID-19 pneumonia across diverse care settings such as hospitals, community 'hospital at home' services, or 'virtual wards'. It emphasises the	

	application of usual professional guidelines, laws, and standards during its usage.	
NG187 Vitamin D (17.12.2020)	This guideline addresses the usage of vitamin D in the context of COVID-19 for individuals of all ages in hospitals and community settings. It recognises the importance of vitamin D for bone and muscle health and its potential role in the body's immune response to respiratory viruses.	
NG188 Managing the long-term effects of COVID-19 (18.12.2020)	This guideline covers identifying, assessing and managing the long-term effects of COVID-19, often described as 'long COVID'. It makes recommendations about care in all healthcare settings for adults, children and young people who have new or ongoing symptoms 4 weeks or more after the start of acute COVID-19. It also includes advice on organising services for long COVID.	Diagnosis and treatment of Long COVID Infection prevention and control in healthcare settings Changes to healthcare provision in primary care
NG191 Managing COVID-19 (11.11.2021)	This guideline covers the management of COVID-19 for babies, children, young people and adults in all care settings. It brings together our existing recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily.	Infection prevention and control in healthcare settings Changes to healthcare provision in primary care Ambulance and paramedics

		Palliative and end of life care for people with COVID-19 DNACPR Clinical Frailty Score
NG200 Vaccine-induced immune thrombocytopenia and thrombosis (VITT) (29.07.2021)	This guideline covers vaccine-induced immune thrombocytopenia and thrombosis (VITT), a syndrome which has been reported in rare cases after COVID-19 vaccination. VITT may also be called vaccine-induced thrombotic immune thrombocytopenia (VIPIT) or thrombotic thrombocytopenic syndrome (TTS). Because VITT is a new condition, there is limited evidence available to inform clinical management, identification and management of the condition is evolving quickly as the case definition becomes clearer. This guideline was produced to support clinicians to diagnose and manage this newly recognised syndrome.	Infection prevention and control in healthcare settings Changes in healthcare provision in primary care 999 and 111 services

Table 3: Summary of guidelines and key topics.

98. The COVID-19 rapid guideline on critical care (NG159) was one of the first rapid guidelines published. It was developed to support critical care teams in their management of patients during a very difficult period of intense pressure in the early stages of the pandemic. The guideline said that on admission to hospital, all adults should be assessed for frailty and that other comorbidities and underlying health conditions should also be taken into account. NICE recommended the use of the Clinical Frailty Scale ["CFS"], a tool that had been around for many years and available from the NHS Specialised Clinical Frailty Network. The CFS is not a

tool developed by NICE. NICE made it clear that clinicians should take any decisions about care in conjunction with patients and their carers where possible.

99. Following publication of the guideline on the 20 March 2020, concerns were raised by patients and groups about the use of the CFS in people with conditions that require them to have help in daily tasks, for example people with autism, learning disabilities and physical disabilities. In addition, the NHS Specialist Clinical Frailty Network made a recommendation that the CFS should not be used in certain groups, including those with learning disability and cerebral palsy. In response, during March and April 2020, NICE published a number of guideline updates to offer additional clarifications on the use of the CFS, as can be seen in **Exhibit PC/10 – INQ000252489**. This included on the 25 March 2020, a rapid clarification that the CFS should not be used in certain groups including people with stable long-term disabilities (for example, cerebral palsy), learning disabilities or autism. It also clarified that an individualised assessment is recommended in all cases where the CFS is not appropriate and that when used it should be part of a holistic assessment.

100. In November 2021 NICE became aware of potential bias in relation to the use of pulse oximeters to measure oxygen saturation levels. Reports in the media identified that the Secretary of State for the DHSC had ordered a review into racial bias in medical devices. As a result, rapid guideline NG191 was updated with the following text:

"*When pulse oximetry is available in primary and community care settings, to assess the severity of illness and detect early deterioration, use:*

- *NHS England's guide to pulse oximetry in people 18 years and over with COVID-19*
- *oxygen saturation levels below 91% in room air at rest in children and young people (17 years and under) with COVID-19.*

Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. For more information about this, see

NHS England's guide on how to look after yourself at home if you have COVID-19 or symptoms of COVID-19.

For information on pulse oximetry at home, see NHS England's COVID oximetry @home service."

101. **Table 4** below identifies the Speciality guides within **Exhibit PC/11 - INQ000252490** and provides a summary of the matters addressed by each guide, initial publication date, as well as identifying which of the topics listed in paragraph 84 above are relevant to each guidance. The full details of the recommendation covered by each guideline can be found in **Exhibit PC/11 - INQ000252490**, 'Speciality Guide Advice' tab. As previously explained, Speciality guides were one-off products, produced by NHSE and published by NICE.

Speciality guide title and initial date published	**Summary of matters addressed**	**Topics covered**
Acute kidney injury in hopitalised patients with COVID-19 outside the intensive care unit (17/04/202)	This guide provides guidance for managing acute kidney injury (AKI) in patients hospitalised with COVID-19, but outside of the intensive care unit (ICU). It outlines the responsibilities of healthcare professionals and the importance of understanding AKI in the context of COVID-19. It emphasises the need for quick recognition and management of AKI, as it presents a risk to mortality and reflects underlying morbidity.	DNACPR. Palliative and end of life care for people with COVID
Critical care (08/04/2020)	This guide provides contemporary information on the care of critically ill adult patients with COVID-19 to practising clinicians at the bedside. This guide summarises the clinical characteristics of COVID-19 and offers advice on:	COVID prevention & control. DNACPR

	• Antibiotics and corticosteroids; • Treatment of other conditions in the context of COVID-19; • Clinical decision-making when resources may be constrained; • Management of respiratory failure; • Management of other organ failure; • Continuous positive airway pressure (CPAP) and non-invasive ventilation (NIV); and • Early intubation – indications and role.	Palliative and end of life care for people with COVID. Lowering O2 saturation in response to limited supply
Delivering midwifery intrapartum care where local COVID-19 escalation protocols are required to be enacted (20/07/2020)	This guide is designed to help maternity services deliver safe, high-quality, one-to-one care in labour during the COVID-19 pandemic, in particular when local COVID-19 escalation protocols need to be enacted. It sets out principles for the engagement of suitably trained and competent individuals, which enables a reduced midwifery workforce to provide one-to-one care.	COVID prevention & control
Maintaining immunisation programmes (not known)	This guide emphasizes the importance of maintaining immunization programs during the COVID-19 pandemic. It highlights that the national immunisation program has been successful in reducing the incidence of serious diseases, and it's crucial to maintain high vaccine uptake to prevent a resurgence of these infections.	COVID prevention & control 999 & 111 services
Management of anticoagulant	This guide focuses on the management of anticoagulant services during the coronavirus pandemic. It emphasizes the importance of	COVID prevention & control

services (31/03/2020)	continuing anticoagulant care while minimizing the burden on the healthcare system. The document provides recommendations and considerations for different categories of patients, including obligatory inpatients, patients requiring initiation of oral anticoagulation, and patients already receiving warfarin or direct oral anticoagulants (DOACs).	
Management of cardiology patients (20/03/2020)	This guide focuses on the management of cardiology patients during the coronavirus pandemic. It provides a framework to ensure essential cardiology care continues while minimising the burden on the NHS. It addresses issues like elective services curtailment, planning to protect resources for the pandemic response, and handling potential compromising situations such as transfer inability, bed shortage, and staff sickness.	COVID prevention & control
Management of emergency department patients during the COVID-19 pandemic (01/11/2020)	This guide aims to provide comprehensive instructions for the management of emergency department patients during the COVID-19 pandemic. It incorporates advice on appropriate personal protective equipment (PPE) for healthcare workers, along with the necessity of binary triage systems to separate patients with suspected or confirmed COVID-19 from other patients. The document highlights the use of same-day emergency care, and the importance of proper follow-up, possibly via remote methods.	COVID prevention & control Primary care
Management of non-coronavirus patients requiring acute treatment: Cancer (23/03/2020)	This guide focuses on the management of non-coronavirus patients requiring acute treatment for cancer during the coronavirus pandemic. It emphasizes the need for doctors to fulfil their general responsibilities related to coronavirus by following national and local guidelines. However, they also have a specific responsibility to ensure that essential cancer care services continue with	COVID prevention & control

	minimal burden on the National Health Service (NHS).	
Management of paediatric critical care patients (26/03/2020)	This guide focuses on the management of paediatric critical care patients during the coronavirus pandemic. It emphasizes the general responsibilities of doctors in relation to coronavirus and the need to follow national and local guidelines. The guidance highlights the importance of ensuring essential care for paediatric critical care patients with minimal burden on the NHS. It is relevant to paediatric intensive care units (PICUs), paediatric high-dependency units (HDUs), and children's wards with high dependency capabilities.	COVID prevention & control DNACPR Palliative and end of life care for people with COVID
Management of palliative care in hospital (22/04/2020)	The guide focuses on the management of palliative care in hospital during the coronavirus pandemic. It emphasizes the importance of best practice palliative care for all patients with palliative care needs or those affected by coronavirus infection. The guide acknowledges that healthcare professionals may need to work outside their specific areas of training and expertise during exceptional circumstances. It highlights the availability of specialist palliative care teams for advice and support but acknowledges the limited capacity for direct care due to the progressing pandemic. The document also addresses symptom management, care of the dying patient, use of personal protective equipment (PPE), verification of death, and coordination of support for the bereaved family. It provides appendixes with management approaches for breathlessness, cough, delirium, and fever, as well as a "three talk" model for shared decision making.	COVID prevention & control Palliative and end of life care for people with COVID

Management of patients requiring transfer for specialist rehabilitation (03/04/2020)	This guide discusses the necessity of maintaining and protecting rehabilitation services during the coronavirus pandemic. It stipulates the importance of patient transfer from acute settings to specialist rehabilitation centres while minimising risk. The document provides a clear referral process, including mandatory details about any coronavirus symptoms or potential exposure. It suspends outreach visits from rehabilitation centres, advocating for teleconference or video conference-based discussions. The guide specifies the screening procedures for patients suitable for transfer, including regular symptom and temperature monitoring, and isolate new arrivals at rehabilitation centres for a period of seven days.	COVID prevention & control
Management of patients with a learning disability, autism or both (24/04/2020)	This guide offers direction for managing patients with a learning disability, autism or both during the coronavirus pandemic. Recognising that people with learning disabilities or autism may be significantly impacted by the pandemic, it provides advice on assessing, diagnosing and treating patients suspected of having or known to have coronavirus. Recommendations include being cognizant of diagnostic overshadowing, taking into account healthcare passports, listening to parents/carers, making reasonable adjustments, understanding behavioural responses to illness, respecting the Mental Capacity Act, and taking care to support mental wellbeing.	COVID prevention & control
Management of people with alcohol dependence (08/04/2020)	This guide addresses the management of people with alcohol dependence during the coronavirus pandemic. It highlights the vulnerability of this population due to prevalent co-morbid physical and mental health problems and the added societal pressures of the pandemic. The guide provides comprehensive recommendations for handling	999 & 111 services

	patients with alcohol dependence across a variety of settings, including emergency departments, acute and mental health trusts, secondary mental health community services, and primary and community care settings. It also introduces the role of a COVID-19 alcohol lead within health trusts and emphasizes the importance of safeguarding children and adults throughout this period.	
Management of remote consultations and remote working in secondary care (27/03/2020)	This guide provides practical information for clinicians and managers in secondary care on delivering remote consultations and remote working during the coronavirus pandemic. It highlights the need to increase remote working to prevent the spread of the virus and guidance on use of remote consultations.	COVID prevention & control
Management of rheumatology patients during coronavirus pandemic (08/04/2020)	This guide addresses the management of rheumatology patients during the COVID-19 pandemic, focusing on the general responsibilities of doctors, the essential role of a rheumatology service and the need to conserve NHS resources. It underlines the vulnerability of rheumatology patients due to immunosuppression and comorbidities and the challenges brought about by factors such as staff sickness, supply chain shortages, and staff redeployment. The guide provides an overview of obligatory inpatients, at-risk patients, and an escalation matrix. It explains the importance of identifying and shielding high-risk patients and lists actions that need to be taken.	COVID prevention & control
Management of stroke patients (16/04/2020)	This guide provides guidance for managing stroke patients during the coronavirus pandemic, with an emphasis on balancing essential care with the added pressures on the NHS. It covers recommendations for all aspects of stroke patient	COVID prevention & control

	care, from emergency department admission through to rehabilitation.	
Management of surge (01/05/2020)	The guide focuses on managing surges in critical care units during the coronavirus pandemic. It acknowledges that while the majority of patients recover from the infection without complications, a small but significant number may experience rapidly evolving respiratory disease, leading to surges of patients requiring hospitalization. The guide aims to share experiences, innovations, and adaptations employed by critical care units to mitigate the challenges posed by surges, with the goal of informing preparations in other hospitals and healthcare facilities.	COVID prevention & control
Management of urgent and emergency spinal surgical patients (14/04/2020)	This guide offers directives for the management of urgent and emergency spinal surgical patients during the COVID-19 pandemic. It recognises the challenges facing healthcare services, including pressure on bed capacity, limited access to theatres, staffing issues, and supply chain shortages. It outlines the expectations of each spinal unit during the pandemic, expressing concern over pathways for urgent and emergency spinal surgical cases. Recommendations are made for maintaining existing assessment and imaging pathways, daily clinical leadership, minimising patient movement, and not denying surgery due to resource constraints.	COVID prevention & control
Optimal use of oxygen therapy (09/04/2020)	This guide focuses on the optimal use of oxygen therapy during the coronavirus pandemic. As the number of COVID-19 patients requiring hospital care increases, the demand on the flow of oxygen delivery within hospitals also rises. To manage the oxygen demand effectively, the guide suggests adjustments to oxygen prescribing targets. For all	Lowering O2 saturation in response to limited supply

	adults treated in NHS hospitals, these should be adjusted from the current range of oxygen saturation 94% - 98% to 92% - 96% initially. This range should be applied to patients with COVID-19 and other conditions, such as stroke and myocardial infarction. The guide also notes that clinical trial evidence suggests hyperoxia can be harmful and lower oxygen target ranges are safe. A target range of 90% - 94% may be considered if deemed clinically appropriate according to the prevailing oxygen flow demands.	
Persons admitted with suspected COVID-19 (19/03/2020)	This guide focuses on caring for adults and children admitted to hospital with suspected COVID-19 infection. It emphasizes the importance of early recognition of patients with suspected COVID-19 to enable timely initiation of infection prevention and control measures. The guidance categorizes different types of clinical syndromes associated with COVID-19 infection, ranging from mild respiratory tract illness to severe pneumonia, acute respiratory distress syndrome (ARDS), sepsis, and septic shock. It provides recommendations for early supportive therapy and monitoring, including the assessment of oxygen supplementation, fluid replacement/resuscitation, empirical antimicrobial treatment, and the use of corticosteroids. It also addresses the use of non-invasive ventilation (NIV) and high-flow nasal oxygen (HFNO), management of hypoxemic respiratory failure and ARDS, septic shock, and cardiac arrest.	COVID prevention & control
Reference guide for emergency medicine (22/04/2020)	This guide is a reference for emergency medicine during the COVID-19 pandemic. Collated from NHS England and NHS Improvement publications, it provides practical tools and clear protocols for managing patient care in this challenging context. The guide addresses several important aspects of	COVID prevention & control

	emergency medical response. It offers criteria for deciding which patients should or shouldn't be conveyed to hospital, instructions for emergency department approaches during the pandemic, admission criteria for COVID-19 and non-COVID-19 patients, and documentation processes for suspected cases. Additionally, it provides radiology guidelines for COVID-19 patients and outlines priorities for same-day emergency care. Notably, it assumes a need for local adaptation of these guidelines based on the evolving understanding of the disease and specific local circumstances.	
Supporting compassionate visiting arrangements for those receiving care at the end of life (11/05/2020)	This guide focuses on facilitating compassionate visiting arrangements for individuals receiving end-of-life care. It provides advice on enabling visits in various settings, including healthcare inpatient settings, care homes, hospices, and homes. The aim is to minimize the risk of infection while allowing close family members, friends, and faith leaders to accompany and say goodbye to their loved ones. The guidance emphasizes the rights of the dying to see their loved ones and receive religious support. It applies at the patient's bedside and aligns with NHS advice on suspension of visiting, palliative care in hospitals during the pandemic, and government advice on social distancing. The guide also addresses specific considerations for different settings, including in-patient healthcare settings, care homes, hospices, and home care. The guide also covers visiting arrangements for pregnant women, children and young people.	COVID prevention & control Palliative and end of life care for people with COVID
The role and use of non-invasive respiratory support in adult patients	This guide provides recommendations for the role and use of non-invasive respiratory support in adult patients with confirmed or suspected COVID-19. It focuses on the appropriate use of continuous positive airway pressure (CPAP), non-invasive	COVID prevention & control Clinical Frailty Scale

with COVID-19 (confirmed or suspected) (26/03/2020)	ventilation (NIV), and high flow nasal oxygen (HFNO) in these patients. The document is based on published evidence, clinical guidelines, and personal communications with colleagues in China and Italy.	
Triaging patients with lower gastrointestinal symptoms (16/06/2020)	This guide provides instructions for managing patients with symptoms potentially indicative of colorectal cancer (CRC) amid the COVID-19 pandemic. The document, underpinned by the NHS's second phase COVID-19 response, prioritises the reinstatement of non-COVID urgent services and continuous referral of suspected CRC cases.	COVID prevention & control

Table 4: Speciality Guides

102. NICE published one Clinical knowledge Summary 'Coronavirus -COVID-19' on the 26 March 2020. It addressed the diagnosis and primary care management of suspected or confirmed COVID-19 infection. It covered the topics ambulances and paramedics, primary care and the diagnosis and treatment of long COVID. The full details of the advice covered can be found in **Exhibit PC/11 - INQ000252490**, 'Clinical Knowledge Summary Advice' tab.

103. Its intended audience was healthcare professionals working within the NHS, in the UK, providing first contact or primary healthcare. The content was largely based on guidance from the NICE COVID-19 rapid guidelines and NG188: Managing the long-term effects of COVID-19, the UKHSA, DHSC and NHSE. Between the 26 March 2020 and the 3 November 2021, it was updated 19 times to reflect the changes in COVID-19 guidance and emerging evidence. The full details of the updates can be found in **Exhibit PC/11 - INQ000252490.**

104. In addition, NICE also signposted, or otherwise directed users, to changes to guidelines and quality standards for various conditions or procedures, including the following:

    a. Ischaemic heart disease;

b. Colorectal or other cancers;

c. Hip or knee replacement surgery;

d. Maternity care; and

e. Children and young people needing access to mental health service.

105. These changes were necessitated by COVID-19 rapid guideline recommendations that related to the clinical practice, diagnosis, assessment or treatment of these conditions or procedures. I exhibit a spreadsheet which provides a list of all the existing previously published guidelines and quality standards and the changes necessitated – **Exhibit PC/12 - INQ000252491,** including:

- A summary of the matters addressed in the guidance or advice;
- For whom the guidance or advice was intended;
- Any professional or other bodies who were consulted or contributed to the formulation of the guidance or advice;
- The date of publication; and
- The date and reason for any revisions or updates.

106. **Table 5** below provides a summary of the guidelines and quality standards that relate to maternity care, hip or knee replacement surgery and colorectal cancer, within **Exhibit PC/12-INQ000252491.**

Ref	Title	Summary of Guidance	Date of Change	Reason for revision / update
NG151	Colorectal Cancer	This guideline covers managing colorectal (bowel) cancer in people aged 18 or over. It aims to improve	15.05.2020	NHSE published a table on interim treatment regimens. This gave possible alternative treatment

	[Exhibit PC/40 – INQ000415404]	quality of life and survival for adults with colorectal cancer through management of local disease and secondary tumours (metastatic disease).		options for use during the COVID-19 pandemic to reduce infection risk. This may have affected decisions for patients with cancer. In addition, NICE produced new C-19 rapid guideline: delivery of systemic anticancer treatments (NG161). Link to NHS interim treatment regimens and NG161 added to overview.
CG192	Antenatal and postnatal mental health: clinical management and service guidance. **[Exhibit PC/41 – INQ000415405]**	This guideline covers recognising, assessing and treating mental health problems in women who are planning to have a baby, are pregnant, or have had a baby or been pregnant in the past year. It covers depression, anxiety disorders, eating disorders, drug- and alcohol-use disorders and severe mental illness (such as psychosis, bipolar disorder and schizophrenia). It promotes early detection and good	19.05.2020	NICE, updated recommendations on anticonvulsants for mental health problems in line with the MHRA guidance on valproate use by women and girls. MHRA warned that Valproate must not be used in women and girls of childbearing potential (including young girls who are likely to need treatment into their childbearing years), unless other options are unsuitable, and the pregnancy prevention programme is in place. The MHRA

		management of mental health problems to improve women's quality of life during pregnancy and in the year after giving birth.		published temporary advice on the valproate pregnancy prevention programme during the COVID-19 pandemic.
CG190	Intrapartum care for healthy women and babies. **[Exhibit PC/42 – INQ000415406]**	This guideline covers the care of healthy women and their babies, during labour and immediately after the birth. It focuses on women who give birth between 37 and 42 weeks of pregnancy ('term'). The guideline helps women to make an informed choice about where to have their baby. It also aims to reduce variation in aspects of care.	02.06.2020	The Royal College of Obstetricians and Gynaecologists (RCOG) produced guidance on COVID-19 and intrapartum care for all midwifery and obstetric services. Link to RCOG advice added to overview.
CG37	Postnatal care up to 8 weeks after birth. **[Exhibit PC/43 – INQ000415407]**	This guideline covers the routine postnatal care that women and their babies should receive in the first 8 weeks after the birth. It includes the organisation and delivery of postnatal care, identifying and managing common and serious health problems in women and their babies, how	02.06.2020	The RCOG produced guidance on COVID-19 and postnatal care for all midwifery and obstetric services. Link to RCOG advice added to overview. Note: this guideline was replaced by NG194.

		to help parents form strong relationships with their babies, and baby feeding. The recommendations on emotional attachment and baby feeding also cover the antenatal period.		
CG62	Antenatal care for uncomplicated pregnancies. **[Exhibit PC/44 – INQ000415408]**	This guideline covers the routine antenatal care that women and their babies should receive. It aims to ensure that pregnant women are offered regular check-ups, information and support.	02.06.2020	The RCOG produced guidance on COVID-19 and pregnancy for all midwifery and obstetric services. Link to RCOG advice added to overview. Note: this guideline was replaced by NG201.
QS115	Antenatal and Postnatal mental health. **[Exhibit PC/45 – INQ000415409]**	This quality standard covers recognising, assessing and treating mental health problems in women planning, during or after pregnancy (up to a year after childbirth). It also covers the organisation of mental health services for women during and after pregnancy. It describes high-quality care in	23.06.2020	Link added following MHRA temporary advice on the valproate pregnancy prevention programme during the COVID-19 pandemic.

		priority areas for improvement.		
NG192	Caesarean birth. **[Exhibit PC/46 – INQ000415410]**	This guideline covers when to offer and discuss caesarean birth, procedural aspects of the operation, and care after caesarean birth. It aims to improve the consistency and quality of care for women and pregnant people who are thinking about having a caesarean birth or have had a caesarean birth in the past and are now pregnant again.	31.03.2021	A COVID statement added to overview to clarify that recommendations in the guidance were developed before COVID-19.
NG194	Postnatal care. **[Exhibit PC/47 – INQ000415411]**	This guideline covers the routine postnatal care that women and their babies should receive in the first 8 weeks after the birth. It includes the organisation and delivery of postnatal care, identifying and managing common and serious health problems in women and their babies, how to help parents form strong relationships with their babies, and	24.04.21	The RCOG produced guidance on COVID-19 and postnatal care for all midwifery and obstetric services. Link to RCOG advice added to overview.

		baby feeding. The recommendations on emotional attachment and baby feeding also cover the antenatal period.		
NG157	Joint replacement (primary): hip, knee and shoulder **[Exhibit PC/48 – INQ000415412]**	This guideline covers care before, during and after a planned knee, hip or shoulder replacement. It includes recommendations to ensure that people are given full information about their options for surgery, including anaesthesia. It offers advice for healthcare professionals on surgical procedures and ensuring safety during operations. It also offers guidance on providing support and rehabilitation before and after surgery.	11.05.2021	A COVID statement added to the overview to clarify that recommendations in the guidance were developed before COVID-19.
NG201	Antenatal care. **[Exhibit PC/49 – INQ000415413]**	This guideline covers the routine antenatal care that women and their babies should receive. It aims to ensure that pregnant women are offered regular check-ups,	19.08.2021	The RCOG produced guidance on COVID-19 and antenatal care for all midwifery and obstetric services. Link to RCOG advice added to overview.

		information and support.		

Table 5: Changes to guidelines relating to maternity care, hip or knee replacement surgery and colorectal cancer.

107. In addition, **Exhibit PC/10 - INQ000252489**, columns I to N, identifies the COVID-19 rapid guidelines that contain recommendations relevant to the conditions or procedures listed in paragraph 93.

Medications recommended

108. A table summarising the list of medicines recommended for consideration of rapid patient access by RAPID C-19 and recommended for use in the treatment of COVID-19 in NICE COVID-19 rapid guidelines, is exhibited as **Exhibit PC/13 - INQ000316255** **Table 6** below illustrates the NICE COVID-19 rapid guideline therapeutic recommendations made during the relevant period.

Medicine name (and drug type)	**Date and type of NICE COVID-19 rapid guideline recommendation**	**Why it was recommended for NICE COVID-19 rapid guidelines**
Baricitinib (Immuno-modulator)	**06/05/2022** Recommendation published (recommendation for) **29/03/2023** Recommendation updated (conditional recommendation for)	Expert Advisory Panel (EAP) rationale: • There is evidence to support the use of baricitinib for moderate to severe COVID-19 in adults in hospital. It shows that baricitinib reduces mortality, duration of hospital stay and disease severity. Corticosteroids are part of standard treatment for COVID-19 in the UK, and there is evidence of an additional benefit when baricitinib is also used.

		• Baricitinib is not licensed for treating COVID-19. Off-label use of baricitinib for COVID-19 may be an option for adults who cannot have tocilizumab (for example, when tocilizumab is not available, the person cannot tolerate intravenous administration, or there are other important patient preferences or circumstances). The panel noted that, when there is clinical deterioration despite treatment with tocilizumab, it may be appropriate to also add baricitinib. • Based on the evidence supporting the use of baricitinib for moderate to severe COVID-19 in adults, the panel agreed that, in the event of severe or deteriorating illness, it could also be considered for children and young people 2 years and over. This is after careful clinical risk assessment and shared decision making that includes expert input from paediatricians and paediatric infectious disease specialists.
Casirivimab + imdevimab (Neutralising monoclonal antibody) [hospital use]	**04/10/2021** Recommendation published (recommendation for) **14/12/2021** Recommendation updated	Expert Advisory Panel (EAP) rationale: • Evidence from 1 randomised, controlled trial in people aged 12 years and over who were hospitalised with COVID-19 and receiving casirivimab and imdevimab suggests possible benefit of this treatment when compared to usual care for seronegative people. The results from this trial suggest that casirivimab and imdevimab reduced

	(recommendation for)	mortality for seronegative people who were hospitalised with COVID-19 when compared to usual care. • The panel decided that the benefits outweighed the risks of treatment based on the available evidence on adverse events in the study and known side effects from the Summary of Product Characteristics (SmPC). As such, this treatment was recommended for seronegative people aged 12 years and over with COVID-19 infection.
Casirivimab + imdevimab(Neutralising monoclonal antibody) [pre-hospital use]	**27/01/2022** Recommendation published (recommendation for) **29/03/2023** Recommendation updated (replaced by TA878)	Expert Advisory Panel (EAP) rationale: • There is evidence that neutralising monoclonal antibodies (sotrovimab, and the combination of casirivimab and imdevimab) reduce the combined outcome of hospitalisation or death, and clinical progression to severe disease, in people who are not in hospital with COVID-19 but are thought to be at high risk of progression to severe disease. • In vitro research data on the efficacy of sotrovimab, and the combination of casirivimab and imdevimab against the new Omicron (B.1.1.529) variant, suggests that neutralising monoclonal antibodies have varying biological efficacy against Omicron. The results suggest this may also be the case with future emerging SARS-CoV-2 variants.

		The panel agreed that more research into this area is needed to guide treatment and made a research recommendation to address this gap in the published evidence.
Dexamethasone (Corticosteroid)	**08/04/2021** Recommendation published (recommendation for)	Expert Advisory Panel rationale: • There is evidence to support using corticosteroids for people with COVID-19 who need supplemental oxygen, or who have a level of hypoxia that needs supplemental oxygen but who are unable to have or tolerate it. It is now established standard practice to offer dexamethasone. The growing evidence base, combined with its widespread availability, ease of administration and acceptable safety profile, supports its continued use. • Hydrocortisone and prednisolone are suitable alternatives if dexamethasone cannot be used or is unavailable. The course duration recommended, for up to 10 days unless there is a clear indication to stop early (including discharge from hospital or a hospital supervised virtual COVID ward), is based on that used in clinical trials.
Hydrocortisone (Corticosteroid)	**08/04/2021** Recommendation published (recommendation for)	Expert Advisory Panel rationale: • There is evidence to support using corticosteroids for people with COVID-19 who need supplemental oxygen, or who have

		a level of hypoxia that needs supplemental oxygen but who are unable to have or tolerate it. It is now established standard practice to offer dexamethasone. The growing evidence base, combined with its widespread availability, ease of administration and acceptable safety profile, supports its continued use. • Hydrocortisone and prednisolone are suitable alternatives if dexamethasone cannot be used or is unavailable. The course duration recommended, for up to 10 days unless there is a clear indication to stop early (including discharge from hospital or a hospital supervised virtual COVID ward), is based on that used in clinical trials.
Molnupiravir (Antiviral)	**23/02/2022** Recommendation published (conditional recommendation for)	Expert Advisory Panel rationale: • There is evidence from 2 randomised controlled trials that treatment with molnupiravir within 5 days of symptom onset reduces the risk of hospitalisation or death compared with placebo in adults who do not need supplemental oxygen and have at least 1 risk factor for development of severe COVID-19 disease. • However, there is uncertainty about the generalisability of the evidence to current clinical practice because the trials only included people who were not vaccinated against COVID-19

		and took place before the emergence of the Omicron variant.
Nirmatrelvir with ritonavir (Antiviral)	**13/04/2022** Recommendation published (recommended for) **29/03/2023** Recommendation updated (replaced by TA878)	Expert Advisory Panel rationale: • There is some clinical evidence suggesting that nirmatrelvir plus ritonavir is effective at treating COVID-19. Nirmatrelvir plus ritonavir is recommended because the likely cost-effectiveness estimates are within what NICE considers an acceptable use of NHS resources.
Remdesivir [hospital use] (Antiviral)	**23/03/2021** Recommendation published (conditional recommendation for) **27/05/2021** Recommendation updated. **14/07/2021** Recommendation updated. **10/08/2021** Updated NHSE clinical commissioning policy	Expert Advisory Panel rationale: • Evidence from 1 randomised controlled trial (PINETREE) in adults who do not need supplemental oxygen and have at least 1 risk factor for developing severe COVID-19 suggests that treatment with remdesivir within 7 days of symptom onset reduces the risk of hospitalisation compared with placebo. • The evidence from this trial in young people aged 12 to 17 is limited because only 1% of people in the study were in this age range. However, the panel were aware that the marketing authorisation for remdesivir for people with COVID-19 who do not need supplemental oxygen includes children and young people who weigh 40 kg or more.

		• Overall, there is uncertainty about the generalisability of the clinical trial evidence to current clinical practice. This is because the trial only included people not vaccinated against COVID-19 and took place before the emergence of the Delta and Omicron variants.
Remdesivir [pre-hospital use] (Antiviral)	**23/02/2022** Recommendation published (conditional recommendation for)	Expert Advisory Panel rationale: • Evidence suggests that remdesivir reduces the risk of death in people in hospital with COVID-19 pneumonia needing low-flow supplemental oxygen. This is likely because it is being used early in the disease course (that is, before the need for high-flow supplemental oxygen, non-invasive ventilation or invasive mechanical ventilation) when viral replication is a driver of the condition. • The evidence for remdesivir in babies, children and young people is limited. However, the panel were aware that the marketing authorisation for remdesivir for people with COVID-19 pneumonia and who need supplemental oxygen includes babies, children and young people aged 4 weeks and weighing 3 kg or more. • The evidence does not suggest any greater benefit with a 10-day course of remdesivir compared with a 5-day

		course but suggests an increased risk of harm. There may also be no benefit in completing the full course of remdesivir if there is progression to high-flow oxygen, non-invasive ventilation or invasive mechanical ventilation during treatment. The panel also acknowledged that using remdesivir for longer would have greater resource implications.
Sarilumab (Immuno-modulator)	**08/04/2021** Recommendation published (conditional recommendation for) **27/10/2021** Recommendation updated. **29/03/2023** Recommendation removed as sarilumab not licensed for use for COVID-19 – recommendation superseded by TA878.	Expert Advisory Panel rationale: • The evidence review found that sarilumab plus standard care is statistically significantly more effective than standard care alone at reducing death at 60 days in adults with COVID-19 in hospital. The evidence also suggests that sarilumab plus standard care has little effect on reducing death at other timepoints and has little effect on adverse events of any severity. • There is sufficient evidence to recommend either tocilizumab or sarilumab. However, the evidence for tocilizumab is more certain. This is because there are more studies and more people in the studies for tocilizumab (7,603 people) than for sarilumab plus standard care (2,053 people). • Although evidence for the effectiveness of sarilumab is uncertain, it is an acceptable alternative if tocilizumab cannot be used or is unavailable. This

		is because, like tocilizumab, it is an interleukin-6 inhibitor and likely to have similar benefits and harms. The panel agreed that sarilumab should be offered if tocilizumab is not available for use in COVID-19. Use the same eligibility criteria as those for tocilizumab.
Sotrovimab (Neutralising monoclonal antibody)	**27/01/2022** Recommendation published [on neutralising monoclonal antibodies] (recommendation for) **29/03/2023** Recommendation updated (replaced by TA878)	Expert Advisory Panel rationale: • There is some evidence suggesting that sotrovimab is likely to be effective at treating COVID-19. Its likely cost-effectiveness estimates are within what NICE considers an acceptable use of NHS resources for people in whom nirmatrelvir plus ritonavir is contraindicated or unsuitable. So, sotrovimab is recommended for this group.
Tocilizumab (Immuno-modulator)	**08/04/2021** Recommendation published (recommendation for) **27/10/2021** Recommendation updated. **29/03/2023** Recommendation updated (replaced by TA878)	Expert Advisory Panel rationale: • There is some clinical evidence suggesting that tocilizumab is effective at treating COVID-19. Tocilizumab is recommended because the likely cost-effectiveness estimates are within what NICE considers an acceptable use of NHS resources.

Table 6: COVID-19 rapid guideline therapeutic recommendations.

109. The therapeutic recommendations made by Rapid C-19 during the relevant period are illustrated in **table 7** below:

Medicine name (and drug type)	**Date of recommendation from RAPID C-19 to CMO**	**Why it was recommended to CMO**
Baricitinib (Immuno-modulator)	09/03/2022 **CMO report** recommending consideration for rapid access. Access was subsequently provided from 05/05/2022.	This medicine was recommended based primarily on the results from the RECOVERY trial which showed that baricitinib reduced death in people with severe or critical COVID-19 in hospital.
Casirivimab + imdevimab (Neutralising monoclonal antibody) [hospital use]	a) 17/06/2021 **first CMO report** (hospital patients) recommending consideration for rapid access subject to licence. Access was subsequently provided from 17/09/2021. Access was withdrawn on 24/02/2022. b) Use of casirivimab plus imdevimab for non-hospitalised patients was also recommended for consideration for rapid access subject to licence following a discussion at the Oversight Group on 23/06/2021. It was not considered necessary to provide a CMO report as CMO had already approved actions to progress towards patient access for this product as a treatment for COVID-19. Preparations for access were discontinued when	a) This medicine was recommended based primarily on the results from the RECOVERY trial which showed that casirivimab plus imdevimab reduced death in seronegative people (who have not mounted a natural antibody response) with severe or critical COVID-19 in hospital. b) This medicine was recommended based primarily on the results from the Study 2067 trial which showed that casirivimab plus imdevimab reduced COVID- related medically attended visit or death in people COVID-19 and risk factors for disease progression, and the treatment

	the company announced that the medicine was ineffective against the Omicron variant. c) 14/07/2021 **second CMO report** (prophylaxis) recommending consideration for rapid access subject to licence. Preparations for access were not subsequently progressed.	cohort of the Study 2069 trial which showed that casirivimab plus imdevimab reduced symptomatic COVID in seronegative people testing positive. c) This medicine was recommended based primarily on the results from Study 2069 which showed that casirivimab plus imdevimab reduced the incidence of symptomatic COVID-19 and asymptomatic SARS-CoV-2 infection in uninfected (SARS-CoV-2 negative and seronegative) household contacts of infected individuals.
Casirivimab + imdevimab (Neutralising monoclonal antibody) [pre-hospital use]	a) 17/06/2021 **first CMO report** (hospital patients) recommending consideration for rapid access subject to licence. Access was subsequently provided from 17/09/2021. Access was withdrawn on 24/02/2022. b) Use of casirivimab plus imdevimab for non-hospitalised patients was also recommended for consideration for rapid access subject to licence following a discussion at the Oversight Group on 23/06/2021. It was not considered necessary to provide a CMO report as CMO had already approved actions to	a) This medicine was recommended based primarily on the results from the RECOVERY trial which showed that casirivimab plus imdevimab reduced death in seronegative people (who have not mounted a natural antibody response) with severe or critical COVID-19 in hospital. b) This medicine was recommended based primarily on the results from the Study 2067 trial which showed that casirivimab plus imdevimab reduced COVID- related

	progress towards patient access for this product as a treatment for COVID-19. Preparations for access were discontinued when the company announced that the medicine was ineffective against the Omicron variant. c) 14/07/2021 **second CMO report** (prophylaxis) recommending consideration for rapid access subject to licence. Preparations for access were not subsequently progressed.	medically attended visit or death in people COVID-19 and risk factors for disease progression, and the treatment cohort of the Study 2069 trial which showed that casirivimab plus imdevimab reduced symptomatic COVID in seronegative people testing positive. c) This medicine was recommended based primarily on the results from Study 2069 which showed that casirivimab plus imdevimab reduced the incidence of symptomatic COVID-19 and asymptomatic SARS-CoV-2 infection in uninfected (SARS-CoV-2 negative and seronegative) household contacts of infected individuals.
Dexamethasone (Corticosteroid)	20/05/2020 First considered by oversight group. Access was subsequently provided from 16/06/2020. Note: this was pre-CMO report process.	This medicine was recommended based primarily on the results from the RECOVERY trial which showed that dexamethasone reduced death in people with severe or critical COVID-19 in hospital.
Hydrocortisone (Corticosteroid)	17/06/2020 First considered by oversight group. Access was subsequently provided from	This medicine was recommended based primarily on the results from the REMAP-CAP trial which showed the hydrocortisone

	03/09/2020. Note: this was pre-CMO report process.	increased organ support-free days in people with severe or critical COVID-19 in hospital, plus the REACT meta-analysis and WHO guidance recommending the use of systemic corticosteroids in severe and critical disease.
Molnupiravir (Antiviral)	07/10/2021 **CMO report** advising of positive signal but awaiting further data. Access was subsequently provided from 16/12/2021.	This medicine was recommended based primarily on the results from the MOVE-OUT trial which showed that molnupiravir reduced hospitalisation or death in non-hospitalised people with COVID-19 and risk factors for disease progression.
Nirmatrelvir with ritonavir (Antiviral)	06/01/2022 **CMO report** recommending consideration for rapid access subject to licence. Access was subsequently provided from 10/02/2022.	This medicine was recommended based primarily on the results from the EPIC-HR trial which showed that nirmatrelvir plus ritonavir reduced hospitalisation or death in non-hospitalised people with COVID-19 and risk factors for disease progression.
Remdesivir [hospital use] (Antiviral)	29/04/2020 First considered by oversight group. Access was subsequently provided via EAMS from 26/05/2020 and via policy from 03/07/2020. Note: this was pre-CMO report process).	This medicine was recommended based primarily on the results from the ACTT-1 trial which showed that people with severe COVID-19 in hospital recovered more quickly with remdesivir.

Remdesivir [pre-hospital use] (Antiviral)	07/10/2021 **CMO report** advising of positive signal but awaiting further data. Access was subsequently provided from 10/02/2022.	This medicine was recommended based primarily on the results from the PINETREE trial which showed that remdesivir reduced hospitalisation or death in people COVID-19 and risk factors for disease progression.
Sarilumab (Immuno-modulator)	06/01/2021 **CMO report** (ICU patients) recommending consideration for rapid access. Access was subsequently provided from 08/01/2021.	This medicine was recommended based primarily on the results from the REMAP-CAP trial which showed that sarilumab increased organ support-free days in people with severe and critical COVID-19 in hospital.
Sotrovimab (Neutralising monoclonal antibody)	17/06/2021 **CMO report** recommending consideration for rapid access subject to licence. Access was subsequently provided from 16/12/2021.	This medicine was recommended based primarily on the results from the COMET-ICE trial which showed that sotrovimab reduced hospitalisation or death in non-hospitalised people with COVID-19 and risk factors for disease progression.
Tocilizumab (Immuno-modulator)	06/01/2021 **first CMO report** (ICU patients) recommending consideration for rapid access. 12/02/2021 **second CMO report** (all hospital patients)	This medicine was recommended based primarily on the results from the REMAP-CAP and RECOVERY trials which showed,

	recommending consideration for rapid access. Access was subsequently provided via policy from 08/01/2021 for ICU patients and from 17/02/2021 for all hospitalised patients with evidence of progressive disease.	respectively, that tocilizumab increased organ support-free days and reduced death in people with severe and critical COVID-19 in hospital.

Table 7: Rapid C-19 therapeutic recommendations

Formulation / publication of clinical tools for healthcare workers.

110. NICE was not involved in the formulation of shielding advice for COVID-19.

111. Similarly, the CfG did not have any involvement in the original formulation, publication or updating of clinical tools for healthcare workers during the pandemic.

112. NICE signposted to externally developed tools, where appropriate, in its COVID-19 rapid guidelines, including, but not limited to the Medical Research Council's dyspnea scale, Clinical Frailty Scale, NEWS2, British Medical Journal emergency care and resuscitation plan, Royal College of General Practitioners Acute Kidney Injury toolkit, Department of Health VTE risk assessment tool and the Yorkshire Rehabilitation Scale.

Rapid endorsement

113. NICE operated a rapid endorsement process to assess external resources, which supported NICE's COVID-19 rapid guidance. The process ensured that the externally produced resource supported the implementation of the guideline and did not contradict any of the recommendations. Under the process NICE issued an endorsement statement to the producer and displayed a link to the resource on the NICE website. NICE did not actively seek out resources but would be notified by health care system partners of possibilities to consider.

114. Four external resources that supported NICE Rapid COVID-19 guidance were endorsed by NICE as illustrated in **table 8** below, namely:

Ref.	Resource	Description	Relevance
RE001	Safe prescribing and monitoring protocol for systemic immunomodulatory therapies for immune-mediated inflammatory skin disease in the context of coronavirus (COVID-19). May 2020	Guys and St Thomas' NHS Foundation Trust protocol which supports recommendations in the COVID-19 Rapid guideline: dermatological conditions treated with drugs affecting the immune response. This resource was for the routine management of systemic immunomodulatory therapies for immune-mediated inflammatory skin disease in the context of COVID-19 (aged 16 years and over).	Hospital admission criteria for patients with and without COVID-19.
RE002	Lung cancer and mesothelioma service guidance during the COVID-19 pandemic. June 2020	Service guidance reflecting recommendations in the COVID-19 Rapid Guideline: delivery of systemic anticancer treatments. This resource was for lung cancer teams. It covered diagnostic and staging, treatments (including curative, systemic and palliative), mesothelioma.	Hospital admission criteria for patients with and without COVID-19.
RE003	Breathlessness Clinical Decision Support Tool. May 2020 (updated 25 February 2021 at the request of the producer)	NHS Digital produced an algorithm and supporting document that accurately reflects recommendations in the COVID-19 Rapid guidelines: managing suspected or confirmed pneumonia in adults in the community and: managing symptoms (including at the end of life) in the community. This resource helped healthcare professionals remotely triage patients with breathlessness and	Triage tools for managing COVID-19 patients; decision making tools for escalation of care for COVID-19 patients.

		suspected COVID-19. It considered red flag symptoms, high-risk and vulnerable groups and other possible causes of breathlessness. It also provided safety netting advice and aided discussion with patients on the advantages and disadvantages of hospital admittance.	
RE005	CARDMEDIC Communication flashcards. July 2020	CARDMEDIC produced digital communication flashcards that accurately reflected recommendations in COVID-19 Rapid guidelines: critical care in adults, managing symptoms (including at the end of life) in the community, community-based care of patients with chronic obstructive pulmonary disease ["COPD"], acute myocardial injury, antibiotics for pneumonia in adults in hospital and acute kidney injury in hospital. The flashcards were to help healthcare professionals communicate with COVID-19 patients, whilst wearing PPE. The tool also included translation of most content into several languages to aid communication.	Communication

Table 8: External resources supporting Rapid C-19 guidance

Shared Learnings

115. NICE also published shared learning case studies describing the experiences of frontline healthcare staff delivering care in the pandemic. These were written by the submitting organisation but published by NICE on the NICE website, as one-off publications. The intended audience was any healthcare professionals or commissioners who were working in the area. They provided case studies of both the implementation of the COVID-19 rapid guidelines, and how services used recommendations to develop and adjust how health care was being delivered. A number of the shared learning case studies related to the use of triage tools for managing COVID-19 patients, decision-making tools for escalation of care and COVID-19 risk assessments for staff and patients. **Table 9** below, sets out the examples:

Shared Learning Title	**Shared Learning Organisation**	**Clinical Tool Category**	**Exhibit Number**
Maintaining a cancer service in the midst of the COVID-19 pandemic: a single centre experience	Bristol Haematology and Oncology Centre	Triage tools for managing COVID-19 patients. COVID-19 risk assessments for staff and patients.	**Exhibit PC/50 - INQ000415414**
Developing and implementing guidance for staff delegating clinical tasks to informal carers and relatives during the COVID-19 pandemic	LiveWell SouthWest	COVID-19 risk assessments for staff and patients.	**Exhibit PC/51 - INQ000415415 (embedded documents INQ000415416, INQ000415417 & INQ000415418)**
Supporting and developing community end of life care during the COVID-19 pandemic: an example of collaborative working	Kent Community Health NHS Foundation Trust	Triage tools for managing COVID-19 patients.	**Exhibit PC/52 - INQ000415419**

Project CARE: supporting people with a positive diagnosis of COVID-19 and reaching out to those in vulnerable groups	Newton Medical Practice	Triage tools for managing COVID-19 patients. Decision-making tools for escalation of care for COVID-19 patients.	**Exhibit PC/53 - INQ000415420**
Managing COVID symptoms (including at the end of life) in a prison setting	Hanham Secure Health	Triage tools for managing COVID-19 patients. Decision-making tools for escalation of care for COVID-19 patients	**Exhibit PC/54 - INQ000415421**
Delivering a paediatric elective surgery service during the COVID-19 pandemic	Bedfordshire Hospitals NHS Foundation Trust	Triage tools for managing COVID-19 patients. COVID-19 risk assessments for staff and patients.	**Exhibit PC/55 - INQ000415422**

Table 9: Shared Learnings Case Studies

116. In addition to publication on the NICE website, the COVID-19 related shared learning case studies would have been included in the NICE's external monthly newsletters 'NICE news' and 'Update for Primary Care'. The case studies 'Developing and implementing guidance for staff delegating clinical tasks to informal carers and relatives during the COVID-19 pandemic' and 'Delivering a paediatric elective surgery service during the COVID-19 pandemic' were also both shortlisted and presented at NICE's 2020 Shared Learning Awards to a large online external audience. For information, from January 2021 onwards NICE no longer actively promoted or encouraged external health care organisations to share case studies.

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.

Personal Data

Signed:

Dated: 15 March 2024