UK COVID-19 INQUIRY

MODULE 3: WRITTEN OPENING SUBMISSIONS ON BEHALF OF THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE ["NICE"]

INTRODUCTION

1. At the outset of Module 3, NICE would like to acknowledge the impact that the pandemic had, and continues to have, on people affected by it in so many ways. NICE offers its sincere and heartfelt sympathies to all those who suffered and lost loved ones in the pandemic. NICE recognises that the pandemic's effects are still being felt. NICE also extends its sympathies to those affected by "long Covid", those whose healthcare was delayed or disrupted by the pandemic and those within the health and care system who are working on the recovery from the pandemic.

2. NICE welcomes the work of the Inquiry. NICE understands the importance of the Inquiry's work and is committed to an open and transparent approach to the Inquiry.

3. As a Core Participant, NICE has had disclosed to it large numbers of documents from other organisations. Rather than responding to that evidence at this point, NICE will carefully consider all the evidence that the Inquiry will see and hear during the Module 3 hearings before reflecting further on its role and identifying any lessons that may come from that.

4. In relation to Module 3, NICE has provided witness statements and exhibits on behalf of the organisation, from the current Chief Executive and the Directors responsible for the main directorates involved in the response to the pandemic, as follows:

   a. Dr Samantha Roberts – NICE's current Chief Executive;
   b. Dr Paul Chrisp – Retired from NICE in March 2024 and was the Director of the Centre for Guidelines ["CfG"] during the pandemic;
   c. Helen Knight – currently Director of Medicines Evaluation, Centre for Heath Technology Evaluation ["CHTE"] at NICE and during the pandemic was appointed to Deputy Director of CHTE and oversaw the Research to Access Pathway for Investigational Drugs in COVID-19 ["RAPID C-19"]. This was a multi-agency initiative aimed at ensuring safe and timely access to therapeutics that showed evidence of the benefit in preventing and treating COVID-19, as part of temporary emergency pandemic arrangements.

5. We will not seek to summarise that material here. The Inquiry will also take oral evidence from Dr Paul Chrisp during the Module 3 hearings.

BACKGROUND TO NICE

6. It may assist to take this opportunity to set out some important aspects of the unique role that NICE plays within the health care system and to provide background to issues that the Inquiry may wish to examine.

7. NICE is an arms length body of the Department for Health and Social Care ["DHSC"]. A framework agreement exists between NICE and DHSC, which sets out the parameters in which NICE can operate and in which it discharges its responsibilities. This is a public document, and a copy of the framework agreement has additionally been disclosed to the Inquiry. NICE's role and responsibilities are defined by the Health and Social Care Act 2012 and its supporting regulations. In fulfilling these functions, NICE balances the best care with value for money across the

NHS and social care, to deliver for both individuals and society as a whole.

8. In plain English; NICE's role is to issue guidance to the NHS and the wider health and social care system. (It does so directly in England, and by arrangements with the devolved governments in Wales and Northern Ireland.) The guidance is intended to improve the care that the NHS and others deliver. NICE's guidance is authoritative, and can only be departed from with good reason, (*R ota Rose v Thanet CCG* [2014] EWHC 1182 (Admin)) but with one exception it is not binding (the exception is that funding must normally be made available for technologies, including medicines recommended by NICE after a health technology appraisal). NICE guidelines come with a standard rubric:

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

9. Other forms of NICE guidance have a broadly similar caveat.

10. NICE guidance is developed after careful consideration with stakeholders of health and care system priorities. Guidance on new topics is usually initiated following referral from DHSC or NHS England ["NHSE"] and existing guidance is kept up to date as new evidence and data becomes available. It is important to understand the limitations of NICE's role. It does not consider affordability (which is, broadly, what can be bought with a finite budget) although it does consider cost effectiveness (which is, again broadly, whether the expected benefit of a treatment represents value for money). It does not issue guidance on professional conduct. It does not authorise medicines as acceptably safe for use, or have a role in their recall if they are found not to be safe (although consideration of safety may inform guidance on clinical effectiveness).

11. Even within its field of making recommendations on clinical and cost effectiveness of, and the clinical uses of, technologies and procedures, NICE shares the space with other bodies, including the Royal Colleges and other professional associations, trusted producers of healthcare evidence such as the Cochrane collaboration, academic writings, and bodies with a similar remit to NICE in other health systems, including, importantly, NICE equivalent bodies in Scotland, the Scottish Intercollegiate Guidelines Network ["SIGN"] and the Scottish Medicines Consortium.

12. NICE was established in 1999 by the then Health Secretary, Frank Dobson MP. Its initial remit, which has been very significantly expanded, was to make recommendations about the use of (usually) new medicines, technologies and interventions in the NHS. There were a number of reasons for NICE's creation. The first was to reduce regional variation in treatment availability (at least in England and those nations that chose to adopt NICE recommendations). The second was

to secure more rapid adoption of cost effective treatments. A third was to provide authoritative evidence based recommendations to inform clinical practice within the NHS.

13. The establishment of NICE was not uncontroversial, and NICE had and has no general powers of compulsion (with the exception noted at paragraph 8 above). It must therefore convince, rather than command. A great deal of work had to be done to build confidence in NICE among its various stakeholders, including clinicians, commissioners, governments, manufacturers, and, importantly, patients.

14. NICE has from its earliest days adopted a particular culture and way of working that reflects a recognition that its decisions may have far reaching consequences for patients, families and the health and social care system. It is broadly based: many of its guidance documents being produced by consensus in independent committees including members from the medical professions, academia, patient groups, and industry. It is transparent: conducting as much of its business in public as possible, publishing its working papers (redacting any confidential information) and consulting on the development and recommendations of individual pieces of guidance and routinely consulting on its methods and processes. It is rigorous in its demand that all of its work is evidence based and on its insistence on high standards of evidence. The most recent iteration of these values can be seen in the "Core Principles" described in Dr Roberts' witness statement at paragraphs 22-23.

15. These values have a consequence in time and resources. There have been frequent requests that NICE should work faster. NICE has sought to respond to these demands with streamlined processes, but it still takes time to produce evidence based guidance.

16. NICE is absolutely confident that its values and approach are the right ones for "business as usual" in the NHS. However, it can be seen that a

pandemic caused by a novel virus posed particular challenges to NICE's ways of working. These included:

a. The need for guidance to be produced at incomparably greater speed than business as usual. (Dr Roberts estimates NICE produced guidelines c.50 times faster during the pandemic (paragraph 44 of her witness statement)).

b. The lack of the usual evidence base. At the start of the pandemic there was very little evidence on the disease or possible treatments of any sort available. As the pandemic progressed more evidence was generated, but (perfectly understandably) very little was of the peer reviewed standard that would usually be the bedrock of NICE's work.

c. The many demands on the time of NICE's collaborators. Clinicians who would normally be available to take part in guidance development had returned to clinical practice. Patient charities were busy responding to the concerns of their communities. Stakeholders within the NHS were busy reconfiguring NHS services to accommodate waves of patients seriously ill with COVID-19, and so on.

17. Accordingly NICE had to adapt its ways of working radically and in real time to respond to these challenges. NICE took the decision to be flexible, agile and responsive to user needs (both in content and timeliness), and understood that there was a risk, but was in favour of acting quickly to support the Health and Social Care system. It believes it was successful in doing so, although, of course, there were areas in which improvements could be made. It has assessed how successful it was in a "lessons learned" exercise in 2022, described at paragraphs 97-147 of Dr Roberts' witness statement, and her exhibits SR7-11, and the Inquiry's attention is respectfully drawn to that material. NICE would particularly highlight that once NICE was approached by NHSE, it was able to quickly adapt methods and processes and make use of rapidly emerging real-world evidence to produce useful COVID-19

guidance to support the needs of the healthcare system. NICE now has in place a process and methods for guidelines developed in response to health and social care emergencies.

18. Although NICE believes its approach was quick and effective, once the role it should play was determined, it recognises that as neither a Category 1 nor a Category 2 responder under the Civil Contingencies Act 2004, nor having had a specified role under the DHSC Emergency Planning regulations and the NHSE National Emergency Preparedness Resilience and Response framework ["EPPR"], it was not formally part of the national pandemic response or discussions in the very early days of the pandemic. The lessons learnt exercise highlighted that NICE's expertise and trusted position as the independent provider of guidance to the health and care system would have been valuable in the very early days of the pandemic, in which a range of bodies had started to produce guidance to the system.

19. Following the lessons learnt exercise, NICE's Chief Medical Officer, Professor Jonathan Benger, now represents NICE on the National EPRR Clinical Reference Group, alongside key national stakeholders and partners including other arms-length bodies. The group is chaired by the National EPRR director at NHSE and meets on a quarterly basis. It provides a mechanism through which NICE can contribute to system-level consideration by the group of emerging issues and identify and communicate, where appropriate, what contribution NICE may make to a system-level response. It provides a rapid commissioning and response mechanism between NICE and the system in future emergency scenarios. NICE considers that the lessons learned from the pandemic and the changes it has implemented will ensure that it, like all organisations, is much better placed to respond to such a situation in future.

CRITICAL CARE AND THE CLINICAL FRAILTY SCORE

20. NICE is grateful to the Core Participants that have highlighted their concerns relating to the NICE critical care guideline – NG159, particularly the use of the Clinical Frailty Score ["CFS"] in people with disabilities, including learning disabilities.

21. Having been commissioned by NHSE on 13th March 2020, NG159 was published on 20th March 2020. The Inquiry will appreciate this was right at the beginning of the pandemic. The guideline on critical care was one of the very first rapid guidelines published. It was developed to support critical care teams in their management of patients during an extremely challenging period of anticipated intense pressure in the early stages of the pandemic. NG159 recommended the use of the CFS in the assessment of frailty. (CFS is a tool that was already in existence to support clinicians when assessing frailty. It was not a tool developed by NICE.)

22. Following publication, patient and voluntary sector organisations alerted NICE to the fact that the use of CFS in this way would be inappropriate in certain patient groups. NICE is very grateful that they did so. NICE immediately accepted that input and that the patients and voluntary sector organisations were right in this regard and a revised version of NG159 was published on 25th March 2020. That version included the wording:

> • *The CFS should not be used in younger people, people with stable long-term disabilities (for example, cerebral palsy), learning disabilities or autism. An individualised assessment is recommended in all cases where the CFS is not appropriate.*

• *Consider comorbidities and underlying health conditions in all cases.*

23. The NHS Specialist Clinical Frailty Network also updated its advice on using CFS, stating that it should not be used in isolation to direct clinical decision-making and that clinicians should make any decisions about care in conjunction with patients and their carers where possible. The revised guideline reflected these clarifications and emphasised the need to consider additional patient factors when interpreting the CFS.

24. To ensure that the revised critical care guideline was effectively communicated to critical care clinicians, NICE did an initial press release, promoted the guideline through the widespread use of social media with links from the NHSE website and developed a specific COVID-19 newsletter, which reached over 40,000 people.

25. NICE wishes to make it clear that the guideline was never intended to cause disadvantage to any group of patients. NICE takes this chance to apologise again for any concerns created and recognises that the guideline should have expanded more on the need for person-centred application of the use of CFS from the start. However, without detracting in any way from NICE's apology, NICE wants to explain that it never doubted the need to consider the groups who could have been adversely affected by NG159 had it been applied at a time when demand for critical care outstripped availability. Prior to publication, the draft guideline was reviewed by the NHS England and NHS Improvement national director of learning disabilities and by the lead for learning disabilities and autism policy at DHSC, as well as by devolved governments. In fact, 178 stakeholder comments were received from 26 organisations and while the issue of CFS came up in these comments, the comments were generally supportive of its use. The use of the CFS in people with disabilities was not raised as an issue during that time. In making those points, NICE does not seek to evade

its responsibility for the final form of the guideline, or for the fact that it had to be changed within five days of publication.

26. During the pandemic, NICE reviewed and updated its approach to developing rapid guidelines as it was learning all the time. Dr Chrisp's witness statement describes the evolution that took place from paragraph 42 onwards.

LONG COVID

27. NHS England and the Chief Medical Officer of the Scottish Government commissioned NICE and SIGN to develop a guideline on the long-term effects of COVID-19. Guideline NG188: Managing the long-term effects of COVID-19 was developed collaboratively by NICE, SIGN and the Royal College of General Practitioners and published on 18th December 2020. The development and maintenance of the guideline followed the interim process and methods for guidelines developed in response to health and social care emergencies, using flexible methods where needed. An Independent Expert Advisory Panel agreed the scope, considered the evidence, developed recommendations and considered stakeholder feedback.

28. As there was still uncertainty about the long-term effects of Covid-19 at that time, the guideline was developed using a 'living' approach – meaning that targeted areas of the guideline (including the case definition) were continuously reviewed and updated in response to a developing and emerging evidence base.

29. A targeted consultation was conducted from 26th November to 1st December 2020. A total of 77 consultees commented, including patient involvement groups, Royal Colleges and medical professional societies and provider and academic organisations. A total of 1066 responses were received and considered by the panel.

30. NICE is grateful to the Inquiry for instructing Professor Brightling and Dr Rachel Evans, who have produced an informative report on long Covid, for Module 3. Whilst NICE is aware of the concerns raised in relation to long Covid, it does not propose to pre-empt the Inquiry's examination of the key issues on this topic and will wait to hear the evidence given to the Inquiry.

CONCLUDING REMARKS

31. The pandemic was extremely challenging for the NHS and for healthcare globally. NHS guidance and information structures were no exception.

32. It seems inevitable that any future pandemic will require bodies issuing clinical advice to make the same rapid pivot that NICE made during the COVID pandemic. NICE believes it did so successfully, although any future pivot could usefully be informed by its lessons learned exercise.

33. NICE welcomes the opportunity to provide evidence and explanation to the Inquiry. It also welcomes the Inquiry's scrutiny, and any recommendations, suggestions or criticisms the Inquiry may have. NICE has a long-standing commitment to transparency and accountability and approaches its engagement with the Inquiry in that spirit.