UK COVID-19 INQUIRY

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

[references to transcripts are in the form dd/mm/yy P[age number] L[ine number]

INTRODUCTION

1. As it did at the outset of Module 3, NICE would like to acknowledge once again the impact that the pandemic had, and continues to have, on people affected by it in so many ways. That impact will no doubt be at the forefront of the Inquiry's mind, as it seeks to identify the lessons to be learned.

2. NICE fully accepts that there are indeed lessons to be learned, and that, despite the best efforts and sacrifices of all those working within the system, the response of healthcare systems to the Covid-19 pandemic could have been better. That is perhaps inevitable when responding to such a serious and novel challenge at speed. But that inevitability in no way diminishes or undermines the quite proper frustrations and concerns that the Inquiry has heard during the course of this module, from patient groups in particular. NICE would like to express its sympathy and its commitment to learning and improvement to them, and to the Inquiry.

3. NICE would also like to thank the Inquiry, the Core Participants and all who have given evidence in module three for the care and attention which they have devoted to the issues raised in that module.

4. These submissions will be in two parts: the first, relating to specific issues relevant to NICE raised in the course of the Module 3 hearings, and the

second, general observations with a view to promoting greater preparedness for any further pandemic

SPECIFIC ISSUES

COVID-19 Rapid Critical Care guideline ["NG 159"] and the use of the Clinical Frailty Score ["CFS"]

5. As explained in NICE's opening statement for this module, 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, but it can be departed from with good reason and does not override clinical judgement or ethical decision-making.

6. As with all NICE guidelines, NG159 was created with independent expert input and engagement tailored to the specific content of the Guideline. The two clinical leads were experts in intensive/critical care with both clinical and academic experience. Their role was to help draft guideline content, identify any existing guidance and to understand the clinical landscape. Specialist help in drafting the recommendations was obtained from additional intensive care experts. There was targeted consultation with 17 specialist organisations including appropriate Royal Colleges and medical societies as well as the patient groups set out in paragraph 9 below.

7. As to the use of the CFS to support decision making at all, in any patient population, Dr Chrisp explained in his witness statement INQ000438429 at paragraph 98 that this is a well established tool, and not one created by NICE or for the pandemic. It is a tool with which many clinicians would have been familiar and, particularly in the early days of the pandemic, there is merit in using familiar tools where appropriate. Its use was supported by the NHS Specialised Clinical Frailty Network. NICE was

urged to recommend its use as it was already widely adopted in many NHS settings.

8. With that said, the use of the CFS had to be confined to those populations in which it had been validated. NICE accepts and apologises that the first iteration of NG159 recommended the use of the CFS without making also clear on the face of the guideline that it should not be used in all patient groups. That should not have been left to be implied by the clinician's knowledge of the CFS. It further accepts and apologises that if the specific patient charities who highlighted the problem with NG159 as originally published had been included in the pre-publication consultation, it seems highly likely that the error would have been corrected before publication. NICE wants the Inquiry and in particular the patient groups affected to understand that it accepts it made an error, that it apologises for that error, and that NICE has learnt from it.

9. By way of explanation rather than exculpation, Dr Chrisp gave evidence that NICE's experience hitherto had been that patient and voluntary community groups preferred to be consulted only on guidance with specific relevance to their areas, because consultation on every piece of guidance NICE produces would be too onerous for them. (30/10/24 P73 L15) He further explained that NICE had consulted inter alia with the Richmond group of charities, (30/10/24 P86 L20) whose members are Age UK, The Alzheimer's Society, Asthma and Lung UK, Breast Cancer Now, The British Heart Foundation, The British Red Cross, Diabetes UK, Macmillan Cancer Support, Mind, Parkinsons UK, Rethink Mental Illness, the Stroke Association, and Versus Arthritis.

10. It would not be fair to say that NICE was blind to the need to involve patient groups in guideline development, even in the context of this very significantly expedited process, in which guidance was being produced within a week of referral. Efforts were made in good faith to do so. But it can be seen that while this group includes patient groups with expertise in care of older adults, mental illness, and/or some forms of cognitive

impairment, it does not include groups with specific expertise in learning disabilities or neurodivergence. Those groups were not intentionally excluded, but NICE accepts that they should have been included from the outset at least where (as was clearly the case here) they would wish to be.

11. Dr Chrisp explained that while an equality impact assessment process was included in the creation of NG159, it was not as thorough as would usually have been the case, because of the speed with which NICE was required to produce the guideline (30/10/24 P81 L6). Professor Powis (speaking of NHS England guidance) spoke of the trade-off between getting guidance out rapidly and doing the consultation that would normally be done, and of being presented with a set of "lousy choices" in that regard "but you have to make that judgement" (7/11/24 P85 L20). It is easy to see the difficulty, particularly in the early days of the pandemic when little was known about the disease and guidance had to be issued very rapidly.

12. NICE moved quickly to correct the guideline as soon as it was drawn to its attention, publishing amended guidance on 25 March 2020 (within five days of initial publication), making clear both 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 and that when the CFS is used, that should be as part of a holistic assessment (Dr Chrisp witness statement INQ000438429 paragraph 99). So far as NICE is aware no criticism has been made that the amended wording was also defective.

13. This revision was promoted through a press release, use of social media, and a specific COVID-19 newsletter, which reached over 40,000 people.

14. Dr Chrisp explained that as the initial phase of the pandemic passed, NICE concluded that the trade-off between speed and consultation could be rebalanced to allow more time for consultation. NICE codified and published its revised ways of working during a pandemic in July 2020

INQ000252483. Paragraph 15 of the Interim process and methods for guidelines developed in response to health and social care emergencies requires that:

"The impact on people with characteristics protected under the Equality Act 2010 is considered during development of the health and social care emergency guideline in line with NICE's equality objectives and equality programme 2016 to 2020. An equalities impact assessment is completed and reviewed by the NICE quality assurance team before submission of the draft guideline to NICE's Guidance Executive. The equalities impact assessment will be made available on the NICE website". Exhibit PC/04 - INQ000252483

15. NICE has confidence that the procedural weakness that led to the initial error in NG159 would not be repeated.

NG159, the CFS and Do Not Attempt Cardiopulmonary Resuscitation "DNACPR" notices

16. NICE is unable to assist the Inquiry on the factual questions of whether or to what extent there was inappropriate use of DNACPR notices, whether any such use was contributed to by NG159 or any other guidance, or whether DNACPR notices were wrongly understood to amount to "do not treat" notices. It has no information on these questions (30/10/24 P84 L18). Clearly, such practices would be of very great concern.

17. NICE's understanding was that NG159 (and indeed all of its guidance) would be applied in the course of normal ethical decision-making (30/10/24 P84 L11, P93 l25). Dr Brydon was correct to state INQ000389244_0012 para55:

"Both iterations of NICE guidance (NG 159 and NG 191) stopped short of setting out the ethical and legal issues relating to triage in situations in which critical care resources were insufficient to meet demand and did not provide advice on how to manage those issues. Instead, the guidance related to making normal ethical decision-making processes more effective and efficient."

18. In her oral evidence to the Inquiry on 08 October 2024, Dr Bryden did not accept a link between the use of CFS and DNACPR notices.

19. As the Inquiry will be aware, "normal ethical decision-making processes" were never abandoned. Accordingly NICE was never asked to prepare any guidance to be used in that context. It would have had grave reservations about its ability to do so had it been asked, for reasons to be given below.

20. NICE respectfully suggests there may be two issues for the Inquiry to consider. First, if the Inquiry finds that NICE guidance gave rise to inappropriate use or understanding of DNACPR notices, how should a similar mistake be prevented in future. Second, if the Inquiry finds there was inappropriate use or understanding of DNACPR notices (regardless of cause) were there missed opportunities to prevent that occurring.

21. On the first issue, although NICE cannot know how its guidance is received and acted on in every clinical setting, it remains of the view that the wording of NG159 could not reasonably be read as recommending or even permitting the use of blanket DNACPR notices, still less that a DNACPR notice should be equated to a do not treat decision. All clinical judgements, whether they are informed by NICE guidance or not, must be taken within a well understood and universally applicable framework of ethical and professional obligations, for example the duty to act in the best interests of a patient, or the duties surrounding informed consent. NICE guidance cannot abrogate these duties because NICE guidance is subject to and subordinate to these duties. Furthermore, NICE is not and has never held itself out to be a body that is empowered to issue ethical

guidance, which would be the role of the General Medical Council ["GMC"] (or other professional regulator) and/or professional bodies.

22. For the same reason NICE is, respectfully, very wary of any suggestion that, if there was misuse or misunderstanding of DNACPR notices in the pandemic (independently of a misunderstanding of NICE guidance itself, which NICE would seek to correct by ensuring its guidance is clear) then NICE guidance would have been an appropriate vehicle to remind clinicians of their ethical and professional duties. NICE suggests that would be wrong in principle. NICE is not a body that issues guidance of this sort. It does not have the expertise or indeed the remit to expound on these issues, which already sit within a governance framework and professional best practice guidance. The status of any NICE guidance would be unclear (would the relevant regulator be expected to enforce it, for example?) And a clinician in need of guidance on ethical or professional standards would not think to look to NICE. They would instead look to their regulator, professional body or professional association. Professor Summers told the Inquiry that training on these issues was a requirement of the GMC, and that it should be embedded as a core part of professional education (09/10/24 P40 L4). That would be outside NICE's remit.

23. There is additionally the practical point that there is no mechanism within the NHS for NICE to know how DNACPR notices are being used and thus has no way to identify that guidance might be needed. NICE does not have a role in the surveillance of professional practice.

24. The same concerns would apply to any suggestion that NICE should create guidance on prioritisation of patients, in a situation where demand exceeds capacity. NICE would respectfully agree with Professor Powis who said: "*In my view it's a discussion that shouldn't be government led, it shouldn't even be led by the profession, it needs to be located within society.*" (7/11/24 p91 L22) NICE does not have the remit to opine on what would be essentially an ethical dilemma. It does not have the

necessary experience and expertise, nor are its evidence-based methods, which have been devised to define a specific scientific problem, assemble and grade the available published evidence, and produce an expert synthesis by discussion and consensus well suited to what would surely be a particularly wide ranging and subjective debate on which reasonable people could well have very widely differing views.

Longer term effects of the first draft of NG159

25. NICE notes that some witnesses (for example Matt Stringer for the Disabilities Charities Consortium, and the evidence submitted on behalf of Mencap) have expressed a concern that the exposure of the first draft of NG159 for five days might nevertheless have had a lasting effect. Mr Stringer says:

"- I think there was some confused guidance, so NICE issued guidance on 20 March, and then there was a two-week period where there was a lot of input into that because we felt that guidance sort of encouraged or opened the door to that slightly more blanket approach. And that was sort of rowed back on 3 April, so about two weeks later. But we felt that, you know, the sort of cat was out of the bag, in essence, or the horse had bolted over those two weeks with that guidance sort of permeating into the Health Service, and people then you know taking that encouragement to maybe use DNACPR notices in a slightly more, sort of, to use your word, blanket fashion. And we've seen evidence of that from, you know, our membership, in essence." 10/10/24 P78 L22

26. On a factual point (and with no disrespect to him) Mr Stringer is mistaken that the defective guidance was live for two weeks. It was live for five days. NICE believes the reference to 3 April 2020 is a reference to a letter sent by NHS England and NHS Improvement ["NHSE&I"] (INQ000216427) in which NHSE&I made clear its own expectations around the use of the CFS and DNACPR notices, which referenced NG159. But that letter repeated the position made clear by NICE on 25

March 2020, rather than withdrawing the guidance published on 20 March 2020.

27. NICE cannot say whether Mr Stringer is factually correct that the earlier defective version of NG159 had negative effects that continued after the revised version of NG159 was published. It has already noted it does not have a mechanism to monitor practice within the NHS, still less does it have a mechanism to monitor the reasons for practices within the NHS. It would also observe that, to the extent that the concern was that NG159 would be inappropriately applied to deny treatment where clinical demand outstripped the facilities available, the NHS never declared that such a situation had arisen.

28. What is clear is that any clinician who was applying blanket DNACPR notices to patients was not following NICE guidance, which was rapidly reinforced by, inter alia, NHS England, as well as contrary to the ordinary ethical and professional standards of the medical profession.

Guidance on Long Covid NG188: initiation, scope and publication

29. In its Opening Statement to Module 3, NICE stated that it did not want to pre-empt the evidence that the Inquiry would hear in relation to Long Covid and it would wait to hear the evidence given. Patients' representatives and others have rightly drawn the Inquiry's attention to the challenges faced by those who suffer from Long COVID, their carers, family and friends. No doubt the Inquiry will be concerned whether all that can reasonably be done for them is being done, and whether NICE's guideline has a role to play in answering that question.

30. Dr Chrisp explained that at that time, NICE only started work on a guideline when the topic in question was referred to it by NHS England or the Department of Health and Social Care ["DHSC"] (30/10/24 P96 L24). Referral of topics in this way is an important safeguard to ensure

that NICE's limited resources are concentrated on topics that will be found valuable in the NHS. He also explained that the topic was referred to NICE on 30 September 2020 (30/10/24 P97 l1), and the guideline was developed collaboratively by NICE, Scottish Intercollegiate Guidelines Network and the Royal College of General Practitioners and was first published on 18 December 2020, giving a development time of just over 11 weeks[1]. Notwithstanding that accelerated process, a consultation exercise produced 1066 comments from 77 consultees. NICE is confident that the Guideline represented the best guidance that could be given when published, considering the limited nature of the available evidence.

Guidance on Long Covid: updates

31. Dr Chrisp explained that NICE now has a prioritisation board that allocates its resources across all of the work NICE is tasked with. The board works to published processes, priorities and criteria. NICE maintains c.350 guidelines that may need updating, as well as developing new guidance. As Dr Chrisp had retired from NICE, he was unable to say specifically why NG188 had not been updated since November 2021, but surmised that the combination of emergence of new evidence, variation in care, impact on people and the quality of the care they received may not be sufficient to make NG188 a priority over the other guidance to which NICE could devote its resources (30/10/24 P99 L21). And Dr Chrisp's witness statement [INQ000438429] at paragraphs 79-85 sets out how NICE kept abreast of the developing evidence base during the pandemic and used that to drive decisions on guideline updating.

32. The Inquiry will appreciate that in deciding where to allocate its limited resources, NICE must both exercise expert scientific judgement as to whether a particular piece of new evidence is sufficiently significant to

[1] Dr Chrisp was asked in his oral evidence whether children and young people were within the original scope, and he did not know the answer at the time. NICE has checked its records, and the answer is that they were initially included.

call for a revision to a guideline and consider the needs of all patients, and seek to allocate committee time where it seems likely to deliver the greatest benefit. This inevitably means that not all projects that might be deserving or important when looked at in isolation can be prioritised.

33. Since the last update of NG188, there has been substantial work on the epidemiology and pathophysiology of Long Covid, but current approaches to the management of the condition are largely symptomatic and supportive, without a strong evidence base. One strand of clinical practice is based on a rehabilitation therapy model of alleviating symptoms and optimising functional performance, whereas others feel that exercise should be minimised or adjusted to avoid symptoms of post-exertional malaise.

34. NICE guidance is dependent on the availability of good quality evidence and at present it does not appear that the evidence base is sufficiently well formed to make additional reliable guideline recommendations. This lack of evidence is reflected in the current NICE Guidance NG188, which has two recommendations for research about exercise interventions and rehabilitation. Further recommendations on the role of exercise would depend on the publication of new, good quality data.

GENERAL OBSERVATIONS AND LESSONS LEARNED

Much went well

35. Necessarily, these closing submissions have so far concentrated on mistakes that were made, criticisms that have been made of NICE, or areas for improvement. The Inquiry will be astute not to lose sight of the fact that this reflects only a very small fraction of NICE's experience during the pandemic. The evidence of NICE's witnesses, Dr Roberts, Helen Knight and Dr Chrisp, set out at length the ways in which NICE rose very successfully to the challenge of the pandemic. NICE would highlight its work on RAPID C-19 (Helen Knight's witness statement

INQ000415330 at paragraphs 35-83), the reconfiguration of its working practices and breadth of its role (Dr Roberts' witness statement INQ000346798 at paragraphs 32-95) and the sheer volume of work carried out (Dr Chrisp's witness statement INQ000438429 at paragraphs 92-97).

Speed may initially have been given too high a priority

36. As Professor Powis is noted as saying above, providing guidance during a pandemic necessarily involves difficult trade-offs between speed and stakeholder engagement. In the early days of a pandemic, where little may be known about the illness or treatments, where clinicians may be being redeployed into clinical areas that are not part of their usual practice, and where stakeholders will be facing their own challenges of adapting to new ways of working, speed will be at a particular priority. The best may be the enemy of the good. As a pandemic progresses, and there is more information to process, the balance may shift back to being able to take longer to prepare guidance and so allow for deeper engagement.

37. NICE has reflected on that trade-off and on the switch back to a process that balances speed and engagement more evenly in the interim process and methods guide which it adopted in July 2020. It would be that guide that would now form the "playbook" for NICE in a new pandemic. The July 2020 guide (which has been kept updated since its creation and sits as appendix L to NICE's main guideline manual) represents a nuanced balance between speed and engagement. Future pandemics will still require what may be a difficult balance to be struck, but the guide makes clear that impacts on equity, equality and health inequality must be expressly considered and recorded as part of the independent advisory expert panel's discussions.

Pandemic preparedness and "business as usual" have been improved

38. NICE conducted its own lessons learned exercise, which is available to the inquiry as exhibit SR8 INQ000252461 to the witness statement of Dr Roberts. That exercise has supported both better pandemic planning, and changes to NICE's usual ways of working. Areas of learning included:
    - the need to further strengthen external relationships before a pandemic strikes, detailed below,
    - streamlined methods and processes and faster guidance production, set out in NICE's current process manual,
    - greater emphasis on health inequalities, informed (amongst other ways) by NICE's voluntary and community sector forum, which gives a voice to charity and patient groups (including Mencap and the National Autistic Society) beyond engagement in specific pieces of guidance, and
    - greater focus on prioritisation informed by user research and the external environment, embodied in specific criteria and processes on prioritisation set out in NICE's manual.

Engagement with stakeholder groups

39. NICE has designated its chief medical officer (CMO) as the pandemic preparedness lead. He is working with DHSC, NHS England, UK Health Security Agency and the Office for Health Improvement and Disparities to position NICE correctly within the NHS England Emergency Preparedness, Resilience and Response framework, to ensure NICE is alerted and engaged at a very early stage of any future pandemic.

40. There is ongoing work to improve NICE's approach to engaging with voluntary and community stakeholder groups. In 2022 NICE established the Voluntary and Community Sector ["VCS"] Forum. In July 2024 NICE approved the "Working Alongside People and Communities Strategy" which outlines its approach to involvement and engagement.

Part of this strategy was the transition of the VCS Forum to the Voluntary and Community Sector Network. This included identifying gaps in membership and encouraging more groups to join. The network currently has 373 voluntary and community sector members, representing a wide range of health conditions from common conditions to very rare diseases, organisations representing different population groups, (including those covered by the Equality Act), local Healthwatches, and organisations highlighting social issues.

41. Moving forward, NICE is looking to establish a number of partnerships with the voluntary and community sector, working together with organisations at a more strategic level to inform and develop its approaches to involvement and engagement. NICE welcomes approaches from any organisations keen to contribute to this. This network also has the advantage of actively engaging groups (including disability groups) so they can provide more strategic input across all of NICE's programmes of work rather than having to register as a stakeholder in every guidance product. This has the potential to address issues relating to disabilities that apply across many guidelines.

42. NICE continues to review its guideline development methods and processes. The methods and processes manual, including appendix L has had several major updates since July 2020, with updates on January 2022 (responding to health and social care emergencies), August 2023 (enhancing the approach to reducing equalities and health inequalities) and January 2024 (general updates to the manual including further strengthening of the Equality Impact Assessment process). This information is all publicly available on the NICE website.

43. In addition, NICE is working on a further review in which it is considering how best to engage with stakeholders who are impacted by its guidance, including people with disabilities or other protected characteristics. The update will be informed by advice from the People and Communities Team and input will be sought from the Voluntary and

Community Sector Network to inform the sections on engagement. The changes to the guideline manual, including appendix L, which outlines NICE's "Process and methods for guidelines developed in response to health and social care emergencies" will be informed by this input from stakeholders.

Multiple sources of guidance

44. The Inquiry will have noted that there was a range of bodies producing guidance during the pandemic. NICE considers that that was appropriate. While NICE has an important role to play, and as noted above, this role has been strengthened by the NICE CMO joining relevant groups relating to national planning and preparedness, any response needs to be coordinated across multiple organisations bringing their expertise to bear in a spirit of cooperation and collaboration. For example, the UKHSA would be expected to lead on guidelines relating to infection prevention and control, while NHS England would lead on guidelines relating to commissioning and service delivery.

CONCLUSION

45. NICE would like to end these submissions by once again expressing its sympathies to those bereaved by COVID-19, to those still suffering from its effects, and to their relatives and friends. It would like to pay tribute to the hard work and bravery of the NHS staff who responded to the challenge of the pandemic, often at great personal cost, and to the other key workers who made that response possible. And finally, NICE would like to thank the Inquiry for its careful attention to its important work. NICE will welcome the recommendations of the Inquiry and looks forward to playing its part in implementing them.