

Witness Name: Professor Sir
Jonathan Montgomery
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF Professor Sir Jonathan Montgomery

I, Professor Sir Jonathan Robert Montgomery, will say as follows: -

Section 1: Background and experience

1. I am Professor of Health Care Law at University College London, Chair of Oxford University Hospitals NHS Foundation Trust, and Chair of the Ethics Advisory Committee of Genomics England.
2. During the Covid-19 Pandemic I was co-chair of the Moral and Ethical Advisory Group (MEAG) and attended meetings of the Risk Stratification Implementation Group to facilitate liaison with MEAG when necessary. I was also Chair of the Ethics Advisory Board to NHSx on the development of its contact tracing app. I was, and remain, a member of the Ethics Committee of the Faculty of Public Health.
3. I hold a BA (Hons) in Law and an LLM from the University of Cambridge.
4. I was made Honorary Fellow of the Royal College of Paediatrics and Child Health in 2005, Knight Bachelor in 2019 (for services to bioethics and health care law), Fellow of the Academy of Medical Sciences in 2021 and Honorary Fellow of the Faculty of Public Health in 2023.

5. I have previously held a number of NHS and public service roles, including Chair of the Human Genetics Commission (2009-12), The Nuffield Council on Bioethics (2012-17), and The Health Research Authority (2012-19).
6. I was a member of the Nuffield Council on Bioethics Working Party on Public Health Ethical Issues, which reported in 2007 and has been influential in the development of the field. The Report included a chapter on infectious diseases that discussed the ethics of vaccination.
7. I was a member of the Committee on the Ethical Aspects of Pandemic Influenza (CEAPI) which sat from September 2006 until December 2009. This Committee drafted the document that was adopted by the Cabinet Office in 2007, *Responding to pandemic influenza: The ethical framework for policy and planning* (JM/1 INQ000119368). With minor updating, this document forms the basis of the current official ethical framework for pandemic planning (JM/2, INQ000501411). The minutes of the CEAPI were published on the Department of Health's website and are available via the National Archives. As part of the work on testing the draft principles, I wrote a paper that was considered by the CEAPI in December 2006 on the application of its principles to prioritizing access to pre-pandemic vaccines (JM/3 INQ000496168).
8. I worked with the Ada Lovelace Institute as part of their programme on vaccine certification. My contribution was to chair an expert rapid deliberation during January and February 2021 that considered the risks and benefits of the potential roll-out of digital vaccine certification schemes, discussed the evidence, deliberated on use cases, explored opportunities and risks, and identified areas of consensus to support government decision makers around the world. The Report is published on the Institute's website (JM/4 INQ000496169).
9. As an academic working on areas of public interest, I am sometimes contacted to give talks and approached to give media interviews, I also undertake research with a view to publication. Such activity during Covid-19 pandemic that is relevant to Module 4 of the Inquiry, based on a review of my diary and files, is

- a. Quoted by Mail on Sunday on ethics of challenge trials, 9 August 2020 (JM/5, INQ000501266).
 - b. Presentation to webinar on 'Epidemic Ethics: Mandates and special privileges for COVID-19 vaccination', 15 March 2021. (JM/6, INQ000501269).
 - c. Opinion piece on policy shifts on covid certification for Sunday Express 4 April 2021 (JM/7, INQ000501267).
 - d. Opinion piece on whether teenagers should have Covid-19 vaccination for Sunday Express 8 August 2021. (JM/8, INQ000501268)
10. I gave evidence to the Scottish Parliament's Select Committee on COVID-19 Recovery on 23 September 2021 on vaccine certification.

Section 2: The purpose, functions and membership of the Moral and Ethical Advisory Group (MEAG)

11. The purpose of MEAG, as set out in its Terms of Reference of December 2019 (JM/9 INQ000048128), was to 'provide independent advice to the UK Government on moral, ethical and faith considerations on health and social care related issues as they occur. This advice will be used to inform management of health-related incidents including but not limited to pandemic flu.'
12. These Terms of Reference include an organogram summarizing the proposed governance structure. There was no such organogram in the earlier draft that was discussed at the initial meeting of the Group on 25 October 2019. It is my understanding that this is the organogram referred to in paragraph 6 of the update provided to the Pandemic Flu Preparedness Board on the establishment of the MEAG on 27 November 2019 (JM/10 INQ000104658). I have reached this conclusion as paragraph 6 is a summary of issues raised by MEAG members and the revised Terms of Reference, including the organogram, were the result of addressing those issues. I am not aware of any other document setting out MEAG's place in decision-making processes.

13. The Terms of Reference that were received and discussed at the initial meeting of the MEAG on 25 October 2019 (Minutes, JM/11 INQ000023082) provided that the MEAG should operate in two modes; response during an emergency, and planning to support the DHSC as it created and maintained contingency plans for health and social care risks, including as a specific example pandemic flu. At this meeting MEAG was briefed that there were current issues around EU Exit planning that might require advice in response mode. Pandemic preparedness was envisaged to be part of planning mode. This was quickly superseded by the emergence of Covid.
14. The impact of the Covid-19 Pandemic meant that 'response' was the only form of work that MEAG undertook before it was stood down. However, we did briefly discuss what the planning mode might involve and 'agreed that MEAG would establish a work programme of issues that should be considered for moral and ethical advice noting that, ultimately, it would be for DHSC to prioritise the issues for consideration. In addition, it was noted that any post-incident learning should be included for discussion during 'peace time' to give the Group an opportunity to reflect on the reasoning for any moral and ethical decisions taken during an emergency which could inform future decisions' (Minute 3.6).
15. Following discussion on 25 October 2019, the scope and responsibilities of MEAG were finalised as to 'provide independent, timely and coordinated moral, ethical and faith related advice in response to questions and issues put to it;...respond to adhoc requests that arise as a result of health-related incidents or events which might need to be considered at pace; in the longer term, the plan will be for MEAG to advise proactively on issues that might be relevant to emergency preparedness planning more generally.'
16. When MEAG was established, it was envisaged that it would be co-sponsored by the Director of Emergency Preparedness and Health Protection (DHSC) and Director of Integration and Communities (MHCLG) and that each would be able to convene the Group. In practice, it was convened by and supported within DHSC.
17. Under the Terms of Reference, meetings of MEAG could be requested by the UK Chief Medical Officers (CMOs); The Clinical Advisory Group (CAG); Director level co-sponsors; Government Departments, Devolved Administrations and Arms' Length

Bodies via the co-sponsors; Ministers/COBRA. In practice, meetings were coordinated by a secretariat; **NR** (until July 2020); **NR** (July/August 2020); **NR** (August 2020-21) and **NR** (2021 until MEAG was stood down).

18. The role of MEAG was advisory and the Terms of Reference made it clear that 'those seeking advice will take MEAG's advice into account in their considerations but will not be obliged to accept or act on it.' In general, discussions at MEAG were exploratory and not directed at specific decisions; so it is not possible to track the impact. Exceptions include the draft 'Ethical Framework for Adult Social Care' (discussed on 10 March 2020) which was amended to take into account comments from MEAG members. In addition, the guidance on attendance at end-of-life and funerals was significantly shaped by MEAG discussion on 8 and 9 April 2020.
19. The appointment of two co-chairs ensured that the contributions from communities and from the health and bioethics experts were fully recognised. We shared responsibility for discussing agendas with the civil servants supporting MEAG. In general, we would alternate chairing of meetings, but where I had been responsible for bringing issues to MEAG after liaison with other groups or for drawing up prompts for consideration, then it was usually easier for Jasvir Singh CBE to handle the meetings themselves. We were supported by two vice-chairs, Rabbi Dr Moshe Freedman and Professor Vivienne Nathanson. They acted as a sounding board for the co-chairs when we were discussing how best to ensure MEAG was as effective as possible.
20. The Membership of MEAG brought together experts in law and bioethics from academic and health professional regulators with senior members from faith and community organisations. Members were appointed in a personal capacity and did not represent bodies or constituencies. However, it was intended that the diverse membership would ensure that the Group was informed of a wide range of perspectives and lived experience as well as expertise from relevant disciplines. A list of members was published on the DHSC website (JM/12, INQ000501415)
21. Meeting summaries were made publicly available via the DHSC website. These summaries had to be cleared by ministers before becoming available and there were significant delays before this happened.

22. MEAG did not publish any documents in its own right. It did discuss the value of drawing up a list of principles on 22 and 29 April 2020. Following the discussion at the former meeting, Jasvir Singh CBE and I wrote to Professor Sir Chris Whitty on 27 April 2020 on behalf of the Group with some observations on its work and inviting him to consider a number of matters. These included whether he would like to commission MEAG to produce a framework to assist decision-makers take moral and ethical issues into account during transitions between phases of the response to Covid-19 (JM/13, INQ000117868) We did not receive a written response but I was able to speak directly to Professor Whitty and we received a very helpful brief from an official from his office at the meeting on 29 April 2020. It was noted that his advice was that work on supplementing the existing ethical framework for pandemic planning might crowd out the capacity of MEAG to address detailed issues on which urgent advice was being sought. There was no instruction not to compile a written framework.
23. On 20 January 2021 MEAG members discussed their views on the role of the Group. I summarized a discussion I had had with the CMO for England (Professor Sir Chris Whitty) earlier in the week. His advice had been that MEAG was most helpful when it helped civil servants understand the complexity of issues and that it provided a valuable sounding board in a context where things moved very fast. Producing documentation that offered recommendations might not be helpful, given the political as well as ethical aspects of decision making. Members recognized that specific ethical recommendations might sometimes create political difficulties when they had to be balanced against other factors that the Government would need to consider. There was already experience of newspaper journalists trying to elicit views from MEAG members in order to criticize the Government. It was noted that other groups were active on ethical issues, including the Nuffield Council on Bioethics and the British Medical Association These had important roles to play. The value of MEAG discussion lay in advising on the complexities of issues, drawing on the diversity of the group's membership, rather than simplifying them to support specific recommendations.
24. My personal view is that MEAG would have been unable to reach a consensus on a principles document in a timely manner. To have pursued this would have made it very difficult to spend time on other matters. I reached this conclusion having attempted to draft a document of such principles for MEAG's consideration. I reviewed published

material and consulted others working on these issues in order to produce a discussion paper for the MEAG meeting on 1 April 2020 (JM/14, INQ000501484). Contributions to that meeting and comments that I received subsequently identified that there were major differences in approach and fundamental principle that would have taken considerable time to resolve. These included the acceptability of 'first come first served' approaches, the use of lotteries to allocate resources, whether the interests of children and/or older persons should get particular weighting, whether background inequalities (e.g. physical disabilities and socio-economic disadvantage) should be taken into account, whether those for whom a treatment is the only chance have a stronger claim than those more likely to benefit from it, and how to take account of religious beliefs in the importance of trying everything even if the chance of survival is remote.

25. These issues are all reasonable points to raise. It would have been difficult and time consuming to seek a consensus on them. It would also have been inappropriate to obscure the complex ethical and moral arguments at stake by suggesting there was a simple recommendation. In my opinion, had MEAG done so it would have reduced its usefulness.

Section 3: Relationships with other bodies examining ethical issues

26. The member of SAGE with bioethics expertise, Professor Mike Parker, was also a member of MEAG. He shared with MEAG papers that he had written for SAGE and was able to inform his unput into SAGE from the MEAG discussion. His witness statement covers this (JM/15, INQ000056579). There was also overlapping membership with the New and Emerging Respiratory Viruses Threats Advisory Group (NERVTAG) and with the Joint Committee on Vaccination and Immunisation (JCVI) sub-committee on Covid-19 through Professor Robert Dingwall who kept MEAG members aware of relevant matters of overlap. I attended the Risk Stratification Implementation Group and this prompted matters being referred to MEAG for advice on a number of occasions. I shared advice from the Ethics Advisory Board to NHSx on the contact tracing app with MEAG members so that they were aware of developments in that area.

27. The Link with the Welsh MEAG was strong, with the chair, Dr Heather Payne, attending MEAG. Wales published *Coronavirus: ethical values and principles for healthcare delivery framework* on 12 April 2020, which developed for the Covid-19 context the CEAPI Principles that MEAG had adopted (JM/16 INQ000081000). MEAG had members appointed from Northern Ireland and Scotland. The authors of *COVID-19 guidance: ethical advice and support framework* issued by the Scottish Government on 3 April 2020, and subsequently revised (JM/17, INQ000233594), were not members of MEAG but that document drew on the CEAPI Principles.
28. The Joint Committee on Vaccination and Immunisation (JCVI) was the body which took the lead on recommendations for the use of vaccines (including prioritization). My MEAG co-Chair, Jasvir Singh CBE, attended a JCVI meeting on 7 May 2020 and briefed JCVI on the ethical framework from CEAPI including the paper on the ethics of vaccine prioritization from 2006 that I had drafted as part of CEAPI's deliberations. The JCVI minute 91 of that meeting records that 'The Committee agreed that JCVI advice would be based on scientific principles from the available scientific evidence and this would not include detailed ethical considerations which were for DHSC to consider, informed by MEAG.' These Minutes are at JM/18, INQ000354439. On 13 May 2020 MEAG discussed the issue of vaccine prioritization, receiving the paper that had been presented to that JCVI meeting (see below).
29. Responsibility for approving research studies and examining ethical issues raised by research methodologies, including 'human challenge' trials, lay in England with the Health Research Authority (HRA). The HRA has a well-established system of Research Ethics Committees to consider whether to approve trials and a National Research Ethics Advisors Panel to assist on novel issues. In my opinion, this expertise was more appropriate for oversight of the ethical issues in research than would have been provided by the membership of MEAG. The licensing of vaccines was the responsibility of the Medicines and Healthcare products Regulatory Agency. There were no arrangements for liaison between MEAG and these bodies. I knew senior staff in both bodies from my time as Chair of the Health Research Authority. I would have been able to approach them for information if MEAG members had felt that would have been productive to do so. However, we did not identify any need for this.

30. Very important work on ethical issues was done by the Nuffield Council on Bioethics (NCoB) throughout the pandemic. Possible membership of MEAG from NCoB was discussed in April 2020 and it was mutually agreed that it was valuable for NCoB to retain its independence of Government rather than being a member of a government advisory body. I maintained regular conversations with the Director of NCoB in which we shared what was being discussed to avoid inadvertent duplication or divergence of views.
31. The UK does not have an official body regulating or overseeing clinical ethics. There is an unofficial and voluntary UK Clinical Ethics Network that provided guidance for organisations grappling with ethical challenges during the pandemic. Support and guidance also came from various health professional bodies, addressed to their members. MEAG benefited from the insights of its members who were working with the General Medical Council, Nursing and Midwifery Council, British Medical Association, Royal College of Nursing. Although members did not represent those groups, they ensured that MEAG was aware of the issues they were dealing with and the positions that they were adopting.

Section 4 An outline of MEAG meetings

32. The initial meeting of the Moral and Ethical Advisory Group was held on 25 October 2019. That meeting considered and made suggestions about the Terms of Reference and membership. It noted that MEAG might be called upon to advise on issues around planning for EU Exit and to inform planning on responses to challenges such as an influenza pandemic. Issues of confidentiality and transparency were raised. MEAG agreed to use CEAPI's 'Ethical Framework for Policy and Planning' to inform its decisions, but to build a review of that Framework into its work programme. The minutes of this meeting, which have not been given a number, have not been published. These minutes are at JM/11, INQ000023082.
33. MEAG held 29 meetings concerning the Covid-19 pandemic. The first was on 10 March 2020 and the last on 28 April 2021. Those concerning issues within the Scope of Module 4 of the Inquiry are discussed in detail below. These were the meetings held on 29 April 2020 (Covid certification); 13 May 2020 (vaccine prioritization); 21 October

2020 (ethical issues in vaccine production); 18 November 2020 (vaccine rollout); 2 December 2020 (Covid certification); 3 March 2021 (vaccine prioritization); 31 March 2021 (vaccination as a condition of deployment); and 28 April 2021 (Covid certification).

34. Other meetings on Covid-19 issues concerned the draft of the Ethical Framework for Adult Social Care (10 March 2020); an overview from Cabinet Office and the Civil Contingencies Secretariat on work to manage the impact of excess deaths caused by the Covid-19 outbreak (16 March 2020); the Coronavirus Bill (20 March 2020); clinical guidance on managing pressure on resources (20 and 25 March 2020); principles to guide advice (1, 22, 29 April 2020); guidance on attendance at end-of-life and funerals (8 and 9 April 2020); shielding (29 April 2020 and 4 November 2020); recovery strategy (13, 20, 27 May 2020); disparities in risks and outcomes of Covid-19 (10, 24 June 2020, 8, 15 July 2020, 12 August 2020); risk stratification (12 August 2020 and 18 November 2020); guidance for the management of aerosol generating procedures (23 September 2020); and backlogs in screening (17 February 2021).
35. I have been asked whether MEAG discussed antiviral treatment, which was one of the examples used in the 2007 Ethical Framework of a step that might be taken to minimize harm. I do not recall discussion of this specifically. However, the 'shielding' policy was an example of a risk minimization intervention and MEAG did discuss that at two meetings and then additionally explored the ethical dimensions of risk stratification which was closely linked. Given the novel nature of Covid-19 it would have been premature to discuss antiviral treatments until evidence emerged of effectiveness, particularly through the RECOVERY Trial. When the 2007 Framework was drafted it was known that Oseltamivir (Tamiflu) was likely to be effective against influenza, but stocks were limited. The position in the Covid-19 was much more uncertain.
36. MEAG discussed some matters outside of the scope of the Covid Inquiry during 2021; the possible criminalisation of hymenoplasty on 8 September 2021, storage time limits for eggs sperm and embryos on 27 October 2021, and the use of Artificial Intelligence in medical imaging on 15 December 2021.

37. MEAG did not meet during 2022 and was officially stood down in October 2022. During the early months of 2022, meeting dates were held in members' diaries but cancelled when no issues had been identified for discussion by civil servants. A three-year review meeting was convened on 10 October 2022 with Professor Sir Chris Whitty (CMO) and William Vineall (Director, NHS Quality, Safety, Investigations, DHSC) to reflect on the operation of MEAG. Prior to that meeting, members were invited to contribute thoughts on the operation as a form of 'post incident learning'. The responses of which I am aware are in two email chains, JM/19, INQ000501488, and JM/20, INQ000501489. The action summary of the meeting is JM/21, INQ000501490. Members were emailed about the outcome, which was to stand the group down, on 27 October 2022 (JM/22, INQ000501491).

38. Plans for the future were explained to the members of MEAG in May 2023 when a reception was arranged to thank them for their contributions. The intention was to use three ways of getting ethics guidance; (1) use existing resources to support ethical policymaking, (2) seek expert advice through the Health Ethics Expert Directory (MEAG members were invited to indicate their interest in being part of this), and (3) convene an ethics advisory group. The email summary provided to members of this approach is JM/23, INQ000501487 and the slightly fuller explanation that I received is JM/24, INQ000501492.

Section 5: Vaccine development and safety

39. On 21 October 2020 MEAG discussed ethical issues arising from concerns about the possible use of fetal cell lines and porcine material in immunization that had been raised by some communities. A paper (JM/25, INQ000501265), presentation, and comments from those familiar with the production of the vaccines informed MEAG members that there would be no fetal cells or products of animal origins in vaccines as administered but they would have been used in the development of vaccines. It was confirmed that vaccination would be not compulsory and consent would be required from recipients. MEAG advised on how best to communicate the facts about potential COVID-19 vaccine candidates, to explain them clearly, and to encourage uptake of a COVID-19 vaccine. The consensus was that honest and clear information

should be provided to allow the public to make an informed choice on vaccination; that this should be realistic about alternatives; the actual concerns of individuals and communities should be given the consideration they deserve; and that vaccines that use animal origin in development should be given the same ethical consideration as vaccines from fetal origin in development. It was generally agreed that mistrust in science and 'fake news' was a significant issue that should be addressed not ignored. Members thought the experience of working with communities to explore options about organ donation was a good model that could be used here. This was a good example of addressing the concerns of communities respectfully. In the context of Covid-19 vaccination, this suggested working through community leaders rather than merely issuing official reassurances of safety and compliance with ethical requirements.

40. MEAG had a brief discussion of vaccine rollout and Patient Group Directions (PGDs) on 18 November 2020 (JM/26, INQ000193133). Members noted the importance of involving the professional regulators in planning the roll-out of the vaccination programme, given the issues this raised for communication, proportionate consent, the information clinicians would need to share with patients, and the clinical guidance to support this. It was noted that final resolution of a number of these issues would have to await clarity on the specific properties of the vaccine(s) to be delivered.

Section 6 Vaccination prioritization and reluctance

41. MEAG first discussed vaccination on 13 May 2020, with officials from the Joint Committee on Vaccination and Immunisation (JCVI) joining. A JCVI Paper (JM/27 INQ000354438) was circulated that drew attention to discussion points: Is a vaccine strategy targeting risk groups preferred over targeting transmission groups?; If a risk group strategy is the preferred option, what are the risk groups and in what priority order should they be considered for vaccination?; What evidence could modify the priority order?; Whether they [i.e. JCVI] are content to provide scientific advice, and for DHSC to consider ethical/legal considerations, when considering priority groups e.g. prioritising younger ages over older frailer individuals?; Which key workers to prioritise? That paper had been discussed at a meeting of JCVI on 7 May that was attended by Jasvir Singh CBE on behalf of MEAG.

42. It was noted that there was considerable uncertainty over whether a safe vaccine could be created; if so when it might become available; for whom it might be licensed (e.g. for which age groups). It was not at that stage known whether any vaccines that were developed would hinder transmission or reduce the impact of the disease and it was recognized that this would affect the prioritization strategy. The paper noted that Covid-19 deaths were higher in areas of deprivation and that people of Indian, Pakistani, Bangladeshi and Black Caribbean ethnic groups had an increased risk of death.
43. Members of MEAG raised issues of which groups of people will have access to the vaccine first and considered which front-line groups faced specific risks and should be prioritized under the principle of reciprocity. This was explained in the CEAPI framework as based on the principle of mutual exchange, so that if people are asked to take increased risks, or face increased burdens, during a pandemic, they should be supported in doing so, and the risks and burdens should be minimised as far as possible (JM/1 INQ000119368). It was noted that risk of exposure was not necessarily risk of disease. The meeting discussed whether age should be one of a number of factors considered and raised issues about whether the design of vaccine trials would generate data on a representative sample of the population to be vaccinated. Other points included the vulnerability of those who work in jobs which cannot be done from home; timeframes for the vaccine's development; and the need for a communications strategy to encourage the uptake of vaccinations. The issue of compulsion was raised but JCVI considered it to be a matter for the Government not them. It was noted that public confidence in vaccines would be important.
44. Interim advice from JCVI in on priority groups for COVID-19 vaccination was subsequently published on 18 June 2020: (JM/28 INQ000496165)
45. The second discussion of vaccine prioritization was on 3 March 2021, when MEAG discussed the JCVI's interim phase 2 vaccination programme advice (JM/29 INQ000496167). Members discussed the significance of the added simplicity of prioritising by age. It was noted that if prioritising this way was much faster, then that alone might significantly mitigate other moral concerns about distribution. Prioritisation of worst affected areas and occupations was discussed. Issues of supply and capacity

for vaccination centres were noted. It was observed that where there was a clear signal on enhanced risk among health and social care workers, the principle of reciprocity (part of the ethical framework for pandemic planning) implied that they should be prioritised. It was noted that encouraging uptake of vaccinations based on occupation, rather than prioritising by occupation, could be an effective way of addressing reluctance. Issues around levels of uptake amongst certain BAME communities, younger adults were considered and members counselled against making assumptions as there were differences of views within these groups. The ethics of vaccinating children was flagged as an appropriate topic for further consideration. The note of the discussion is at JM/30, INQ000496176. MEAG did not return to the issue of vaccinating children, although individual members contributed to public discussions in their personal capacity. My contribution was a newspaper article (JM/8, INQ000501268).

Section 7: Covid-Status Certification

46. The first MEAG discussion of Covid-19 certification was on 29 April 2020. Members received a paper (JM/31, INQ000117876) seeking comments on the ethical considerations associated with a number of issues: providing individuals with antibody test results but not changing any social distancing advice (at least during the pilot period) to minimise impact on the rest of society; conferring rights on one small group of citizens that are not available to other citizens (and whether this changes given the size or characteristic breakdown of the group and the nature by which these benefits are conferred e.g. number of factors taken into considerations); any proposals that allow public authorities or employers to require someone to take an antibody test or use the results of that antibody test in ways that could be considered discriminatory (e.g. requiring an employee to work in a more public-facing role); conferring rights on an individual on the basis of a positive PCR/swab test (i.e. had the virus) compared to having a positive antibody test (i.e. has developed some level of immune response to the virus).
47. MEAG members raised concerns about the potential of risk-seeking behaviour if some people saw benefits gained from having a certificate; fraud, data privacy and

surveillance issues; the potential for exclusion of people who do not have smart phones; the effects on people from BAME backgrounds and from faith communities already disproportionately affected by Covid-19; and the risk of people losing out on employment if they lack a certificate as well as discrimination against those without certificates. The note of the discussion is at JM/32, INQ000117880.

48. The main MEAG discussion of Covid certification took place on 2 December 2020. The meeting received a paper that I had drafted with assistance of a number of MEAG colleagues. (JM/33, INQ000118224). In the discussion it was noted that there were some fundamental scientific questions that remained outstanding, regarding both immunity to reinfection conferred by a past infection and its duration, as well as the effectiveness of the vaccine to not only reduce the seriousness of disease in the recipient but also transmission of the virus to others. Answers to these questions would influence and inform the discussion of the value of certification. Concerns were raised that human rights, public engagement and trust had not received the attention that they deserved. The note of the discussion is at JM/34, INQ000401397.
49. I subsequently collaborated with Professor Mike Parker and Professor Robert Dingwall to produce a paper on ethical issues from covid certification for SAGE on 9 December 2020. This paper was informed by the MEAG discussion and subsequently published by SAGE on 5 July 2021 (JM/35, INQ000496182).
50. The final MEAG discussion of Covid-Status certification took place on 28 April 2021. A presentation was received on the work of the Covid Certification Review. Discussion focused on questions from officials on when exemptions to certification requirements should be considered. Issues included those who did not wish to be vaccinated due to risks, conscientious objection or age. Members noted that the purpose and basis of certification needed to be explained before it was possible to determine what exemptions might be appropriate. If controls based on certification were being used to protect others from risks, then exemptions would undermine this purpose. If certification were used in the near future, then the fact that many people, including young persons, will not have access to vaccinations was a significant concern. The note of the discussion is at JM/36, INQ000401399.

51. I have been asked to explain how MEAG addressed issues of lack of scientific knowledge. The phrase used in the MEAG minutes that 'there were some fundamental scientific questions outstanding' is probably misleading as it might be taken to suggest that questions would at some point become resolved and so it was possible to wait for the answer and then confirm advice. However, the issues that we were concerned about, such as the effect of the vaccines on transmission, would vary as the virus mutated. This would also vary between different vaccines. Length of protection could only be known as time elapsed. There were also differing degrees of confidence in the reliability of conclusions depending on the available evidence. MEAG aimed to give its advice on the best available evidence at the time when it was sought, usually through being able to question presenters at its meetings.
52. The approach that was taken in the paper that was submitted to SAGE in December 2020 (JM/35 INQ000496182) was to give conditional advice that identified the relevant scientific issues that impacted on the ethical acceptability of proposed uses of certification. It also commented on the degree of confidence in scientific findings that would be needed to make certification ethical. This judgment might depend on balancing competing values, as in the need for high degree of confidence where there is a need to restrict liberty significantly (e.g. remain at home) in comparison with a situation where people will be asked to adopt precautions but still able to do their planned activities (e.g. wearing masks). There a lower degree of confidence might be sufficient to justify recommending those measures.
53. An illustration of this approach, taken from the paper of 9 December 2020 (JM/35, INQ000496182), is as follows: 'The strongest ethical case for certification of vaccination arises where it gives both immunity against being infected and also prevents the person vaccinated carrying and transmitting the virus. Certification would enable such vaccinated persons to get the personal benefit of being released from restrictions, and also bring collective social and economic benefits by moving towards more normal social interactions. However, if vaccination gives protection to individuals but does not prevent them carrying and transmitting the virus then the benefit to the vaccinated individual would be at the expense of others who would in fact face increased risk if those certified were permitted wider social interactions. This would seem to amount to treating vaccinated individuals as if they mattered more than the non-vaccinated. Scientific advice is required on this. It would be

reasonable to suggest that a high degree of confidence would be required that those vaccinated would not be asymptomatic carriers before certification was adopted.'

54. A different approach to ethical advice can be adopted when specific proposals are put forward. In such situations, it is possible to probe the arguments offered in support of the policy and ask whether they are consistent with ethical principles, internally coherent, and supported by a sufficiently convincing scientific rationale. This is illustrated by the discussion at the MEAG meeting on 28 April 2021.

Section 8 Vaccination as a condition of deployment

55. MEAG discussed on 31 March 2021 Government plans to consult on whether and how to create a requirement for older adult care home providers to deploy only staff who have been vaccinated against Covid-19. Members noted that the ethics of mandating vaccinations for staff is in part contingent on the scale of the risks to care home residents and the effectiveness of this approach at mitigating these risks. They also noted that is a lack of evidence that mandating vaccinations will be effective at increasing uptake, as there is a mixed record on this kind of public health intervention. They suggested considering other avenues for encouraging vaccine uptake and protecting those in social care and taking time to assess the effectiveness of policies already in place, such as the use of rapid testing and providing more targeted information to communities with lower uptake. It was noted that there were risks to civil liberties, but these might be morally justified if those in mortal danger were protected.

56. MEAG did not receive any further information on the scientific evidence about risks and effectiveness after its meeting on 31 March 2021. However, it is clear from the introduction to the consultation document that was issued in April 2021 (JM37, INQ000501414) that these points were carefully considered.

57. Concerns were raised that the policy would disproportionately effect women, ethnic minorities, and those on a low income. The Group raised possible mitigations and also considered which exemptions would be appropriate. Members recognized that, given

the danger care home residents may be in, a case can be made against allowing any exemptions, even on medical grounds. They expressed concern that mandating could increase the number of people who seek exemptions and sought further information on how exemptions would be assessed and provided.

58. Members stressed the importance of clarifying and justifying the scope of the proposals and their legal basis. If staff were to be required to be vaccinated this might constitute a change of their employment contract. If employers were required to dismiss staff who declined to be vaccinated, it would be important to clarify whether they would be protected from or otherwise indemnified against litigation. Paragraph 41 of the consultation that was held between 14 April 2021 to 26 May 2021 stated that 'During the consultation period, we intend to discuss directly with employers the anticipated impact on individuals and the employment law consequences.' (JM/37, INQ000501414)

59. The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) Regulations 2021, SI 2021/891 subsequently addressed this by requiring care home operators to exclude non-vaccinated persons from their premises. This was achieved by amending the definitions of the duties to provide safe care and treatment.

60. Members also enquired as to whether there is a principle behind this policy being applied to older adult care homes but not to other care homes or closed community settings, as well as behind mandating vaccinations for staff but not visitors. These issues were raised because MEAG members were concerned about consistency of approach. This would be important if there was to be consideration of other areas where vaccination was made a condition of work. The note of the discussion is at JM/38, INQ000401347. Paragraph 18 of the subsequent consultation specifically asked for respondents' views on the scope of the requirements (JM/37, INQ000501414). This ensured that the point that MEAG members made was considered by the Government.

61. MEAG did not subsequently receive any specific report on vaccination as a condition of deployment. The Government consultation addressed the ethical issues that MEAG

raised but I am not able to say whether this was a direct consequence of our discussions.

Section 9: Reflections

62. MEAG reviewed its workings on a number of occasions; Meeting 8 (22 April 2020), Meeting 19 (9 September 2020); Meeting 22 (4 November 2020); Meeting 25 (20 January 2021). Initially it was felt that bringing health professionals, bioethicists and community leaders together was a challenge, but this was quickly overcome. There was some frustration with the fact that in 'response' mode it was necessary to deal with lots of issues that were not primarily for MEAG to lead; so that a 'task and finish' approach was not possible, and it was not possible to follow through on many of the issues explored. MEAG members got little feedback on what had been done with their advice and some felt as though advice was being given into a vacuum.

63. The main mechanism for MEAG advice being taken by DHSC and others was by the attendance at MEAG meetings by civil servants and other decision-makers. This included Professor Sir Chris Whitty (CMO), Dame Jenny Harries (DCMO), Mark Harvey (Chief Social Worker for England), Professor Jonathan Benger (CMO for NHS Digital). Members of the SAGE and JCVI Secretariats also attended on a number of occasions. Officials from the Cabinet Office joined a few meetings. Lord Bethell joined one meeting. Given the speed at which decisions needed to be taken, that circumstances and context changed frequently, that knowledge of the effects of the virus, treatments and vaccines developed rapidly, I believe that this was an efficient and effective way to ensure that key decision-makers were kept informed about ethical issues. It also meant that should MEAG have identified serious ethical concerns that were not being considered, then there was direct access to these individuals, especially the CMO for England who specifically encouraged me to contact him if I felt the wrong issues were being prioritized for MEAG meetings.

64. MEAG members felt on a number of occasions that they could have been more helpful if they had been consulted earlier. This was raised particularly in relation to vaccine rollout where there was a long delay between the two substantive MEAG discussions.

I have been made aware by the Inquiry team of an email of 2 October 2020 (JM/39, INQ000070986) that mentions the possibility of commissioning a short framework setting out the ethical considerations for prioritizing vaccine distribution. I was not aware of this at the time. However, I spoke with Sir Chris Whitty about the work of MEAG on 5 October 2020 and one of the points we discussed was that officials would not need to come to MEAG where the issues were already apparent to officials. It would not surprise me if he thought this was the case in relation to vaccine distribution. Sir Jonathan van Tam (DCMO) and indeed the CMO himself have considerable expertise in vaccination ethics and already had the support of the JCVI. I do not believe that additional MEAG discussions on this issue would have led to different decisions being made as when we did discuss it the points raised were familiar and not in conflict with the direction that had been taken.

65. In contrast, MEAG was consulted early on issues around certification and was able to contribute to the development of policy. This was also an area where the views of MEAG were shared widely through a 'teach in', an online session open to all civil servants on 22 January 2021 at which I presented the conclusions that had been shared with SAGE the previous December.

66. The work of MEAG felt quite England centric. Wales had its own group, but we were not aware of an equivalent in Northern Ireland or Scotland. Work did not come from CMOs outside of England despite contacts being made with their offices to check whether they wanted support.

67. There was no platform for engaging with public opinion, as some researchers succeeded in doing during the pandemic. This is now a normal part of exploring bioethical issues. Members of MEAG brought information from their networks but something more robust and systematic might have been helpful. This could take the form of the capacity to commission surveys, such as in Wilkinson et al, 'Which factors should be included in triage? An online survey of the attitudes of the UK general public to pandemic triage dilemmas' BMJ Open 2020;10:e045593 (JM/40, INQ000501485), or deliberations such as the work from Kings College London reported in Carroll et al 'Resource allocation, age and COVID-19 Deliberative study' (Ipsos Mori 2020) (JM/41, INQ 000501486).

68. MEAG played an important role in supporting Government decision making that depended on it providing a safe and confidential forum for advice that could support the development of policy at an early stage. This is a different role from that of providing external critical commentary such as that offered by the Nuffield Council on Bioethics. Both these functions are important if there is to be robust moral and ethical challenge. It is unrealistic to expect the same group to perform both of these functions.
69. The general role played by MEAG is also different from the need for specific expert support for ethical thinking in relation to particular projects, such as the Ethics Advisory Board to NHSx on the development of its contact tracing app, which I also chaired. The membership of such a group would not necessarily be the same for such a project as for the MEAG itself. This can be illustrated by the way in which the MEAG discussion of Hymenoplasty on 8 September 2021 led to the creation of a specific expert panel on that issue, which I co-chaired with a clinician who had not been a member of MEAG. Some MEAG members joined that panel, but it needed additional expertise in the particular issues. The report of that specially convened panel led to the criminalization of Hymenoplasty under the Health and Care Act 2022.
70. Looking towards preparations for the next pandemic it will be necessary to consider whether the model should be a standing generic panel or one tailored to the circumstances of the particular crisis. SAGE is convened with a particular emergency in mind and is usually quite a small body of appropriate experts. It will often be appropriate to take a similar approach to convening a MEAG in future emergencies. I understand this to be the logic behind the decision to stand down MEAG in its previous form and convene a specially selected group when this is necessary.
71. I have some concern that it may be difficult to identify appropriate members. The Government Chief Scientific Advisor and the Chief Medical Office will know which experts are appropriate to address the specific scientific and medical questions that are likely to arise as this is their primary area of competence. There is no equivalent 'Chief Ethics Advisor' within Government and selecting and convening an appropriate group may therefore not always be easy. This is a role that could be given to the Nuffield Council on Bioethics as it generally plays the role of the UK's National Ethics Committee in international meetings. The task of convening issue specific MEAGs in

the future will be facilitated by the directory of health ethics experts that the Department of Health and Social Care invited MEAG members to join (JM/23, INQ000501487).

Statement of Truth

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

Signed:

Personal Data

Dated: 13 September 2024