Witness Name: Dr Patrick O'Brien
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF Dr Patrick O'Brien, Former Vice-President of the Royal College of Obstetricians and Gynaecologists (RCOG)

I, Patrick O'Brien, will say as follows: -

1. The Royal College of Obstetricians and Gynaecologists (RCOG or the College) is a registered charity, with a mission to set standards to improve women's health and the clinical practice of Obstetrics and Gynaecology (O&G) in the UK and across the world.

2. The RCOG develops education, training and exam programmes for doctors wishing to specialise in O&G, publishes clinical guidelines, sets standards for high-quality women's healthcare, and provides a Continuous Professional Development programme for qualified O&G clinicians. The College plays a key role in contributing to public policy development that affects women's health outcomes, the wider health system, and our members. We regularly advise the Government and other public bodies on such matters. The RCOG is not a public body, and its remit is based upon both its mission as a registered charity and its role as a professional body; to raise the profile of women's healthcare and raise the standards of professional practice in Obstetrics and Gynaecology. The College holds no statutory or regulatory responsibilities.

3. The College is governed by its Royal Charter, from which are derived the College Regulations, which guide the governance, management and business arrangements of the College. The Board of Trustees comprises 10 trustees, who

are ultimately responsible for the financial, legal and business operations of the RCOG. The Chief Executive and the executive team manage the day-to-day affairs of the College. The College has approximately 170 members of staff.

4. RCOG Council is responsible for furthering the College's mission and for setting its long-term priorities and goals. Council establishes and oversees the clinical, educational, professional, academic and ethical activities of the College. It is chaired by the RCOG President and meets 6 times a year. The President is elected by the membership of the UK and Ireland and serves a three year term. Council elects five Vice Presidents who each serve for a maximum of three years.

5. As the professional body for Obstetricians and Gynaecologists in the UK, the RCOG supports and represents 9,100 members across England, Scotland, Wales and Northern Ireland, as well as another 8,400 globally.

6. A key function of the College is the production of patient information materials for healthcare professionals to disseminate to their patients and for patients to access directly via the RCOG website. In line with the College mission and expertise, the RCOG produced a comprehensive suite of guidance for healthcare professionals relating predominantly to the delivery of maternity services and the care of pregnant women during the COVID-19 pandemic. The College also played a key role in providing information and advice for pregnant women and their families.

7. We know that RCOG guidance on coronavirus and corresponding information for women was used extensively by staff working in women's health services and by women and families seeking reliable information, both in the UK and across the globe. Information on COVID-19 on the RCOG website has been visited almost 7 million times since the start of the pandemic, with over 6 million impressions on social media for our content on COVID-19 and pregnancy. The RCOG became the go-to place for trusted, evidence-based information about COVID-19, pregnancy and vaccination for healthcare professionals and women and families alike. More information on the RCOG's guidance and wider activities during the pandemic can be found in our submission to Module 3 of the inquiry [POB/1 - INQ000470853].

8. In terms of vaccines specifically, the College played an important role in advocating for pregnant women to be able to access the vaccine, and in ensuring the availability of reliable, trusted information for women and healthcare professionals. We had several concerns about how pregnant women were considered in relation to the development and roll out of the COVID-19 vaccine, which are explored in this statement, including the exclusion of pregnant women from clinical trials, the delay in prioritising them for vaccination, the spread of misinformation about vaccines, and hesitancy in vaccine uptake for some pregnant women.

Vaccine subgroup

9. One of the College's first actions in its work on vaccines was to established a vaccine subgroup of the COVID-19 Guidance Cell (established by the RCOG and RCM in early 2020, to act as the central mechanism for the RCOG response to the pandemic), in January 2021. The vaccine subgroup met weekly to discuss the latest safety data in relation to vaccinated pregnant women and vaccine trials, progress on vaccinating eligible pregnant women, questions and concerns from healthcare professionals involved in the vaccination programme, and how to communicate reliable information to women.

10. The subgroup was initially chaired by Professor Lucy Chappell, then the NIHR (National Institute for Health Research) Research Professor in Obstetrics at King's College London. From August 2021 the vaccine subgroup was co-chaired by me, as Vice President of the RCOG, and Dr Mary Ross-Davie, the then Director of Professional Midwifery at the RCM.

11. Membership comprised of clinicians supporting the delivery of the COVID-19 vaccine to eligible pregnant women and representatives from UKOSS (UK Obstetric Surveillance Service), UKTIS (UK Teratology Information Service), MHRA (Medicines and Healthcare Regularity Authority), NHSE (NHS England), Scottish Government, Welsh Government, PHE (Public Health England), Public Health Wales, Public Health Scotland, Public Health Agency (Northern Ireland), NHS England, RCGP (Royal College of General Practitioners) and academics involved in COVID-19 vaccination trials.

Engagement with government and public bodies

12. An important part of the ROCG's work during the pandemic was to amplify the voice of our members and of women who use maternity services, to urge national decision makers to understand and reflect the specific needs of pregnant women. Throughout the development and roll out of the vaccine, the College was committed to working in partnership with health leaders and government officials, via the subgroup and other mechanisms, to ensure the unique needs of pregnant women were being recognised.

13. As previously stated, the vaccine subgroup included representatives from public health departments in all four nations, NHS England, the Scottish and Welsh governments, and the key agencies involved in the COVID-19 vaccination programme.

14. In addition, the RCOG regularly engaged with national clinical leaders throughout the pandemic, including on the issue of vaccines. This includes, but is not limited to: the Chief Medical Officer (CMO) for England, Professor Sir Chris Whitty; the Deputy CMO for England, Professor Dame Jenny Harries; the Chief Nursing Officer (CNO) for England, Dame Ruth May; the Chief Midwifery Officer for England, Jacqueline Dunkley-Bent; the CMO in Scotland, Dr Catherine Calderwood; National Clinical Director for Maternity at NHS England, Dr Matthew Jolly; National Specialty Advisors for Obstetrics at NHS England, Dr Misha Moore, Dr Alison Wright and Dr Donald Peebles; the National Medical Director at NHS England, Professor Stephen Powis; the Senior Medical Officer for Maternal and Child Health in Welsh Government, Dr Heather Payne; and the Senior Medical Officer in Northern Ireland, Dr Carol Beattie. Alongside collaboration with national clinical leaders, RCOG regularly engaged with working-level officials in governments and arms-length bodies.

15. Direct engagement with Secretaries of State and Ministers responsible for health across all four nations was less common throughout the pandemic, due in large part to our effective relationships with clinical leaders and officials. However, the

RCOG and RCM did write to the Prime Minister on 18 November 2020 in the early stages of the vaccination programme, asking the UK Government to support a national effort to research the suitability of COVID-19 vaccines for use in pregnancy, using the expertise of the NIHR [POB/2 - INQ000517426]. We also offered to bring together industry and health leaders to enable this work to begin.

16. Throughout the development and roll out of the vaccine, the JCVI (Joint Committee on Vaccination and Immunisation) was a key stakeholder. While the College had many informal interactions with the JCVI during this time, we made two specific formal interventions that we would like to highlight.

17. Firstly, on 2 February 2021, the President of the RCOG, CEO of the RCM and lead of the vaccine subgroup, wrote formally to Professor Wei Shen Lim, Chair of the JCVI COVID-19 sub-committee, asking that obstetricians and midwives be consulted on the next key decisions around vaccines for pregnant women. This followed discussions at subgroup meetings where several key issues were raised relating to vaccination, including the need to ensure adequate counselling for women around use of an unlicensed medication in pregnancy, vaccine delivery and data collection on safety. The letter highlighted that the RCOG and RCM could usefully support the JCVI's decision-making, particularly when considering whether to include pregnant women in the roll out of vaccines to priority group six [POB/3 - INQ000517434].

18. Secondly, on 12 March 2021, the subgroup sent a briefing paper to the JCVI, recommending that COVID-19 vaccination be offered to pregnant women in line with JCVI priority groups, so no different from non-pregnant women. The paper noted that women can make an individualised decision based on benefits and risks [POB/4 - INQ000517435]. We were pleased that this recommendation was accepted by the JCVI – in April 2021 it announced it would offer all pregnant women the COVID-19 vaccine, in line with the vaccine roll out plan for the UK.

Guidance and information for healthcare professionals

19. During the pandemic, the RCOG played a key role in providing information and advice for healthcare professionals.

20. In December 2020, the Government approved the Pfizer-BioNTech and Oxford University/AstraZeneca vaccines for use. The JCVI confirmed on 30 December 2020 that COVID-19 vaccination could be considered in pregnant women, but only those at high risk of exposure or serious illness.

21. Following this announcement, vaccination for pregnant women was first included as a topic in version 13 of the RCOG 'Coronavirus (COVID-19) Infection in Pregnancy' guidance, published on 19 February 2021 [POB/5 - INQ000517436]. The guidance included the updated advice from the JCVI, and confirmed that the available data did not indicate any safety concerns or harm to pregnancy, and that vaccination in pregnancy should be considered where the risk of exposure to COVID-19 infection is high or cannot be avoided. The guidance also included the JCVI statement that vaccination should be considered where a woman has an underlying condition that puts her at very high risk of serious complications of COVID-19, and that similar advice was issued for breastfeeding women.

22. As new evidence emerged – by 7 June 2021, 120 000 pregnant women from diverse ethnic backgrounds in the United States had received a COVID-19 vaccine with no evidence of harm being identified – and eligibility for vaccination changed, the RCOG published 'Coronavirus COVID-19 Vaccination in pregnancy' guidance on 30 June 2021 [POB/6 - INQ000517437]. It was written as temporary guidance and summarised the evidence presented in existing COVID-19 vaccination guidance from the Public Health England/Department of Health Green Book, as well as leaflets and information from Public Health England and the NHS. This guidance continued to advise that pregnant women be counselled to come to an informed decision about whether to have a vaccination. The document was incorporated into version 14 of the 'Coronavirus (COVID-19) Infection in Pregnancy' guidance, published on 25 August 2021 [POB/7 - INQ000517438].

23. Vaccination was included as a standalone chapter in all subsequent versions of the 'Coronavirus (COVID-19) Infection in Pregnancy' guidance.

24. As with all RCOG guidance, the vaccination guidance featured the College's standard disclaimer, stating that the RCOG "has produced this guidance as an aid to good clinical practice and clinical decision-making. This guidance is based on the best evidence available at the time of writing, and the guidance will be kept under regular review as new evidence emerges. This guidance is not intended to replace clinical diagnostics, procedures or treatment plans made by a clinician or other healthcare professional and RCOG accepts no liability for the use of its guidance in a clinical setting. Please be aware that the evidence base for COVID-19 and its impact on pregnancy and related healthcare services is developing rapidly and the latest data or best practice may not yet be incorporated into the current version of this document. RCOG recommends that any departures from local clinical protocols or guidelines should be fully documented in the patient's case notes at the time the relevant decision is taken."

Exclusion of pregnant women from clinical trials

25. From the outset of discussions about the vaccination programme, the RCOG was an early and forceful advocate of the need to establish greater understanding of the suitability of COVID-19 vaccines for use in pregnancy, in terms of both efficacy and safety.

26. As is so often the case in trials of new drugs and vaccines, pregnant women were excluded from initial COVID-19 vaccine trials. This follows the pattern of most research, including the development of vaccines and treatments, from which pregnant women are generally excluded. In the context of the COVID-19 pandemic, this was of great concern, as it prevented the collection of data on the efficacy and safety of vaccination for a sizeable number of women: at any one time in the UK over a million women are pregnant or breastfeeding. This denied a large cohort of pregnant women, already known to be at increased risk of severe COVID-19, the potential protection of vaccination.

27. These concerns lay behind the decision to write to the Prime Minister in December 2020 (as detailed in paragraph 15). The RCOG felt it of the utmost importance to raise the issue of the exclusion of pregnant women from trials and the potential to mobilise the NIHR's network of clinical research midwives and obstetricians who could move at pace to establish the appropriate research.

28. The problem of excluding pregnant women from research more generally has been well documented, not least by the report 'Healthy Mum, Healthy Baby, Healthy Future: The Case for UK Leadership in the Development of Safe, Effective and Accessible Medicines for Use in Pregnancy', published in 2022. As that report explains, only two medicines have ever been developed specifically for pregnancy-related conditions, and not a single new medicine for some of the most serious pregnancy-specific conditions has reached women in decades [POB/8 - INQ000517439].

29. Developing, testing and bringing to market medicines for pregnancy is seen as inherently risky by regulators, industry, academia and the insurers that underwrite clinical trials, due to the lack of fundamental biology, safety knowledge and advice. This is perpetuated by the legacy of thalidomide, and other medicines in the past that were shown to have adverse effects in unborn children.

30. The exclusion of pregnant women from all the early COVID-19 vaccine trials had a significant effect on their willingness to be vaccinated. For many, this exclusion implied that the vaccine must not be safe in pregnancy. An RCOG/ RCM survey, carried out from 16 to 26 February 2021, highlighted the challenges relating to acceptability of COVID-19 vaccination in pregnancy [POB/9 - INQ000517440].

31. Of the 1,627 respondents, 601 had already been offered a COVID-19 vaccine (likely priority groups 1, 2, 4). Of these, 201 women had been vaccinated, whilst 400 women had declined. Of the 1,040 women not offered vaccination, around a third indicated they probably or definitely would accept vaccination, half probably or definitely would not accept vaccination, and 15% were unsure. Women cited

wanting to protect themselves/their baby as the main reason for accepting vaccination in pregnancy. Women cited concerns about harm to their baby and waiting for more information on the safety of COVID-19 vaccines in pregnancy as main reasons for declining vaccination.

32. As these results show, there was a great deal of uncertainty among women about whether the vaccines were effective and safe in pregnancy. Although public messaging changed once real-world data became available, and pregnant women were advised to get vaccinated, by that point the message had become confused, with many pregnant women and health professionals believing the vaccine was unsafe in pregnancy. Including pregnant women in trials from the outset would have provided better data more quickly, and would have avoided the uncertainty that resulted from changing messaging.

33. This lack of confidence in the vaccine undoubtedly contributed to the fact that, by October 2021, one in five of the most critically ill COVID-19 patients in hospitals were pregnant women and that 99% of pregnant women admitted to hospital with symptomatic COVID-19 were unvaccinated.

34. The RCOG welcomed the clinical trials in pregnant women that started in the second half of 2021, but the late start and small numbers involved meant that it remained the case that recommendations, informed by the best available evidence, needed to be made in the absence of clinical trial data for pregnant women throughout 2021.

Roll-out of vaccines for pregnant women

35. By June 2021, at least one dose of COVID-19 vaccination had been offered to all pregnant women in the UK over the age of 18. As more data were published about the safety of the vaccine in pregnancy and the harm from developing COVID-19, the RCOG and RCM changed its language from 'strongly consider' to 'strongly recommend' the vaccine in pregnancy. This was reflected in version 14 of the 'Coronavirus (COVID-19) Infection in Pregnancy' guidance, published on 25 August 2021, from [POB/10 - INQ000517438]. This was then replicated by the

NHS and governments, which shows how our evidence-based approach was trusted by political and health leaders.

36. Evidence gathered during 2021 demonstrated the safety of the vaccine in pregnancy and the risks of remaining unvaccinated: alongside known risks of contracting COVID-19 during pregnancy, data from the United States, where more than 177,000 pregnant women had received a COVID-19 vaccine (either Pfizer BioNTech or Moderna) did not raise any safety concerns, and over 100,000 pregnant women in England and Scotland had also received a COVID-19 vaccine (almost all mRNA) with no adverse effects recorded on the pregnancy.

37. Research from across six studies in four countries, involving more than 40,000 pregnant women, showed that having the COVID-19 vaccine during pregnancy did not increase the risk of miscarriage, preterm birth or stillbirth, nor did it increase the risk of a small-for-gestational age baby, or the risk of congenital abnormalities. Preliminary data from the UK concurred, with the stillbirth rate, proportion of babies with low birthweight, and proportion of premature births being similar for women who were vaccinated and those who were unvaccinated, demonstrating the safety of the COVID-19 vaccine on birth outcomes.

38. However, rates of vaccination remained low, and women felt uncertain about whether to get vaccinated. UKHSA confirmed that, as of August 2021, only 22.2% of women giving birth had received at least 1 dose of the COVID-19 vaccine.

39. A repeat RCOG/RCM survey of 1300 pregnant women, undertaken in June 2021, found that of those who had been offered the vaccine, 42% had accepted the vaccine and 58% declined the vaccine. Of those who had not yet been offered the vaccine 40% definitely or probably would accept the vaccine, 41% definitely or probably would not accept the vaccine and 18% were undecided. The reasons women gave for declining the vaccine included because they were worried that it would harm the baby (65%) and because they were waiting for

more information about the safety of COVID-19 vaccines in pregnancy (57%) [POB/11 - INQ000517417]. .

40. This low level of uptake meant it was paramount to remove any barriers to access for pregnant women who were considering taking up the offer of a COVID-19 vaccine, or those who had been double-vaccinated from accessing a booster vaccine. At the time, pregnant women were not included in a priority group for vaccination, and were therefore being called alongside non-pregnant people in their age group, even though it was by now well-established that COVID-19 was more severe in pregnant women than in the their non-pregnant peers.

41. On 30 July 2021 the Chief Midwifery Officer at NHS England wrote to midwives and GP practices in England, stressing the importance of encouraging pregnant women to get vaccinated, as the most effective way of protecting women and their babies against the effects of COVID-19. The RCOG and RCM issued a joint statement thanking the Chief Midwife for her efforts to encourage pregnant women to get vaccinated and urging women to get vaccinated as soon as possible [POB/12 - INQ000517418].

42. The RCOG was disappointed that pregnant women were not prioritised for booster jabs in the initial announcement in December 2021 despite them being at increased risk of falling seriously ill. We released a joint statement with the RCM on 13 December expressing this disappointment, and continued to raise the need to prioritise pregnant women with the JCVI and the NHS via our ongoing contact with clinical leaders and officials [POB/13 - INQ000517419].

43. The College was therefore extremely pleased with the JCVI's decision to include pregnant women in group 6 (those with underlying health conditions that put them at higher risk of severe disease) in December 2021, following our concerted efforts. This meant they were prioritised for vaccination.

44. However, the emergence of the Omicron strain meant that all age groups were eligible for boosters, making it more challenging for pregnant women to be able

to access their vaccination. The RCOG was very concerned that despite now being defined as at higher risk of severe disease, as well as being a group with low levels of vaccine uptake, there was no clear route for pregnant women to be prioritised for vaccination, in particular those who had yet to take up the offer of a first or second dose.

45. In December 2021 the RCOG and RCM published a briefing paper, 'Increasing uptake of COVID-19 vaccination in pregnant women', setting out our concerns and asking governments across the UK to urgently consider all options available to ensure pregnant women were able to get vaccinated [POB/14 - INQ000517420].

46. In the paper, we called on governments to work in partnership to set a time-bound target to rapidly increase uptake of COVID-19 vaccination in pregnant women, so that it matched uptake across the general population: at 2 December 2021 this stood at 88.7%, compared to around 22% of women giving birth.

47. The paper called for COVID-19 vaccines to be delivered wherever possible within or in close proximity to antenatal clinics in hospitals and in the community, to make it as easy as possible for pregnant women to get vaccinated, and for the NHS across all four nations to rapidly develop UK-wide guidance for vaccine delivery in antenatal clinics.

48. We recommended looking at ways in which the system could prioritise pregnant women coming forward to access their first or second dose. This included considering allowing pregnant women to skip queues at walk-in centres, as well as how booking through GPs and through the national booking system could accommodate prioritisation of pregnant women as a group.

49. We continued to press the case for measures to increase vaccination of pregnant women in informal communications with clinical leaders and officials following the publication of the briefing paper.

Providing accurate information and tackling disinformation

50. The RCOG has a long track record of providing accurate, accessible information for women and families, often sitting alongside our clinical guidance for healthcare professionals. We continued to perform this function throughout the pandemic, including on the issue of vaccination.

51. The College published its first Q&A for women and families on COVID-19 in pregnancy [POB/15 - INQ000517421] on 9th March 2020, to coincide with the publication of the first version of the 'Coronavirus (COVID-19) Infection in Pregnancy' guidance [POB/16 - INQ000176662]. Information setting out the latest government updates on vaccination in pregnancy and while breastfeeding was included from December 2020 and was regularly updated throughout the pandemic to reflect the most up-to-date RCOG clinical guidance and the guidance and regulations from Government and arms-length bodies. The Q&A on vaccines included answers to common questions asked by pregnant women and their families about vaccination, pregnancy, fertility and breastfeeding. The Q&A is still available on the RCOG website [POB/17 - INQ000517423].

52. The RCOG was deeply concerned at the spread of misinformation that proliferated throughout the pandemic, which contributed to hesitancy in vaccine uptake for some pregnant women. This was particularly noticeable among Black and Asian women, and among women from socially deprived areas, potentially reflecting an existing mistrust of health services. We have seen ongoing vaccine hesitancy for other vaccines recommended in pregnancy since the COVID-19 vaccination programme, including pertussis most recently.

53. To try to tackle this misinformation, the RCOG developed a COVID-19 vaccination and pregnancy information sheet and decision aid in January 2021, to support pregnant women offered vaccination to make an informed decision [POB/18 - INQ000517424]. This document was updated regularly and used by obstetric and midwifery teams across the UK to counsel pregnant women. The decision aid was printed for every pregnant woman in Scotland and a QR code link to the decision aid featured in the Public Health England posters encouraging uptake among pregnant women in every maternity unit in England.

54. The College also developed a public facing information campaign about COVID-19 vaccination and pregnancy, including infographics and animations, that reached more than three million people via our social media channels by June 2021. This campaign started in January 2021, and was updated as eligibility for vaccination changed, to provide pregnant women with accurate information on the risks and benefits of vaccination and how to access a vaccine.

55. In January 2021 the RCOG became aware that there was misinformation circulating about the impact of COVID-19 vaccines on fertility specifically, and that this was causing concern among women considering pregnancy. In response to this misinformation, the RCOG and RCM issued a statement reassuring women that there was no evidence to suggest that COVID-19 vaccines will affect fertility and that claims of any effect of vaccination on fertility were speculative and not supported by any data [POB/19 - INQ000517425].

56. In December 2021, as part of our ongoing efforts to provide women with reliable up-to-date information they could trust, the RCOG and RCM published an updated version of the decision aid [POB/20 - INQ000517427]. We used our briefing paper, 'Increasing uptake of COVID-19 vaccination in pregnant women', to strongly encourage the NHS and Governments across all four nations to distribute the decision aid as widely as possible to both women and healthcare professionals, to ensure the right information was in the right hands [POB/21 INQ000517420]. As part of this push, we recommended that the NHS send a letter to every pregnant woman living in the UK encouraging them to take up the offer of a COVID-19 vaccine, with a copy of, or a link or QR code that led to, the most recent version of the RCOG and RCM decision aid. The RCOG and RCM offered their support in the development of this letter.

57. At this time the College also expressed its concerns that out-of-date information and advice was present in information leaflets and posters, on intranets and online, causing unnecessary concern and confusion for pregnant women. We felt there was a real risk of healthcare professionals and women not having access to up-to-date evidence to support them to make the most informed decision

possible in relation to vaccination in pregnancy. We therefore called on the UK Government to write to key stakeholders at every level of the NHS (including NHS Trusts, Primary Care Networks, CCGs and ICSs) and regional/local governments across the four nations and British Isles to encourage them to ensure that all information around COVID-19 vaccination in pregnancy that was available to women and healthcare professionals in their area contained only the most current evidence and advice. We recommended that links to the national poster from the UKHSA and the RCOG COVID-19 landing page should be the primary sources of information.

58. The briefing paper also called on the UK Government to ensure that participants on its Community Champions scheme were receiving up-to-date, evidence-based information about the benefits and risks of COVID-19 vaccination in pregnancy. We recommended the Department of Health and Social Care and the Department for Levelling Up, Housing and Communities needed to agree how pregnant women would be explicitly considered in future messaging and projects within the scheme, which engaged local partners to promote vaccine uptake and tackle misinformation among groups at greatest risk from COVID-19.

59. In January 2022, as a result of ongoing informal dialogue with health leaders and officials on the need to do more for pregnant women, the Government launched a national vaccination campaign targeted at pregnant women, in partnership with the RCOG and RCM. The campaign urged pregnant women who had not yet had their first, second, third or booster dose of a COVID-19 vaccine to get their jab as soon as possible. Testimonies of pregnant women who had been vaccinated were featured in adverts on social media and television and radio stations across the country.

60. Data from the UKHSA found that nearly two thirds (65.8%) of women giving birth in February 2022 had received at least one dose of the vaccine, a significant increase from previous months.

Tackling disparities in vaccination rates

61. Prior to the COVID-19 pandemic, existing evidence showed significant disparities in pregnancy outcomes for women and their babies in Black, Asian and minority ethnic women compared to white women. Evidence began to emerge at the start of the pandemic that pregnant and non-pregnant people from a Black, Asian or minority ethnic background were at higher risk of developing severe complications from COVID-19, while some Black, Asian and minority ethnic people were also at higher risk of developing the infection. It was therefore immediately concerning to the College when UKOSS data from April 2020 showed a significantly higher prevalence of COVID-19 amongst pregnant Black, Asian and minority ethnic women, alongside greater risk of severe symptoms.

62. From May 2020, RCOG clinical guidance stated that pregnant women from a Black, Asian or minority ethnic background should be advised that they might be at higher risk of COVID-19 complications and they must seek help early if concerned. The guidance advised clinicians to be aware of this increased risk, and have a lower threshold to review, admit and consider multidisciplinary escalation of women from a Black, Asian or minority ethnic background [POB/22 - INQ000308985]. The College contributed to communications and the development of resources from NHS England to provide information for women and clinicians about the increased risk of COVID-19 complications for pregnant Black, Asian and minority ethnic women.

63. It was extremely concerning, therefore, when UKHSA data for August 2021 showed ethnic and socioeconomic disparities in the proportions of women giving birth who had received at least one dose of the COVID-19 vaccine. Data showed that between June and August 2021, where 17.5% of white women had been vaccinated, only 5.5% of Black women and 13.5% of Asian women had been vaccinated. Data also showed that for women giving birth between June and August 2021, only 7.8% of those from the most deprived quintile of the population, compared to 26.5% of those from the least deprived quintile, had been vaccinated [POB/23 - INQ000312423]. Given the known disparities in both maternal and neonatal outcomes between women of different ethnic

backgrounds, and women living in the most and least deprived areas, this disparity in vaccine uptake was alarming.

64. The College called on governments across the UK to set a target to reduce and eliminate the disparities in uptake as part of an action plan setting out how they would strive to increase vaccination in pregnancy.

65. We also raised our concerns in our submission to the APPG on Coronavirus inquiry in July 2021 [POB/24 - INQ000517430]. Our response called on governments to continue to work to ensure everyone, including those from Black, Asian and minority ethnic communities, feel confident to accept a COVID-19 vaccination. We highlighted that a record of uptake and any adverse outcomes was essential for vaccine confidence in the pregnant population. Data linkage between the vaccination systems and maternity datasets needed to be prioritised so as to send a clear message that acquisition of safety data is important. This must be followed by rapid data sharing, analysis (with input of appropriate individuals) and dissemination, to increase confidence of women and healthcare professionals, enabling increased vaccine uptake in due course.

66. The College's response highlighted our concerns that without the inclusion of pregnant women from all ethnic backgrounds in clinical trials, we will fail to gain the confidence of pregnant women who are concerned that the safety data provided is not representative of their group or translatable to them as individuals.

67. Figures on vaccine uptake for January 2022 continued to show worrying disparities. The College released a press statement drawing attention to the stark inequality in uptake and continued to urge governments to do more to increase rates of vaccination among women of Black ethnicity and women living in the most deprived areas, who were the least likely to have been vaccinated [POB/25 - INQ000517431].

68. The College also undertook research during the pandemic to gain greater insight into inequalities in maternity care. The CMEP project (COVID Maternity Equality

Project), funded by the Health Foundation, examined whether and how changes to maternity care in England during the COVID-19 pandemic affected existing inequalities [POB/26 - INQ000517432].

69. Maternity staff interviewed for the project reflected that there were many reasons that women from minority ethnic groups could have experienced worse outcomes, including having English as a second language, being from more deprived areas, and being more likely to have more complex pregnancies. Staff hypothesised that, had COVID-19 restrictions been applied flexibly according to the need of individuals, these vulnerable groups may have received comparatively better, and more personalised, care.

70. For example, some Trusts, where ethnic inequalities in maternal and perinatal outcomes were actually reduced during the pandemic, set up (or increased the capacity of) maternity helplines, online question and answer sessions, or email addresses for women to contact midwives about their concerns. One such Trust created a COVID-19 Surveillance programme, where COVID-19 positive women were contacted daily by midwives. One clinician theorised that this increase and flexibility in communication would have had a positive effect on inequalities, reducing the "variance in care".

71. Trusts also described an increase in team working and communication, an early appreciation of the severity of COVID-19 which was responded to with confidence and expertise and proactive, multi-disciplinary decision-making.

72. The project found that better teamworking, more proactivity, more ownership over changes to services, and more flexibility in the use of staffing and other resources, may have been responsible for improvements in care during the first COVID-19 wave. The findings suggest that these characteristics are important to drive improvement in care for women from minority ethnic groups in a time of great service change.

73. The project recommended that initiatives to reduce inequalities in maternal and perinatal outcomes for ethnic minority women prioritised interventions to

strengthen clinical teamworking and allowed for innovation and flexibility in individual maternity units.

Lessons learned and recommendations for the future

74. The overall response to future pandemics and public health crises, including the development and implementation of vaccination programmes, must consider the unique nature of pregnancy and the postnatal period, and actively and systematically consider the needs of this group. The implementation of public health measures to respond to a pandemic must consistently consider pregnant women, and carefully balance the need to be cautious in order to protect the health of women and their pregnancy, with the potential harms from being over-cautions, for example delayed roll-out of vaccines which exposes women and babies to the risk of infection. It is also imperative to provide clear communication on known risks. Communication of new guidance and regulations must be tailored to pregnant women and their families, and kept accurate and up-to-date to avoid misinformation and disinformation from spreading.

75. The impact of a lack of clear information from official sources, and the resulting spread of misinformation and disinformation about vaccines during the pandemic, should not be underestimated. Not only did some pregnant women become seriously unwell, which could have been avoided if they had been vaccinated, we have also seen falling rates of other vaccinations recommended in pregnancy among pregnant women since the pandemic. Throughout the pandemic the RCOG consistently strove to provide clear, up-to-date, information and advice, based on the evidence available at the time.

76. A current lower than expected uptake of the vaccine that contains protection against whooping cough (pertussis) has led to higher rates of confirmed cases than in previous years across all the whole UK. Vaccine uptake levels have steadily fallen in the past five years in pregnant women, babies and young children, with significant regional variation in uptake.

77. The RCOG welcomes the NHS Vaccination Strategy, published in December 2023, but there must be swift implementation of its proposals to improve vaccination rates given the decrease in uptake of routine vaccines year on year. NHS England, and equivalent bodies across the nations, must prioritise public facing targeted campaigns to improve vaccine coverage as the only way to tackle these harmful illnesses. This will help restore confidence in vaccination, and put the UK in better stead for any future mass vaccination programme that needs to be rolled out at speed.

78. As part of this, the RCOG would like to see a commitment to the provision of clear resources that outline the latest data on vaccine safety and efficacy in pregnancy to support pregnant women and their healthcare professionals to make informed decisions on vaccination. All materials should be developed in partnership with professional bodies including the RCOG and RCM, as existing sources of high quality, trusted expert advice.

79. The practicality of getting a vaccine must also be considered. Many pregnant women reported that difficulty booking COVID-19 vaccination in advance meant they ended up having to queue for vaccinations, which particularly for heavily pregnant women created an additional barrier. Ensuring that pregnant women are able to skip queues for walk-in vaccination centres, as well as a booking system that ensures advanced booking is easily accessible, is important.

80. Where appropriate, the offer of multiple vaccines in one visit will likely increase overall uptake. For example, offering pregnant women vaccination against pertussis, COVID-19 and flu in one visit, ideally delivered alongside antenatal appointments in the community, primary or secondary care.

81. The implementation of the NHS vaccination strategy must also put genuine priority on the need to address inequalities in uptake, as well as wider health inequalities. With evidence that shows pregnant women are at higher risk of severe disease and poorer neonatal outcomes if they contract illnesses such as COVID-19, addressing these inequalities is crucial.

82. It is important that those delivering vaccination services have an understanding of the demographics of the population they serve, to better understand potential challenges and solutions to vaccine delivery. Vaccine service providers should engage with partners in the local community (e.g. faith leaders, community groups) to ensure there are champions for vaccination in every community who have access to the resources and information they need to reduce vaccine hesitancy in the populations they work with.

83. Alongside this, evidence-based, high-quality information with regards to vaccination, including safety and efficacy, should be available in a range of formats and translated into languages that are common in the local population. National funding should be made available to translate existing high-quality resources, such as the RCOG decision aid, into common languages aside from English. It is important to recognise the important role of social media in any future pandemic or public health emergency planning. Social media is increasingly where people go for a wide variety of information, including about what to do during a pandemic, so its powerful role in disseminating both accurate and inaccurate information has to be recognised.

84. One of the biggest challenges in increasing uptake of the COVID-19 vaccination in pregnant women during the pandemic was the lack of data from clinical trials meaning that initial guidance recommended exclusion of pregnant women from vaccination. As real-world evidence emerged that demonstrated the safety of COVID-19 vaccination in pregnancy, the pace at which new guidance was published and disseminated was often too slow, resulting in disproportionately high numbers of pregnant women severely ill from COVID-19, with the associated poorer outcomes.

85. Guidance published in 2018 from the Pregnancy Research Ethics for Vaccines, Epidemics and New Technologies (PREVENT) Working Group recommended the 'presumption of inclusion of pregnant women in vaccine studies and programmes, together with incentive mechanisms to stimulate search and development including pregnant women' [POB/27 - INQ000517433]. The RCOG is supportive of this statement, and it is essential that concerted effort is put

towards creating incentives amongst regulators and pharmaceutical companies to ensure pregnant women are included in clinical trials for vaccines and other drugs and therapeutic interventions. This should include work to encourage pregnant women to enter research studies in carefully controlled circumstances.

86. Finally, we should not confine the learnings of this Inquiry to future pandemics. Instead we must recognise that much of the learning can be applied more widely to improve access to and uptake of vaccination in pregnancy generally, and therefore help improve outcomes for pregnant women and their babies.

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: 10/12/2024