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This report discusses the Witness Statement of Professor Martin McCaffrey (MM), dated 1st March 2023 In the matter of NHS [] Integrated Care Board and RN.

Specifically, I have been asked to comment on the statement as to whether it would have had any bearing on policy recommendations issued to the UK government by the Joint Committee on Vaccination and Immunisation (JCVI), of which I was a member during the period of the COVID-19 pandemic, had the information and opinions expressed within it been made available to them during that period.

1. I am Professor of Paediatrics at the University of Bristol and Honorary Consultant in Paediatric Infectious Diseases and Immunology at Bristol Royal Hospital for Children. I have a particular interest and expertise in vaccines both for children and adults. I was an active member of the JCVI throughout the pandemic period and attended all the meetings at which policy on COVID-19 vaccine deployment were discussed and played an active part in those discussions.

Summary of the report by MM.

2. MM's statement provides information about his training and experience and about trisomy, including trisomy 13.
3. The statement proposes that, although the mechanisms underlying the pathogenesis of trisomies in general are complex and poorly understood, they are thought to influence the regulation of gene transcription and translation and may also increase susceptibility to oxidative stress and thus inflammation.
4. On this basis MM proposes that patients with trisomy, including trisomy 13, may be more likely to experience adverse side-effects of COVID mRNA vaccines and in particular cardiac inflammation (myocarditis and pericarditis).
5. Using published data on the reported incidence of these side effects following mRNA COVID-19 vaccination in young male adults and hypothesised higher rates of such side effects in patients with trisomy, based on the mechanisms of pathogenesis of these conditions that he postulates, alongside incidence figure of severe illness due to SARS COV2 infection in young adults, he concludes that the risk-benefit balance in RN's case falls on the side of not receiving vaccination.

Commentary on the report.

6. As regards the question I have been asked to address, the answer is unequivocally that the calculations and predictions presented in the report would have had no influence whatsoever on public health policy recommendations around COVID-19 vaccination during the pandemic, because they do not reach the standard of evidence required for such recommendations to be made.
7. The epidemiological evidence that drove JCVI recommendations, including extension of vaccination to adults with severe learning difficulties (and even teenagers in this group before vaccines had been authorised for the under-18s),

were based on clear evidence of enhanced risk of severe disease and death in this broad risk group which emerged during 2021. (Ref 1)

8. There is a consensus that patients with Trisomy 21(Down Syndrome) which is the commonest trisomy, are prone to severe COVID-19 although, even now, the quality of the published evidence to support this view is poor. (Ref 2)
9. Within the severe learning disability group, evidence regarding the frequency and severity of adverse reactions to vaccination in patients with trisomies, including trisomy 13, were and remain lacking. Accordingly, there was, and remains, no clear evidence upon which to base exceptional (in the sense of advising differently from the rest of the severe learning difficulty risk group) vaccine recommendations for this group.
10. In the context of this report, it is also important to note that the occurrence of myo/pericarditis after the second dose of mRNA COVID-19 vaccines in young adult males appears to have been much higher where a dose interval of 3-4 weeks was strictly adhered to (as in the USA) than where an extended dose interval was adopted (as in the UK). (Refs 3 and 4)
11. On this basis, in my opinion, the calculations and conclusions set out in the report, had they been provided to JCVI at the time, would not have resulted in policy recommendations regarding patients with trisomies, including trisomy 13, that they should not be offered COVID-19 vaccination with the vaccines available at the time.

Comments on changes in recommendations over time

12. In the context of this case and the time that has elapsed since the question whether RN should be vaccinated arose, it seems relevant to point out significant changes in the drivers of policy recommendations around COVID-19 vaccination with the passage of time. In 2020-21 there was little or no population immunity either from infection or from vaccination, there were large epidemic waves occurring with associated vast health and economic costs and burdens and information on vaccination risks and benefits were still emerging. In particular, down payments were made against COVID-19 vaccine purchase so that the consideration of cost-benefit which applies to all health interventions in normal times were set aside and decisions were framed on risk-benefit considerations alone. It was also unclear at that time to what extent widespread immunisation would prevent virus transmission and thus indirectly protect vulnerable individuals who were less capable of mounting protective immune responses to vaccine or to infections. Policy at that time was framed around trying to protect the most exposed (e.g. health care workers) and the most vulnerable (e.g. the elderly) as fast as possible using the limited vaccine supplies available as they came through.
13. By contrast, in 2024, SARS CoV2 infection remains endemic at a relatively low level with much smaller epidemic waves driven in part by emergence of novel virus subvariants. Almost everyone has some degree of specific immunity from vaccination, infection and in most cases, both. It has become clear that the protection provided against infection and diseases by vaccine booster doses are relatively short lived and that widespread immunisation, while it prevents many cases of serious illness, has done little to halt circulation of the virus. Vaccine

policy recommendations have thus been adjusted to focus on boosting immunity amongst the most high risk individuals, particularly the very old and those with reduced immune function or increased vulnerability because of underlying medical conditions.

14. Many people, including many in risk groups, have now had one or more episodes of infection with SARS CoV2 infection. This both strengthens and broadens any immunity they may previously have acquired from vaccination and illustrates, to some extent, their individual propensity to become seriously ill from this infection (which varies widely between individuals for reasons that are only partly understood, and which are difficult to measure or predict).
15. Finally cost-benefit considerations are now beginning to be applied to policy decisions in a more normal way.
16. Thus, while COVID-19 vaccination policy continues to play an important role in minimising the health and economic burdens of the SARS CoV2 virus, many aspects of the risk-benefit calculus both at the population and the individual level have changed dramatically.

References

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Signed:

Adam Finn
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