Altered vaccination schedules and informed consent

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By Jennifer O'Neill.

According to the General Medical Council (GMC) publication Good Medical Practice**,** medical treatments should be provided *"...based on the best available evidence"* with a favourable balance between benefit and risk. Legal principles of informed consent and shared decision-making recognise the patient's right to be informed of the risk-benefit profile of a treatment before consenting to it. Such informed consent is recognised as a way to build patience trust and confidence and so represents a key facet of all successful interventions involving patients with capacity. This is also true of vaccination programmes. Information disclosure in informed consent can be used to tackle misinformation, address vaccine hesitancy and build to vaccine confidence.

However, the Joint Committee for Vaccination and Immunsation (JCVI) recently changed the vaccination dosing schedules for Pfizer/BioNTech vaccines in a way which was not supported by evidence from clinical trials. In a recent BMJ Opinion post, five prominent UK academics denounced the move, asserting that *"[t]he current UK strategy with the Pfizer mRNA vaccine is, in our view, a non-randomised, uncontrolled population experimental study without pilot data".* There have been growing calls for the government to halve the time interval between doses of the Pfizer/BioNTech COVID-19 vaccine.

In recent weeks, the Department for Health and the MHRA (Medicines and Healthcare Products Regulatory Agency) have granted temporary authorisation for the supply and use of COVID-19 vaccines from Pfizer/BioNTech, Oxford/AstraZenica and Moderna. In accordance with Regulation 174 of the Human Medicines Regulations 2012, these vaccines received temporary approval due to their use in response to the spread of the pathogenic agent responsible for COVID-19, SARS-CoV-2. Information provided to healthcare professionals outlines the recommended vaccination schedule for each vaccine, as determined by the clinical trial evidence. The Pfizer/BioNTech and Moderna vaccines are the first of a new generation of vaccine, based upon mRNA technology whilst the Oxford/AstraZenica vaccine uses a more traditional approach.

The aim of a vaccine is to simulate pathogenic infection in a non-harmful way to allow the immune system to recognise the pathogen and prepare for a future encounter with it. The immune system can be trained to recognise the proteins on the surface of a virus with the aim of substantially reducing the symptoms or effects of a subsequent infection with the virus itself. Vaccines can achieve this end goal in various ways – the tried and tested approach of the Oxford/AstraZenica vaccine uses a modified virus to expose the immune system to the 'surface proteins' found on the SARS-CoV-2 virus responsible for COVID-19. A new technology, used in the vaccines from Pfizer/BioNTech and Moderna, works by delivering a set of instructions – mRNA – directly to body cells, so that they can temporarily make these surface proteins to elicit an immune response. Each method involves training the immune system so that it is prepared for any future battle.

All of the approved COVID-19 vaccines require two doses, with a specified interim period to maximise efficacy. Pfizer/BioNTech's mRNA vaccine, which is reported to have up to 95% efficacy, requires a follow up dose after 21 days. Oxford/AstraZenica reports 62-90% efficacy with the two doses recommended to be given 4 to 12 weeks apart. Data suggest that this longer interval *could* provoke a greater immune response, however *"overall participant numbers were small"*. Furthermore, the Oxford/AstraZenica "*efficacy and safety data are limited in individuals over 65 years of age"* – an important consideration given that the over 60 age group falls within the top five groups for vaccination prioritisation outlined by the Joint Committee on Vaccines and Immunisation. Moderna's mRNA vaccine, of which 17 million doses have been ordered, is also said to have 95% efficacy when doses are given 28 days apart.

The statement released by the JCVI in late December 2020, advised that the second vaccine dose for the Pfizer and Oxford AstraZenica vaccines be extended to 12 weeks. Whilst recognising that *"[f]or both vaccines the second dose completes the course and is likely to be important for longer term protection"*, their new priority was that *"as many people on the JCVI priority list as possible should sequentially be offered a first vaccine dose"*. Yet by January 2021, 944,539 people had already received their first Pfizer vaccine *having consented to the original vaccination schedule which was supported by clinical trial evidence*. Pfizer/BioNTech have since cautioned that the safety and efficacy of an altered Pfizer vaccine schedule has not been evaluated and there was no data to show that protection after one dose lasts beyond 21 days. Experts from Israel's Sheba Medical Centre also suggest that delaying the second dose Pfizer vaccine substantially reduces efficacy as their findings show full immunisation results in a *"six to 12 fold increase in antibodies"*.

Furthermore, there is also growing concern that vaccines may be 50% less effective to new SARS-CoV-2 variants with it not yet known how effective just a *single* dose would be. Moderna, which also manufactures an mRNA vaccine, also emphasises the importance of receiving both doses of its mRNA vaccine on time, cautioning that "*individuals may not be protected until 14 days after the second dose"*. It is increasingly evident that whilst the delay may be beneficial for Oxford/AstraZenica's *traditional* vaccine, there is no evidence to support this approach to mRNA vaccines.

The Supreme Court judgement in the landmark consent case of *Montgomery v Lanarkshire Health Board* emphasised the importance, for a 'patient's entitlement to decide whether or not to incur…risk', of consent being appropriately informed. Where a patient can prove that they were *not* sufficiently informed about a course of medical treatment; that they would *not* have consented to medical treatment had they been provided with such information; or indeed, that they would have chosen an alternative treatment, then a case may be established in medical negligence. For patients who have already received their first dose of the Pfizer vaccine, it is possible that they would not have consented to vaccination with a *delayed* second dose, absent any scientific evidence of efficacy.

However, such an argument would require consideration of whether the two vaccine doses represent a single course of medical treatment. As per the US "the foundational consent case" of *Schloendorff v Society of New York Hospital* any change to the treatment plan requires the consent of the patient. This was also considered in the UK case of *Kathleen Jones v Royal Devon and Exeter NHS Foundation Trust* [2015]. Although the case does not address vaccination, it does highlight the duty to inform the patient of

all material issues relevant to treatment. The intention of the JCVI was to offer protection to more individuals, however there is little evidence to suggest that one dose of the Pfizer vaccine confers a high standard of protection against COVID-19.

Changing the vaccination schedule without an evidential basis, and after the process of vaccination has begun, calls into question the validity of the consent of patients who have already received the first dose. It has been shown that "*efficacy and safety are important factors associated with public acceptability of a COVID-19 vaccine*". Therefore, in order to build vaccine confidence, each of the vaccines should be utilised according to clinical trial evidence to ensure maximum efficacy. It is important that, amid the current crisis, we do not deviate from the ordinary standards of health care ethics that require evidence-based practice, consideration of beneficence and non-maleficence and respect for patient autonomy. For this, or any future vaccination strategy to be effective, patients should be informed so as not to undermine vaccine confidence.

Author: Jennifer O'Neill

Affiliations:

Lecturer, University of Glasgow, College of Medical, Veterinary & Life Sciences

Course Co-ordinator for Clinical Bioethics and Legal Medicine, European University Cyprus, School of Medicine

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Social media accounts of post author: @j_o_neill_

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