

FLU008 study, Jenner Institute, Nuffield Department of Medicine Professor Adrian Hill, Chief Investigator

What was your study about?

The FLU008 study was a phase I, open label study to determine the safety and immunogenicity of candidate influenza vaccine MVA-NP+M1, manufactured on the AGE1.CR.pIX novel avian cell line. Earlier trials had already shown this vaccine to be safe and effective in producing an immune response, but the way it was produced previously meant that it was difficult to make large enough amounts. The vaccine used in the FLU008 study was developed using a new, more efficient process aiming to show that this new process did not change the safety or effectiveness of the vaccine.

We enrolled a total of 6 healthy adult volunteers aged 18 to 50. The vaccine was administered by intramuscular injection (into the muscle of their upper arm) on the day of vaccination and volunteers were followed up for 4 weeks.

How did you involve patients and/or the public?

At the time of publication of the FLU008 study and as part of our commitment to research participants, we sent a plain-language summary of the findings to those who took part in the FLU008 study. We wanted to make sure that we presented the research results to our participants in a format understandable to laypersons, therefore we took the initiative to involve the general public in the development and review of the summary prior to sending it to the study participants.

We advertised this PPI opportunity to the general public through the Patients Active in Research (PAIR) platform, which is run by the NIHR Oxford Biomedical Research Centre. Within a few days, we received a response from 6 people interested in contributing to this PPI activity. The initial draft of the study summary was sent to them via email for feedback and any further correspondence with the PPI contributors was also via email.

What was the impact of involving patients and/or the public?

We received very valuable feedback from the PPI contributors. We incorporated most of the suggested changes, which overall related to the wording and terminology used and the layout of the summary document. By involving the general public in the writing of the study summary, we are ensuring that the information sent to research participants is clear, understandable and jargon-free.

What were the challenges and how did you overcome these?

The main challenge was to compile and consider all the feedback and comments from the PPI contributors, as this was time consuming. One member of our team, alongside the FLU008 study lead doctor, took the time to consider each of the comments made by the PPI contributors and made the changes to the study summary accordingly. In addition, a thank you email was sent to the PPI contributors with the final draft of the study summary, explaining:

1) how their feedback had helped us shape/modify the document; and 2) the rationale behind for not incorporating some of the suggestions that some PPI contributors had made.

What advice do you have for other researchers considering patient and public involvement activities?

The main advice is that you need to consider all the feedback given by the PPI contributors and provide meaningful feedback back to your contributors. Providing feedback helps transparency and continuity in the research process; it also shows to the contributors that you value their input and respect the time they committed to your PPI activity; and it also increases their confidence and keeps their motivation and commitment going to stay involved in research.