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COVID VACCINES

Bureaucracy has created a mess for Novavax volunteers like me

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Be in a trial, I tweeted. Trials are great, I said on the radio. But now I wonder if I should swallow my words.

Along with tens of thousands of others, I signed up to Novavax's UK vaccine trial, starting in October 2020. I trusted the process, rolled up my sleeve, and was convinced I'd had the placebo, until my arm swelled up impressively after my second inoculation. The trial results came out in late January 2021: 89% effective after the second dose. Excellent! A dose of luck for me (an early, effective vaccine), and a side gift of my data to the research community.

Except it hasn't worked out like that. At each trial visit I've asked what's happening with the European Medicines Agency's approval of the vaccine, and each time I'm told something is expected "soon." I thought, you know the vaccine works,¹ so what does it matter about the approval?

But now in Scotland we have vaccine passports to access facilities on proof of vaccination. Novavax participants like me aren't quite eligible. The government has sent me two letters, intended as "proof of vaccination." The first is a simple letter stating I had been vaccinated, and the second contained the same information together with a unique reference barcode. This has worked fine for me to get in to venues in Scotland—in place of the smartphone app that peoples who have had the NHS vaccine can get (and which Novavax trial participants can't). Many countries will accept a vaccination passport for travel purposes, as long as that vaccine is EMA approved. But Novavax is not. That means I'm treated as though I've had no vaccine, with extra PCR tests and quarantine restrictions on arrival.

I could put a luxury like international travel aside. But now come the boosters. This is the part of the mess I am most upset about. I wanted to be in a trial because I wanted to contribute towards high quality research. This now falls apart.

At first I was told I would likely to be offered participation in a Novavax booster programme. Then I was sent a letter saying the booster would instead be done as part of the national programme.

It is easy for frontline health workers to book a booster. But organising a first vaccine in the national programme, after having had two in a trial, is not. The vaccination helpline eventually told me, after a couple of hours of being passed from person to person, that they would send me an appointment letter within a few days; that was four weeks ago—and still nothing. Meanwhile in October we heard that Novavax participants would be offered two doses of the Pfizer vaccine to ensure they had a

full vaccination certification status for travel purposes. This is kindly meant, but the problem is that this is being done outside a trial, with none of the careful monitoring that trial participants should expect. It means that thousands of doses are being used for the purpose of complying with certification, not for public health, wasting vaccines and health service time. Most recently, and after asking over many weeks, I now have a "patient specific directive," a letter with a directive from the trials team to say I should have Pfizer's vaccine at my booster appointment, which I still haven't got. I'm not holding my breath.

We will need more vaccine trials in the coming years: intervals, mixing, different mechanisms of action, age groups. We need more people to take part. But bureaucracy has created a mess for Novavax volunteers like me. There may always be little niggles in a massive administration scheme to sort out, but chief medical and scientific officers could sign up to a new declaration swiftly, in an international exchange scheme of cooperative trial vaccine acceptance between countries, with countries honouring a mutual pledge. This is too important to lose the goodwill of volunteers.

Competing interests: MMcC is a GP partner, honorary senior lecturer at the University of St Andrews, and freelance writer and broadcaster who receives royalties for three books. She is a council member and trustee of the Royal College of General Practitioners, and these are her own views. She is an honorary senior associate at the CEBM Oxford.

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¹ Heath PT, Galiza EP, Baxter DN, et al 2019nCoV-302 Study Group. Safety and efficacy of NVX-CoV2373 covid-19 vaccine. *N Engl J Med* 2021;385:1172-83. doi: 10.1056/NEJMoa2107659 pmid: 34192426

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