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COVID INQUIRY

Implementation of covid-19 vaccination in the United Kingdom

Decisions about approving covid-19 vaccines and strategies for their use in the UK must be rapid and transparent, say Azeem Majeed and colleagues, and a sustainable infrastructure should be put in place for delivering covid-19 vaccines to the public

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Key messages

- The development of safe and effective covid-19 vaccines is one of the great success stories of the covid-19 pandemic
- Decisions about implementing vaccination programmes in the UK must be robust, clear, and open to public and professional scrutiny
- A sustainable infrastructure for vaccine delivery is needed that integrates with general practices and pharmacies
- The UK needs to ensure that it has the academic and industrial infrastructure to develop, test, and secure vaccines for the current and any future pandemics

Within one year of the genome of SARS-CoV-2 being sequenced, vaccines had been developed, tested in randomised controlled trials, and rolled out in population based vaccination programmes across the world. This is one of the great success stories of the covid-19 pandemic. Vaccination offers countries a method of suppressing the number of people with a serious illness that could lead to hospital admission or death, thereby allowing societies to return to a more normal way of living and working.[1]

The vaccination programme in the United Kingdom has been described by the government as "world beating" on many occasions.[2] But is this the case? Does the UK remain a world leader in vaccination? What can be learnt from the approval of vaccines in the UK and the implementation of vaccination programmes by the NHS? Because vaccination had such a key role in the pandemic, it is essential to review the vaccine programme in the UK and define the key questions about the programme that need to be considered by the public inquiry. We focus on implementation in England because health in the UK is a devolved responsibility and implementation of vaccination programmes differed between the four UK countries.[3]

The covid-19 vaccination programme started well in the UK and sooner than in other countries; it began to decelerate in summer 2021 before speeding up again towards the end of the year and slowing down again in early 2022. The UK has been overtaken by many other countries in the proportion of the population vaccinated with two doses (fig 1), although it does remain ahead of many countries in the proportion of adults who have had three vaccinations. The UK was also slower to approve vaccines for use in children than some other countries, with vaccination for all children aged 12 and over approved in September 2021 and for all 5-11 year olds approved for a limited period in February 2022.

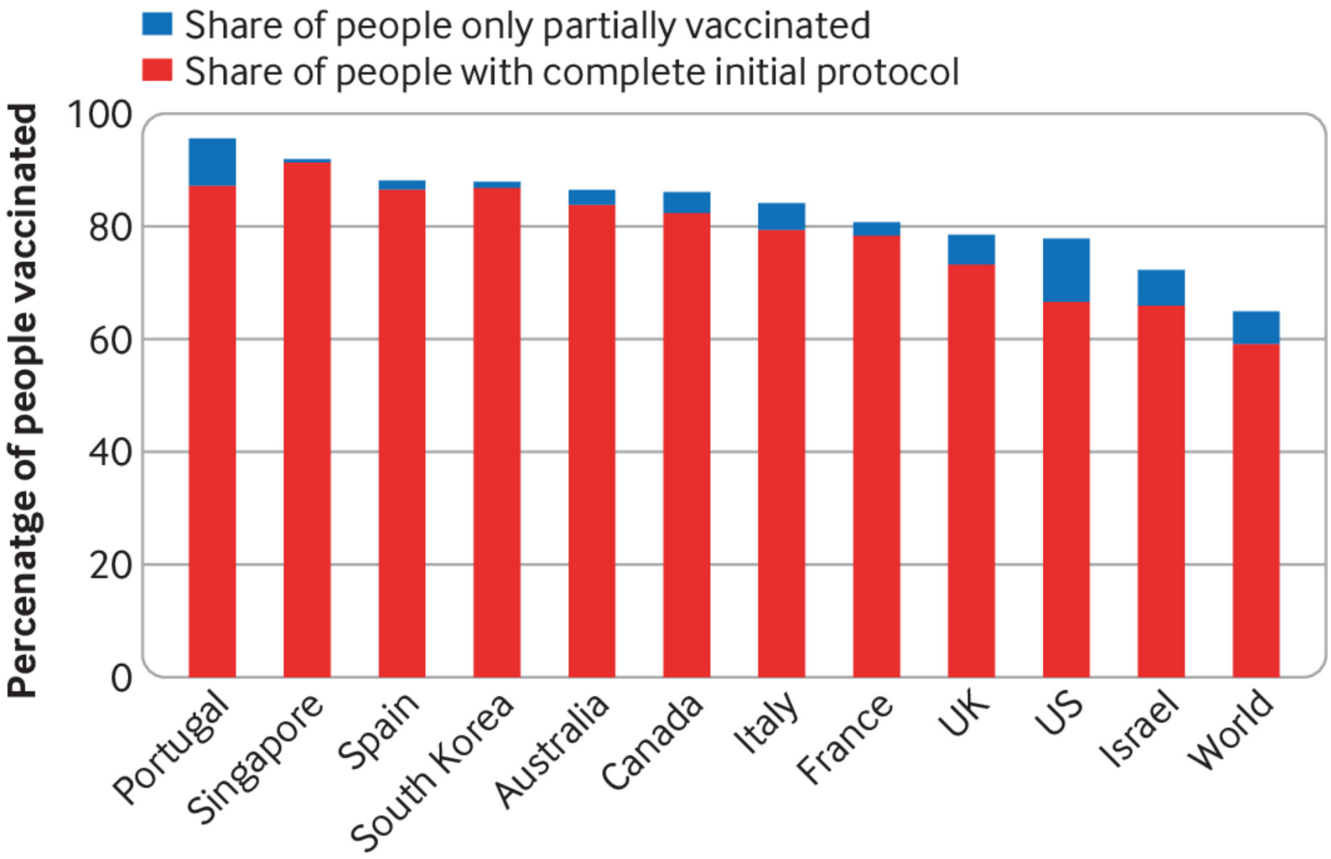

Fig 1 | Development and testing of covid-19 vaccines

The first covid-19 vaccines developed fell into two broad groups: mRNA vaccines and viral vector vaccines. Early results from randomised controlled trials of both types showed excellent efficacy against covid-19, with good protection against serious illness and death, and no major safety concerns.[4 5] Subsequent evaluations using real world data on much larger populations confirmed the general safety and effectiveness of these vaccines in adults.[6 7] One limitation of current vaccines is that although they are very successful in reducing the number of serious cases of covid-19, they are less effective in preventing infection from SARS-CoV-2, which means that vaccinated people can still become infected and infect others. Early in the vaccination programme, this was often not communicated well to the public, leading to unrealistic expectations about how well vaccines would suppress the risk of infection, particularly with the emergence of new variants that reduced vaccine efficacy.[8]

Approval of vaccines in the UK

Responsibility for licensing vaccines for use in the UK lies with the Medicines and Healthcare Products Regulatory Agency (MHRA), which developed dedicated work programmes to secure the necessary scientific resources to support vaccine developers and to establish a dialogue on areas such as manufacturing, efficacy, and toxicology. It also started a new process called "rolling reviews," which allowed drug companies to submit data to regulators in an ongoing fashion rather than submitting all data together at one point in time within a full dossier for regulatory approval. In the rolling review, data on areas such as manufacturing, quality, toxicology, pharmacology, and clinical development are submitted as they emerge, allowing for a timely, detailed assessment of each set of data and substantially shortening the overall time for regulatory evaluation and approval. The UK also has legal provisions for emergency use authorisation in exceptional circumstances, such as population-wide vaccination campaigns during pandemics.[9]

The UK became the first country in Europe to grant emergency use authorisation for a covid-19 vaccine when the MHRA gave approval for use of the Pfizer-BioNTech vaccine in adults on 2 December 2020. The AstraZeneca vaccine was approved for use in adults on 30 December 2020. These decisions took place when the UK was still operating under EU law and were therefore unrelated to Brexit.

After MHRA approval, the Joint Committee on Vaccination and Immunisation (JCVI) makes recommendations on the use of the vaccines by the NHS and the prioritisation of different groups of people for vaccination. Final decisions about the implementation of vaccine programmes are made by the UK and devolved governments. The UK government was also responsible for decisions about which vaccines should be procured and in what quantity, through a vaccine task force established to support the pandemic response. The UK procured many more vaccines than it needed, and some procured vaccines were not included in the UK's vaccination programme. The purchase in advance of such large quantities of vaccines by the UK and other wealthy countries raises questions about global vaccine equity.

Given the limited supply of vaccines available to the UK in the early part of the programme, the JCVI produced a priority list for vaccination, largely based on age as modelling data showed that the greatest population benefits from vaccination would come from

targeting older people (box 1). High priority for vaccination was also given to health and care workers and the residents and staff of care homes. The rationale was to vaccinate the groups most at risk from serious illness and death and those at greatest occupational risk of exposure to infection first, before moving on to other groups.[10] Overall, the policy was fair but was criticised for not including ethnic minority groups or key occupational groups other than health and care workers, such as people working in public transport or teaching. The pandemic had major effects on the education of children, for example, and it could be argued that staff working in schools should have been prioritised in the same way as NHS staff to reduce the disruption caused by the pandemic to children's education.[11]

Box 1: JCVI advice on priority groups for covid-19 vaccination (30 December 2020)

- Residents in a care home for older adults and their carers
- All those 80 years of age and over and frontline health and social care workers
- All those 75 years of age and over
- All those 70 years of age and over and clinically extremely vulnerable individuals
- All those 65 years of age and over
- All individuals aged 16 years to 64 years with underlying health conditions that put them at higher risk of serious disease and mortality
- All those 60 years of age and over
- All those 55 years of age and over
- All those 50 years of age and over

Shortly after the start of the vaccination programme in the UK, the government made the decision to prioritise delivery of the first dose of covid-19 vaccine over the second dose, based on advice from the JCVI. Practically, this meant a delay in giving the second dose of vaccine from 3-4 weeks after the first dose to 12 weeks. The rationale was that more people would receive one dose of vaccine and thereby gain protection against covid-19. In theory, this would boost protection from SARS-CoV-2 in the population, but at the cost of a short term reduction in protection for people whose second dose was delayed.

Covid-19 case numbers were high in the UK for long periods in 2021. Delaying second doses could drive transmission of infection in a partially vaccinated population, leading to the risk of developing SARS-CoV-2 vaccine escape variants. Seen by some as radical and as a departure from the evidence from clinical trials, particularly for the mRNA vaccines, this delayed booster approach was not widely adopted by other countries. Subsequent research, however, did indicate some population benefits in delaying the second vaccine dose,[12] but no benefit was seen in infection rates from a delayed second dose in the participants in the SIREN randomised controlled trial.[13]

The immunisation programme was disrupted by this decision, with many people having their appointments for their second doses cancelled. Much of the information that the JCVI used to recommend a delay in the second dose was available before the start of the vaccine programme. Key questions for the covid-19 public inquiry are why the JCVI did not consider a delayed second dose policy before the programme started and why there seemed to be no clear mechanism for evaluating the effects of its recommendation on clinical outcomes such as infection, hospital admission and case fatality rates and on the delivery of the vaccine programme.

Approval of vaccines for adolescents and children

Although the UK was an early adopter of covid-19 vaccines for use in adults, it was slower than many other countries to implement vaccination for 16-17 year olds, then for 12-15 year olds, and finally for 5-11 year olds. The delay in authorising vaccination for 12-15 year olds resulted in programmes not beginning until after the start of the 2021-22 school year (August 2021 in Scotland, September 2021 elsewhere in the UK). The programme was then beset by delays (particularly in England), resulting in slow progress with vaccination at a time when many schools faced large covid-19 outbreaks.

The policy in the UK was to initially offer one dose to younger people to limit the remote risk of cardiac inflammation. But a one dose policy would reduce the benefits of vaccination, particularly against the delta variant of SARS-CoV-2 that became the predominant strain in the UK in summer 2021 and against the omicron variant later in the year.[14] In December 2021, a two dose approach was finally agreed for 12-15 year olds. Booster doses were later approved for 16-17 year olds.

The JCVI faced considerable criticism for its delay in recommending vaccination for children and adolescents. But, early on, there was a lack of data supporting the unequivocal benefits versus risks for the use of covid-19 vaccines in children. The vaccines were initially tested in trials designed to analyse safety and efficacy in adults. Severe disease is much rarer in children (even though infection with SARS-CoV-2 is common) than in older people.[15] The risk-benefit analysis was therefore finely balanced, particularly in boys aged 16-19 years, for whom there was evidence of a risk of myocarditis after vaccination. Emerging data indicate that vaccine associated myocarditis and pericarditis, although extremely rare and usually self-limiting, might be more widely spread across the vaccinated population than previously thought, particularly after the second dose.[16]

Third primary doses and booster doses

Additional problems arose after the decision to give some immunocompromised people a third primary dose of vaccine.[17] The rationale was that immunocompromised people often had a poor response to two doses of vaccine and that a third dose would prime their immune system better and offer improved protection from serious illness. The programme was rolled out with little central or local planning, resulting in considerable confusion among both the public and NHS staff and leading to delays in many eligible people getting their third primary vaccine dose.[18] Key lessons from this component of the vaccination programme were the need to give the NHS adequate time to plan and to ensure that NHS staff are fully briefed in advance of any public announcement or media briefing about vaccination policy.

Around the same time, the NHS also began to offer selected groups of people a booster vaccine dose. Real world evaluations of vaccine efficacy indicated that protection from vaccines began to decline a few months after the second dose and that a booster dose offered increased protection from serious illness and death. This was especially true for the omicron variant of SARS-CoV-2.[19] The JCVI announced another booster programme in spring 2022 for selected groups, followed by a wider booster programme for autumn 2022. The autumn 2022 booster programme does not use the AstraZeneca vaccine, casting doubt on its continued use in the UK despite its lower cost and easier storage requirements than mRNA vaccines.

IT systems

In England, a decision was made at the start of the vaccination programme to record data using IT systems separate from patients' medical records (box 2).[3] One of the main reasons for this decision was that not all vaccination sites would have access to the electronic medical record systems used by NHS primary care teams. After vaccination, data were transferred to the patient's general practice to ensure that the vaccination showed up in their electronic primary medical care record. This process sometimes failed, resulting in missing vaccination data for many patients. There were also issues with recording third primary vaccines and vaccines for people who had been vaccinated in another UK country or overseas.

Box 2: IT systems for covid-19 vaccination in England

- *National booking service*—used by the public to book vaccination appointments
- *NHS Foundry*—data collection, processing, and visualisation platform
- *National immunisation management system*—records vaccination details and adverse reactions
- *Outcomes4Health (Pinnacle)*—used by community vaccinations sites to record details of vaccinations
- *National immunisation and vaccination system*—used to record vaccinations in hospital sites
- *GP electronic patient record systems*—not directly used in the vaccination programme but were used to identify patients in clinical risk groups. Vaccination records from other systems are sent electronically to these systems.

Other problems arose in the transfer of vaccination data to the NHS app in England, which is essential to show the proof of full vaccination often required for international travel (sometimes referred to as "vaccine passports"). Because vaccine sites did not usually have full access to patients' medical records, they were not able to deal with these queries. General practices therefore faced many questions from patients about data and vaccine passport problems and about eligibility for additional vaccinations in immunocompromised people. A key lesson for the future is to have well functioning IT systems as well as clear processes for recording vaccines for people who were vaccinated outside the UK's official programme.

Tackling vaccine hesitancy

Concerns about covid-19 vaccination and the resulting vaccine hesitancy are important problems globally.[20] Early survey data showed that the UK had lower overall rates of vaccine hesitancy than many other countries and that people in the youngest age groups and those from ethnic minority groups were more likely to say that they would decline covid-19 vaccination. When vaccination started in the UK, vaccination rates were lowest in these groups, leaving around 7% of people aged 12 and over currently unvaccinated across the UK, with vaccination rates lowest in large urban areas such as London. One key lesson for the future is to have clear plans in place to improve confidence in vaccines and vaccine uptake, particularly among younger people, those from ethnic minority groups, and people living in deprived areas. Local community engagement is essential, and there are numerous examples from around the UK of local initiatives that helped to improve vaccine uptake.

Infrastructure for vaccine delivery

The NHS has used a range of sites to deliver vaccines, including locations run by hospitals as well as GP led and community pharmacy sites. In the first phase of the vaccination programme (for people aged 18 and over), most vaccines were delivered at GP led sites. The NHS needs to decide how covid-19 vaccines will be delivered in the longer term. A GP led programme, supported by pharmacies and hospital sites, offers many potential benefits, including easier access for patients to GP and pharmacy sites than hospitals and high vaccination rates as a result of the ongoing relationships that primary care teams have with their patients. The greater frequency of contact between NHS primary care staff and patients also provides the opportunity for health promotion activities, including co-administration of other vaccines such as for influenza.

Monitoring vaccine uptake, safety, and efficacy

One area in which the UK excelled internationally was using data from the NHS, covid-19 testing, and national mortality records to monitor vaccine uptake, safety, and effectiveness. Public Health England established a dashboard that allowed daily vaccine delivery data from the four UK nations to be viewed (this work later transferred to the Health Security Agency).[21] Other outputs included weekly vaccination publications with more detailed data on vaccine uptake by age group. Some vaccine efficacy data were also included in these publications.[22]

Additional data on vaccine safety and efficacy came from electronic GP records linked to other data and the yellow card scheme that allows professionals and patients to report side effects.[9] This allowed research on the effectiveness of vaccines (in preventing hospital admissions and deaths, for example) and on the side effects of vaccination. Because randomised controlled trials are generally too small to identify rare but serious side effects, large clinical databases are needed. In the UK, this includes databases such as OpenSAFELY and QResearch.[23,24] Real world data have also informed vaccination policy in groups that lack data from clinical trials—for example, pregnant women and young people.

In the longer term, the large clinical databases established in the UK will provide information for public health planning globally. This would include information on how quickly vaccine efficacy weakens in different groups and the effectiveness of booster doses, which will guide policies on the necessity and frequency of additional vaccinations. It will also be possible to compare the safety and efficacy of different vaccines and examine the effectiveness of vaccines against any new variants of SARS-CoV-2 that emerge.[9]

Ensuring vaccine supply for the UK

Early on in its vaccination programme, the UK government found itself in a dispute with the European Commission related to AstraZeneca's failure to supply the contracted volumes of vaccine to member states of the European Union.[25] The European Commission then threatened to reduce export of Pfizer vaccines to the UK. In the end, no restrictions were imposed, and the UK continued to receive its due quantities of Pfizer vaccine. But the UK is currently very reliant on overseas manufactured mRNA vaccines from Pfizer and Moderna. With the US also prioritising its own citizens for vaccines, the UK government will need to consider how it works with the drug industry, biotechnology companies, and universities to ensure that the UK can develop, test, and manufacture vaccines for the current and any future pandemics at the speed and quantity needed. The decision by Moderna to build a research and manufacturing centre in the UK will start to tackle this issue.[26]

Lessons for the future

The UK's covid-19 vaccination programme had many successes, such as the excellent data on vaccine uptake and effectiveness and the rapid rollout of vaccination by the NHS, but it also encountered problems that need to be examined in the covid-19 public inquiry. One key lesson is that investment in the UK's scientific infrastructure is essential so that the UK is prepared for any future pandemics. Sharing of scientific information and data between countries is also important.[27] We need rapid systems for approving vaccines for use in the UK, as well as the rapid acquisition and analysis of data for monitoring safety and effectiveness. Good IT systems are essential for identifying patients in priority groups for vaccination and for establishing vaccine booking and recording systems that are easy for the public to use and that seamlessly transfer data to primary care medical records and the NHS app.

A sustainable infrastructure for vaccine delivery would allow high uptake of vaccines to be achieved rapidly in all population groups, including those who are vaccine hesitant or who are less concerned about the risks of infection. A recent National Audit Office study reported that vaccinations delivered though primary care sites—as seen with many other healthcare interventions—were substantially cheaper than those delivered at other sites, such as hospital based vaccine clinics.[28]

Finally, we need an effective public and professional dialogue on all decisions about the approval of vaccines so that the public has full confidence in decisions taken by bodies such as the JCVI, particularly when the UK veers away from policies in many other developed countries, such as in the use of vaccines in children and adolescents and in modifying dosing schedules. This might require, for example, the JCVI holding meetings in public, having rigorous press conferences after its meetings, and responding to written questions from the public and from professional organisations about its recommendations. Publication of JCVI meeting minutes is laudable but insufficient for the widespread communication of decisions, particularly during times of national crisis. The continued threat of emerging infections with pandemic potential means that the work of the JCVI remains critical to preserving confidence in vaccines. So greater transparency about the work of the JCVI and a level of public dialogue that is appropriate for the 21st century are essential to maintain public confidence in the decisions made by the JCVI, reduce levels of vaccine hesitancy, and maintain high vaccine uptake in the UK.

Questions for the inquiry

- What should we be doing to secure the legacy of the covid-19 vaccine research and delivery strategy for vaccine science, vaccine manufacturing, public health, and pandemic preparedness?
- Why hasn't the UK established a pipeline for the rapid development of RNA vaccines?
- Why did the UK lag behind many other countries in recommending covid-19 vaccines for children?
- How would we respond to a future pandemic causing high levels of morbidity and mortality in children?
- Was sufficient attention paid to targeting groups who were likely to be vaccine hesitant?
- What can be done to build on the JCVI's communications and operations—particularly around public and patient involvement and engagement and its position on equality, diversity, and inclusion?
- Why did the JCVI not recommend a delayed second dose strategy in its initial recommendations to the government in 2020? What impact did this have?
- What is the best method of covid-19 vaccine delivery in the future?
- Should staff working in schools also have been included in the initial occupational groups targeted for vaccination (such as health and care workers) reduce the effect of the pandemic on schools, given the many adverse effects of the pandemic on the education, social development, and the physical and mental health of children?
- Did the UK government take the correct decisions about vaccine procurement? Was the UK correct to work alone on procurement or should there have been greater collaboration with the EU?
- What impact did the over-procurement of vaccines by developed countries such as the UK have on vaccine equity and on the supply of vaccines for lower income countries early in the pandemic?

Contributors and sources: AM is a professor of primary care and public health whose general practice is a member of a GP Federation delivering covid-19 vaccines. He has published on areas such as the logistical issues in vaccination programmes and addressing vaccine hesitancy. He works with local and national organisations to improve vaccine uptake. KP is senior clinical research fellow in vaccinology and honorary consultant physician at Imperial College London. She is chief and principal investigator for clinical trials of novel vaccines including the Imperial College London self-amplifying RNA covid-19 vaccine candidate and the Oxford Astra Zeneca covid-19 vaccine, as well as for experimental medicine studies of prototype immunogens and human immunology studies of vaccine responses. She is leading the Imperial College London vaccine research response to covid-19. SH is an NHS GP trainer, appraiser, primary care network lead and local medical committee member based in Watford. He has published opinion pieces and educational modules on GP topics including continuity of care, advanced care planning, and the covid-19 vaccination programme. His practice was a first wave covid-19 vaccination site. MP is a visiting professor at Imperial College London. She is former senior scientific adviser at the European Medicines Agency where she worked for over 25 years with a focus on scientific, technical, and therapeutic innovation in pharmaceuticals. She has published in areas such as biotechnology and nanotechnology based medicinal products, gene therapy, cell therapy, pharmacogenetics, biomarkers, and clinical trials methodology.

Patient involvement: We received feedback on the article from public and patient groups linked to the NIHR Applied Research Collaboration NW London and the NIHR Imperial Clinical Research Facility. The feedback emphasised the importance of clear, positive messages about vaccination for the public; and personalised support for people who were vaccine hesitant or who had concerns about vaccination to help increase vaccine uptake. Access to vaccination at a local site was also important, particularly for older people or those with limited mobility.

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