

THE LANCET

The UK Government's Vaccine Taskforce: strategy for protecting the UK and the world

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No vaccine in the history of medicine has been as eagerly anticipated as that to protect against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Vaccination is widely regarded as the only true exit strategy from the pandemic that is currently spreading globally.

The UK is at the forefront of a huge international effort to develop clinically safe and effective vaccines. The Vaccine Taskforce was the brainchild of Sir Patrick Vallance, the UK Government's chief scientific advisor, who saw the need for a dedicated, nimble private-sector team of experts embedded in the Government to drive forward the development of vaccines for the UK and internationally. The Vaccine Taskforce was set up under the Department for Business, Energy and Industrial Strategy in May, 2020, and I was asked to chair the taskforce, reporting directly to the prime minister, and working alongside Deputy Chair Clive Dix. The Vaccine Taskforce aims to ensure that the UK population has access to vaccines as soon as possible, while working with partners to support equitable access for populations worldwide, whether rich or poor.

However, we do not know that we will ever have a vaccine at all. It is important to guard against complacency and over-optimism. The first generation of vaccines is likely to be imperfect, and we should be prepared that they might not prevent infection but rather reduce symptoms, and, even then, might not work for everyone or for long.

Our strategy has been to build a diverse portfolio across different formats to give the UK the greatest chance of providing a safe and effective vaccine, recognising that many, and possibly all, of these vaccines could fail. We have focused on vaccines that are expected to elicit immune responses in the population older than 65 years: over three-quarters of deaths caused by SARS-CoV-2 infection are in this older population,^{1, 2} so it is essential that any vaccine is able to protect this group. Scalability of vaccine manufacture was also a key criterion, with the goal being to manufacture in the UK, if possible, to secure supply and create long-term resilience. We considered only vaccines that have the potential for approval by the Medicines and Healthcare products Regulatory Agency and European Medicines Agency and for vaccine delivery as early as the end of 2020 or, at the latest, in the second half of 2021.

The Vaccine Taskforce has now secured access to six vaccines (from more than 240 vaccines in development) across four different formats: adenoviral vectors, mRNA, adjuvanted proteins, and whole inactivated viral vaccines, which are promising in different ways. The most advanced vaccines, such as those developed by AstraZeneca and the University of Oxford, BioNTech and Pfizer, and Janssen, are based on novel formats for which we have little experience of their use as vaccines, although the initial immunogenicity and safety data are encouraging.^{3, 4, 5} Vaccines based on frequently used vaccine formats, such as adjuvanted protein vaccines developed by Novavax, and by GSK and Sanofi, and inactivated whole viruses developed by Valneva, will not be available until late in 2021.

We also have an agreement with AstraZeneca to supply a neutralising antibody cocktail as a prophylactic treatment once clinical trials are completed and it is approved by regulators. This treatment will be provided in the short term for people who cannot receive a vaccine, such as people who are heavily immunosuppressed and cannot mount an immune response, or people who need immediate protection, such as health-care workers.

The Vaccine Taskforce has options to purchase sufficient doses of each vaccine type to vaccinate the appropriate UK population. Following the interim advice by the UK's Joint Committee of Vaccination and Immunisations,⁶ vaccination would be recommended for adults older than 50 years, health-care and social-care workers on the front line, and adults with underlying comorbidities. The precise dose required will be determined as part of the clinical trials and by the decisions made by the UK Government on the basis of the advice from the Joint Committee on Vaccination and Immunisation. We anticipate that most vaccines will require two doses, and we are also investigating whether annual or biannual revaccination booster shots might be required to maintain durable protection. Developers of COVID-19 vaccines range from small biotechnology companies to big pharmaceutical companies, each with different commercial objectives and with different amounts of funding to support manufacturing scale-up and clinical trials. In some cases, the Vaccine Taskforce is investing at risk to support these activities before we know whether the vaccine is safe and effective, and, in other cases, we have negotiated an advanced purchase agreement. In both instances, government funding is usually linked to reaching clinical, regulatory, and other milestones. If a vaccine is not going to work, then we will stop funding.

Some of the developers, such as AstraZeneca, GSK and Sanofi, and Janssen, are pursuing the development of a vaccine on a non-profit basis, at least for the pandemic period; whereas others view the resources and risk that they are assuming as justification for seeking a profit.

The first phase 3 efficacy data from the leading vaccine candidates are due by the end of 2020, subject to accruing sufficient rates of infection within the clinical trial cohorts to show the vaccines' efficacy. The primary endpoint is to show that the vaccine can protect against SARS-CoV-2 infection and reduce symptom burden. Two phase 3 efficacy clinical trials are now underway in the UK; the Oxford AstraZeneca adenovirus-vectored vaccine (NCT04400838) and the world's first phase 3 study for Novavax's protein-adjuvant vaccine (NCT04368988), both occurring at various sites across the UK. Numerous phase 3 studies are in preparation to start in the UK in 2020 and 2021 with US, European, Australian, and possibly Chinese vaccine developers, reflecting the UK's strong reputation for running clinical trials and postauthorisation pharmacovigilance of high quality.

To help to accelerate the development of successful vaccines, we launched the National Health Service COVID-19 vaccine registry⁷ and have enrolled over 295 000 volunteers,⁸ with a focus on populations who are at high risk of severe infection and mortality from COVID-19. We plan to accelerate recruitment in disease hotspots with mobile research teams informed by robust PCR testing, and have provided funding for clinical trials of crucial importance, including Janssen's two-dose Ad26 protocol (NCT04505722), Imperial College London's self-amplifying RNA (ISRCTN17072692), and Valneva's whole inactivated vaccine. We are also exploring the potential for future controlled human challenge studies, dependent on ethics and regulatory approvals. These studies have the potential to assess the efficacy of vaccines more quickly and with far fewer participants than a standard phase 3 trial. The Vaccine Taskforce is also supporting the development of heterologous boost clinical protocols, through the National Institute for Health Research, to explore whether different vaccine combinations can increase immunity or durability of protection.

To harmonise results from the various clinical trials, and to help to define immune correlates of protection, we have supported development of standardised, accredited assays, including quantitative high-throughput spike-protein ELISAs, live viral-neutralisation assays, and T-cell assays, which will be available to all vaccine developers.

A major challenge is that the global manufacturing capacity for vaccines is vastly inadequate for the billions of doses that are needed, and the UK manufacturing capability to date has

been equally scarce. The Vaccine Taskforce has provided funding for flexible and surge production in several new UK sites for vaccine manufacture to provide the UK population with a new vaccine in less than 9 months from the identification of the pathogen. We also plan to bring new vaccine technologies and capabilities to the UK for future pandemic preparedness.

No-one has ever done mass vaccination of adults anywhere in the world before and the two-dose regimen, plus cold-chain restrictions for some vaccines, adds to the complexity of this deployment operation. National Health Service England has flexible deployment plans to start the vaccination of prioritised cohorts as soon as the vaccines are approved by the regulatory authorities, currently not to be coadministered with the influenza vaccination (although clinical trials are exploring coadministration of influenza and COVID-19 vaccines). Deployment plans have been developed for a range of settings from mass vaccination sites to large and small mobile (eg, pop-up) sites, general-practitioner surgeries and pharmacies, and even roving teams to visit people in care homes and people who are housebound or shielding.

We cannot, however, protect the UK without working with our international partners to protect the world. SARS-CoV-2 is a global pandemic with a toll of over 1.1 million deaths. No one is safe until we are all safe. Pandemic viruses do not respect national borders.

There will not be one successful vaccine, or one single country, that is able to supply the world. We urgently need international cooperation to pool risks and costs, address barriers to access, and scale up the manufacturing capacity to produce sufficient doses to protect everyone at risk of SARS-CoV-2 infection globally.

The UK is committed to ensuring that everyone at risk of SARS-CoV-2 infection, anywhere in the world, has access to a safe and effective vaccine. The COVID-19 Vaccines Global Access Facility, to which the UK has committed £548 million, will deliver vaccines for the UK population and provide access to vaccines for lower income countries: initially 2 billion doses for 1 billion people worldwide. Working with Gavi, the Vaccine Alliance, Coalition for Epidemic Preparedness Innovations, WHO, and a broad alliance of 180 nations, this pooling of resources maximises the chances of securing access to a vaccine and making it available to all who need it. But we now need to make this global facility a permanent one: ready to respond to future pandemics quickly in the future and to control COVID-19.

The SARS-CoV-2 virus is likely to evolve, and other zoonotic pathogens are likely to pose future risks. China, Europe, the USA, and the UK need to work together. If we establish international collaboration right now, then we will be better prepared to control future pandemics without causing the largest global recession in history and the biggest threat to lives in living memory.