Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination

30 December 2020

Introduction

This advice is provided to facilitate the development of policy on COVID-19 vaccination in the UK.

JCVI advises that the first priorities for the current COVID-19 vaccination programme should be the prevention of COVID-19 mortality and the protection of health and social care staff and systems. Secondary priorities could include vaccination of those at increased risk of hospitalisation and at increased risk of exposure, and to maintain resilience in essential public services. This document sets out a framework for refining future advice on a national COVID-19 vaccination strategy.

This advice has been developed based on a review of UK epidemiological data on the impact of the COVID-19 pandemic so far (1), data on demographic and clinical risk factors for mortality and hospitalisation from COVID-19 (2-3), data on occupational exposure(4-7), a review on inequalities associated with COVID-19 (8), Phase I, II and III data on the Pfizer-BioNTech mRNA vaccine and the AstraZeneca vaccine, Phase I and II data on other developmental COVID-19 vaccines (9-20), and mathematical modelling on the potential impact of different vaccination programmes (21).

Considerations

Pfizer-BioNTech vaccine

The Committee has reviewed published and unpublished Phase I/II/III safety and efficacy data for the Pfizer BioNTech mRNA vaccine. The vaccine appears to be safe and well-tolerated, and there were no clinically concerning safety observations. The data indicate high efficacy

in all age groups (16 years and over), including protection against severe disease and encouraging results in older adults. The Committee advises that this vaccine be used in the first phase of the programme, according to the priority order set out below. While there is some evidence to indicate high levels of short-term protection from a single dose of vaccine, a two-dose vaccine schedule is currently advised as this is likely to offer longer lasting protection. (See below).

AstraZeneca vaccine

The Committee has reviewed published and unpublished Phase I/II/III safety and efficacy data for the AstraZeneca vaccine. The vaccine appears to have a good safety profile, and the data indicate high efficacy in adults aged 18 years and over, including protection against severe disease and encouraging results in older adults. Existing data are consistent with high levels of short-term protection following the first dose of vaccine, with further protection obtained following the second dose of vaccine which may be given between 4 – 12 weeks after the first dose. The Committee advises that this vaccine be used in the first phase of the programme, according to the priority order set out below. A two-dose vaccine schedule is currently advised as this is likely to offer longer lasting protection. (See below)

Vaccine schedule

For both Pfizer-BioNTech and AstraZeneca vaccines, a two-dose schedule is advised.

In the context of the epidemiology of COVID-19 in the UK in late 2020, the JCVI places a high priority on promoting rapid, high levels of vaccine uptake amongst vulnerable persons. Therefore, given data indicating high efficacy from the first dose of both Pfizer-BioNTech and AstraZeneca vaccines, the Committee advises that delivery of the first dose to as many eligible individuals as possible should be initially prioritised over delivery of a second vaccine dose. This should maximise the short-term impact of the programme. The second dose of the Pfizer-BioNTech vaccine may be given between 3 to 12 weeks following the first dose. The second dose of the AstraZeneca vaccine may be given between 4 to 12 weeks following the first dose.

JCVI advises that the second vaccine dose should be with the same vaccine as for the first dose. Switching between vaccines or missing the second dose is not advised as this may affect the duration of protection.

Vaccine choice

There have been no clinical trials directly comparing the Pfizer-BioNTech and AstraZeneca vaccines. In Phase III trials of the respective vaccines, efficacy against symptomatic disease for the Pfizer-BioNTech vaccine was higher than for the AstraZeneca vaccine. Differences in study setting, study design, study population (age, ethnicity, social demographics, etc), and efficacy endpoints may account for some of the observed differences. Both vaccines give very high protection against severe disease, which is the primary aim of the first phase of the programme, and both vaccines have good safety profiles.

The logistical challenges posed by the storage and distribution requirements for the Pfizer-BioNTech vaccine mean that in some populations, the AstraZeneca vaccine is the only vaccine which can be deployed rapidly, and without substantial vaccine wastage.

JCVI does not advise a preference for either vaccine in any specific population. For operational and programmatic reasons, such as to enable more extensive and timely vaccine coverage, one vaccine may be offered in certain settings in preference over another vaccine.

This statement will be updated following consideration of Phase III safety and efficacy data on other COVID-19 vaccines.

Direct protection vs transmission reduction

JCVI has considered a number of different vaccination strategies, including those targeting transmission and those targeted at providing direct protection to persons most at risk.

In order to interrupt transmission, mathematical modelling indicates that we would need to vaccinate a large proportion of the population with a vaccine which is highly effective at preventing infection (transmission). At the start of the vaccination programme, good evidence on the effects of vaccination on transmission will not be available, and vaccine availability will be more limited. The best use of

available vaccine will also, in part, be dependent on the point in the pandemic the UK is at.

Given the current epidemiological situation in the UK, the best option for preventing morbidity and mortality in the initial phase of the programme is to directly protect persons most at risk of morbidity and mortality.

Age

Current evidence strongly indicates that the single greatest risk of mortality from COVID-19 is increasing age and that the risk increases exponentially with age (1-3). Mathematical modelling indicates that the optimal strategy for minimising future deaths or quality adjusted life year (QALY) losses is to offer vaccination to older age groups first. These models assume an available vaccine is both safe and effective in older adults (21). Data also indicate that the absolute risk of mortality is higher in those over 65 years than that seen in the majority of younger adults with an underlying health condition (see below). Accordingly, the Committee's advice largely prioritises based on age.

Age-based programmes are usually easier to implement and therefore achieve higher vaccine uptake. An age-based programme is also likely to increase uptake in those with clinical risk factors as the prevalence of these increases with age.

Older adults resident in care homes

There is clear evidence that those living in residential care homes for older adults have been disproportionately affected by COVID-19 (22-25) as they have had a high risk of exposure to infection and are at higher clinical risk of severe disease and mortality. Given the increased risk of outbreaks, morbidity and mortality in these closed settings, these adults are considered to be at very high risk. The Committee's advice is that this group should be the highest priority for vaccination. Vaccination of residents and staff at the same time is considered to be a highly efficient strategy within a mass vaccination programme with the greatest potential impact (see below).

Health and social care workers

Frontline health and social care workers are at increased personal risk of exposure to infection with COVID-19 and of transmitting that infection

to susceptible and vulnerable patients in health and social care settings. The Committee considers frontline health and social care workers who provide care to vulnerable people a high priority for vaccination. Protecting them protects the health and social care service and recognises the risks that they face in this service. Even a small reduction in transmission arising from vaccination would add to the benefits of vaccinating this population, by reducing transmission from health and social care workers to multiple vulnerable patients and other staff members. This group includes those working in hospice care and those working temporarily in the COVID-19 vaccination programme who provide face-to-face clinical care.

There is evidence that infection rates are higher in residential care home staff (22-25), than in those providing domiciliary care or in healthcare workers. Care home workers are therefore considered a very high priority for vaccination.

Prioritisation amongst health and social care workers

Frontline health and social care workers at high risk of acquiring infection, at high individual risk of developing serious disease, or at risk of transmitting infection to multiple vulnerable persons or other staff in a healthcare environment, are considered of higher priority for vaccination than those at lower risk. This prioritisation should be taken into account during vaccine deployment.

Clinically Extremely Vulnerable (Shielding patients)

Individuals considered extremely clinically vulnerable have been shielding for much of the pandemic (26). This means that available data are likely to underestimate the risk in this group. Many of those who are clinically extremely vulnerable are in the oldest age groups and will be among the first to receive vaccine. Considering data from the first wave in the UK, the overall risk of mortality for clinically extremely vulnerable younger adults is estimated to be roughly the same as the risk to persons aged 70 – 74 years. Given the level of risk seen in this group as a whole, JCVI advises that persons aged less than 70 years who are clinically extremely vulnerable should be offered vaccine alongside those aged 70-74 years of age. There are two key exceptions to this, pregnant women with heart disease and children (see below).

Many individuals who are clinically extremely vulnerable will have some degree of immunosuppression or be immunocompromised and may not respond as well to the vaccine. Therefore, those who are clinically extremely vulnerable should continue to follow Government advice on reducing their risk of infection. Consideration has been given to vaccination of household contacts of immunosuppressed individuals. However, at this time there are no data on the size of the effect of COVID-19 vaccines on transmission. Evidence is expected to accrue during the course of the vaccine programme, and until that time the committee is not in a position to advise vaccination solely on the basis of indirect protection. Once sufficient evidence becomes available the committee will consider options for a cocooning strategy for immunosuppressed individuals, including whether any specific vaccine is preferred in this population.

Women who are pregnant

There is no known risk associated with giving non-live vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child.

Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.

JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.

JCVI does not advise routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after vaccination.

Women who are breastfeeding

There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines.

The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

Children less than 16 years of age

Following infection, almost all children will have asymptomatic infection or mild disease. There are very limited data on vaccination in adolescents, with no data on vaccination in younger children, at this time. The Committee advises that only those children at very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination with either the Pfizer-BioNTech or the AstraZeneca vaccine. Clinicians should discuss the risks and benefits of vaccination with a person with parental responsibility, who should be told about the paucity of safety data for the vaccine in children aged < 16 years. More detail on vaccination in children is set out in the Green Book – Immunisation Against Infectious Disease.

Persons with underlying health conditions

There is good evidence that certain underlying health conditions increase the risk of morbidity and mortality from COVID-19. When compared to persons without underlying health conditions, the absolute increased risk in those with underlying health conditions is considered generally to be lower than the increased risk in persons over the age of 65 years (with the exception of the clinically extremely vulnerable – see above). The Committee's advice is to offer vaccination to those aged 65 years and over followed by those in clinical risk groups aged 16 years and over. The main risk groups identified by the Committee are set out below.

- Chronic respiratory disease, including chronic obstructive pulmonary disease (COPD), cystic fibrosis and severe asthma
- Chronic heart disease (and vascular disease)
- Chronic kidney disease

- Chronic liver disease
- Chronic neurological disease including epilepsy
- Down's syndrome
- Severe and profound learning disability
- Diabetes
- Solid organ, bone marrow and stem cell transplant recipients
- People with specific cancers
- Immunosuppression due to disease or treatment
- Asplenia and splenic dysfunction
- Morbid obesity
- Severe mental illness

Other groups at higher risk, including those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill, should also be offered vaccination alongside these groups.

Individuals within these risk groups who are clinically extremely vulnerable are discussed separately (see above). Further advice on risk groups, including clear definitions, are set out in the Green Book - Immunisation Against Infectious Disease.

Mitigating inequalities

Multiple social and societal drivers are recognised to contribute towards increased risk from COVID-19. JCVI considered it important to understand the factors underlying health inequalities in COVID-19 giving due consideration to relevant scientific evidence, ethical principles and vaccine programme deliverability. The issues considered are set out in Annex A.

There is clear evidence that certain Black, Asian and minority ethnic (BAME) groups have higher rates of infection, and higher rates of serious disease, morbidity and mortality. There is no strong evidence that ethnicity by itself (or genetics) is the sole explanation for observed differences in rates of severe illness and deaths. What is clear is that certain health conditions are associated with increased risk of serious disease, and these health conditions are often overrepresented in certain Black, Asian and minority ethnic groups. It is also clear that societal factors, such as occupation, household size, deprivation, and access to healthcare can increase susceptibility to COVID-19 and worsen

outcomes following infection. These factors are playing a large role in the inequalities being seen with COVID-19.

Good vaccine coverage in Black, Asian and minority ethnic groups will be the most important factor within a vaccine programme in reducing inequalities for this group. Prioritisation of persons with underlying health conditions (see above) will also provide for greater vaccination of BAME communities who are disproportionately affected by such health conditions.

The Committee's advice is for NHS England and Improvement, the Department of Health and Social Care, Public Health England and the devolved administrations to work together to ensure that inequalities are identified and addressed in implementation. This could be through culturally competent and tailored communications and flexible models of delivery, aimed at ensuring everything possible is done to promote good uptake in Black, Asian and minority ethnic groups and in groups who may experience inequalities in access to, or engagement with, healthcare services. These tailored implementation measures should be applied across all priority groups during the vaccination programme.

Occupational vaccination (other than frontline health and social care workers)

The Committee considered evidence on the risk of exposure and risk of mortality by occupation. Under the priority groups advised below, those over 50 years of age, and all those 16 years of age and over in a risk group, would be eligible for vaccination within the first phase of the programme. This prioritisation captures almost all preventable deaths from COVID-19, including those associated with occupational exposure to infection. As such, JCVI does not advise further prioritisation by occupation during the first phase of the programme.

Occupational prioritisation could form part of a second phase of the programme, which would include healthy individuals from 16 years of age up to 50 years of age, subject to consideration of the latest data on vaccine safety and effectiveness.

The impact of vaccine delivery on non-pharmaceutical interventions.

In a situation of constrained vaccine supply, population level protection will not be achievable immediately.

Once we have evidence of the impact of the programme on morbidity and mortality amongst vulnerable persons, the initial phase of the vaccination programme could allow the subsequent relaxation of non-pharmaceutical interventions in some sectors of the population. Government advice on non-pharmaceutical interventions should continue to be followed.

Vaccine priority groups: advice on 30 December 2020

Phase 1 – direct prevention of mortality and supporting the NHS and social care system

JCVI advises that the first priorities for the COVID-19 vaccination programme should be the prevention of mortality and the maintenance of the health and social care systems. As the risk of mortality from COVID-19 increases with age, prioritisation is primarily based on age. The order of priority for each group in the population corresponds with data on the number of individuals who would need to be vaccinated to prevent one death, estimated from UK data obtained from March to June 2020 (3)

1	Residents in a care home for older adults and their carers
2	All those 80 years of age and over Frontline health and social care workers
3	All those 75 years of age and over
4	All those 70 years of age and over Clinically extremely vulnerable individuals*
5	All those 65 years of age and over
6	All individuals aged 16 years** to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality***
7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

*	Clinically extremely vulnerable individuals are described here. This advice on vaccination does not include all pregnant women or those under the age of 16 years (see above)
**	The AstraZeneca vaccine is only authorised for use in those aged 18 years of age and over, however, JCVI is of the view that this vaccine may be used in those 16-17 years of age where there is no access or availability to an alternative approved COVID-19 vaccine
***	This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

It is estimated that taken together, these groups represent around 99% of preventable mortality from COVID-19.

JCVI advises that implementation of the COVID-19 vaccine programme should aim to achieve high vaccine uptake. An age-based programme will likely result in faster delivery and better uptake in those at the highest risk. Implementation should also involve flexibility in vaccine deployment at a local level with due attention to:

- mitigating health inequalities, such as might occur in relation to access to healthcare and ethnicity;
- vaccine product storage, transport and administration constraints;
- exceptional individualised circumstances; and
- availability of suitable approved vaccines e.g. for specific age cohorts.

JCVI appreciates that operational considerations, such as minimising wastage, may require a flexible approach, where decisions are taken in consultation with national or local public health experts. To be assured that outcome is maximised however, JCVI would like to see early and regular comprehensive vaccine coverage data so that the Committee can respond if high priority risk groups are unable to access vaccination in a reasonable time frame.

The next phase – further reduction in hospitalisation and targeted vaccination of those at high risk of exposure and/or those delivering key public services

As the first phase of the programme is rolled out in the UK, additional data will become available on the safety and effectiveness of COVID-19 vaccines. These data will provide the basis for consideration of vaccination in groups that are at lower risk of mortality from COVID-19. The Committee is currently of the view that the key focus for the second phase of vaccination could be on further preventing hospitalisation.

Vaccination of those at increased risk of exposure to SARS-CoV-2 due to their occupation could also be a priority in the next phase. This could include first responders, the military, those involved in the justice system, teachers, transport workers, and public servants essential to the pandemic response. Priority occupations for vaccination are considered an issue of policy, rather than for JCVI to advise on. JCVI asks that the Department of Health and Social Care consider occupational vaccination in collaboration with other Government departments.

Wider use of COVID-19 vaccines will provide a better understanding of whether they can prevent infection and onward transmission in the population. Data on vaccine impact on transmission, along with data on vaccine safety and effectiveness, will potentially allow for consideration of vaccination across the rest of the population.

As trials in children and pregnant women are completed, we will also gain a better understanding of the safety and effectiveness of the vaccines in these persons.

Further work

JCVI will continually monitor data on vaccines in development. As more Phase III data become available on candidate COVID-19 vaccines the Committee will be able to prepare further advice for policy makers in the UK.

JCVI will review data on vaccine coverage, in particular focussing on inequalities, and the impact of actions being undertaken to mitigate inequalities. Vaccine safety will be continually monitored by the MHRA and PHE, and JCVI will regularly review data on vaccine safety as the programme rolls out. Vaccine efficacy and any potential impacts on transmission will be monitored by PHE. Data will be considered at the earliest opportunity to facilitate discussions on prioritisation after the first phase of the programme.

Background

JCVI met to consider COVID-19 vaccination on 7 May, 3 June, 6 July, 1 September, 29 November, 30 November, 1 December, 22 December and

29 December 2020. Between 24 September 2020 and 22 December 2020, a JCVI COVID-19 sub-committee met most weeks to consider key issues in greater depth. The advice provided is to support the government in development of a vaccine strategy for the procurement and delivery of a vaccination programme to the population.

SARS-CoV-2 (COVID-19)

COVID-19 disease first emerged as a cause of severe respiratory infection in Wuhan, China in late 2019. The first two cases in the UK were seen in late January 2020. In March 2020, the WHO declared a SARS-Cov-2 pandemic.

In adults, the clinical picture varies widely. A significant proportion of individuals are likely to have mild symptoms and may be asymptomatic at the time of diagnosis. Symptoms are commonly reported as a new onset of cough and fever, but may include headache, loss of smell, nasal obstruction, lethargy, myalgia, rhinorrhoea, taste dysfunction, sore throat, diarrhoea, vomiting and confusion. Fever may not be reported in all symptomatic individuals. Progression of disease, multiple organ failure and death will occur in some individuals.

As with other Coronaviruses, SARS-CoV-2 is an RNA virus which encodes four major structural proteins. Most vaccine candidates focus on immunisation with the spike glycoprotein, which is the main target for neutralising antibodies following infection. Neutralising antibodies that block viral entry into host cells by preventing interaction between the spike protein and the host cell are expected to be protective.

Pfizer-BioNTech vaccine

The Pfizer/BioNTech vaccine is a lipid nanoparticle-formulated mRNA vaccine. The mRNA encodes the SARS-CoV-2 full length spike protein. The mRNA in the vaccine is translated and transcribed by the body to produce the spike protein. The protein then acts as an intracellular antigen to stimulate the immune response. The mRNA in the vaccine is normally degraded within a few days and cannot incorporate into the host genome. Data from the Pfizer/BioNTech vaccine trials undertaken in over 40,000 individuals indicate high vaccine efficacy, with no serious safety concerns observed.

AstraZeneca COVID-19 vaccine

The AstraZeneca COVID-19 vaccine uses a replication deficient chimpanzee adenovirus as a vector that encodes the full-length SARS-CoV2 spike protein. Chimpanzee adenoviruses are non-enveloped viruses, meaning that the glycoprotein antigen is not present on the surface of the vector, but is only expressed at high levels once the vector enters the target cells. Genes are deleted from the adenovirus to render the virus replication incompetent, and to enhance immunogenicity. Once the vector is in the nucleus, mRNA encoding the spike protein is produced that then enters the cytoplasm. This leads to translation of the target protein which acts as an intracellular antigen. Data from vaccine trials undertaken indicate high vaccine efficacy, with no serious safety events related to the vaccine.

Other vaccines in development

Other COVID-19 vaccines are in development, with some in late stage trials. When sufficient data on vaccine safety and efficacy are available, these will be considered by JCVI and this statement will be updated.

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