Top Lines and Q&A for stakeholders – Covid-19 vaccine

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Top messages

- An effective vaccine is the best way to protect people from coronavirus and will save thousands of lives.
- Following extensive safety trials and authorisation by the independent regulator, the MHRA, effective COVID-19 vaccines are available in the UK for free.
- 3.2 million of the most vulnerable and those who care for them have already received their first dose.

Key messages

- Almost 1,200 vaccination sites have already been set up across the UK and hundreds more are opening soon to help those who are most at risk from COVID-19 to access vaccines for free, regardless of where they live.
- Just under 40% of over 80s have received their first dose between 8 December and 10 January.
- The NHS has opened the first seven NHS Vaccination Centres to vaccinate people aged 80 and over, along with health and care staff.
- We all have an important part to play to help the NHS:
 - Please do not contact the NHS to seek a vaccine, the NHS will contact you;
 - When you are contacted, please attend your appointments.
- We will continue to follow the JCVI advice and vaccinate those most at risk first, and those who work closest with them care home residents and staff, followed by people over 80 and health and social care workers, then other people in order of age and risk.
- An effective vaccine is one that saves lives and reduces hospitalisations. We don't yet know how long people who are vaccinated will be protected from Covid-19 or if it prevents transmission. Once we have more data about how these vaccines perform and we will know the best way to use them to save the most lives.
- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and will only be authorised once it has met globally recognised standards of effectiveness, safety and quality by the medicine's regulator, the MHRA.

Total vaccination statistics - up to 15 January 2021

UK total first dose: 3,234,946

UK total second dose: 443,234

Vaccine statistics are updated daily and the latest figures can be found here

Latest quotes and statements

Coronavirus vaccines will begin to be delivered at High Street pharmacies from today (14/01/20210)

Health and Social Care Secretary, Matt Hancock, said:

"It is fantastic that high-street pharmacies will now begin deploying COVID-19 vaccinations. Pharmacies sit at the heart of local communities and will make a big difference to our rollout programme by providing even more local, convenient places for those that are eligible to get their jab.

"Pharmacists have worked tirelessly throughout the pandemic, often acting as the first port of call for medical advice – and often staying open when all around have closed. I want to extend my thanks to every pharmacy for their efforts to support the national response to the pandemic and keep people safe."

THE LARGEST VACCINATION PROGRAMME IN BRITISH HISTORY (11/01/2021) Health and Social Care Secretary Matt Hancock said:

"It's taken a tremendous amount of hard work and dedication to make such an incredible start to this ambitious deployment programme. Our vaccine deployment plan sets out exactly how we will harness these efforts to expand the programme quickly and safely. "Our UK Covid-19 vaccines delivery plan maps our route back to normality, but it does not mean we can be complacent and it is mission critical that everybody abides by the restrictions in the coming weeks.

"The next few months will present a significant opportunity to turn the tide of battle against Covid – I am looking forward to watching these plans bring more reassurance and hope back to people's lives after a difficult year."

Business Secretary Kwasi Kwarteng said:

"This historic vaccination programme is a truly national effort and shows the whole of the UK coming together to quickly and effectively protect the British public against this terrible virus. "It's fantastic to see so many people stepping forward to help out, and I encourage businesses, wherever possible, to allow their staff time and scope to volunteer. This is the greatest logistical challenge of our time and we must all play our part."

Minister for Covid-19 Vaccine Deployment Nadhim Zahawi said:

"The UK Vaccines Delivery Plan is a culmination of all our hard work so far, and sets some very promising and challenging ambitions for the next few months.

"I have every faith the NHS will rise to the task and meet these ambitions, providing thousands of vulnerable and at risk individuals that crucial extra protection they need."

New NHS Vaccination Centres Open Their Doors (11/01/2021)

Professor Stephen Powis, the NHS's national medical director, said:

"Increasing supplies means the NHS can open even more vaccination services and protect even more people this week.

"While my NHS colleagues are working hard to ensure we can offer vaccines to all of those who would benefit most over the next month, at the same time as providing care for everyone who needs it, we need the public to help us.

"Please don't contact the NHS to seek a vaccine, we will contact you. When we do contact you, please attend your booked appointments. And whether you have had a vaccine or not, please continue to follow all the guidance to control the virus and save lives – that means staying at home as much as you can, and following the 'hands, face, space' guidance when you can't."

Detailed Q&A

Who will receive the vaccine, where/when and can you choose which one?

Which groups will be vaccinated over the next six weeks?

- The Government set a target to offer vaccines to everyone in the top four priority groups, as outlined by the JCVI, by 15 February:
- 1. Residents in a care home for older adults and their carers
- 2. Those over 80 and frontline health and social care workers
- 3. Those 75 and over
- 4. Those 70 years and over and the clinically extremely vulnerable

How many people in total is that?

• Around 13 million in England.

Does this mean you will have vaccinated all vulnerable people by spring?

• We want to vaccinate as many people as possible as quickly as possible. Deploying a vaccine at this scale is unprecedented, and timing will be subject, in part, to manufacturing timescales and supply.

Should people who have already had Covid get vaccinated?

• Yes, if they are in a priority group identified by JCVI. The MHRA have looked at this and decided that getting vaccinated is just as important for those who have already had Covid-19 as it is for those who haven't.

Can people choose what vaccine they have? It has been suggested that vaccines could be mixed and matched?

• No. Any vaccines that are available will have been approved because they pass the MHRA's tests on safety and efficacy, so people should be assured that whatever vaccine they get will be highly effective and protect them from coronavirus.

If you're given one type of vaccine does that mean you have to stick with that vaccine forever?

- The Pfizer/BioNTech vaccine is rapidly being rolled out across the UK, starting with the highest priority groups.
- The AstraZeneca/Oxford vaccine and other candidates is being deployed alongside the Pfizer/BioNTech vaccine to increase the pace and volume of the UK programme.
- More evidence is needed to understand whether a seasonal vaccination or booster dose might be needed.
- The vaccines people are offered will be appropriate for them. This decision is based on clinical judgement supported by the advice of Joint Committee on vaccination and immunisation. This will take into account individual vaccine characteristics, which may mean they are more suitable for some groups of people, and not others for example, some may be less well tolerated or effective in certain age groups.

When was the first patient vaccinated?

• The first Pfizer/BioNTech vaccinations took place on 8 December 2020 and the first AstrZeneca/Oxford vaccines were given on 4 January 2021.

Which vaccine is better/more effective?

- Both Pfizer/BioNTech and Oxford/AstraZeneca are very effective vaccines. Comparisons between the vaccine efficacies are unhelpful due to the different methodologies used.
- Both vaccines have been approved because they pass the MHRA's tests on safety and efficacy, so people should be assured that whatever vaccine they get will be highly effective and protect them from Coronavirus.

Vaccine Delivery Plan

What is the Vaccines Delivery Plan?

• The UK COVID-19 Vaccines Delivery Plan sets out how the Government will work with the NHS, devolved administrations, local councils and the Armed Forces to deliver the largest vaccination programme in British history.

The plan is split into four main areas:

- **Supply** including the development and manufacturing of vaccines, ensuring their safety and effectiveness;
- **Prioritisation** insight into the first two phases of deployment;
- **Places** ensuring simple, fair and convenient access to vaccinations for the public, regardless of where they live; and

• **People** - mobilising the workforce and providing information on vaccinations to local communities.

What does the Vaccine Delivery Plan set out and what will be in place by the end of January?

- By the end of January, everyone in England will be within 10 miles of a vaccination site or, for a small number of highly rural areas, the vaccine will be brought to them via mobile teams.
- There will also be capacity to deliver at least two million vaccinations in England per week by the end of January and all residents and staff in over 10,000 care homes across the country will be offered a vaccine by the end of the month.
- This will be made possible by the rapid expansion of the programme, including:
 - 206 active hospital sites;
 - o 50 vaccination centres; and
 - around 1,200 local vaccination sites including primary care networks, community pharmacy sites and mobile teams
 - This will mean every at-risk person has easy access to a vaccination centre, regardless of where they live.
 - The expansion of the programme will also mean all adults will be offered a vaccine by the autumn.

How many places can now give vaccinations?

- Around 1,200 sites have already been set up across the UK and hundreds more will be coming online in the coming weeks/months.
- Seven large-scale vaccination centres have opened on 11, January 2021 and will be followed by dozens more.
- •

The 7 centres are as follows:

- Robertson House, Stevenage
- Excel Centre (London Nightingale)
- Centre for Life, Newcastle
- Etihad Tennis centre Manchester
- Epsom Racecourse
- Ashton Gate Stadium
- Millennium Point, Birmingham

How can people use the new vaccination centres?

- The NHS will contact you. Please don't contact the NHS to seek a vaccine. When the NHS contact you, please attend your booked appointments.
- Letters are being sent out to more than 600,000 people aged 80 who live up to a 45 minute drive from one of the new centres, inviting them to book an appointment.
- The letters will explain how people can book a slot over the phone or online through the national booking service.
- The centres are an additional option for people, who can book an appointment at one of the seven centres through the national booking service online or over the phone. If it is not convenient for them, they can instead be vaccinated at one of their local vaccination centres in the coming weeks.
- People should wait until they are invited and should not call their GP but use the booking line. If an appointment has already been offered by the GP, people can choose which appointment suits them best.

What about local care providers?

- Hundreds of local vaccination services run by family doctors and their teams opened across England w/c 14/12/2020.
- Groups of health providers are setting up local vaccination centres in villages, towns and cities covering every part of the country.
- Nurses, paramedics, pharmacists and other NHS staff will work alongside GPs to vaccinate those aged 80 and over, as well as care home workers and residents, identified as priority groups for the life-saving vaccine.

When are pharmacies going to start rolling out Covid-19 vaccines?

• The first pilot sites started vaccinations on 14 January 2021 with up to 70 more taking bookings for next week and hundreds opening by the end of the month.

Where are the pilot sites?

The pilot sites are:

- Boots, Halifax
- Andrews Pharmacy, Macclesfield
- Appleton Village Pharmacy, Widnes
- Superdrug Pharmacy, Guildford
- o Cullimore Chemist, Edgware
- Woodside Pharmacy, Telford

Why were these pilot sites chosen?

• Stores capable of delivering large volumes, while allowing for social distancing, are initially being selected to give the best geographical spread.

How many pharmacies will carry out Covid-19 vaccinations?

• Two hundred community pharmacies are due to come online over the next fortnight as more vaccine supplies come on stream by the end of the month.

Can you choose to have your vaccine at a pharmacy site?

• People invited to make an appointment through the new national booking service will be given a choice between a vaccination centre or a pharmacy service.

Can anyone book an appointment via the Covid-10 Vaccination booking service for a vaccine at a pharmacy site?

It will not be possible to use the NHS COVID-19 Vaccination Booking Service if you
have not received an invitation letter. Doing so risks someone, who has, not being
able to get through and book their appointment.

Vaccine length of protection and impact on transmissibility

When will you know if the vaccines prevent transmission?

- PHE will employ existing surveillance systems and enhanced follow-up of cases to monitor how effective the vaccine is at protecting against a range of outcomes including: infection, symptomatic disease, hospitalisations, mortality and onwards transmission.
- It is likely to be some time until we have sufficient data to provide a clear picture of how vaccination impacts on onward transmission.

How long will the vaccines protect people for?

• PHE will employ existing surveillance systems and enhanced follow-up of cases to monitor how effective the vaccine is at protecting against a range of outcomes including: infection, symptomatic disease, hospitalisations, mortality and onwards transmission.

• It is likely to be some time until we have sufficient data to provide a clear picture of how long the protective effect of vaccination lasts.

Changes to dose interval

Why are you changing the interval between the first and second doses?

- One dose of either vaccine provides a high level of protection from Covid-19.
- The decision to update the dosing interval is based on advice from the JCVI and MHRA and is designed to maximise the impact of the programme and save lives.
- Having studied evidence on both the Pfizer/BioNTech and Oxford/AstraZeneca vaccines the JCVI has advised that we should prioritise giving as many people in atrisk groups their first dose, rather than providing two doses in as short a time as possible.

What vaccines will we have?

- The UK has secured access to seven different possible vaccines, across four different vaccine types, reflecting the government's strategy to ensure the UK has a supply of vaccines should they prove safe and effective in clinical trials. These are at separate stages of development.
- We have secured early access to over 367 million vaccines doses through agreements with several separate vaccine developers at various stages of trials, including:
- o 100 million doses of University of Oxford/AstraZeneca vaccine
- 40 million doses of BioNTech/Pfizer vaccine
- 17 million doses of Moderna vaccine
- o 60 million doses of Novavax vaccine
- o 60 million doses of Valneva vaccine
- o 60 million doses of GSK/Sanofi Pasteur vaccine
- o 30 million doses of Janssen vaccine
- We have invested over £230m into manufacturing any successful vaccine and an enormous amount of planning and preparation has taken place across Government to be able to quickly roll out the vaccine, including ensuring we have adequate provision, transport, PPE and logistical expertise to do so. We are also working at pace to prepare for the delivery of any potential COVID-19 vaccination programme as quickly as possible.

Vaccine ingredients

Do the COVID-19 vaccines contain animal products?

 The MHRA has confirmed that the COVID-19 Vaccine AstraZeneca and Pfizer/BioNTech COVID-19 vaccine do not contain any components of animal origin.

Pfizer/BioNTech

A full list of ingredients for the qualitative and quantitative composition of the Pfizer/BioNTech vaccine can be found <u>here</u>.

AstraZeneca/Oxford

A full list of ingredients for the qualitative and quantitative composition of the vaccine can be found <u>here</u>.

New variant of COVID-19

• A variant of SARS-COV-2 is a version of the virus that has undergone some genetic changes (mutations). Some mutations may change the characteristics of the virus and how it interacts with humans. We have named this VUI – 202012/01 (the first Variant Under Investigation in December 2020). We are concerned that one of the

mutations found in VUI-202012/01, called N501Y, has a potential impact on the characteristics of the SARS-CoV-2 virus.

Is this new variant resistant to the vaccine?

- There is currently no evidence to suggest that the Pfizer/BioNTech or Astra/Oxford vaccine would not protect people against the new variant.
- Further laboratory work is currently being undertaken to understand this.

Lockdown restrictions, tiering, vaccine passports

Now that we have two vaccines, can we end restrictions and lockdowns?

- Effective vaccines will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began. A huge step forward in our fight against coronavirus, potentially saving tens of thousands of lives.
- We will closely monitor the impact of vaccinations on individuals, on NHS pressures and on the spread of the virus.

Why are some patients receiving Covid-19 vaccination record cards?

• When patients are vaccinated, they are likely to receive a vaccine record card that notes the date of their vaccination, the suggested date for their second dose and details of the vaccine type and batch.

Is this card a vaccine ID card showing proof of vaccination?

- This is a vaccine record card, similar to those given to patients for other NHS vaccinations as a note of when they received their vaccine.
- It is not intended to be used for any other purpose, or as an immunity certificate.
- All vaccinations are recorded on the patient's record with their GP.

Where else will the vaccination be recorded?

• All vaccinations are recorded on the patients record with their GP.

Will you make the vaccine compulsory?

• There are no plans to make the Covid-19 vaccine compulsory. The UK operates a system of informed consent for vaccinations.

How will care home staff be identified as eligible for vaccination at hospital hubs or centres outside of the care homes where they work?

- To ensure that care home staff are able to access flu and COVID-19 vaccines as a priority in any setting, we are asking employers to collect and securely provide their NHS numbers. This allows the NHS to tag them as care home workers on the national system we are using to invite and keep track of who has been vaccinated.
- A letter to care homes providers setting out setting out the requirement and legal basis for the collection off staff details to support the national flu and COVID-19 vaccination programme is in development with representative bodies and will be issued separately as soon as possible.

Administering and availability of vaccines

How will I know it's my turn to get a vaccine?

• The NHS will let you know when it's your turn to have the vaccine. It's important not to contact the NHS for a vaccination before then. Once you have received your letter you can book your vaccination appointment online, or for those who cannot access online booking service, they can book by calling 119.

- You will need your ten-digit NHS number, it will be on the letter sent to you. You can also find it on your prescriptions or through your GP online service.
- If a patient cannot go to one of the large vaccination centres, they can choose to have their vaccination at their GP surgery when it's available there or a pharmacy.

Who is going to be administering the vaccines?

- Nurses, paramedics, pharmacists, GPs and other NHS staff are working hard to get the vaccine to those most vulnerable.
- Recruitment of workforce has focused on those who already have experience in handling vaccinations but may currently work outside of NHS settings, for example, independent nurses or allied health care professionals.
- Existing schemes such as NHS Bring Back scheme have also been utilised in order to fill roles.
- A comprehensive training package has been put together by NHS England and NHS Improvement (NHSE-I), with professional groups and Public Health England (PHE). New vaccinators will have undergone both a comprehensive training programme and competency assessment to ensure they can safely administer vaccines to patients under the clinical supervision of an experienced health care professional. This training will include how to deal with possible adverse reactions to a vaccine.

Who will administer vaccines for care home residents and staff?

- This group are a high priority and so as soon as it is possible for them to do so, GPs and local primary care networks will begin vaccinating care home residents.
- In the first instance we will be working to vaccinate as many care home staff as safely as possible in hospital hubs in the immediate days and weeks, including bringing in staff.
- Taking the vaccine into the community and into care homes will come over the following weeks.

How is consent for receiving the vaccine managed in a care home setting?

- The NHS is supplying the care home providers with consent forms to use for different circumstances of the individual. There is an additional consent form for care home staff.
- The COVID-19 vaccination consent form letter templates are available in different software versions and can be downloaded from the Health Publications website and adapted to suit the needs of local healthcare teams. These resident forms are available for those who are able to consent for themselves, for those with a relative who has power of attorney for them and a relative's agreement form.

Are you using volunteers yet?

- The vaccine centres will be the first to deploy trained volunteers from both St John Ambulance and the NHS Volunteer Responder scheme.
- This will be alongside NHS staff more than 80,000 of whom have so far completed the clinical training needed to administer vaccines.

What role will the military have in distributing the vaccine?

- The MOD works hard to identify where it can most effectively assist other government departments. The Armed Forces have personnel, including specialist planners, logisticians, and medics ready to support responses to the outbreak however required.
- As part of prudent planning, a reserve force of 250 Army medically qualified military personnel has been placed on standby to support this work if needed.

How much vaccine do you have in the country?

- Our vaccine supply and scheduled deliveries will fully support vaccination of JCVI priority cohorts 1-4 by 15 February.
- We have signed deals for substantial future supply of both vaccines to replenish our stocks and enable swift vaccination of first and second doses across the UK in the weeks and months ahead.

Safety, speed of development and regulation of vaccines

How can we be sure that safety won't be compromised due to the speed of development of a Covid-19 vaccine?

- There are extensive checks and balances required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development process are bypassed.
- All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard.
- Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel.
- The data from each phase then goes to the regulator in a "rolling" review rather than once the trials have completed, which means the regulator can start looking at the results earlier than normal.
- Companies also made decisions to begin large scale production of vaccines whilst still in trials.

How are vaccines regulated and authorised for use?

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's independent regulator. Their role is to ensure medicines, devices and vaccines work effectively and are safe for use.
- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and will only be authorised once it has met robust standards of effectiveness, safety and quality.
- Teams of scientists and clinicians carefully, methodically, scientifically rigorously review all data on safety, effectiveness and quality as soon as they become available, and have done so throughout all tests and trials
- The data looked at includes all the results from laboratory studies, clinical trials, manufacturing and quality controls and testing the product. The public on that basis should be very confident that all tests are done to the very highest standards, and only then will a COVID-19 vaccine be made available

Is the vaccine safe for people with pre-existing conditions?

- The trials for both vaccines have involved people with chronic underlying conditions deliberately, and they have involved people from very broad age ranges and quite a lot of people in the elderly bracket. The JCVI have looked at this, there's no indication that there should be any difficulty in giving it to people with chronic underlying conditions.
- The JCVI has picked out, not just by age, but people 18 to 65 with at-risk conditions. And, and the reason for that is that they are at extremely high risk from coronavirus compared with the general population.

Can pregnant women have the Pfizer/BioNTech or Oxford/AstraZeneca vaccines?

• The latest advice form the JCVI sets out that vaccination with either vaccine in pregnancy should be considered where the risk of exposure SARS-CoV2 infection is high and cannot be avoided, or where the woman has underlying conditions that

place her at very high risk of serious complications of Covid-19, and the risks and benefits of vaccination should be discussed.

- The Pfizer/BioNTech vaccine should only be considered for use in pregnancy when the potential benefits outweigh any potential risks for the mother and baby. Women should discuss the benefits and risks of having the vaccine with their healthcare professional and reach a joint decision based on individual circumstances. Women who are breastfeeding can also be given the vaccine.
- Those who are trying to become pregnant do not need to avoid pregnancy after vaccination, and breastfeeding women may be offered vaccination with either vaccine following consideration of the woman's clinical need for immunisation against COVID-19. The UK Chief Medical Officers agree with this advice

Vaccine prioritisation

The full prioritisation list can be found <u>here</u> and is as follows (in order of priority):

- 1. Residents in a care home for older adults and their carers
- 2. All those 80 years of age and over and frontline health and social care workers
- 3. All those 75 years of age and over
- 4. All those 70 years of age and over and clinically extremely vulnerable individuals
- 5. All those 65 years of age and over. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and
- 6. 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

How many people need to receive the Covid-19 vaccine in JCVI's first phase?

• There are approximately 13 million people in England in the top four priority groups.

Why do the JCVI's recommendations focus on reducing people's individual risk and not stopping transmission?

- The most important thing is that we protect those who are most at risk of dying. At the start of any vaccination programme, we won't know the impact of the vaccine on transmission and so we will vaccinate those who are at highest risk of serious illness and death. This includes older people and care home residents.
- As vaccination programmes roll out globally, our understanding of the safety and effectiveness of each vaccine will increase, and these data will be used to develop advice on the next phase of the programme.

Why aren't BAME groups being prioritised?

- 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.
- There is clear evidence that certain Black, Asian and minority ethnic (BAME) groups have higher rates of infection, and higher rates of serious disease and mortality. The reasons are multiple and complex.
- Prioritisation of people with underlying health conditions will also provide for greater vaccination of BAME communities who are disproportionately affected by such health conditions.
- Tailored local implementation to promote good vaccine coverage in Black, Asian and minority ethnic groups will be the most important factor within a vaccine programme in reducing health inequalities in these groups.

• The NHS will provide advice and information at every possible opportunity, including working closely with BAME communities, to support those receiving a vaccine and to anyone who has questions about the vaccination process.

Additional points:

 9.6% of participants in the Phase 2 and 3 Pfizer BioNtech clinical trials were Black and 4.6% were Asian. The phase 2/3 study was considered sufficiently representative of the UK population as a pre-authorisation study. Further effectiveness studies in representative populations are planned post-approval. In addition, MHRA have now published the Public Assessment Report on their website which has more information on demographics:

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccinefor-covid-19

Why aren't you vaccinating economically active people? Surely that would be a good approach to get the economy back up and running again?

- The full impact of vaccination on infection and transmission of the virus will not become clear until a large number of people have been vaccinated.
- The Joint Committee on Vaccination and Immunisation (JCVI) are the independent experts who advise Government on which vaccine/s the United Kingdom should use and provide advice on prioritisation at a population level.
- The Committee have advised that the first priorities for any COVID-19 vaccination programme should be the prevention COVID-19 mortality and 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.
- Given the current epidemiological situation in the UK, all evidence indicates that 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.

What about people who are immunocompromised who can't benefit from a vaccine?

- The Government is exploring all avenues available to us, to ensure that a treatment for COVID-19 is found.
- Treatments containing COVID-19 neutralising antibodies have been secured from AstraZenaca to support immunocompromised people who will not be able to benefit from a COVID-19 vaccine.
- The antibody treatment currently being developed by AstraZeneca is a combination of two monoclonal antibodies and has the potential to be given as a preventative option for people exposed to the virus, and to treat and prevent disease progression in patients already infected by the virus if successful.

Why are we not prioritising homeless people?

- People who are homeless are eligible for the vaccine in the same way that any other member of the public would be.
- The Government is following the independent advice of the Joint Committee on Vaccination and Immunisation (JCVI), which agrees priority groupings for vaccine. Anyone who is homeless and falls into these groups is eligible for the vaccine and we are working closely with partners to ensure they can access it.
- This continues to be a challenging period for people right across the country, particularly vulnerable people who are homeless and we have invested over £700 million on concerted efforts to tackle homelessness and rough sleeping through a range of initiatives.

Why is vaccination not recommended for children?

 Almost all children with COVID-19 have no symptoms or mild disease and the vaccines not yet been tested in younger children. The Committee advises that only children at very high risk of catching the virus and serious illness, such as older children with severe neuro-disabilities in residential care, should be offered vaccination.

Does the availability of the Oxford/AstraZeneca mean you can start vaccinating secondary school children?

- We are following the advice from independent experts on the JCVI on which groups of people to prioritise for Covid-19 vaccines.
- They advised the immediate priority should be to prevent deaths and protect health and care staff, with old age deemed the single biggest factor determining mortality.
- We understand this is a challenging period for many, and the NHS is working hard to vaccinate those most at risk as soon as possible.

Why are care home workers prioritised over NHS staff?

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

As with the flu vaccines, will people be able to jump the vaccine queue and buy this vaccine privately?

- The UK government has secured early access to 367 million vaccine doses through agreements with seven separate vaccine developers, giving the UK the best chance of securing a safe and effective vaccine at the quickest speed.
- The vaccines are available from the NHS for free to everyone who would benefit, starting with those most at risk.

Monitoring and adverse incidents

There have been reports of adverse reactions to the Pfizer/BioNTech vaccine – what has happened?

- Since the immunisation campaign commenced on Tuesday 8 December, the MHRA has been notified of two reports of anaphylaxis, and a further possible allergic reaction, shortly after receiving the Pfizer/BioNTech COVID-19 vaccine. The individuals received prompt treatment and recovered.
- Incidents such as these are common with new vaccines and the MHRA has tried and tested processes to deal with them. The public can be reassured that we continue to adhere to the highest standards of safety as we provide this life-saving vaccine to those who need it most.

Updated guidance from MHRA on managing allergic reactions (issued 30 December 2020).

- We are no longer advising as a precaution that individuals with a history of anaphylaxis to any vaccine, medicine or food do not get the vaccine. However, our advice remains that individuals should not get the vaccine if they have had a severe allergic reaction to any of the vaccine ingredients or if they experience anaphylaxis after the first dose.
- Standard clinical procedure advises that vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment
- This updated advice follows enhanced surveillance since the initial precautionary advice was issued, which has found no evidence of an increased risk of anaphylaxis

in those with prior severe allergic reactions, other than to the vaccine and its ingredients.

How do you monitor for problems, such as injuries or allergic reactions?

- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and will only be approved by the independent regulator, the MHRA, once it has met robust standards of effectiveness, safety and quality. Right through the tests and the trials, teams of scientists and clinicians carefully, methodically, scientifically rigorously review all data on safety, effectiveness and quality as soon as they become available.
- The independent expert working group have supported MHRA proposals for a proactive safety monitoring strategy. This comprises the Yellow Card scheme and a special active monitoring programme which we are inviting people to join.
- Approved COVID-19 vaccines will be monitored continuously after roll out by the MHRA and PHE to ensure that the benefit of the vaccines continues to outweigh any risk.
- You can report suspected side effects to COVID-19 vaccines through the Coronavirus Yellow Card reporting portal <u>https://coronavirus-yellowcard.mhra.gov.uk/</u>
- The MHRA will work in collaboration with partners in the health system to rapidly assess all available safety data in real time and communicate any emerging issues, as necessary.

Are there any side effects?

- Every single vaccine authorised for use in the UK has been authorised by the MHRA. The three components of authorisation are a safety assessment, an effectiveness assessment and a manufacturing quality assessment.
- Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them.
- These are important details which the MHRA always consider when assessing candidate vaccines for use.
- For the Pfizer/BioNTech vaccine, like lots of others, they have identified that some people might feel slightly unwell, but they report that no significant side effects have been observed in the over 43,000 people involved in trials.
- All patients will be provided with information on the vaccine they have received, how to look out for any side effects, and what to do if they do occur, including reporting them to the MHRA.

Some side effects may include:

- \circ a sore arm where the needle went in
- o feeling tired
- o a headache
- o feeling achy
- feeling or being sick
- All patients are given information on the vaccine they have received, how to look out for any side effects, and what to do if they do occur, including reporting them to the Medicines and Healthcare products Regulatory Agency (MHRA).

Healthcare professionals are asked to report any suspected side effects to COVID-19 vaccines. Report using the <u>dedicated Coronavirus Yellow Card reporting site</u> or the Yellow Card app.

More info here on patient information leaflets from PHE

https://www.gov.uk/government/publications/covid-19-vaccination-guide-for-older-adults More information on the vaccination from NHS

https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/?priority-taxon=774cee22-d896-44c1-a611-e3109cce8eae

How can people be confident there won't be long term side effects?

• Every single vaccine authorised for use in the UK has been authorised by the MHRA and the three components of authorisation are a safety assessment, an effectiveness assessment and a manufacturing quality assessment.

If there are any significant medical incidents, could rollout be halted?

- Each COVID-19 vaccine candidate is assessed on a case-by-case basis and will only be approved once it has met robust standards of effectiveness, safety and quality. Right through the tests and the trials, teams of scientists and clinicians carefully, methodically, scientifically rigorously review all data on safety, effectiveness and quality as soon as they become available.
- Once a vaccine has been rolled out, PHE will continue to closely monitor safety data. In the rare instance of a medical incident, DHSC will review the available data.
- The government is clear that all vaccines being rolled out must continue to meet high standards of safety and efficacy.

Importance of vaccine trials

- Clinical trials into the vaccines against Covid-19 continue at pace, and it is essential that these do so. We will need data about a number of vaccines and their safety and effectiveness, in order to protect the population.
- No one vaccine is likely to be suitable for everyone, the first vaccine may not be the most effective and easiest to use, and we must make sure that the other studies continue to allow us to have a selection of vaccines to protect the whole population. We are likely to need several vaccines to provide enough doses for everyone at risk, as early as possible.

How many people have taken part in clinical trials and what about ages, ethnic backgrounds and medical conditions?

- All of the vaccines will be tested on between 15,000 to 50,000 people across the world. They are tested on both men and women, on people from different ethnic backgrounds, and of all ages between 18-84.
- The studies have also looked as to whether the vaccines work on people with certain medical conditions and in older people, as their immune responses can work less effectively and therefore give them less protection through vaccines. As a result of this testing on a representative sample of the population, we can be confident that an approved vaccine will be effective for the wider population in the UK.

Will people on vaccine trials be able to have a Covid-19 vaccine when available?

 Yes, we will have a process in place so people on vaccine studies are not disadvantaged. People taking part in the vaccine research will still be able to have an approved vaccine when this is available. Taking part in a study is the best way to help effective vaccines to be identified and made available to everyone earlier and may even give you early access to a vaccine later found to be effective.

Communications and Campaigns

What patient information is available to accommodate the different needs of patients in accessible formats?

- To help NHS organisations and communications teams with rolling out a COVID-19 vaccine campaign, there is a range of free print, digital and social campaign materials available on <u>PHE's Campaign Resource Centre</u>.
- Various versions of the leaflets and posters have been developed, with different callto-actions to be used depending on vaccine availability. Large print, braille and Easy

read versions and translated versions are also available for download. There will be BSL videos for the 'adults', 'what to expect' and 'pregnancy' leaflets shortly.

• You can also place orders for these resources via the <u>health publications website</u>.

What is the government doing about the spread of disinformation?

- False information about COVID-19 vaccines could cost lives.
- The government is working with health experts to provide information and advice at every possible opportunity.
- The Government's Counter Disinformation Unit, led by DCMS works to tackle disinformation and misinformation relating to COVID-19.
- The Unit works closely with social media platforms to help them identify and take action to remove incorrect claims about coronavirus, and to promote authoritative advice and information.
- The Government published the Full Government Response to the Online Harms White Paper consultation in December 2020, which sets out new expectations on companies to keep their users safe online.
- The new laws will have robust and proportionate measures to deal with disinformation that could cause significant physical or psychological harm to an individual, such as false information about Covid-19 and COVID-19 vaccines.
- We have developed the <u>SHARE checklist</u> which aims to increase audience resilience by educating and empowering those who see, inadvertently share and are affected by false and misleading information. The checklist provides the public with five easy steps to identify false content, encouraging users to stop and think before they share content online.
- We have also partnered with the University of Cambridge to create a game called "Go Viral!". Our aim is to build the public's resilience to false information, mitigating the risk of undermining the uptake of Covid-19 vaccines, treatments and diagnostics.