

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

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Quotes and statements

MHRA authorises Moderna vaccine (08/01/2021)

Health Secretary Matt Hancock said:

“This is further great news and another weapon in our arsenal to tame this awful disease.

“We have already vaccinated nearly 1.5 million people across the UK and Moderna’s vaccine will allow us to accelerate our vaccination programme even further once doses become available from the spring.

“While we immunise those most at risk from Covid, I urge everyone to continue following the rules to keep cases low to protect our loved ones.”

Latest Covid-19 vaccine statement - Health Secretary Matt Hancock said (07/01/2020):

“Every part of the government and the NHS are working around the clock to rapidly scale up our Covid-19 vaccination programme so we can protect those most at risk from this awful disease as quickly as possible.

“The Oxford/AstraZeneca vaccine can be transported easily and I’m delighted care home residents will begin receiving their first Oxford/AstraZeneca jabs this week. More than 1.3 million people have already been vaccinated in the UK, including 23 percent - or over 650,000 - of the over-80s in England.

“We are aiming to offer vaccinations to the majority of care home residents by the end of January and all 13 million people in the top four priority cohorts by mid-February. This will ensure the most vulnerable are protected and will save tens of thousands of lives.

“As our vaccination programme ramps up, I urge everybody to continue following the latest restrictions to keep cases low and protect loved ones.”

First people to receive the Oxford University/AstraZeneca Covid-19 vaccine (04/01/2021):

Health Secretary Matt Hancock said (04/01/2021):

“I am delighted that today we are rolling out the Oxford vaccine – a testament to British science. This is a pivotal moment in our fight against this awful virus and I hope it provides renewed hope to everybody that the end of this pandemic is in sight.

“Through its vaccine delivery plan the NHS is doing everything it can to vaccinate those most at risk as quickly as possible and we will rapidly accelerate our vaccination programme.

“While the most vulnerable are immunised, I urge everybody to continue following the restrictions so we can keep cases down and protect our loved ones”.

Top messages

- Vaccines are the way out of this pandemic. 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.

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- The NHS has a clear vaccine delivery plan and will contact you when it's your turn to get the vaccine as quickly and easily as possible.
- 1.5m of the most vulnerable and those who care for them have already been vaccinated. A quarter of all over 80s have been vaccinated and will be protected from coronavirus when their immunity develops in 14 days.
- This will be a marathon, not a sprint, and we cannot let down our guard. People must follow the rules to stop the spread of coronavirus.

Key messages

- More than 730 vaccination sites have already been established across the UK and hundreds more are opening this week to take the total to over 1,000, helping those who are most at risk from COVID-19 to access vaccines for free, regardless of where they live.
- 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.
- The UK has ordered 40 million doses of the Pfizer/BioNTech vaccine and 100 million doses of the Oxford/Astra Zeneca vaccine, both of which are now being given to people across the UK.
- 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.
- The Oxford/ AstraZeneca vaccine has been authorised for use but each batch also needs to be checked and approved. As soon as this happens the NHS can deliver.
- We will have 530,000 doses available in the UK from Monday (4 January) and more on the way.
- There will be tens of millions more doses delivered during Q1 and the UK has secured a total of 100 million doses of the AstraZeneca vaccine.

General vaccines messages

- Vaccines are the most effective way to prevent infectious diseases.
- Vaccines save lives. After clean water, vaccination is the most effective public health intervention in the world.
- Vaccination is the most important thing we can do to protect ourselves and our children against ill health. Vaccines prevent up to 3 million deaths worldwide every year.
- Vaccines are the only way to eradicate disease. We have eradicated smallpox and are near to eradicating polio, both through using vaccines.
- Measles vaccination alone has prevented 20 million measles cases and 4,500 deaths in the UK.
- Vaccines teach your immune system how to create antibodies that protect you from diseases. It's much safer for your immune system to learn this through vaccination than by catching the diseases and treating them. Once a vaccine has trained your immune system to know how to fight a disease, it can often protect you for many years.

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- Neither HIV nor malaria have vaccines, which shows just how challenging the process of developing a vaccine can be.
- To create a vaccine for a disease, the germ which causes it is weakened, or completely inactivated so that it cannot cause the disease in question.
- When this weakened or 'dead' germ is introduced to the immune system, it trains the immune system to recognise the disease and fight it off if you come into contact with it in the future.
- Vaccines are now safer than ever before. Any vaccine must first go through the usual rigorous testing and development process and be shown to strict standards of safety, quality and effectiveness before it can be deployed.

Q&A

Top vaccine questions

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.
- It's not as simple as saying one vaccine is better than the other. An effective vaccine will save lives and reduce hospitalisations.
- Comparing vaccines on a simple percentage of effectiveness is a mistake. A vaccine with slightly lower headline efficacy than another may prove to be the one that offers more durable protection or a greater effect on transmission
- 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.

When will the vaccines be delivered?

AstraZeneca/Oxford

- The UK was the first country in the world to procure and authorise the Oxford vaccine, and we were the first country in the world to start a vaccination programme with it this week.
- The Oxford vaccine is a British success story – it has had UK government backing throughout.
- We already have 530,000 quality checked doses available to the UK from Monday, with more available this month and tens of millions by the end of Q1 2021.
- The first Oxford/AstraZeneca vaccinations will be delivered at hospitals for the first few days, as is standard practice, before the bulk of supplies are sent to hundreds of GP-led services and care homes later in the week.
- The MHRA set out conditions with their authorisation on 30 December and batch testing is taking place to ensure the vaccines consistently meet these strict requirements. This could not be done before the conditions were outlined by the MHRA.
- If each batch meets the quality standards then they are released and delivered to the NHS & Devolved Administrations.

Pfizer

- The UK was the first country in the world to start a vaccination programme using the Pfizer/BioNTech vaccine and because of our swift and decisive action there has been a regular and steady supply of vaccine doses arriving into the UK since early December.

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- We have sufficient doses to maintain our vaccination programme as it continues to accelerate and are working closely with Pfizer to ensure vaccines keep arriving into the UK.
- More than a million people in the UK have already been vaccinated with the Pfizer/BioNTech vaccine and its roll out will continue at pace.
- As of 25 December, we had received 22 deliveries of the Pfizer/BioNTech vaccine to the UK. We have plans in place with the company to ensure sufficient supply throughout 2021.
- We have been monitoring the requirements across the supply chain from supplier through to patient for some time. There are clear supply chain plans in place for both the supply and onward deployment of all vaccine candidates. This includes materials, manufacturing, transport, storage and distribution.
- The Vaccines Taskforce has conducted supply chain risk assessment and is working with the vaccine suppliers to understand the optimal logistics and timings.

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.

Can you break that number down by group?

- The NHS will set out more details on the rollout in the coming days.

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.

How many vaccines needed each week to achieve that?

- The NHS is doing everything it can to vaccinate as many at-risk people as quickly as doses can be manufactured and quality checked.
- More than 1.5 million people in the UK have received a first dose, including 23 per cent — or over 650,000 — of the over-80s in England.

How many places can now give vaccinations?

- More than 730 sites have already been set up across the UK and hundreds more are opening this week, taking the total to over 1,000.
- Next week, we will also have 7 vaccination centres opening in places like sports stadiums and exhibition centres.

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

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.

Dose intervals

Should both vaccines be given in two doses?

- The MHRA authorisation includes conditions that the Oxford/AstraZeneca vaccine should be administered in two doses, with the second dose given between 4 and 12 weeks after the first.
- The MHRA has also clarified that for the Pfizer/BioNTech vaccine, the interval between doses must be at least 3 weeks (21 days). This also aligns with the EMA position on the Pfizer vaccine.
- For both vaccines, data provided to MHRA demonstrate that whilst efficacy is optimised when a second dose is administered both offer considerable protection after a single dose, at least in the short term. For both vaccines the second dose completes the course and is likely to be important for longer term protection.

What has changed to make 12 weeks safe for the dose interval when it wasn't last week?

- Throughout this global pandemic we have always been guided by the latest scientific advice. 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 at-risk groups their first dose, rather than providing two doses in as short a time as possible.
- The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services
- This is because the evidence shows that one dose of either vaccine provides a high level of protection from Covid-19.
- For both vaccines, data provided to MHRA demonstrate that whilst efficacy is optimised when a second dose is administered both offer considerable protection after a single dose, at least in the short term. For both vaccines the second dose completes the course and is likely to be important for longer term protection
- The NHS across the UK will prioritise giving the first dose of the vaccine to those in the most high-risk groups. Everyone will still receive their second dose and this will

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be within 12 weeks of their first. The second dose completes the course and is important for longer term protection.

- The JCVI's independent advice is that this approach will maximise the benefits of both vaccines allowing the NHS to help the greatest number of people in the shortest possible time. It will ensure that more at-risk people are able to get meaningful protection from a vaccine in the coming weeks and months, reducing deaths and starting to ease pressure on our NHS.

Why are you prioritising the first dose?

- The JCVI has recommended that as many people on the JCVI priority list as possible should be offered a first vaccine dose as the initial priority.
- The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services.
- Operationally this will mean that second doses of both vaccines will be administered towards the end of the recommended vaccine dosing schedule of 12 weeks. This will maximise the number of people getting vaccine and therefore receiving protection in the next 12 weeks.
- NHS delivery plans should prioritise delivering first vaccine doses to as many people on the JCVI Phase 1 priority list in the shortest possible timeframe. This will allow the administration of second doses to be completed over the longer timeframes in line with conditions set out by the independent regulator, the MHRA, and advice from the JCVI. This will maximise the impact of the vaccine programme in its primary aims of reducing mortality and hospitalisations and protecting the NHS and equivalent health services.

What about people who have already had their 2nd dose after 3 weeks? Is this safe? Will they be protected?

- Yes. The updating of the dosing interval is not a safety issue but is designed to maximise the impact of the vaccination programme, as advised by the JCVI.

Surely most vulnerable need more protection – why don't you give them the two closer together and then prioritise first dose for less vulnerable?

- The JCVI has recommended that as many people on the JCVI priority list as possible should be offered a first vaccine dose as the initial priority.
- The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services.
- For both vaccines, data provided to MHRA demonstrate that whilst efficacy is optimised when a second dose is administered both offer considerable protection after a single dose, at least in the short term. For both vaccines the second dose completes the course and is likely to be important for longer term protection.

Why has this decision only just been taken – we could have vaccinated more people quicker.

- We are following the science and are acting on updated advice from the JCVI, MHRA and UK CMOs.

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- The JCVI's independent advice is that this approach will maximise the benefits of both vaccines. It will ensure that more at-risk people are able to get protection from a vaccine in the coming weeks and months, reducing deaths and starting to ease pressure on our NHS.

If you had taken this decision sooner could we have avoided T4

- Public safety has been and continues to be the Government's top priority. We are following the science and are acting on updated advice *[from the JCVI, MHRA and UK CMOs]*.

Length of protection, impact on transmissibility?

Does one dose of the vaccine offer protection?

- The JCVI has recommended that as many people on the JCVI priority list as possible should be offered a first vaccine dose as the initial priority. This is because one dose of the vaccine offers important protection and we want to reach as many at risk people as possible in order to offer protection until the second dose can be administered.
- They have advised that the second dose of the Pfizer-BioNTech vaccine may be given between 3 to 12 weeks following the first dose, and that the second dose of the AstraZeneca (Oxford) vaccine may be given between 4 to 12 weeks following the first dose. The clinical risk priority order for deployment of the vaccines remains unchanged and applies to both vaccines. Both are very effective vaccines.

What protection is given by each vaccine after the first dose?

- The Pfizer/BioNTech and Oxford/AstraZeneca trials did not define a case of Covid using a common definition so vaccine efficacy numbers are not directly comparable between the two trials. Furthermore, VE measures how the vaccine prevents disease (whether mild or severe).
- What we want are vaccines that prevent hospitalisations and deaths and reduce transmission; both vaccines are highly likely to do this but we have to wait to get those data in full.
- JCVI has looked at all the data it can and is strongly convinced that both are good vaccines and both offer substantial protection after 1 dose, but that a second is needed to complete the course for longer term protection.

Can you choose which vaccine to have?

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.

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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.

In rare cases can the Pfizer/BioNTech and AstraZeneca/Oxford vaccine be mixed and matched?

- We do not recommend mixing the COVID-19 vaccines – if your first dose is the Pfizer vaccine you should not be given the AstraZeneca vaccine for your second dose and vice versa.
- However, there may be extremely rare occasions where the same vaccine is not available, or where it is not known what vaccine the patient received.
- Our guidance is very clear that every effort should be made in these instances to give the same vaccine to the patient, but where this is not possible it is better to give a second dose of another vaccine than not at all.
- This is a reasonable measure on a very exceptional basis, when the alternative is to leave someone with an incomplete course – which is the greater concern, especially if the individual is likely to be at immediate high risk or is considered unlikely to attend again.
- In these rare circumstances, as both vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose.
- While there is no evidence on the interchangeability of the COVID-19 vaccines at this time, this is a pragmatic and scientific approach agreed by many scientists and vaccine experts, including the UK's Deputy Chief Medical Officer.

Ingredients, Controversial Substances, Moral and Ethical Advisory Group (MEAG)

COVID-19 vaccine ingredients

- The MHRA has confirmed that the COVID-19 Vaccine AstraZeneca and Pfizer/BioNTech COVID-19 vaccine do not contain any components of animal origin.
- A full list of ingredients for the qualitative and quantitative composition of the vaccine can be found at point 2 in the [Information for Healthcare Professionals of COVID-19 Vaccine AstraZeneca](#).
- A full list of ingredients for the excipient composition of the vaccine can be found at point 6.1 in the [Information for Healthcare Professionals of COVID-19 Vaccine AstraZeneca](#).
- A full list of ingredients for the qualitative and quantitative composition of the vaccine and a full list of the excipient composition of the vaccine can be found at point 6 in the [Information for Recipients of COVID-19 Vaccine AstraZeneca](#).

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.

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Is this strain 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 strain.
- Further laboratory work is currently being undertaken as a priority 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.

Does this make it more likely that we will get back to normal by spring (restrictions loosened)?

- As large numbers of people from at risk groups are given an effective vaccine, we will be able to gather the evidence to prove the impact on infection rates, hospitalisation and reduced deaths; if successful this should in time lead to a substantial reassessment of current restrictions
- The full impact on infection rates will not become clear until a large number of people have been vaccinated, but as larger numbers do get vaccinated, we will hopefully move further along the path back to a more normal way of life.

Are you introducing vaccine passports?

- We have no plans to introduce immunity passports following this vaccination programme.

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 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.

Operational delivery (NHS)

Now two vaccines have been approved, will the NHS have capacity to deliver both vaccines or will one have to be prioritised?

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- We have been planning extensively for this and a range of different scenarios, so if we get stocks of more than one at the same time this will potentially allow us to go further and faster. But we are not there yet.

What type of sites will give it out? Are they all large sites and what if I can't get there?

- No, the NHS has been working together with local partners to ensure that people are not disadvantaged because of where they live, whether they own a car or if they are able to get about. This is why the NHS has developed three different models of delivery.

How will patients be invited for a vaccination?

- When it is the right time people will receive an invitation to come forward. For most people this will be in the form of a letter either from their GP or the national booking system; this will include all the information they need, including their NHS number.
- We know lots of people will be eager to get protected but we are asking people not to contact the NHS to get an appointment until they get their letter.

How will GPs be told who to vaccinate?

- The JCVI will set criteria on an ongoing basis for who should get the vaccine when. GPs will be able to call in or go out to patients based on this, using their patient records. A national invite and recall system, drawn from GP patient records, may also be used.

When will Covid-19 vaccines be administered at local GPs and practices?

- Hundreds of local vaccination services run by family doctors and their teams opened across England on 14 December.
- 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.
- The NHS will contact people in the priority groups when it is their turn to receive the vaccine.

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 the requirement and legal basis for the collection of 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.

How many vaccines are you expecting to do on day one? Is there an hourly/weekly/monthly target?

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- The most important thing here is that the NHS aims to vaccinate as many people as safely and quickly as possible.

Now two vaccines are proved safe and effective, will the NHS have capacity to deliver both vaccines or will one have to be prioritised?

- We have been planning extensively for this and a range of different scenarios, so if we get stocks of more than one at the same time this will potentially allow us to go further and faster. But we are not there yet.

Deployment and Timing

When was the first patient vaccinated?

- The first vaccinations took place on Tuesday 8 December with the Pfizer/BioNTech vaccine.

Where/how are vaccines going to be administered?

- Vaccination for at-risk groups will take place at the most appropriate settings to encourage uptake. This includes administering vaccination to at risk individuals in their usual place of residence. The three models of delivery are:
 - Hospital Hubs – NHS providers vaccinating staff onsite. From December, more than 70 hospitals began delivering the Pfizer/BioNTech vaccine across the UK.
 - Local Vaccination Services – Community and primary care-led service based on local and logistical considerations but is likely to include GP practices, local authority sourced buildings or other local facilities, and potentially roving teams if vaccines are transportable in this way.
 - Vaccination Centres – Large scale centres such as sports and conference venues set up for high volumes of people.

Who is going to be administering these vaccines?

- 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.

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.

Is one easier to deliver?

- All vaccines will present different logistical requirements, but the NHS has been planning for all eventualities, and people should be assured that the vaccine they will

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be offered is available because it has been assessed and approved by experts as being safe and effective.

Will vaccinations be available across the UK?

- Vaccination will be managed by the health services in each nation: NHS England and NHS Improvement, NHS Wales, NHS Scotland, and Health and Social Care Northern Ireland. The UK government is working closely with the Devolved Administrations to ensure an aligned approach to COVID-19 vaccine deployment across the UK.
- The vaccine will be available for free across the UK. We have procured vaccines on behalf of all parts of the country. And the Government is working with the devolved administrations to ensure it is deployed fairly across the UK.

What role will the military have in distributing the vaccine?

- 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.
- The whole of government is working closely with the NHS to put plans in place to distribute the vaccine, including military planning teams to help coordinate regional and national deployment activity.
- The NHS is well prepared to deliver the vaccine and keep pace with supplies as they increase over the coming weeks.
- 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.
- 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.

Will you use the Oxford vaccine more because it's cheaper and easier to store?

- The vaccines that the NHS uses and in what circumstances will be decided by the MHRA.
- The results that we have seen for all the vaccines so far have been very encouraging and if borne out by the final assessment each of them would be classed as being very effective.

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.

Speed and safety

Can the government 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.

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- All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease.
- 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 have made decisions to begin large scale production of vaccines which are still in trials. This means that if the vaccines are not shown to be safe and effective and are not approved for use the companies will have to destroy what they have manufactured. If, however the vaccines are successful, that means the vaccines are ready to be distributed.

How have the Covid-19 vaccines been developed so fast?

- Vaccine technology and the technological approaches to making vaccines are getting better and better and we couldn't have done it in this timeframe if we went back to the 2009 pandemic and we had a new virus about which we knew very little. We're in a different place today because of the technology.
- It was very clear that it was a global public health emergency from the word go and governments were prepared to put in lots of funding to manufacturers, without any guarantee of success, but hoping that they would find a solution
- Manufacturers knew this had to be a straight run through, they didn't have time for investment decisions and pausing or thinking about a commercial market at the end of it. It had to happen with real urgency.
- But the vaccine trials have been just the same as normal vaccine trials. Phase one, phase two and phase three. Where time has been saved is by recruiting participants in advance, so at the moment the study protocol is in place, the Ethics Committee is in place, so are the vaccine trial participants – which speeds up the process. And that happened at phase one, phase two and phase three and therefore things ran very fast.

How can a vaccine be developed in nine months?

- These vaccines have been through phase 1, phase 2 and phase 3 clinical trials just like ordinary vaccines. The Pfizer vaccine clinical trial size was around 45,000 people. These are very, very big studies.
- Time has been gained is instead of getting an investment decision then going to ethics committee then starting to recruit volunteers, all of the recruiting volunteers was done in advance so that the people were completely ready to go and the ethics committees moved very fast to approve the trials.
- Organisations like the National Institute for Health Research made this their top priority and plans were made for the next phase by the companies without having to wait for things like investor decisions.
- But the numbers of people in the trials were the same as you would expect for any other vaccine, and on top of that the safety assessments and the assessments of effectiveness at the end are the same – it's the same regulators doing the same job.

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- Companies have made decisions to begin large scale production of vaccines which are still in trials. This means that if the vaccines are not shown to be safe and effective and are not authorised for use the companies will have to destroy what they have manufactured. If, however the vaccines are successful, that means the vaccines are ready to be distributed.

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.

Regulation and Authorisation

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

Prioritisation

The full prioritisation list can be found [here](#) and is as follows (in order of priority):

- 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 which 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

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

- The JCVI recommendations of vaccination by age and risk factors is estimated to cover over 25 million people in phase 1.
- The vaccination of the top two cohorts is estimated to cover over 6 million people.

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.

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- 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 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.
- 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.
- 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-vaccine-for-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.

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- Treatments containing COVID-19 neutralising antibodies have been secured from AstraZeneca 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 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 addition 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.

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

- The trials 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 JCVI has amended its previous precautionary advice on Covid-19 vaccines and pregnancy or breastfeeding.
- The new advice 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

Why are care home workers prioritised over NHS staff?

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- 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.

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.

Has the MHRA approved care home jobs?

- The MHRA has now given the approval in principle for the vaccine to be moved and the trays of vaccines to be split in very specific and controlled circumstances.
- This is a new vaccine and has never been used before, and the scale we're all working at means there is only a small number of providers who can do this right now.
- The MHRA has set out how this can be expanded to GP-led vaccination channels.

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.

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 vaccine doses through agreements with several separate vaccine developers at various stages of trials, including:

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- 100 million doses of University of Oxford/AstraZeneca vaccine 40 million doses of BioNTech/Pfizer vaccine
- 17 million doses of Moderna vaccine
- 60 million doses of Novavax vaccine
- 60 million doses of Valneva vaccine
- 60 million doses of GSK/Sanofi Pasteur vaccine
- 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.

Why doesn't JCVI's advice include anything about the other vaccine candidates?

- After JCVI has been given the opportunity to review Phase III data on the vaccines, the statement will be updated. 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.

Vigilance, surveillance 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

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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 <https://coronavirus-yellowcard.mhra.gov.uk/>
- 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?

- 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.

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 are clear that all vaccines being rolled out must continue to meet high standards of safety and efficacy.

Vaccine trials importance

- The encouraging news about vaccines is thanks to clinical study participants volunteering to take part and shows the importance of this vaccine research.
- 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.
- There will be further studies to look at how best to use the different vaccines, for example, which vaccine is most effective in which individuals and what sized dose is most effective. A number of vaccines remain in development, and these may offer benefits over the first approved vaccine/s.
- All this ongoing research will be vitally important to ensure we get the best protection from the vaccine. Research and vaccine development will not end with the first approved vaccine - there will be a process of continuous improvement.

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

Are you launching a campaign with celebrities to promote vaccinations?

- An effective vaccine will be the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began, potentially saving thousands of lives.
- We will provide advice and information at every possible opportunity to support those who have been prioritised to receive a vaccine and anyone who has questions about the vaccination process.

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 [PHE's Campaign Resource Centre](#).
- Various versions of the leaflets and posters have been developed, with different call-to-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 [health publications website](#).

What is the government doing about the spread of disinformation?

- False information about COVID-19 vaccines could cost lives.

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- 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 [SHARE checklist](#) 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.