

# Stakeholder Vaccine FAQ, from the Department of Health and Social Care

Please note that text that is highlighted blue has been updated on 17 September 2021 by the Department of Health and Social Care

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### **Top lines**

- Vaccines are the way out of this pandemic. Vaccines are the best way to protect people from coronavirus and have saved more than 100,000 lives in the UK alone.
- Vaccinated people are far less likely to get COVID-19 with symptoms and even more unlikely to get serious COVID-19, to be admitted to hospital, or to die from it and there is evidence that they are less likely to pass the virus on to others.
- The first dose of the vaccine offers good levels of protection, but to get maximum protection everyone must get a second dose, so we are urging all people to come back when they are contacted or if they have an appointment booked.
- 48.5 million people have now received their first COVID-19 vaccine dose. 44.2 million have had their second dose.
- All those aged 18 and over can book their vaccination through the NHS booking service. You can also call 119 free of charge, anytime between 7am and 11pm seven days a week.
- Everybody aged 16 and over has now been offered their first dose of a COVID-19 vaccine.
- Children and young people aged 12 15 years with specific underlying health conditions or who are household contacts of someone who is immunosuppressed, have also been offered the vaccine.
- All those aged over 50 and the clinically extremely vulnerable have been offered their second dose of a COVID-19 vaccine.
- Second doses have been accelerated for all over 18s, by reducing the dosing interval from 12 weeks to 8 weeks.
- People who have received two doses of an NHS administered COVID-19 vaccine in the UK (plus 14 days) or are on a formally approved UK vaccine clinical trial, returning to England from amber list counties no longer need to quarantine.
- People who have received two doses of COVID-19 vaccine will no longer need to self-isolate if they are identified as a close contact of someone with COVID-19.
- You can book via the NHS website here: <a href="https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/book-coronavirus-vaccination/">https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/</a>
- The COVID-19 vaccination programme is the biggest vaccination programme in NHS history.
- We are in constant contact with the vaccine manufacturers and remain confident that the supply of vaccine to the UK will not be disrupted.
- PHE estimates based on the direct effect of vaccination and vaccine coverage rates, are that around 230,800 hospitalisations have been prevented in those aged 45 years and over in England as a result of the COVID-19 vaccination programme, up to 5 September.
- Estimates suggest that 112,300 deaths and 24,702,000 infections have been prevented as a result of the COVID-19 vaccination programme, up to 27 August.

# Vaccine deployment statistics

Latest number on vaccines can be found on the gov.uk coronavirus dashboard here.

NHS.uk statistics, updated weekly, can be found here.

Total vaccination statistics - up to and including 17 September 2021:

Note: The headline vaccination uptake presented for the UK and nations has been updated to include 16 and 17 year olds in the denominator. The ONS 2020 mid-year estimates for those aged 16 and over are now used.

UK total first dose: 48,528,901 (89.3% of adult population)

UK total second dose: 44,298,076 (81.5% of adult population)

	1 <sup>st</sup> dose	2 <sup>nd</sup> dose	Total
England	40,703,518	37,092,855	77,796,373
Scotland	4,150,157	3,798,938	7,949,095
Wales	2,371,337	2,206,377	4,577,714
Northern Ireland	1,303,889	1,199,165	2,503,795

# Top announcements and lines in the last seven days:

#### NHS begins COVID-19 booster vaccination campaign (16.09.2021)

The NHS has started delivering COVID booster jabs to people in eligible groups from today, as the biggest and most successful vaccination programme in health service history moves to the next stage.

In line with new advice set out by the Joint Committee on Vaccination and Immunisation (JCVI) on Tuesday 14 September, the NHS vaccination programme will now invite eligible people, who had their second COVID jab at least six months ago, for a top up.

Hospital hubs have started vaccinating frontline health and care workers as well as identifying other eligible patients for their booster vaccine immediately, with GP-led local vaccination services to follow in the coming days.

Full vaccination rollout will begin from next week, as more vaccination centres and community pharmacy-led sites come online following final checks, giving people further protection from the virus ahead of winter.

The booster programme will be delivered through existing vaccination sites including pharmacies, hospital hubs, GP practices and vaccine centres.

Local NHS areas will be prioritising care home residents and staff ensuring they are offered a vaccine by the beginning of November.

### Dr Nikki Kanani, GP and Deputy Lead for the COVID-19 Vaccination Programme

said: "Alongside one of our busiest summers in the NHS, our hardworking staff have also been gearing up to deliver the autumn booster programme, to give further protection to healthcare and social care workers and those most at risk from the virus.

"Now that the advice has been set out by the JCVI and once the relevant checks are in place, the NHS will invite you for your booster vaccination. There is no need to contact the NHS - we will be in touch with you when it is your turn to get your booster vaccine - at least six months on since your last dose.

"The fast preparations of staff to get ready for boosters comes on the back of our biggest vaccination drive in health history which has delivered more than 77 million vaccinations across the country.

"Getting the vaccine remains the best way to protect yourself and those around you from COVID – so please do come forward for this top up of protection when you are invited".

Health and Social Care Secretary Sajid Javid said: "It is brilliant to see that the first booster jabs are being rolled out today - thanks to the phenomenal efforts of the NHS who continue to work tirelessly to help us fight COVID-19 and protect the most vulnerable.

"We know vaccines save lives and with every jab our wall of defence across the country gets higher, with more than 112,300 lives saved and over 24 million cases prevented in England alone. "I urge everyone who is eligible to come forward for their booster when invited, to prolong the protection that the vaccine offers those most at risk as we approach the winter months".

#### **Full Press Release**

# <u>Temporary medical exemptions for COVID-19 vaccination of people working or deployed in care homes (15.09.2021)</u>

A letter from the Director of Adult Social Care Delivery to local authorities, directors of adult social services, care home providers, care home managers and agencies.

Regulations were approved by Parliament on 22 July 2021 to make vaccination a condition of deployment for staff working in CQC-regulated care homes in England, unless they have a medical exemption. A 16-week grace period was put in place to ensure staff who haven't been vaccinated could take up the vaccine before the regulations come into force on 11 November 2021.

Thanks to the incredible efforts of people across the care sector to encourage and reassure colleagues about vaccination, as of 9 September, 90.4% of care home workers have now had a first dose of a COVID-19 vaccine, with 82.2% of care home staff now fully vaccinated.

On a temporary basis, from 15 September, people working or volunteering in care homes who have a medical reason why they are unable to have a COVID-19 vaccine will be able to self-certify that they meet the medical exemption criteria, using the forms attached to this letter.

Care home workers who are exempt will need to sign the form attached to this letter and give this to their employer as proof of their temporary exemption status. This temporary self-certification process has been introduced for a short period prior to the launch of the new NHS COVID Pass system which will go live imminently. Once the NHS COVID Pass system is launched, care home workers will need to apply for a formal medical exemption through that process. This temporary self-certification will expire 12 weeks after the NHS COVID Pass system is launched.

#### **Full Letter**

#### Most vulnerable to be offered COVID-19 booster vaccines from next week (14.09.2021)

Millions of the UK's most vulnerable are to be offered a COVID-19 booster vaccine from next week.

- UK accepts advice from the independent JCVI on who to prioritise for a booster dose
- Further details on deployment to be set out in due course

Millions of vulnerable people are to be offered a COVID-19 booster vaccine from next week as the government confirms it has accepted the final advice from the independent Joint Committee on Vaccination and Immunisation (JCVI).

The programme will be rolled out to the same priority groups as previously. This means care home residents, health and social care workers, people aged over 50, those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19, adult carers, and adult household contacts of immunosuppressed individuals will be prioritised.

However, there will be flexibility in the programme, allowing all those eligible to receive their booster from 6 months after their second doses. This approach will allow more vulnerable people to be given their boosters quicker.

The move will ensure the protection vaccines provide for those most at risk of severe illness from COVID-19 will be maintained over the winter months. Data published by ONS yesterday shows people who have not been vaccinated account for around 99% of all deaths involving COVID-19 in England in the first half of this year. All 4 nations of the UK will follow the JCVI's advice.

Health and Social Care Secretary Sajid Javid said: "Our vaccine rollout has been phenomenal. It's vital that we do everything we can to prolong the protection our vaccines offer, particularly for those most vulnerable to COVID-19 as we head into the Autumn and Winter months. I have today accepted the advice from the independent experts at the JCVI to offer a booster vaccine to those most at risk. The booster programme will start next week thanks to the extensive preparations the NHS has already made to ensure booster jabs can be rolled out as quickly as possible. I urge all those eligible to get their COVID-19 and flu vaccines as soon as they can, so you have the strongest possible protection over the winter months."

Vaccinations will begin next week and the NHS will contact people directly to let them know when it is their turn to get their booster vaccine.

The JCVI has also advised that the flu and COVID-19 vaccines can be co-administered. The NHS will now consider where it's appropriate for co-administration to be used to support the roll-out of both programmes and where waiting to deliver one vaccine does not unduly delay administration of the other. It is important people take up the offer of both vaccines when they receive it, so people are encouraged to get both vaccinations as soon as possible rather than waiting for the possibility of getting them together.

People will be offered either a full dose of the Pfizer/BioNTech vaccine or a half dose of the Moderna vaccine, following scientific evidence showing that both provide a strong booster response. This will be regardless of which vaccine the individual previously had.

A total of 44,108,746 people have received two doses (89.2%) and 48,458,700 people have received one dose (81.2%).

**Full Press Release** 

### JCVI issues updated advice on COVID-19 booster vaccination (14.09.2021)

The Joint Committee on Vaccination and Immunisation (JCVI) has updated its advice on the COVID-19 vaccine booster programme.

The vast majority of the UK population has received a COVID-19 vaccine since the vaccine programme was launched in December 2020 - including 89.1% of the population who have received a first dose and 81% who have received both doses.

It is expected that coronavirus (COVID-19) infections will continue to circulate in the coming months, alongside seasonal influenza and other respiratory viruses.

The COVID-19 vaccines provide high levels of protection against hospitalisation or dying from the virus. To maintain this high level of protection through the coming winter, the JCVI is advising that booster vaccines be offered to those more at risk from serious disease, and who were vaccinated during Phase 1 of the vaccine programme (priority groups 1 to 9).

#### This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19, and adult carers
- adult household contacts of immunosuppressed individuals

The JCVI advises that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course, in the same order as during Phase 1.

People vaccinated early during Phase 1 will have received their second dose approximately 6 months ago. Therefore, it would be appropriate for the booster vaccine programme to begin in September 2021, as soon as operationally practical.

Professor Wei Shen Lim, Chair of COVID-19 Immunisation for the JCVI, said: "The UK's COVID-19 vaccination programme has been hugely successful in protecting people against hospitalisation and death, and the main aim of the booster programme is to prolong that protection and reduce serious disease as we head towards the colder months.

The JCVI is advising that a booster dose be offered to the more vulnerable, to maximise individual protection ahead of an unpredictable winter. Most of these people will also be eligible for the annual flu vaccine and we strongly advise them to take up this offer as well."

**Full Press Release** 

Research Study: Vaccine effectiveness and duration of protection of Comirnaty, Vaxzevria and Spikevax against mild and severe COVID to 19 in the UK (14.09.2021)

<u>Dr Mary Ramsay, Head of Immunisation at PHE, said:</u> "This real-world study provides the first evidence from the UK that vaccine effectiveness against severe disease starts to wane slightly

around 20 weeks after vaccination. Waning appears to be greater in older adults and at-risk groups, so it is important that they are prioritised for booster doses as set out by the JCVI.

"We expect this waning to gradually continue over time, and we will keep monitoring the data to understand the duration of protection in the longer term."

#### **Key findings**

Our data provides evidence of waning of protection against symptomatic infection following both AstraZeneca and Pfizer vaccines from 10 weeks after the second dose. Protection against hospitalisation and death, however, was sustained at very high levels for at least 20 weeks after the second dose. Beyond 20 weeks, we observed more waning with AstraZeneca compared to Pfizer. Waning of protection against hospitalisation was greater among older adults and in those in a clinical risk group. Among >65 year-olds who were not in a clinical risk group, however, protection against hospitalisation remains close to 95% with Pfizer and just under 80% with AstraZeneca beyond 20+ weeks after the second vaccine dose.

#### Health and Social Care Secretary Sajid Javid statement in House of Commons (14.09.2021)

We've been continuing the rollout of our vaccination programme – with 81 per cent of people over the age of 16 having had the protection of both doses we've expanded our testing capacity yet further, opening a new megalab in Leamington Spa and we've continued supporting research into Long Covid – taking our total investment to £50 million.

The link between cases, hospitalisations, and deaths has weakened significantly since the start of the pandemic and deaths from Covid-19 have been mercifully low, compared to previous waves.

The latest statistics from the ONS show that almost 99% of Covid-19 deaths in the first half of this year were people who had not received both doses of a Covid-19 vaccine.

This shows the importance of our vaccination programme - and by extending this programme further, we can protect even more people.

Almost 6 million people over the age of 16 remain unvaccinated in the UK - and the more people that are unvaccinated, the larger the holes in our collective defences.

This morning, we published the JCVI advice on a booster programme.

They've recommended that people who were vaccinated in Phase 1 - that's priority groups 1 to 9 - should be offered a booster vaccine. That this vaccine should be offered no earlier than 6 months after the completion of the primary vaccine course and that as far as possible, the booster programme should be deployed in the same order as Phase 1.

I can confirm that I have accepted the JCVI's advice, and that the NHS is preparing to start offering booster doses from next week.

This booster programme will protect the most vulnerable throughout the winter months, and strengthen our wall of defence even further.

All young people aged 16 to 17 in England have already been offered a dose of a Covid-19 vaccine to give them protection as they return to school.

And yesterday, the UK's Chief Medical Officers unanimously recommended making a universal offer of a first dose of a vaccine to people aged between 12 and 15.

The Government has accepted this recommendation too, and we'll move with urgency to put this into action.

We'll keep encouraging people to take steps to keep seasonal illnesses at bay - including Covid-19 and flu.

The best step we can all take is to get vaccinations for Covid-19 and flu if we're eligible.

And so along with our Covid-19 vaccination programme, the next few months will see the largest ever flu vaccination campaign this country has ever seen.

#### Young people aged 12 to 15 to be offered a COVID-19 vaccine (13.09.2021)

People aged 12 to 15 in England will be offered a first dose of a COVID-19 vaccine.

- Move follows unanimous advice to ministers from the 4 UK Chief Medical Officers
- Parental consent will be sought prior to vaccination

People aged 12 to 15 in England will be offered one dose of the Pfizer/BioNTech COVID-19 vaccine, following advice from the 4 UK Chief Medical Officers (CMOs), the Health and Social Care Secretary has announced today (Monday 13 September).

In line with the recommendation of the independent Joint Committee on Vaccination and Immunisation (JCVI), the government sought the views of the 4 UK CMOs on the wider issues that are relevant to the health of children.

The government has accepted the advice of the 4 UK CMOs and the NHS is preparing to deliver a schools-based vaccination programme, which is the successful model used for vaccinations including for HPV and Diphtheria, Tetanus and Polio (DTP), supported by GPs and community pharmacies. Invitations for vaccination will begin next week.

Parental, guardian or carer consent will be sought by vaccination healthcare staff prior to vaccination in line with existing school vaccination programmes.

Health and Social Care Secretary, Sajid Javid said: "I have accepted the recommendation from the Chief Medical Officers to expand vaccination to those aged 12 to 15 - protecting young people from catching COVID-19, reducing transmission in schools and keeping pupils in the classroom. I am very grateful for the expert advice I have received from the Joint Committee on Vaccination and Immunisation and UK Chief Medical Officers. Our outstanding NHS stands ready to move forward with rolling out the vaccine to this group with the same sense of urgency we've had at every point in our vaccination programme."

**Full Press Release** 

<u>Letter from UK CMOs to Secretary of State, Cabinet Secretary and ministers, offering their advice on COVID-19 vaccinations for healthy 12-15 year olds (13.09.2021)</u>

#### **Advice**

All drugs, vaccines and surgical procedures have both risks and benefits. If the risks exceed benefits the drug, vaccine or procedure should not be advised, and a drug or vaccine will not be authorised by MHRA. If benefits exceed risks then medical practitioners may advise the drug or vaccine, but the strength of their advice will depend on the degree of benefit over risk.

At an individual level, the view of the MHRA, the JCVI and international regulators is that there is an advantage to someone aged 12 to 15 of being vaccinated over being unvaccinated. The COVID-19 Delta variant is highly infectious and very common, so the great majority of the unvaccinated will get COVID-19. In those aged 12 to 15, COVID-19 rarely, but occasionally, leads to serious illness, hospitalisation and even less commonly death. The risks of vaccination (mainly myocarditis) are also very rare. The absolute advantage to being vaccinated in this age group is therefore small ('marginal') in the view of the JCVI. On its own the view of the JCVI is that this advantage, whilst present, is insufficient to justify a universal offer in this age group. Accepting this advice, UK CMOs looked at wider public health benefits and risks of universal vaccination in this age group to determine if this shifts the risk-benefit either way.

Of these, the most important in this age group was impact on education. UK CMOs also considered impact on mental health and operational issues such as any possible negative impact on other vaccine programmes, noting that influenza vaccination and other immunisations of children and young people are well-established, important, and that the annual flu vaccine deployment programme commences imminently.

The UK CMOs, in common with the clinical and wider public health community, consider education one of the most important drivers of improved public health and mental health, and have laid this out in their advice to parents and teachers in a previous joint statement. Evidence from clinical and public health colleagues, general practice, child health and mental health consistently makes clear the massive impact that absent, or disrupted, face-to-face education has had on the welfare and mental health of many children and young people. This is despite remarkable efforts by parents and teachers to maintain education in the face of disruption.

The negative impact has been especially great in areas of relative deprivation which have been particularly badly affected by COVID-19. The effects of missed or disrupted education are even more apparent and enduring in these areas. The effects of disrupted education, or uncertainty, on mental health are well recognised. There can be lifelong effects on health if extended disruption to education leads to reduced life chances.

Whilst full closures of schools due to lockdowns is much less likely to be necessary in the next stages of the COVID-19 epidemic, UK CMOs expect the epidemic to continue to be prolonged and unpredictable. Local surges of infection, including in schools, should be anticipated for some time. Where they occur, they are likely to be disruptive.

Every effort should be taken to minimise school disruption in policy decisions and local actions. Vaccination, if deployed, should only be seen as an adjunct to other actions to maintain children and young people in secondary school and minimise further education disruption and therefore medium and longer term public health harm.

On balance however, UK CMOs judge that it is likely vaccination will help reduce transmission of COVID-19 in schools which are attended by children and young people aged 12 to 15 years. COVID-19 is a disease which can be very effectively transmitted by mass spreading events, especially with Delta variant. Having a significant proportion of pupils vaccinated is likely to reduce the probability of such events which are likely to cause local outbreaks in, or associated with, schools. They will also reduce the chance an individual child gets COVID-19. This means vaccination is likely to reduce (but not eliminate) education disruption.

Set against this there are operational risks that COVID-19 vaccination could interfere with other, important, vaccination programmes in schools including flu vaccines.

Overall however the view of the UK CMOs is that the additional likely benefits of reducing educational disruption, and the consequent reduction in public health harm from educational disruption, on balance provide sufficient extra advantage in addition to the marginal advantage at

an individual level identified by the JCVI to recommend in favour of vaccinating this group. They therefore recommend on public health grounds that ministers extend the offer of universal vaccination with a first dose of Pfizer-BioNTech COVID-19 vaccine to all children and young people aged 12 to 15 not already covered by existing JCVI advice.

If ministers accept this advice, UK CMOs would want the JCVI to give a view on whether, and what, second doses to give to children and young people aged 12 to 15 once more data on second doses in this age group has accrued internationally. This will not be before the spring term.

In recommending this to ministers, UK CMOs recognise that the overwhelming benefits of vaccination for adults, where risk-benefit is very strongly in favour of vaccination for almost all groups, are not as clear-cut for children and young people aged 12 to 15. Children, young people and their parents will need to understand potential benefits, potential side effects and the balance between them.

If ministers accept this advice, issues of consent need to take this much more balanced riskbenefit into account. UK CMOs recommend that the Royal Colleges and other professional groups are consulted in how best to present the risk-benefit decisions in a way that is accessible to children and young people as well as their parents. A child-centred approach to communication and deployment of the vaccine should be the primary objective.

If ministers accept this advice, it is essential that children and young people aged 12 to 15 and their parents are supported in their decisions, whatever decisions they take, and are not stigmatised either for accepting, or not accepting, the vaccination offer. Individual choice should be respected.

Chief Medical Officer for England Prof. Christopher Whitty

Chief Medical Officer for Northern Ireland Sir Michael McBride

Chief Medical Officer for Scotland Dr. Gregor Smith

Chief Medical Officer for Wales Dr. Frank Atherton

Full letter."

<u>Dr June Raine, MHRA Chief Executive announces regulatory change to enable booster doses of Pfizer and AstraZeneca COVID-19 vaccines (09.09.21):</u> "We are committed to getting safe and effective COVID-19 vaccines to the UK public. This means ensuring that existing COVID-19 vaccines can continue to be used in the most effective way possible.

We know that a person's immunity may decline over time after their first vaccine course. I am pleased to confirm that the COVID-19 vaccines made by Pfizer and AstraZeneca can be used as safe and effective booster doses. This is an important regulatory change as it gives further options for the vaccination programme, which has saved thousands of lives so far. It will now be for the JVCI to advise on whether booster jabs will be given and if so, which vaccines should be used.

We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance will include booster jabs."

Full Statement

# Department of Health and Social Care response to MHRA announcement about booster vaccines (09.09.2021):

"Our independent regulator, the MHRA, has confirmed the AstraZeneca and Pfizer vaccines are safe and effective to be used as booster jabs and third doses for people who are immunosuppressed.

"We continue to prepare for an autumn booster programme to ensure those most vulnerable to COVID-19 have protection extended ahead of winter and against new variants. "Any booster programme - including which vaccines might be recommended for use - will be based the final advice of the independent Joint Committee on Vaccination and Immunisation."

### Q&A

# Vaccine efficacy, length of protection, impact on transmissibility, deaths prevented

- PHE estimates based on the direct effect of vaccination and vaccine coverage rates, are that around 230,800 hospitalisations have been prevented in those aged 45 years and over in England as a result of the COVID-19 vaccination programme, up to 5 September.
- Estimates suggest that 112,300 deaths and 24,702,000 infections have been prevented as a result of the COVID-19 vaccination programme, up to 27 August.
- Vaccinated people are far less likely to get COVID-19 with symptoms and even more
  unlikely to get serious COVID-19, to be admitted to hospital, or to die from it and there is
  evidence that they are less likely to pass the virus on to others.
- The vaccines have made a life-changing difference to so many of us and continue to help us build a stronger wall of defense every day.
- With over 24 million infections prevented, vaccines are keeping people safe from harm and helping us reclaim our freedoms so we can return to normal life.
- Getting the vaccine has never been easier, thanks to sites being made available across a
  variety of sites including places of worship, festivals, and sporting grounds so please
  ensure you get your jab as soon as possible to ensure yourself, your loved ones and the
  people around you are protected.
- Obtaining two vaccine doses remains the most effective way to ensure protection against the COVID-19 Delta variant of concern dominant in the UK today.
- Based on antibody testing of blood donors, 93.2% of the adult population now have antibodies to COVID-19 from either infection or vaccination compared to 16.6% that have antibodies from infection alone.
- Almost 100% of people tested positive for antibodies 14 or more days after their second vaccine dose, highlighting the importance of getting both doses for the best possible protection as restrictions are eased
- Analysis by Public Health England (PHE) shows that two doses of the COVID-19 vaccines are highly effective against hospitalisation from the Delta (B.1.61.2) variant.
  - The Pfizer-BioNTech vaccine is 96% effective against hospitalisation after 2 doses.
  - The Oxford-AstraZeneca vaccine is 92% effective against hospitalisation after 2 doses.
- These are comparable with vaccine effectiveness against hospitalisation from the Alpha variant.

 Protection from Covid does not happen instantly after your first dose. It usually takes at least two or three weeks before you get a good antibody response, and even then, you need to get your second dose to get the fullest possible protection.

# <u>Vaccines still effective against Delta variant of concern, says Oxford-led study of the COVID-19 Infections Survey (18.08.2021)</u>

Obtaining two vaccine doses remains the most effective way to ensure protection against the COVID-19 Delta variant of concern dominant in the UK today, according to a study from the University of Oxford.

Conducted in partnership with the Office of National Statistics (ONS) and the Department for Health and Social Care (DHSC), the study found that with Delta, Pfizer-BioNTech and Oxford-AstraZeneca vaccines still offer good protection against new infections, but effectiveness is reduced compared with Alpha.

Two doses of either vaccine still provided at least the same level of protection as having had COVID-19 before through natural infection; people who had been vaccinated after already being infected with COVID-19 had even more protection than vaccinated individuals who had not had COVID-19 before.

However, Delta infections after two vaccine doses had similar peak levels of virus to those in unvaccinated people; with the Alpha variant, peak virus levels in those infected post-vaccination were much lower.

Professor Sarah Walker, Professor of Medical Statistics and Epidemiology at the University of Oxford and Chief Investigator and Academic Lead for the COVID-19 Infection Survey, said: "We don't yet know how much transmission can happen from people who get COVID-19 after being vaccinated - for example, they may have high levels of virus for shorter periods of time.

"But the fact that they can have high levels of virus suggests that people who aren't yet vaccinated may not be as protected from the Delta variant as we hoped. This means it is essential for as many people as possible to get vaccinated - both in the UK and worldwide."

#### **Full Press Release**

#### COVID-19 vaccines prevent over 143,000 hospitalisations in England (02.09.2021)

The latest PHE estimates suggest that 143,600 hospitalisations have been prevented in those aged 65 years and over in England as a result of the COVID-19 vaccination programme, up to 22 August.

Approximately 36,100 admissions were prevented in those aged 65 to 74, 58,800 in those aged 75 to 84, and 48,700 in those aged 85 and over.

Therefore, the figure of 143,600 hospitalisations prevented is likely to be an underestimate.

The number of hospitalisations averted by vaccination can be estimated by considering vaccine effectiveness against hospitalisation, vaccine coverage and observed hospitalisations, as well as through modelling.

Dr Jamie Lopez Bernal, Consultant Epidemiologist at PHE, said: "These figures show the vital role that vaccines play in preventing hospitalisations and in turn reducing the pressure on the NHS.

The vaccine helps protect you and those around you. To gain maximum protection, it is important that you get 2 doses of the vaccine."

**Full Press Release** 

# <u>Latest REACT-1 study findings show COVID-19 infection rates three times lower for double vaccinated people (04.08.2021)</u>

- Findings covering 24 June to 12 July from Imperial College London and Ipsos MORI show fully vaccinated people were three times less likely than unvaccinated people to test positive for COVID-19
- Ministers urge caution as society opens up, with some fully vaccinated people still able to test positive
- Study shows infections have increased four-fold compared to the last report in late May, with 1 in 160 people infected, although growth appeared to be slowing

Findings from the latest report of REACT-1, one of the country's largest studies into COVID-19 infections in England, have been published today (Wednesday 4 August) by Imperial College London and Ipsos MORI.

Over 98,000 volunteers took part in the study in England between 24 June and 12 July to examine the levels of COVID-19 in the general population. The latest data show infections in England have increased fourfold from 0.15% to 0.63% since the last REACT-1 report which covered the period 20 May to 7 June.

Despite this increase, the findings indicate the spread of the virus was slowing as of 12 July and infection rates for double vaccinated people are three times lower than in unvaccinated.

Analysis by Imperial College suggests double vaccinated people are also less likely to pass on the virus to others.

Full release

#### PHE Covid-19 vaccine surveillance report Week 29 (22.07.2021):

Based on antibody testing of blood donors, 93.2% of the adult population now have antibodies to COVID-19 from either infection or vaccination compared to 16.6% that have antibodies from infection alone. Over 93% of adults aged 30 or older have antibodies from either infection or vaccination. Seropositivity among those aged 17 to 29 has begun to rise over the last few weeks. The latest estimates indicate that the vaccination programme has directly averted over 52,600 hospitalisations. Analysis on the direct and indirect impact of the vaccination programme on infections and mortality, suggests the vaccination programme has prevented between 11 and 12.5 million infections and between 35,200 and 38,600 deaths.

#### Link to all reports

Almost 100% of people have antibodies after second vaccine (15.07.2021): Data highlights the importance of getting both doses for the best possible protection as restrictions are eased.

 Over 207,337 participants took part in a home surveillance study for COVID-19 antibodies between 12 and 25 May 2021

- Almost 100% of people tested positive for antibodies 14 or more days after their second vaccine dose, highlighting the importance of getting both doses for the best possible protection as restrictions are eased
- Findings show vaccine uptake remained high in May

#### Full statement

#### Vaccines highly effective against hospitalisation from Delta variant (14.06.2021)

New analysis by Public Health England (PHE) shows for the first time that two doses of the COVID-19 vaccines are highly effective against hospitalisation from the Delta (B.1.61.2) variant.

The analysis suggests:

- The Pfizer-BioNTech vaccine is 96% effective against hospitalisation after 2 doses.
- The Oxford-AstraZeneca vaccine is 92% effective against hospitalisation after 2 doses.

These are comparable with vaccine effectiveness against hospitalisation from the Alpha variant. Further work remains underway to establish the level of protection against mortality from the Delta variant. However, as with other variants, this is expected to be high.

The analysis included 14,019 cases of the Delta variant – 166 of whom were hospitalised – between 12 April and 4 June, looking at emergency hospital admissions in England.

PHE has <u>previously published analysis</u> showing that one dose is 17% less effective at preventing symptomatic illness from the Delta variant, compared to Alpha, but there is only a small difference after two doses.

#### Link

#### **Boosters**

#### What is the COVID-19 booster programme?

 The COVID-19 booster programme is the rollout of a third vaccine dose to those most vulnerable to COVID-19 in order to maintain protection against severe COVID-19 throughout the Winter months and to protect the NHS.

#### Why is the COVID-19 booster programme needed?

We want to provide the people that are most likely to become seriously ill from COVID-19
and those who care for them with the best possible protection for this Winter. The Joint
Committee on Vaccination and Immunisation (JCVI) has reviewed available data and
provided advice that COVID-19 boosters are offered to the most vulnerable in order to
maintain protection from COVID-19 throughout the Winter months, and to protect the
NHS.

 The flu vaccination programme is now running which protects people from serious complications from getting flu. We would encourage people, if eligible, to get their flu vaccine, regardless of their eligibility for a COVID-19 booster vaccine. More information on the flu vaccination is at www.nhs.uk/fluiab.

#### When will COVID-19 boosters be offered?

- JCVI advises that the booster vaccine dose is offered to individuals no earlier than six months after the completion of their primary vaccine course. The NHS plans to offer booster vaccines to the most vulnerable from next week.
- The JCVI advises that the booster programme should be deployed in the same order as during Phase 1, with operational flexibility exercised where appropriate to maximise delivery.

#### How soon after a second dose will a booster be offered?

 JCVI advises that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course (your second dose).

#### Who is eligible to receive a COVID-19 booster?

- JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who
  received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 19) should be offered a third dose COVID-19 booster vaccine. This includes:
  - Those living in residential care homes for older adults
  - All adults aged 50 years or over
  - Frontline health and social care workers
  - All those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the Green Book) and adult carers
  - Adult household contacts of immunosuppressed individuals
- As most younger adults will only have received their second COVID-19 vaccine dose in late summer or early autumn, the benefits of booster vaccination in this group will be considered at a later time when more information is available.
- JCVI will review data as they emerge and consider further advice at the appropriate time on booster vaccinations in younger adult age groups, children aged 12 16 years with underlying health conditions, and women who are pregnant.

#### Where will booster vaccine appointments be available?

- The vaccine is currently being delivered from a range of settings such as walk-in and mobile vaccination sites to make accessing the vaccination offer as convenient as possible, particularly for our deprived and underserved communities. As with the Phase 1 and 2 roll-out, booster jabs will be available at a range of locations.
- People will be offered the vaccine in a range of ways. Primary care teams will vaccinate
  care home staff and residents. Health and social care staff will be directed to book their
  appointments through employers, and members of the public will be invited to get their
  booster through a GP-led service and/or be contacted by the NHS to book through the
  national COVID-19 vaccination booking service to get their vaccination in a designated
  pharmacy, vaccination centre or GP-led service.

#### Which vaccine will be administered during the COVID-19 booster vaccination programme?

- After reviewing data on booster responses from different combinations of COVID-19 vaccines, JCVI advises a preference for the Pfizer vaccine to be offered as the third booster dose, irrespective of which vaccine someone has received as their primary course. There is good evidence that the Pfizer vaccine is well tolerated as a third dose and will provide a strong booster response.
- Alternatively, individuals may be offered a half dose of the Moderna which is also likely to
  provide a strong booster response. A half dose of Moderna vaccine is advised over a full
  dose due to the levels of reactogenicity (side-effects) seen following boosting with a full
  dose within the COV-BOOST trial.
- Where mRNA vaccines cannot be offered e.g. due to contraindication, vaccination with the AstraZeneca vaccine may be considered for those who received AstraZeneca vaccine in their primary course.

#### Does this mean there will be an annual COVID-19 vaccination programme?

At present, it is not known whether recurrent boosters will be required in the long term.
This advice on booster vaccinations only applies to this highly active phase of the
pandemic. This programme is timed to maximise the impact of a booster programme on
individual protection against severe disease and to protect the NHS during the winter
months.

<u>Dr June Raine. MHRA Chief Executive announces regulatory change to enable booster doses of Pfizer and AstraZeneca COVID-19 vaccines (09.09.2021):</u> "We are committed to getting safe and effective COVID-19 vaccines to the UK public. This means ensuring that existing COVID-19 vaccines can continue to be used in the most effective way possible.

We know that a person's immunity may decline over time after their first vaccine course. I am pleased to confirm that the COVID-19 vaccines made by Pfizer and AstraZeneca can be used as safe and effective booster doses. This is an important regulatory change as it gives further options for the vaccination programme, which has saved thousands of lives so far. It will now be for the JVCI to advise on whether booster jabs will be given and if so, which vaccines should be used.

We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UKapproved COVID-19 vaccines and this surveillance will include booster jabs." Full Statement

# <u>Department of Health and Social Care response to MHRA announcement about booster</u> vaccines (09.09.2021):

"Our independent regulator, the MHRA, has confirmed the AstraZeneca and Pfizer vaccines are safe and effective to be used as booster jabs and third doses for people who are immunosuppressed.

"We continue to prepare for an autumn booster programme to ensure those most vulnerable to COVID-19 have protection extended ahead of winter and against new variants. "Any booster programme - including which vaccines might be recommended for use - will be

based the final advice of the independent Joint Committee on Vaccination and Immunisation."

#### Most vulnerable could be offered booster COVID-19 vaccines from September (30.06.2021)

Millions of people most vulnerable to COVID-19 may be offered a booster vaccination from September to ensure the protection they have from first and second doses is maintained ahead of the winter and against new variants, following interim advice from the Joint Committee on Vaccination and Immunisation (JCVI).

The JCVI's interim advice is to plan to offer COVID-19 booster vaccines from September 2021, in order to prolong the protection vaccines provide in those who are most vulnerable to serious COVID-19 ahead of the winter months, in a two-stage programme alongside the annual flu vaccination programme. Further details of the flu vaccination programme will be set out in due course.

The final JCVI advice will be published before September and will take into account the latest epidemiological situation, additional scientific data from trials such as Cov-Boost, real-time surveillance of the effectiveness of the vaccines over time and emerging variants. The final advice could change from the interim advice as further data is analysed.

The government is working closely with the NHS to ensure that if a booster programme happens it can be deployed rapidly from September. Further details will be set out in due course.

#### See full press release

The JCVI's interim advice is that a third booster jab is offered to the following groups in two stages:

**Stage 1.** The following people should be offered a third dose COVID-19 booster vaccine and the annual influenza vaccine, as soon as possible from September 2021:

- adults aged 16 years and over who are immunosuppressed;
- those living in residential care homes for older adults;
- all adults aged 70 years or over;
- adults aged 16 years and over who are considered clinically extremely vulnerable;
- frontline health and social care workers.

**Stage 2.** The following people should be offered a third COVID-19 booster vaccine as soon as practicable after Stage 1, with equal emphasis on deployment of the influenza vaccine where eligible:

- all adults aged 50 years and over
- all adults aged 16 49 years who are in an influenza or COVID-19 at-risk group as outlined in the Green Book
- Adult household contacts of immunosuppressed individuals

#### JCVI issues interim advice on COVID-19 booster vaccination (30.6.2021):

The JCVI's interim advice is that any potential COVID-19 booster programme should be offered in 2 stages from September, starting with those most at risk from serious disease. This includes care home residents, people aged over 70, frontline health and social care workers, clinically extremely vulnerable adults and those who are immunosuppressed.

#### See full press release

<u>Third shot of Oxford/AstraZeneca vaccine 'could be effective booster'. A third shot of the Oxford/AstraZeneca vaccine could be an effective booster jab without the need for tweaks, new research suggests (28/06/2021).</u>

An Oxford University study found that giving people a third dose more than six months after their second led to a substantial rise in antibodies and increased the body's T-cell ability to fight coronavirus, including its variants.

### Blood clots and the Oxford/AstraZeneca vaccine

# <u>University of Oxford research that finds that Covid carries 'far higher' risk of blod clots than vaccine. 27.08.21</u>

Covid-19 is associated with a far greater risk of cerebral venous thrombosis than the vaccinations that protect against it, early research from the University of Oxford has shown.

The results show that the risk of cerebral venous thrombosis "is many-fold higher after covid-19 than after receiving a vaccine," Maxime Taquet, NIHR academic clinical fellow in psychiatry at the University of Oxford and an author of the study, told journalists at a Science Media Centre briefing in London on 15 April. "That is the case, if you look at the Pfizer and Moderna vaccine that we had direct access to, and that is also the case if you look at the Oxford-AstraZeneca vaccine, if you look at data from the European Medicines Agency."

#### Full article

# MHRA Quote and statement on blood clots and the Oxford/AZ vaccine (updated 03.06.21)

Full statement

#### Dr June Raine, MHRA Chief Executive said:

"Over 65 million doses of vaccines against COVID-19 have now been administered in the UK, saving thousands of lives through the biggest vaccination programme that has ever taken place in this country.

"No effective medicine or vaccine is without risk. These specific kinds of blood clots with low platelets reported following COVID-19 Vaccine AstraZeneca remain extremely rare and unlikely to occur. Our advice remains that the benefits of the vaccine outweigh the risks in the majority of people.

"It is still vitally important that people come forward for their vaccination and for their second dose when invited to do so.

"We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the <u>Coronavirus Yellow Card website</u>."

#### JCVI quote and statement on blood clots and the Oxford/AZ vaccine

**Full statement** 

# The government's statement following updated advice from the Joint Committee on Vaccination and Immunisation (JCVI) - (7 May 2021).

A government spokesperson said:

The Oxford/AstraZeneca vaccine is safe, effective and has already saved thousands of lives in the UK and around the world.

As the MHRA – the UK's independent regulator – and the Joint Committee on Vaccination and Immunisation have said, the benefits of the vaccine far outweigh the risks for the vast majority of adults.

The government will follow today's <u>updated advice</u>, which sets out that, as a precaution, it is preferable for people under the age of 40 with no underlying health conditions to be offered an alternative vaccine where possible once they are eligible, and only if doing so does not cause a substantial delay in accessing a vaccination.

More than 50 million vaccines overall have already been administered, and our current vaccine supply and rate of infection means we are able to take this precautionary step while remaining on track to achieve our target of offering a vaccine to all adults by the end of July.

Everybody who has already had a first dose of the Oxford/AstraZeneca vaccine should receive a second dose of the same jab, irrespective of age, except for the very small number of people who experienced blood clots with low platelet counts following their first vaccination.

When people are called forward, they should get their jab. Vaccines are the best way out of this pandemic and provide strong protection against COVID-19.

**Full Statement** 

#### Which vaccines have been authorised in the UK?

- Four vaccines have been authorised in the UK. Pfizer/BioNTech, AstraZeneca/Oxford, Moderna and Janssen.
- The University of Oxford/AstraZeneca vaccine, BioNTech/Pfizer and Moderna vaccine are now available across the UK.
- Janssen's single-dose COVID-19 vaccine has been authorised for use by the UK medicines regulator.

# Research, Development and Manufacturing

How were the vaccines developed so quickly?

- These vaccines have had three stages of clinical trials and have been tested on tens of thousands of people around the world.
- The trial phases were run in parallel, speeding up the overall time of vaccine production, but not the critical research time.
- Time has also been gained because:
- Vaccine trial volunteers were recruited at the start of the process, so they were ready to go once the vaccine was ready to trial
- The National Institute for Health Research (NIHR) made this their top priority
- Plans were made for the next phase of trials by the companies without having to wait for investor decisions.
- Companies made decisions to begin large scale production of vaccines which are still in trials. So, if vaccines were found to be safe and effective, they would be ready to be distributed.

How many vaccines are being manufactured in the UK?

- Three of the UK's eight COVID19 vaccines are being manufactured in the UK, this
  includes Valneva's whole inactivated virus vaccine, Novavax VLP protein adjuvant
  vaccine and Oxford/AstraZeneca's vaccine, which is delivered through a majority UK
  supply chain.
- We have invested over £300m 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.

### How much money has been spent on vaccines?

- As announced in the Spending Review, the Government has made available more than £6 billion to develop, manufacture and procure Covid-19 vaccines.
- This funding will also be allocated to manufacturing, research and development and other
  areas needed to develop vaccines, including fully funding the University of Oxford's
  clinical trials, as well as funding trials for other vaccines such as Novavax, Janssen and
  Valneva.
- The total cost to purchase, manufacture and deploy a vaccine will be approx. £11.7bn

#### Are trials ongoing?

- There will be further studies to look at how best to use the different vaccines, such as 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.
- The NIHR holds a registry of vaccine trial participants, and welcomes people wanting to take part in health and social care research. <a href="https://www.nhs.uk/sign-up-to-be-contacted-for-research">https://www.nhs.uk/sign-up-to-be-contacted-for-research</a>

# Have Covid vaccines been tested on a wide range of people, including different ethnic minorities?

- Each of the vaccines are tested on tens of thousands of people across the world. They are tested on both men and women, on people from different ethnic backgrounds, representative of the UK population and of all ages between 18-84.
- Pfizer/BioNTech trials took place in the US, Europe, Turkey, South Africa and South America. Approximately 42% of global participants and 30% of U.S. participants had racially and ethnically diverse backgrounds
- AstraZeneca trials took place in the UK, Brazil and South Africa. The non-white demographic in the UK trial was 7.1%. In the Brazil trial it was 31.4% and in South Africa it was 87%.

# Details on specific vaccines/manufacturers

Oxford University/AstraZeneca

Does the Oxford / AstraZeneca vaccine cause blood clots?

- MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
- The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
- The MHRA issued updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for 4 or more days after vaccination
- Vaccines are the best way to protect people from COVID-19 and have already saved thousands of lives. Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.
- Full MHRA statement (07/04/2021)

#### How did the AstraZeneca/Oxford vaccine become available so quickly?

- The UK was the first country in the world to procure and authorise the Oxford/AstraZeneca vaccine, and we were the first country in the world to start a vaccination programme with it w/c 4<sup>th</sup> January.
- The Oxford vaccine is a British success story it has had UK government backing throughout.
- 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

#### Can the Oxford/AstraZeneca vaccine be used for all adults regardless of age?

- MHRA advice regarding blood clots and the Oxford / AstraZeneca vaccine (07/04/2021)
  - The benefits of vaccination continue to outweigh any risks but MHRA advises careful consideration to be given to people who are at higher risk of specific types of blood clots because of their medical condition.
  - The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
  - Full statement (07/04/2021)
  - Update to JCVI advice to include all those under 40 to be given an alternative vaccine where possible (07.05.2021). <u>Full statement</u>

#### Is the Oxford/AstraZeneca vaccine safe for people over 50?

- MHRA advice regarding blood clots and the Oxford / AstraZeneca vaccine (07/04/2021)
  - The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
  - Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have these side effects should come forward for their second dose when invited.
  - o Full statement
- The vaccine has been thoroughly assessed by MHRA the UK medicines regulator for its safety and efficacy.
- Routine safety monitoring and analysis of the approved COVID-19 vaccines by the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA),

shows that the safety of these vaccines remains as high as expected from the clinical trial data that supported the approvals. (5 February)

#### Pfizer/BioNTech

- The UK was the first country in the world to start a vaccination programme using the Pfizer/BioNTech vaccine.
- 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.
- 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.

#### How effective is the Pfizer vaccine?

• **Public Health England data (17/03/21)** shows efficacy of 60% for those aged 70 and over against symptomatic COVID19 from either vaccine. Full report.

#### Moderna

#### How effective is the Moderna vaccine?

The Moderna vaccine has been shown to be 94% effective in its Phase Three clinical trials.

#### When will the first doses become available and how many doses will we have by 1 April?

- The Moderna vaccine has started to be rolled out in Wales (first dose administered on 6/4/2021) and England (first dose administered 13/4/2021)
- The UK has an agreement to purchase 17 million doses of Moderna.
- Moderna are currently scaling up their European supply chain.
- There have been some revisions to Moderna's supply chain (16/4/2021):
  - A Moderna spokesperson said: "In response to continuing high levels of global demand, Moderna and its drug substance manufacturing partner Lonza are working to deliver a sustained supply of COVID-19 Vaccine Moderna, in the shortest possible timeframe. However, taking into account the current supply, demand and distribution landscape, Moderna will be making adjustments to expected Q2 delivery quantities in a number of countries, including the UK and others...

"The Company remains in close contact with all governments, recognizing the importance of delivery planning for vaccination rollout. Moderna maintains the highest level of quality across all its manufacturing operations with its partners. Moderna continues to make substantial capital investments to support production increases of the COVID-19 Vaccine Moderna globally and explore other potential collaboration opportunities.

#### See full statement

#### A Department of Health and Social Care spokesperson said:

"Our vaccination programme continues to make phenomenal progress – with over 41 million vaccines administered so far. We've always been clear supply will fluctuate. We remain in

constant contact with all vaccine manufacturers to understand and manage supply issues. We have hit our target to offer a vaccine to everyone in phase one of the vaccination programme and we remain on track to offer a jab to all adults by the end of July."

#### Is it true we've paid more for Moderna doses compared to EU countries?

- The financial information in our contracts is commercially sensitive, so we are unable to disclose this at the present time.
- The price of any vaccine is a commercial decision for the company developing it. We take this into account when deciding whether or not to procure any vaccine.

#### **Novavax**

A press statement from Novavax on 11/03/2021 said they had confirmed high efficacy against both original and variant COVID-19 strains in United Kingdom and South Africa Trials. In it's <a href="mailto:press">press</a> statement, the company said:

"100% protection against severe disease

"Final analysis in U.K. trial confirms 96% efficacy against original strain of COVID-19

"Efficacy against variants confirmed in U.K. and South Africa"

Read full statement.

#### How effective is the Novavax vaccine?

- The Novavax vaccine has been shown to be 89.3% effective in its Phase Three clinical trials.
- If approved by the medicines regulator, the MHRA, the Novavax vaccine will be a significant boost to our vaccination programme.
- Novavax's candidate differs from those currently being used in the UK, combining an
  engineered protein from the virus that causes Covid-19 with a plant-based ingredient to
  help generate a stronger immune response.

#### Janssen (Johnson & Johnson)

DHSC press release: Janssen Covid-19 vaccine authorised by UK Medicines Regulator (28/05/21)

- Janssen single-dose COVID-19 vaccine authorised by the MHRA
- Government has secured 20 million doses for all of UK
- Doses expected to be available from later this year

#### Health and Social Care Secretary Matt Hancock said:

"This is a further boost to the UK's hugely successful vaccination programme.

"As Janssen is a single-dose vaccine, it will play an important role in the months to come as we redouble our efforts to encourage everyone to get their jabs and potentially begin a booster programme later this year."

#### Full statement

#### **MHRA Statement**

#### When will doses arrive?

Doses will become available later this year.

#### Who will the vaccine be given to as a priority?

We will follow the advice of the independent Joint Committee on Vaccination and Immunisation (JCVI) on which groups to prioritise for vaccination.

This is a single dose vaccine so could be used for people who are unlikely to come back for a second dose, such as homeless people. Is this something you are considering?

We will follow the advice of the independent Joint Committee on Vaccination and Immunisation (JCVI) on which groups to prioritise for vaccination.

Are you concerned about the risk of blood clots? Will this vaccine only be given to the over-40s like AstraZeneca?

We will follow the advice of the independent Joint Committee on Vaccination and Immunisation (JCVI) on which groups to prioritise for vaccination.

There have been very rare cases of thrombosis occurring together with thrombocytopenia (low levels of platelets) reported in other countries where the vaccine is already approved. The MHRA is working closely with international counterparts in understanding the global safety experience of COVID-19 vaccines and on the rapid sharing of safety data and reports.

#### How effective is it?

Results from a clinical trial involving people in the United States, South Africa and Latin American countries found that COVID-19 Vaccine Janssen was effective at preventing COVID-19 in people from 18 years of age. This study involved over 44,000 people. Half received a single dose of the vaccine and half were given placebo (a dummy injection). People did not know if they had been given COVID-19 Vaccine Janssen or placebo.

The trial found a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received COVID-19 Vaccine Janssen (116 cases out of 19,630 people) compared with people given placebo (348 of 19,691 people). This means that the vaccine had a 67% efficacy. Similar efficacy was seen after 4 weeks.

#### How long does protection last?

Protection with COVID-19 Vaccine Janssen starts around 14 days after vaccination but we do not currently know how long protection lasts. The people who were vaccinated in the clinical trials will continue to be followed for 2 years to gather more information on effectiveness over time.

#### Valneva

Where is the latest on the Valneva vaccine and where is it being manufactured (updated 28/01/2021)

- Thanks to the UK Vaccine Taskforce, we have ordered up to 100 million jabs of Valneva's promising vaccine if it proves to be safe, effective and suitable in its clinical trials this year.
- By starting manufacturing, we will have a running start at rolling these out as quickly as possible to protect the British public if it receives regulatory approval.
- This facility in Scotland, backed by millions from the Government, will help us beat coronavirus and boost our resilience against future pandemics.

# 'Mix and Match', Heterologous Prime Boost

Mixing AstraZeneca and Pfizer Covid jabs 'generates robust immune response' (28/06/2021) Mixing doses of the Oxford/AstraZeneca and Pfizer/BioNTech vaccines generates a robust immune response against coronavirus, research suggests.

The study found that using Pfizer followed by Oxford or vice versa induced high concentrations of antibodies against the spike protein of the virus when doses were given four weeks apart. The findings could allow flexibility in the UK and global vaccine rollouts, allowing people to receive whatever jab is available, rather than waiting for a matching one. However, given the UK's vaccine supply position it is unlikely the schedule will change at the moment.

#### Full report

# 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 will be 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.

# 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.
- The Pfizer/BioNTech vaccine is being rolled out as fast as possible by the NHS across the UK. Now authorised, the AstraZeneca/Oxford vaccine will be deployed alongside the Pfizer/BioNTech vaccine to increase the pace and volume of the UK programme. There are no current plans to mix these vaccines.
  - A new clinical trial, backed by £7 million of government funding, is looking into alternating Covid-19 vaccine doses. The study, run by the National Immunisation Schedule Evaluation Consortium (NISEC) across eight National Institute for Health Research (NIHR) supported sites, will examine whether different vaccines can safely be used for two dose regimes in the future. The current programme of two doses of the same vaccine over twelve weeks remains unchanged

- The study will also gather immunological evidence on different intervals between the first and second dose for a mixed-vaccine regimen against control groups when the same vaccine is used for both doses.

# 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.
- MHRA advice on blood clots resulting from the Oxford / AstraZeneca vaccine (07/04/2021)
  - MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
  - Anyone who did not have these side effects should come forward for their second dose when invited.
  - Anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of COVID-19 Vaccine AstraZeneca should not have their second dose. Anyone who did not have these side effects should come forward for their second dose when invited
  - Full statement
  - Update to JCVI advice to include all those under 40 to be given an alternative vaccine where possible (07.05.2021). <u>Full statement</u>

# Vaccine quantities in the UK, availability of supply

#### Will there be a sufficient numbers of vaccine doses?

- All approved vaccines offer considerable protection after the first dose and the second dose is important for longer-term protection.
- We are in constant contact with the vaccine manufacturers and remain confident in the continued supply of vaccine for the UK.

#### Why won't you publish UK wide figures?

- Our focus remains on getting the vaccine to those who need it.
- We publish daily statistics around the number of people who have received the 1st and 2nd dose of the vaccine and more detailed data on a weekly basis.

 We have signed deals for substantial future supply of both approved vaccines to replenish our stocks and enable swift vaccination of first and second doses across the UK in the weeks and months ahead.

#### How does the UK supply chain work?

- The UK Government has secured and purchased vaccines on behalf of the whole United Kingdom, and we are distributing them quickly, fairly and proportionately to all four nations.
- The UK Government has developed detailed plans for its supply chains with AstraZeneca, Pfizer and Moderna. We are not able to disclose details of these for security reasons.

# What happens to the unused doses that may be left over at the end of the day? Can they be given to people to avoid being wasted?

- No vaccines should be wasted.
- Local vaccination sites should be managing their appointment lists to ensure all
  appointments are filled and they have a back-up list of patients and staff who can
  receive the vaccine at short notice.
- 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.
- It is estimated that vaccinating everyone in the priority groups would prevent 99% of deaths, including those associated with occupational exposure to infection.
- Everybody aged 30 and over, the clinically vulnerable and health and social care workers have been offered a vaccine.
- The NHS will continue to offer vaccines to people in cohorts 1 to 9 who have not yet come forward and will be offering people their second doses within 12 weeks in line with the guidance from the JCVI.
- Our target remains to offer a vaccine to all adults by the end of July.
- The NHS guidance to Primary Care Networks/GPs is that vaccines should not be given to people outside of the eligible cohorts. It is absolutely permissible, and indeed encouraged, to have reserve lists of recipients, who can come in at short notice if vaccine is still available. However, these lists should only be drawn from eligible recipients in these cohorts.

### UK signs deal with Pfizer/BioNtech for 35 million covid-19 vaccine doses for 2022 (23.08.2021)

The UK has agreed a contract for 35 million more doses of the Pfizer/BioNTech vaccine, to be delivered from the second half of next year.

The government, through the Vaccine Taskforce, is putting in place preparations to future-proof the country from the threat of COVID-19 and its variants through safe and effective vaccines, as the UK's world-renowned vaccination programme continues to protect the population.

These include robust plans for ensuring the country remains ahead of the virus for years to come and for any future booster programmes, as well as working to make the UK a global centre of excellence for the next generation of vaccines.

The Vaccine Taskforce has contracts in place with multiple vaccine manufacturers.

#### Full press release

#### **Vaccine Roll Out**

- Everybody aged 18 and over has now been offered their first COVID-19 vaccine
- All adults should have a chance to have a second dose by mid September
- All 16-and-17-year olds have been sent letters inviting them to book one dose of the vaccine. 17 year olds within 3 months of their 18<sup>th</sup> birthday can book their jab via the National Booking System.
- Children aged 12 to 15 who are clinically vulnerable to COVID or live with adults who
  are at increased risk of serious illness from the virus will be contacted by the NHS and
  invited for their vaccine over the coming weeks.

#### How do I book my appointment?.

- All those aged 18 and over can book their vaccination through the NHS booking service. You can also call 119 free of charge, anytime between 7am and 11pm seven days a week.
- If a patient cannot go to one of the large vaccination centers, they can choose to have their vaccination at their GP surgery when it's available there or a pharmacy.

#### Should people who have already had Covid get vaccinated?

- Yes. 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.
- As with all new viruses, we won't know how long those who have recovered from coronavirus or the level of their immunity.

#### Global access to vaccines

- The Covid-19 pandemic is a global problem which requires a global solution.
- Diseases do not respect borders. None of us will be safe until everyone is safe.
- That's why the UK is making a crucial contribution to the global fight against Covid-19. It is in our national interest to do so.
- The UK was at the forefront of efforts to establish COVAX in 2020 and has provided a total of £548 million to fund vaccines for lower income countries. The scheme has delivered more than 152 million vaccine doses to over 137 countries and territories, including in 83 lower-middle income countries.(17.08.21)

#### UK and Australia agree to share vaccines to tackle global pandemic (03.09.21)

UK and Australia to share 4 million COVID-19 vaccine doses with each other to enhance roll-out of life-saving jabs.

- Next batch of more than 2 million UK doses delivered to vulnerable countries across Africa and Asia through COVAX
- Almost 9 in 10 over 16s in the UK have now received their first COVID-19 jab, and sharing will have no impact on UK roll-out or any future booster programme

The UK and Australia will share COVID-19 vaccine doses to benefit each other's life-saving vaccine roll-out programmes, the government has announced today.

The UK will send 4 million Pfizer/BioNTech vaccines to Australia to rapidly enhance their vaccination programme, with the first batch of 292,000 doses due to be shipped shortly. Australia will return the same overall volume of doses before the end of the year.

#### UK donates COVID-19 vaccines to Egypt (17.08.21)

The UK has delivered 299,700 doses of Oxford-AstraZeneca vaccine to Egypt as part of its efforts to ensure the most vulnerable are vaccinated.

The package donated by the UK was shipped via COVAX, with the support of UNICEF and WHO, and arrived in Cairo yesterday (16 August). This is part of the first tranche of the 100 million vaccines that the British Prime Minister Boris Johnson pledged the UK would share by June 2022 at the G7 Summit in Cornwall, with 30 million due to be sent by the end of the year. At least 80 million of the 100 million doses will go to COVAX.

This donation follows the recent COVAX shipment of 1.7 million doses, which the UK is also supporting. The UK was at the forefront of efforts to establish COVAX in 2020 and has provided a total of £548 million to fund vaccines for lower income countries. The scheme has delivered more than 152 million vaccine doses to over 137 countries and territories, including in 83 lower-middle income countries.

The British chargé d'affaires and Deputy Ambassador to Egypt, Qudsi Rasheed, said: Yesterday, the UK sent around 300,000 vaccines to Egypt, through COVAX, the first batch of the 100 million doses our Prime Minister has pledged we will share with countries around the world within the next year. This is another milestone in our partnership with Egypt to help support the government's response to the Covid-19 pandemic and part of the UK's goal to end the pandemic by 2022.

#### UK-donated COVID-19 vaccine doses reach African countries (13.08.2021)

- 119,200 doses of the AstraZeneca COVID-19 vaccine shared by the United Kingdom are landing in Zambia and 51,840 in the Democratic Republic of the Congo (DRC) on 13 August. 119,040 doses are due to arrive in Malawi on 14 August, 140,160 doses in Senegal on 15 August, 299,680 doses in Egypt on 16 August, and 299,520 doses are scheduled to touch down in Uganda on 18 August.
- The UK has pledged to share 80 million doses of COVID-19 vaccines with COVAX, as part
  of a broader pledge to share 100 million doses with the rest of the world. The UK
  Government has already committed £548 million in funding to the Gavi COVAX Advance
  Market Commitment.

Health and Social Care Secretary Sajid Javid said: "The UK is proud to be a major supporter of COVAX and the crucial work it does in getting vaccines to countries that need them most. The five million doses donated to COVAX are part of our pledge to contribute 100 million vaccines within the next year to help accelerate global access, and it's fantastic that from today the doses will be making a difference to millions of lives. I am hugely grateful to the University of Oxford and AstraZeneca for producing this vaccine at cost – after all, we are not safe from COVID-19 until the whole world is safe."

Full GAVI Press Release

#### Disabilities and vaccine

Our priority during the pandemic has been to save lives and protect those who are at risk of severe outcomes from Covid-19, which includes many disabled people

We are supporting and protecting disabled people from Covid-19 through a range of actions. This includes:

- Prioritising vaccinations for those who are deemed to be clinically extremely vulnerable, following the advice of the Joint Committee on Vaccination and Immunisation.
- Allocating £3.6m in 2020/21 to disability voluntary sector organisations providing direct, practical support to mitigate the impact of Covid-19 for disabled people, their families and carers.
- Providing guidance and advice for individuals and health and social care providers and professionals to mitigate the risks of Covid-19.

The NHS Volunteer Responders programme is available for anyone self-isolating. Volunteers can collect and deliver shopping, medication and other essential supplies and provide a short-term telephone support (Check-in and Chat) for those at risk of loneliness.

#### Learning disabilities and the vaccine

- The advice of the Joint Committee on Vaccination and Immunisation (JCVI) remains that adults with severe and profound learning disabilities, and those with learning disabilities in long-stay nursing and residential care settings, should be offered the vaccine in priority group 6 (people with Down's syndrome are included in group 4). Adults with less severe learning disabilities are not currently prioritised.
- However, GP systems may not always capture the severity of someone's disability, meaning some adults who are more severely affected by learning disabilities may not be invited for vaccination alongside people with other long-term health conditions.
- JCVI asked the <u>OpenSAFELY</u> team to perform an updated analysis in those with various code sets for learning disabilities on GP systems and to include data from wave 2 of the pandemic.
- The updated analysis confirmed a higher risk of mortality and morbidity in those on the GP register with learning disabilities it's expected that individuals with more severe learning disabilities are more likely to be on the list.
- To ensure those most at risk of death or hospitalisation are prioritised for vaccination,
  JCVI supports the plan to invite anyone on the GP Learning Disability Register as well as
  adults with other related conditions, including cerebral palsy for vaccination as part of
  priority group 6.
- JCVI also supports an approach for the NHS to work with local authorities to identify
  adults in residential and nursing care, and those who require support, for example as part
  of assisted living in the community, and those in shared accommodation with multiple
  occupancy.
- This will mean at least 150,000 more people with learning disabilities will now be offered the vaccine more quickly.

#### Reference - Vaccinations for people with Learning Disabilities

 JCVI advises inviting all people on the Learning Disability Register for vaccine - Gov.uk news story

 Letters from the Health and Social Care Secretary and JCVI on COVID-19 vaccination in people with learning disabilities <u>Read letters here</u>

This is not a change in the JCVI priority list but an operational clarification to ensure those with a severe and profound learning disability receive their offer as part of cohort 6

How will consent be gained for the vaccine to be administered to people with reduced capacity to make independent decisions? (12/4/2021)

- Everyone who receives a vaccine will be required to have completed a consent form.
- A standardised consent form is available to download from the <u>Health Publications</u> website.
- Some people who will be offered the vaccine may lack mental capacity to make decisions about vaccination. This will include some (but not all) people living with dementia, learning disabled and autistic people, people with mental health difficulties and people with acquired brain injury. These people, if they are aged 16 or over, are protected by the empowering, decision-making framework set out under the Mental Capacity Act 2005.

What steps are being taken to issue information on the COVID-19 vaccine and support to people with learning disabilities to help them access the vaccine as soon as possible. (25/02/2021)

- NHS England and NHS Improvement learning disability and autism programme has
  worked collaboratively across the NHS, with Public Health England and other partners to
  support the delivery of reasonable adjustments in the vaccination programme.
- This has included a range of training resources for vaccination teams on communicating
  with people with a learning disability and autistic people and making reasonable
  adjustments training materials for COVID 19 vaccinators and volunteers; a suite of
  accessible information including an easy read vaccination invitation letter and vaccination
  consent form; production of a film about the Covid-19 vaccine. Resources have been
  shared widely across the healthcare system.
- Individuals and families are being encouraged to raise any need for a reasonable adjustment required ahead of vaccination appointments.

# Immunocompromised people

Health and Social Care Secretary Sajid Javid response to the announcement on new advice from the JCVI for immunosuppressed people (01.09.2021):

"Today I have accepted the expert recommendations from the independent Joint Committee on Vaccination and Immunisation to offer a third vaccine dose to people aged 12 and over with severely weakened immune systems as part of their primary schedule following data from trials of those who are immunosuppressed.

We know people with specific conditions that make them particularly vulnerable to COVID-19 may have received less protection against the virus from two vaccine doses. I am determined to ensure we are doing all we can to protect people in this group and a third dose will help deliver that.

"The NHS will contact people as soon as possible to discuss their needs and arrange an appointment for a third dose where clinically appropriate.

"This is not the start of the booster programme - we are continuing to plan for this to begin in September to ensure the protection people have built from vaccines is maintained over time and ahead of the winter. We will prioritise those most at risk to COVID-19, including those who are eligible for a third primary vaccine, for boosters based on the final advice of the JCVI.

"COVID-19 vaccines have saved more than 105,000 lives and prevented 24 million infections in England alone. They are building a wall of defence and are the best way to protect people from serious illness. I encourage everybody who is eligible to get their jabs as soon as they can."

Professor Jonathan Van Tam, Deputy Chief Medical Officer, said in response to JCVI announcement on third doses (01.09.2021): "We know there are people with severe immunosuppression for whom the first two doses of vaccine have not provided the same level protection as for the general population. The degree of protection will vary by individual, according to degree of immunosuppression and the underlying reasons for that.

"So I welcome the advice from JCVI to offer a third primary dose to those with severe immunosuppression, at a bespoke interval, advised by their specialist clinician, and guided by the UK's immunisation handbook, the Green Book.

"We should be doing all we reasonably can to ensure that this group is not disadvantaged, and a third primary dose is one step in this direction. We are also working hard to ensure there are other medical interventions that can be used in these groups, including specific treatments like antivirals and monoclonal antibodies."

#### JCVI issues advice on third dose vaccination for severely immunosuppressed (01.09.2021)

The Joint Committee on Vaccination and Immunisation (JCVI) is advising that people with severely weakened immune systems should have a third vaccine dose as part of their primary COVID-19 vaccination schedule.

This third dose should be offered to people over 12 who were severely immunosuppressed at the time of their first or second dose, including those with leukaemia, advanced HIV and recent organ transplants. These people may not mount a full response to vaccination and therefore may be less protected than the wider population.

This offer is separate to any potential booster programme. The JCVI is still deliberating the potential benefits of booster vaccines for the rest of the population and is awaiting further evidence to inform this decision.

Immunosuppression varies widely in severity and in duration. Many people who are immunosuppressed have lower levels of antibodies after COVID-19 vaccination, as some studies have shown.

Preliminary data from the OCTAVE trial showed that almost everyone who was immunosuppressed mounted an immune response after 2 doses, as indicated by either antibodies or T cells. However, in around 40% of people, the levels of antibodies were low. It is not clear how much this may affect protection against COVID-19 as antibodies represent only part of a person's immune response.

People with severe immunosuppression are more likely to be severely ill if they do catch COVID-19.

Studies are ongoing to see how effective a third dose is for immunosuppressed people, but it is very unlikely to cause any harm. Therefore, on balance, the JCVI's view is that a third dose can be safely offered as it may increase their protection.

Professor Wei Shen Lim, Chair of COVID-19 Immunisation for the JCVI, said: "We want people with severely suppressed immune systems to have the best chance of gaining protection from COVID-19 via vaccination. Therefore, we are advising they have a third vaccine dose on top of their initial 2 doses, as we hope this will reduce their risk of severe outcomes such as hospitalisation and death."

The JCVI advises that for adults aged 18 and older, either the Moderna or Pfizer-BioNTech COVID-19 vaccines be administered for the third dose, as a number of studies have reported an increased immune response in some immunosuppressed people after a third dose of an mRNA vaccine. For those aged 12 to 17, the Pfizer-BioNTech vaccine is preferred.

The decision on the timing of the third dose should be made by their specialist. As a general guide, the third dose should usually be at least 8 weeks after the second dose but with flexibility to adjust the timing so that, where possible, immunosuppression is at a minimum when the vaccine dose is given.

This will enable a better immune response to be generated. For example, it is preferable to give a vaccine dose before someone undergoes chemotherapy, rather than during their treatment.

Those with less serious immunosuppression are not included in this advice but are likely to become eligible for another dose as part of a potential booster programme, pending further advice from the JCVI.

In the event of a booster programme, it is expected that severely immunosuppressed people will also be offered a booster dose, at a suitable interval after their third dose.

A third primary dose is an extra 'top-up' dose for those who may not have generated a full immune response to the first 2 doses. In contrast, a booster dose is a later dose to extend the duration of protection from the primary course of vaccinations.

Full Press Release

# New study to test third COVID-19 vaccine for people with weakened immune systems (24.08.3031)

A new clinical trial will investigate whether a third dose of vaccine for people with weakened immune systems gives a stronger immune response than 2 doses.

- Participants will be given either Pfizer, Moderna or Novavax as a third dose of vaccine
- The government-funded study follows the results of the OCTAVE trial showing that 89% of people who are immunocompromised or immunosuppressed generate antibodies, and 60% generate a strong antibody response after 2 doses

A new clinical trial to determine whether a third dose of vaccine will improve the immune response for people who have weakened immune systems is launching in the UK.

The study, OCTAVE DUO, will offer people who are immunosuppressed or immunocompromised a Pfizer, Moderna or Novavax vaccine to determine whether this will give a stronger immune response than 2 doses.

The OCTAVE trial has published preliminary data today showing that 89% of people who are immunocompromised or immunosuppressed generate antibodies following vaccination, and 60% generated a strong antibody response following 2 doses of a vaccine.

However, 40% of people in these groups mounted a low, or undetectable, immune response after 2 doses, and the level of antibody response varies between the groups studied.

**Full Press Release** 

A Department of Health and Social Care spokesperson said, when asked about immunocompromised groups and Step 4 (07.07.2021): "Two doses of the vaccine offer protection, including to those who are immunocompromised, so it's important everyone gets their first and second dose.

"People who suffer with long-term conditions or are vulnerable will want to take extra precautions to minimise any risk of exposure to COVID-19. As ever, if someone is worried they should speak to their GP for advice on how to manage the risks of COVID-19 according to their personal situation.

"The standard guidance for clinically extremely vulnerable people will be updated ahead of step 4 to reflect the lifting of restrictions on 19 July, if the decision is taken to move to the next step of the roadmap."

Dr Mary Ramsay, Head of Immunisation at PHE, said (9 July 21): "This real-world data shows for the first time that most people who are clinically vulnerable to COVID-19 still receive high levels of protection after 2 doses of vaccine.

"It is vital that anyone with an underlying condition gets both doses, especially people with weakened immune systems as they gain so much more benefit from the second dose."

**Full Statement** 

When will we have an effective treatment for Covid-19?

Health and Social Care Secretary Sajid Javid - statement, House of Commons (1230; 06.07.2021)

"And for those people who sadly do find themselves having to go to hospital, we have better treatments than ever before. Last week, on my visit to St Thomas' Hospital, clinicians were telling me just how transformative dexamethasone has been for their live-saving efforts. Taken together, the link between cases, hospitalisations and deaths is being severely weakened – and this means we can start to learn to live with COVID-19.

• The NHS is now rolling out the monoclonal antibody treatments tocilizumab and sarilumab. The international REMAP-CAP trial, part-funded by the UK Government, found in January that tocilizumab and sarilumab reduced the relative risk of death by 24%, when administered to patients within 24 hours of entering intensive care.

- Additionally, tocilizumab has been shown to reduce the relative risk of death for a patient on oxygen by 14% when used alongside the steroid, dexamethasone, which has already saved millions of lives worldwide.
- Alongside our fantastic vaccination programme, medicines are a vital weapon to protect our loved ones from this terrible virus, which is why we are bringing together a new Antivirals Taskforce to supercharge the search for new treatments.
- On 16 June 2020, the government-funded RECOVERY trial became the first to identify the benefits of dexamethasone in reducing mortality by 20% in patients requiring oxygen support and 35% for ventilated patients, following a readout from the RECOVERY trial and later supported by the WHO and REMAP-CAP.
- More recently, the REMAP-CAP trial demonstrated the benefits of tocilizumab and sarilumab, as well as the RECOVERY trial which found tocilizumab reduced the relative risk of death for patient on oxygen by 14%, when administered in addition to dexamethasone.

# People who are homeless or rough sleepers

JCVI advises prioritising homeless people and rough sleepers for COVID-19 vaccine (11/03/2021) (press release).

What is the government doing to help rough sleepers have access to vaccinations against COVID-19?

- The government has immediately accepted the advice of the independent experts at the JCVI to prioritise all homeless people and those rough sleeping for vaccination alongside priority group 6. We have asked the NHS to put the change of approach into action This will mean we will save more lives, among those most at risk.
- MHCLG is working closely with DHSC, PHE, and NHS England to ensure the health and care needs of vulnerable people experiencing homelessness can be met during the COVID-19 pandemic - including access to vaccination.
- Our ambition is to ensure the COVID-19 vaccine is accessible to everyone experiencing rough sleeping and homelessness, including those in emergency accommodation, in line with JCVI advice on COVID-19 vaccination prioritisation.
- On 8 January, Secretary of State asked all local authorities to ensure that even more rough sleepers are safely accommodated, backed by £10 million, and we are asking that this opportunity is actively used to make sure that all rough sleepers are registered with a GP and are factored into local area vaccination plans, in line with Joint Committee on Vaccination and Immunisation (JCVI) prioritisation.
- Local authorities should work with their local health partners to ensure individuals experiencing homelessness are able to access the vaccine by other means if mainstream provision is unsuitable.

#### Are we prioritising homeless people?

- The Government is following the independent advice of the Joint Committee on Vaccination and Immunisation (JCVI), which agrees priority groupings for vaccine.
- We know those who are rough sleepers or experiencing homelessness aren't always able to access healthcare routinely and therefore can often have a range of health issues which can leave them at an increased risk of this virus.
- The independent experts at the JCVI have recommended local teams now consider vaccinating those experiencing homelessness and rough sleeping in their area.

- The government has immediately accepted the advice of the independent experts at the JCVI to prioritise all homeless people and those rough sleeping for vaccination alongside priority group 6. We have asked the NHS to put the change of approach into action This will mean we will save more lives, among those most at risk
- 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.
- The NHS is working tirelessly to bring an end to this pandemic through vaccinations. NHSEI are working with Voluntary Community and Social Enterprise partners, inclusion health providers and others to develop an accessible model for delivery of the vaccine to people from inclusion health populations. As a result of having two vaccines now deployable, we are considering a number of options and will co-design these with partners based on the different local and logistical considerations.
- We are asking partners to support their clients and service users to register with a General Practice, where they are not already, and, if they have health conditions that would make them clinically vulnerable / clinically extremely vulnerable that this is recorded to ensure they receive the vaccine in line with the Joint Committee on Vaccinations and Immunisations advice on prioritisation.

#### Can people who are homeless get the vaccine?

- The government has immediately accepted the advice of the independent experts at the JCVI to prioritise all homeless people and those rough sleeping for vaccination alongside priority group 6. We have asked the NHS to put the change of approach into action This will mean we will save more lives, among those most at risk in society.
- MHCLG has asked local authorities to support everyone sleeping rough or brought into emergency accommodation to register with a GP, through which they can access the COVID-19 vaccine (in line with JCVI prioritisation) and have their wider health needs met.
- As part of this, MHCLG have asked all local authorities to ensure that even more rough sleepers are safely accommodated, and are asking that this opportunity is actively used to make sure that all those accommodated are registered with a GP, where they are not already, and are factored into local area vaccination plans, in line with the prioritisation approach set out by the Joint Committee on Vaccination and Immunisation.
- Local authorities should work with their local health partners to ensure individuals
  experiencing homelessness are able to access the vaccine by other means if mainstream
  provision is unsuitable.
- Everyone in England is entitled to register with a GP. Many people that experience health inequalities can face barriers when trying to register. Practices should not turn people away because they do not have proof of ID, address, or immigration status. People can also register if they do not know their NHS number or where they have not been issued with one
- We recognise that many people experiencing homelessness have health problems and may struggle to access the support they need.
- MHCLG announced £10 million in January 2021 to further support local authorities to bring people sleeping rough into emergency accommodation.

## Children and young people

#### JCVI issues updated advice on COVID-19 vaccination of children aged 12 to 15 (03.09.21)

The JCVI has reviewed the evidence on vaccinating children aged 12 to 15 who do not have underlying health conditions that put them at increased risk from severe COVID-19.

The assessment by the Joint Committee on Vaccination and Immunisation (JCVI) is that the health benefits from vaccination are marginally greater than the potential known harms. However, the margin of benefit is considered too small to support universal vaccination of healthy 12 to 15 year olds at this time.

It is not within the JCVI's remit to consider the wider societal impacts of vaccination, including educational benefits. The government may wish to seek further views on the wider societal and educational impacts from the Chief Medical Officers of the UK 4 nations.

#### Full statement

### Half of All 16 and 17-Year-Olds Receive Lifesaving Covid Vaccine (02.09.2021)

New figures published today show 50% of all teens aged 16 and 17 have had their first Covid jab, just four weeks after the green light was given for this age group.

More than 620,000 young adults aged 16 and 17 in England have now been jabbed as the fastest and largest vaccination programme in NHS history continues at pace.

England's top GP is now urging teenagers to "grab their jab" as the new school term starts and they return to school or college.

Today's figures show NHS staff have now delivered more than 75 million doses, since the NHS in England administered the first jab outside of clinical trials to Maggie Keenan in December 2020, with almost four in five adults now double vaccinated.

Dr Nikki Kanani, GP and Deputy Lead for NHS England's vaccination programme, said: "Uptake among young people continues to be strong and thanks to the non-stop efforts of NHS staff and volunteers, half of all 16 and 17 year olds have had their vaccine since becoming eligible last month, giving them the best possible protection against coronavirus.

"As school and college terms are due to start back shortly, it is really important that young people continue to come forward for their life-saving vaccine and visit the NHS Grab-a-jab finder to find a convenient site, with walk-in vaccinations taking place at nightclubs, university campuses and places of worship this weekend.

"It has never been easier to drop in and get your vaccine: it is safe, effective and will provide vital protection for you and your family and friends."

In line with guidance from the Joint Committee of Vaccination and Immunisation (JCVI), the NHS is vaccinating this age group with a single dose of the vaccine at GP and walk-in sites.

Children aged 12 to 15 who are clinically vulnerable to COVID or who live with adults who are at increased risk of serious illness from the virus are also being contacted by the NHS and invited for their vaccine.

#### Full Press Release

Health and Social Care Secretary Sajid Javid response to 50% of people aged 16 to 17 in England having received their first COVID-19 vaccine (02.09.2021): "It is fantastic to see the enthusiasm of young people to get the jab and great news that more than half of 16 to 17s in England are now vaccinated with a first dose as they return to colleges and sixth forms.

"Thank you for playing your part in helping us live safely with this virus so we can continue to enjoy the freedoms we missed like seeing friends and family.

"Jab by jab we are building a wall of defence that has already saved more than 105,000 lives and prevented 128,000 hospitalisations in England alone. Do not delay - please come forward and get both of your vaccines as soon as you can."

#### NHS invites young people for their life-saving COVID jab ahead of their 18th birthday 12.08.21

Thousands of young people nearing their 18th birthday can book in for their life-saving COVID jab from today (Thursday).

Teenagers within three months of turning 18 can now book their vaccine appointment online through the <u>National Booking Service</u> or by calling 119.

Text messages will be sent to more than 100,000 eligible teens inviting them to arrange their jab at one of hundreds of convenient vaccine sites in England.

NHS chiefs are urging young people to get protected against the virus ahead of going to university in September.

Full Press Release

#### COVID-19 jab invite letters sent to one million 16 and 17 year old (19.08.21)

Invitations to get a COVID vaccine are landing on the doormats of all 16 and 17 year olds from today, in a further effort to boost take-up in this age group, as the biggest and most successful vaccination programme in NHS history expands further.

Over 360,000 people aged 16 and 17 have already had their jab - which includes those who were eligible previously eligible due to an underlying health condition, with more than 125,000 getting their jab in the two weeks since the NHS was given the green light to offer all 16 and 17 years olds the life-saving jab.

From today, (Thursday), 16 and 17 year olds will begin receiving letters, inviting them to come to their nearest walk-in centre with many already receiving invitations from their GP and taking up the offer.

#### Full release

#### Moderna COVID-19 vaccine approved by MHRA in 12-17 year olds (17.08.21)

The UK regulator has confirmed the vaccine is safe and effective in this age group.

An extension to the current UK approval of the Spikevax vaccine (formerly COVID-19 Vaccine Moderna) that allows its use in 12- to 17-year-olds has today been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

**Dr June Raine, MHRA Chief Executive said:** "I am pleased to confirm that that the COVID-19 vaccine made by Moderna has now been authorised in 12-17 year olds. The vaccine is safe and effective in this age group.

We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance will include the 12- to 17-year age group.

It is for the Joint Committee on Vaccination and Immunisation (JCVI) to advise on whether this age group should be vaccinated with the COVID-19 vaccine made by Moderna as part of the deployment programme."

No new side effects were identified and the safety data in children was comparable with that seen in young adults. As in young adults, the majority of adverse events were mild to moderate and relating to reactogenicity, such as a sore arm or tiredness.

## JCVI issues updated advice on COVID-19 vaccination of young people aged 16 to 17 (04.08.2021)

The Joint Committee on Vaccination and Immunisation (JCVI) is today advising that all 16- and 17-year olds receive their first dose of the Pfizer-BioNTech vaccine.

In the last few weeks, there have been large changes in the way COVID-19 has been spreading in the UK, particularly in younger age groups. The adult vaccine programme has progressed very successfully and more safety data has become available, so it was important to review the advice for the vaccination of children and young people.

This updated advice means we can be confident that young people will be afforded around 80% protection against hospitalisation following receipt of their first dose. It is expected that protection will probably be even higher as younger people respond better to vaccines and some will have already had the COVID-19 infection, meaning they will have an even better response to a first dose.

Professor Wei Shen Lim, COVID-19 Chair for JCVI, said: "After carefully considering the latest data, we advise that healthy 16- to 17-year-olds are offered a first dose of Pfizer-BioNTech vaccine. Advice on when to offer the second vaccine dose will come later.

"While COVID-19 is typically mild or asymptomatic in most young people, it can be very unpleasant for some and for this particular age group, we expect one dose of the vaccine to provide good protection against severe illness and hospitalisation."

Full release here

Full advice here

#### **Key points:**

- Where and when will 16-17 year olds receive the vaccine?
  - o 16 and 17 year olds to continue to be vaccinated through the adult COVID-19 vaccination system supported if required by the GP led primary care system.
- Do 16 and 17 year olds require parental consent to access a COVID-19 vaccine?
  - Once young people reach 16, they are presumed in law to be competent to give consent for themselves. This includes for their own surgical, medical or dental treatment, and any associated procedures, such as investigations, anaesthesia or nursing care. This would include receiving the COVID-19 vaccine.

In response to the JCVI, Health and Social Care Secretary, Sajid Javid said: "Today's advice from the independent Joint Committee on Vaccination and Immunisation (JCVI) means more young people aged 16 and over can benefit from COVID-19 vaccines. I have accepted their expert recommendations and I have asked the NHS to prepare to vaccinate those eligible as soon as possible.

"The JCVI have not recommended vaccinating under-16s without underlying health conditions but will keep its position under review based on the latest data.

"Those aged 12 to 15 with severe neuro-disabilities, Down's Syndrome, immunosuppression and multiple or severe learning disabilities, as well as people in this age group who are household contacts of individuals who are immunosuppressed, are already eligible for vaccination. JCVI will continue to review data and provide updates on at risk groups aged 12-15 and whether any additional groups will be added.

"COVID-19 vaccines have saved more than 60,000 lives and prevented 22 million infections in England alone. They are building a wall of defence against the virus and are the best way to protect people from serious illness. I encourage everyone who is eligible to come forward for both their jabs as quickly as possible."

The MHRA concludes positive safety profile for Pfizer/BioNTech vaccine in 12 to 15-year-olds (O4.06.2021): following a rigorous review of the safety, quality and effectiveness of the vaccine in this age group.

**Dr June Raine, MHRA Chief Executive said**: "We have carefully reviewed clinical trial data in children aged 12 to 15 years and have concluded that the Pfizer/BioNTech COVID-19 vaccine is safe and effective in this age group and that the benefits of this vaccine outweigh any risk."

A Department of Health and Social Care spokesperson said: "Following a robust review of the evidence, the MHRA has concluded that the Pfizer/BioNTech COVID-19 vaccine meets the high standards of safety, effectiveness and quality required and has authorised its use for young people aged 12 to 15.

"The government has asked the independent experts at the Joint Committee on Vaccination and Immunisation (JCVI) to advise whether routine vaccination should be offered to younger people aged 12 to 17.

"We will be guided by the expert advisors and will update in due course."

#### Full statement

Pfizer-BioNTech announce positive top line results of COVID-19 vaccine study in adolescents (31/03/2021)

Pfizer-BioNTech announced that, in a Phase 3 trial in adolescents 12 to 15 years of age with or without prior evidence of SARS-CoV-2 infection, the Pfizer-BioNTech COVID-19 vaccine BNT162b2 demonstrated 100% efficacy and robust antibody responses, exceeding those recorded earlier in vaccinated participants aged 16 to 25 years old, and was well tolerated. See full release.

The U.S. Food and Drug Administration has expanded the emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents of 12 years old through to 15 years of age (10/05/21). See full announcement

FDA Commissioner Dr Janet Woodcock said the move was aimed at "bringing us close to returning to a sense of normality and to ending the pandemic".

Dr Woodcock said: "Parents and guardians can rest assured that the agency undertook a rigorous and thorough review of all available data, as we have with all of our Covid-19 vaccine emergency use authorisations.

## Time between first dose and second dose, changes to dosage interval

#### Secretary of State oral statement to House of Commons (05.07.2021)

#### **Dosing intervals**

"I can tell the House we are reducing the dose interval for under 40s from 12 weeks to 8 which will mean every adult should have the chance to be double jabbed by mid-September."

#### Secretary of State for Health Matt Hancock statement to Parliament (17/05/2021)

#### **Dosing interval:**

"Since January, we've been following a dosing interval of twelve weeks for second doses. Because of the extra protection you get from the second dose, particularly amongst those most likely to end up in hospital or dying, it is incredibly important that everyone comes forward for that second dose.

"Now, it is important to accelerate the second doses of all those most vulnerable to ending up in hospital or dying. So, our vaccination strategy for all parts of the UK, including the areas of surge vaccination, will stick by the clinical advice set out by the JCVI.

"First, prioritise anyone over 50 who has not yet been vaccinated. Next, second doses to those over 50 are vital which will now be done at a schedule of eight weeks. Then, follow the cohorts in priority order, and the age groups as we open them. This clinically approved approach is the best way to save the most lives rather than jumping ahead with first doses for younger people.

"While the JCVI of course keeps this under constant review, we are clear that their advice is the best way to protect those most in need of protection and so, save as many lives as we can.

"The NHS will be reiterating this advice to all vaccination centres, and all directors of public health, and I'm very, very grateful to everyone in the NHS, in local authorities and in the whole system supporting this vaccination programme for following it."

#### Should both vaccines be given in two doses? Can I just have one dose?

- 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.

 Further data on vaccine efficacy for the Oxford/AstraZeneca and Pfizer-BioNTech vaccines has been published by PHE showing how vaccines reduce severe Covid in older adults. (Full statement and research here).

#### New variants and vaccine effectiveness

#### Public Health England COVID-19 variants data published (06.08.21)

PHE has published the latest <u>Variant Technical Briefing</u>. It shows that delta is still overwhelmingly dominant across the UK, accounting for approximately 99% of cases. The briefing includes updated hospitalisation data for Delta, which shows that in the period since the last update (19 July to 2 August), 1,467 people were hospitalised with cases of Delta confirmed by sequencing or genotyping. Of these, 808 (55.1%) were unvaccinated, while 512 (34.9%) had received both doses of the vaccine. While vaccines provide high levels of protection, they are not 100% effective and will not stop everyone catching COVID. As more of the population gets vaccinated, we will see a higher relative percentage of vaccinated people in hospital.

The Technical Briefing also includes some initial findings which indicate that levels of virus in those with Delta who have been vaccinated, may be similar to levels found in unvaccinated people. This may have implications for people's infectiousness, whether they have been vaccinated or not. However, this is early exploratory analysis and further targeted studies are needed to confirm whether this is the case.

PHE has also published the <u>risk assessment</u> on VUI-21JUL-01, also known as B.1.621. VUI-21JUL-01 was designated a Variant Under Investigation on 20 July, based on apparent spread into multiple countries, as well as importation to the UK and mutations of concern, which include E484K, N501Y and K417N. These mutations have also been detected in other VUIs and VOCs. As of 4 August 2021, there were 37 confirmed VUI-21JUL-01 cases in England. Cases have been detected across six English regions, with most cases in London. Cases have also been reported in several other countries.

There is preliminary laboratory evidence to suggest that vaccination and previous infection may be less effective at preventing infection with VUI-21JUL-01. However, this data is very limited and more research is required. There is no evidence to suggest that VUI-21JUL-01 is more transmissible than the dominant Delta variant.

PHE has also published the weekly COVID-19 variant cases data.

Full statement

#### Vaccines highly effective against hospitalisation from Delta variant (14.06.2021)

New analysis by Public Health England (PHE) shows for the first time that two doses of the COVID-19 vaccines are highly effective against hospitalisation from the Delta (B.1.61.2) variant. The analysis suggests:

- The Pfizer-BioNTech vaccine is 96% effective against hospitalisation after 2 doses.
- The Oxford-AstraZeneca vaccine is 92% effective against hospitalisation after 2 doses.

These are comparable with vaccine effectiveness against hospitalisation from the Alpha variant. Further work remains underway to establish the level of protection against mortality from the Delta variant. However, as with other variants, this is expected to be high.

The analysis included 14,019 cases of the Delta variant – 166 of whom were hospitalised – between 12 April and 4 June, looking at emergency hospital admissions in England. PHE has <u>previously published analysis</u> showing that one dose is 17% less effective at preventing symptomatic illness from the Delta variant, compared to Alpha, but there is only a small difference after two doses.

**Health and Social Care Secretary Matt Hancock said:** "Our UK vaccination programme continues at pace and has already saved thousands of lives. It is our way out of this pandemic.

"This evidence of the effectiveness of two doses against variants shows just how crucial it is to get your second jab.

"If you have had your first dose but haven't booked your second yet - please do so. It will help save lives and boost us on the road to recovery."

**Dr Mary Ramsay, Head of Immunisation at PHE, said:** "These hugely important findings confirm that the vaccines offer significant protection against hospitalisation from the Delta variant.

"The vaccines are the most important tool we have against COVID-19. Thousands of lives have already been saved because of them.

"It is absolutely vital to get both doses as soon as they are offered to you, to gain aximum protection against all existing and emerging variants."

#### Link

## Do the [restrictions/measures] models take into account the new variant / escape variants?

- The models were constructed using the latest epidemiological data available, but do not take into account the risk of new variants of concern.
- We are working hard to ensure that our vaccine portfolio is resilient to new variants. This
  includes assessing the impact of new and future variants on the efficacy of the vaccines
  currently in our portfolio.
- There is currently no strong evidence that the existing vaccines will not work to a degree against new variants, particularly preventing serious illness and mortality. So the existing vaccine rollout is mission critical for tackling new variants.
- We will continue to monitor the picture with variants as it develops.

#### How likely is it that we have an escape variant that can overcome vaccine-induced immunity?

 The indications are that current vaccines still offer a level of protection against all variants currently in wide circulation and we are working with pharmaceutical companies to develop new vaccines.

If new variants are more likely to arise when prevalence is high, shouldn't we stay locked down until prevalence falls to protect the gains of the vaccination campaign?

 When determining the roadmap we have to balance the need to control the virus with the wider impact on people and their livelihoods. The number of people vaccinated continues

to rise rapidly and we expect the protection conferred by vaccines to help reduce prevalence over time even as restrictions are eased.

#### Do the current vaccines protect against the current variants / potential future ones?

- 1. Both the Pfizer/BioNTech and Oxford/AstraZeneca vaccines are safe and effective against the COVID-19 variants currently dominant in the UK. In terms of other variants, even if a vaccine demonstrates reduced effectiveness against other variants in preventing infection, there may still be protection against severe disease that can lead to hospitalisation and death. The continued rollout of the vaccine is therefore essential to save lives and to protect our NHS.
- Further data on vaccine efficacy for the Oxford/AstraZeneca and Pfizer-BioNTech vaccines has been published by PHE showing how vaccines reduce severe Covid in older adults. (Full statement and research here).

#### MHRA announcement on fast tracking covid variant vaccines. Full press notice

- Authorised COVID-19 vaccines that are modified in response to new variants will not need
  a brand new approval or "lengthy" clinical studies. The guidance, developed by the MHRA
  and its ACCESS partners, lays out what information the medicines regulators would need
  to approve any modifications to authorised COVID-19 vaccines, should virus mutations
  make them less effective at preventing the disease.
- Vaccine manufacturers would need to provide robust evidence that the modified vaccine produces an immune response, but time-consuming clinical studies that do not add to the regulatory understanding of a vaccines safety, quality or effectiveness would not be needed.
- The vaccine manufacturer would also be expected to provide evidence showing the
  modified vaccine is safe and is of the expected quality. In addition, data from the original
  robust clinical trials and the ongoing studies on real-world use in millions of
  people could be used to support any decision by the regulators.
- This approach is based on the tried and tested regulatory process used for seasonal flu vaccines, for which annual modifications are needed to match the strains circulating each year.
- MHRA chief executive Dr June Raine said: "We don't have evidence at this moment that any of the vaccines in deployment are significantly lacking in effectiveness. They're effective against Kent and we believe South Africa. We know that there has been some data from South Africa, we believe effectiveness here is maintained, and we're working hard on the Brazil variant. As of today there's no imperative that we fast-track a new variant-effective vaccine but we are prepared.
- Health Secretary Matt Hancock, said: "We will have a fast-track approach to safely approving future vaccines that work against a variant of Covid-19. The vaccine programme has clearly been a huge UK success story, and part of the reason that we have been able to develop the vaccines so far so quickly is because of the MHRA's rigorous yet flexible approach, which has been based entirely on looking as quickly as possible at the safety and efficacy of vaccines. I'm delighted that they're taking that same principled approach to the approval process for vaccines that may work against variants."

#### What is the UK doing to prevent future pandemics?

 The UK is leading on a global approach to preventing future pandemics. The UK's Five Point Plan sets out our ambitions for: a global network of zoonotic research hubs, increased research and development and manufacturing capacity for treatments and vaccines, improved horizon scanning and early warning systems, strengthened global protocols and guidance, and reduced trade barriers

## Vigilance, side effects and adverse incidents

#### Are there any side effects with Covid vaccines?

- Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, lasting no longer than a week, and not everyone gets them. These may include:
  - o a sore arm where the needle went in
  - o feeling tired
  - o a headache
  - feeling achy
  - o feeling or being sick
- The MHRA always considers side effects when assessing candidate vaccines for use.
- MHRA advice on blood clots resulting from the Oxford / AstraZeneca vaccine (07/04/2021)
  - MHRA's scientific review of UK reports of extremely rare and unlikely to occur specific blood clots with lowered platelets has concluded that the evidence of a link with COVID-19 Vaccine AstraZeneca is stronger but more work is still needed.
  - By 31 March 20.2 million doses of the COVID-19 Vaccine AstraZeneca had been given in the UK meaning the overall risk of these blood clots is approximately 4 people in a million who receive the vaccine
  - The data suggest there is a slightly higher incidence reported in the younger adult age groups and the MHRA advises that this evolving evidence should be taken into account when considering the use of the vaccine.
  - Vaccines are the best way to protect people from COVID-19 and have already saved thousands of lives. Everyone should continue to get their vaccination when asked to do so unless specifically advised otherwise.
  - Full statement
  - Update to JCVI advice to include all those under 40 to be given an alternative vaccine where possible (07.05.2021). <u>Full statement</u>
- 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.

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

• 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 many adverse reactions have there been?

- As of 8 September, an estimated 22.1 million first doses of the Pfizer/BioNTech vaccine and 24.8 million first doses of the COVID-19 Vaccine AstraZeneca had been administered, and around 18.6 million and 23.9 million second doses of the Pfizer/BioNTech vaccine and COVID-19 Vaccine AstraZeneca respectively. An approximate 1.4 million first doses and approximately 1 million second doses of the COVID-19 Vaccine Moderna have also now been administered.
- Up to and including 8 September 2021, the MHRA received and analysed 113,312 UK Yellow Cards from people who have received the Pfizer/BioNTech vaccine. These reports include a total of 320,570 suspected reactions (i.e. a single report may contain more than one symptom). The first report was received on 9 December 2020.
- Up to and including 8 September 2021, the MHRA received and analysed a total of 231,161
   UK reports of suspected ADRs to the COVID-19 Vaccine AstraZeneca. These reports include a total of 823,202 suspected reactions (a single report may contain more than one symptom). The first report was received on 4 January 2021.
- Up to and including 8 September 2021, the MHRA received and analysed a total of 15,565
   UK reports of suspected ADRs to the COVID-19 Vaccine Moderna. These include a total
   49,771 suspected reactions (a single report may contain more than one symptom). The
   first report was received on 7 April 2021.
- Full MHRA ADR Report

#### Dr June Raine. MHRA Chief Executive said:

"Our approved COVID-19 vaccines are safe and effective. Over 91m doses of vaccines against COVID-19 have now been administered in the UK, saving tens of thousands of lives through the biggest vaccination programme that has ever taken place in this country.

"No effective medicine or vaccine is without risk. Our advice remains that the benefits of the vaccine outweigh the risks in the majority of people. It is still vitally important that people come forward for their vaccination and for their second dose when invited to do so.

"We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the Coronavirus Yellow Card website."

#### 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.

## 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.
- 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.

#### 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.

#### Is the COVID-19 vaccine part of the Vaccine Damage Payments Scheme? (added 19/4/2021)

- The vaccine damage payments scheme (VDPS) covers all approved COVID-19 vaccines.
- There have been 32 applications relating to two vaccines currently being processed, with no payments made so far.
- Personal confidentiality regulations means we are unable to comment on individual cases.
- 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.
- To be eligible for VDPS applicants will need to prove, on the balance of probabilities that the vaccination caused the disability and be assessed as being 60% disabled.

- The VDPS is not a compensation scheme. Rather, it provides a one-off, tax-free lump sum-currently £120,000 for those suffering a severe disability as a result of a vaccine against a disease listed under the Vaccine Damage Payments Act.
- All claims must be filed within 6 years of receiving the vaccination in question. Time taken to assess a case varies depending on individual circumstances
- A list of existing diseases included within VDPS eligibility
- Full information on the VDPS and COVID-19 vaccine can be found

## Vaccines as a condition of deployment

Consultation on mandatory vaccination for frontline health and care staff (09.09.2021)

A consultation was launched today on protecting patients by mandating vaccination for frontline health and social care staff in England.

- Consultation launches today on making vaccination a condition of deployment for frontline workers in health and care settings
- Staff may be required to have COVID-19 and flu vaccines to protect patients from infection, serious illness or death
- 92% of NHS staff have had their first dose and 88% both doses of a COVID-19 vaccine, and Ministers urge remainder to take up offer now to keep themselves and those they care for safe

#### **Full Press Release**

Everyone working in care homes to be fully vaccinated under new law to protect residents (16.06.2021):

Care home residents will be better protected from death and serious illness, following confirmation people working in care homes will need to be fully vaccinated against COVID-19.

The new legislation means from October – subject to parliamentary approval and a subsequent 16-week grace period - anyone working in a CQC-registered care home in England for residents requiring nursing or personal care must have two doses of a COVID-19 vaccine unless they have a medical exemption.

It will apply to all workers employed directly by the care home or care home provider (on a full-time or part-time basis), those employed by an agency and deployed by the care home, and volunteers deployed in the care home.

Those coming into care homes to do other work, for example healthcare workers, tradespeople, hairdressers and beauticians, and CQC inspectors will also have to follow the new regulations, unless they have a medical exemption.

The responses to the consultation made a case for extending this policy beyond care homes to other settings where people vulnerable to COVID-19 receive care, such as domiciliary care and wider healthcare settings.

Based on this evidence, the government will launch a further public consultation in due course on whether or not to make COVID-19 and flu vaccination a condition of deployment in health and

care settings. This is a complex issue and the government is looking for a wide range of perspectives from across the health and care sector about whether this should be introduced and how it could be implemented.

#### Full press notice

#### Health and Social Care Secretary, Matt Hancock said:

"Vaccines save lives and while staff and residents in care homes have been prioritised and the majority are now vaccinated we need to do everything we can to keep reducing the risk.

"Through our consultation we have listened to the experiences and concerns of providers and people living and working in care homes to help shape our approach.

"We have a responsibility to do all we can to safeguard those receiving care including in the NHS and so will be consulting further on whether to extend to other health and social care workers.

"This is the right thing to do and a vitally important step to continue protecting care homes now and in the future. I'd urge anyone working in care homes to get their jab as soon as possible."

There will be exceptions for visiting family and friends, under 18s, emergency services and people undertaking urgent maintenance work.

Data from <u>Public Health England</u> indicates the COVID-19 vaccination programme has so far prevented 14,000 deaths and around 42,000 hospitalisations in older people in England (up to 30 May).

The new regulations follow an extensive consultation with the social care sector, staff, residents and their families on the issue.

## **BAME** uptake

#### NHS Covid 'Grab-A-Jab' Initiative Boosts Ethnic Minority Vaccinations (28.08.21)

The NHS Covid vaccination programme has protected more than 700,000 people from ethnic minority backgrounds since rolling out the Grab-A-Jab campaign.

An analysis of one Grab-A-Jab weekend in July found that 2 in 5 of the 80,000 walk-in doses administered were to people from ethnic minority groups, significantly more than the proportion in the wider community.

People have been able to turn up and 'grab a jab' at festivals, mosques, town halls, football grounds and other convenient sites since the campaign began earlier this summer.

The fastest growth in vaccinations was from people of mixed Asian and white backgrounds between 20th June and 22nd August, with numbers growing by a quarter from 81,000 to 101,000, closely followed by mixed white and Black African groups.

There was also a significant increase in people from Black communities getting the jab with 142,000 people receiving their first dose of the life-saving vaccine. More than 3 in 5 of those were Black African, with the number of people getting a first dose increasing by 20.9%. Meanwhile, the increase in vaccinations among white people was 11.1%.

#### What is the Government doing to increase uptake among BAME communities?

- COVID-19 vaccines are the best way to protect people from coronavirus and have saved more than 100,000 lives in the UK alone.
- DHSC and the NHS provide advice and information at every opportunity to those eligible, including how to get a vaccine and its benefits. Vaccines are only authorised for use if they have met the medicines regulator's strict standards of safety, quality and effectiveness.
- We are working with faith and community leaders to increase vaccine uptake, holding regular meetings to discuss the best ways to provide advice and information to their communities
- Vaccination uptake varies; however, initial data suggests that uptake amongst people on lower incomes and ethnic minorities is lower than for other groups. Weekly statistics on people vaccinated by ethnicity is available here: (https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/)
- The NHS continues to improve the detail and regularity of the data supplied to local authorities. We aim to publish even more granular data on those vaccinated in due course. We take our transparency obligations very seriously and are working with our colleagues at PHE and NHS England to ensure our data reporting is as accurate and robust as possible.
- We recognise the importance of raising awareness of the benefits of vaccination within Black, Asian and minority ethnic (BAME) communities who are known to be more at risk from COVID-19. We have met with faith leaders and the Moral and Ethical Advisory Group (MEAG), on COVID-19 immunisation and sought consideration of how best to clearly communicate about the benefits of the vaccine.
- We published a vaccine uptake plan on 13 February which outlines how we're working with local communities to boost vaccine uptake.
- Our communications include information and advice via TV, radio and social media. This
  has been translated into 13 languages including Bengali, Chinese, Filipino, Gujarati, Hindi,
  Mirpur, Punjabi and Urdu. Print and online material, including interviews and practical
  advice has appeared in over 600 national, regional, local and specialist titles including
  BAME media for Asian, Bangladeshi, Bengali, Gujarati and Pakistani communities.
- The Government is expanding the community champions scheme so that communities have trusted local leaders who can help answer questions about the vaccine and work with the NHS and public health teams to support local communities. £23 million funding has been allocated to 60 councils and voluntary groups across England to expand work to support those most at risk from COVID-19 and boost vaccine take up.
- Recognising that accessibility can be a factor, the NHS is supporting the work of local
  vaccination services such as a mobile facility for people who cannot leave their home to
  ensure that people with either seen or unseen disabilities can access a vaccine safely and
  easily when it is their turn. It is also taking steps to promote vaccine uptake among those
  caring for some of the most vulnerable in our society, including health and social care
  staff, and continues to monitor how effective these measures are.

#### Increasing take-up in BAME groups (Vaccine Uptake Plan 13 February 2021)

• New vaccine update plan published on 13 February to boost vaccine uptake in all communities, based upon local initiatives already in place that are successfully boosting uptake. The plan came ahead of 15 February target date to give all top 4 priority groups their first jabs.

#### **Working with BAME communities**

- Vaccines are the best way to protect people from coronavirus and will save thousands of lives. We want every eligible person to benefit from the offer of a free vaccine, no matter their ethnicity or religious beliefs.
- The Department of Health and the NHS are working closely with Black, Asian, and minority ethnic communities to support those receiving a vaccine and help anyone who may have questions about the vaccination process.
- As part of this we're working with faith and community leaders to give them advice and information about the universal benefits of vaccination and how their communities can get a vaccine.
- We are investing a huge amount of time and effort to strengthen the partnership between central and local government and to bring communities closer together in this effort.
- The Government is expanding the community champions scheme so that communities have trusted local leaders who can help answer questions about the vaccine and work with the NHS and public health teams to support local communities.
- We are working with faith leaders, grassroots organisations representing our diverse communities and charities and have listened to their ideas about how we can protect our communities from coronavirus and get vaccines to as many people as possible
- £23 million funding has been allocated to 60 councils and voluntary groups across England to expand work to support those most at risk from COVID-19 and boost vaccine take up,
- Through the **Community Champions scheme** councils and voluntary organisations will deliver a wide range of measures to communicating accurate health information.
- The funding is specifically targeted at areas with plans to reach groups such as older people, disabled people, and people from ethnic minority backgrounds who according to the latest evidence are more likely to suffer long-term impacts and poor outcomes from COVID-19. Each of the sixty councils have developed their own plan to improve communications with these groups including helplines, school programmes, workplace engagement, phoning those in at risk groups as well as training sessions to help people provide information and advice.
- The Community Champions will tap into their local networks to provide advice about COVID-19 and the vaccines. Champions will also work with councils to identify barriers to accessing accurate information and to provide tailored support, such as phone calls for people who are digitally excluded, helplines, and linking to GP surgeries.

Employers unite to encourage over a million staff to get the COVID-19 vaccine (14.05.2021).

Leading employers across the UK including Asda, IKEA and Santander come together to encourage their staff to get the COVID-19 vaccine when eligible. Many businesses have pledged their flexibility to help staff get the vaccine during work hours. Government is calling on all businesses, organisations and industry bodies to make a similar commitment to drive vaccine uptake across the UK

Link to statement

Link to toolkit

### COVID-Status certification review (so-called 'vaccine passports')

#### **NHS Covid Pass:**

**Extracts from Minister Zahawi Oral Statement updating on the vaccines programme (22 July 2021):** "Mr Speaker, this week, after a successful trial, we have rolled out the NHS Covid Pass. This allows people, safely and securely, to demonstrate their COVID status whether it's proof of vaccination status, test results or natural immunity. Anyone can access a Pass via the NHS app on the NHS website or by calling 119 and asking for a letter to demonstrate vaccine status. People will also be able to demonstrate proof of a negative test result.

"Although we don't encourage its use in essential settings, like supermarkets other businesses and organisation in England can adopt the Pass as a means of entry where it's suitable for their venue or premises and when they can see its potential to keep their clients or their customers safe. But for proprietors of venues and events where large numbers are likely to gather and likely to mix with people from outside their households for prolonged periods deploying the Pass is the right thing to do.

"The Pass has an important role to play in slowing the spread of the virus and so we reserve the right to mandate its use in the future.

#### Vaccination as a condition of entry:

"Next, Mr Speaker, I'd like to update the House on vaccination as a condition of entry.

"We all know the benefits that both doses of a vaccine can bring. Data from Public Health England estimates that two doses of a Covid-19 vaccine offers protection of around 96 per cent against hospitalisation. And today Mr Speaker we have new data from PHE that estimates the vaccination programme in England alone has prevented 52,600 hospitalisations that's up 6,300 from two weeks ago.

"A fitting example, I am sure you will agree Sir, of the protective wall that our vaccination programme has given us – a wall that's getting stronger every day. It's this protection that's allowed us to carefully ease restrictions over the past few months but we must do so in a way that's mindful of the benefits that both doses of the vaccine can bring.

"This strategy, this philosophy has underpinned our approach over these critical next few months.

"This week, as part of our Step 4 measures, we allowed fully vaccinated adults — and all children — to return from amber listed countries without quarantine with the exception of France, due to the persistent presence of cases of the Beta variant. From the 16th of August, children under 18 and people who are fully vaccinated will no longer need to self-isolate as contacts, given their reduced risk of catching and passing on the disease

"And as I updated the House on Monday, at the end of September we plan to make full vaccination a condition of entry to those high risk settings where large crowds gather and interact. By this point everyone aged 18 and over will have had the chance to be fully vaccinated and so everyone will have that opportunity to gain the maximum possible protection.

"So, as a condition of entry to these venues, people will need to show that they are fully vaccinated and proof of a negative test will no longer be sufficient.

"This is not a step that we take lightly, Mr Speaker. But all throughout this pandemic — just like Governments all across the world, whether it's Singapore or Australia or Germany and France, we've had to adapt our approach to meet the threat of this deadly virus. And this is no different. But we will always keep these measures, like all our measures, under review with the goal of returning to the freedoms that we love and cherish."

#### Link to full statement

#### Self-isolation to be eased for fully vaccinated adults in Step 4 (06.07.2021)

From 16 August, double jabbed individuals and under 18s will no longer need to self-isolate if they are identified as a close contact of someone with COVID-19.

Contacts of a positive case will continue to be asked to take a PCR test to detect COVID-19 and help manage variants of concern.

#### Full release

Health and Social Care Secretary Sajid Javid told Parliament: "Asking people with COVID-19 and their close contacts to self-isolate has played a critical role in helping us get this virus under control, and I'm so grateful to the millions of people across the UK who have made sacrifices to keep the virus at bay.

"Thanks to the UK's phenomenal vaccine programme and the huge wall of defence, we can safely take steps to reduce self-isolation for people who are fully vaccinated, and those aged under 18, and instead advise people to take a PCR test. Positive cases will still need to self-isolate.

"Step-by-step, and jab-by-jab, we're replacing the temporary protection of the restrictions, with the long-term protection of a vaccine."

## Vaccine Passports, International Travel

## <u>Quarantine-free travel to resume on 19 July for fully vaccinated passengers returning from</u> amber list countries (08.07.2021)

On 8 July the Government set out the details to enable people who have been fully vaccinated with an NHS administered vaccine, plus 14 days, to travel to amber list countries without having to quarantine on their return to England, from Monday 19 July. The recommendation for people not to travel to amber list countries was also removed from 19 July.

Those who have been fully vaccinated with an NHS administered vaccine in the UK and are returning from amber countries will still be required to complete a pre-departure test before arrival into England, alongside a PCR test on or before day 2 after arrival. They will not have to take a day 8 test or self-isolate. Any positive results will be genomically sequenced to continue to manage the risk from importing variants.

#### Full news story

**Transport Secretary, Grant Shapps said:** "Thanks to our successful vaccine rollout, we're now able to widen quarantine-free travel to NHS administered fully vaccinated adults and children under the age of 18, and take another step towards fully reopening international travel.

"As we continue with the domestic unlocking, it's only right we get people travelling again - whether that's for business to help create jobs, overdue holidays or reconnecting family and friends. However, protecting public health still remains our priority and we will act swiftly if action is needed."

**Health Secretary, Sajid Javid said**: "Vaccinations have severely weakened the link between COVID-19 cases, hospitalisations and deaths, building a wall of protection across the country.

"As we learn to live with this virus, due to the tremendous progress of the vaccine programme - with more than 3 in 5 people now double jabbed - we can safely take steps to ease restrictions on travel, as we are doing at home. Allowing quarantine-free travel for fully vaccinated people means they can be reunited with loved ones overseas and we can return to normality as quickly as possible."

#### Demonstrating your COVID-19 vaccination status when travelling abroad (11/05/2021)

- Demonstrating your COVID-19 vaccination status allows you to show others that you've had a full course of the COVID-19 vaccine when travelling abroad to some countries or territories.
- A full course is currently 2 doses of any approved vaccine.
- COVID-19 vaccination status is available to people who live in England.
- You can get your vaccination status in digital or paper format.
- Further guidance on COVID-19 vaccination status

#### **Clinical trials**

#### **Human Challenge**

- Researchers call on healthy young people to volunteer for the study, which will play a key role in developing effective Covid-19 vaccines and treatments
- Up to 90 volunteers aged 18 30 years will be exposed to Covid-19 in a safe and controlled environment to increase understanding of how the virus affects people
- Human Challenge Programme begins (08/03/2021)
- The Human Challenge study (HCP) begins, with the volunteers entering quarantine at the Royal Free for a fortnight. They will be injected with the virus on Monday 8/3/2021.
- The doctors/scientists there will then closely monitor them over the fortnight to see how
  the symptoms develop, and they will be able to leave quarantine around 23 March. Over
  this time, the scientists will be establishing the smallest amount of virus needed to cause
  infection, which will give doctors greater understanding of COVID-19 and help support the
  pandemic response by aiding vaccine and treatment development.
- A Department of Health and Social Care spokesperson said: "The Human Challenge Programme will improve and accelerate the development of vaccines and treatments against COVID-19, and the first group of volunteers have now started the virus characterisation study at the Royal Free Hospital in London. These carefully selected adults will be exposed to the virus in a safe and controlled environment, with medics and scientists on hand to monitor and look after them 24 hours a day."



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

#### **COVID-19 vaccine ingredients**

- A full list of ingredients for the qualitative and quantitative composition of the vaccine can be found at point 2 in the <u>Information for Healthcare Professionals of COVID-19 Vaccine</u> <u>AstraZeneca</u>.
- 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.

## Do the vaccines contain animal products? What engagement has DHSC had with faith/vegetarian/vegan groups on vaccine components?

- The MHRA has confirmed that the COVID-19 Vaccine AstraZeneca and Pfizer/BioNTech COVID-19 vaccine do not contain any components of animal origin.
- We have met with faith leaders and the Moral and Ethical Advisory Group (MEAG), on COVID-19 immunisation and sought consideration of how best to clearly communicate about potential COVID-19 vaccines candidates.

#### Do the vaccines contain foetal material?

- No foetal material is present in the final vaccine; it is all removed during the manufacturing process.
- Some vaccines are made by growing cultures of the target virus (including modified viruses such as found in the AstraZeneca vaccine) in cells and so some vaccines can be grown in cell-lines derived from mammals, including humans. Such cell lines used to grow the virus are derived from a primary culture of cells from an organ of a single animal which has then been propagated repeatedly in the laboratory, often over many decades.
- The best-known human cell line is MRC5. These cells derive from a pregnancy that was terminated for medical reasons in 1966. This cell-line is used to grow viruses for vaccines against rubella, chickenpox and hepatitis A. Other foetal cell lines have been used for other vaccines, including influenza vaccine and some of the new COVID-19 vaccines.
- The HEK293 cell line which is used in the manufacture of the AstraZeneca vaccine was derived in Holland from a single aborted foetus in the early 1970s.
- The issues around the use of vaccines grown on foetal cell lines have been discussed
  within the Catholic church. In 2017, the Pontifical Academy for Life in Rome issued a
  statement that said: "We believe that all clinically recommended vaccinations can be used
  with a clear conscience and that the use of such vaccines does not signify some sort of
  cooperation with voluntary abortion." <a href="http://www.academyforlife.va/content/pav/en/the-academy/activity-academy/note-vaccini.html">http://www.academyforlife.va/content/pav/en/the-academy/activity-academy/note-vaccini.html</a>
- The Catholic church re-confirmed this position in a statement in December 2020 clarifying
  the original statement as follows: "When ethically irreproachable Covid-19 vaccines are
  not available (e.g. in countries where vaccines without ethical problems are not made
  available to physicians and patients, or where their distribution is more difficult due to
  special storage and transport conditions, or when various types of vaccines are
  distributed in the same country but health authorities do not allow citizens to choose the

vaccine with which to be inoculated) it is morally acceptable to receive Covid-19 vaccines that have used cell lines from aborted foetuses in their research and production process".

## Pregnancy, childbirth, fertility

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered the COVID-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group.

Data shows that vaccines are effective in protecting people from serious illness from COVID-19. Though uncommon, severe illness due to COVID-19 is more likely in later pregnancy. Pregnant women who do get symptomatic COVID-19 infection are 2 to 3 times more likely to give birth to their baby prematurely.

Figures released in July showed that no pregnant women with both doses of the vaccine had been admitted to hospital.

Since May, just three women had been admitted after having their first vaccine. In contrast, almost all (98%) pregnant women admitted to hospital with COVID-19 had not been jabbed.

There have been no specific safety concerns identified with any brand of COVID-19 vaccines in relation to pregnancy.

Real-world data from the United States show that around 90,000 pregnant women have been vaccinated, mainly with mRNA vaccines including Pfizer-BioNTech and Moderna, without any safety concerns being raised.

Based on these data, the JCVI advises that it is preferable for pregnant women in the UK to be offered the Pfizer-BioNTech or Moderna vaccines where available. There is no evidence to suggest that other vaccines are unsafe for pregnant women, but more research is needed.

Women who are planning pregnancy, are in the immediate postpartum, or are breastfeeding can be vaccinated with any vaccine, depending on their age and clinical risk group.

#### Can women who are trying to conceive have the vaccine?

• Those who are trying to become pregnant do not need to avoid pregnancy after vaccination. The UK Chief Medical Officers agree with this advice.

#### Does the Covid-19 vaccine affect fertility?

- There is no evidence that the vaccine affects fertility. The theory that immunity to the spike protein could lead to fertility problems is not supported by evidence. Most people who contract COVID-19 will develop antibody to the spike and there is no evidence of fertility problems after Covid-19 disease.
- Read the latest advice from the Royal College of Obstetricians and Gynaecologists: <a href="https://www.rcog.org.uk/covid-vaccine">https://www.rcog.org.uk/covid-vaccine</a>
- The RCOG has prepared this <u>information sheet</u> to help pregnant women who are eligible for and have been offered vaccination make an informed choice. Please also read the RCOG Q&As on COVID-19 vaccination, pregnancy and breastfeeding.

 Public Health England has produced <u>advice in a range of formats for pregnant</u>, breastfeeding and women of childbearing age.

#### New study into COVID-19 vaccine dose interval for pregnant women (03.08.2021)

Extensive real-world data shows vaccines are safe and highly effective for pregnant women.

- New government-funded clinical trial investigating best coronavirus (COVID-19) vaccine dose interval for pregnant women launched in England
- Research shows pregnant women more likely to become seriously ill from COVID-19 and 98% of those in hospital due to COVID-19 are unvaccinated

The country's largest clinical trial investigating the best gap between first and second COVID-19 vaccine doses for pregnant women is being launched in England today (Tuesday 3 August).

Following 130,000 pregnant women being vaccinated in the US and no safety concerns being raised, the Pfizer/BioNTech and Moderna vaccines were recommended by the independent experts at the Joint Committee on Vaccination and Immunisation (JCVI) for pregnant women in the UK. Almost 52,000 pregnant women in England have now been vaccinated – similarly, with no safety concerns reported.

Minister for COVID-19 Vaccine Deployment Nadhim Zahawi said: "Pregnant women are more likely to get seriously ill from COVID-19 and we know that vaccines are safe for them and make a huge difference – in fact no pregnant woman with 2 jabs has required hospitalisation with COVID-19.

"This government-backed trial will provide more data about how we can best protect pregnant women and their babies, and we can use this evidence to inform future vaccination programmes.

"I encourage anyone who is pregnant and eligible to sign up and contribute to research that will save lives for years to come."

Full press release

#### NHSE Release: Chief midwife urges pregnant women to get NHS Covid jab (30.07.21)

England's top midwife is urging expectant mums to get the COVID-19 vaccine after new data shows the overwhelming majority of pregnant women hospitalised with the virus have not had a jab.

The new figures, released today, also reveal that no pregnant women with both doses of the vaccine had been admitted to hospital.

Since May, just three women had been admitted after having their first vaccine. In contrast, almost all (98%) pregnant women admitted to hospital with COVID-19 had not been jabbed.

Jacqueline Dunkley-Bent, Chief Midwifery Officer for England, has written to fellow midwives and GP practices across the country stressing the need to encourage pregnant women to get the jab to protect them and their baby.

Full press release

#### Health chiefs encourage more pregnant women to get their COVID-19 vaccine (22 July 21)

Health chiefs are encouraging more pregnant women to come forward for their COVID-19 vaccine, as new data from Public Health England (PHE) show for the first time that 51,724 pregnant women in England have received at least one dose.

These were all women aged under 50 years of age, who reported that they were pregnant or could be pregnant at the time of receiving the vaccine. Of these, 20,648 women have received their second dose.

Full release

#### JCVI issues new advice on COVID-19 vaccination for pregnant women (16/04/2021)

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that pregnant women should be offered the COVID-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group.

Full release

### Vaccine hesitancy, misinformation, disinformation

#### (Updated 27.08.21)

- The Government takes the issue of disinformation very seriously.
- Giving the public accurate information about coronavirus is more important than ever as we battle this disease.
- During times of uncertainty, particularly in this national crisis, people understandably look to the Government to provide authoritative sources of information.
- That's why DCMS is leading work across Government to tackle disinformation and misinformation relating to Covid-19.
- The Cross-Whitehall Counter Disinformation Unit was stood up on 5 March 2020, bringing together cross-Government monitoring and analysis capabilities. Its primary function is to provide a comprehensive picture of the extent, scope and the reach of disinformation and misinformation linked to Covid-19, and to work with partners to stamp it out.
- It is essential that people are able to access accurate information about COVID-19 and the vaccine to ensure they are able to make informed decisions about their health.

#### Is enough being done to tackle vaccine hesitancy?

By <u>reassuring</u> through promoting authoritative information. Across Government we are spending £10s of millions on public health communications, and you will have seen a significant increase in public vaccine communications. The NHS website remains the most trusted health website.

By <u>rebutting</u> false information especially where the intent is malicious or dangerous to public health. We have the full power of Whitehall behind this brought together by the Counter

Disinformation Unit - there are hundreds of analysts and communications officials supporting this effort, including the Rapid Response Unit.

By making sure platforms play their part by <u>removing</u> posts. They must not profit from anti-vax material and we expect them to respond within 48 hours setting out what steps they are taking. If they fail to deliver on their promises, I will not rule out further Government intervention.

#### What is HMG doing to respond to COVID-19 vaccine disinformation and misinformation?

Vaccine misinformation is harmful and it is everyone's responsibility to access information from authoritative sources and not share false or misleading information.

Since the start of the pandemic, specialist government units [DN: The Counter Disinformation Unit] have been working at pace to identify and rebut false information about coronavirus.

It is essential that people are able to access accurate information about COVID-19 and the vaccine to ensure they are able to make informed decisions about their health.

We are also working closely with social media platforms to help them identify and take action to remove incorrect claims about the virus in line with their terms and conditions, including false information that could endanger people's health.

An effective vaccine is the best way to protect the most vulnerable from coronavirus and the biggest breakthrough since the pandemic began, potentially saving thousands of lives.

As we go on with the rollout of the coronavirus vaccine, we will continue to provide clear information to the public and urge people to seek NHS advice so they have the right information to make an informed choice.

## **Community Champions scheme**

(updated 25/01/2021)

- The expansion of the Community Champions scheme will help everyone get the advice and information they need about COVID-19 vaccines.
- £23 million funding has been allocated to 60 councils and voluntary groups across England to expand work to support those most at risk from COVID-19 and boost vaccine take up.
- Through the Community Champions scheme councils and voluntary organisations will deliver a wide range of measures to communicating accurate health information.
- The funding is specifically targeted at areas with plans to reach groups such as older people, disabled people, and people from ethnic minority backgrounds who according to the latest evidence are more likely to suffer long-term impacts and poor outcomes from COVID-19. Each of the sixty councils have developed their own plan to improve communications with these groups including helplines, school programmes, workplace engagement, phoning those in at risk groups as well as training sessions to help people provide information and advice.
- The Community Champions will tap into their local networks to provide advice about COVID-19 and the vaccines. Champions will also work with councils to identify barriers to accessing accurate information and to provide tailored support, such as phone calls for people who are digitally excluded, helplines, and linking to GP surgeries.