

A Letter From the CEO

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Christmas will be strange this year because of the restrictions that we all face. With the ongoing challenge of the pandemic it is important that we all are able to have time off and share some time with our families.

There have been concerns that NHS England would require practices to work over the Christmas period. NHS England have indicated in their [primary care bulletin](#) this week, that general practices are not expected to open for delivery of core services over the weekend and Bank Holidays for this coming Christmas and New Year period. Local commissioners and primary care providers can therefore continue to plan on the basis of their planned cover arrangements.

At the start of the pandemic we were asked to introduce a system of total triage to protect patients, our communities and all who work in general practice. All too often this is perceived by patients as the practice being 'closed' and this is reflected in negative comments about access.

To support general practice, the NHS England has created [an animation to help explain to the public how they can continue to access GP services](#), including how to get in contact, the different ways care may be delivered, and how face-to-face appointments have changed.

If you think this would be helpful consider sharing this animation with your patients.

Stay well and stay safe.



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Covid-19 Vaccination



The great news this week was that the Pfizer BioNTech vaccine has been licensed by the UK Regulator (MRHA) with other vaccines waiting for approval.

The UK has received 800,000 doses of the Pfizer BioNTech vaccine and the distribution of these has already started. Initially the vaccine will go to hospital vaccination hubs to immunise the over 80s who are attending the hospital out-patients, selected in-patients, hospital staff and local care homes staff. This will be followed by the community vaccination centres which are based in PCN groupings.

The response from general practice in Wessex has been fantastic. Despite the enormity of the task ahead and the fast pace that this is taking place which inevitably means that things change and a number of things are not yet available. It truly shows that general practice will rise to the challenge and find solutions even in difficult and uncertain times and this is a great tribute to the professionalism, dedication and commitment from GPs, Practice Managers and all general practice staff.

Give us the tools, the resources and flexibility - we can deliver and have done so many times.

The Enhanced Service Specifications for the Covid Vaccination Programme (CVP), has been re-published to include modifications following discussion with MHRA and to ensure patients from non-participating practices can be provided vaccinations. [Click here](#) to view this document.

There is also a letter that responds to the issues raised by practices and highlighted at the recent LMC England conference. This does though continue to be a very fluid and fast changing situation as more information becomes available about vaccine availability and the logistics of delivery. NHS England have provided further information, including details on the first wave of vaccinations and a collaborative agreement.

All details can be seen if you [click here](#).

The community vaccination centres based in PCN groupings and delivered by general practice will start vaccinating their population from the 15th December. Initially this will be 280 PCN Groups (Wave 1) which have been selected based on a number of criteria including the number of patients over 80, ability to start vaccination at short notice and ensuring a fair and equitable distribution.

The LMC considers the Wave 1 sites as the early adopters and these should be supported to identify and solve any problems rapidly as we expect all PCN Groups to follow rapidly.

These initial sites should receive a box of 975 Pfizer BioNTech vaccines on or close to 14th December, to enable them to start vaccinating from the following day. Following the regulatory requirements set by MHRA they will need to use the vaccine within 3.5 days, not the previously suggested 5 days, and so need to ensure patients are invited to attend within that timescale.

Patients will need to be offered a second appointment 28 days later for their second vaccination. Vaccines are being held back nationally to ensure they are available to provide this second dose. For the Pfizer BioNTech Vaccine the gap between the first and second vaccine must be a **minimum** of 21 days and will normally be 28 days which is what we believe will be the required for AstraZeneca vaccine.

NHS England will be writing to sites identified as part of Wave 1 on Monday, setting out full details of vaccine supply dates, delivery of other consumables and equipment to the site, and the process for assuring readiness before delivery of vaccines.

This will include a delivery of IT equipment necessary to deliver the programme and a fridge and freezer for each site. Access to necessary training will be provided and sites will be given full support to mobilise within the timescale.

There has been early confirmation that Pfizer BioNTech vaccine can be moved sites up to twice in any 12 hour period, once thawed. It is still preferable not to move it. This makes it suitable to be transported undiluted and used in a care home. The Pfizer vaccine cannot be moved once it is diluted, so this will not be suitable for the housebound because of the potential waste. .

Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine - GOV.UK (www.gov.uk) - [click here](#).

The **COVID-19 Vaccination Collaboration Agreement** has been published recently and can be found [here](#). This is designed to support the delivery of the CVP by setting out the responsibilities and relationships between collaborating practices. GPC England has had legal support to scrutinise the document and is satisfied that it is fit for purpose, being in line with other similar collaboration agreements already in place.

Public Health England (PHE) has published [Guidance for healthcare professionals delivering the COVID-19 vaccine](#). This includes information about the vaccines (as they become available), vaccine recommendations and eligibility, contraindications and precautions, and vaccine administration issues.

PHE has also published a [new COVID-19 chapter in the Green Book](#) which has guidance on the vaccine, provisional priority groups, advice on high risk groups and on potential adverse effects, which current evidence suggests are mild and short-term.

GPC guidance on the COVID-19 vaccine programme

The [GPC's guidance page about the COVID-19 vaccination programme](#) has been updated to and has FAQs throughout to answer questions from practices. This is updated regularly, as and when new information becomes available, so please refer back to this guidance page.

The GPC has also published [guidance on how practices can utilise extra workforce](#) to deliver the COVID-19 vaccine programme.

Members of staff already qualified to provide vaccinations are likely to be the main part of the workforce administering vaccine in general practice, and most of the programme should be delivered by staff other than GPs, who will be more useful in other areas.



What do we know about the Pfizer BioNTech Vaccine?

This is a non-amplifying mRNA vaccine which is very different from the Flu vaccine.

At any single moment a human cell has 5000+ different RNA messages, and they are all temporary messages, like post-it notes that get torn up by the cells within minutes or hours after being read, or like snapchat messages that expire.

RNA vaccines do NOT and more importantly CANNOT become a permanent part of your body. They are temporary messages instructing cells to make one viral protein temporarily.

In RNA COVID-19 vaccines, the non-replicating RNA message is for 1 single coronavirus protein. It takes 25 different coronavirus proteins to make a coronavirus, so there is no worry about the vaccine RNA making a virus.

Over 70,000 doses of COVID-19 RNA vaccines have been given to people now in clinical trials, and the independent safety boards (not controlled by the companies) have reported no serious concerns. The FDA/EMA/MHRA will also review all the immunogenicity and safety data prior to providing market authorisation.

"Safe" does not mean "did not hurt at all" or "no fever" – while designed to mimic human RNA, an immune reaction is designed to occur – so like sore muscles after exercise a bit of pain can be a positive sign that good things are happening.

Primary efficacy analysis demonstrates Pfizer BioNTech vaccine to be 95% effective against COVID-19 beginning 28 days after the first dose. They have over 43,000 people have taken part in their trials and the vaccine was shown to be well tolerated in all age groups with no serious safety concerns. The minor side effects were fatigue in 3.8% of people and headache in 2%. During the trial 170 people who were vaccinated developed Covid-19, 162 of these were in the placebo group and only 8 in the Covid-19 vaccinated group.

What do we know about the AstraZeneca Vaccine?

This is a non-replicating adenoviral vector vaccine. It is expected that this will be the second Covid-19 vaccine to be licensed and hopefully that will take place in the near future.

In trials this vaccine was shown to be 90% effective if given a half dose first then followed 28 days later by a full dose. If the same dose was given then the effectiveness was only 62%. The experts report that it is not uncommon in vaccinations to see this sort of effect. It should be remembered that the Flu vaccination is only 40-60% effective.

There is a large safety database from over 24,000 volunteers from clinical trials in the UK, Brazil and South Africa, with follow up since April.

There were no hospitalised or severe cases in anyone who received the AstraZeneca vaccine.

Early indication suggests that the vaccine could reduce transmission from an observed reduction in asymptomatic infections.

Crucially, this vaccine can be easily administered in existing healthcare systems, stored at 'fridge temperature' (2-8°C) for up to 6 months, with no restrictions on transport.

Which vaccine should I have?

This is the advice from Professor Saul Faust, Consultant Paediatric Immunologist at University Hospital Southampton and the Lead for the Southampton arm of the Oxford AstraZeneca Covid Vaccination Trial.

1. Any deployed vaccine will have been fully evaluated by the MHRA. The main uncertainties are not about safety (but about how long immunity will last, how often vaccines should be given, how well they work in different groups eg elderly, immunosuppressed, children, pregnant women etc)
2. There is/will be a media frenzy.... if we as health care professionals hesitate so will everyone else.
3. Please take the first vaccine offered to you! (he says he will take the first vaccine offered to him and I certainly will be doing the same).

Saul gave an excellent presentation about Covid vaccinations at our recent New Update to watch his presentation - [click here](#).

Guidance for clinically extremely vulnerable people

This week lockdown has ended and been replaced by a three-tiered system.

Due to this, the Government has sent a [letter](#) this week with updated guidance to all clinically extremely vulnerable (CEV) people on the Shielded Patient List.

In each tier, there is a set of rules that everyone in that area must follow. The letter, which sets out the new guidance, no longer advises CEV people to stay away from work or school, but does suggest limiting the number of social interactions.

Read the government's [guidance for clinically extremely vulnerable people at each local tier](#).

The DHSC has also announced that people on the CEV list and those in residential and nursing care homes will receive [free winter supply of Vitamin D](#) to help support general health, in particular bone and muscle health, during the winter months, which is even more important for those that have been shielding and may not have been able to obtain enough vitamin D from sunlight.

NHS Digital has [published letter templates](#) for high-risk patients for use by GPs when notifying patients newly identified as clinically extremely vulnerable from COVID-19. The GPC have also updated their [guidance about clinically extremely vulnerable people](#).



Legal mechanism for the administration of the vaccine

A document produced by NHS England outlines the legal mechanism for the administration of COVID-19 vaccines that explains why a Patient Specific Direction (PSD) will be required in the short-term - [click here](#) for the full document.



A vaccine is a prescription only medicine and can therefore only be supplied to patients if one of the four instructions are in place:

1. A prescription.
2. A Patient Specific Direction (PSD).
3. A Patient Group Direction (PGD).
4. A National Protocol.

Currently we do not have a PGD or a national protocol in place, we hope that the PGD will be produced before general practice start vaccinating on the 15th December but in case that is not the case, for Wave 1- early adopters there needs to be a mechanism put in place to allow the programme to commence.

It is therefore proposed that the PSD mechanism, based on the framework agreed paper referred to above, is used to prescribe the vaccine until the national PGD/national protocol is available. This will provide a legal mechanism for the administration of the vaccine as a short-term interim measure.

This is not a viable long term solution but is the pragmatic way we can start the vaccination programme(we are pushing to get the PGD made available ASAP) because:

1. The prescriber needs to be a Medical Practitioner, Independent Nurse or Pharmacist prescriber - who are trained and experienced in vaccination.
2. A Prescriber will need to give an authorised instruction to administer a medicine to a list of individually named patients where each patient on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of the patient's health and be satisfied that the medicine to be administered serves the individual needs of each patient on that list.
3. There is no restriction in law as to who can administer the medicine to the patient, under a PSD however the prescriber has a duty of care and is professionally and legally accountable for the care, he/she provides, including tasks delegated to others. Therefore, the prescriber must be satisfied that the person to whom practice is delegated has the qualifications, experience, knowledge and skills to provide the care or treatment involved.

All of the above will mean that the initial sites are going to need to plan to have more clinical involvement and this process will reduce the initial efficiency.

A standardised template produced nationally is available - see attached document. This also provides you with a useful check list.

Consent

Consent must be obtained before starting any treatment or physical investigation or before providing personal care for a patient. This includes the administration of all vaccines.

There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given.



The individual must be informed about the process, benefits and risks of immunisation and be able to communicate their decision. Information given should be relevant to the individual patient, properly explained and questions should be answered fully.

For the Covid-19 vaccination programme consent is one of the challenges that has been identified. This is a new vaccine which is vital to end the pandemic that continues to have such a devastating impact to our communities. The population must be informed of the benefits, the potential side effects and their concerns need to be addressed.

Consent for people in residential homes or those who lack capacity are more complex but equally important.

The following is taken from e-Learning for people participating in the vaccination programme.

What should an adult be able to do to be considered to have capacity?

The 5 principles of the Mental Capacity Act:

- **Principle 1** - Assume a person has capacity unless proved otherwise.
- **Principle 2** - Do not treat people as incapable of making a decision unless all practicable steps have been tried to help them.
- **Principle 3** - A person should not be treated as incapable of making a decision because their decision may seem unwise.
- **Principle 4** - Always do things or take decisions for people without capacity in their best interests.
- **Principle 5** - Before doing something to someone or making a decision on their behalf, consider whether the outcome could be achieved in a less restrictive way.

If an adult is able to do the following three things, then they should be considered to have capacity and their decision should be respected:

1. Understand the information that you are giving them about the vaccine and any potential risks from it or from the disease it protects against.
2. Consider the information you have given them and retain it for long enough to make a decision on whether to accept or decline the offer of vaccination.
3. Communicate their decision to you.

Consent - continued

What actions can be taken to support and optimise a person's ability to make a decision?

As a person's capacity to consent can fluctuate, there are some actions that can be taken to support and optimise a person's ability to make a decision.

These include:

Making reasonable adjustments to facilitate decision making or accommodate individual needs

Using communication tools such as 'Easy read' leaflets

Speaking with them at their best time of day

Asking someone who the person knows and trusts to speak to them If an adult does not have capacity, a best interest decision will need to be made.

This process should be documented.

It is good practice to inform nursing or care home management teams of any plans to vaccinate residents in advance of the scheduled date. This will allow time to address any potential issues.

Training requirements

For all those who are involved in the Covid Vaccination Programme are required to complete some mandatory

COVID19 vaccinator e-learning training programme

<https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>

Vaccinator training recommendations

<https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations>

Vaccinator competency assessment

<https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool>

I have attached the training requirement document produce in Hampshire which you may find useful.

