

## **Regional Clinical Advice Response Service 18/02/21**

**For any COVID-19 vaccination related queries or to escalate an incident please contact: [england.swcovid19-voc@nhs.net](mailto:england.swcovid19-voc@nhs.net)**

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### **Vaccinating Under 18s**

Please note that the AZ vaccine is not authorised for use in those under the age of 18. Should any young staff members or volunteers (aged between 16 -18) present for vaccination they should be referred to their GP or local hospital hub where they can access the Pfizer vaccine which is authorised for this age group. Please make clinical teams and reception staff aware of this. A flag has been added into the Pinnacle system, but it does require that the system is used at the point of care and not retrospectively for this to be effective. Vaccinating those under 18 for the AZ vaccine is an exclusion in the PGD and national protocol.

### **Clinical Updates to the Greenbook (Chapter 14a)**

On 12th February 2021, the Greenbook (Chapter 14a) was Updated to include information on the Moderna mRNA vaccine, further changes to the advice on managing allergic history and allergies after dose 1 and updated information and clarification of advice on pregnancy and breastfeeding. Please share and ensure all colleagues are familiar with all updates where relevant. Please see updates below.

#### **1. Pregnancy and Breastfeeding and Covid-19 Vaccinations – Updated Advice**

Although the available data do not indicate any harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine.



JCVI has advised that vaccination in pregnancy should be considered, however, where the risk of exposure to SARS-CoV-2 infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the

risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy. If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy if she is considered at high risk. Alternatively, vaccination should be offered as soon as possible after pregnancy.

Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of the inadvertent administration of COVID-19 vaccines in early pregnancy is being conducted for the UK by the PHE Immunisation Department, to whom such cases should be reported <https://www.gov.uk/guidance/vaccination-in-pregnancy-vip>.

As above, women who are inadvertently vaccinated in early pregnancy may be considered for the second dose during pregnancy where the risk of exposure is high or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19.

There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer BioNTech, Moderna and AstraZeneca COVID-19 vaccines. Chapter 14a - 15 COVID-19 - SARS-CoV-2 Chapter 14a - COVID-19 - SARS-CoV-2 12 February 2021 The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

## **2. Allergic History and Allergy after Dose 1**

Pfizer BioNTech vaccine. Following close national surveillance, the MHRA is no longer advising that individuals with a history of anaphylaxis to any vaccine, medicine or food do not get the vaccine. Anyone with a previous history of allergic reactions to the ingredients of the vaccine should not receive it, but those with any other allergies (such as a food allergy) can now have the vaccine.

The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of this vaccine. (Sellaturay P et al, 2020). It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine.

The rate of anaphylaxis reported to date to the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines. The AstraZeneca vaccine does not contain PEG but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody

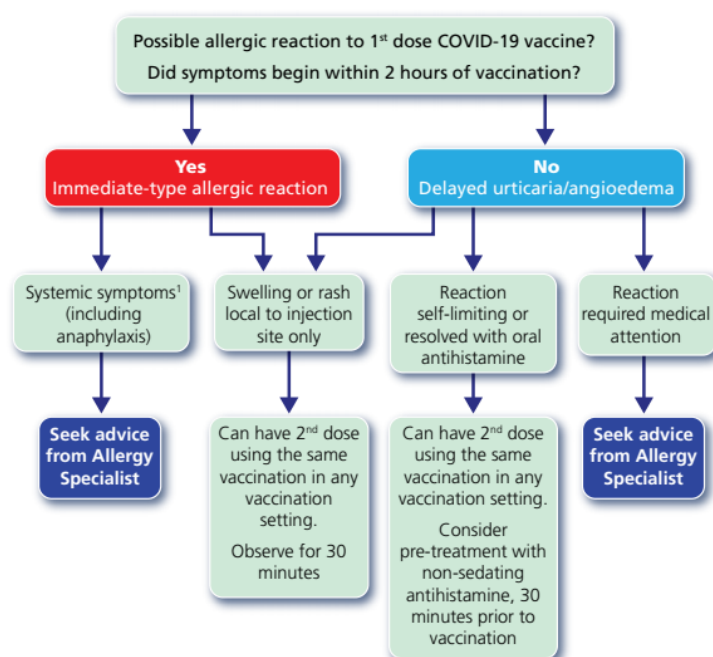
preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate the AstraZeneca vaccine. This is summarised in table 4 below:

Table 4: Management of patients with a history of allergy

	Proceed with vaccination	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	<ul style="list-style-type: none"> <li>previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified)</li> <li>family history of allergies</li> <li>previous non-systemic reaction to a vaccine</li> <li>hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen</li> <li>mastocytosis</li> </ul>	<ul style="list-style-type: none"> <li>history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy)</li> <li>history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative)</li> <li>history of idiopathic anaphylaxis</li> </ul>	<ul style="list-style-type: none"> <li>prior systemic allergic reaction to the COVID-19 vaccine</li> <li>for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine</li> <li>prior allergic reaction to a component of the vaccine, including PEG</li> </ul>
ACTIONS	<ul style="list-style-type: none"> <li>proceed with vaccination as normal, according to local guidelines</li> </ul>	<ul style="list-style-type: none"> <li>discuss with allergy specialist and consider possibility of PEG-allergy</li> <li>consider observation for 30 minutes if vaccination proceeds (see precautions)</li> <li>some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction</li> </ul>	<ul style="list-style-type: none"> <li>do not give vaccine in question</li> <li>refer to allergist</li> </ul>

The British Society for Allergy and Clinical Immunology (BSACI) has advised that individuals who have a reaction to the first dose of a COVID-19 vaccine may be able to receive a 2nd dose of vaccine, as in the flowchart (figure)

Figure: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine



Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting.

The Greenbook chapter (14a) can be accessed via the below link:

[COVID-19 Greenbook chapter 14a \(publishing.service.gov.uk\)](https://publishing.service.gov.uk/government/publications/covid-19-greenbook-chapter-14a)

### **Clinical Updates to: COVID-19 Vaccination: Information for Healthcare Practitioners**

Advice added regarding inadvertent administration of a different COVID-19 vaccine at a short interval after the first dose was added on 11<sup>th</sup> February 2021. Please share and ensure all colleagues are familiar with this update where relevant.

#### **Inadvertent administration of a different COVID-19 vaccine at a short interval after the first dose:**

If a dose of a different COVID-19 vaccine is inadvertently given a few days after the first dose was given, the person should be offered a third dose of vaccine a minimum of 28 days after the second dose was given. As clinical trials showed that compared with the first dose, adverse reactions reported after the second dose of the AstraZeneca vaccine were milder and reported less frequently, it is recommended that the AstraZeneca vaccine is given for this third dose where possible as it is likely to be less reactogenic as an additional dose.

If different COVID-19 vaccines are given a minimum of 21 days apart, these doses should be counted as a completed course and no further doses are needed (unless subsequent mixed vaccine schedule studies show otherwise).

Please see below link for the full document including updates:

[COVID-19 vaccination: information for healthcare practitioners - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/covid-19-vaccination-information-for-healthcare-practitioners)

### **Vaccination of JCVI Cohorts 5-6 and Additional Funding for Vaccination in Residential Settings**

Letter from Directors of Primary Care Dated 13<sup>th</sup> February 2020

Dear LVS sites

Thank you for your ongoing efforts to promote maximum uptake of the NHS's offer to vaccinate everyone in JCVI cohorts 1-4 by 15 February. We have provided clarification on the position on vaccinating children and young people on the Clinically Extremely Vulnerable (CEV) list, and this is attached to this letter (Annex A).

Next week and the week after (i.e. the weeks commencing 15 and 22 February), PCN sites should focus their efforts on inviting **JCVI cohort six**, which includes a wider group of people at higher clinical risk, including carers and young adults in residential settings.

Building on the outstanding success General Practice has already shown in targeting vaccines for the clinically extremely vulnerable, it makes sense now to ask PCNs to focus on this JCVI group 6 given the relationship between general practice and those with long term conditions, and your important role in maintaining continuity of care. At the beginning of next week, we will also be sharing some further information about the prioritisation of people using an enhanced clinical stratification tool.

Further operational guidance on invitations to cohort six is attached to this letter (Annex B).

Please help to make sure no one gets left behind. Continue to do all you can to minimise any inequalities in vaccine uptake between different patient groups wherever possible, working with CCG, LA and community partners, mindful of deprivation, ethnicity and all factors impacting COVID risk. Template letters for contacting these groups are available on Future NHS ([FutureNHS Collaboration Platform - FutureNHS Collaboration Platform](#))

As PCN-led sites focus on cohort 6, **cohort 5** (those aged 65-69) will shortly start receiving an invitation from the national booking service (NBS) to attend a vaccination centre or community pharmacy setting. PCN sites may still vaccinate patients in this cohort and be paid for doing so should a patient request an appointment.

### **Vaccination in residential settings**

In the coming weeks, PCN groupings, and in some cases community pharmacies when requested by NHS England, will need to deliver vaccinations in residential settings, such as care homes for people with learning disabilities or mental health problems, or hostel/hotel accommodation for the homeless, where it would not be possible for these patients to attend vaccination sites. PCN groupings should work with CCG, ICS, local authority and other partners to establish the most effective ways to serve all of these residential settings and specific groups and determine the most appropriate vaccination delivery model for them.

**In such cases from 15 February onwards, a PCN grouping or community pharmacy contractor will be able to claim an additional supplement of £10 for each vaccination administered to eligible residents and staff in these settings, on top of the £12.58 Item of Service fee.** All payments made under this mechanism will be made to GP practices under Section 96 of the NHS Act 2006 (as amended) "Assistance and support: Primary Medical Services", on the terms set out in this letter. This arrangement will be in place until further notification otherwise. A contract variation will be provided to any community pharmacy contractor requested to provide this service. The provision of this supplement is only for COVID-19 vaccination and does not apply to wider vaccination programmes.

We also confirm that there is nothing to prevent PCN groupings from subcontracting this service to another contractor under the existing arrangements and we support innovative models of professional collaboration to ensure patients are vaccinated as quickly as possible.  
Recording the setting of the vaccination event

The Pinnacle/Outcomes4Health Point of Care System will be updated to include an additional field relating to the collection of data to support payment of the £10 residential settings supplement. Any vaccinations recorded as '*Long-stay care home or long-stay residential facility*' will automatically flow to the NHS Business Services Authority to support the payment of the £10 supplement alongside the Item of Service fee.

## How to claim

Guidance on how PCN groupings and community pharmacy contractors should submit claims will be published shortly on the FutureNHS workspace ([FutureNHS Collaboration Platform - FutureNHS Collaboration Platform](#)). A Post Payment Verification (PPV) process and review of a sample of practice claims will be carried out. In accessing this funding, practices agree to this process.

Further details on the claims process will also be shared with CCGs and NHSE/I regions shortly.

## Movement of the Oxford/Astra-Zeneca vaccine

We issued a position statement on the use of the COVID-19 Oxford/AstraZeneca vaccine to visit housebound patients last month, which provides guidance on safe transport and use of punctured vials. We have recently issued equivalent guidance for the use of the AstraZeneca vaccine in and between care homes. Please read and follow both sets of guidance to ensure safe transfer of vials between residential settings in line with aseptic technique.

Yours sincerely

Dr Nikita Kanani Ed Waller

Medical Director for Primary Care Director of Primary Care

NHS England and NHS Improvement NHS England and NHS Improvement

## **Annex A: COVID-19 Vaccination of Children and Young People (CYP) in the Clinically Extremely Vulnerable (CEV) Group**

In January, a letter was issued to all CEV patients from the Department of Health and Social Care, informing them that they would be invited to have a vaccine. As we are now offering vaccinations to those who are clinically extremely vulnerable, it is important that parents of children on the CEV list, as well as clinicians, are clear on the clinical policy for vaccinating children against COVID-19.

All CEV children have been included on the shielding list following a mandatory assessment by a paediatrician, based on the criteria published by the Royal College of Paediatrics and Child Health (RCPCH) which can be seen [here](#).

Children included on the CEV list fall broadly into the following two categories:

- Group A - mainly immunodeficiency or with types of cancer;
- Group B – range of other conditions thought to put them at risk e.g. cardiology, neurology, respiratory etc.

The independent Joint Committee for Vaccination and Immunisation and Public Health England's Green Book are clear that the majority of children should not be vaccinated at this time, on the basis of a low morbidity/mortality risk from COVID-19 infection; limited safety data; and overall uncertainty regarding efficacy.

For a small number of children, over the age of 12 years, the Green Book states:

Given the very high risk of exposure to infection and outbreaks in institutional settings, vaccination may be considered for children with severe neuro-disabilities who tend to get



recurrent respiratory tract infections and who frequently spend time in specialised residential care settings for children with complex needs.

It is estimated that approximately 1,500 to 2,000 children and young people fall into this category. No other children aged less than 16 years old are recommended to be vaccinated.

### **CEV aged 16 to 18+ years**

The Astra Zeneca vaccine is authorised for patients aged over 18 years and Pfizer BioNtech vaccine for those over 16 years. The AZ vaccine would need to be authorised for all CYP by a prescriber (doctor) as it is “off licence”. Pfizer can be administered under PGD or national protocol for CYP aged from 16 years, but to prescribe it for those below this age would be off licence. The Green Book states that either vaccine can be used.

It is recommended that the Pfizer vaccine be the vaccination of choice for CYP as it is authorised for those over the age of 16 years. Pfizer is not currently available at Vaccination Centres, therefore CYP would be vaccinated in Hospital Hubs or at PCN sites.

The following approach should now be actioned for those children and young people who have severe neuro-disabilities and who tend to get recurrent respiratory tract infections and who frequently spend time in specialised residential care settings:

1. From age 16-18 years called to PCN for administration of Pfizer. This is on licence.
2. From age 12-16 years called to PCN for administration of Pfizer. This will be off licence and discussions with RCGP indicates that GPs should seek advice from the patient's paediatrician prior to administration.
3. Aged less than 12 years, not called for vaccination.

It is important to emphasise that there is a low risk to CYP from COVID-19 infection. The scientific view on which cohorts should be offered vaccination is outlined by the JCVI, and Medical Royal Colleges, such as RCPCH (here) and RCGP, support future work to further refine the understanding of at risk groups and the role of vaccine.

### **Annex B: Vaccination of cohort 6 in LVSSs**

From 15 February 2021, we would like you to focus on cohort 6. The majority of people in this cohort will be vaccinated in Local Vaccination Services, building on your existing relationships around the care of long-term conditions and supporting continuity of care. Adult carers who are flagged within GP systems will also be offered vaccination through this route. This note sets out how to approach this cohort.

### **Summary and eligibility**

JCVI priority Cohort 6 includes ‘all individuals aged 16 years to 65 years with underlying health conditions which put them at higher risk of serious disease and mortality’. This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

Cohort 6 is further defined in Green Book Chapter 14a as “Adults aged 16 to 65 years in an at-risk group”. The list of at-risk conditions can be further subdivided into three main sub-cohorts:

- Adults aged 16 to 65 years in an at-risk group which includes:
  - Chronic respiratory disease
  - Chronic heart disease and vascular disease
  - Chronic kidney disease
  - Chronic liver disease
  - Chronic neurological disease, including severe or profound learning disability
  - Diabetes mellitus
  - Immunosuppression
  - Asplenia or dysfunction of the spleen
  - Morbid obesity
  - Severe mental illness
- Younger adults in long-stay in-patient, nursing and residential care settings
- Adult carers:
  - Those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person, someone who has a severe mental illness or whose welfare may be at risk if the carer falls ill.

## **Actions for PCN LVSs**

PCN LVSs should commence the issue of invitations for individuals within cohort 6 from receipt of allocation information, with appointments for vaccination commencing from Monday 15/02/21.

PCN LVSs should invite individuals aged 16 to 65 with corresponding flags within their clinical record for vaccination. Each clinical condition within cohort 6 has been mapped to clinical codes (SNOMED) available within patient records. The mapping to these flags within SNOMED should be the primary determiner of eligibility for at risk conditions within cohort 6.

Those aged 65-69 are separately being invited to attend Vaccination Centres. If you have patients in that age group who fall into one of the categories above, you may also invite them to attend an appointment at the LVS.

As with previous cohorts, there will be no end date to cohort eligibility i.e., individuals can choose to accept the offer of vaccination at any time once their cohort has commenced.

Second doses of vaccine should be administered approximately 11 to 12 weeks after the first dose. Sites receiving supplies of Pfizer/BioNTech vaccine will be advised of corresponding second dose supplies in a coordinated manner to enable the appropriate scheduling of second dose clinics.

## **Asthma**

An individual with a more severe case of asthma may have been included in the Clinically Extremely Vulnerable group, in which case they will be vaccinated in group 4.

People with asthma which requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, will be vaccinated in priority group 6.

This will include:

- anyone who has ever had an emergency asthma admission or;



- those who have an asthma diagnosis and have had 3 prescriptions for oral steroids over a 3-month period (each prescription must fall within separate individual month windows), as an indication of repeated or continuous oral steroids.

## **Learning disability**

JCVI determined that those with severe and profound learning disability are in cohort 6. GPs can use GP Learning Disability Registers and SNOMED codes (which describe the impact of learning disability although there is variation in how these are applied) to help identify this group.

We recognise that there may still be people who are not on these registers and the NHS needs to make an extra effort to put this right. GPs should use clinical discretion to ensure the right people who meet the severe and profound learning disability definition are on the register.

Alongside this the NHS is asking our key stakeholders and our voluntary and third sector partners to encourage people who have a severe and profound learning disability to come forward to their local GP. GPs should then assess the individual and if appropriate, add them to the list to be vaccinated. When organising their COVID-19 vaccination, we also advise GPs to use this important opportunity to offer people with a learning disability their annual health check and to book them in for their flu vaccine, so the NHS makes every contact count for this important group of people.

## **Severe Mental Illness (SMI)**

JCVI also determined that those with schizophrenia or bipolar disorder, or any mental illness that causes severe functional impairment are within cohort 6, and we would encourage GPs to take a similar approach for this group of people, to that being proposed for learning disability, working in partnership with secondary care mental health services and VCS partners to ensure appropriate outreach mechanisms are in place.

## **Settings of multiple occupancy**

Green Book Chapter 14a states:

“Younger adults in long-stay nursing and residential care settings: Many younger adults in residential care settings will be eligible for vaccination because they fall into one of the clinical risk groups (for example learning disabilities). Given the likely high risk of exposure in these settings, where a high proportion of the population would be considered eligible vaccination of the whole resident population is recommended.”

The proposed definition for inclusion of such settings is “a closed community with substantial facilities shared between multiple people, and where most residents receive the kind of personal care that is CQC regulated (rather than help with cooking, cleaning and shopping)”.

This would include CQC registered care homes (excluding older people’s care homes who were included in Cohort 1) and those identified as part of the Mental Health Services Dataset (MHSDS) as well as Learning Disability settings sites which are not in the MHSDS and Special residential colleges and supported living.

Shared student accommodation, detained estates (including prisons and immigration removal centres) are excluded within this definition. The COVID-19 Vaccination Programme is

addressing vaccination within detained estates separately in conjunction with Health and Justice teams. Vaccination within these settings for individuals within JCVI cohorts 1-4 has already commenced.

Local systems and regions are best placed to map and assure in-reach to the majority of settings of multiple occupancy through their delivery model mix of providers and should continue to advance their plans for delivery to these settings including the immediate mapping of such settings if this has not already commenced.

Further guidance in the form of a mobilisation support pack including; considerations in advance of a visit to such settings; the consenting process and support to prepare for vaccination for homes, residents and families, will be issued week commencing 15/02/21 on how to support vaccinations in settings of multiple occupancy.

### **Adult carers**

Eligible adult carers will be contacted via the National Booking System (NBS) to receive an invitation to book vaccination through Vaccination Centres, Community Pharmacy LVSs or Hospital Hubs, once a list compiled by NHSE/I in conjunction with Local Authorities has been produced.

Local systems may choose to flex these arrangements based on the needs of their populations and PCN LVSs should be prepared to administer vaccination to eligible adult carers who choose to receive vaccination in LVS settings and are coded as such on the GP system.

Local systems including both the NHS and Local Authorities should continue to collaborate to ensure that individuals within cohort 6 who are resident in settings of multiple occupancy or are adult carers not flagged within GP systems can be appropriately offered vaccination. Further guidance relating to the vaccination of eligible adult carers will be published as a Standard Operating Procedure (SOP) week commencing 15/02/21. This SOP will detail the specific actions that will be required by Local Authorities, carers organisations, DWP, the NHS and adult carers themselves.

We recognise the difficulties in identifying people in this group. We are asking the third sector to help us identify people through public campaigns, with an 'ask' that eligible unpaid carers contact their local authority to make themselves known so they can be prioritised for vaccination through the National Booking Service.

PCN LVSs should also prioritise **invitations to carers aged 16 and 17 flagged within their systems** to align with their known allocations of Pfizer/BioNTech vaccine. The Pfizer/BioNTech vaccine is the only currently authorised vaccine under Regulation 174 which can be used for individuals aged 16 and 17.

PCN LVSs should coordinate the offer of vaccination to carers flagged in their systems so that the carer and the at-risk individual they care for can be vaccinated at the same time if both individuals are registered within a practice in that PCN.

When administering vaccinations to at risk individuals who are housebound, the PCN LVS should, where it is clinically appropriate to do so, vaccinate both the at-risk individual and their main carer (if present) at the same time.

PCN LVSs should ensure that minimum data set within Pinnacle/ NIMS is utilised to capture the status of eligible unpaid carers at the point of care which will ensure that the Validated Vaccination Event (VVE) can be appropriately counted as the vaccination of an adult carer.

**The letter (including Annex A and B as above) can be viewed at the link below:**

[Coronavirus » Vaccination of JCVI cohorts 5-6 and additional funding for vaccination in residential settings \(england.nhs.uk\)](#)

**Covid-19 Publications (e.g. leaflets, forms & posters), Patient Information Leaflets and Record Cards: How to Order Additional Copies**

There are different types of patient information leaflets available to support the Covid-19 Vaccination Programme. Public Health England (PHE) has produced a range of publications a range of key clinical publications (forms, leaflets, posters, stickers) and they should be used to give to patients, care home residents, eligible frontline health care and social care workers to enable informed consent.

There are also leaflets provided with the vaccine delivery: record cards and patient information leaflets (PILS) relating to the vaccine.

Please see attached guidance on how to order.

**All COVID-19 vaccination queries and incidents should be directed to:**  
[england.swcovid19-voc@nhs.net](mailto:england.swcovid19-voc@nhs.net)