

**COVID-19 Vaccination Programme:
Medical Individualisation or Localised Interpretation
and Implementation**

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CLASSIFICATION:	Procedure
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**COVID 19 Vaccination Programme: Medical Individualisation or Localised
Interpretation and Implementation**
February 2021

Introduction

Birmingham and Solihull STP (BSol) have established a programme to facilitate COVID-19 vaccination of the population as per JCVI guidance and NHSEI policy. Vaccination is currently being delivered from a combination of large vaccination centres, hospital hubs, primary care network designated sites, community pharmacists and roving community models providing for the care homes, housebound and 'hard to reach' groups.

Although JCVI prioritisation is transparent and appropriate for population stratification, and the Green Book provides wider clinical guidance, there are occasions where both local interpretation and individual assessment of need may be required. There is understandably a high degree of external scrutiny surrounding the vaccination programme, with equity of access and consistency of provision key principles. Any deviation from standard access principles must therefore be approached in a transparent manner attempting to provide consistent practice within the local BSol system.

This paper outlines areas where local interpretation in delivering COVID-19 immunisation may be required. Categories are based upon frequency of queries raised to the vaccination team, and addresses potential solutions where more individualised or localised guidance may be required.

Recognising the speed of change within the COVID-19 vaccination programme, this document will be reviewed every two weeks within the clinical oversight group with changes made as required.

1. Pregnancy

As with most new drugs, the currently available vaccines have not undergone rigorous testing in pregnancy. Information available is reviewed within the Green Book. Recommendation for administration in pregnancy is as below:

JCVI has advised that vaccination in pregnancy should be considered....where the risk of exposure to SARS-CoV2 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

BSol vaccination programme will provide COVID-19 vaccine to women who are pregnant only after appropriate counselling by ante-natal services defined by national standards. Local maternity services (LMS) have agreed a counselling approach based on national guidance and will supply women with letters explicit that counselling has occurred (appendix 1).

Vaccination in pregnancy cannot be delivered under a Patient Group Direction (PGD) and therefore prescription via a paper Patient Specific Direction (PSD) will occur with appropriate storage of records.

2. Inpatient vaccination

Patients within appropriate JCVI cohorts may have delayed access to community vaccination if currently within an inpatient setting.

Green Book guidance for vaccination states as precautions that:

- Vaccination should be avoided in those who are acutely unwell
- Vaccination in individuals with COVID-19 should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.

Within the BSol programme it is recommended that an inpatient is only vaccinated if they have recovered from the acute presentation such that any adverse effects of the vaccine are not confused with the acute illness. In addition it is recommended that an inpatient is not vaccinated for a minimum of 28 days after commencement of symptoms or first positive test. Vaccination should be delayed further if any adverse effects may complicate diagnostic management.

There will however be a subset of patients, residing in an inpatient setting across BSol who will fall within a JCVI priority cohort who are suitable for COVID-19 vaccination and be more at risk of developing COVID-19 because of their current or future residential status. Vaccination will be provided via a PGD using Astra Zeneca vaccine with concurrent documentation via NIVS. Clear communication must occur with any transfer of health care responsibility that vaccination has occurred stating vaccine type, date of administration, any significant side effects and date that second vaccine is required if appropriate.

Suitable for inpatient vaccination include:

- Within currently identified JCVI priority cohorts
- Not acutely unwell, afebrile and recovered sufficiently from acute presentation to receive vaccination

- At least 28 days from COVID-19 diagnosis (either by symptoms or asymptomatic positive specimen) and well enough to receive a vaccination, or having a negative COVID-19 test within the past 72 hours

This is likely to include primarily (but not limited to)

- Patients in non-acute beds entering Pathway 2 within acute hospital, community or care home settings
- Patients in pathway 3 if not immediately entering an end of life phase
- Patients resident within a mental health facility including longer stay inpatient units, older adults and acute inpatient services where appropriate.

If a best interests decision needs to be made, use toolkit (Appendix 2) and ensure incorporated into patient notes.

3. Prior to major surgery

It appears that outcomes from major surgery are markedly worsened in the context of concurrent COVID-19 disease (The Lancet May 29th 2020). It is therefore proposed that individuals due to undergo such surgery receive COVID-19 vaccination as part of a pre-surgical pathway, if they have not already received as part of a JCVI priority cohort, with the dual aims of reduction of morbidity associated with surgery and reduction of cancellation associated with COVID-19 in those scheduled for surgery.

Vaccination should ideally be performed at least two weeks prior to elective surgery to allow development of an immune response and to reduce the likelihood of any immediate common side effects of vaccination occurring close to a surgical date. This group does not at present fall strictly with current JCVI priority cohorts and must therefore be carefully scrutinised.

Current internal recommendations as examples are:

- Major organ resection e.g. bowel, lung, liver
- ASA grade 3-5
- Major or complex major on BUPA schedule

Details of patients due to undergo major surgery within the next 6 weeks will be forwarded to a Medical Director panel who will scrutinise and approve as appropriate.

4. Prior to significant immunosuppressive therapy.

Individuals who are currently receiving , or who have recently received , significant immunosuppressive therapy that is likely to markedly increase their risk of complications associated with COVID-19 should be classified as clinically extremely vulnerable (CEV) and thus fall into a current JCVI priority cohort.

The Green Book also states:

The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. . Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID-19 and from their underlying condition.

Further explicit definition of to whom this applies is not available. Current local interpretation is that this statement applies to individuals:

- Currently immunocompetent such that it is reasonable to assume that an immune response will be mounted, **and**
- that the proposed immunosuppression can be withheld until at least two weeks after the second dose.

Specialities are asked to forward details of groups of patients where it is felt that these criteria apply. A Medical Director panel will scrutinise and approve as appropriate to the spirit of current guidance.

5. Vaccination of those with previous history of anaphylaxis/severe allergy

When Pfizer vaccine was first introduced there was considerable concern about its use in those with a previous history of anaphylaxis. Advice has now been refined and is outlined within the Green Book. A summary is provided below and details of expanded advice for ICS partners is within appendix 4.

Many patients with a previous history of anaphylaxis or severe allergy to food or drugs (where the trigger is known) can be safely given a Covid-19 vaccination however should be observed carefully after vaccination. This also applies to those with a family history of allergy, previous non-systemic reaction to a vaccine and hypersensitivity to non-steroidal anti-inflammatory drugs. Mastocytosis is not a contra-indication. Vaccination to an influenza vaccine is also not a contraindication.

Patients with possible allergy to polyethylene glycol (PEG) (eg bowel prep, laxatives) may potentially also be allergic Pfizer BioNTech vaccine and it may be more appropriate to consider vaccination with AstraZeneca vaccine.

Patients with idiopathic anaphylaxis (ie without identified triggers) especially if recurrent if being vaccinated (preferably with AstraZeneca vaccine) should be vaccinated with facilities for observation and support. Referral to immunology Advice and Guidance prior to vaccination can be considered. Immediate advice can also be obtained from the Vaccinations Medical Advice Line..

Prior known anaphylaxis or severe reaction to previous Covid-19 vaccination or its constituents is a contraindication to vaccination without advice from immunology Advice and Guidance.

Advice pathways are summarised in Appendix 4.

This includes;

Review of advice within Green Book

Access to UHB consultant delivered vaccinators' help line

Referral to UHB Allergy service for further advice before vaccination

References

General information; COVID-19 vaccination programme

<https://www.gov.uk/government/collections/covid-19-vaccination-programme#guidance>

JCVI priority guidance:

<https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020/joint-committee-on-vaccination-and-immunisation-advice-on-priority-groups-for-covid-19-vaccination-30-december-2020>

JCVI first dose strategy

<https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement/optimising-the-covid-19-vaccination-programme-for-maximum-short-term-impact>

Green Book chapter

<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31182-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31182-X/fulltext)

Appendix 1; letters for pregnant women

February 2021

Clinical Team
Vaccination Hub
Birmingham Acute Hospitals

Patient Identification Label

Dear Colleague,

The above named woman is currently pregnant and is a healthcare worker, and is seeking Covid-19 vaccination.

This is to confirm that we have discussed the potential risks and benefits of receiving Covid-19 vaccination compared to the risks of not receiving the Covid-19 vaccination.

To inform this discussion we have used the RCOG Information Leaflet published on 12th January 2021, covering the different options, risks, benefits and side effects, a copy of which has been made available to the woman.

She understands and acknowledges that there is no published data relating to the safety or efficacy of any of the current Covid-19 vaccines, and would like to proceed with vaccination. We would be grateful if you could provide this woman access to vaccination.

Yours sincerely,

Name

Position (If under midwifery care can be a senior midwife rather than obstetrician)

GMC/NMC Number

Date

Copy: GP

February 2021

Clinical Team
Vaccination Hub
Birmingham Acute Hospitals

Patient Identification Label

Dear Colleague

The above named woman is currently pregnant and is classified within the provisions of the Covid-19 pandemic as being Clinically Extremely Vulnerable, and is seeking Covid-19 vaccination.

This is to confirm that we have discussed the potential risks and benefits of receiving Covid-19 vaccination compared to the risks of not receiving the Covid-19 vaccination.

To inform this discussion we have used the RCOG Information Leaflet published on 12th January 2021, covering the different options, risks, benefits and side effects. A copy of which has been made available to the woman.

She understands and acknowledges that there is no published data relating to the safety or efficacy of any of the current Covid-19 vaccines, and would like to proceed with vaccination. We would be grateful if you could provide this woman access to vaccination.

Yours sincerely,

Name

Position

GMC / NMC Number

Date

Copy to GP

Appendix 2. Best interests decision making tool kit.



Tool to assess capacity to make the decision to receive the Covid-19 vaccine

Patient details	
Patient's surname/family name:	
Patient's first name(s):	
Date of birth:	
NHS number (or other identifier):	
Date and Time of Assessment:	
Detail any efforts made to assist the patient to make this decision him/herself (Including details of information given to the patient and the format (e.g. Interpreter services, large print, letter boards etc.):	
Name and job title of the person responsible for this mental capacity assessment:	

1 Section 1: Impairment Test	
Does the patient have an impairment of, or a disturbance in, the functioning of their brain or mind?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Details of impairment of, or disturbance in, the functioning of the patient's brain or mind: eg. Dementia (This need not necessarily be a formal diagnosis but, if the patient has one, record it here)	
If the answer to question 1 is 'yes', proceed to Section 2 below. If the answer to question 1 is 'no', then the patient has capacity in relation to this decision. Return to question 3 of the Capacity for Vaccination checklist.	
2 Section 2: Functional test of mental capacity	
2.1 Patient is able to understand the information relevant to this decision	Yes <input type="checkbox"/> No <input type="checkbox"/> Rationale:
2.2 Patient is able to retain the information for long enough to make this decision (where necessary, using aids to memory such as documents, photos, video or voice recordings, tablets etc)	Yes <input type="checkbox"/> No <input type="checkbox"/> Rationale:
2.3 Patient is able to weigh up the information in order to make this decision i.e. they can: • Evaluate the information • Use the information to make a decision • Make the decision without undue influence, persuasion or to please another	Yes <input type="checkbox"/> No <input type="checkbox"/> Rationale:
2.4 Patient is able, with any necessary aids or assistance, to communicate their decision in the way they would prefer to communicate.	Yes <input type="checkbox"/> No <input type="checkbox"/> Rationale:
If yes to ALL 4 questions 2.1 to 2.4, the patient has capacity to make the decision. Return to question 3 of the Capacity for Vaccination checklist.	
If "No to any of the 4 questions 2.1 to 2.4, patient does not have capacity to make decision at this time, so a best interests decision is required. Go to Covid-19 Vaccination Best Interests Form at Annex 2.	

Covid-19 Vaccination Best Interests Decision Tool

Patient details	
Patient's surname/family name:	
Patient's first name(s):	
Date of birth:	
NHS number (or other Identifier):	
Date:	
Name of Decision Maker:	
Contact details:	

1	Has the patient been assessed as lacking capacity to make this decision?	Yes <input type="checkbox"/>	➔ Step 2	Date of capacity assessment
		No <input type="checkbox"/>	Use the tool at Annex 1 to assess patient's capacity to decide to receive Covid-19 vaccine	
2	Has the person made an Advance Decision stating that they do not want to receive the Covid-19 vaccination?	Yes <input type="checkbox"/>	➔ If the Advance Decision is legally binding ¹ - you cannot administer the vaccine.	
		No <input type="checkbox"/>	➔	Go to Step 3
3	Is there a valid Lasting Power of Attorney or a Court appointed deputy with authority to make healthcare decisions?	Yes <input type="checkbox"/>	➔ Ask LPA to provide consent on behalf of patient.	
		No <input type="checkbox"/>	➔	Go to Step 4
4 Consider any information regarding patient's wishes and beliefs in relation to this decision, including: (I) past and/or present wishes or feelings relating to the decision? (II) values/beliefs that relate to the decision (including cultural/religious considerations) (III) Any other factors that the patient would want to be considered in relation to this decision For example, the patient may have expressed strong views against Covid-19 vaccine or vaccines in general. On the other hand, they may have supported use of vaccines for the benefit of e.g. their family, neighbours or the population in general.				
	Name (and contact details, where appropriate):	Role/relationship to the patient (e.g. NOK, LPA, paid or other Carer)	Information obtained (in particular, record any relevant statements made when patient had capacity)	

¹ If the patient has appointed a person with Lasting Power of Attorney after the date of the Advance Decision, the Advance Decision is not legally binding unless it is referred to in the LPA. If you need advice, contact the legal team

When completed, this form must be stored in the patient's record

Appendix 3: Vaccinators' medical advice line

VACCINATIONS - FREQUENTLY ASKED QUESTIONS RELATED TO THE PGDs – Pfizer & AstraZeneca		
	Questions	Response
1.	<p>I am on blood thinning medication such as: -</p> <ul style="list-style-type: none"> ➤ Warfarin ➤ NOACs or heparin or antiplatelets – Apixaban, Rivaroxiban, Deltaparin, enoxaparin, clopidrogel <p>OR - A mixture of the above blood-thinning medication*</p>	<p>For warfarin if INR known should ideally be under 4.5 or if INR not known, patient stable on warfarin and no significant bleeding/ bruising -> Give Vaccine BUT hold gauze swab to puncture site for min 2-3 mins - (<u>DO NOT RUB</u>)</p> <p>Give vaccine BUT hold gauze swab to puncture site for min 2-3 mins - (<u>DO NOT RUB</u>)</p> <p>*Discuss with Medical Advice line before proceeding</p>
2.	<p>I am pregnant but have no additional risk factors</p> <p>I have had the vaccination but now realise I am pregnant, do I need to worry?</p>	<p>Specific clinical trials have not been done. Patients should discuss this with their GP/obstetrician/midwife prior to being referred for vaccination (with a letter summarising discussions). They can then can be vaccinated (but this needs a PSD signed by a registered prescriber (doctor, nurse prescriber, pharmacist)) [we are setting up a pathway to make this easier]</p> <p>There is no known risk but please do advise your GP/obstetrician/midwife at your routine appointments. Termination of pregnancy is not recommended.</p>

	<p>Should I have a COVID-19 vaccine if I plan to become pregnant?</p> <p>I had the first vaccination, I am now pregnant, should I have my second vaccination?</p> <p>I am breast feeding/planning on breast-feeding, can I be vaccinated/receive my second vaccination?</p> <p>Will the vaccines cause infertility?</p>	<p>Women who are trying to become pregnant do not need to avoid pregnancy after both vaccinations.</p> <p>Delay the second dose until after the pregnancy is over; or after discussing this with their GP/obstetrician/midwife they are referred for vaccination (with a letter summarising discussions). They can then be vaccinated (but this needs a PSD signed by a registered prescriber (doctor, nurse prescriber, pharmacist))</p> <p>There is no known risk. Patients should still be offered vaccination (under the PGD – a PSD is not needed)</p> <p>There is no evidence and no reason to believe that either vaccine will cause infertility.</p>
3.	<p>Can I have the vaccine if I am allergic/Anaphylaxis to</p> <ul style="list-style-type: none"> ➤ A drug – i.e. Penicillin ➤ A group of Drugs ➤ Insect bites/stings ➤ Food substances ➤ Metals ➤ Xray Contrast ➤ Other non-Covid vaccinations: e.g. Flu 	<ul style="list-style-type: none"> ➤ Yes proceed with vaccination ➤ Yes proceed with vaccination (either) ➤ Yes proceed with vaccination <p>Observe Patient for a minimum additional 15 mins</p>

	<p>➤ **Polyethylene Glycol - PEG (used in bowel prep (e.g. macrogol))</p>	<p>(Minimum 30 mins for Pfizer, Minimum 15 mins for AstraZeneca)</p> <p>**The Pfizer Vaccine <u>does contain PEG</u>, therefore avoid this specific vaccine. AstraZeneca <u>does not contain PEG</u>, therefore patients who may be known to have an allergy specific to PEG should be referred for the AstraZeneca vaccine instead, which is safe for them to receive.</p> <p>Some patients are particularly anxious about anaphylaxis and may wish to have Astra Zeneca vaccine – this can be arranged at the mass vaccination centres.</p> <p>If mass vaccination centre used for high risk patient, on booking</p> <ul style="list-style-type: none"> • Inform Nurse in Charge that patient is high risk • Do not book at same time as other high risk patients • Do not book at end of day
4.	<p>Can I have the vaccine if I have had an anaphylactic reaction to an unknown trigger?</p> <p>What if multiple unrelated severe reactions?</p>	<p>Discuss with Immunology service.</p> <p>If vaccination proceeds for 30 mins observation and consider pre-dosing with anti-histamine</p>
5.	<p>Can I have the 2nd dose of vaccine if I have had an Anaphylactic or Anaphylactoid response to the previous Covid vaccination?</p> <p>Can I have the 2nd dose of vaccine if I</p>	<p>Do not give, Immunology service for advice</p> <p>Yes but observe for 15 – 30mins after</p>

	fainted or had a minor reaction to the previous vaccination?	vaccination.
6.	What should I do if I have a letter from a GP advising never to have any other vaccines?	Refer to Medical Advice Line
7.	What if I have had another vaccination within the last 7 days?	<u>Do not give any Covid Vaccine</u> – Request patient rebooks appointment once the 7 day period has passed – also inform patient to refrain from having any other vaccines between 1 st and 2 nd dose of Covid vaccine once they do receive it.
8.	How long after having Coronavirus infection can I have the vaccine?	A minimum of 28 days from the start of the illness /significant symptoms. If severely unwell, recommend patient allows a minimum of 28 days from start of recovery
9.	How long after a positive COVID test can I have the vaccination?	Some patients may continue to have a positive test after recovering from Covid infection, they can be vaccinated. A patient with a new positive Covid test should wait 28 days.
10	Can I have the vaccine if I have an Autoimmune condition, or on immunosuppressant drugs or Hormone deficiency?	Yes proceed with vaccination
11	Can I have the vaccination if I am currently having chemotherapy/ Radiotherapy or have had within the past 12 months?	Yes proceed with vaccination
12	What if I have had a previous local reaction to the flu jab or other vaccinations	Not contraindicated – proceed with Covid Vaccine
13	Can I have the vaccine if I have been diagnosed with:- ➤ Thalassaemia	➤ Yes proceed with vaccination

	<ul style="list-style-type: none"> ➤ Sickle cell traits or disease ➤ Migraine ➤ Anaemia ➤ transverse myelitis- then possible contraindications 	<ul style="list-style-type: none"> ➤ Yes proceed with vaccination ➤ Yes proceed with vaccination ➤ Yes proceed with vaccination ➤ GP should refer to Immunologist before proceeding
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VACCINATORS' MEDICAL ADVICE LINE

07799 007414

**PLEASE USE FOR ALL VACCINATION ADMINISTRATION
RELATED QUERIES FROM VACCINATION TEAMS**

Appendix 4: Primary care and ICS partner process for anaphylaxis / serious allergy advice



BSol UHB vaccine
allergy process 23032