NHS Greater Glasgow and Clyde

CLINICAL GUIDELINE

Immunisation best practice

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Contents

1.0 INTRODUCTION

This guideline is intended to ensure good clinical governance and the safe and effective administration of vaccines delivered in a patient centred manner. It is expected that all staff referring patients for vaccination or actually administering vaccines will adhere to this guidance.

Consequently, this guideline is for immunisers, medical practitioners, other healthcare workers, referrers and administration staff who may support the management or delivery of vaccinations to patients in any setting, across NHS Greater Glasgow and Clyde (NHS GGC) Health Board. This document is pertinent not only to the established immunisation teams, but also for anyone who has a role to play in the safe and effective delivery of immunisations, from the initial referral through to vaccine administration.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these discussion and communicate them to others involved in the care of the patient.

2.0 BACKGROUND AND NATIONAL POLICY

The introduction of new vaccination programmes and recommendations relating to existing vaccination programmes are based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), an independent Expert Committee of the UK Department of Health.

Vaccination policy has developed over a number of years in response to recommendations on new vaccination programmes and in response to incidents and outbreaks. The current immunisation programme is managed nationally by Public Health Scotland (PHS), in partnership with territorial boards and Scottish Government, through the Scottish Vaccination and Immunisation Programme.

The operational delivery of vaccinations in Scotland is the responsibility NHS Boards. Eligibility cohorts are communicated via professional guidance and CMO letters to the NHS.

This document is not intended to be exhaustive, and the relevant chapters of the Immunisation against Infectious Disease (Green Book) should be accessed for more specific clinical information as this can occasionally be updated frequently during a particular focused vaccination programme timetable.

In addition, guidance and information will be circulated locally via CMO letters and Public Health Protection Unit (PHPU) communications.

Information on national immunisation programmes, including the timetable of routine childhood immunisations, and additional vaccines for those at risk can be found on the links below:

- Scottish Vaccination and Immunisation Programme
- Green Book Chapter 11 – Immunisation Schedule
- NHS Inform – Immunisation

3.0 IMMUNISATION MANAGEMENT

3.1 Accountability and Responsibility

The overall responsibility and accountability for all the immunisation programmes is held by the NHS Board and the Director of Public Health. The NHS Board is tasked with achieving government mandated vaccination uptake targets across all programmes and implementing new programmes as necessary.

3.2 Public Health

The NHS Board delegate responsibility for all immunisation programmes to the Immunisation Coordinator. This person is a Consultant in Public Health Medicine or equivalent, and has responsibility for the coordination of safe and effective delivery of care, governance and monitoring of all immunisation programmes across NHS GGC.

The Immunisation Coordinator reports directly to the Director of Public Health and the NHS Board. They work closely with the Immunisation Programme Manager, Service Manager and Lead Nurses for Immunisations to ensure effective programme monitoring and leadership, and quality improvement.

3.3 Facility Managers

The safe receipt, storage, and correct handling of vaccines is the responsibility of all onsite operational managers. They, along with clinical staff, must ensure staff have access to appropriate facilities, sundries and vaccine supplies. Facility Managers are responsible for the safe use of the venue and have responsibility to ensure that the venue they are working in has been risk assessed and that staff are aware of evacuation protocols, muster points etc.

3.4 Registered Health Care Practitioner

3.4.1 Clinical Management

Regardless of the setting where immunisation is being delivered, healthcare staff involved with administering vaccines need to be knowledgeable concerning:

- Documentation
- Resources and equipment
- Preparation of vaccine
- Skin preparation
- Waste disposal

An immunisation clinic checklist (Appendix 1) has been developed which can be used when preparing for a clinic.

Direct safe and effective delivery of vaccine at clinics is the responsibility of the Clinical Lead or Ward Manager that has responsibility over single vaccination delivery on a ward or via a community based mass clinic. They are onsite to support Immunisers in their assessment, and administration of vaccines.

Managers or Clinical Leads need to be assured that the Immunisers, under their supervision, are appropriately trained and competent in their roles, plus that staff have all read, understood and signed the PGDs and can work under these instructions.

Clinical Leads or Ward Managers need to ensure that vaccines and sundry supplies are ordered and available for clinics, and ensure there is appropriate provision for sharps and other waste disposal and uplift.

They have responsibility to ensure that the venue they are working in has been risk assessed and that staff are aware of evacuation protocols, muster points etc.

Within mass clinic venues, Clinical Leads are also required to ensure good queue management in liaison with the public, triaging where necessary.

3.4.2 Immunisers

The Immuniser has a responsibility to deliver safe and effective person-centred care. They must be competent in the storage, handling and administration of vaccines and understand the effects and side effects of the vaccines that they are providing.

Various different grades and professions can administer vaccines. However, it is important that staff adhere to their professional guidelines and ensure that they have gained the necessary competencies in vaccine administration. (Please refer to Section 5 – Training and Education).

When administering medications the Immuniser must exercise their professional judgement and apply their knowledge and skill to the given situation.

Prior to each vaccination, Immunisers must be assured that:

- There is access to a phone and additional staff in case of an emergency
- Appropriate anaphylaxis/resuscitation equipment is available
- The cold chain has been maintained
- There is informed consent
- Patient Information Leaflets are provided
- Vaccine is in date and not expired
- Vaccine has been prepared as appropriate and the correct needle size is used
- An assessment of the individual's fitness for immunisation has been made
- There are no known contra-indications to the vaccination(s)
- Patients/parents/carers/guardians are advised about the actions to be taken in the event of an adverse reaction occurring

3.5 Pharmacy Public Health (PPH)

Pharmacy Public Health (PPH) are responsible for the accurate, safe and secure procurement, receipt, storage and distribution of vaccines, in order to meet the needs of the population.

PPH work closely with other pharmacy colleagues and healthcare staff to coordinate vaccination programmes, vaccine deliveries and vaccine storage and handling audit

schedules. Issues with cold chain management and breaches, out of date stock or inadvertent administration of expired vaccines.

3.6 Patient Group Directions and Patient Specific Directions

The vaccination programmes are primarily delivered by trained Nursing staff, with the support of trained Healthcare Support Workers (HCSW) Vaccinators. Nursing staff can supply or administer vaccinations using a Patient Group Direction (PGD) or a Patient Specific Direction (PSD).

HCSW Vaccinators may administer a non-live vaccine after it has been prescribed, provided there are appropriate training, supervision and governance arrangements in place.

As vaccines are prescription only medicines, there is a legal requirement for them to be prescribed. However, there are other alternatives to prescribing if service and patient need determines such model.

3.6.1 Patient Group Directions (PGDs)

A PGD is defined as a written instruction for the sale, supply and/or administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment. PGDs are legal documents and it is important that the process around the use of these documents is very carefully followed. A PGD is not a form of prescription.

Registered Health Professionals working under a PGD should ensure that:

- They are authorised to work under a PGD.
- The document they are working under is in date and that they have signed a copy of the latest iteration.
- They have read the document thoroughly and understand which patients they can treat under the PGD.
- They understand the clinical governance requirements for working with PGDs e.g. appropriate patient records required.
- They are up to date with any specialist skills listed in the PGD.

A healthcare professional operating under a PGD is responsible for the clinical assessment of the patient against the criteria within the PGD.

If a patient or clinical situation falls outside of the inclusions listed for the relevant PGD, or meets any of the exclusion criteria, the PGD cannot be used for administration and a Patient Specific Direction (PSD) should be obtained.

Individuals requiring copies of the latest vaccine PGDs should first speak to their line manager or clinical lead. Alternatively they can request a copy of an authorised PGD from ggc.patientg.generic@nhs.scot.

Clinical enquiries about the content of vaccine PGDs should be directed to ggc.pharmacypublichealth@nhs.scot or tel. 0141 201 4464.

3.6.2 Patient Specific Direction (PSD)

A PSD is different from a PGD as this is a written instruction to supply or administer for an individually named patient who has been clinically assessed by the prescriber. A template PSD is available for vaccine prescribing if needed, though a PSD does not need to be on this template to be a legal instruction as long as the document contains the necessary legal information for prescribing.

More information about working under PGD and PSDs and a list of healthcare professionals who may do so can be found here found below:

- Specialist Pharmacy Services – PSD
- Specialist Pharmacy Services - PGD
- UKHSA - PGDs

3.6.3 National Protocols (NP)

In response to the Covid-19 pandemic, emergency legislation introduced National Protocols (NPs). They were introduced by amendment 247A of the Human Medicines Regulation (HMR) 2012. When operating under an NP, as long as consent and clinical assessment of fitness (to be vaccinated) is taken by a professional who could vaccinate under a PGD, then the preparation, administration and recording of vaccines can be undertaken by any appropriately trained health care worker, whether professionally registered or not. NPs only apply to flu and Covid vaccines. 247A is subject to a "sunset clause". That is it will automatically cease to operate in 2026. A UK government consultation on the most appropriate replacement is underway at time of approval of this guideline.

4.0 RECORD KEEPING

4.1 Documentation

The vaccine record is part of the medical record and therefore a legal document. The following information should be recorded accurately:

- Vaccine name, batch number and expiry date
- Dose administered
- Site(s) used – including clear description of which injection was administered in each site, particularly where two vaccines have been administered in the same limb (see Best Practice Guidance – Green Book Chapter 4).
- Date immunisation(s) were given
- Venue if applicable
- Names and signature of vaccinator

Vaccine administration information should be recorded in the Immunisation Recording Systems agreed with each service i.e.:

- TURAS Vaccine Management Tool
- Patient Held Record or Personal Child Health Record (PHCR)
- Patient's GP record or other patient record depending on location where possible.
- Child Health Information System (SIRS)

4.2 Access to Immunisation Details

Please note the Public Health Directorate do not hold vaccine records.

For childhood vaccines, immunisation details may be visible on Clinical Portal either via the immunisation tab or on a child's EMIS Summary tab.

Information on a child's immunisation status, can be obtained by professional staff, directly from Child Health by emailing:

- school.screening@ggc.scot.nhs.uk for vaccine history for a school age child
- childhealth.screening@ggc.scot.nhs.uk for vaccine history for a pre-school children

Patients looking for adult vaccine records should approach their GP in the first instance. Child Health hold vaccine records for individuals vaccinated in NHS GGC born after 1984.

5.0 REFERRAL PROCESSES

5.1 Adult Immunisation Delivery Team

Eligible patients are scheduled for all routine and selective National Public Health Immunisation Programmes through the National Vaccination Scheduling System (NVS) or local scheduling systems, depending on the vaccine programme. More information on the Scottish vaccination schedule can be found on NHS Inform.

5.2 Adult non routine appointments

Patients are referred for all non-routine vaccinations through the SCI Gateway Referral Pathway to the Contact Centre for triaging by Clinical Team and appointing at local community clinics. For referrers who do not have access to SCI Gateway, the alternative MS Form should be used.

5.3 Childhood Immunisation Delivery Teams

The routine schedule can be found on NHS Inform.

5.3.1 Pre School 0 - 5 Years of age

Child Health and Screening Department call and recall children for routine vaccinations via Scottish Immunisation Recall System (SIRS) to local NHS GGC childhood community clinics.

SIRS extracts are sent to the local Preschool Immunisation Teams fortnightly, and parent/carers are sent invite letters from Child Health and Screening Department with appointment details. Parents/Carers also receive a telephone call and text reminder from their local Preschool Immunisation Team.

5.3.2 School Age 6 – 16 years of age

All primary school aged pupils P1 - P7 are offered the Flu Immunisation Programme annually through the National Child Health Surveillance System.

All Secondary School aged pupils S1 - S6 are offered the routine National Immunisation Programmes at school using the National Child Health Surveillance System.

The National Child Health System receives an annual education download to assign a school code to records held on the national system. The system is used to generate eligible lists and consent forms.

5.3.3 Non routine Vaccinations (Childhood)

Non Routine Child Vaccination referrals for children up to 18 years are received via SCI Gateway referral pathway. All referrals are triaged by a clinical team for appointing at local community clinics.

5.4 Travel Health and Travel Health Clinics

Registered Healthcare professionals can access the Travel Health Pro (NaTHNaC) for advice on travel health.

For further local information about travel clinics visit Overseas Travel Vaccinations - NHSGGC.

For information and a list of clinics providing yellow fever vaccination go to NHS Inform – Yellow Fever.

Further information on travel vaccines is available on NHS Inform – Travel Health and Travel Vaccinations.

5.5 BCG Programme

The BCG programme is specifically targeted to children whose parent or grandparents are from high risk countries as defined by the World Health Organisation (WHO).

Babies at risk should be referred for BCG by Midwifes or Health Visitors by using the agreed BCG online referral form.

The school BCG programme was discontinued in 2005. Now only individuals with specific risk factors are offered BCG. Therefore the groups recommended for BCG vaccination include:

- Infants and young people under 16 years whose parents or grandparents were born in a country where the annual incidence of TB is 40/100,000 or greater
- Previously unvaccinated new immigrants under 16 years of age from countries where the annual incidence of TB is 40/100,000 or greater
- Contacts of cases known to be suffering from active pulmonary TB

See Green Book Chapter 32 for occupational and travel recommendations.

For further information please contact PHPU by telephone on 0141 201 4917.

For information on high risk countries please see WHO TB Data.

5.6 Babies at Risk of Hepatitis B

Screening is offered to mothers during pregnancy for Hepatitis B, Hepatitis C, and HIV. The aim of BBV screening in pregnancy, is to ensure an appropriate plan for treatment and management for affected individuals and their babies can be implemented. This plan is designed to reduce the risk of mother to child transmission and improve the long-term outcome of both mother and child.

Following identification of a Hepatitis B surface antigen (HBsAg) positive test from the mother's booking blood sample, the West of Scotland Specialist Virus Centre writes to the clinician in charge of the patient and the nominated obstetrician. This letter highlights if the child requires Hep B vaccination or if they also require immunoglobulin to be given at birth.

Clinicians should follow the Hepatitis B Positive, Management of Women identified through antenatal screening protocol.

Babies born to mothers who are chronic carriers of hepatitis B virus (HBV) follow an augmented hepatitis B vaccination schedule compared to all other babies. Therefore they should receive the first dose of hepatitis B vaccine at birth in hospital. The paediatrician then notifies Child Health who schedule an appointment at 4 weeks for a single dose of vaccine. The baby then receives 3 doses within the 6:1 vaccine at 8 weeks, twelve weeks and sixteen week, then a final single dose at 13 months. See Green Book Chapter 18 for further details.

Once the baby reaches a year old, they are referred for Hepatitis B surface antigen (HBsAG) screening, irrespective of vaccine status.

6.0 TRAINING AND EDUCATION

A high level of knowledge and a positive attitude to immunisation in Registered Healthcare Professionals is widely acknowledged as being important determinants in achieving and maintaining high vaccine uptake. It is therefore vital that Registered Healthcare Professionals working within immunisation delivery are confident, knowledgeable and up to date. Good foundation training and regular updates must be provided and undertaken to achieve this.

The UK Health Protection bodies in co-operation with the Royal College of Nursing[i] have developed minimum standards for immunisation training, which have been endorsed by

a range of Registered Health Professional bodies including the Royal College of General Practitioners (NHS HDL (2007) 18)[ii].

6.1 Promoting Effective Immunisation Practice (PEIP)

Based on the above, HPS and NHS Education Scotland have developed an e-learning package for all healthcare workers who have a remit in immunisation: "Promoting Effective Immunisation Practice" (PEIP). This is an easily accessible learning tool and is available on TURAS.

It is considered NHSGGC Board best practice that all staff involved in the delivery of immunisations or who are required as part of their Public Health role, to provide advice and guidance on immunisations, e.g. Midwives and Registered Healthcare Professionals, School Nurses and Health Visiting Staff complete the PEIP programme.

More information on this programme is available on TURAS. Staff should create a TURAS account that they can access via their NHS.scot account or personal email address.

They can sign up directly to the PEIP course on TURAS learn, local support for mentorship is available.

All staff providing information, advice and administering vaccines should also have access to and consult Immunisation against Infectious Disease (The Green Book).

6.2 Anaphylaxis and Resuscitation

Staff involved in administering vaccines must complete annual anaphylaxis and annual resuscitation face to face Basic Life Support (BSL) training.

For training on anaphylaxis procedures go to:

- Completion of LearnPro module GGC: 027 Anaphylaxis (alternatively, you can refer to Recognition and Management of Anaphylaxis – hosted by our colleagues within NHS Highland)
- Ensure you are up to date with the anaphylaxis guidance from The Resuscitation Council
- Watch the Emergency Treatment of Anaphylactic Reactions video (YouTube)
- Anaphylaxis Campaign

* Please note if acute staff have undertaken AL2 course within the last 12 months the BLS Community Resuscitation Officer and Emergency acute lead have confirmed this as sufficient.

6.3 PGDs and PSDs

Most of the immunisation programmes are delivered using PGDs. Thus professionals working under PGDs should have complete the PGD module training on TURAS Learn.

6.4 Competency Criteria

Staff must ensure they attend regular updated training sessions/webinars regarding immunisations as required. Staff must read and sign all relevant governance documents i.e. PGD's/PSD's/National Protocols as required prior to immunising.

Information on training governance resources such as the self-declaration form can be accessed at NHS GGC Immunisation webpage. The self-declaration form is a useful generic tool which should be used to monitor Governance and staff compliance within teams.

Prior to administering any vaccines staff should be competent in both intramuscular and deep subcutaneous injection techniques. Information on these techniques is contained within the Green Book, chapter 4 – immunisation procedures.

In addition, all staff should be aware of the requirements for infection prevention and control, especially the safe disposal of waste, including sharps and should incorporate appropriate training into their continuing professional practice (CPD) arrangements.

All staff directly employed by the NHS and subject to Agenda for Change (AfC) now need to meet the requirements of the Knowledge Skills Framework (KSF) described for their post. eKSF is available on TURAS. Outlined below are how evidencing competence in different elements of immunisation may be utilised against KSF dimensions.

Criteria		
Aware of and can describe current vaccine schedule. (KSF HWB1.2)	Reflect on your clinical decision making in relation to immunisation practice. (KSF core 4.2/5.2)	Work with members of the multi-disciplinary team in relation to immunisation programmes. (KSF core 1.2)
Advise patients with uncertain immunisation history. (KSF core 1.2/HWB2.2)	Evaluate your consultation style with patients/clients in immunisation clinics. (KSF core 4.2/5.2)	Reflect on own practice and identify when support from others is required. (KSF core 3.2)
Demonstrate up to date knowledge of ordering, handling and storage of vaccines. (KSF EF1.2)	Access literature and data about immunisations. (KSF IK3.1)	Provide support and guidance to other professional. (KSF G1.2)
Demonstrate an understanding of the immune system and how vaccines work. (KSF HWB3.2)	Review and monitor your standard of vaccine administration and record keeping. (KSF core 4.2/5.2)	Access and use current PGDs ensuring they are signed by the appropriate people. (KSF core IK3.2)

Demonstrate an understanding of public health aspects of immunisation. (KSF core 3.2/HWB1.2)	Discuss immunisation issues with other professionals. (KSF core 5.2)	Demonstrate ability to identify and manage adverse events, including anaphylaxis. (KSF HWB7.3)
Demonstrate up to date knowledge about professional accountability in relation to administration and recording of immunisations.	Demonstrate knowledge of patient confidentiality in light of current legislation regarding the handling of personal data. (KSF core 6.2/3.2)	Review and monitor your own practice in connection with professional and policy guidelines and immunisation standards. (KSF core 4.2/5.2)
Demonstrate up to date knowledge of the principles of consent and recording in patient records. (KSF IK3.2)		

7.0 CONSENT

For anyone, consent or shared decision making for any treatment requires to be fully informed and the individuals receiving the treatment must be able to understand what the treatment is for and how it will affect them. Shared decision making means that patients have a voice in all aspects of their healthcare.

Assessing the capacity to consent of the person receiving vaccination is the Immuniser's responsibility. It is deemed best practice that consent is recorded but that is not a legal requirement as the person is passively consenting since they presented for vaccination. However the discussion on consent, the vaccines and after effects should all be documented.

Please also see NHS GGC's policy on Consent to Treatment.

7.1 Clinician's responsibility

- To seek authorisation to proceed with immunisation from parent/guardian/patient, it is good practice to provide the relevant verbal and written information at an appropriate time to allow them to make an informed decision. This should include benefits and risks and should not involve any deceit.
- Consent needs to be given freely in that there has been no pressure placed on the patient and that they are not under influence from family, health professionals or others.
- The clinician should be able to answer adequately any questions the parent/patient may have about the immunisation. The Green Book provides comprehensive

information on all vaccines.

- To communicate effectively with other members of the healthcare team any knowledge and information they may have regarding parents/patients desires relating to immunisation.
- In order to ensure they have fully understood, individuals for whom their first language is not English or they use British Sign Language, support from Translation Services should be sought.

7.2 Adults with Incapacity

The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.

If a Certificate of Incapacity is in place, the decision on whether or not to vaccinate should be discussed with the individual and their guardian and/or next of kin. Even if a Certificate is in place the individual may still have the capacity to decide on basic health care matters so involving them in the discussion is good practice. Please also refer to the Adults with Incapacity (Scotland) Act 2000.

7.3 Children Rights

Children aged 16 or over are presumed to have decision making capacity.

If a child, under the age of 16, is capable of understanding the nature and possible consequences of the treatment, and this has been assessed by a medical professional, they are deemed to have the legal capacity to consent on their own behalf. Please also refer to the Age of Legal Capacity (Scotland) Act 1991.

The immuniser should consider the European Rights of the Child and apply the Gillick competency to ensure the child has the capacity to decide on their treatment. This usually gives the age of maturity to be a child who has reached puberty.

Immunisers, parents or guardians, cannot override a valid, competent decision made by the child to accept or decline vaccinations. For example, a 14 year old can consent to HPV vaccination, in their own right, even if their parents are opposed to them receiving this vaccine.

7.4 Parental Rights

Any adult with parental responsibilities for a child (including grandparents, unmarried fathers, and legal guardians) can legally provide consent for vaccinations. Thus, professionals can accept consent from parent, legal guardian or the main caregiver with legal responsibility when the young person is not able to provide their own consent and it is not within the knowledge of the professional that the parent of the young person would refuse to the consent.

Furthermore, the person with parental responsibility need not to be present for immunisation and the child may be brought for example by a childminder or grandparent. In these circumstances, the clinician must be satisfied that the person has the necessary authority i.e. the person with parental responsibility has previously indicated that they

wish their child to be included in the programme and there is no indication that the parent has negative views of immunisation.

If parental consent has been withheld for the routine childhood vaccination programme, a Scottish Immunisation Recall System (SIRS) non participation form must be completed and returned to the Child Health Department in order to prevent subsequent automatic call-up of a child for immunisation.

8.0 VACCINE ADMINISTRATION

Details of vaccine administration best practice are shown in chapter 4 of the Green Book, with some key features highlighted below.

Before injecting the immuniser should check that:

- Consent has been given
- The correct vaccine has been selected
- The vaccine is in date
- Correct dose is drawn up (if a multi-vial)
- The colour and composition of the prepared vaccine is within expected parameters.

The following aspects of immunisation technique are important as when performed correctly they can improve immunogenicity and reduce risk of local reactions:

- Preparation
- Injection technique
- Choice of needle length
- Injection site

8.1 Preparation

8.1.1 Skin Preparation

Clean skin does not require further cleaning. Alcohol and other disinfectants can inactivate live vaccines. The vaccination area should be completely exposed, and if visibly dirty washed with soap and water.

8.1.2 Vaccine Preparation

To avoid errors and maintain efficacy, vaccines should only be reconstituted and drawn up when required and not before the immunisation session.

Freeze dried vaccines should only be reconstituted using the diluent supplied and used within specified time. The diluent should be drawn up using a green (21G) needle and slowly added to vaccine to avoid frothing. The needle should be changed prior to administration of the vaccine.

The vaccine colour and consistency should be checked prior to administration. The expected colour is noted in the PGD. Any discoloured vaccine or where particulate matter is observed should be destroyed.

8.2 Injection Technique and Site

The technique, as described in the Green Book Chapter 4 should be used.

Vaccines MUST NOT be given intravenously.

It is important the vaccine is injected into muscle and not into fat. This is why the deep subcutaneous route is no longer recommended for most vaccines.

Babies and young people should be sat sideways, securely in the lap of the parent/guardian.

For infants under 1 year, the anterolateral aspect of the thigh is preferred injection site.

Over age of 1 year the deltoid is preferred site. The buttocks must be avoided due to higher risk of injecting into fat and possibility of sciatic nerve damage.

If multiple injections are required at one visit, they should, as far as possible be administered in different limbs. If this is not possible then injections in the same limb should be 2.5 cm apart.

8.3 Choice of Needle

The majority of vaccines are given Intramuscularly (IM). For IM injections, the needle needs to be long enough to ensure vaccine is injected into muscle. A 25 mm needle is suitable for most except for pre-term or very small infants when 16 mm should be used or for larger adults, where 38 mm may be necessary. The Green Book Chapter 4 has additional information on appropriate needle sizes.

Sometimes the vaccine manufacturer supplies needles as part of the product and there is an expectation that those needles will be used to administer the vaccine. These needles (non-safety or safety) form part of the product license and the vaccinator must use this as substituting these for another type makes the vaccine administration an unlicensed provision of care. This would transfer product liability from the manufacturer to the vaccinator.

Where staff are using separate needles and syringes, it is important to ensure that the needle is firmly attached to the syringe.

In NHSGGC there has been a policy decision made that vaccine should be delivered using safety needles as part of the Health and Safety Executive directive Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.

8.4 Waste Disposal

Waste used for vaccination, including used vials and ampoules, should be properly disposed of at the end of a session in line with NHS Scotland waste policies

Where live vaccines are used, staff must exercise due care and attention in order to eliminate the risk of hands or surfaces being contaminated.

All reconstituted vaccines, opened single and multi-dose vials, empty vials and ampoules

and used needles and syringes should be disposed of in appropriate sharps bin (UN-approved, BS 7320), which should be replaced once 2/3 full. These sharps bins must be suitable for medicine waste e.g. blue lidded.

Any materials contaminated either by vaccine spillage or body fluids (including the disposable towels) must be placed in appropriate bins specifically for medicinal products waste (yellow/blue lidded) specifically for consignment to disposal by incineration.

9.0 COLD CHAIN MAINTENANCE

It is essential that vaccines are stored correctly, and cold chain is maintained as far as possible between 2°C and 8°C. Any individual managing or handling vaccines should be appropriately trained on cold chain requirements:

- Cold Chain Management- LearnPro GGC:097 Cold Chain Management

All users should apply the NHS GGC Vaccine Handling and Storage policy and also be aware of the PHS Vaccine Storage and Handling guideline.

9.1 Cold Chain Incident Reporting

All incidents relating to a breach in the cold chain (i.e. temperatures are out with 2°C and 8°C) should be reported to PPH as soon as possible on ggc.pharmacypublichealth@nhs.scot, telephone: 0141 201 4424 / 0141 201 4824 who will provide advice on immediate action which is necessary and then provide a more detailed investigation if required.

In event of the incident occurring during outside of normal working hours, the vaccines should be quarantined in another functioning fridge and the original fridge marked as “do not use” until PPH are able to provide more specific advice.

All cold chain incidents should also be reported on DATIX, but not closed to enable Pharmacy Public Health to add any investigation outcomes and approve.

10.0 VACCINE ERRORS AND REPORTING

This section deals with vaccine errors, that is, mistakes in the preparation and administration of vaccines. Errors in storage or cold chain failures are detailed above in section 8.0.

Whilst the majority of vaccine errors will result in no direct harm, errors may leave individuals unprotected from infectious disease and have a significant resource burden in follow up, and can reduce the trust and confidence in vaccine programmes.

All vaccine errors should be reported to the Public Health Protection Unit (PHPU) by phone during office hours. When connected please state that you are calling regards a vaccine error, as that will ensure your call is triaged appropriately. PHPU staff recognise the distress an error can cause, and will try as far as possible to prioritise your call.

PHPU and PPH can help with risk assessment of the error, and provide advice on future vaccination.

10.1 Yellow Card Scheme

Please also see the Green Book Chapter 9 surveillance and monitoring for vaccine safety, for more details.

Adverse events subsequent to vaccination, such as anaphylaxis, or other vaccine related side effects are outside the scope of this guidance and should be reported through the same mechanisms as adverse events from other medicines.

For vaccines that are subject to additional monitoring by the Commission on Human Medicines (CHM) and the Black Triangle Scheme. Any suspected or actual adverse reaction must be reported using the Yellow Card Scheme and completing the on line form or by phoning 0131 242 2919.

10.2 DATIX

Vaccine errors may occur in even the most prepared organisations. We need to learn from them, and introduce systems and practices that minimise the risk of errors happening in the future. Learning can only happen in an open and trusting environment. It is therefore important that all vaccine errors are reported via the DATIX system and discussed as part of local procedures.

11.0 APPENDIX 1 - IMMUNISATION CLINIC CHECKLIST

Part A: Clinic Facilities and Equipment			
Clinic Facilities	**Yes**	**No**	**Comment**
Room has adequate space			
Waiting area has adequate space			
There are staff to support the clinic			
Patient records are available and accessible to review and record in the clinic			
Hand washing facilities are available in the room and meet infection control standards			
Facilities for drawing up and checking vaccines meet infection control standards			
There is a system in place in the event of an adverse reaction, including availability of emergency medicines			
Immunisation supplies are stored in safe and secure environment			
Identified members of staff to be responsible for vaccine stock rotation and cold chain management			
Vaccines are stored and maintained to preserve cold chain			
Vaccine storage is monitored and records are audited			
Sharps disposal containers are accessible			

Part B: Preparation, administration and recording			
	Yes	**No**	**Comment**
Prior to clinic staff delivering immunisation clinic must ensure that vaccines have been maintained in the cold chain e.g. 2^{o} – 8^{o} degrees			
System is in place to check patient is fit and well to be immunised, and that informed consent has been given			
Name and appearance of vaccine, expiry date and batch number are all checked prior to administration on an individual basis			
Routine practice of vaccines being drawn up for each individual patient after screening is being followed			
Staff drawing up vaccine should administer the vaccine			
Staff administering vaccine records immunisation. The following information should be recorded: • Vaccine name • Batch number • Expiry date • Date given • site given • electronic signature e.g. MM PHR (Patient Held Record), VMT			

12.0 APPENDIX 2 - VACCINE SPECIFICS

12.1 Tetanus Containing Vaccines and Human Tetanus Immunoglobulin

Tetanus as a single vaccine is no longer in use and is only available as part of a combined product. Following injury (e.g. wound, burns, and compound fractures) selection of the most appropriate tetanus-containing vaccine will depend on the age and immunisation status of the patient. Please see Green Book Chapter 30 on tetanus vaccine.

12.2 Infants Born to Mothers on Biological Immunosuppressive Therapy (pregnancy or breastfeeding)

Babies who have been exposed to immunosuppressive biologics in utero should delay BCG, or any other live vaccination, until 12 months of age.

Babies who are being breastfed by a mother receiving immunosuppressive biologics are advised to have vaccination delayed for as long as there is a possible postnatal influence on the baby's immune status. The bioavailability in breast milk will vary between immunosuppressant's, and expert advice should be sought if there is doubt as to whether to proceed with vaccination.

13.0 APPENDIX 3 - INDIVIDUALS WITH UNCERTAIN OR INCOMPLETE IMMUNISATION

The general principles of vaccination of individuals with uncertain or incomplete immunisation status are:

- Unless there is a reliable vaccine history, individuals should be assumed to be unimmunised and a full course of immunisations planned
- Individuals coming into the UK part way through their immunisation schedule should be transferred onto the UK schedule and immunised as appropriate for age
- If the primary course has been started but not completed, continue where left off there is usually no need to repeat doses or restart the course.
- IPV should be used to complete a vaccination course which may have been started with OPV (Oral Polio Vaccine).
- aP should be used to complete a primary course which may have been started with whole cell pertussis vaccine.
- From summer 2025, there will be no vaccine that has a HiB component that is suitable for vaccination of adults.
- A minimum of one year should be left between DTaP/IPV/Hib/HepB (infanrix hexa) primary course and 1st booster and a minimum of five years should be left between the 1st and 2nd boosters.

For further information visit

Vaccination of individuals with uncertain or incomplete immunisation status - GOV.UK (www.gov.uk)

14.0 APPENDIX 4 - PATIENTS WITH IMMUNOSUPPRESSION AND VACCINATION NEEDS

Patients who undergo, or about to undergo immunosuppressive therapy, including treatment for cancer, chronic inflammatory conditions and biologic therapy, may require a clinical assessment of their vaccination status.

Public Health Scotland provide patient cohorts for Covid-19, seasonal influenza, Respiratory syncytial virus (RSV), pneumococcal and shingles vaccinations based on current JCVI eligibility for that programme. Eligibility is drawn from several sources, including GPIT systems and HEPMA; note that infrastructure for using HEPMA in outpatient clinic settings is still being implemented.

In general, it is the responsibility of the clinician who diagnoses the immunosuppressive/at risk condition or who initiates the immunosuppressive therapy to refer for additional vaccination. If this occurs in secondary care, it is inappropriate to request the GP make the referral.

If a clinician assesses a patient as requiring additional vaccination, this request should be completed via the appropriate referral form to the local contact centre (either via MS Forms or SCI-gateway; this will be replaced in due course with a Trakcare referral).

Some medical conditions may result in increased risk of complications from infectious diseases. In general, those with immunosuppression (because of condition or treatment, including those who are HIV+), asplenia (absence or dysfunctional spleen) or those young children born prematurely will need consideration.

Further information is provided in Chapter 6 (contraindication and special considerations) and Chapter 7, (Immunisation of individuals with underlying conditions), Green Book.

Clinicians should refer to the relevant disease chapters within Part 2 of the Green Book[4] for specific advice on immunisation requirements.

Some specialist society guidelines go beyond the Green Book recommendations or use more complex algorithms. NHS GGC support the use of the Green Book recommendations.

14.1 Immunosuppression

For those with immunosuppression, is preferable to have any boosting or re-vaccination completed before any treatment begins or to wait until there is an improvement in immunity. It is recommended to have vaccinations done at least two weeks prior to starting immunosuppressive therapy, though this may not be practical or achievable. In these cases, vaccination should take place as soon as possible and consider revaccination once treatment is finished and patient has recovered.

Many live vaccines are contra-indicated in immunosuppressed individuals and those patients with immunosuppression and HIV infection should always be administered inactivated vaccines in line with current guidelines.

14.2 Stem cell transplant patients

Following transplant, it is likely that all proactive antibodies will be lost. It is advisable for these patients to be re-immunized. Clinicians should follow the advice within the PHS

Scottish Hematology Society guidelines for revaccination of patients following stem cell transplant or CAR-T treatment[3].

14.3 Immunosuppressive (non-cancer) Treatments

There are several drug treatments that can cause immunosuppression. For some vaccination programmes, the degree of immunosuppression is considered i.e. severity. Green Book Chapter 28a Shingles contains a helpful description of immunosuppression, though this is in relation to requirement for shingles vaccination.

There have been differences between the spring and autumn/winter eligibility cohorts to date (July 2024) so clinicians are advised to check the Green Book Chapter 14a and the most recent CMO letter for eligibility criteria for Covid-19 before referring patients. These groups are defined as those with weakened immune systems or severely weakened immune systems.

14.4 Immunisation Considerations for Patients Starting on Biologic Therapies

In addition to the above, patients commencing on biologic therapies, including anti-TNF or JAK inhibitors, may require additional vaccinations as they may be at risk of infection or respond less well to some vaccinations and require additional ones. Clinicians are advised to consider immunosuppressive status of the individual patient and recommend appropriate vaccinations as per appropriate Green Book chapters.

14.5 JCVI Statement (November 2024)

It should be noted that JCVI have published updated advice related to shingles (herpes zoster) programme in November 2024. This advice recommends provision of Shingrix® vaccination to all severely immunocompromised patients aged 18 years and older.

It is expected that this advice will be included into the programme cohorts from 2025 onwards but clinicians should check CMO advice before recommending.

14.6 Asplenia

Patients are at increased risk of severe infection particularly from pneumococcus, haemophilis influenza B, and Neisseria meningitides infections. These patients should be fully vaccinated according to the national schedule but as they are particularly susceptible to pneumococcus, these patients should be offered a 5 yearly booster for pneumococcal. Opportunity to vaccinate against MenACWY should also be considered at appropriate times.

Approximately 30% or adult patients with coeliac disease are also considered to have a dysfunctional spleen and should be offered these additional vaccines if they have known splenic dysfunction. Coeliac patients without evidence of splenic dysfunction do not require 5 yearly vaccination.

14.7 Other medical conditions

Further advice on what vaccinations that may be required can be found in the Green Book, chapter 7. Advice is based on the increased risk of infection as a result of the medical condition. As well as reviewing chapter 7, individual disease chapters should also be consulted.

RSV vaccination is an age-related programme, and those with immunosuppression are not routinely called unless within the specified age range.

14.8 Frequency of Vaccinations

Seasonal influenza and Covid-19 may be administered annually or twice annually (subject to JCVI advice for Covid-19). With exception of pneumococcal 5 yearly boosters for those with asplenia, all other vaccines are administered once in line with the national recommendations and do not require repeated doses.

REFERENCES

1. NHS GGC Immunisation and Best Practice Guideline (Immunisation and Best Practice (162) | Right Decisions (scot.nhs.uk))
2. Immunisation against infectious disease - GOV.UK (www.gov.uk)
3. Scottish Haematology Society | SHS Guidelines (scothaem.org)
4. Immunisation against infectious disease - GOV.UK (www.gov.uk)

15.0 APPENDIX 5 - ADMINISTRATION OF MORE THAN ONE LIVE VACCINE

In February 2014 the JCVI agreed that guidance to administer two live vaccines on the same day or at a four week interval period should not be generalised to all live vaccines.

See chapter 11 of the Green Book Chapter 11 for full details, including the live vaccine combinations where dose interval considerations apply.

16.0 APPENDIX 6 - COMPONENTS OF VACCINES

Vaccines are made with a variety of ingredients including antigens, stabilizers, adjuvants, and preservatives. They also contain residual by-products from the production process e.g. antibiotics.

Knowing precisely what is in each vaccine can be helpful when choosing alternative products for patients' who have allergies, as these components may be the key to allergic reactions and should be taken into consideration when investigating adverse events.

Since package inserts can change and there are sometimes small modifications in the components, the most recent package inserts must be reviewed to verify specific information. For information on excipients and allergens, please refer to guide and Electronic Medicines Compendium summaries of product characteristics.

16.1 Porcine Gelatine

For some ethnic minority and religious groups, vaccines containing animal products may be unacceptable.

In the UK within the routine immunisation programmes, there are two vaccines that contain porcine gelatine. These are:

- MMR VaxPro – a vaccine that protects against measles, mumps and rubella but this can be substituted with Priorix as it does not contain porcine.
- FluenzTetra - nasal spray that protects children against flu however children can be given the non-live IM flu vaccine instead.

Further information is available on UK Government Immunisations Vaccines and Porcine Gelatine leaflet (link required).

REFERENCES

[i] Royal College of Nursing (2018) Immunisation knowledge and skills competence assessment tool. Available: https://www.rcn.org.uk/professional-development/publications/immunisation-knowledge-and-skills-competence-assessment-tool-uk-pub-010-074

[ii] Scottish Executive (2007) Storage of Vaccines in GP Practices. Available: http://www.sehd.scot.nhs.uk/mels/HDL2007_18.pdf