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.

Version Number:	5
Does this version include changes to clinical advice:	No
Date Approved:	19th January 2023
Date of Next Review:	31st January 2025
Lead Author:	Gillian Penrice
Approval Group:	Primary Care & Community Clinical Governance Forum

Important Note:

The Intranet 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.

INTRODUCTION

This guideline is designed to provide information and support to staff in the management of these clinics. This is not an exhaustive guideline but designed to be added to by individuals and used by staff to support their continuing professional development. Information changes frequently and so some internet resources are listed to provide links for further information. In addition, guidance and information will be circulated locally via CMO letters and Public Health Protection Unit (PHPU) newsletters

https://www.nhsggc.scot/your-health/public-health/public-health-protection-unit/immunisation/

More detailed general information about vaccination and individual vaccines are given in the Immunisation against Infectious Disease (Green Book)

https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

CONTENTS

1.0 IMMUNISATIONS ROUTINE AND OTHERWISE

1.1 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, through the Scottish Immunisation Programme.

In terms of the operational delivery of JCVI recommendations, and the delivery of vaccinations in Scotland, this is done through NHS Health Boards. Priorities and targets are communicated via professional guidance and CMO letters to the NHS.

Information on national immunisation programmes, including the timetable of routine childhood immunisations, can be found at http://www.immunisationscotland.org.uk/when-to-immunise/immunisation-schedule.aspx

1.2 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, 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 on tetanus vaccine The Green Book on immunisation - chapter 30 tetanus (publishing.service.gov.uk)

1.3 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 primary course has been started but not completed, continue where left off – NO NEED TO REPEAT DOSES OR RESTART 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
    - MenC/Hib combined vaccine can be used when Hib alone or Hib/MenC is required
    - 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)

1.3.1 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
Green book chapter 11 The UK immunisation schedule (publishing.service.gov.uk)

1.4 Other Non-Routine Immunisations

1.4.1 Hepatitis B Immunisation of 'At-risk' Infants

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.

Following the first dose of hepatitis B vaccine at birth in hospital, the paediatrician notifies Child Health who schedule an appointment at 4 weeks for single dose of vaccine. The baby then receives 3 doses within the 6:1 vaccine at 2,3 and 4 months, then a final single dose at 13 months along with MMR, Hib/MenC/ pneumococcal and MenB.

1.4.2 BCG

The school BCG programme was discontinued in 2005. Now individuals with specific risk factors are offered BCG.

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/travel recommendations https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/14851 1/Green-Book-Chapter-32-dh_128356.pdf

For further information please contact PHPU by tel: 0141 201 4917.

1.4.3 Travel Health and Travel Clinics

Healthcare professionals can access the TRAVAX website www.travax.scot.nhs.uk for advice on travel health. TRAVAX is a national resource, provided by NHS since 1984, to help healthcare professionals who are advising patients on how to avoid illness when travelling abroad. The site provides detailed information on the illnesses specific to each destination. It is accessed through a log-in address, the registration system is straightforward and the database easy to use.

The public can use the Fit for Travel section at www.fitfortravel.scot.nhs.uk which provides good and updates information and links to a number of other websites including the Foreign and Commonwealth website which gives safety

recommendations for travellers.

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 Health and wellbeing services | NHS inform

1.5 Consent

1.5.1 Clinicians' responsibilities

- To seek authorisation to proceed with immunisation from parent/guardian/patient at each episode.
- To provide the relevant verbal and written information to the parent/guardian/patient at an appropriate time to allow them to make an informed decision. This should include benefits and risks.
- To obtain consent voluntarily: this means without pressure, deceit or under influence from family, health professionals or others.
- To answer any questions the parent/patient may have about the immunisation. The Green Book provides comprehensive information on all vaccines. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- To know that there is no legal requirement for consent to be in writing. Consent may be given in writing, verbally or by co-operation.
- To communicate effectively with other members of the healthcare team any knowledge and information you may have regarding parents/patients desires relating to immunisation.

Staff obtaining consent should be cognizant of the

- Adults with Incapacity (Scotland) Act 2000 - https://www.legislation.gov.uk/asp/2000/4/contents
- Age of Legal Capacity (Scotland) Act 1991 Age of Legal Capacity (Scotland) Act 1991 (legislation.gov.uk)
- Understanding of Fraser Guidelines and Gillick Competencies - Gillick competence and Fraser guidelines | NSPCC Learning
- NHS Greater Glasgow and Clyde: Consent Policy on Healthcare Assessment, Care and Treatment; September 2021 - http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Key%20Information/Pages/ConsenttoTreatmentPage.aspx

1.5.2 Parental responsibility

Mothers automatically have parental responsibility. Fathers also have parental responsibility if they were married to the mother when the child was conceived or born or married to her later. An unmarried father who is the natural father can also acquire parental responsibility if named on the birth certificate (births registered on or after 4th May 2006).

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. The clinician must be satisfied that the circumstances indicate 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.

1.5.3 Patients' rights

- Parents or those with parental rights have the right to decide whether their child is immunised.
- Children aged 16 or over are presumed to have decision making capacity.
- Children under the age of 16 have the legal capacity to consent to immunisation where, in the opinion of the clinician, they have the capability of understanding its nature and consequences.
- Children under 16 who do not have the capability to understand, a parent or adult with parental responsibility can make the decision on their behalf.
- Children over 16 who lack the capacity to make decision regarding immunisation must be treated under Part 5 of the Adults with Incapacity (Scotland) Act 2000.
- Parents/patients have the right to receive verbal and written information of immunisation.
- Parents/patients have the right to change their mind.

For further information see 'NHS Greater Glasgow and Clyde: Consent Policy on Healthcare Assessment, Care and Treatment; September 2021' provides a comprehensive guide to consent.
http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Clinical%20Governance/Key%20Information/Pages/ConsenttoTreatmentPage.aspx

1.6 Scottish Immunisation Recall System (SIRS)

1.6.1 Why SIRS?

The Scottish Immunisation Recall System (SIRS) was introduced to ensure that all pre-school children are invited to receive full courses of all routine primary and booster immunisations. The main benefits are:

- The automated call and recall of children for immunisation
- The availability of standard reporting
- Linkage with other Community and Preventive Care Systems (CPC) – including the Community Health Index (CHI) and the Child Health Surveillance Programme Pre-School (CHSP-PS) and School (CHSP-S)
- The availability of information for statistical analysis

1.6.2 Who uses SIRS?

The two principal groups of users are staff who administer immunisations and the screening department who facilitate the call/recall process which includes the recording of the immunisation results.

1.6.3 The SIRS child event cycle

This is a standard sequence of events applying to all children who are registered on

SIRS from notification of birth.

After a child is registered on SIRS, the 'Health Visitor First Visit Report' (HVFVR) is produced with labels for the 'Family Health Record' and the 'Personal Child Held Record', which are sent to the health visitor attached to the GP practice as notified by the maternity hospital. For areas who have rolled out EMIS, Child Health record the birth details onto EMIS and create an inbound referral to the local admin team, who in turn allocate to a health visitor.

On return of the completed HVFVR form the information is recorded onto the CHSP-PS which automatically updates the mandatory SIRS data fields which includes the SIRS treatment centre number and any exceptions/refusals to immunisation.

Children are given an appointment via a confidential invitation produced by SIRS. This informs the parent/carer where, when and what the child is due to attend for. The child's treatment centre receives an immunisation schedule which lists the children appointed and immunisations due.

After the immunisation clinic, the completed schedule should be returned as soon as possible to Child Health where the page will be processed and the child's record updated accordingly on SIRS and in the EMIS record. The child would then be re-scheduled where appropriate to the next available session.

If you have any queries regarding this or any questions about SIRS, please do not hesitate to contact someone in the Child Health Team – Screening Department.

1.7 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 group 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.

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 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
- They thoroughly understand any storage requirements related to the medicines they are administering. This is particularly important for vaccines.

More information about working under PGDs and a list of healthcare professionals who may do so can be found here MHRA https://www.nice.org.uk/Guidance/MPG2

Individuals requiring copies of the latest vaccine PGDs should first speak to their clinical lead. Alternatively they can request a copy of an authorised PGD from patient.groupdirections@ggc.scot.nhs.uk

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

2.0 IMMUNISATION KNOWLEDGE AND SKILLS

2.1 Accountability and Responsibility

The NMC Standards for Medicines Management 2015 and Code of Professional Conduct indicate the nurse is personally accountable for his/her practice. And when administering medications the nurse must exercise his/her professional judgement and apply his/her knowledge and skill to the given situation.

TRAINING AND COMPETENCE

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]. Based on these, 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** (https://learn.nes.nhs.scot/).

It is considered best practice that all staff undertaking vaccinations or who are required to provide advice and guidance on immunisations, e.g. Health Visitors, School Nurses, Midwives and Registered Healthcare Professionals complete the PEIP programme. More information on this programme is available on TURAS (https://learn.nes.nhs.scot/). All staff have 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, Local support for mentorship is available.

Promoting Effective Immunisation Practice (PEIP) eLearning programme

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

Staff involved in administering vaccines must complete annual anaphylaxis and annual resuscitation face to face BLS training.

2021 Resuscitation Guidelines | Resuscitation Council UK

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**

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

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.

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.

2.2 Competency Criteria

All staff directly employed by the NHS and subject to Agenda for Change now need to meet the requirements of the Knowledge Skills Framework (KSF) described for their post. 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)		

2.3 Operational Standards for Immunisation Clinics

Regardless of what setting immunisation is being delivered, healthcare staff 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.

2.4 Correct Administration of Vaccines and Documentation

2.4.1 Vaccine Administration

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

In addition, correct and safe disposal of waste and accurate documentation are essential parts of good vaccine technique.

Details of vaccine administration best practice are shown in chapter 4 of the Green Book, with some key features highlighted below.
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf

- 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 dilutent supplied and used within specified time. The dilutent should be drawn up using a green (21G) needle and slowly added to vaccine to avoid frothing
- Before injecting the immuniser should check that consent has been given, the correct product, in date and at correct dose, and the colour and composition following final

checks should be performed.

- Vaccines should 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.
- For IM injection, needle needs to be long enough to ensure vaccine is injected into muscle. A 25mm needle is suitable for most except for pre-term or very small infants when 16mm should be used or for larger adults, where 38mm may be necessary.
- 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.
- 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 2.5cm apart.
- The buttocks should be avoided due to higher risk of injecting into fat and possibility of sciatic nerve damage.
- The vaccination area should be completely exposed, and if visibly dirty washed with soap and water
- Clean skin does not require further cleaning. Alcohol and other disinfectants can inactivate live vaccines.
- Babies and young people should be sat sideways, securely in the lap of the parent/guardian.
- The technique, as described in the Green Book should be used.
- All reconstituted vaccines, opened single and multidose vials, empty vials and ampoules and used needles and syringes should be disposed of in appropriate sharps bin, which should be replaced once 2/3 full.

2.4.2 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, especially where two injections were administered in the same limb
- Date immunisation(s) were given
- Names and signature of vaccinator

This information should be recorded in all three:

- Patient held record or Personal Child Health Record (PHCR) for children (the Red Book)
- Patient's GP record or other patient record depending on location where possible
- Child Health Information System
- Vaccine Management Tool

2.5 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 dealt with in the 'NHS GGC Vaccine Ordering, Storage and Handling Guideline. Adverse events subsequent to vaccination, such as anaphylaxis, or other side effects are also outside the scope of this guidance section and should be reported through the same mechanisms as adverse events from other medicines.
Vaccine Ordering, Storage and Handling (410) (nhsggc.org.uk)

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 discussed as part of local procedures, which are demonstrated in the flowchart on page 16.

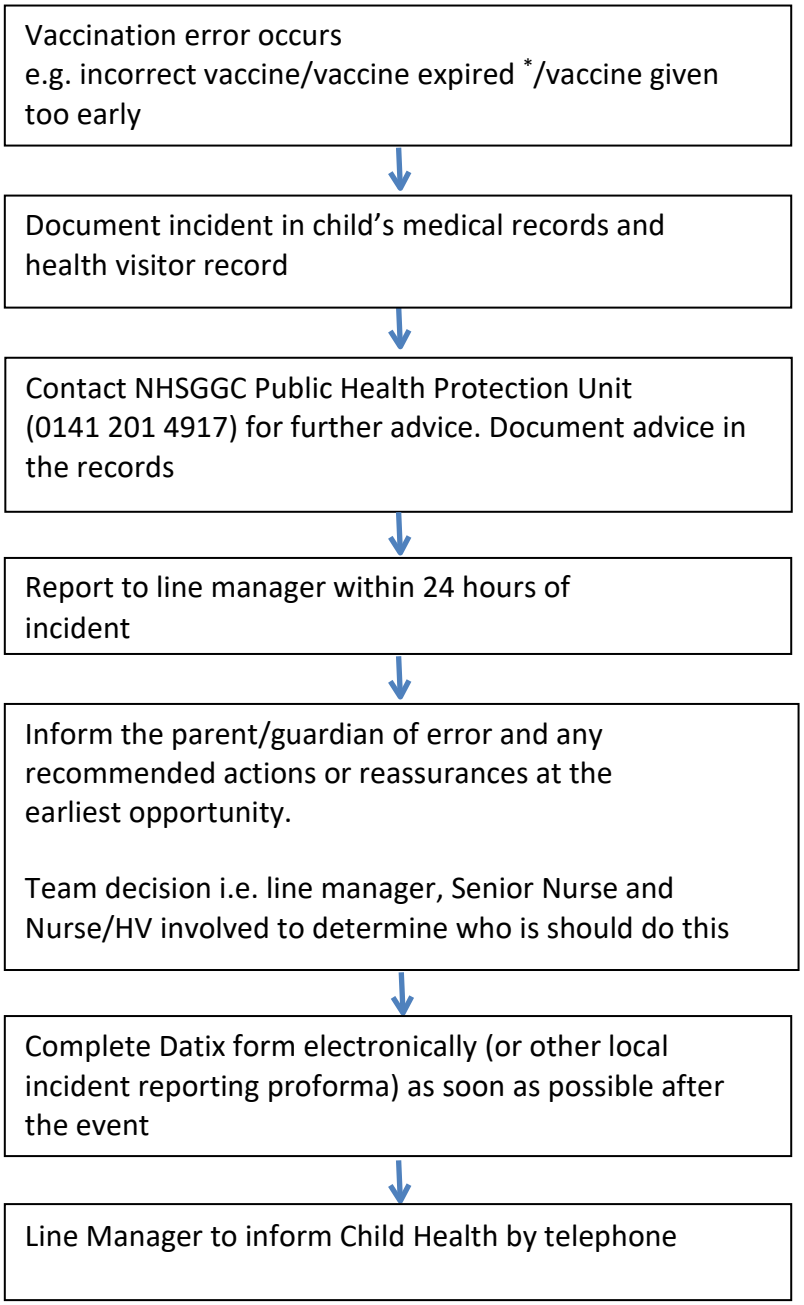
Whilst the majority of vaccine errors will result in no direct harm, errors can leave individuals unprotected from infectious disease and have a significant resource burden in follow up, and can reduce the trust and confidence in vaccine programmes.

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. PHPU staff recognise the distress an error can cause, and will try as far as possible to prioritise your call.

PHPU can help with risk assessment of the error, and provide advice on future vaccination. This advice is based on the Green Book and the national Vaccine Incident Guidance
http://www.documents.hps.scot.nhs.uk/immunisation/general/vaccine- incident-guidance-2013-09.pdf as well as the experience and knowledge of the PHPU staff.

If an error is identified by Child Health they will contact the relevant practice to investigate and advice can be sought from PHPU (0141 201 4917).

Flow chart to be followed in the event of a single vaccine error identified in the primary care setting.



*In the event of expired vaccination administration pharmacypublichealth@ggc.scot.nhs.uk can be contacted by the PHPU consultant as further information may be available from the vaccine manufacturer before any decision is made in regards to potential for revaccination.

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 A: Preparation, administration and recording			
Prior to clinic staff delivering immunisation clinic must ensure that vaccines have been maintained in the cold chain e.g. 2-8 degrees			
Check child's vaccination history prior to immunisation			
System is in place to check child is fit and well to be immunised, and that parent/guardian are fully informed to be able to give informed consent			
Staff are aware of correct sites for administration			

of vaccines: a) Anterior-lateral thigh for under 1 year b) Preferably deltoid area of arm for over 1 year, or anterior-lateral thigh *N.B. When 2 vaccines are administered on same limb there must be at least 2.5cm between sites.*			
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 child after screening is being followed			
Staff drawing up vaccine should personally administer the vaccine			
Staff administering vaccine records immunisation. The following information should be recorded accurately on: <u>SIRS:</u> • Vaccine name • Batch number • Expiry date • Date given <u>EMIS/Vision:</u> • vaccine name • batch number • expiry date • site given • electronic signature e.g. MM <u>PHR (Patient Held Record):</u> The vaccine given, date and site can be added in comments box.			
SIRS sheet is sent to Child Health on same day as clinic is held, even if all children failed to attend			

[i] Royal College of Nursing (2018) Immunisation knowledge and skills competence assessment tool. Available: https://www.rcn.org.uk/professional-development/publications/pdf-006943

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