

## PATIENT GROUP DIRECTION FOR THE ADMINISTRATION OF MMR VACCINE

This Patient Group Direction (PGD) is a specific written instruction for the administration of MMR Vaccine to groups of patients who may not be individually identified before presentation for treatment.

This will enable the appropriate registered healthcare professional to supply/administer treatment in accordance with the following protocol, the recommendations of the Department of Health 1998, the codes and standards of conduct of their professional bodies and any guidelines issued by those bodies on the supply and administration of medicines.

The majority of clinical care should be provided on an individual, patient specific basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patients care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Definition of clinical situation/condition	Immunisation against Measles, Mumps and Rubella in all patients aged 6 months and over.  During outbreaks of measles, mumps or rubella, or for postexposure vaccination, or for use in previously unvaccinated individuals of any age.
Name of organisation(s) within which the PGD will operate	NHS Tayside, General Practices and community pharmacies contracted to supply services to NHS Tayside within NHS Tayside.
Name(s) of clinical areas and locations where the PGD will operate	All appropriately trained NHS Tayside staff. All clinics and wards within NHS Tayside. General Practices. Educational establishments. Community pharmacies. Primary Care Treatment and Care Hubs Community Clinics. Domiciliary environments.
Criteria for inclusion	As part of the routine immunisation schedule -     schedule <a href="http://www.immunisationscotland.org.uk/when-to-immunise/immunisation-schedule.aspx">http://www.immunisationscotland.org.uk/when-to-immunise/immunisation-schedule.aspx</a> In children, the first dose is currently recommended between 12

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	and 13 months of age, but MMR vaccine can be given to children of any age over 6 months.
	Patients 6 months or older if the risk of infection is felt to be significant, e.g. during an outbreak or travelling to an endemic area.
	Unimmunised travellers aged 6 months and older who are known to be susceptible to one or more of the diseases who are travelling to areas where those diseases are circulating.
	Individuals of any age, who have not been previously vaccinated.
Precautions	These are not exclusions but a risk assessment and care should be taken.
	People with a Bleeding Disorder - An individual risk assessment should be undertaken prior to vaccination. As with any intramuscular (IM) vaccination, the injection should be given with caution to patients with thrombocytopenia or any coagulation disorder as bleeding may occur following an intramuscular administration to these subjects. Therefore, patients with known bleeding disorders or on anticoagulant therapy should receive the vaccine by deep subcutaneous injection route to reduce the risk of bleeding. Individuals should be informed of the risk of developing haematoma and what to do if this occurs.
	<ul> <li>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. Patients, who are acutely unwell with fever, should have vaccination deferred until fully recovered in order to prevent confusion of the symptoms of the illness with any adverse effects of the vaccine.</li> </ul>
	The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of the vaccine may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.
	Undiagnosed neurological complications following a previous dose of a vaccine. Advice on management of these individuals in Chapter 24 of the Green Book. If the condition is stable and has an identified cause, the child can be vaccinated as normal.
	Female patients should be counselled to avoid pregnancy for one month following vaccination.
	Live attenuated vaccines should not routinely be given to people who are clinically immunosuppressed (either due to

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	drug treatment or underlying illness). If primary care professionals are in any doubt as to whether a person due to receive a live attenuated vaccine may be immunosuppressed at the time, immunisation should be deferred until secondary care specialist advice has been sought, including advice from an immunologist if required.
Criteria for exclusion	Patients may receive the administration of MMR vaccine under this PGD unless:
	Infants under 6 months
	There is no valid consent
	They have known anaphylactic hypersensitivity to any of the excipients which include neomycin and gelatine.
	They have had a confirmed anaphylactic reaction to a previous dose of MMR vaccine - a doctor should be consulted.
	<ul> <li>They have a history of severe (i.e. anaphylactic) allergy to latex. Check against SPC. Vaccination should be deferred unit it can be ascertained that the vaccine to be used is latex free. For latex allergies other than anaphylactic allergies (e.g. contact allergy to latex) vaccination may proceed as normal.</li> </ul>
	<ul> <li>They have severe impaired immune response whether natural or drug induced, including high dose corticosteroids, radiotherapy, cytotoxic or other agents. This does not apply to patients receiving topical or low-dose corticosteroids as replacement therapy, e.g. for Addison's disease or prophylaxis, e.g. asthma. Refer to the Green Book chapters 6 and 7.</li> </ul>
	<ul> <li>They have primary and secondary immunodeficiencies (may be given to HIV positive individuals with a CD4 count of greater than 200 who are otherwise well). Refer to the Green Book chapters 6 and 7.</li> </ul>
	<ul> <li>They have active untreated tuberculosis, blood dyscrasias, leukaemia, and lymphomas of any type or other malignant neoplasms affecting the bone marrow or lymphatic systems. Refer to the Green Book chapters 6 and 7.</li> </ul>
	<ul> <li>They have received varicella or shingles vaccines within the preceding 4 weeks. MMR should ideally be given at the same time as these vaccines otherwise, a four-week interval is recommended.</li> </ul>
	<ul> <li>They have received Yellow Fever vaccine within the preceding four weeks. Yellow Fever and MMR should not be administered on the same day.</li> </ul>
	Acute severe febrile illness - immunisation should be

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	postponed until fully recovered.	
	<ul> <li>Within 3 months of receiving blood products. When MMR is given within 3 months of receiving blood products the measles component can be reduced. If immediate measles protection is required in someone who has recently received blood products, MMR should still be given. To confer long term protection MMR should be repeated after 3 months.</li> </ul>	
	Evolving neurological conditions. Immunisations should be deferred until resolved or stabilised.	
	Known to be pregnant.	
Action if excluded	Advice should be sought in the first instance, from the patient's clinician or the Health Protection Team on the vaccine and circumstances under which it could be given. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be document in clinical records.	
	Inform the appropriate clinician, e.g. GP/Health Visitor/Family Nurse/Pediatrician/ treating physician.	
	Children who are excluded using the above criteria will be referred to their General Practitioner (GP). This will be documented in the child health records or/and on the computerised Child Health Surveillance Programme (CHSP) system.	
	Temporary Exclusion	
	In case of postponement due to acute febrile illness, arrange a future date for immunisation. Document in clinical records.	
	In the case of postponement due recently receiving blood products arrange date for vaccination in 3 months time. Document in clinical records.	
	If pregnant or planning to get pregnant, postpone until patient has delivered.	
Action if patient declines	Advise individual/parent/carer/guardian about the benefits and protective effects and possible side effects of the vaccine, the risks of infection and complications relating to infection. Ensure they have additional reading material (patient information leaflet) available to them. Document advice given and decision reached.	
	Inform the appropriate clinician, e.g. GP/ Health Visitor/Family Nurse/Pediatrician/treating physician.	
	Child Health should be informed of any children and/or parent/carer/guardian refusing to consent.	

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Follow up of patient e.g. hospital admission/by GP/none required Children will be called for repeat vaccination as appropriate, by the Scottish Immunisation Call and Recall System (SIRS) in line with national routine vaccination programme.

For specific "at risk" patients follow the guidance set out in "Immunisation against Infectious Diseases – The Green Book". https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book



### CHARACTERISTICS OF STAFF AUTHORISED TO TAKE RESPONSIBILITY FOR THE SUPPLY OR ADMINISTRATION OF MEDICINES UNDER THIS PATIENT GROUP DIRECTION

Qualifications Required	A registered practitioner enabled under HDL (2001)7 to administer or supply medicines under a Patient Group Direction.
Additional Requirements	Approved by the organisation as competent:  To work within this patient group direction.
	<ul> <li>To undertake all aspects of immunisation and discussing issues related to benefits and risk of immunisation, contraindications, side effects and complications relating to the specific infections that the vaccine protects individuals from.</li> </ul>
	In intramuscular and subcutaneous injection techniques as appropriate.
	<ul> <li>In assessing the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent.</li> </ul>
	In assessing the individual's fitness for immunisation.
	In the recognition and immediate management of anaphylaxis in accordance NHS Tayside training e.g. Resuscitation Council (UK) <a href="http://www.resus.org.uk/pages/reaction.pdf">http://www.resus.org.uk/pages/reaction.pdf</a>
	<ul> <li>In basic life support and resuscitation techniques as per the published standard.</li> </ul>
	The practitioner should have an understanding of and access to:
	NHS Tayside Immunisation Policy.
	This PGD
	Summary of Product Characteristics for the vaccines being used <a href="https://www.medicines.org.uk/emc">https://www.medicines.org.uk/emc</a>
	Latest edition of the British National Formulary <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a>
	Latest edition of the Green Book <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a>
	<ul> <li>All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) <a href="http://www.sehd.scot.nhs.uk/index.asp?category=9">http://www.sehd.scot.nhs.uk/index.asp?category=9</a></li> </ul>

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	Risk assessment to be completed prior to each immunisation session.  Immediate access to adrenaline/epinephrine 1:1000 injection for Intramuscular (IM) use. The use of epinephrine in an emergency situation does not require a PGD or a prescription.
	<ul> <li>There must be easy access to a telephone in order to contact the emergency services if required.</li> </ul>
Continuing Training Requirements	It is the responsibility of the individual to :
	Keep up to date with all aspects of immunisation, including contraindications, side effects etc.
	Attend annual training in the recognition and management of anaphylaxis.
	Attend annual update on cardio-pulmonary resuscitation.
	Training on use of PGD 3 yearly in line with PGD reviews or earlier if appropriate.

Profession	Registered Nurse or Midwife
Applicable professional codes and standards of	The current NMC Code of Professional Conduct: Standards of Conduct, Performance and Ethics
conduct	https://www.nmc.org.uk/standards/code/
	All professionals should also take cognisance of the Royal Pharmaceutical Society guidance on handling medicines.
	https://www.rpharms.com/resources/professional-standards/safe- and-secure-handling-of-medicines
Applicable guidelines for supply and	Practitioners operating the PGD should be familiar with:  NHS Tayside Immunisation Policy
administration of medicines	NHS Tayside PGD Policy <a href="http://staffnet.tayside.scot.nhs.uk/NHSTaysideDocs/groups/working-safely/documents/documents/prod_226903.pdf">http://staffnet.tayside.scot.nhs.uk/NHSTaysideDocs/groups/working-safely/documents/documents/prod_226903.pdf</a>
	NHS Tayside Safe and Secure Handling of Medicines Policy <a href="http://www.nhstaysideadtc.scot.nhs.uk/SSHM/MAIN/Front%20page.htm">http://www.nhstaysideadtc.scot.nhs.uk/SSHM/MAIN/Front%20page.htm</a>
	Immunisation against Infectious Disease [Green Book] <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a>
	All relevant Scottish Government Health Directorate advice including the relevant CMO letter(s) <a href="http://www.sehd.scot.nhs.uk/index.asp?category=9">http://www.sehd.scot.nhs.uk/index.asp?category=9</a>
	UK Guidance on Best Practice in Vaccine Administration <a href="http://www.wales.nhs.uk/sitesplus/documents/861/UK%20best/620practice%20guidance%20vacc%20admin%202001.pdf">http://www.wales.nhs.uk/sitesplus/documents/861/UK%20best/620practice%20guidance%20vacc%20admin%202001.pdf</a> Construction      **Construction**  **C

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HPS Guidance on Vaccine Storage & Handling
 <a href="http://www.hps.scot.nhs.uk/immvax/resourcedetail.aspx?id=194">http://www.hps.scot.nhs.uk/immvax/resourcedetail.aspx?id=194</a>

Profession	Pharmacist
Applicable professional codes and standards of conduct	The current GPhC Standards for Pharmacy Professionals and Standards for Registered Pharmacies. <a href="https://www.pharmacyregulation.org/standards">https://www.pharmacyregulation.org/standards</a>
Applicable guidelines for supply and administration of medicines	None, but guiding principles laid out in the above document



# DESCRIPTION OF TREATMENT AVAILABLE UNDER THIS PATIENT GROUP DIRECTION

for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.  Preparation  The vaccines should only be reconstituted with the supplied diluen and either used within one hour or discarded. (0.5ml)  Dose/s  2 x 0.5ml doses  Preferred Route Intramuscular injection  Bleeding Disorder  An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.  Site	Name of Medicine	MMR is available from Sanofi Pasteur MSD Limited as MMRVAXPRO® and from GlaxoSmithKline UK as Priorix®	
Presentation  Both vaccine preparations are presented as a powder containing live attenuated measles, mumps and rubella virus strains for reconstitution with the supplied diluent.  The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.  Preparation  The vaccines should only be reconstituted with the supplied diluen and either used within one hour or discarded. (0.5ml)  Dose/s  2 x 0.5ml doses  Preferred Route Intramuscular injection  Bleeding Disorder  An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.  Site  In children over the age of one year and adults the deltoid region of the upper arm is the recommended site.  The anterolateral (outer) thigh muscle is the recommended site in	POM/P/GSL	POM	
live attenuated measles, mumps and rubella virus strains for reconstitution with the supplied diluent.  The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.  Preparation  The vaccines should only be reconstituted with the supplied diluen and either used within one hour or discarded. (0.5ml)  Dose/s  2 x 0.5ml doses  Preferred Route  Intramuscular injection  Bleeding Disorder  An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.  Site  In children over the age of one year and adults the deltoid region of the upper arm is the recommended site.  The anterolateral (outer) thigh muscle is the recommended site in	PGD Ref No		
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Intramuscular injection  Bleeding Disorder  An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.  Site  In children over the age of one year and adults the deltoid region of the upper arm is the recommended site.  The anterolateral (outer) thigh muscle is the recommended site in	Dose/s	2 x 0.5ml doses	
the upper arm is the recommended site.  The anterolateral (outer) thigh muscle is the recommended site in	Route	Intramuscular injection  Bleeding Disorder  An individual risk assessment should be undertaken prior to vaccination of individuals with a known bleeding disorder. Vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. Injections should be given with the needle at a 45° angle to the skin and the skin should be bunched, not stretched. Pressure (no rubbing) should be applied to the injection site for at least 5 minutes following vaccination.	
The vaccine must <b>not</b> be administered via oral, intradermal or intravenous route.		The anterolateral (outer) thigh muscle is the recommended site in infants under one year of age.  The vaccine must <b>not</b> be administered via oral, intradermal or	

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#### Total dose number

Primary immunisation consists of two 0.5ml doses given by IM injection or deep SC into the upper arm or anterolateral thigh at specified time intervals. In children, the first dose is currently recommended between 12 and 13 months of age, but MMR vaccine can be given to children of any age over 6 months.

The second dose of MMR vaccine is normally given before school entry at three years four months to five years of age but can be given routinely at any time from three months after the first dose if under 18 months of age. If children attending for a preschool booster have not been immunised with MMR, they should be offered a first MMR and arrangements made for a second dose to be given in four weeks time.

Children younger than 12 months of age should not routinely receive MMR.

#### **Travel to Endemic Areas**

Adults and infants from six months of age travelling to mumps and measles endemic areas or to an area where there is a current outbreak should receive MMR. As the response to MMR in infants is suboptimal, where the vaccine has been given before one year of age, immunisation with two further doses of MMR should be given at the recommended ages.

Children who are travelling who have received one dose of MMR at the routine age should have the second dose brought forward to at least one month after the first. If the child is under 18 months of age when the second dose is given, then the routine pre-school dose (a third dose) should be given in order to ensure full protection.

The parent, guardian or person with parental responsibility must be advised that MMR vaccine is not licensed to be given under the age of 9 months however, it can be given from 6 months of age if the risk of infection is felt to be significant.

#### **Incomplete Immunisations**

Children coming to the UK who have a history of completing immunisations in their country of origin may not have been fully protected against all antigens currently used in the UK. For country specific information, please refer to

http://apps.who.int/immunization monitoring/globalsummary

Children with no reliable history of immunisations should be offered the full UK recommendations.

### Advice to be given to the patient

Supply the appropriate marketing authorisation holder's patient information leaflet (PIL) provided with vaccine.

Advise individual to seek emergency medical advice in case of severe adverse reaction.

The patient/parents/carers/guardians will be advised to contact GP

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if they experience severe symptoms, or if symptoms do not settle in a few days.

The patient/parents/carers/guardians should be advised to contact GP/NHS24 is they have any concerns following vaccination.

Inform patient/parents/carers/guardians of normal local and systemic reactions and how to minimise these including administration of paracetamol for reduction of pyrexia.

Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms of vaccination. For full details refer to the marketing authorisation holder's Summary of Product Characteristics. https://www.medicines.org.uk/emc

Side effects may include a rash, especially in the period five to ten days after immunisation.

The patient/parents/carers/guardians should be reassured that post-immunisation symptoms are not infectious.

If appropriate, advise individual when subsequent doses are due and if any follow up is required.

Further information is also available at <a href="https://www.nhsinform.scot/healthy-living/immunisation">https://www.nhsinform.scot/healthy-living/immunisation</a>

# Identification and management of possible adverse effects

For full details/information on possible adverse reactions, refer to the marketing authorisation holder's Summary of Product Characteristics. https://www.medicines.org.uk/emc

Adverse reactions following the MMR vaccine (except allergic reactions) are due to effective replication of the vaccine viruses with subsequent mild illness. Such events are to be expected in some individuals.

Events due to the measles component occur six to 11 days after vaccination.

Events due to the mumps and rubella components usually occur two to three weeks after vaccination but may occur up to six weeks after vaccination. These events only occur in individuals who are susceptible to that component, and are therefore less common after second and subsequent doses.

Other adverse effects include upper respiratory tract infection, malaise, rash and fever. These occur most commonly about a week after immunisation and last for two to three days.

Parotid swelling occurs in about 1% of children of all ages up to four years, usually in the third week.

Six to eleven days after immunisation, about 1 in 1000 children may have a febrile seizure.

Uncommon adverse effects include otitis media, lymphadenopathy, anorexia, nervousness, abnormal crying, insomnia, conjunctivitis, bronchitis, cough, diarrhoea and vomiting.

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The following reactions have been reported rarely following MMR: meningitis, thrombocytopenia, thrombocytopenic purpura, anaphylactic reactions, transverse myelitis, Guillain Barré syndrome, peripheral neuritis, orchitis, encephalitis, erythema multiforme, arthralgia and arthritis. However these events are less likely to occur after vaccination than after infection.

Suspected and confirmed adverse reactions should be reported to the MHRA via the Yellow Card Scheme. Please visit <a href="https://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> for further guidance.

Any serious adverse reaction to the vaccine should be documented in an individual's health record. The relevant health professional should also be informed e.g. Health Visitor/Family Nurse/Midwife/Pediatrician/treating physician.

Adverse events should also be reported through the NHS Tayside Datix system.

#### **Anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur.

The use of epinephrine in an emergency situation does not need a PGD or prescription.

NHS Tayside guidance on resuscitation and the treatment of anaphylaxis should be followed. http://www.resus.org.uk/pages/reaction.pdf

If a patient is thought to be experiencing an anaphylactic reaction in the community an ambulance should be called (999) immediately.

### Referral for medical advice

Patients with a current febrile illness will be advised to attend once the illness has resolved.

Other patients who are excluded using the exclusion criteria will be referred for a final medical decision on immunisation.

Advise patient/parents/carers/guardians to seek emergency medical advice in case of severe adverse reaction.

The patient/parents/carers/guardians should be advised to contact GP/NHS24 is they have any concerns following vaccination.

The patient/parents/carers/guardians will be advised to contact GP if they experience severe symptoms, or if symptoms do not settle in a few days.

### Facilities and supplies required

The designated hospital pharmacies **OR** community pharmacy are the sole procurement point

All practice dealing with medicines and vaccines should be in accordance with the NHS Tayside Safe and Secure Handling of Medicines policy

http://www.nhstaysideadtc.scot.nhs.uk/SSHM/MAIN/Front%20page .htm and the NHS Tayside Immunisation Policy.

Access to 'Immunisation against Infectious Disease' (Green Book) 2013 and the latest update available via the appropriate Green

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#### for medicines

Book chapter on immunisation procedures and comply with its recommendations.

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

Access to this PGD.

#### **Storage and Transport**

Vaccine should be stored in the original packaging and not exposed to light.

Vaccine will be stored in a temperature controlled refrigerator between 2°C and 8°C and not frozen. Refrigerators should have maximum and minimum temperatures recorded daily. Temperatures should be maintained between 2°C and 8°C.

If vaccine requires to be transported to a community setting, the cold chain must be maintained according to the criteria identified in NHS Tayside Immunisation Policy. Storage and transport in validated vaccine porters is acceptable.

Any excursions out with the acceptable temperature range (2°C and 8°C) should be reported to Vaccine Services and the vaccines quarantined and not used until further guidance is sought.

If the vaccine has been frozen, it should be discarded.

#### **Resuscitation Equipment**

Resuscitation equipment including epinephrine (adrenaline) injection (1 in 1,000) or pre-filled syringes such as Epipen and oxygen (if available) should be available in accordance with published standards for immunisation training e.g. Resuscitation Council (UK) <a href="https://www.resus.org.uk/pages/reaction.pdf">http://www.resus.org.uk/pages/reaction.pdf</a>.

Practitioners must have immediate access to a telephone.



#### **Treatment Records**

The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. All records must be clear and legible and, in an easily retrievable format.

The information relating to immunisation of each individual must include as a minimum:

- Patient's name and date of birth
- · Valid consent given
- Name, brand, batch number and expiry date of vaccine
- Dose
- Route of injection (IM or SC)
- Site of injection (L/R arm or L/R leg)
- Date given and by whom.

Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

- · GP practice computer
- · Individuals GP records
- Pharmacy PMR
- Child Health Systems e.g. SIRS
- Personal Held Child Record (red book)
- EMIS
- Clinical case notes

Patient records should be updated as soon as possible after immunisation and should be completed within two weeks of the date of the vaccination.

### Patients on concurrent medication

MMR vaccine can be given at the same time as other inactivated vaccines or at any time interval before or after inactivated vaccines. Likewise inactivated vaccines can be given at any time interval before or after MMR.

MMR can be given at the same time as other live vaccines with the exception of Yellow Fever vaccine. MMR and Yellow fever vaccines cannot be given on the same day and a four week interval between these vaccines is required.

If not administered on the same day, a four-week interval is also required between MMR and varicella or shingles vaccines.

No specific interval is required for other live vaccines. Other live vaccines (BCG, rotavirus, live attenuated influenza vaccine (nasal)

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	oral typhoid) can therefore be given at any time interval before or after MMR.	
	If given at the same time as other vaccinations, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at a separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.	
	For more information on concurrent administration of live vaccines see the Green book  (https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) and the Recommendations for giving more than one live attenuated vaccine in current use in the UK https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine  MMR vaccine should not be given within 3 months of an injection of immunoglobulin or a blood transfusion	
Patient Consent	Informed consent must be obtained from the patient/parent/carer/guardian prior to treatment.	
	This will be recorded in the case notes and in the treatment record form as either signed consent or verbal consent.	
	The NHS Tayside Informed Consent Policy and Immunisation Policy gives guidance on systems to be adopted.	
Audit Trail	The use of a separate treatment record sheet or consent form will facilitate the audit process. An annual audit should be carried out.	
	To facilitate the audit, information relating to immunisation of each individual must include as a minimum:	
	Patient's name and date of birth	
	Valid consent given	
	Name, brand, batch number and expiry date of vaccine	
	• Dose	
	Route of injection (IM or SC)	
	Site of injection (L/R arm or L/R leg)	
	Date given and by whom.	
Adverse Reactions and adverse incidents	It is NHS Tayside policy that all incidents and near misses are reported through the correct local electronic procedure (Datix). <a href="http://fernie.tnhs.tayside.scot.nhs.uk/datix/live/index.php">http://fernie.tnhs.tayside.scot.nhs.uk/datix/live/index.php</a>	
	All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded in the appropriate place (e.g. EMIS and the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the General Practice Record). Where appropriate a Yellow Card Report will be forwarded to the	

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Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at <a href="http://yellowcard.mhra.gov.uk/">http://yellowcard.mhra.gov.uk/</a>

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#### **AUDIT OF PATIENT GROUP DIRECTION**

# Annual audit of documentation and recording of information

Who will carry this out and to whom will it be reported?

Each clinical area/lead should undertake an annual audit of their service's documentation and information recording in associated with this PGD.

The results of practitioner's documentation and information recording should be reported to their line manager /service lead.

Areas where issues are identified an action plan to mitigate and address any risks should also be devised.

This action plan and the audit results should be copied to the Immunisation Coordinator and Vaccine Programmes Manager so that areas of good practice and/or risks are escalated to the Tayside Immunisation Steering Group.

Community Pharmacists should report the outcomes of their audit through the Consultant in Public Health Pharmacy.

## Periodic audit of clinical outcome(s)

- Audit should be carried out at least annually; more often if required.
   What are the audit questions?
- Who will carry out the audit(s)

To whom will the audit be reported?

Each practitioner should undertake an annual audit of their own clinical area associated with this PGD.

A clinical audit tool that facilitates auditing of the environment, suitability of accommodation, quality and availability of equipment and resources is available as an appendix to the NHS Tayside Immunisation Policy.

A review of adverse events and any yellow cards should be analysed.

Issues of adequate consent should be examined.

It is also good practice for each area to review any Datix events, including needle stick injuries reported in relation to immunisations.

The results of practitioner's audits and reviews should be reported to their line manager /service lead.

Areas where issues are identified an action plan to mitigate and address any risks should also be devised.

This action plan and the audit results should be copied to the Immunisation Coordinator and Vaccine Programmes Manager so that areas of good practice and/or risks are escalated to the Tayside Immunisation Steering Group.

Community Pharmacists should report the outcomes of their audit through the Consultant in Public Health Pharmacy.



### **MANAGEMENT & MONITORING OF PATIENT GROUP DIRECTION**

Develo	ped By:
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Date Effective:

**Review Date:** 

[Note: development of any PGD for antimicrobial agents requires the involvement of and approval by the local Antimicrobial Management Group]

Medical Practitioner:	Dr Daniel Chandler	Signature:
Nurse:	Mrs Jane Forbes	Signature:
Pharmacist:	Mr Andrew Radley	Signature:
(Other):		Signature:
Approved By: <u>Lead Clinician</u> Name:		Signature
Tayside Area Drug & Therapeutics Committee  Name: Professor Colin Fleming		Signature:

Plans must be made to ensure completion of a review on or by the date above. The revised PGD will then follow on immediately. If the review date is reached and no review has taken place, then the PGD will be null and void. Interim review will be required as and when new safety information comes to light

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## DECLARATION This protocol is authorised for use within \_\_ (practice/hospital etc) by the individuals named below: Clinical Lead \_\_\_\_\_ Date \_\_\_\_\_ I have read and understood this PGD and have received the specified local training to implement it effectively. Name \_\_\_\_\_ Designation \_\_\_\_\_ \_\_\_\_ Date \_\_\_\_ Name \_\_\_\_\_ Designation \_\_\_\_\_ Signed \_\_\_\_\_ Date \_\_\_\_ Name \_\_\_\_\_\_ Designation \_\_\_\_\_ \_\_\_\_ Date \_\_\_\_ Name \_\_\_\_\_ Designation \_\_\_\_\_ Signed Date Name \_\_\_\_\_ Designation \_\_\_\_\_ \_\_\_\_ Date \_\_\_\_ Name \_\_\_\_\_ Designation \_\_\_\_\_ Signed Date Name \_\_\_\_\_ Designation \_\_\_\_\_ \_\_\_\_\_ Date \_\_\_\_ Name \_\_\_\_\_\_ Designation \_\_\_\_\_ Signed \_\_\_\_\_\_ Date \_\_\_\_\_ Name Designation Signed \_\_\_\_\_ Date \_\_\_\_

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## REGISTER OF NAMED INDIVIDUALS WHO MAY SUPPLY CARE UNDER THIS PATIENT GROUP DIRECTION

Date	Name	Qualifications

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# PATIENT GROUP DIRECTION MMR IMMUNISATION CONSENT SHEET

Patient Name		DOB/CHI
Address		
Town		POSTCODE
Gender: (Please circle)	Male / Female	
CONSENT TO TREATMEN	<b>NT</b>	
		n my care (please delete as appropriate) can delete as appropriate) under the appropriate
Signed	patient/pa	arent//carer/guardian
IF SIGNED CONSENT IS N THE PRACTITIONER WILI		L CONSENT HAS BEEN OBTAINED, THEN
Signed (practitioner)		Print Name
Recorded in case notes		
Recorded on computer s	ystem	
Patient Information Leafl	et issued (from pack)	
PLEA	SE COMPLETE TREATMENT	RECORD SHEET

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## PATIENT GROUP DIRECTION MMR IMMUNISATION TREATMENT RECORD SHEET

PATIENT AND CONSULTATION DETAILS	
Patient Name	
Date of Birth/CHI	
Place of Issue	

#### **CRITERIA FOR EXCLUSION**

The patient will be excluded from treatment under this PGD and referred immediately to a medical practitioner if any of the following criteria apply.

Under 6 months of age?	Yes	No
Confirmed severe, anaphylactic reaction to a previous dose of MMR vaccine or known anaphylactic hypersensitivity to any of the excipients which include neomycin and gelatine and latex?	Yes	No
Severe impaired immune response whether natural or drug induced, including high dose corticosteroids, radiotherapy, cytotoxic or other agents.	Yes	No
Received varicella or shingles or yellow fever vaccines within the preceding 4 weeks?	Yes	No
Evolving neurological condition(s)?	Yes	No
Known to be pregnant?	Yes	No
Untreated TB?	Yes	No
Acute febrile illness?	Yes	No
No valid consent?	Yes	No

INFORMATION		
Does the patient have unanswered questions regarding this vaccine?	Yes	No
Advised on management of symptoms following immunisation?	Yes	No
Information leaflet issued?	Yes	No

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DECLARATION			
The above information is correct to the best of my knowledge. I have been informed about the use of this vaccine and understand the advice given to me by the practitioner.			
Patient's Signature: Date:			
The patient is unable to give written consent. The patient/parent/caconsent.	rer/guardian has given verbal		
Practitioner's Signature:	Date:		
The action specified was based on the information available to me and given to me by the patient/parent/carer/guardian and that to the best of my knowledge is correct.			
Practitioner's Signature: Date:			

ACTION TAKEN						
MMR vaccine giv	/en				Yes	No
Vaccine Name	MMRVAXPRO	Priorix				
Batch Number		Expiry D	ate			
Site	Left Arm / Right Leg		Left Arm / Right Leg			
Given by	Intramuscular Injection Sub Cut Injection					

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### CHILDHOOD PRESCHOOL IMMUNISATION CHECKLIST

This checklist is to support the administration of childhood immunisations under Patient Group Directions (PGD). Immunisations should not be given under PGD if the child meets the exclusions criteria or does not meet the inclusion criteria detailed in PGD. A discussion with the child's GP and/or treating physician and the possibility of a Patient Specific Direction (PSD) or alternative options should be considered. The checklist must be completed prior to the administration of all routine childhood immunisation.

checklist must be completed prior to the administration of all routine childhood immunisation.						
CHILDS NAME	СНІ					
and list the date. If vaco	VACO  from SIRS /EMIS/Vision cine history cannot be es cessary defer immunisat	stablished, refer to guida				
8 weeks	12 weeks	16 weeks	1 year		years 4 onths	
DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB	DTaP/IPV/Hib/HepB	Hib/MenC	D	ΓaP/IPV	
PCV		PCV	PCV			
Rotavirus	Rotavirus		MMR	MI	MR	
MenB		MenB	MenB			
Date:	Date:	Date:	Date:	Da	ate:	
VACCINES FOR ADM DTaP/IPV/Hib /Hep B Rotavirus	INISTRATION TODAY Hib/MenC DTaP/IPV	(please circle all va MenB LAIV Flu	MMR	vated FLu	PCV	
ASSESSMENT QUESTIONS						
than months/years.	For children under the a ver 14 weeks 6 days before.					
Has the child received any vaccines in the last 4 weeks? (If yes immuniser to assess if this will impact vaccines for administration today e.g. live vaccine spacing) <sup>3</sup>			YES	NO		
Has the child ever received any travel vaccines? (If yes assess details provided to determine if vaccines are required. If unable to access details postpone vaccines and check GP records)			YES	NO		
Has there been an appropriate gap between immunisations?				YES	NO	
(Please ensure a minim vaccine)	num of 27 day gap betwe	een primary immunisatio		e same of days		
Has the child received	d Paracetamol within th	ne last 4 hours?			YES	NO
	mperature or been unves without fever or syster				YES	NO
Is there a history of an evolving or unstable neurological condition?			YES	NO		

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Is there any history of convulsions within 72 hours of a vaccine?

NO

YES



ACCECOMENT OLIECTIONS		
ASSESSMENT QUESTIONS		
Has the child ever been unwell after receiving a vaccine?	YES	NO
(Pyrexia post vaccine or slight swelling to vaccine site are not exclusion criteria)		
Does the child currently attend the GP or hospital for any medical concerns?	YES	NO
(If yes immuniser to assess if this meets PGD exclusion criteria)		
Does the child have any known allergies (food, medication)?	VEC	NO
(If yes immunisation nurse to assess if this meets PGD exclusion criteria)	YES	NO
Does the child have any history of any blood clotting disorders?	YES	NO
(If yes, risk assess and administer vaccine via subcutaneous route)		NO
Is the child currently receiving high dose steroids, chemotherapy or other cytotoxic drugs that would impair their immune system?	YES	NO
Is the child fit to receive vaccines?	YES	NO
ROTAVIRUS ONLY - Does the child have known malformation of the gastric tract? (predisposed to intussusception)	YES	NO
MMR ONLY - Has the child received any blood products in the last 3 months?	YES	NO
If yes, Immuniser to contact Child Health to suspend calling for MMR until 3 month period lapsed. All other vaccines can be given.  Date bloods received		
Men B ONLY - Does the baby have a recorded last weight on EMIS Web above		
3.00kg?	YES	NO
If No, a PSD or prescription from the GP will already be arranged by the Health Visitor and		
emailed to the Immunisation Team. The Immuniser should administer Paracetamol at the point of immunisation.  Comment		

CONSENT - Adult Accompanying child					
Name:	Relationship to child:				
Does the person signing consent have parental rights responsibilities?					
(Child's mothe	r or father if listed on birth certificate.)	YES NO			
If the parent is not present is there signed consent from the parent for immunisations or is there any reason to believe that the legal parent would object to vaccines being administered?			NO		
If an adult other than the parent is accompanying the child, is there any documentation relating to withheld consent in the records?			NO		
Checklist completed by					
Signature					
Print Name					
Designation	Date		•		
1 Vaccination of inc	ividuals with uncertain or incomplete immunisation status: <a href="www.gov.uk/government/publications/vaccing">www.gov.uk/government/publications/vaccing</a>	nation-of-			

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individuals-with-uncertain-or-incomplete-immunisation-status 2 The Green Book: <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a> 3 Administering more than 1 live vaccine: <a href="https://www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine">www.gov.uk/government/publications/revised-recommendations-for-administering-more-than-1-live-vaccine</a>



#### PATIENT GROUP DIRECTION PATIENT INFORMATION SHEET

An appropriate patient information sheet should be given to each patient treated under this Patient Group Direction.

Further information for patients/parents/carers/guardians can be obtained at Immunisation – NHS Inform - <a href="https://www.nhsinform.scot/healthy-living/immunisation">https://www.nhsinform.scot/healthy-living/immunisation</a>

What to expect after immunisations: Babies and children up to 5 years, national information leaflet given to all parents. This leaflet is available in multiple languages and easy read format. <a href="http://www.immunisationscotland.org.uk/publications/index.aspx">http://www.immunisationscotland.org.uk/publications/index.aspx</a>