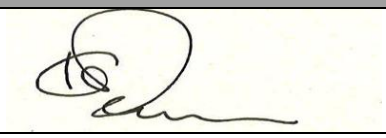
Public Health England

NHS England

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Amendment Dates:	**Page(s)**	**Brief Description**	

Patient Group Direction for administration of MEASLES, MUMPS & RUBELLA VACCINE

Approved By

NHS England and Staffordshire Area Team	Name	Signature
Medical Director	Dr Ken Deacon	
LPN Pharmacy Chair	Dr Manir Hussain	
Head of Public Health Commissioning	Rebecca Woods	

Date of patient group direction approved	Nov 2014
Date this patient group direction becomes due for review	May 2015 or in response to new local/national guidelines.

STAFF CHARACTERISTICS

Provider of NHS services within NHS England (Shropshire & Staffordshire Area Team)

- Registered nurse with current NMC registration

Specialist competencies or qualifications:

- The health care professional must have a good understanding of the NICE Good Practice Guidance on Patient Group Directions.

- The NICE competency framework: For health professionals using Patient Group Directions should be used by health care professionals planning to work under this PGD to identify any gaps in their knowledge. The gaps should be addressed before the healthcare professional is authorised to work under this PGD.

- The clinical manager/ lead GP/commissioner must have evidence that the health care professional has undertaken training to carry out clinical assessment of patient leading to confirmation that the patient requires treatment according to the indications listed in the PGD.

- The healthcare professional must provide evidence of training, appropriate annual updates and continued professional development undertaken to support their competence for administration of this treatment.

- The clinical manager/ lead GP must have assessed the competency of the healthcare professional to work to this Patient Group Direction. The NICE competency framework: For health professionals using Patient Group Directions should be used to support this assessment.

- The health care professional must have undertaken training and annual updates in the recognition and treatment of anaphylaxis, including practical in Basic Life Support and has immediate access to an in-date supply of adrenaline 1mg in 1ml (1:1000) at the time of the consultation. (The practitioner must be deemed competent in basic life support and in emergency administration of adrenaline)

  - The health care professional must have access to all relevant sources of information e.g. information issued by the Department of Health (Green Book), British National Formulary (BNF), Summary of Product Characteristics (SPC), and the clinical guideline concerning medicine(s) within this Patient Group Direction (PGD).

  - The practitioner must be competent and knowledgeable in vaccine cold chain standards.

  - The registered health care practitioner is professionally accountable for supply or administration under the PGD as defined in their own profession's Code of Professional Conduct and Ethics.

YOU MUST BE AUTHORISED BY NAME BY YOUR CLINICAL LEAD UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

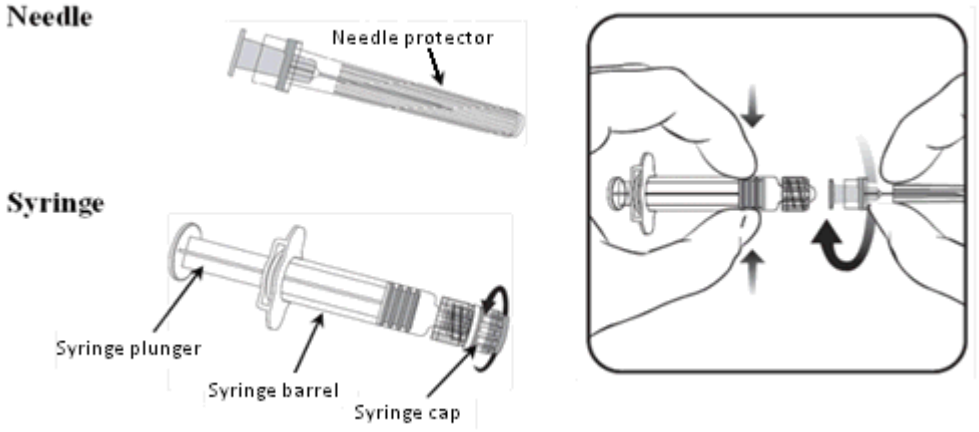
PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

CLINICAL CONDITION	
Clinical need addressed	Active immunisation against Measles, Mumps & Rubella as recommended in the childhood immunisation schedule. (https://www.gov.uk/government/collections/immunisation#childhood-immunisation-schedules)

Inclusion criteria	• Children meeting criteria for MMR under routine childhood immunisation schedule. (See chapter 11 of the Green Book for schedule of UK's routine childhood immunisations).
	• Where immediate protection against measles is required (i.e. in an outbreak or following exposure) MMR may be given from six months of age.
	  ○ NB. Response to MMR in children ≤ 12 months of age is sub-optimal and immunisation with two further doses of MMR should be given as per schedule for UK's routine childhood immunisations.
	  ○ As vaccine induced **measles** antibody develop more rapidly than that following natural infection, MMR may be used to protect susceptible contacts during a measles outbreak. To be effective, the vaccine must be administered within 3 days of exposure. However, even where it is too late to provide effective post exposure prophylaxis with MMR, the vaccine can provide protection against future exposure to all three infections.
	• Children who have not received MMR vaccine as per schedule for UK's routine childhood immunisations (i.e. children who have missed one or both MMR doses).
	• Individuals (adults and children) who fall outside the routine childhood immunisation schedule, in whom MMR immunisation status is either uncertain or incomplete.

Exclusion criteria (for full details of interacting medicines refer to current Summary of Product Characteristics (SPC) www.medicines.org.uk & BNF)	• Declined consent • Those who are immunosuppressed (see Chapter 6 Contraindications and special considerations Green Book) • History of hypersensitivity to any measles, mumps, or rubella vaccine, • Hypersensitivity to any of the excipients of vaccines including neomycin • Children with acute febrile illness (vaccine should be deferred). Minor infections without fever or systemic upset are **not** reasons to postpone immunisation. • Pregnant women

Caution/need for further advice /Interactions	Yellow Fever and MMR: A four week minimum interval period should be observed between the administration of these two vaccines. Yellow Fever and MMR should not be administered on the same day. Varicella (and zoster) vaccine and MMR: If these vaccines are not administered on the same day, then a four week minimum interval period should be observed. Apart from the above combinations MMR can be administered at any time before or after other live vaccines. (Revised recommendations for the administration of more than one live vaccine) When concomitant administration with other vaccine(s) is necessary the vaccines must be given at different injection sites, preferably into different limbs. If given in the same limb the injection sites should be at least 2.5cm apart. **Egg Allergy** SPCs for both M-M-R VAXPRO® and Priorix® advise caution for use in children with confirmed egg allergy however All children with egg allergy should receive the MMR vaccination as a routine procedure in primary care (Green Book Chapter 6)
Management of excluded patients	• Document in the individual's notes, advise and counsel accordingly. The risk of not vaccinating must be considered. • Refer to medical practitioner or seek appropriate advice from a Consultant in Health Protection if necessary. • For individuals temporarily excluded due to acute or febrile illness advise when the vaccine may be given and arrange another appointment.
Action for patients not wishing to receive care under this PGD	• Advise the individual about the protective effects of the vaccine, the risks of infection, including potential complications. • Document action and advice given (record declined vaccine in the individuals clinical record). • Refer to doctor or independent prescriber.
Treatment and Drug details	
Name form and strength of medicine	**M-M-RVAXPRO®**: Powder and solvent for suspension for injection in pre-filled syringe Live Measles, Mumps, and Rubella vaccine (before reconstitution, the powder is a light yellow compact crystalline cake and the solvent is a clear colourless fluid). **Priorix®:** Powder and solvent for solution for injection Live Measles, Mumps and Rubella vaccine (the lyophilised Measles-Mumps-Rubella component is a white to slightly pink powder /the solvent is a clear and colourless liquid). **These vaccines do not contain thiomersal or any other preservatives. The vaccines contain live organisms that have been attenuated (modified).**
Legal classification	POM – Prescription only medicine.
Black triangle warning Suspected adverse reactions. Should be reported using the Yellow Card reporting scheme (www.yellowcard.gov.uk).	No

Method of obtaining supply	Order through the ImmForm website (www.immform.dh.gov.uk)
Site for treatment	• GP surgeries • Health Centres
Route/method	**Reconstitution instructions M-M-RVAXPRO®** To reconstitute, use the solvent supplied. The solvent is a clear colourless liquid. Before mixing with the solvent, the powder is a light yellow compact crystalline cake. When completely reconstituted, the vaccine is a clear yellow liquid. Inject the entire content of the syringe into the vial containing the powder. Gently agitate to mix thoroughly. The reconstituted vaccine must not be used if any particulate matter is noted or if the appearance of the solvent or powder or of the reconstituted vaccine differs from that described above. Withdraw the entire content of the reconstituted vaccine vial into the same syringe and inject the entire volume. If two needles are provided: use one needle to reconstitute the vaccine and the other for its administration to the person to be vaccinated. After reconstitution, the vaccine should be used immediately; however, in-use stability has been demonstrated for 8 hours when refrigerated at 2°C-8°C. **Reconstitution instructions Priorix®** The solvent 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 solvent or reconstituted vaccine. The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder. To attach the needle to the syringe, refer to the drawing below. However, the syringe provided with Priorix® might be slightly different (without screw thread) than the syringe described in the drawing. In that case, the needle should be attached without screwing.  1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise. 2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture). 3. Remove the needle protector, which on occasion can be a little stiff. Add the solvent to the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the

	solvent. Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuschia pink without deterioration of the vaccine's potency. A new needle should be used to administer the vaccine. Contact with disinfectants should be avoided The vaccine should be injected promptly after reconstitution. If this is not possible, it must be stored at 2°C - 8°C and used within 8 hours of reconstitution. **Vaccine administration** • Vaccines are routinely given intramuscularly into the upper arm or anterolateral thigh. However, for individuals with a bleeding disorder, vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding. • MMR vaccine can be given at the same time as other vaccines such as DTaP/IPV, Hib/MenC, PCV and hepatitis B. The vaccine 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. • MMR should not be mixed with other vaccines in the same syringe
Dose	**Schedule for UK routine childhood immunisation** • A first single 0.5ml dose for infants over the age of 12 months. • A second single 0.5ml school entry dose (three years four months or soon after) **Individuals with uncertain or incomplete immunisation** • Individuals <18 months of age who have missed their first MMR dose should receive an initial dose followed by a second dose given within the routine childhood immunisation schedule at three years and four months (school entry dose). • Individuals >18 months of age but < 3 years and 4 months, who have not received any previous MMR vaccination, should receive an initial dose followed by a second dose given within the routine childhood immunisation schedule at three years and four months (school entry dose) NB. there should be a minimum interval of one month between first dose and second dose. • Individuals >3 years and 4 months, who have not received any previous MMR vaccination, should receive an initial dose followed by a second dose - leaving a gap of at least one month between first and second dose. • An individual who has an incomplete immunisation status i.e. only received one previous dose of MMR should receive a second dose to ensure that they are protected. • An individual who has an uncertain measles immunisation status should receive an initial dose followed by a second dose - leaving a gap of at least one month between first and second dose. **In cases of outbreaks or exposure to confirmed cases** • Children from six months to ≤12 months of age - single 0.5ml dose (continue with further dose at 13-15 months and the pre-school second dose i.e. as per schedule for UK routine childhood immunisation.) • Where children who have received the first dose of MMR require immediate protection against measles, the interval between the first and second doses may be reduced to one month. 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. As vaccine induced measles antibody develop more rapidly than that following natural infection, MMR may be used to protect susceptible contacts during a measles outbreak. To be effective, the vaccine must be administered within 3 days of exposure. However, even where it is too late to provide effective post exposure prophylaxis with MMR, the vaccine can provide protection against future exposure to all three infections, so vaccination of individuals with uncertain or incomplete immunisation history should still be considered.
Number of times treatment may be administered	Two doses of 0.5ml at the **recommended interval** in the childhood immunisation schedule. (https://www.gov.uk/government/collections/immunisation#childhood-immunisation-schedules)
Quantity to be supplied or administered	0.5ml dose (single dose)
Side effects *Full details of side effects are available in the SPC. www.medicines.org.uk* *Suspected adverse reactions to drugs including vaccines should be reported on the yellow card available at the back of the BNF. Also at www.yellowcard.gov.uk*	**Common side effects:** • Fever (38.5°C or higher) • Injection site reactions erythema, pain, swelling, bruising • Rash • Upper respiratory tract infection (Priorix® only) Measles virus inhibits the response to tuberculin so that a false negative tuberculin test may be found for up to a month following MMR vaccination. Adverse effects are less common with second MMR dose.
Additional Information (including storage and disposal)	• Store in a refrigerator (+2^{0}C to + 8^{0}C) • Do not freeze • Store in original packaging • Protect from light • Equipment used for vaccination should be disposed of by placing in a proper, puncture-resistant 'sharps' box according to local authority regulations and guidance in Health Technical Memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)
Advice to patient/carer	BEFORE TREATMENT**:** • Advise parent/guardian of possible side effects. For full details see product's summary of product characteristics. Advise action to be taken if side effects are experienced AFTER TREATMENT: • Provide patient information leaflet • Advise parent/guardian about next scheduled vaccination
Follow up	Inform of possible side effects and their management. • Any serious adverse reaction to the vaccine should be documented in a child's health records and on their medical records. GP should also be informed.
Suspected adverse reactions	Patient presenting with suspected adverse drug reaction should be referred to a doctor for further investigations. All serious suspected reactions following vaccination should be documented in

	the patient's medical record and reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card scheme at http://yellowcard.mhra.gov.uk/
Error reporting	Any incidents or near-miss issues must be reported via the organisation's internal reporting system.
RECORD KEEPING	
Documentation needed/treatment records to be kept for audit purposes *A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes.*	• Patient's name, address, date of birth and registered GP • Record of informed consent • Manufacturer, vaccine name, product name, batch number, expiry date • Dose administered • Date of administration • Anatomical site of vaccination • Route of administration • Advice given to patient (including advice given if vaccination is declined) • Details of staff who administered (sign and print name) • Details of any adverse drug reactions, and action taken including informing GP • Record as supplied via Patient Group Direction (PGD) in patient's clinical record All records should be clear, legible and contemporaneous. This information should be recorded as appropriate in the patient's General Practitioner record or other patient record, depending on location AND the personal Child Health record (PCHR) – the Red Book. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes. If vaccination has been completed by a provider other than the GP practice, timely communication to the GP practice to enable the patient's record to be updated must be completed. Any noted adverse effects following vaccination must also be reported to the GP practice. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. Data must be stored in accordance with Caldicott guidance and the Data Protection Act. • Reconciliation – stock balances should be reconcilable with receipts, administration records and disposal.

Register of practitioners qualified to administer and/or supply Measles, Mumps & Rubella Vaccine under this Patient Group Direction	
Name of clinical manager/GP Lead/Commissioner	
Signature of clinical manager/GP Lead / commissioner	Date:
A copy of this page should be retained by the authorising manager for 2 years for audit purposes	
Please state clinical area where this PGD is in use	

Healthcare professional individual declaration

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD

- **PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY**.
- It is the responsibility of each professional to practice only within the bounds of their own competence.
- All practitioners operating in accordance with this PGD should have a current, signed copy of it readily available for reference.
- If a practitioner is asked to supply, or administer a medicine not covered by this or any other PGD then a patient specific direction is required from a doctor, dentist or independent prescriber.

Name of professional (please print)	Signature	Authorising Manager (Must sign against each entry)	Date of authorisation

The clinical lead should review competency of authorised practitioners annually.
Authorisation to use this PGD does not remove inherent professional responsibility and accountability

References

DOH Immunisation against infectious disease 'Green Book' Chapter 6 & 21 www.dh.gov.uk
Summary of Product Characteristics: **M-M-RVAXPRO** www.emc.medicines.org.uk
Summary of Product Characteristics: **Priorix®** www.emc.medicines.org.uk
Revised recommendations for the administration of more than one live vaccine (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/353085/11092014_PHE_live_vaccine_interval_v3.pdf)
British National Formulary (Oct 2014) www.bnf.org
Acknowledgement: Medicines Management Team, Telford & Wrekin CCG for developing the PGD.