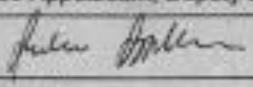
WORK INSTRUCTION

WI 44 – ADMINISTRATION OF VACCINATIONS IN CLINICALTRIALS

Version	2.0
Effective Date	25/09/2020
Review Date	24/09/2023
Author & Position	Suzanne Wilkins, Senior Research Nurse
Signature	
Date	08 OCT 2020
Approver & Position	Andrew Appelbaum, Deputy Director of Research
Signature	
Date	28/09/2020

Controlled document

This document has been created following the Royal Devon and Exeter NHS Foundation Trust Policy for the Development, Ratification & Management of Procedural Documents. It should not be altered in any way without the express permission of the author or their representative.

It is the responsibility of all users of this Work Instruction to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0	2 March 2012	Clinical Research Nurse	New SOP
1.1	31 December 2014	Clinical Research Nurse	No significant changes. Minor change to format and content
2.0	25 September 2020	Divisional Team Lead	Review with some changes to reflect both Local Policy updates and national guidelines.

Associated Trust Policies/ Procedural documents:	Innoculation (Contamination) Incident Policy Control of Substances Hazardous to Health (COSHH) Policy and Spillage Procedures Trust/National anaphylaxis/BLS guidelines Trust Infection Control guidelines Injectable Medicines Policy Preparing Injectable Medicines SOP Administering Injectable Medicines SOP Informed Consent SOP
Key Words:	R&D Work Instruction Vaccine Administration
In consultation with: Research and Development - Quality Assurance Group Research and Development – Governance Oversight Group (GOG)	

Contents

1 INTRODUCTION 4

2. PURPOSE 4

3. SCOPE 4

4. DEFINITIONS 4

5. DUTIES AND RESPONSIBILITIES OF STAFF 4

6. PROCEDURES 5

6.1 Prior to Administration 5

6.2 Preparation 5

6.3 Administration 6

6.4 Documentation 7

6.5 Maintaining Competency to Ensure Safe Practice 8

7. DISSEMINATION AND TRAINING 8

8. MONITORING COMPLIANCE AND EFFECTIVENESS 8

9. ARCHIVING ARRANGEMENTS 9

10. REFERENCES 9

1 INTRODUCTION

The RD&E has been undertaking vaccine studies for over 10 years. These studies could involve giving either an intramuscular, subcutaneous, or nasal vaccine. The vaccines may be classed as an Investigational Medicinal Product (IMP) or may be an already licensed vaccine but being given as part of the research trial. It is important that all nurses perform these studies according to the study Investigator Brochure (IB)/ Summary of Product Characteristics (SmPC), and National policy/guidelines to ensure both trial participant safety, and drug efficacy.

2. PURPOSE

This Work Instruction (WI)) is to establish the principles of how to administer vaccination injections as part of a clinical trial. For nasal vaccinations the Immunisation against infectious disease-GOV UK states no additional training is required, however to refer to manufacturer guidelines/ Patient Group Direction (PGD). Administration of nasal vaccines has therefore not been included in this WI.

3. SCOPE

This WI is to be used by all research staff that administer clinical trial vaccinations both within Trust sites, and also in participant homes.

This WI is applicable for all clinical trials of vaccines both sponsored and hosted by the Trust.

This WI relates to participants that have consented to a study that requires a research nurse giving a vaccination.

4. DEFINITIONS

CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IB	Investigator's Brochure
IM	Intramuscular
IMP	Investigational Medicinal Product
PGD	Patient Group Direction
R&D	Research & Development
SC	Subcutaneous
SOP	Standard Operating Procedure
WI	Work Instruction

5. DUTIES AND RESPONSIBILITIES OF STAFF

It is the responsibility of the registered nurse administering the vaccine to check that all the applicable regulatory approvals are in place prior to any research activity taking place for that study.

It is the responsibility of the nurse administering the vaccine to have undertaken a recognised vaccine immunisation course and also completed Royal College of Nursing/National Institute of Health Research vaccine competencies prior to performing this task, including supervised practice. Up to date Trust anaphylaxis training must also have been completed prior to undertaking this task.

Before administering a vaccination the nurse should refer to the Public Health England Immunisation against Infectious Disease online publication for further information relating to the principles, practices and procedures in relation to immunisations, and any licensed vaccinations and vaccines.

6. PROCEDURES

6.1 PRIOR TO ADMINISTRATION

6.1.1 Nurse to check that informed consent has been given by the participant to take part in the clinical trial. Please refer to S15 Informed Consent.

6.1.2 Discuss the vaccine, possible side effects and the procedure with the adult/child/ parent/guardian, actively involving them in this process. Allow adequate time for questions.

6.1.3 If a previous dose of the vaccine has been given, discuss how the participant was following this, to ensure there are no contraindications to the administration of a further dose.

6.1.4 Transcribe any relevant information, (as guided by study protocol), into the paper/ electronic case report form (CRF) or source document.

6.1.5 Discuss the participant's current health to ascertain any possible contraindications to vaccination.

6.1.6 Check the interval between each dose using the records available to you. These may be in paper or electronic form (CRF, clinical trials prescription and child's Parent Held Record (red book)).

6.1.7 Check the participant's temperature, using the thermometer provided by the study, Is the participant apyrexial? Check the study protocol for any temperature guidelines. Record this in the CRF or source document.

6.1.8 Nurse is then to wash hands.

6.1.9 Arrange all equipment in the vaccine tray and then place this in a convenient and safe place. Ensure all young children are being observed and pets are secured out of the area.

6.2 PREPARATION

6.2.1 Check with the child / adult and their parent / guardian as appropriate that they are happy to proceed with the vaccination and explain which vaccines are going to be administered.

6.2.2 If relevant remove the vaccine box from the cool box, ensuring the temperature has been maintained within the range specified in the study protocol which is usually between 2^0C and 8^0C (This must be recorded in the temperature log). Allow vaccine to reach room temperature.

6.2.3 Identify the vaccine and the participant's study ID using the label on the front of the vaccine box to cross check with the participant/carer and vaccine details on the clinical trials prescription.

6.2.4 Check the vaccine name, or identifying letters and numbers, (in the case of a trial vaccine).

6.2.5 Check the details on the vial, the diluent, if supplied, and their expiry dates and cross check this against the information provided on the clinical trials prescription.

6.3 ADMINISTRATION

6.3.1 Ensure adrenaline 1:1000 or an Epipen is easily accessible, and within expiry date, in order to use post vaccination if required. (Please refer to the Trust/National anaphylaxis/BLS guidelines).

6.3.2 Before use, the colour and composition of the vaccine must be examined to ensure that it conforms to the description as stated in its IB/SmPC.

6.3.3 Apply a 21g (green) or drawing up needle according to manufacturer guidelines to the appropriate sized syringe, usually 1ml or 2ml. (If the vaccine arrives pre-prepared in a syringe, simply apply the correct size needle).

6.3.4 Draw up the stated dose of vaccine according to the leaflet, the study protocol, and the prescription.

6.3.5 If the vaccine needs to be reconstituted then follow the manufacturer's instructions and using the diluent provided, draw up the vaccine.

6.3.6 For multi-dose vials, the length of time a vial can be used for should be specified in the protocol/SmPC. If the vial has been used previously, the date and time of reconstitution or first use, the initials of the person who reconstituted or first used the vial, the period that the vaccine can be used for and the expiry date/time should be clearly marked on the vial. If this is not labelled the vial must be discarded.

6.3.7 Remove the 21g (green) or drawing up needle and immediately place in the sharps container. Apply a 23g (blue) or 25g (orange) 25mm needle (in larger adults a longer length e.g. 38 mm may be required or a 16mm needle in pre-term or very small infants).

6.3.8 Ensure that the adult / child / infant is sitting comfortably or held securely by the parent / guardian or research assistant (by parental request).

6.3.9 Identify the site for administration depending on type of injection to be given:

- For infants under 1 year of age the preferred intramuscular (IM) site is the anterolateral aspect of the thigh. (Fig.1) (please refer to study protocol)
- In older children and adults the preferred site is the deltoid muscle unless specified differently in the study protocol (Fig.2).

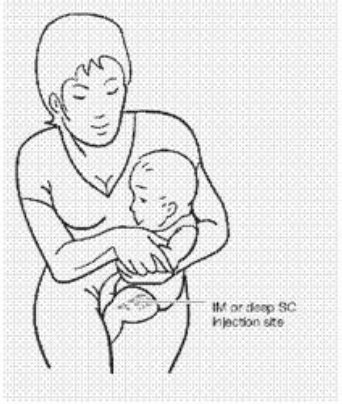


Fig 1

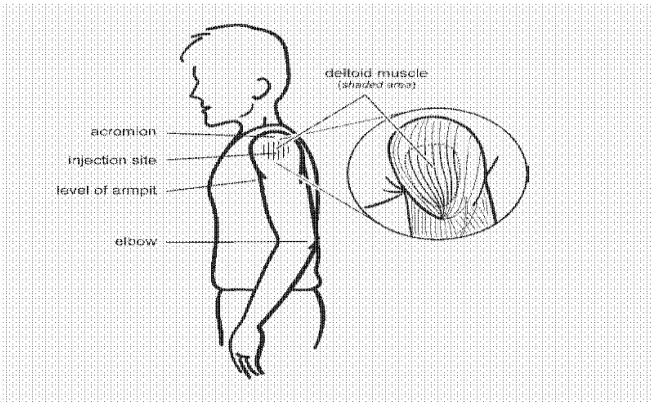


Fig 2

6.3.10 Where two or more injections need to be administered at the same time, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb, they should be administered at least 2.5cm apart.

6.3.11 For IM injections stretch the skin and insert the needle at a 90 angle down to the hub using the most appropriate technique in order to give an IM injection (Fig 3). Deep subcutaneous (SC) injections should be given with the needle at a 45º angle to the skin and the skin should be bunched, not stretched.

6.3.12 Remove the needle as you apply firm pressure to the injection site, using gauze.

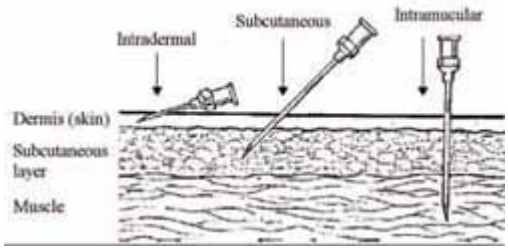


Fig 3

6.3.13 Continue applying firm pressure until bleeding ceases. Any blood spillage please refer to the Trust Control of Substances Hazardous to Health (COSHH) Policy.

6.3.14 Discard the needle immediately into the sharps container.

6.3.15 Return all reusable equipment to the vaccine box, such as the tray used to place the vaccinations in. Return all waste to the department to be disposed of in an appropriate clinical waste bag.

6.3.16 Observe the subject for a minimum of 20 minutes post vaccination for any signs of an anaphylactic reaction. This may be extended to 30 minutes following administration of a study vaccine, or according to study protocol.

6.3.17 Check the vaccination site for redness, lumps or swelling prior to the participant leaving.

6.3.18 Ensure any study specific vaccine/other relevant written information sheet has been given. This may only be provided for use with certain vaccine studies.

6.3.19 Give the participant a contact card listing phone numbers of both the research team and also who to contact in the case of an out of working hours emergency.

6.4 DOCUMENTATION

6.4.1 Document the temperature of the cool box in the temperature log provided for the study prior to administering the vaccine.

6.4.2 Document the vaccine, dose, date, site of administration and the batch number in the CRF according to GCP guidelines.

6.4.3 Record the immuniser name, signature, date and name of the vaccination given, on the clinical trials prescription.

6.4.4 Record the vaccinations given on the immunisation page of a child's red book. Also document that the participant is enrolled into the vaccine study in their personal and hospital records as appropriate including the name of the study.

6.4.5 Complete the form for the Child Health Database and GP surgery advising them of the vaccinations given and date of vaccination.

6.5 MAINTAINING COMPETENCY TO ENSURE SAFE PRACTICE

6.5.1 In the case of an inoculation injury please refer to the Trust Inoculation (Contamination) Incident Policy.

6.5.2 The correct PPE to be worn as per Trust Standard Infection Control Procedures and Policy (including Hand Hygiene).

7. DISSEMINATION AND TRAINING

7.1 This WI and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this WI should ensure that they take time to read and understand the content of this WI.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

8.1 In order to monitor compliance with this WI, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Vaccine recorded as having been given as per protocol, with vaccine location specified.	Spot check CRFs/eCRFs
2.	Batch number/expiry dates of vaccine recorded in CRF/eCRF	Spot check CRFs/eCRFs
3.	Prescription fully completed and signed by nurse.	Spot check prescriptions

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

Lang S, Ford KJ, John T, Pollard AJ, McCarthy ND. (2014) Immunisation errors reported to a vaccine advice service: intelligence to improve practice, Qual Prim Care, 22(3), pp.139-146. http://primarycare.imedpub.com/immunisationerrors-reported-to-a-vaccine-advice-serviceintelligence-to-improve-practice.pdf

Nursing and Midwifery Council. Medicines management. www.nmc-uk.org

Public Health England. 2013. Immunisation against infectious disease-GOVUK [Online]. [8 September 2020]. Available from: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

Public Health England and Royal College of Nursing (2018) National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners, PHE: London. Available at: www.gov.uk/government/publications