Pneumococcal Vaccine Schedules Study

Checklist of procedures to monitor in the HCF

Date of visit: __/___/___HCF: _____: Name of study nurse:

Core activity	Field activities	Remarks
Registration of patients	In each visit observe/review: • Check if the right version of EMR or other documents are being used. • Registration of all patients in EMR • Completeness of registration in EMR • Is the government staff available to do the registration? • Is the registration been done on paper or in the EMR? • Is in-patient screening been performed? • Crosscheck the inpatient screening form with U5 admission book	
Clinical pneumonia Screening	**Are you conducting primary end-point QC?** Yes/No If Yes, observe or review: • Correct application of diagnostic criteria for clinical pneumonia • If blinding is ensured? • Are all eligible patients been screened?	 Yes / No Yes / No Yes / No

Disease surveillance	In each visit:
	• Witness at least 1 patient episode
	Observe:
	• Informed consent process:
	  • Individual given time to read/hear the IC content
	  • Individual given time to ask questions
	  • Individual completing and signing the ICF
	  • Storage of ICF
	• Completion of study forms
	• Collection of samples:
	  • Phlebotomy technique.
	  • Distribution of blood collected into different	

NPS sample collection technique.	vials according to type of vial and specimen. **Are you conducting primary end-point QC? Yes/No** If Yes, observe or review: • Is the technique appropriate? • Where are the samples stored right after taking them? • Are labels been used and managed correctly?	Yes / No Yes / No Yes / No
Review of completed and stored study forms	Ask the PVS nurse for and review where applicable: • Place of storage of completed study paper forms • Check completion of ICD • Availability of storage cabinet • Crosscheck the information in the clinical logbook to the paper or EMR • Confirm if the clinical logbook is up to date and been filled correctly. • Correct use of pre-print paper • Are there enough patient envelopes? • Is there adequate number of blank forms available? • Nurse recording the issuing of the patient CRF envelope in a logbook Observe: • Data uploading procedures • Check all pending forms	
Management of samples	Observe • Storage location of blood culture bottles before use. • Storage conditions of samples collected before transportation Shipper • Observe how shipper is weighed on scale • Is there availability of lock on the shipper? • Review the dry shipper weight monitoring sheet Sample Transport • Randomly check to see if the samples in the shipper has been recorded on the sample transport log sheet. • Are sample transport log sheets available? • Review a filled/filed sample transport log sheet for completeness and correctness. • Processing of samples at the site of location (if applicable) • Procedures to receive and process samples at	

	the designated lab • Are there extra labels to accompany samples? X-ray Unit (if applicable) • Check to see if the precaution warning sign is posted on the door or post of the Xray room. • Is the entrance red indicator light available and functioning? • Is there availability of Xray protective lead aprons? • Are the bulbs in the Xray room functioning? • Is there availability of gloves? • Crosscheck the information in the X-ray logbook to the paper or EMR Requisition and record of stock of materials • Check for availability of requisition book • Are there adequate stock of materials e.g. BC, NPS, gloves, needles & syringes etc	
Flow charts	Observe/Review • Availability of study related algorithm documents • Study related flowcharts	
Drug Issues	Review • Drug accountability	
Adherence to Covid-19 preventive measures	Observe • If staff is wearing appropriate PPE per setting as recommended by MRC guidelines • If there is at least 1-meter physical distancing between clinical staff and patient in the Consulting Room (CR) • If accompanying parent is wearing cloth mask and if patients with respiratory symptoms are provided with tissue in the CR • If frequently touched surfaces are routinely disinfected/cleaned • If hand sanitizer is available in the consulting room and provided to patients/mothers presenting for consultation. • Correct donning and doffing of PPE	
Other complaints and observations (e.g. accommodation, state of laptop, etc)		

Actions/ Comments:

Conducted by (Name and sign):