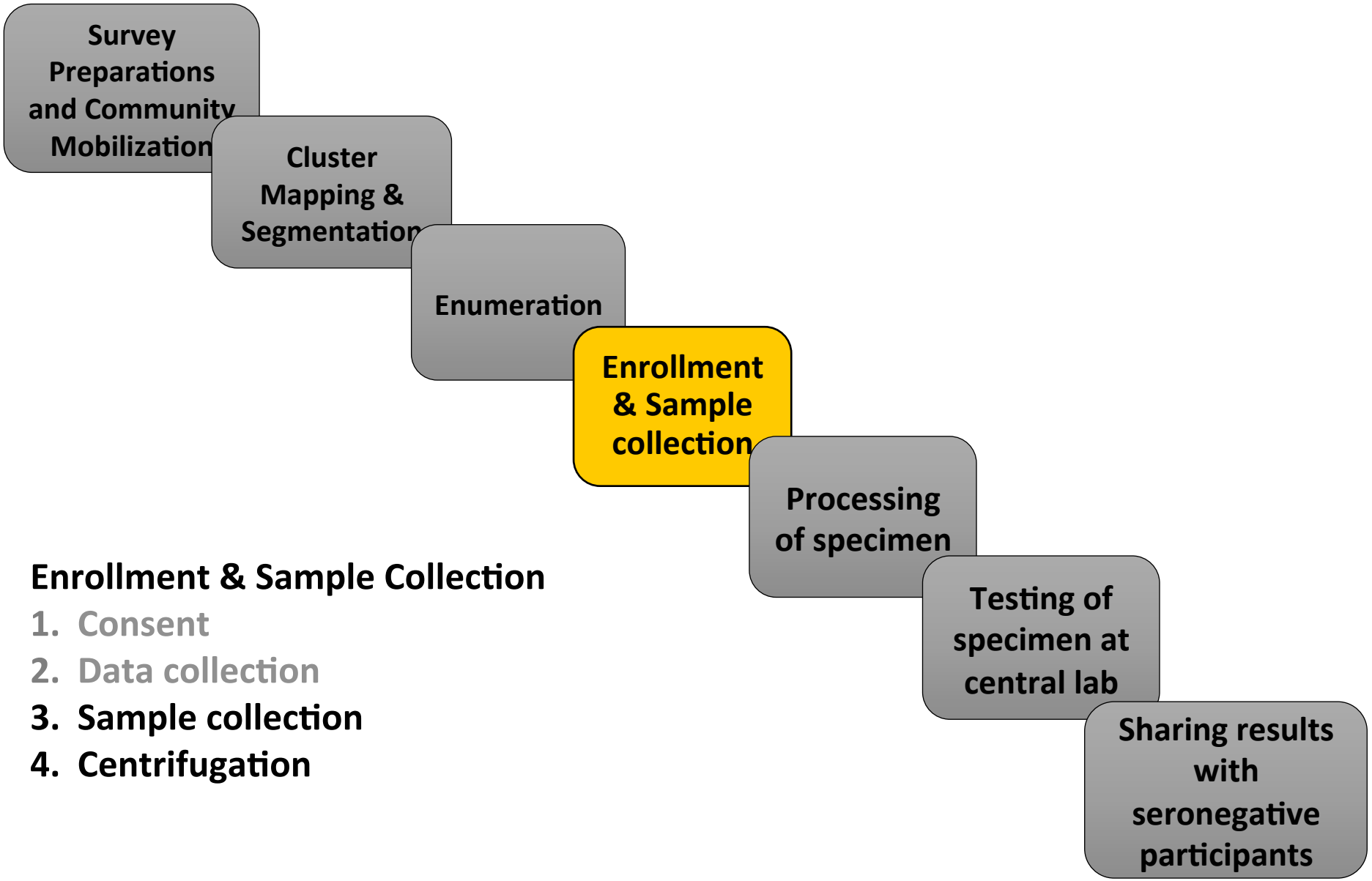
Measles and Rubella Serosurvey with venous blood collection

Blood Collection, Serum Separation Labelling, Transportation

Project Workflow



Enrollment & Sample Collection

1. Consent
2. Data collection
3. **Sample collection**
4. **Centrifugation**

Responsibilities of field team and laboratory staff

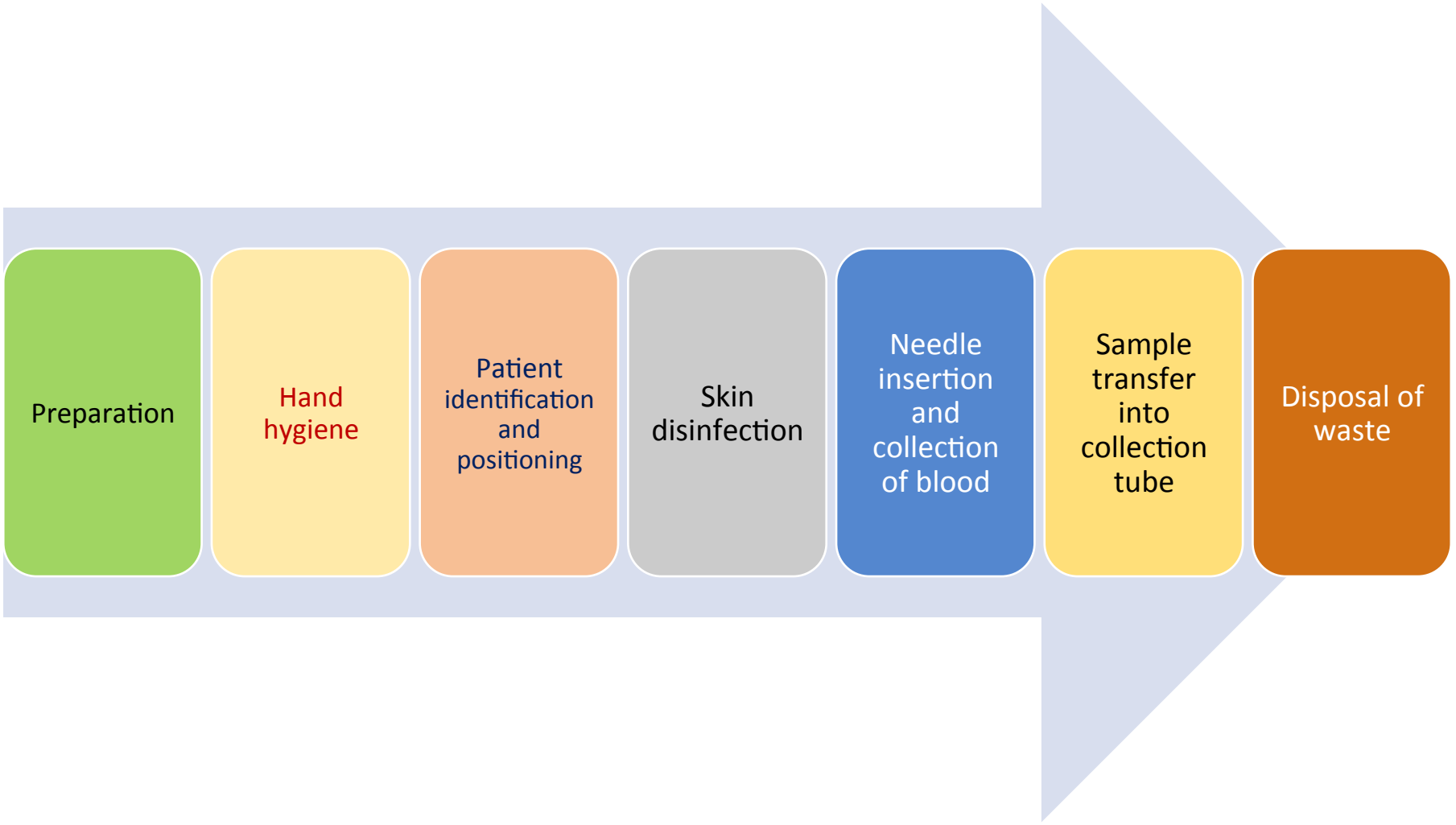
Field team	Unit Lab Technician/Site Team
Gather supplies for blood sample collection in field	Receiving and verifying samples collected by field team
Blood collection in field	Centrifugation (if required)
In field centrifugation	Processing/ Aliquoting of samples
Packaging of samples in field	Safe storage of sample boxes in -20˚C
Proper disposal of waste from field	
Documentation: entry into field tally sheet & tablet questionnaire	Documentation: making entry in laboratory register & Lab Tally Sheet
Transport of samples to site	Coordinating sample shipment to central lab

Venipuncture involves some risk.
Follow safe practices.

Standard Precautions and Safe Blood Collection Practices

- Considering all specimens of blood, body fluids and materials contaminated with them as potentially infectious
- Use appropriate Personal protective equipment (PPE) while handling potentially infectious material (eg: lab coat and gloves)
- Avoid recapping needles
- Use needle destroyer to remove needle; never break or bend them with hands
- Dispose sharps in a puncture-proof sharps container
- Use hand sanitizer to clean hands before putting on gloves, after removing gloves, and immediately after skin contamination
- Use a clean pair of gloves for every participant
- Clean up any blood spills with alcohol wipe
- *Ensure all staff received required vaccines as per site policy (eg: Hepatitis B etc)*

Steps in blood sample collection



Key rules for blood collection

- Maximum volume of blood: **2 mL**
- Maximum number of needle pricks: **2**
- Blood collection device:
  - *Provided syringe and needle (2ml and 5ml) for blood collection*
  - *Butterfly needles also provided as back up*
    - *May be easier to use in younger children and reduce hemolysis*
- Avoid hemolysis after collection and during transport
  - *Immediately put sample tubes in racks at room temperature. Do not move for 30 minutes.*
  - *Centrifuge in field, where possible.*

Step 1: Preparation at the institute

Arranging the items required

At Institute

Item	No. required
Vaccine carrier	2 per team
Ice packs	4 per vaccine carrier (plus additional backups in medium cold box)
Serum separation tubes (SST)(Yellow-topped) (5ml)	50
Microtainer tubes (Yellow topped) (500ul)	10
Tube rack for SST	1 per team
Label sheets for sample tubes and forms	3 sheets per cluster (one each for Group A, B and C)
Thin permanent marker	2
Lab coat	1
Non-sterile gloves	1 box per team
Hand sanitizer	1 per team
Scissor	1
Cello Tape	1 roll
Tote bag for carrying supplies	1 per team
Portable centrifuge	1 per team

*Make sure to carry these to field

Arranging the items required (Contd..)

At Institute

Item	No. required
Tourniquet	2 per team
Alcohol swabs/wipes	60 Nos. per team
Cotton swabs	60 Nos. per team
Sterile gauze piece	60 Nos. per team
Syringe with needle (5ml)	50
Syringe with needle (2ml)	20
Needle destroyer	1 per team
Sharps container	1 per team/ cluster
Band aid	1 packet
Plastic beaker (fits in vaccine carrier)	2 per team (1 per vaccine carrier)
Cotton swabs	1 roll
Rubber bands	1 packet
Red bag (for soiled biohazardous waste)	2-3
Black bag (for non hazardous waste)	1-2

*Make sure to carry these to field

Arranging vaccine carrier and gel packs

At Institute

+

+

All other supplies

Vaccine carrier (2/team)

Need **frozen* ice packs** on enrollment day (8/team; 4/vaccine carrier plus additional ice packs in small cooler boxes)

- ***Freezing of ice packs will be the responsibility of ULT**
- ***Ice packs should be conditioned by LT in field and verified by coordinator/supervisor.**

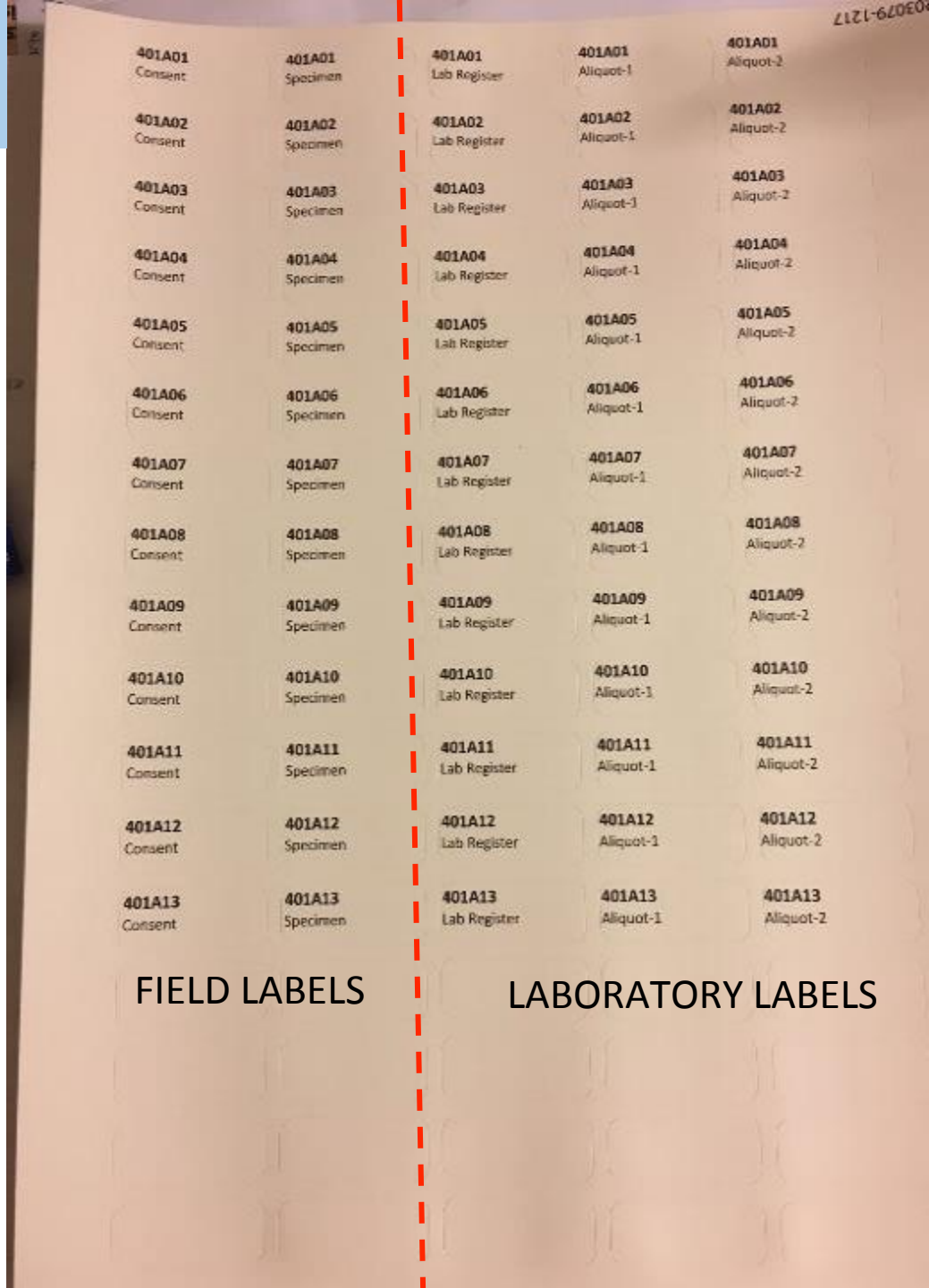
Arranging the supplies at the site

Preparing labels

1 sheet of labels per cluster and age group = 3 sheets total per cluster (A, B, and C)

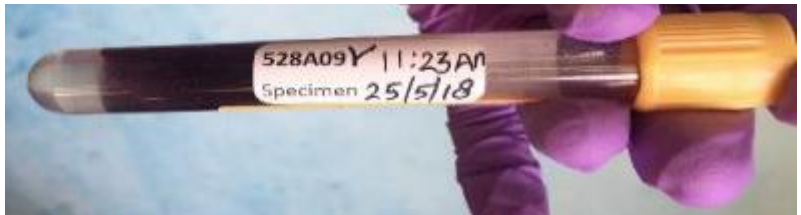
1 row per participant (5 labels)

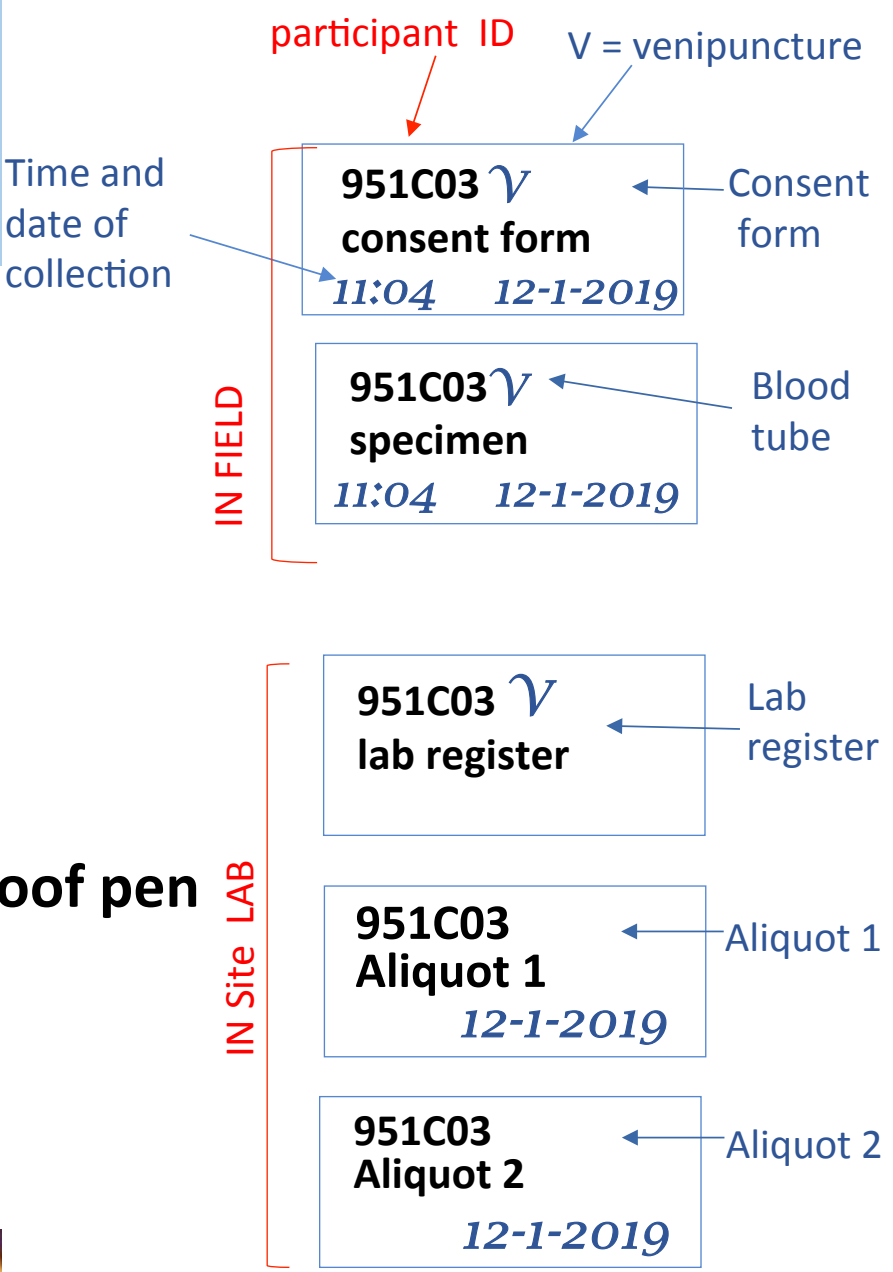
4 rows of extra blank labels



Preparing labels (Contd..)

- Pre-print labels to reduce errors
- Labels printed by central team
- 5 labels per selected participant
  - 1 Vacutainer or microtainer tube
  - 1 Consent form
  - 1 Lab register
  - 2 Storage vials in lab (venous blood)
- Add to label with **Sharpie waterproof pen**
  - V = venous blood
  - Time of collection HH:MM am/pm
  - Date (DD-MM-YY)



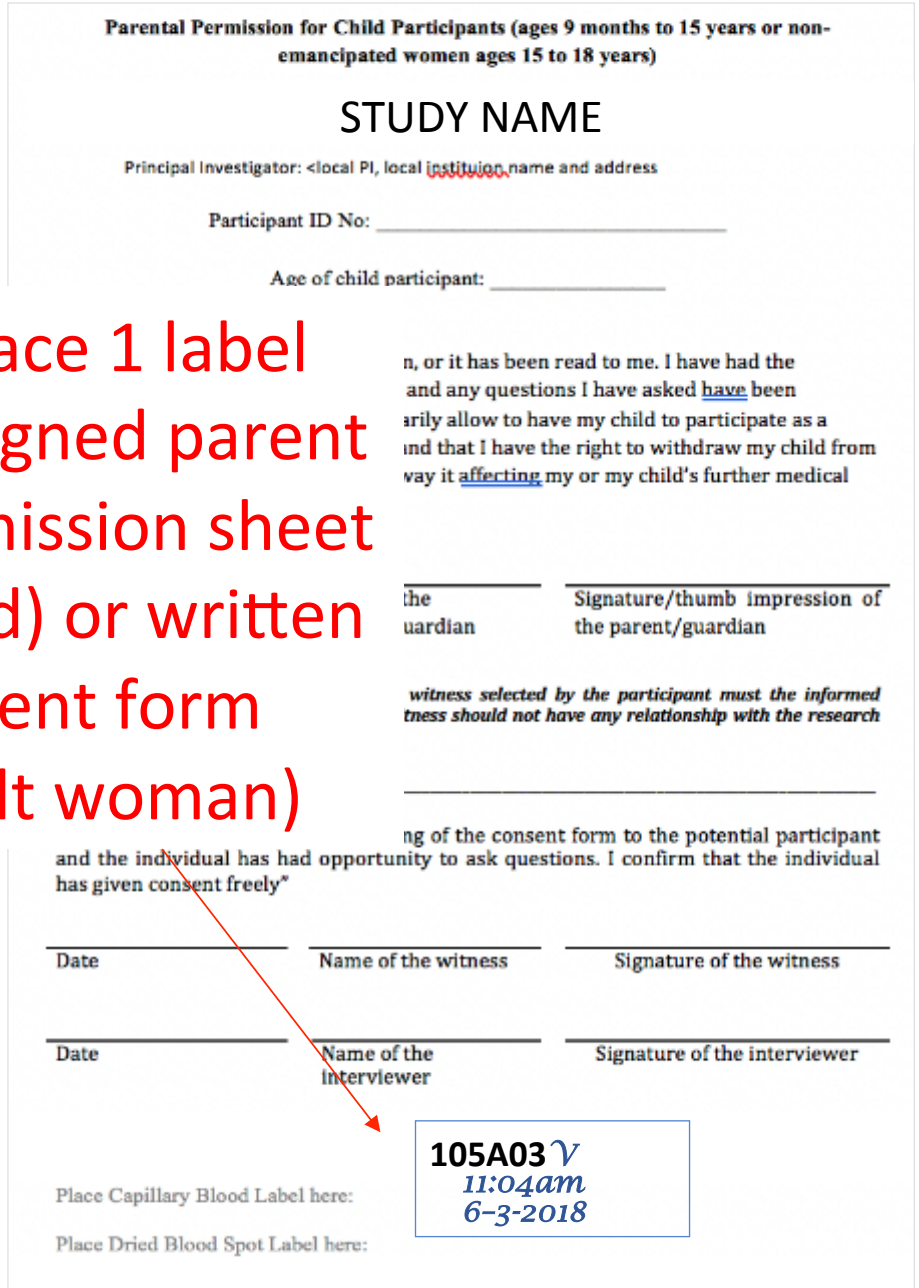


Preparing labels

2. Place 1 label on vacutainer tube

*Can write time of collection on specimen label after blood collection

1. Place 1 label on signed parent permission sheet (child) or written consent form (adult woman)



Step 2: Participant identification, explanations and consent

*"We will now take **a blood sample from you/your child to test the level of protection in your/your child's blood against measles and rubella viruses** and possibly other pathogens that can cause vaccine-preventable diseases.*

*The sample will be collected by drawing blood. **Up to two attempts will be made to collect a sample by drawing blood from your/your child's vein**. When we are finished we will observe you/your child for 5 minutes to make sure you/your child are/is feeling well."*

Collect Consent (as described in consent/ assent sessions)

Participant preparation

- Ask the participant to sit comfortably.
- Ask the participant to repeat his/her name and age and check signed consent forms.
  - For a child, ask the parent.
- If family is anxious:
  - Ask if the participant had a blood test before, and whether he/she had any difficulty during it.
  - Use this opportunity to address any concerns of subject or parents before proceeding with blood draw.

Positioning small children for venipuncture

- **For blood collection in small children:** Ask the caregiver to sit on a chair with the child on his/her lap and to warm the child's hand by holding and rubbing it.
- Show caregiver how to immobilize the child:
- Position guardian's legs around the child's legs in a cross-leg pattern
- Ask the guardian to extend their arm across the child's chest and tuck the child's free arm underneath. With that same hand, the guardian should grasp the child's other arm at the elbow (i.e. the hand to be pricked), and hold it securely
- Ask the guardian to use their other arm to firmly grasp the child's wrist, holding it palm down so that the fingers are below the elbow, tilted downwards
- Alternatives: Mothers can breastfeed child while blood is drawn.

Image courtesy: WHO

Step 3: Hand hygiene

*Will be demonstrated

Locating the site of venipuncture and applying a tourniquet

- Locate the site for venipuncture
  - *Non-dominant hand*
  - *Clearly visible vein, preferably median cubital vein*
  - *Free from skin lesions, injuries etc.*
- Apply a clean tourniquet around 4-5 finger breadths above the planned site of puncture
- Do not leave the tourniquet in place for more than 2 minutes
- Ask the patient to make a fist to make the veins more prominent

6. Ask the patient to form a fist so that the veins are more prominent.

Image courtesy: WHO

Step 4: Skin disinfection

- Put on well-fitting, non-sterile gloves. (Use a new pair for each participant.)
- Using an alcohol swab soaked clean the venipuncture site by rubbing in a circular fashion, moving from centre to periphery, over a 2 cm area, for 30 seconds
- Allow the site to dry for 30 seconds
- Do not touch the site or palpate the vein after disinfection; if touched, disinfect again

Image courtesy: WHO

Step 5: Needle insertion and blood collection

- Use a 23G needle attached to a syringe
- Anchor the vein by pressing down on skin about 2 inches below the site of puncture
- Pierce the skin at an angle of about 30˚C and enter the vein
- Stabilize the syringe by holding on the syringe and collect 2 mL of blood
- Release the tourniquet
- Withdraw the needle gently
- Place a gauze piece on the puncture site
- Ask the patient to keep the hand extended and press down at the site of puncture for a few minutes

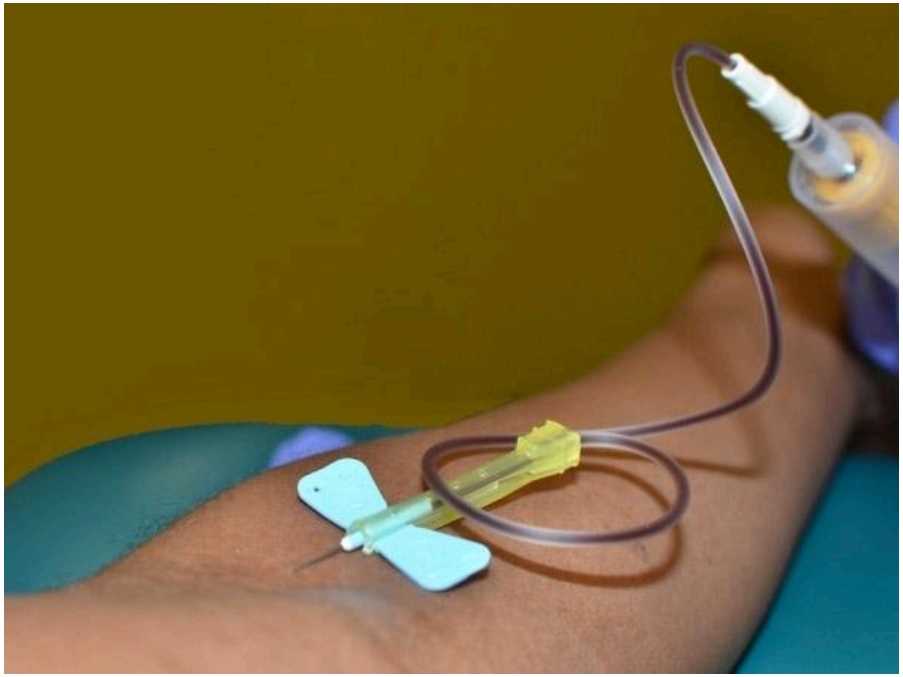
Image courtesy: WHO

Step 6: Transfer sample into sample tube

- Pierce the cap of the yellow-topped tube with the needle
- The sample will flow into the tube under the effect of vacuum
- If blood remains in syringe after flow has stopped, ***gently*** push the piston of syringe to move remaining volume
- At this point, observe the participant, and ask him/her/the child if they are comfortable.

Venepuncture with butterfly needle

For younger children*(RARE)*



Notes for using butterfly needle:

At the time of vein puncture the other end of the tube should be open and free.

Once the blood starts flowing in the tube then attach the hub of the syringe to the end of tube to draw blood in the syringe.

Question to ask technicians during training: Are you comfortable using butterfly needles?

Venipuncture using a butterfly needle (scalp vein set)

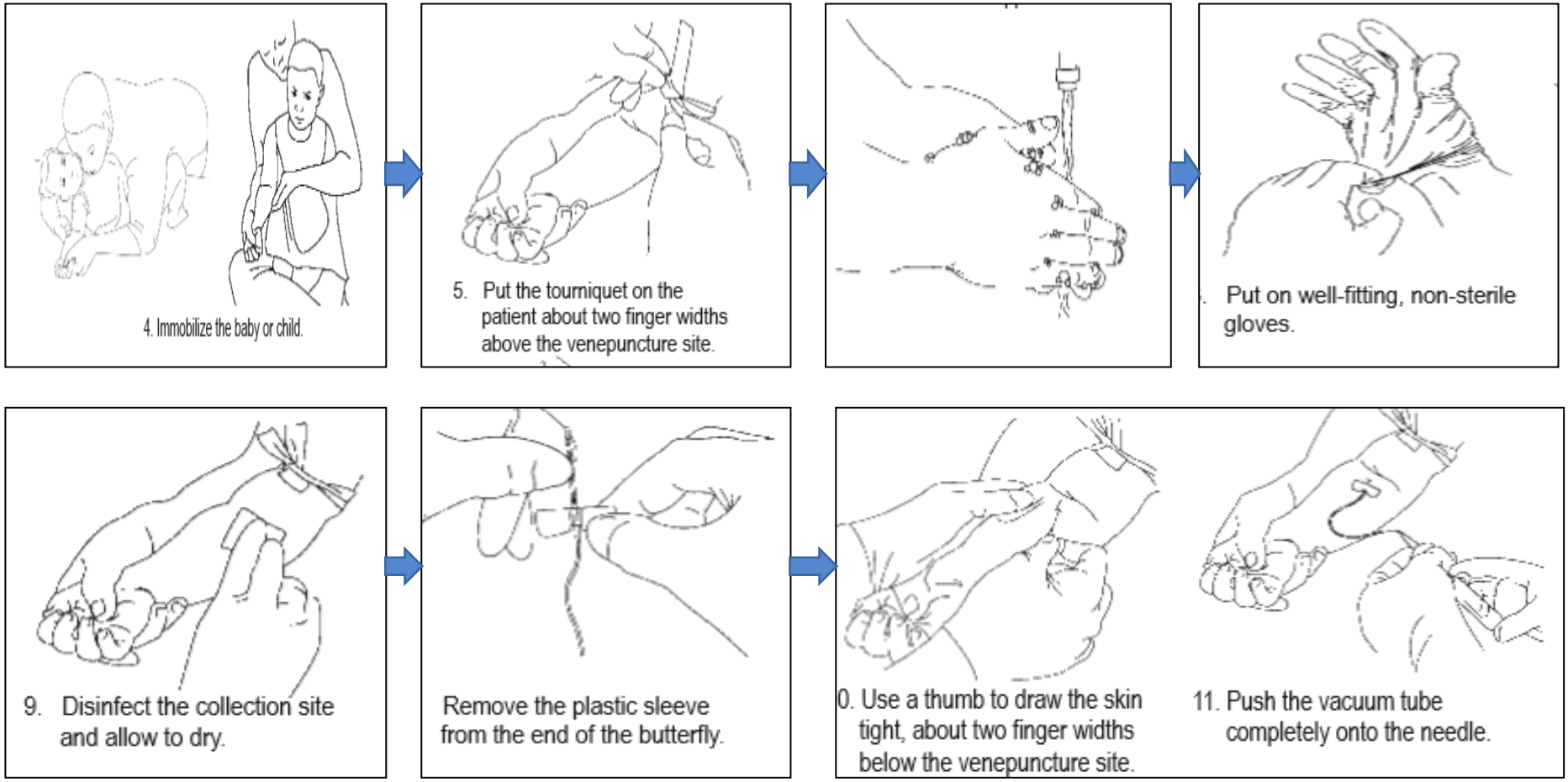


Image courtesy: WHO

Venipuncture using a butterfly needle (scalp vein set)

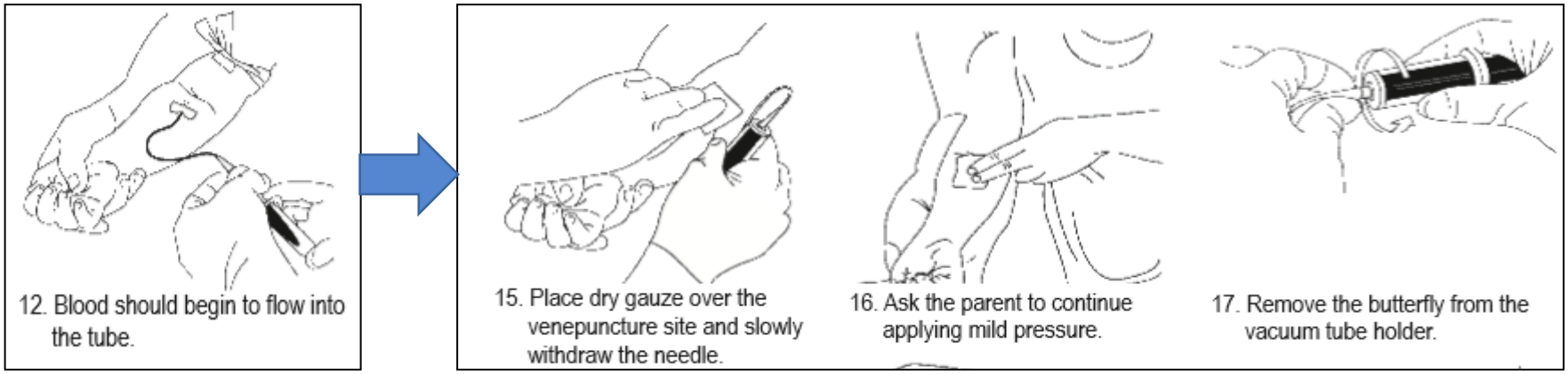
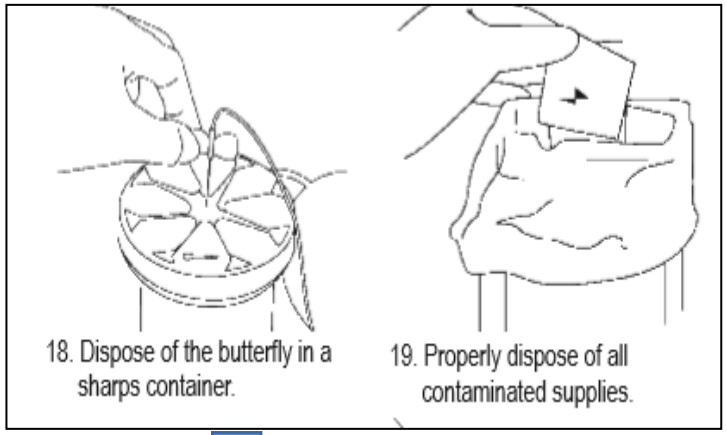


Image courtesy: WHO

Venipuncture using a butterfly needle (Contd..)

Detach the syringe from butterfly, attach syringe needle and transfer the blood sample into the sample tube



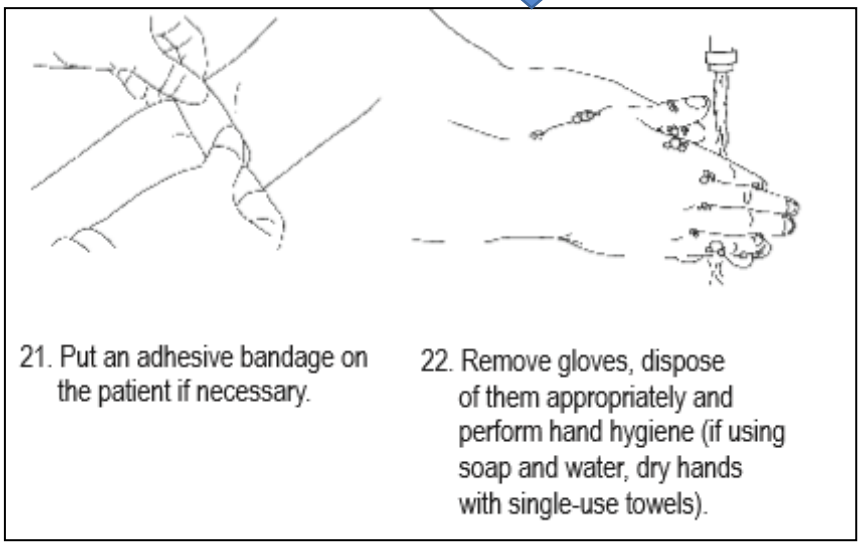


Image courtesy: WHO

Step 7: Disposal of sharps and waste

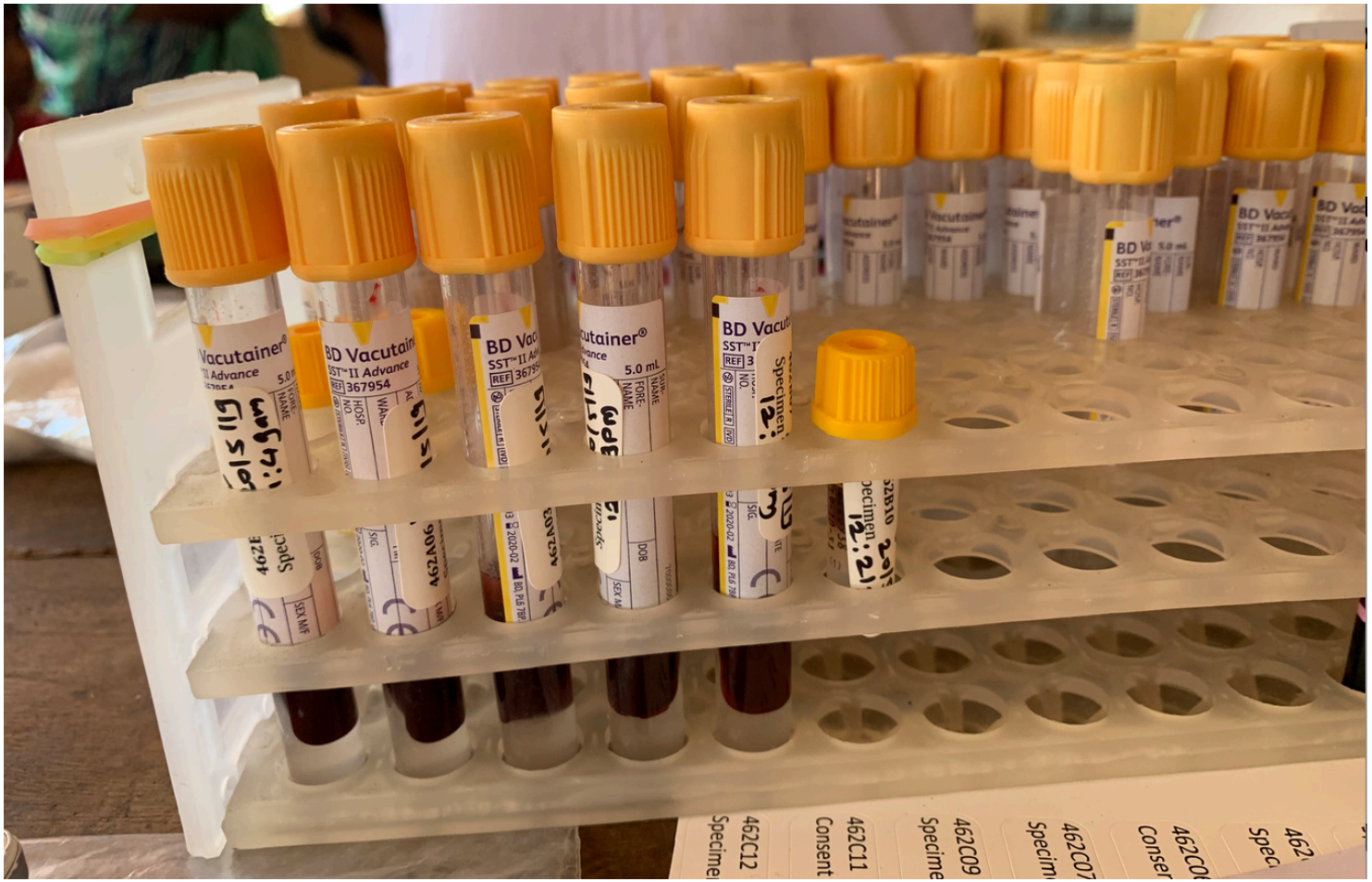
- Using the needle destroyer, cut the needle
- Immediately put the remains of the syringe into the sharps container
- If any blood spilled during collection, clean surface using alcohol wipe
- Discard the cotton swabs and gauze piece and any other contaminated material into the biohazard disposal bag (red bag)
- Discard non-contaminated material (e.g., wrappers of syringe, needle caps etc.) into the black bag
- Tie and seal each red and black bag with cello tape
- Take the red and black bags to the Site lab for terminal disinfection/ disposal
- Remove the gloves and perform hand hygiene with hand sanitizer.

Safe disposal of sharps material

- Cut needle using needle cutter and throw the rest of the syringe into sharps container
- Avoid re-capping needles
  - *If you re-cap needle, use one-handed re cap method to avoid needle stick injury*
- Avoid direct transfer of sharps between work tray or container
- The sharps container should be
  - *Sturdy*
  - *Puncture-proof*
  - *With a tamper-proof lid*
  - *Filled only to 2/3rd its capacity*

Steps prior to serum separation

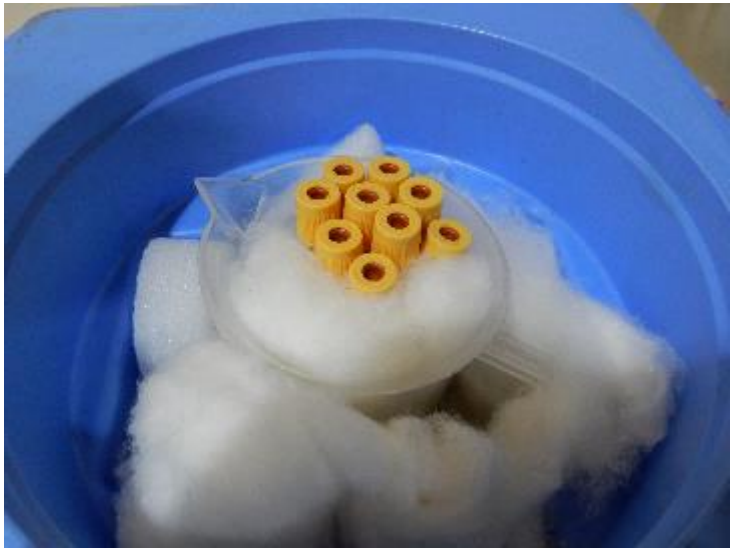
- Immediately after collection keep the sample tubes on the sample racks, undisturbed, at room temperature, for 30 minutes, to allow clotting.



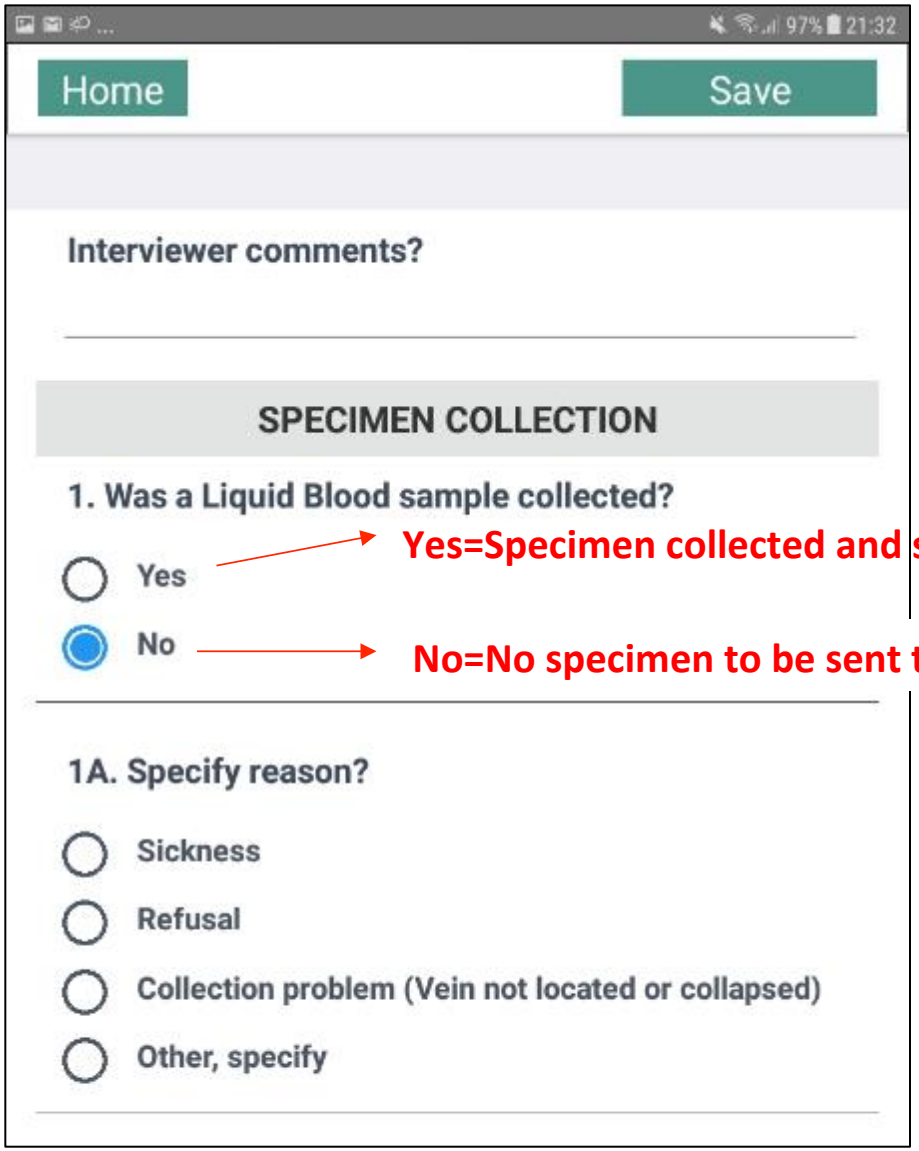
Transport of venous specimens during field work

- Recommend wrapping the tubes together with a rubber band
- Place set of tubes in a beaker filled with cotton then place beaker in vaccine carrier at 2 – 8^0C with conditioned ice packs after clotted (at least 30 mins at RT before vaccine carrier)

*For household specimen collection, recommend keeping tubes in a rack in a set location for first 30 minutes at RT



Tablet data collection



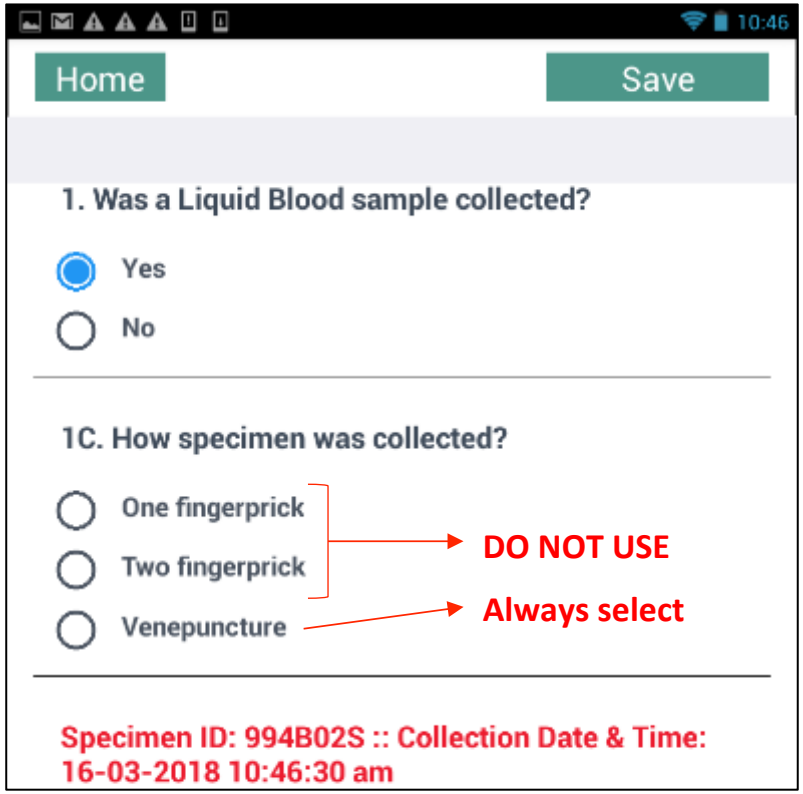
VENOUS BLOOD QUESTIONS

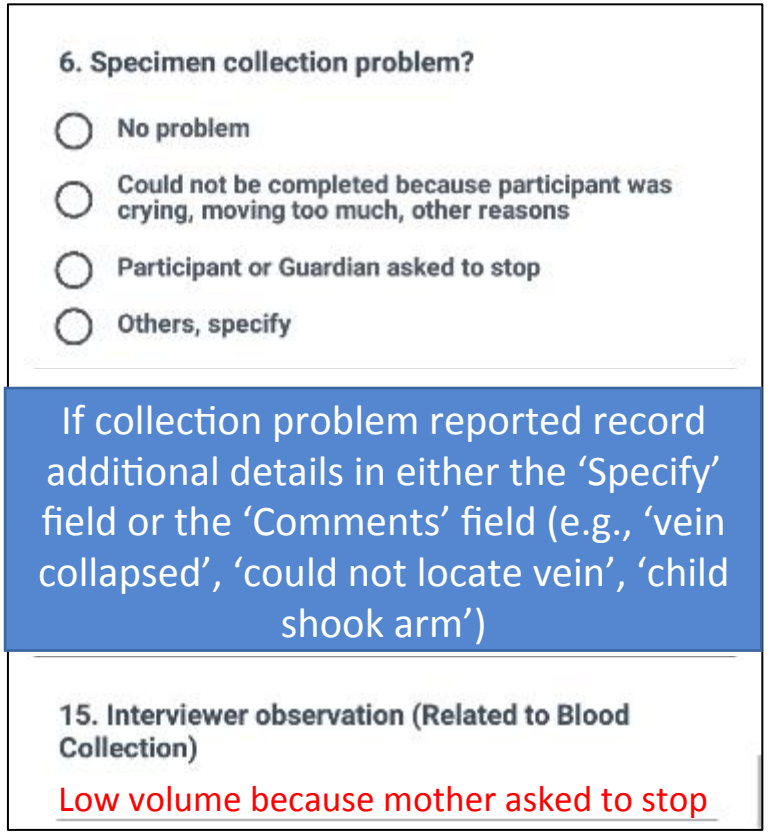
Yes=Specimen collected and sent to Site (even if low volume)

No=No specimen to be sent to Site

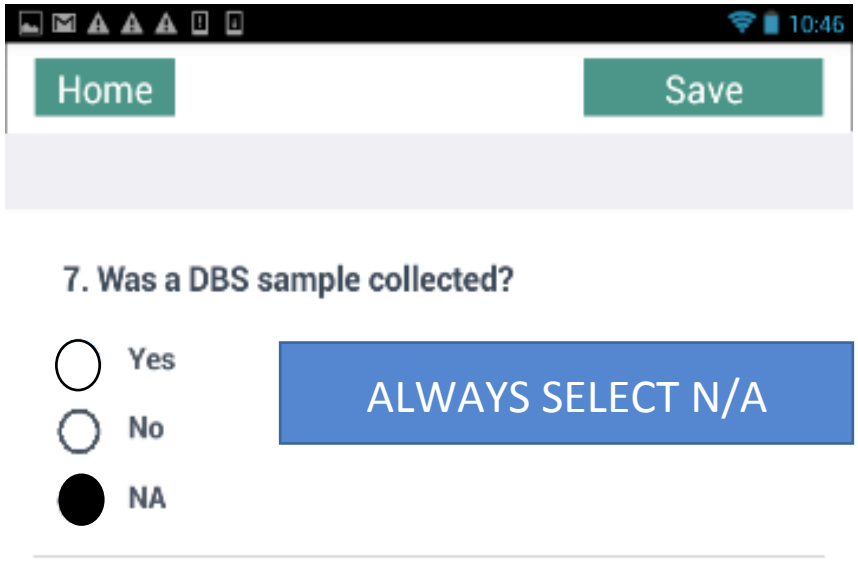
Tablet data collection

VENOUS BLOOD QUESTIONS





Tablet data collection



On-site centrifugation

- Locate source of electricity at the local health facility or other building *(may be done on Day 1 or Day 2)*
- Storage conditions before centrifugation
  - 30 minutes at room temperature (immediately after collection)
  - 30 minutes in vaccine carrier (2-8C)
- Confirm presence of clot formation before centrifugation
- Ensure tubes are properly closed
- Balance tubes
- Centrifuge operation
  - 10 min at 3000 RPM
  - Do not open lid during spinning
- Cleaning
- Accident/breakage (BRING TO SITE)

Car battery can also be used

Disposal of biological and other wastes

On the day of enrollment bring <u>two</u> bags to the field and both bags must be brought back to the Site at the end of the field day.

Color		Waste type	Examples
	Black	Non-soiled waste	Packaging materials, unsoiled cotton, bandaid wrapping
	Red	Soiled waste	Soiled cotton and other soiled non-plastic materials, syringes, gloves and needle cap, alcohol swabs

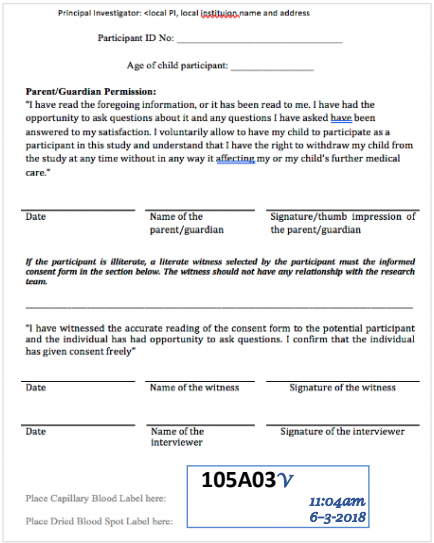
Verify specimens collected

- Field coordinator or team member must confirm all specimens are correctly labeled in vaccine carrier prior to transport
  - Match IDs on blood tubes against field tally sheet and signed consent forms

Blood tube

ClusterID	HH NO	Name	Head	Sex	Sno	AgeGroup	DOB	Age in Yrs (Calculated)	Need Verbal Assent?	Need Written Assent?	Need Parent Permission?	Need Written Consent?	ParticipantID	StatusaD1a	StatusaD2a	Specimen Verified
501	2	Ajay Kumar	Suresh Kumar	M	9	B	17-07-2009	8.7	Yes	No	Yes	No	501-B-09	✓+		Yes
501	3	Muthu Raj	Mohan Raj	M	1	A	23-12-2016	1.6	No	No	Yes	No	501-A-01	-	✓+	Yes
501	4	Mukesh Raj	Mohan Raj	M	1	B	20-11-2007	10.5	Yes	No	Yes	No	501-B-01	-	X	
501	4	Sanjay	Mohana	F	1	C		33	No	No	No	Yes	501-C-01	✓+		

Field tally sheet


Principal Investigator: <local PI, local institution name and address

Participant ID No: _____

Age of child participant: _____

Parent/Guardian Permission:

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I voluntarily allow to have my child to participate as a participant in this study and understand that I have the right to withdraw my child from the study at any time without in any way it affecting my or my child's further medical care."

Date | Name of the parent/guardian | Signature/thumb impression of the parent/guardian

If the participant is illiterate, a literate witness selected by the participant must the informed consent form in the section below. The witness should not have any relationship with the research team.

"I have witnessed the accurate reading of the consent form to the potential participant and the individual has had opportunity to ask questions. I confirm that the individual has given consent freely"

Date | Name of the witness | Signature of the witness

Date | Name of the interviewer | Signature of the interviewer

Place Capillary Blood Label here:

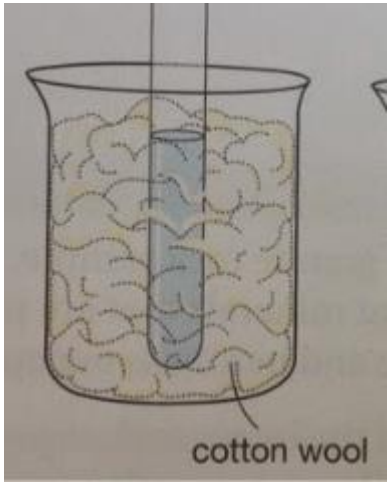
Place Dried Blood Spot Label here:

105A03✓
11:04am
6-3-2018

Consent form

Packing venous blood specimens in vaccine carrier

Carefully transfer **vacutainer** from **tube racks** to **beaker** inside **vaccine carrier**.



Secure vacutainer tubes in **beaker** and **cotton wool** in vaccine carrier

Secure vacutainer tubes in **beaker** and **cotton wool** in vaccine carrier

Transport to Site/ Institute

- Field coordinator or team member carries specimens in vaccine carrier (+2-8 C) to Site by end of day.
- Points to take care during transportation
  - Secure tubes in vaccine carrier
  - Ensure tubes are placed upright
  - Secure vaccine carrier in vehicle. Use extra caution on bumpy roads.
  - Do not transport on 2-wheeler

Transport in 4-wheel vehicle only

Transport to Site/ Institute

- Hand deliver vaccine carrier to unit lab tech to process
  - Unit Lab Technician (ULT) must be at lab to meet you. Do not leave vaccine carrier in lab.
  - ULT must verify receipt of all specimens for the day and record in lab register (check labels, status of hemolysis etc)
  - ULT must ensure sample storage at 4 C fridge in case of late receipt but must ensure processing within 24 hours.

Vaccutainer tubes in beaker in 4 C fridge

Lessons:
Ways to avoid hemolysis

- During collection
  - Tourniquet should not be in place for more than 2 minutes
  - Do not push the sample through needle into tube
- Let sample sit undisturbed for at least 30 minutes at room temperature after collection
- Use **conditioned** ice packs to avoid freezing tubes
  - Observe for sweating (water drops) on ice packs shake the ice packs to hear the water move inside
- Do not let tubes touch ice pack in vaccine carrier
- Secure tubes in beaker with cotton wool to prevent shaking during transport

Transport in 4-wheel vehicle only

Drive slowly and secure specimens on bumpy roads

Lessons: Venous Blood Collection

- If sufficient blood could not be collected by venipuncture on first attempt, or initial sample was hemolyzed during collection, technician may attempt one additional prick by venipuncture
  - Use a **different vacutainer** since initial sample may have clotted.
  - If small volume (less than 0.5 ml) use microtainer tube instead of vacutainer tube.
    - If using microtainer tube, place the top on tube after collection and invert tube 3 times to allow the coagulant in the microtainer to mix with the sample.
  - Use blank label for the new specimen container; record specimen ID, date, and time of collection.
- 2 ml is the target volume for collection; if approximately 1 ml collected there is no need to prick again to collect additional volume.

Thank you!