DMID 20-0024
Memory Aid v4.0 11 MAY 2022

PTID: _____

Date of Meningococcal vaccination: _____

Post Vaccination Day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
Date (dd/MMM/yyyy)								
Solicited systemic reactions								
Axillary temp (°C)								
Temperature severity grade								
Irritability								
Drowsiness/Lethargy								
Decrease Eating/Anorexia								
Vomiting								
Feverish								
NB: The reactions are grade 2 or 3, must be referred to the doctor at the CVD-Mali Clinical site.								
NB: All medications taken during the visit must be reported to the clinical doctor at CVD-Mali.								

Enter the severity grade for each solicited systemic reaction based on the following grading scale:

Systemic (Subjective)	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life-Threatening (Grade 4)**
Irritability	Causes no or minimal interference with usual social & functional activities with no intervention indicated	Causes greater than minimal interference with usual social & functional activities with intervention indicated	Causes inability to perform usual social & functional activities with intervention or hospitalization indicated	Inability to perform basic self-care function AND hospitalization indicated
Drowsiness/ Lethargy				
Decrease Eating/Anorexia				
Vomiting	Transient or intermittent AND no or minimal interference with oral intake	Frequent episodes with no or mild dehydration	Persistent vomiting resulting in orthostatic hypotension OR aggressive rehydration indicated (e.g., IV fluids)	Life-threatening consequences (e.g., hypotensive shock)
Fever (Axillary)	38.0 to <38.6°C	≥38.6 to <39.3°C	≥39.3°C to <40.0°C	≥40.0°C

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Feverish	Events that are usually transient and maybe require only minimal or no treatment or therapeutic intervention and generally do not interfere with the subject's usual activities of daily living	Events that are usually alleviated with additional specific therapeutic intervention. The event interferes with usual activities of daily living, causing discomfort but poses no significant or permanent risk of harm to the research participant.	Events interrupt usual activities of daily living, or significantly affects clinical status, or may require intensive therapeutic intervention. Severe events are usually incapacitating.	Events that are potentially life-threatening and require hospitalization.

Meningococcal vaccine injection site: ☐ Right anterolateral aspect of the thigh
(Location of local assessment) ☐ Left anterolateral aspect of the thigh

Solicited local reactions (meningococcal vaccination site only)								
Post Vaccination Day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8
Is a vaccine-related erythema or induration visible?	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No	☐Yes ☐No
Erythema/redness largest diameter (cm)								
Erythema/redness % surface area								
Erythema/redness Severity grade								
Induration/swelling largest diameter (cm)								
Induration/swelling % surface area								
Induration/swelling severity grade								
Pain/tenderness severity grade								
NB: The reactions are grade 2 or 3, must be referred to the doctor at the CVD-Mali Clinic site.								
NB: All medications taken during the visit must be reported to the clinic doctor.								

Enter the severity grade for each solicited local reaction based on the following grading scale:

Local Reaction	**Mild (Grade 1)**	**Moderate (Grade 2)**	**Severe (Grade 3)**	**Potentially Life-Threatening (Grade 4)**
Pain/tenderness	Causes no or minimal limitation of use of limb	Causes greater than minimal limitation of use of limb	Inability to perform usual social & functional activities with the limb	Inability to perform basic self-care function OR hospitalization indicated

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Swelling/induration	≤2.5 cm in diameter	>2.5 cm in diameter with <50% surface area of the extremity segment involved (e.g., thigh)	≥50% surface area of the extremity segment involved (e.g., thigh) OR ulceration OR secondary infection OR phlebitis OR sterile abscess OR drainage	Potentially life-threatening consequences (e.g., abscess, exfoliative dermatitis, necrosis involving dermis or deeper tissue)
Erythema/Redness	≤2.5 cm in diameter	>2.5 cm in diameter with <50% surface area of the extremity segment involved (e.g., thigh)	≥50% surface area of the extremity segment involved (e.g., thigh)	Potentially life-threatening consequences (e.g., abscess, exfoliative dermatitis, necrosis involving dermis or deeper tissue)

Comments on solicited local and systemic reactions: _____

_____

Adverse Events								
Any others AE?	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑	Yes ❑ No ❑
Please describe								

IF ANY REACTION OR ADVERSE EVENT COULD BE SEVERE OR SERIOUS, CONTACT IMMEDIATELY THE STUDY COORDINATOR.

If any concomitant medications taken provide details here:		
Comments (as needed):		
Name of staff completing the worksheet	**Signature**	**Date**