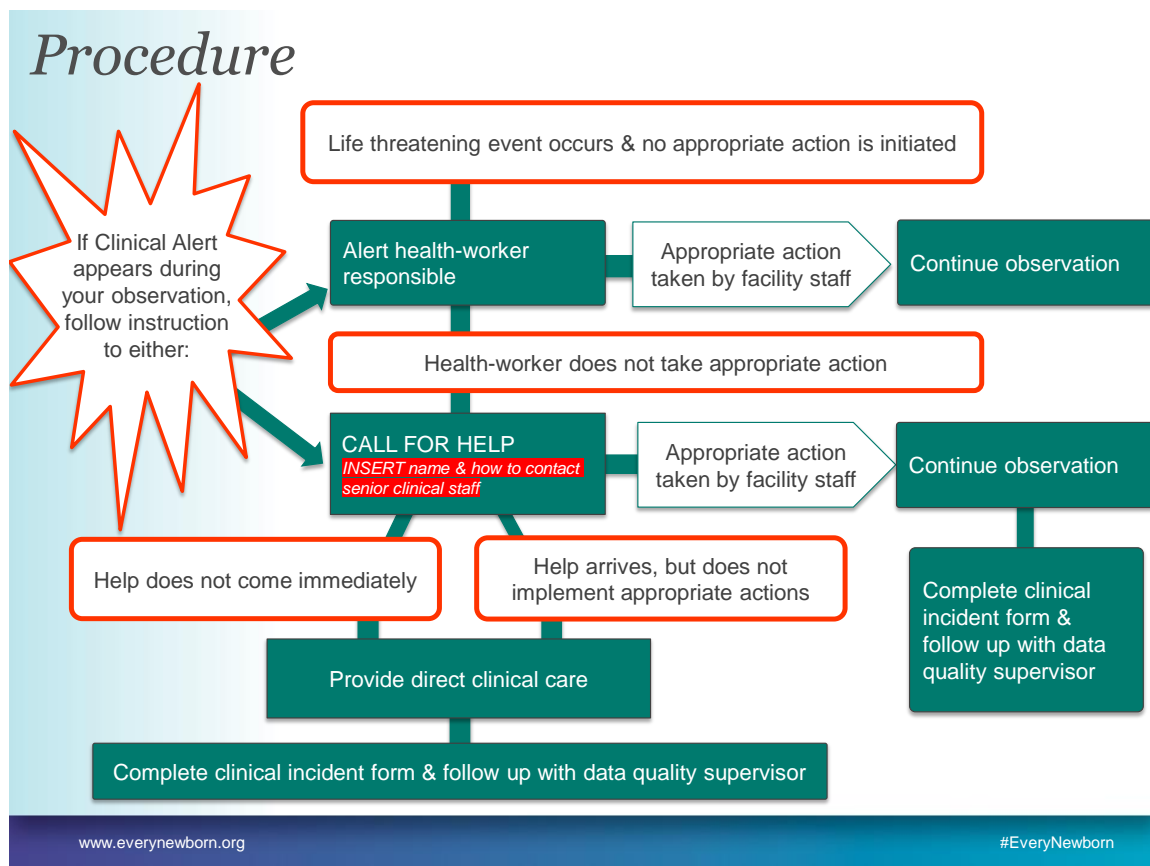


PROCEDURE FOR LIFE THREATENING EVENTS WITHOUT AN APPROPRIATE RESPONSE

Since this research is being conducted in hospital settings where clinical care is being delivered, we expect that clinical observers will collect data during life-threatening situations. There is a risk that clinical observers may observe a life-threatening situation where appropriate action has not been initiated / implemented by facility healthcare staff. In the event the safety (or life) of a patient is deemed to be endangered, action should be taken in line with Figure 1.

Figure 1. Procedure for life-threatening events where no appropriate action is being taken



All selected facilities will identify a senior healthcare provider (physician or midwife depending on the facility level) who must be present in the facility (or immediately reachable and available) at all times during data collection. A rota with clear on-call system can be utilised. This requirement will be agreed with the in country senior PI, the MOH and every facility manager where we are working.

In addition, all clinical observers are expected to have completed training updates on the interventions of study within the last three years. A brief update on each intervention of interest will also be provided as part of standard observer training and observers will need to pass knowledge testing before commencing work in a clinical site.

Follow up:

Observers should complete the clinical incident form with their research supervisor. Each health facility should identify a named person responsible from hospital management to be contacted in all cases where observers need to implement the SOP in accordance with Figure 1. The named person responsible from hospital management will work with the research team following clinical incidents and should receive a copy of the clinical incident form. Clinical incident forms should be collated and reviews at facility, country and LSHTM level and are the basis for monthly (can be more frequent at facility level if required) case review and updates.