

## NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit



# Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit

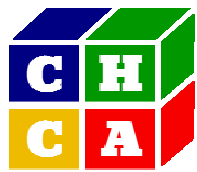
The use of “triggers,” or clues, to identify adverse events (AEs) is an effective method for measuring the overall level of harm in a health care organization. This Trigger Tool for Measuring Adverse Events in the Neonatal Intensive Care Unit provides instructions for conducting a retrospective review of patient records using triggers to identify possible AEs in the **Neonatal Intensive Care Unit (NICU)**. This tool includes a list of potential AE triggers and instructions for collecting the data you need to measure the rate of AEs in your NICU (the total number of AEs per 100 admissions), and the percentage of admissions with an AE) in your NICU. A full test of these triggers was conducted in order to construct a valid neonatal Trigger Tool. The details of this study can be found in the following article:

Sharek PJ, Horbar JG, Mason W, et al. Adverse events in the neonatal intensive care unit: Development, testing, and findings of a NICU-focused Trigger Tool to identify harm in North American NICUs. *Pediatrics*. 2006;118(4):1332-1340.

<http://pediatrics.aappublications.org/cgi/content/abstract/118/4/1332>

This NICU Trigger Tool contains:

- ❖ Background
- ❖ Definitions
- ❖ Sampling and Methods for Conducting Trigger Chart Review
- ❖ List of AE Triggers
- ❖ FAQs about the Trigger Reviews
- ❖ Data Collection Form: Individual Patient NICU Triggers Data Collection Form
- ❖ Data Collection Form: NICU AE Monthly Summary Sheet



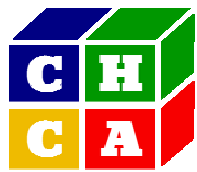
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### BACKGROUND

The Harvard Medical Practice Study (1991) found that 3.7% of patients experience serious adverse events related to medical management. Early findings from the Institute for Healthcare Improvement (IHI) trigger projects have found that 19% of all peri-operative patients and 55% of all adult ICU admissions had adverse events. Traditional efforts to detect AEs have focused on voluntary reporting and tracking of errors. However, only 10% to 20% of errors are ever reported and, of those, 90% to 95% cause no harm to patients. Hospitals need a more effective way to identify events that do cause harm to patients, in order to select and test changes to reduce harm. This tool provides an easy-to-use method for accurately identifying AEs (harm from medications, tests and treatments) and measuring the rate of AEs over time.

The Institute for Healthcare Improvement (IHI) formed the Idealized Design of the Medication System (IDMS) Group in May 2000, which developed the first IHI Trigger Tool system. Since that time, IHI has expanded its Trigger Tools to include non-medication events (see [www.ihl.org](http://www.ihl.org)), and other groups have developed population-specific Trigger Tools, such as a Pediatric Trigger Tool to detect adverse drug events in pediatric inpatients developed in 2001-2003 by the Child Health Accountability Initiative (CHAI) of Child Health Corporation of America (CHCA). CHCA and the Vermont Oxford Network (VON) have identified the need for a NICU-specific Trigger Tool based on the following factors:

- IHI Trigger Tool testing has found a very high level of harm in ICU and surgical patients (as noted above)
- The CHAI Pediatric Trigger Tool may not be ideal for use in the NICU population:
  - Although the NICU population seemed prone to a high number of adverse drug events (ADEs) due to their fragile medical condition and their increased risk for weight-based dosing errors, the CHAI ADE tool identified a similar rate of ADEs in the neonatal population when compared to the general pediatric population. This suggested that the CHAI ADE Trigger Tool was not sensitive enough in the high-risk Neonatal Intensive Care Unit population.
  - The triggers which were associated with ADEs in the neonatal population were quite different from those most commonly associated with ADEs in other pediatric patients.
  - The tool identified only drug-related adverse events, and thus did not detect adverse events related to procedures or non-medication-based therapies.



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### DEFINITIONS

**Adverse event (AE):** An injury, large or small, caused by the use (including non-use) of a drug, test, or medical treatment. This may be as harmless as a drug rash or as serious as death (modified from IHI definition of an adverse drug event, or ADE). Special note: Intentional drug overdoses are not classified as AEs.

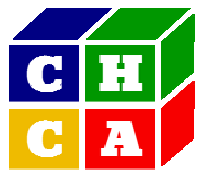
**Unique adverse event** (see Individual Patient NICU Triggers Data Collection Form at the end of this toolkit): An adverse event that is independent of other adverse events. For example: If a patient developed acute renal failure (identified by the trigger “increased creatinine”), and developed a nosocomial infection (identified by the trigger “antibiotic use”), these would be two unique adverse events. If however, a patient had a massive intraventricular hemorrhage (identified by the trigger “abnormal cranial imaging”) and this massive intraventricular hemorrhage also was identified by the trigger “hypotension,” then this adverse event (intraventricular hemorrhage) identified by two separate triggers (“abnormal cranial imaging” and “hypotension”) reflect the same adverse event (i.e., one unique adverse event).

**Medical error:** Any error, large or small, in the medication, testing or treatment process from the time a drug, test, or treatment is ordered until the patient receives it (modified from the IHI definition of medication error).

**Harm:** Temporary or permanent impairment of the physical, emotional, or psychological function or structure of the body and/or pain requiring intervention (modified from NCC MERP definition).

**Severity of adverse events:** Events are rated using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for Categorizing Errors (NCC MERP, 2001; see <http://www.nccmerp.org/medErrorCatIndex.html>). Although designed for medication errors, these categories are easily applied to adverse events. NCC MERP categories E through I are relevant as defined below.

- Category E: Contributed to or resulted in temporary harm to the patient and required intervention
- Category F: Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
- Category G: Contributed to or resulted in permanent patient harm
- Category H: Required intervention to sustain life
- Category I: Contributed to or resulted in the patient’s death



## NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit

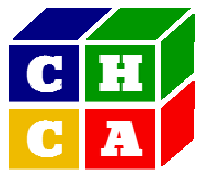
Events in NCC MERP categories A through D do **not** involve patient harm, and are thus not relevant:



- Category A: Circumstances or events that have the capacity to cause error
- Category B: An error occurred but the error did not reach the patient (An "error of omission" does reach the patient)
- Category C: An error occurred that reached the patient but did not cause patient harm
- Category D: An error occurred that reached the patient and required monitoring or intervention to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

The NCC MERP provides the following definitions:

- Monitoring: To observe or record relevant physiological or psychological signs
- Intervention: May include change in therapy or active medical/surgical treatment
- Intervention Necessary to Sustain Life: Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)



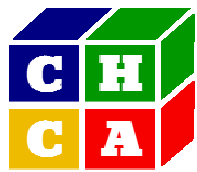
## NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit



### SAMPLING AND CHART REVIEW METHODS

A standardized list of triggers (see below for the “Individual Patient NICU Triggers Data Collection Form”) that provide “clues” to potential adverse events (AEs) is provided below. The trigger chart review should be conducted as follows:

1. Take a random sample of 20 patients who were in the NICU (minimum of 2 days stay in the NICU) and who were discharged, transferred out, or died in the relevant month. (See instructions on how to do this in Appendix A or use the randomization tool at <http://www.randomizer.org/form.htm>.)
2. Obtain patient records from the Medical Records Department for each of these 20 subjects.
3. Review each patient record, using the trigger list, paying particular attention to the following sections (in order of review):
  - a) Discharge summary: Look for AEs or hints at AEs
  - b) ICD-9 coding (if available in your charts). Review “E Codes” also if they are included in your coding summary.
  - c) Laboratory reports: Look for trigger lab results (e.g., elevated potassium levels)
  - d) Physician orders or Medication Administration Records (MARs): Look for trigger medications (e.g., Naloxone use)
  - e) Nursing flow sheets
  - f) Nursing/Multidisciplinary progress notes
4. List all triggers found on the “Individual Patient NICU Triggers Data Collection Form” (see below). **Multiple doses of an antidote given to counteract a single AE or multiple laboratory measurements to monitor a single AE should be considered ONE count of that trigger only!** This has historically been a problem in trigger work. A critical concept here is that triggers should reflect a possible adverse event. See the following examples:
  - a. Example 1: If Naloxone (Narcan) is given 4 times for a single episode of opioid-induced respiratory depression, *these 4 doses should only count as one trigger*.
  - b. Example 2: If a patient’s creatinine is above 1.0 for 6 straight lab draws, and this reflects one episode of severe hypotension that resulted in acute renal failure, *this should only be counted as one trigger*.
  - c. Example 3: If Ampicillin and Gentamycin are given for a rule out sepsis, this is one trigger only. If the patient is ruled out for sepsis, but 2 days later is started on Ampicillin and Gentamycin again for another rule out sepsis, this would constitute a second trigger (2 potential adverse events, thus 2 separate triggers).
5. For each trigger identified **during the NICU stay**, read through the appropriate parts of the patient record to determine if an AE has occurred. Sometimes professional judgment will be required to make this determination. One rule of thumb: If an adverse event was treated as though it happened then consider it a true adverse event.



## NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit



For example: Patient was treated with a full 14-day course of antibiotics, even though all cultures were negative and all CRPs were normal, this should still be considered an adverse event because this patient was treated for clinical sepsis. Intentional drug overdoses are not classified as AEs.

6. If an AE occurred, review this adverse event with your site Neonatologist to confirm that this was a true adverse event. (Remember, we are not suggesting an *error* occurred. Rather, we are suggesting that some *harm* occurred. Preventability should not be factored into the decision of whether an adverse event occurred or not.)
7. If an AE occurred and is confirmed by your site Neonatologist, describe the event on the Individual Patient NICU Triggers Data Collection Form.
8. Determine all triggers associated with each unique adverse event on the Individual Patient NICU Triggers Data Collection Form.
  - a. Example 1: If you identified the adverse event “acute renal failure,” you might list the triggers of “Hypotension” (T-4) and “Rising Serum Creatinine” (T-10) that identified/contributed to the adverse event “acute renal failure.”
  - b. Example 2: If you identified the adverse event “death,” you might list the triggers of “Nosocomial Infection” (T-1), “NEC” (T-11), “Hypotension” (T-4), “Abnormal Cranial Imaging” (T-14) that all identified/contributed to the adverse event “death.”
9. Once you have completed one Individual Patient NICU Triggers Data Collection Form for each of the 20 patients, summarize your findings in the NICU Adverse Event Monthly Summary Sheet (see below). For each patient record reviewed, document whether an AE occurred, and the total number of AEs that did occur.
10. Use the NICU AE Monthly Summary Sheet to calculate the rate of patients with an AE. This value is the total number of AEs identified divided by the number of patient charts reviewed (20).
11. Track the rate of AEs per patient over time in a run chart to determine if changes you are making are affecting the safety of the patients in your NICU.



# NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit



## LIST OF AE TRIGGERS

The following triggers were tested and kept for their usefulness in identifying adverse events in the NICU population:

Trigger	Definition of trigger	Cause for trigger to appear	Potential AEs
T <sub>1</sub> Nosocomial Infection	Includes sepsis, VAP (ventilator-associated pneumonia), abscess, wound infection, central line infections, and all other nosocomial infections. <b>INCLUDE ONLY infections that developed 3 days or more after delivery or admission.</b>	Poor handling of lines, inappropriate insertion technique, etc.	Nosocomial infection
T <sub>2</sub> Antibiotic Use	Any antibiotic used at any time during the NICU stay ( <b>includes prophylactic antibiotics, EXCEPT prophylactic fluconazole</b> )	Poor handling of lines, inappropriate insertion technique, etc.	Nosocomial infection
T <sub>3</sub> Unplanned Extubations	Any removal of an endotracheal tube that was not planned	Poor taping, undersedation, excessive ventilation	Accidental extubation requiring reintubation, respiratory compromise, required tracheotomy, cardiorespiratory arrest
T <sub>4</sub> Hypotension	MAP <25 for gestational age <30 weeks MAP <30 for gestational age 30-35 weeks MAP <35 for gestational age >35 weeks Hypotension occurring during titration of continuous drip of inotropes or vasodilators or sedatives will not be considered an AE unless there was an abrupt stop or change in the titration drip or some other trigger associated with the titration.	Medication error, sepsis, arrhythmia, poor ventilator management, missed diagnosis (e.g., adrenal insufficiency)	Hypotension, nosocomial infection, arrhythmias, cardio-respiratory arrest
T <sub>5</sub> Respiratory Arrest	Any event outside of the delivery room associated with a respiratory rate of zero and requiring endotracheal intubation	Medication error, pneumothorax, CLD, BPD, obstructed airway (includes ETT), birth trauma, intracranial hemorrhage, etc.	Respiratory arrest
T <sub>6</sub> Death	Death	Any cause of death (infection, respiratory arrest, cardiac arrest, severe head bleed, etc.)	Death





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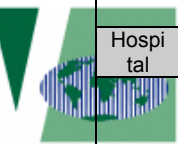


T <sub>7</sub> Catheter Infiltration/Burn	Evidence of excessive redness, edema, extravasation, skin sloughing in an area associated with a present or recent IV	Poor insertion technique, poor maintenance, wrong medication or concentration infused	Catheter infiltration/burn
T <sub>8</sub> Naloxone (Narcan)	This drug is a narcotic antagonist. Use of Narcan often indicates overdosage of narcotics. If Narcan was used and the patient's condition changed, excessive narcotic administration probably has occurred.	Narcotic overdose	Respiratory depression/arrest
T <sub>9</sub> Anticoagulant (Lovinox, warfin, heparin drip)	Evidence in the chart (orders or MAR) that a medication used for anticoagulation was ordered. <b>This EXCLUDES the use of heparin to maintain line patency.</b>	Medical paralysis, catheter complication, delay in diagnosing a hypercoagulative state	Embolus/thrombus
T <sub>10</sub> Rising Serum Creatinine	Creatinine >1.0 or an increase $\geq 0.4$ mg/dL within 24 hours	Nephrotoxic medication, catheter misplacement, hypotension	Renal insufficiency or failure
T <sub>11</sub> NEC	NEC may be associated with serial KUBs, abrupt feeding stoppage, emesis, or guaiac positive stools, notation in RN notes, MD exam, or progress notes identifying abdominal distension	Feeding mismanagement, catheter placement, indocin overuse	NEC
T <sub>12</sub> Seizures	Evidence of seizure activity as defined by clinical description (progress notes, RN notes) or EEG findings	IV fluid/TPN errors, iatrogenic hypoxia, prolonged delivery, cardiorespiratory arrest	Seizures
T <sub>13</sub> Phenobarbital	Loading dose of 10-20 mg/kg of phenobarbital initiated (noted in the orders or MAR)	IV fluid/TPN errors, iatrogenic hypoxia, prolonged delivery, cardiorespiratory arrest	Seizures
T <sub>14</sub> Abnormal Cranial Imaging	Any abnormal cranial imaging (including but not limited to cranial imaging with evidence of significant ischemia or grade 3-4 hemorrhage)	Fluctuations in blood pressure, cardiorespiratory arrest, electrolyte imbalances	Intraventricular hemorrhage (IVH), Ischemia <b>NOTE: Congenital anomalies should NOT be considered AEs</b>
T <sub>15</sub> Hyperglycemia	Glucose > 200	IV fluid/TPN error, nosocomial infection, steroid overdose	Osmotic diuresis, sepsis, IVH,
T <sub>16</sub> Unplanned Return to Surgery	Any return to surgery that was not anticipated	Unrecognized bleeding, retained sponge, wound dehiscence	Anemia, nosocomial infection, retained foreign body



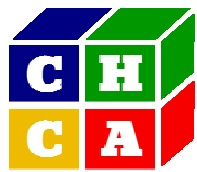


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## Individual Patient Neonatal Intensive Care Unit (NICU) Triggers Data Collection Form

Hospital	Patient Number	Gestational Age at Birth (weeks)	Birth Weight (kg)	Gender	* AE Harm Categories: E: Contributed to or resulted in temporary harm to the patient and required intervention F: Contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization G: Contributed to or resulted in permanent patient harm H: Required intervention to sustain life I: Contributed or resulted in patient's death				
		Length of Stay in the NICU (min 2 days) =		<input type="checkbox"/> F <input type="checkbox"/> M					
Triggers		# Times Trigger is Present	# Adverse Events Associated with This Trigger	Comments about Trigger		Description of Adverse Event	AE Harm Category*	Was AE preventable?	Did the AE/ADE occur in the NICU?
T <sub>1</sub> Nosocomial Infection								Y   N	Y   N
T <sub>2</sub> Antibiotic Use								Y   N	Y   N
T <sub>3</sub> Unplanned Extubations								Y   N	Y   N
T <sub>4</sub> Hypotension								Y   N	Y   N
T <sub>5</sub> Respiratory Arrest								Y   N	Y   N
T <sub>6</sub> Death								Y   N	Y   N
T <sub>7</sub> Catheter Infiltration/Burn								Y   N	Y   N
T <sub>8</sub> Naloxone (Narcan)								Y   N	Y   N
T <sub>9</sub> Anticoagulant (Lovinox, warfin, heparin)								Y   N	Y   N
T <sub>10</sub> Rising Serum Creatinine								Y   N	Y   N
T <sub>11</sub> NEC								Y   N	Y   N
T <sub>12</sub> Seizures								Y   N	Y   N
T <sub>13</sub> Phenobarbital								Y   N	Y   N
T <sub>14</sub> Abnormal Cranial Imaging								Y   N	Y   N
T <sub>15</sub> Hyperglycemia								Y   N	Y   N
T <sub>16</sub> Unplanned Return to Surgery								Y   N	Y   N



NICU Trigger Tool:  
Measuring Adverse Events in the Neonatal Intensive Care Unit



**NICU Adverse Event Monthly Summary Sheet**

Date \_\_\_\_\_

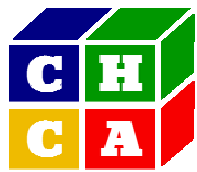
Patient	AE Found? (Yes/No)	Total Number of AEs for This Patient
Pt #1		
Pt #2		
Pt #3		
Pt #4		
Pt #5		
Pt #6		
Pt #7		
Pt #8		
Pt #9		
Pt #10		
Pt #11		
Pt #12		
Pt #13		
Pt #14		
Pt #15		
Pt #16		
Pt #17		
Pt #18		
Pt #19		
Pt #20		
	Total:	Total:

**Adverse Event Rate**

The total number of adverse events (total in column 3 above) divided by the total number of patient records in the sample (20)

**Percent of NICU Admissions with an Adverse Event**

The total number of patients identified as having experienced any adverse event from a sample of patient records (total of "Yes" responses from column 2) divided by the total number of patient records in the sample (20); multiplied by 100

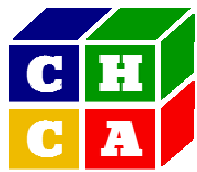


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## Frequently Asked Questions about Triggers

How is the trigger chart review different from a regular chart review?	Trigger chart review is a very focused review, intended to be completed in 15 to 20 minutes per chart. As you are learning to do the review, it may take longer.
What if I notice an adverse event that's not associated with a trigger (e.g., it was captured via voluntary reporting)?	Record the adverse event and indicate there is no trigger (e.g., a dash or "N/A").
Should I include all adverse events from my internal reporting system?	Include only adverse events associated with your sample of 20 patients
What time period should my charts come from?	Admission could occur at any time, but the patient must have been discharged from, transferred out of, or died in your institution during the month of interest.
What about events that are not due to an error?	The goal is to capture HARM, not error, so you should include both preventable and non-preventable events.
Is intervention (treatment) necessary for the event to be an adverse event?	No, if some other severity definition was met, such as prolonged hospitalization, permanent harm, or death.
Who should do the trigger review?	We recommend the charts be reviewed by a nurse, pharmacist or physician and that adverse events be confirmed by a Neonatologist. The most common scenario is initial review by a nurse or pharmacist and confirmation by a Neonatologist.
If a reviewer remembers triggers that are not documented, should the reviewer include them?	Do not record triggers that aren't documented, but if the reviewer identifies an actual documented adverse event as a byproduct of their memory of a trigger, then record that adverse event (and put a dash or N/A for the trigger).
Can I include more than one severity level for a single adverse event? For example, nosocomial infection resulted in an antibiotic intervention (Severity E) prolongation of the hospital stay (Severity F), and death (Severity I).	No. Label the adverse event with the highest severity rating applicable. In this example, the severity level would be "I."



## NICU Trigger Tool: Measuring Adverse Events in the Neonatal Intensive Care Unit



### Appendix A Randomization Instructions

To determine a random sample:

1. Create a list of all patients in Excel who had a minimum of a 2-day stay in the NICU AND were discharged, transferred out, or died in the month of interest.
2. Insert a blank column in front of the first column of the spreadsheet.
3. In the first blank cell of the column type the following equation: =RAND()
4. Sort the first column in ascending order and select the first 20 patients.

Alternatively, use the randomization tool available at  
<http://www.randomizer.org/form.htm>.