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# Detecting Adverse Drug Events Using a Nursing Home Specific Trigger Tool

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Adverse drug events (ADEs) are defined by the Institute of Medicine (IOM) as, "injuries resulting from a medical intervention related to a drug."[1] Institutionalized elderly experience ADEs at a rate as high as 10.8 events per 100-patient months, often as a result of polypharmacy, multiple comorbid illness, and difficulty with monitoring prescribed medications.[2–4] This translates into approximately 135 ADEs each year in an average size nursing home (NH; bed size of 105) or approximately 2 million events a year among all U.S. NH patients. ADEs represent the most clinically significant and costly medication-related problems in NHs and are associated with 93,000 deaths a year and in as much as $4 billion of excess healthcare expenditures.[5–6] Despite the consequences and costs associated with ADEs, the vast majority of these events go undetected using traditional methods including comprehensive chart reviews, direct observation, and voluntary reporting. Therefore, alternative surveillance strategies are needed in NHs to supplement existing detection strategies and minimize the potential consequences of ADEs.

The trigger tool methodology, developed in part by the Institute of Healthcare Improvement (IHI), greatly simplifies the chart review process by allowing rapid and systematic examination of charts to extract relevant data for the detection of potential ADEs. The technique, which requires minimal training, appears to increase the rate of ADE detection 50-fold from traditional reporting methods.[7] The triggers themselves represent specific events including the ordering of certain medications (e.g., antidotes, such as Vitamin K), the results of certain laboratory studies (e.g., supratherapeutic serum medication concentrations, such as digoxin level), and change in clinical status or new sign or symptom (e.g., drug-induced fall or drug-related rash). Since the triggers are likely to differ based on specific clinical setting, multiple IHI trigger tools have been developed including those for: mental health settings, adult inpatient, adult outpatient, adult intensive care units, adult peri-operative care units, pediatric inpatient, and neonatal intensive care units.[8] Many of the clinical setting-specific trigger tools have been successfully used to demonstrate the benefits of low-cost error detection strategies that produce consistent, reliable, and relevant data.[9–13]

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Recently, a study was completed to develop a consensus list of agreed upon laboratory, pharmacy, and Minimum Data Set triggers to expand the use of the trigger tool methodology to the NH setting.[14] The authors conducted a comprehensive literature search for potential ADE triggers, followed by an Internet-based, two-round, modified Delphi survey of physician, pharmacist, and advanced practitioner experts in geriatrics. Panelists reached consensus agreement on 40 triggers: 15 laboratory/medication combinations, 12 medication concentrations, 10 antidotes, and 3 Resident Assessment Protocols (RAPs). Highest consensus scores (4.6; 95% CI, 4.4–4.9 or 4.4–4.8) were for naloxone when taking opioid analgesics; phytonadione when taking warfarin; dextrose, glucagon, or liquid glucose when taking hypoglycemic agents; medication-induced hypoglycemia; supratherapeutic international normalized ratio when taking warfarin; and triggering the Falls RAP when taking certain medications.

The IHI formally adopted this set of 40 triggers as the "Nursing Home Adverse Drug Event Trigger Tool."[15] We suggest that this tool be incorporated into the consultant pharmacist medication regimen review (MRR) process. The State Operations Manual provides a definition for MRR (i.e., F428), as a thorough evaluation of the medication regimen of a resident, with goal of promoting positive outcomes and minimizing adverse consequences. The review includes preventing, identifying, reporting, and resolving medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team.[16] According to these new guidelines, F428 emphasizes that consultant pharmacists are expected to perform MRRs at least every 30 days, and expedited reviews for short-stay residents, as well as those residents who experience an acute change in condition.[17]

The IHI recommends either one of the two following strategies to detect triggers and investigate them to determine if an ADE has occurred: 1) review a *sample* of resident charts (**letters A through I**), or 2) review *all* resident charts (**letters B through G**):

- **A.** Select a random sample of 20 resident records.
- **B.** Obtain incident report information (e.g., medication error, adverse drug event, and falls reports) from the nursing home administrator, director of nursing, or risk management (if permissible).
- **C.** Review each resident record, paying particular attention to the following sections:
    - **a.** Physician orders and Medication Administration Records (MARs): Look for trigger medications.
    - **b.** Laboratory reports: Look for trigger lab results.
    - **c.** Consultant pharmacist medication regimen review notes, consultations, and recommendations made to the attending physician. Look for previous recommendations made for monitoring, gradual dose reduction, or to stop drug, change drug, change dose, change directions, change schedule, or other (e.g., add a drug, change formulation).
    - **d.** Physician and nursing progress notes looking for acute or gradual change in condition such as new or worsening cognitive or functional status, falls, lethargy, gastrointestinal problems, hypotension, rash, nausea/vomiting, or other adverse events that may be associated with the use of a medication. Also, take note of any unplanned hospitalization and emergency department evaluations.
- **D.** List all triggers found on the ADE Resident Record Review Sheet (Table 1).

**E.** For each trigger found, read through the appropriate parts of the resident record to determine if an ADE has occurred. Sometimes professional judgment will be required to make this determination. Some ADEs will result in more than one trigger; use your best judgment in determining the number of ADEs that occurred in this situation.

**F.** If an ADE occurred, assign a category of harm (E through I) and provide a brief description of the ADE (Table 1).

**G.** After you have completed the ADE Patient Record Review Sheet for the patient records in the sample, summarize your findings in the ADE Monthly Summary Sheet (Table 2). For each patient record reviewed, document the following: whether an ADE occurred; the number of ADEs; and (if you collected data on doses) the total number of medication doses received.

**H.** Use the data in the ADE Monthly Summary Sheet to calculate one or both of these important measures:

- **a.** Percent of residents with an ADE
  - **i.** The total number residents identified as having experienced any ADEs from a sample of resident records, divided by the total number of records in the sample; multiplied by 100 to express as a percentage.
- **b.** ADEs per 1,000 Doses
  - **i.** The total number of ADEs identified in a sample of resident records, divided by the total number of medication doses administered to those residents. Multiply the result by 1,000.

**I.** Track the measures (Percent of Admissions with an ADE, ADEs per 1,000 Doses) over time in a run chart, to see if changes you are testing are making the medication system safer. You can use the Improvement Tracker on IHI.org to automatically track and graph these measures over time.

The IHI recommends using the results of this tool to measure the number of ADEs in an organization over time, and determine whether or not the changes a facility is making results in improvement. Similar to other NH quality improvement initiatives, the results can be summarized and reported to the quality assessment and assurance (QAA) committee that is required to meet at least quarterly as described in F520.[18] During these meetings, the committee can develop and implement plans of action to correct the future occurrence of ADEs, including monitoring the effect of implemented changes and making needed revisions to the action plans.

The future of ADE detection in the NH setting will likely rely on utilizing health information technology. This is consistent with the IOM and other patient safety organizations recommendation that all healthcare settings assess the safety of medication use through active monitoring systems within a culture of safety.[1, 16–22] Although most NHs have yet to adopt a significant amount of health information technology[23], the majority generate laboratory, pharmacy, and Minimum Data Set data in electronic format that can be used by active medication monitoring systems to automate the detection of ADEs. Recently, investigators have developed and tested an active medication monitoring system using the consensus set of NH triggers accepted by IHI.[24] They found that they could detect ADEs with a high degree of accuracy and at a rate of nearly 2.5 times greater than that of *usual care* (i.e., pharmacist-conducted manual chart review).

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## Table 1

Trigger Tool for Measuring Adverse Drug Events in the Nursing Home

| **Nursing Home Resident Record Review Sheet** | |
|---|---|
| **Patient Identification Number:** _____ | |
| **Admission Date:** _____ | **Patient's Age:** _____ |
| **Review Date:**_____ | |
| **Trigger Number** | **Laboratory/Medication Combination Signals** |
| **T1** | Hypoglycemia (as indicated by a low or decreasing glucose concentration) is found in an individual taking a drug that may cause or worsen hypoglycemia |
| **T2** | Supratherapeutic (above upper limit of normal range) international normalized ratio (INR) is found in an individual taking warfarin |
| **T3** | *Clostridium difficile* toxin is found in an individual taking a drug that may cause pseudomembranous colitis |
| **T4** | Hyperkalemia (as indicated by a high or increasing potassium concentration) is found in an individual taking a drug that may cause or worsen hyperkalemia |
| **T5** | Hypokalemia (as indicated by a low or decreasing potassium concentration) is found in an individual taking a drug that may cause or worsen hypokalemia |
| **T6** | Thrombocytopenia (as indicated by a low or decreasing platelet count) is found in an individual taking a drug that may cause or worsen thrombocytopenia |
| **T7** | Supratherapeutic activated partial thromboplastin time (PTT) is found in an individual taking heparin |
| **T8** | Subtherapeutic concentration (below lower limit of normal range) of thyroid-stimulating hormone (TSH) or elevated concentration of thyroxine (T4) is found in an individual taking a drug that may cause hyperthyroidism |
| **T9** | Hyponatremia (as indicated by a low or decreasing sodium concentration) is found in an individual taking a drug that may cause or worsen hyponatremia |
| **T10** | Leukopenia (as indicated by a low or decreasing white blood cell count) is found in an individual taking a drug that may cause or worsen leukopenia |
| **T11** | Elevated alanine aminotransferase (ALT) or aspartate aminotransferase (AST) concentration is found in an individual taking a drug that may cause hepatocellular toxicity |
| **T12** | Elevated creatinine or blood urea nitrogen (BUN) concentration is found in an individual taking a drug that may increase creatinine or BUN |
| **T13** | Supratherapeutic concentration of TSH or decreased concentration of T4 is found in an individual taking a drug that may cause hypothyroidism |
| **T14** | Agranulocytosis or neutropenia (as indicated by a low or decreasing neutrophil count) is found in an individual taking a drug that may cause or worsen agranulocytosis or neutropenia |
| **T15** | Elevated creatine phosphokinase (CPK) concentration is found in an individual taking a drug that may increase CPK |
| | **Medication Concentration Signals** |
| **T16** | Aminoglycoside peak or trough concentration is supratherapeutic in an individual taking an aminoglycoside antibiotic (e.g., amikacin, gentamicin, or tobramycin) |
| **T17** | Phenytoin concentration is supratherapeutic in an individual taking phenytoin |
| **T18** | Lithium concentration is supratherapeutic in an individual taking lithium |
| **T19** | Theophylline trough concentration is supratherapeutic in an individual Taking theophylline |
| **T20** | Digoxin concentration is supratherapeutic in an individual taking digoxin |
| **T21** | Procainamide concentration or N-acetylprocainamide (NAPA) concentration is supratherapeutic in an individual taking procainamide |
| **T22** | Primidone (Mysoline) concentration or phenobarbital concentration is supratherapeutic in an individual taking primidone |
| | **Medication Concentration Signals (continued)** |
| **T23** | Quinidine concentration is supratherapeutic in an individual taking quinidine |

| | |
|---|---|
| **T24** | Valproic acid concentration is supratherapeutic in an individual taking valproic acid |
| **T25** | Phenobarbital concentration is supratherapeutic in an individual taking phenobarbital |
| **T26** | Carbamazepine concentration is supratherapeutic in an individual taking carbamazepine |
| **T27** | Disopyramide (Norpace) concentration is supratherapeutic in an individual taking disopyramide |
| | **Antidote Signals** |
| **T28** | Naloxone (Narcan) is given to an individual taking an opioid analgesic |
| **T29** | Phytonadione (vitamin K) in oral, subcutaneous, or intravenous form is given to an individual taking warfarin |
| **T30** | Dextrose 50%, glucagon, or liquid glucose is given to an individual taking a drug that may cause hypoglycemia |
| **T31** | Protamine sulfate is given to an individual taking heparin |
| **T32** | Digoxin immune Fab (Digibind) is given to an individual with a supratherapeutic digoxin concentration |
| **T33** | Epinephrine is given to an individual taking a drug that may cause an anaphylactic reaction |
| **T34** | Metronidazole (oral) or vancomycin (oral) is given to an individual who has recently taken a drug that may cause pseudomembranous colitis |
| **T35** | Benztropine (Cogentin), diphenhydramine, or trihexyphenidyl (Artane) is given to an individual taking a drug that may cause extrapyramidal symptoms |
| **T36** | Lepirudin (Refludan) is given to an individual taking a drug that may cause heparin-induced thrombocytopenia |
| **T37** | Sodium polystyrene (Kayexalate) is given to an individual taking a drug that may cause hyperkalemia |
| | **Resident Assessment Protocol Signals** |
| **T38** | Falls RAP is triggered in an individual taking a drug that may cause or worsen falls (falls with or without injury) |
| **T39** | Delirium RAP is triggered in an individual taking a drug that may cause or worsen delirium (periodic disordered thinking or awareness) |
| **T40** | Dehydration/Fluid Maintenance RAP is triggered in an individual taking a drug that may cause or worsen dehydration (fluid loss exceeding the amount of fluid intake) |

Adapted from Handler SM, et al. Consensus list of signals to detect potential adverse drug reactions in nursing homes. J Am Geriatr Soc 2008;56(5): 808–15.

| Triggers found: | ADE Found? | | Harm Category* | Description of ADE |
|---|---|---|---|---|
| | Yes | No | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Total ADEs for this resident: | | | | |
| Total number of doses of medication for this resident (if available): | | | | |

*Harm Category (adapted from NCC-MERP Index; Categories A-D do not cause harm):

**Category E:** Temporary harm to the patient and required intervention

**Category F:** Temporary harm to the patient and required initial or prolonged hospitalization

**Category G:** Permanent patient harm

**Category H:** Intervention required to sustain life

**Category I:** Patient death

## Table 2

ADE Monthly Summary Sheet

| **Date** _____ | | | |
|---|---|---|---|
| **Patient** | **ADE found (Yes/No)?** | **Total Number of ADEs for this patient:** | **Total number of doses of medications for this patient (if available):** |
| 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:** | **Total:** |

Percent of Residents with an ADE

The total number patients identified as having experienced any ADE from a sample of patient records (Column 1 Total), divided by the total number of records in the sample; multiplied by 100 to express as a percentage.

ADEs per 1,000 Doses

The total number of ADEs identified in a sample of patient records (Column 2 Total), divided by the total number of medication doses administered to those patients (Column 3 Total). Multiply the result by 1,00