A Call to Action: Raising Awareness for Reducing Medication-Related Adverse Events in Nursing Homes

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CMIO UPMC Community Provider Services

Clinical Vignette

• Mr. Brown is an 86 y.o. resident who has diabetes, chronic kidney disease and dementia. He receives finger-stick blood glucose (FSBG) monitoring 4 times a day. He is on sliding scale insulin (SSI) monotherapy which was started during his last hospital stay which was just 14 days ago.
• The nursing staff frequently give him orange juice because of hypoglycemic episodes. They don’t bother calling the attending physician since managing these episodes is part of the SSI protocol.
• Over the last 2 days, he has decreased eating and drinking. You receive a page during this meeting that his FSBS is 30 mg/dL, is dehydrated, and he has a change in mental status. The staff want to send him to the hospital.
Medication Use in NHs

- We rely heavily on pharmacotherapy to palliate symptoms, improve functional status and quality of life, cure or manage disease and prolong survival.

- Drugs are the most frequently used and misused form of therapy, with NH residents taking an avg. of 8.3 meds/day.
  

- The benefits of drug therapy in older adults must be counterbalanced by the problems that they pose.
  

THE MEDICATION USE PROCESS IN LONG-TERM CARE

1. PRESCRIBING
   - Evaluate resident
   - Determine need for medication
   - Select appropriate medication

2. DOCUMENTING
   - Write order in chart or transcribe verbal order
   - Transmit order to pharmacy
   - Transcribe order to medication administration record (MAR)

3. DISPENSING
   - Receive, review, and confirm order at pharmacy
   - Prepare and dispense medication to facility

4. ADMINISTERING
   - Review MAR
   - Administer the right medication, in the right dose or rate, in the right route, at the right time, to the right patient
   - Record administration in MAR

5. MONITORING
   - Assess patient response to medication
   - Report and document outcomes

Handler SM, Am J Geriatr Pharmacother, 2004
Adverse Drug Events (ADEs)

• Are defined by the Institute of Medicine (IOM) as *injury or harm* resulting from a medical intervention related to a drug

  Kohn, National Academies Press, 2000

• Are the most frequent medication-related adverse events in the NH setting, with an incidence as high as 10.8 events per 100-resident/months
  – Translates into approximately 135 ADEs/NH or 2 million ADEs/year when all U.S. NHs are combined


Systems Analysis of ADEs in NHs

• Only the presence of *polypharmacy* has consistently been found to increase the likelihood of developing an ADE

  Leape LL, et al. JAMA, 1995

• Approximately half of the events are considered preventable (i.e., medication errors)


• Most (80%) of the preventable events are associated with *monitoring* rather than *prescribing* errors

Incidence of Adverse and Temporary Harm Events (stays < 35 days)

• 22% of Medicare SNF residents experienced adverse events during their SNF stays
  – 21,777 post-acute Medicare SNF residents experienced at least one adverse event

• An additional 11% of residents experienced temporary harm events

Incidence of Adverse and Temporary Harm Events (cont.)

**Medication Events**
- Medication-induced delirium or other change in mental status
- Excessive bleeding due to anticoagulant medication
- Fall or other trauma with injury secondary to effects of medication

**Resident Care Events**
- Fall or other trauma with injury related to resident care
- Acute kidney injury (AKI) secondary to fluid maintenance
- Exacerbations of preexisting conditions resulting from an omission of care

**Infection Events**
- Aspiration pneumonia and other respiratory infections
- SSI associated with wound care
- CAUTI

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Incidence of Adverse and Temporary Harm Events (cont.)

**Patient Harm by Category of Harm**

<table>
<thead>
<tr>
<th></th>
<th>Adverse Events</th>
<th>Temporary Harm Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>37%</td>
<td>37%</td>
</tr>
<tr>
<td>Resident Care</td>
<td>26%</td>
<td>40%</td>
</tr>
<tr>
<td>Infections</td>
<td>17%</td>
<td>17%</td>
</tr>
</tbody>
</table>

# Adverse Event Types

## Table 3: Adverse Events Identified Among Medicare SNF Residents by Category

<table>
<thead>
<tr>
<th>Types of Adverse Events</th>
<th>Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events Related to Medication</td>
<td>37%</td>
</tr>
<tr>
<td>- Medication-induced delirium or other change in mental status</td>
<td>12%</td>
</tr>
<tr>
<td>- Excessive bleeding due to medication</td>
<td>5%</td>
</tr>
<tr>
<td>- Fall or other trauma with injury secondary to effects of medication</td>
<td>4%</td>
</tr>
<tr>
<td>- Constipation, obstipation, and ileus related to medication</td>
<td>4%</td>
</tr>
<tr>
<td>- Other medication events</td>
<td>14%</td>
</tr>
</tbody>
</table>

## Table 4: Temporary Harm Events Identified Among SNF Residents by Category

<table>
<thead>
<tr>
<th>Types of Temporary Harm Events</th>
<th>Percentage*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Events Related to Medication</strong></td>
<td>43%</td>
</tr>
<tr>
<td>- Hypoglycemic episodes (e.g., low or significant drop in blood glucose)</td>
<td>16%</td>
</tr>
<tr>
<td>- Fall or other trauma with injury associated with medication</td>
<td>9%</td>
</tr>
<tr>
<td>- Medication-induced delirium or other change in mental status</td>
<td>7%</td>
</tr>
<tr>
<td>- Thrush and other nonsurgical infections related to medication</td>
<td>4%</td>
</tr>
<tr>
<td>- Allergic reactions to medications (e.g., rash, itching)</td>
<td>3%</td>
</tr>
<tr>
<td>- Other medication events</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Events Related to Resident Care</strong></td>
<td>40%</td>
</tr>
<tr>
<td>- Pressure ulcers</td>
<td>19%</td>
</tr>
<tr>
<td>- Fall or other trauma with injury associated with resident care</td>
<td>8%</td>
</tr>
<tr>
<td>- Skin tear, abrasion, or breakdown</td>
<td>7%</td>
</tr>
<tr>
<td>- Other resident care events</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Events Related to Infections</strong></td>
<td>17%</td>
</tr>
<tr>
<td>- CAUTI</td>
<td>5%</td>
</tr>
<tr>
<td>- SSI associated with wound care</td>
<td>5%</td>
</tr>
<tr>
<td>- Other infection events</td>
<td>7%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100%</td>
</tr>
</tbody>
</table>

*The percentages for conditions listed within the clinical categories do not sum to 100 percent because of rounding. See Appendix D for percentage estimates and confidence intervals. See Appendix F for a complete listing of all temporary harm events identified by the reviewers. Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.
### Table 6: Percentage of Preventable Adverse and Temporary Harm Events by Clinical Category

<table>
<thead>
<tr>
<th>Types of Adverse and Temporary Harm Events</th>
<th>Percentage of Preventable Adverse and Temporary Harm Events (n = 155)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events Related to Medication</td>
<td>66%</td>
</tr>
<tr>
<td>Events Related to Resident Care</td>
<td>57%</td>
</tr>
<tr>
<td>Events Related to Infections</td>
<td>52%</td>
</tr>
</tbody>
</table>

Source: OIG analysis of SNF stays for 653 Medicare beneficiaries discharged in August 2011.

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### Preventability Rationale

### Table 7: Adverse and Temporary Harm Events by Preventability Rationales

<table>
<thead>
<tr>
<th>Adverse and Temporary Harm Preventability Rationale</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventable Events</td>
<td></td>
</tr>
<tr>
<td>Appropriate treatment was provided in a substandard way</td>
<td>56%</td>
</tr>
<tr>
<td>The resident's progress was not adequately monitored</td>
<td>37%</td>
</tr>
<tr>
<td>Necessary treatment was not provided</td>
<td>25%</td>
</tr>
<tr>
<td>Error was related to medical judgment, skill, or resident management</td>
<td>14%</td>
</tr>
<tr>
<td>Resident care plan was inadequate</td>
<td>11%</td>
</tr>
<tr>
<td>Care plan was incomplete or not sufficient in describing resident's condition</td>
<td>7%</td>
</tr>
<tr>
<td>The resident's health status was not adequately assessed</td>
<td>4%</td>
</tr>
</tbody>
</table>
Recommendations

1. AHRQ and CMS should raise awareness of adverse events in post-acute care and seek to reduce harm to NH residents through methods used to promote hospital safety:
   a) AHRQ and CMS should collaborate to create and promote a list of potential NH adverse events
   b) CMS should include potential events and information about resident harm in its quality guidance to NHs
   c) AHRQ and CMS should encourage NHs to report adverse events to Patient Safety Organizations

2. CMS should instruct NH surveyors to review facility practices for identifying and reducing adverse events

How can we improve medication safety in the NH?
Methods for Detecting ADEs in the NH

Voluntary Reporting:
- Medication Error/Adverse Drug Event Reports
- Incident Reports

Involuntary Methods:
- Comprehensive chart review
- Trigger-based chart review
- Direct Observation

Automated Methods of Detection

Manual Methods of Detection

Integrated Data Sources

Medication Profile
Laboratory Data
Allergy Profile
Administrative/Billing Data
Clinical Narratives

Encourage ADE/Med Error Reporting

- Reasons for reporting:
  - Makes people aware of potentially correctable problems
  - Facilitates QI efforts to reduce future occurrence
  - Establishes base rates of errors/events

- Common modifiable barriers to reporting include lack of:
  - Readily available reporting systems
  - Information on how to report an error/event
  - Feedback to the reporter/facility on errors/events

Encourage Use of ADE Trigger Tool

• To develop a consensus list of laboratory, pharmacy, and Minimum Data Set signals that can be used to detect potential adverse drug events in NHs

• A panel of 13 advanced practitioners, 10 pharmacists, and 13 physicians completed an internet-based modified Delphi study

• A total of 40 signals were accepted (15 laboratory / medication combinations; 12 medication concentrations; 10 antidotes; and 3 RAPs)

Handler S, Hanlon J. Ann Longterm Care, 2010

http://tinyurl.com/IHIADETriggerTool

Nursing Home Adverse Drug Event Trigger Tool

Submitted by: Division of Geriatric Medicine, and Department of Biomedical Informatics, University of Pittsburgh Pittsburgh, PA USA

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Joseph T. Hanlon, PharmD, MS, BCPS
Stephanie A. Studenki, MD, MPH
Scott B. Stephens, RPh
Michael J. Beckich, MD, PhD
Determined the utility (positive predictive value [PPV] and time requirement) of the ADE trigger tool and described the most common types of events detected with the tool.

Among 321 veterans, 50.5% (n = 162) had at least one abnormal laboratory value contained in the trigger tool.

The overall PPV of the ADE trigger tool was 40.1% (65/162), and the average time to complete resident assessments was 8.8 (standard deviation ± 5.7) minutes.


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### Table 2. Most Common Potential Adverse Drug Events (ADEs) by Type Among Those with a Trigger Alert (N = 162)

<table>
<thead>
<tr>
<th>Potential ADE*</th>
<th>Residents with an ADE (n, %)</th>
<th>Most Common Medication Classes Associated with Potential ADEs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laboratory Abnormality</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>30 (18.5)</td>
<td>ACE inhibitors/ARBs (N = 18)</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>18 (11.1)</td>
<td>Loop diuretics (n = 6)</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>13 (8.0)</td>
<td>Insulin (n = 14)</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>10 (6.2)</td>
<td>ACE inhibitors/ARBs (n = 6)</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>6 (3.7)</td>
<td>Loop diuretics (n = 2)</td>
</tr>
</tbody>
</table>

*Adding up this column may result in a value > 100% since some veterans may have had abnormal laboratory results for more than one laboratory value; those veterans who had > 1 abnormal value of the same laboratory test were only counted once in this table.

**Abbreviations**: ACE = Angiotensin-converting enzyme, ARB = Angiotensin II receptor blocker, INR = International normalized ratio, N/A = Not applicable, SSRI = Selective serotonin-reuptake inhibitor.

Trigger Tool for CMS Innovation Award

- **Acute Kidney Injury** (RIFLE Criteria):
  - Risk: \((1.5 \text{ SCr} \uparrow)\)
  - Injury \((2x \text{ SCr} \uparrow)\)
  - Failure \((3x \text{ SCr} \uparrow \text{ or } \uparrow \text{ of } 0.5 \text{ if SCr } \geq 4)\)
- **Hypoglycemia** \((\text{BS} \leq 70 \text{ mg/dL})\)
- **Drug induced anemia** \((\geq 2 \text{ g/dL decrease})\)
- **Hyperkalemia** \((K \geq 5.5 \text{ mmol/L})\)
- **Hypokalemia** \((K < 3.5 \text{ mmol/L})\)
- **Hyponatremia** \((Na \leq 130 \text{ mEq/L})\)

Funding Support: CMS Innovation Award 1E1CMS331081-01-00

Monitoring Errors in the NH

- Monitoring errors refer to inadequate lab evaluation of drug therapies OR a delayed response or failure to respond to signs or symptoms of drug toxicity or laboratory evidence of toxicity
- Frequently caused by a loosely coupled system, leading to poor communication and errors of omission and commission
Impact of Medication Monitoring on ADEs


Encourage Routine Lab Monitoring

- To determine the minimal frequency of laboratory monitoring of 30 types of chronic medications/classes that are administered to NH residents

- Consensus agreement was reached for 33 of 35 parameters amongst 20 pharmacists, 48 physicians, and 48 nurse practitioners

- They selected three or six months as the minimum interval for 30 of 35 parameters (85.7%), one month as the minimum for two parameters, and 12 months as the minimum for one parameter

Routine Lab Monitoring (Cont)

As part of our CMS Innovation Award, we recommend the following routine labs monitoring:

<table>
<thead>
<tr>
<th>Trigger Medications</th>
<th>Antipsychotic Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete blood count (CBC)</td>
<td>Vital signs, BMI</td>
</tr>
<tr>
<td>Basic metabolic panel (BMP)</td>
<td>Fasting lipid profile</td>
</tr>
<tr>
<td></td>
<td>HgbA1C</td>
</tr>
<tr>
<td></td>
<td>CBC</td>
</tr>
</tbody>
</table>

Handler SM, Shirts BH, Perera S, Becich MJ, Castle NG, Hanlon JT. Consult Pharm 2008

Enhancing the Detection and Management of Adverse Drug Events in the Nursing Home

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Michael Fine, MD, MSc
Subashan Perera, PhD
Sandy Kane-Gill, PharmD, MS
Colleen Culley, PharmD

Stephanie A. Studenski, MD, MPH
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David A. Nace, MD, MPH
Melony Sorbero, PhD, MS, MPH
Rich Boyce, PhD

Support from an AHRQ R01HS018721 and NIA K07AG033174.
(PI= Handler)

ClinicalTrials.gov identifier: NCT01531088
Specific Aims

• The **primary outcome** is to determine if physicians who receive active medication monitoring alerts from medication safety pharmacists:
  
  1. **have more ADEs detected and managed** compared to physicians providing usual care in the NH.
  
  2. **have a faster ADE management response time** compared to physicians providing usual care in the NH.

• The **secondary outcome** is to determine the perceived *importance* and *performance* of the pharmacy service provided in the intervention compared to the control group.

Components of the intervention:

1. Academic detailing prior to and during the study (provide tools, information, and details about a collaborative practice agreement for medication therapy management).*

2. Be available to physicians for consultation during the study to answer any questions, make laboratory monitoring recommendations, suggest alternative medications, etc.*

Knowledgebase of:

- 145 med-lab or therapeutic drug monitoring EZ alerts
- AND acute kidney injury (AKI) alert

Consultant Pharmacist Notification of Potential ADEs

- Email
- Consultant Pharmacist Notification of Potential ADEs
- Access Additional Information from IT or Clinician Resources as Needed

Construct ADE Alert:

- Situation
- Background
- Assessment
- Response

Attending Physician Notification through preferred method of communication

Respond to ADE Alert:

- Situation
- Background
- Assessment
- Response

Pharmacist-Physician Partnership

**Components of the intervention**
ADE Alert to be Reviewed by a Pharmacist

**ADE: Drug-Associated Acute Kidney Injury**

**Admit Diagnosis:** CARE INVOLVING OTHER SPECIFIED REHABILITATION PROCEDURE, OTHER

**Demographics & renal function**
- Age: 78 years
- SCr: 4.18 mg/dL
- CrCl: 9 ml/min/Cockcroft-Gault; weight used=75 kg
- Sex: F
- Height: 61 in (155 cm)
- Weight: 145.2 lbs (66 kg)

**Possible drug associated ACUTE KIDNEY FAILURE.**

This patient's CREATININE has increased greater than or equal to 3 fold relative to the nadir value (1.2 mg/dL) found in the past 365 days and has at least 1 active order(s) for a drug associated with acute kidney injury.

**Most Recent Serum Creatinine:** CREATININE = 4.18 mg/dL (COMPREHENSIVE METABOLIC PANEL W/ Ca, Urea, Creatinine, 05/04/2013)

**Nadir Serum Creatinine:** Creatinine = 1.2 mg/dL (Basic Metabolic Profile Collected: 07/10/2012 06:18:00)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Start</th>
<th>End</th>
<th>Status</th>
<th>Pat Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furosemide TAB 40MG</td>
<td>40 MG PO QD</td>
<td>08/31/2012</td>
<td>ACTIVE</td>
<td>I</td>
<td></td>
</tr>
</tbody>
</table>

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(AiDE-MD: ADE Alert)
Detailed info sent to your UPMC email. Please respond to the email or call Monica Aspinall at **412-328-4490** before 4:00 PM today.

Monica B. Aspinall, PharmD
412-328-4490
aspinallmb@upmc.edu

Annemary A. Kizic, PhD, FASCP, CGP
412-328-5650
kizicaa@upmc.edu

University of Pittsburgh
Department of Biomedical Informatics and Division of Geriatric Medicine
Mr. Brown Redux

- Hypoglycemic episodes could have been reported and led to physician notification to manage events
- ADE Trigger tool could have been used to detect the hypoglycemic events or AKI and led to physician notification to manage events
- Active medication monitoring system could have led to real-time detection of the hypoglycemic events or AKI and could be coupled to physician notification and recommendations
- Routine lab draws could have detected hypoglycemic events or AKI and led to physician notification to manage events
- Telemedicine could have been used to do a real-time MRR and suggested alternate therapies to SSI monotherapy to the physician
Future Direction

• Analyze results of AHRQ-funded RCT
  – Primary outcome assessment
  – Physician perception of importance and performance of pharmacist collaboration
• Collaborate with IHI and release the NH global trigger tool (GTT)
• Participate in the CMS Raising Awareness for Reducing Adverse Events in NHs campaign
• Promote adherence to the Choosing Wisely® Campaign to not use SSI as monotherapy
• Expand the use of telemedicine in NHs to improve the medication regimen review process

Thank you!
QUESTIONS?

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