Adverse Drug Events: A Collaborative Approach for Improvement

Mary Kathryn Cone, PGY-2
**Background**

Adverse drug events are far more common than any hospital employee or patient would like to think. Thankfully, most do not cause immediate, serious harm, but this potential certainly exists. In fact, one study in a French teaching hospital in which pharmacy staff observed nurses preparing and administering drugs over a three-day period showed an error rate of 7.5%, much higher if timing errors were included. These data have been similarly documented in many other settings as noted in numerous review articles concerning medication safety.

In 2009, the Ohio Children’s Hospital Solutions for Patient Safety was founded in an effort to reduce unnecessary harms for children receiving inpatient care. The organization’s initial main focus was to reduce adverse drug events and surgical site infections. In recent years, the organization was given a grant by CMS to establish a formal safety improvement system with the goal of reducing all harms by 40% and readmissions by 20%, a challenge it has taken on by expanding its organization of participating hospitals.

Participating hospitals openly share their data on adverse drug events, surgical site infections, and other harms such as central-line associated bloodstream infections (CLABSI), catheter-associated UTIs (CAUTI), and falls, in an effort to pool resources and experiences from across the member hospitals to reduce harms in all of them. Palmetto Health became a part of this partnership in 2012 and has active committees meeting regularly to evaluate adverse drug events, CLABSI, surgical site infections, CAUTIs, and falls, among others.

The Adverse Drug Events (ADE) committee at Palmetto Health Children’s Hospital (PHCH) began meeting in 2012. At that time, there was no clear systematic approach to reporting and evaluating ADEs, so first steps included establishing and advertising a reporting system to better assess PHCH’s current rate of ADEs and other adverse events. Information on using “a line to report,” a telephone line leading to a voicemail where adverse events could be recorded, was widely disseminated, and the ADE committee began to meet monthly to evaluate these events.

The first goal for improvement was to determine how often a child is harmed by a medication - whether improper dose, timing, or administration, as the extent of the local problem was truly unknown due to lack of a well-established, consistently-used reporting system. The first step toward this goal was to establish an easy, reliable method for recording and evaluating ADEs and other harms without employees feeling as if they were endangering their own job or a co-worker’s job for reporting these events.

The goals for change at PHCH have been driven by and evolved with the goals of the Ohio Children’s Hospital SPS organization, of which PHCH is a member. From the initial assessment of ADEs, the committee led by Dr. Elizabeth Mack along with other committees in the SPS collaborative has identified numerous specific areas of difficulty and strategies for tracking them. Each has now become an area of focus for improvement as detailed in the “methods” section below.

The primary aim at the outset of PHCH’s participation in this collaborative was to understand the extent of the problems in our own hospital and establish reliable data collection, then determining, as part of the SPS collaborative, specific goals for harm reduction. Specific goals for 2014 include reducing ADEs grade E and higher as determined by the SPS reporting guidelines (see Appendix 1) to less than 15 events for the entire year and to have 85% compliance with the “bundle” of policies already in place to ensure medication safety.
Methods

Ethical Considerations

A systematic approach to evaluating adverse drug events has been implemented stepwise since
the PHCH’s joining the SPS collaborative, and throughout the development of this process, numerous
ethical issues have been raised. First, the problem of employees being fearful of reporting adverse events
had to be addressed. Efforts were made through widespread advertising of “a line to report” and regularly
emailed “Qualit-E News” newsletters to change this environment of inward-focused anxiety over reporting
to one of outward focus: every report makes the hospital a safer place for children and improves the work
we do. The pediatric residency program also began to hold monthly quality meetings in which adverse
events were reviewed and discussed. These efforts emphasized the team aspect of quality improvement.

Patient confidentiality was also an ethical concern as adverse events are reported on a voicemail
system and a committee of people not directly involved in the patient’s care meets to discuss these
events. To minimize confidentiality breaches, an established group of employees in the Risk Management
department transcribed the voicemails, and at committee and residency program meetings, reported
events were discussed without using the patients’ names.

Tracking Outcome Measures

ADEs were chosen as a focus for intervention because they are part of the OCH SPS collaborative
project. The first step in decreasing ADEs was to determine how many occurred and what were the
medications, settings, and patient diagnoses with the highest rates of ADEs. The reporting tool described
above helped accomplish this: any PHCH employee can call 4-ALTR, the in-house reporting voicemail,
and leave detailed information about the patient and the adverse event. Employees were also
encouraged, by educational events, flyers, posters, emails, and communication from their supervisors, to
call in any error, adverse event, or near miss, as a near miss also indicates that a problem occurred that
may have been preventable. In addition to the reporting line, charts were pulled via EHR software if any of
the following had been administered: naloxone, >10% dextrose, glucagon, or sodium polystyrene
sulfonate. These medications are antidotes; these charts were searched to identify possible overdosing
events that caused harm and determine any policy or procedure changes that might minimize risk of
another similar event. An ADE committee comprised of physicians, nursing supervisors, staff nurses,
pharmacy staff, and other medical providers met monthly to review the reported events and grade them
using the tool shown in appendix 1 below, used by all SPS collaborative participants. SPS requires
reporting of all events of grade E and higher; these are errors that caused harm to the patient. The goal for
2014 is less than 15 ADEs grade E and higher.

Tracking Process Measures

Process measures include: hospital-wide compliance with weight-based dosing protocol (“WBD,”
see appendix), percent compliance with the requirement for two RNs to sign off on “high-alert”
medications (HAMs) when they are administered, frequency of use of “guardrails” on IV pumps, and
frequency of scanning patient and medication barcodes when administering medication. For evaluation of
HAMs, charts with insulin drips, TPN, morphine PCAs, or fentanyl and versed drips were pulled. For
evaluation of weight-based dosing guidelines, charts recording administration of ceftriaxone were pulled
as this is a medication used in a wide variety of clinical scenarios in order to include a variety of patient
diagnoses and types of provider (i.e. ENT, general peds, peds surgery, peds ortho) in the audit. The HAM
charts were searched by one individual to determine the total number of HAMs administered and what
percent of the time they were double-checked. Events to be double-checked include dose administration for scheduled or PRN meds and hanging of a new bag, verifying the bag hanging at shift changes, and rate changes for drips. The WBD charts were searched to determine the total number of medications prescribed and the number of times the weight-based dosing calculator in the EHR was used to calculate the dose. The policies for HAM and drips and for WBD calculations are included in the appendix. The pharmacy computer system reported the number and percentage of meds administered with a barcode scan and the percent of the time the “guardrails” on IV pumps, meant to ensure a safe rate of fluid administration, were followed or overridden. The total number of events in all these categories was tracked along with the total number of compliant events - a med barcoded, insulin double-checked - and is reported as a percentage. This is referred to as the “bundle compliance” percentage. The goal is 85%, totaled across all categories.

**Ongoing process changes/PDSA structure**

To move beyond simply reporting ADEs and work toward reducing them, monthly review included assessing which types of ADE were most common: was a specific drug often administered incorrectly, was dosing unclear, was labeling confusing, was the process of giving a particular medication too cumbersome, leading to shortcuts? Results from this review would then lead to interventions accordingly - labeling changes, requirement to double-check a medication, or a pharmacy, nursing, or house-staff educational meeting, for example. In this way, the PDSA structure is used to determine necessary changes and implement them. However, as discussed below, the complex structure of this process makes isolating each distinct PDSA cycle very difficult.

Internal evaluation of the intervention has occurred monthly with review of adverse events. Rates of ADEs are compared to previous months and the number of occurrence reports to 4-ALTR is reviewed by hospital unit. Specific numbers tracked include number of ADEs, number of ADEs grade E and above. For external review, the data are also submitted to the SPS collaborative where they are discussed with other participants via email communication and webinars. The collaborative’s goal is “all learn, all teach,” and members commit to complete transparency with their data on adverse events. This group of 79 children’s hospitals shares data on events, common problem areas, and solutions they are using to improve quality across all hospitals.

The SPS collaborative uses a rubric that participating hospitals use to self-report their progress toward harm reduction across all committees, of which ADE is only one. This is attached in the appendix as well and covers all committees working with the collaborative. The main focus of this discussion is limited to adverse drug events.

**Results**

The first meeting of the ADE committee was in 2012. By the end of the committee year for 2012, outcomes data were reported and by late 2013, PHCH also began to report process data. Both are tracked on a monthly basis. Process and outcomes measures to date are shown in the table 1 below. A flow sheet depicting the process of generating these data and subsequent steps after data analysis is shown in figure 1 below. In addition to these steps, all data are reported monthly to the SPS collaborative and discussed in monthly webinars with other participating hospitals. Policy or guideline changes suggested for one hospital’s high-frequency adverse events are shared with all participating hospitals.
The flow sheet in Figure 1 indicates “specific interventions” targeted to specific, identifiable problems found in chart audits. The ADE committee has implemented several interventions so far in 2014. For example, a nursing educational meeting on Octreotide was held after a over-dosing near miss. Guidelines for high-alert medications are being revised to decrease the number of double-checks required in an effort to boost compliance for medications with highest rates of adverse events such as, for our hospital, insulin. Changes to IV pump guardrails are being planned to make them more closely match bedside nursing needs and thus reduce the number of necessary “overrides,” making an override a more reliable red flag that the medication to be administered may be improperly dosed. Nursing leadership is encouraging reporting on a “grass-roots” level, unit by unit, to improve nursing reports of guardrail overrides. Data audits lag by two months, so these ongoing improvement efforts and recent interventions have not yet been evaluated by audit. Although much work has been done to establish this monitoring and improvement system, it is still in early stages.

Table 1

<table>
<thead>
<tr>
<th>Year</th>
<th>Outcomes measures (number of ADEs)</th>
<th>Process measures (bundle compliance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>0 events F+ 2 events E+</td>
<td>n/a</td>
</tr>
<tr>
<td>2013</td>
<td>4 events F+ 13 events E+</td>
<td>62/104 (59.6%)</td>
</tr>
<tr>
<td>2014 - YTD</td>
<td>YTD totals: 1 event F+ 5 events E+</td>
<td>Most recent month’s data (Feb 2014): 20217/24461 (82.6%) total</td>
</tr>
</tbody>
</table>
|       | TT: not available | BCMA: by unit:  
CBD 2244/2482 (90%)  
CHA 5573/6444 (86%)  
IT 4126/4600 (89.7%)  
PICU 3858/4984 (77%)  
HAM: 159/456 (35%)  
WBD: 98/160 (61%)  
GR:  
3-20kg 2803/3441 (81%)  
21-70kg 1356/1894 (71%) |

BCMA = barcode medication administration  
HAM = high-alert meds  
TT = trigger tools  
GR = guardrails  
WBD = weight-based dosing  
CHA = child and adolescent unit  
CBD = cancer and blood disorders unit  
IT = infant and toddler unit  
PICU = pediatric intensive care unit
Discussion

Tracking, grading, reporting, and addressing adverse drug events is an ongoing, constantly evolving process. Lasting steps already taken in this effort at PHCH include establishment of a systematic approach to monitoring adverse events, publicizing the effort, and recruiting employees from many different backgrounds working in many different areas of the hospital. However, there are many challenges to continuing this effort. Strengths of this system of reporting, auditing, and collaborating with a large group of other hospitals include generalizability and long-term commitment to continue the process. Our outcomes at PHCH are combined with those of 78 other hospitals and discussed - we all benefit from one another’s experience, establishing process changes that have been tried elsewhere. This collaboration means that more process changes can be made at PHCH, and made faster, than if PHCH working entirely on its own.

However, this system also comes with challenges. Given that several different interventions are occurring simultaneously, causal relationships between interventions and outcomes can be difficult to
establish. Maintaining commitments from a large number of people to continue working on this project is also a challenge. As we continue to encourage reporting of events, more events are reported - does this mean that there are more errors, or simply that employees are more aware of these errors and the reporting process? PHCH is also a fairly small hospital, and the number of adverse events each year is, thankfully, fairly small, so a change of even one event per year will make a large statistical difference. The real benefits of this complex and continually changing effort cannot be seen easily on a month-to-month basis, but the steady establishment of a culture of reporting and monitoring events to improve patient safety is the long-term gain.
Appendix 1

NCC MERP Index for Categorizing Medication Errors

Definitions
- Harm: Injury to the patient that may have contributed to or resulted in permanent patient harm.
- Prevention: Injury to the patient that may have contributed to or resulted in permanent patient harm.
- Near-Miss: An error occurred that reached the patient and required no further intervention.
- Incident: An error occurred that reached the patient and required no further intervention.
- Error, Harm: An error occurred that reached the patient and resulted in permanent patient harm.
- Error, No Harm: An error occurred that reached the patient and resulted in temporary patient harm.
- Error, No Error: An error occurred that may have contributed to or may be revealed in permanent patient harm.
- Error, Death: An error occurred that may have contributed to or may be revealed in permanent patient harm.


* Permission is hereby granted to reproduce this form provided the reproduction shall not exceed the text and shall include the copyright notice appearing on the page from which it was copied.
Appendix 2

PALMETTO HEALTH

CH- Verification of Medications and IV Drips

Facility: PHR
Department: Nursing

Effective: Date
Reviewed: 08/2013
Revised: Date

Name of Associated Policy: Medication Administration; IV Therapy

RESPONSIBLE POSITIONS (TITLE):

MD order is required
Administered by RN: must be checked and signed on the eMAR by two RNs

EQUIPMENT NEEDED:

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. Any change in drug dose, route or frequency must be reviewed and verified in the electronic medical record.

2. High alert medications, vasoactive infusions, TPN, Lipids, IV fluids, chemotherapy medications, PCAs, Epidurals, and narcotic drips will be verified and signed on the eMAR by two RNs with every dose change, rate adjustment, or when the syringe or bag is changed.

3. Pharmacy will be responsible for preparing all continuous infusions except in an emergency situation. During an emergency, the RN may prepare vasopressor infusions as ordered and may use them for the duration of his/her shift. Drips must be verified and signed on eMAR by 2 RNS. When possible, the RN will request drips 1-2 hours prior to anticipated need.

4. At shift change, or any time the patient assignment changes, all vasopressor drips, narcotic infusions (to include PCAs and epidurals), neuromuscular blocking agent infusions, insulin infusions and heparin infusions will be checked by the on-coming and off-going RN. Drug, dose, route, and frequency must be verified against the most current physician order. Both RNS will sign the eMAR.

Comment [w1]: Erika says we should keep Dig on the list. I don’t disagree, but how do we delineate what is and isn’t on this list. And, are there any more (other than dig) that we need to add?

Comment [e2]: Help me with this wording… Does this make sense?

Comment [e3]: Can we leave this in there??
Policy Statement

Palmetto Health Richland will develop, implement and maintain policies and procedures to support prescribing and ordering of drugs for pediatric patients which ensure the safe, clear and legal use of drugs in this patient population.

REQUIREMENTS:

1. A pediatric patient is defined as any patient less than 19 years of age, regardless of location or nursing unit within Palmetto Health Richland, with the exception of patients under the care of an Obstetrician's or Adult Trauma Surgeon's service or in the Operating Room or Recovery Room.

2. Medication orders for pediatric patients must include the current weight of the patient and height and body surface area (BSA), if applicable. Patient weight should be documented in grams (g) or kilograms (kg). If a weight other than the patient’s actual weight is being used to dose medications (ie. Drip weight, dry weight, or estimated/historical weight), this should be noted on the order.

3. Pediatric patients greater than 12 years of age and weighing >50 kg may be dosed according to adult dosages, and a confirmatory dosage expressed in amount/kg/day or dose is not required. Orders for medications that are dosed in amount/kg/day or dose for adult patients (ie. enoxaparin, aminoglycosides) should include the patient’s weight, regardless of patient’s age.

4. The following must be included for the pediatric medication order to be complete:
   a. Patient's allergies or NKDA (only required on admission or transfer order)
   b. Patient’s current weight in kg
   c. Total dose of medication in mg, mcg, mEq, or units as it is applicable
   d. The weight-based dosing (confirmatory dosage parameter in amount/kg/dose or day, with the word “day” or “dose” clearly written out) utilized to calculate the medication regimen (with the following exceptions). The pharmacist may round to the nearest appropriate dosage within 15% of the ordered amount.

   **Items not subject to confirmatory dosage requirements**

<table>
<thead>
<tr>
<th>Ophthalmic, otic, or nasal products</th>
<th>Antacid preparations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lotions, creams, ointments, or shampoos</td>
<td>Multivitamin preparations</td>
</tr>
<tr>
<td>Mouthwashes or Nystatin suspension</td>
<td>Inhalers</td>
</tr>
<tr>
<td>Medications dosed by age-based dosing (ie. Loratidine, Cetirizine, Montelukast, etc.)</td>
<td></td>
</tr>
</tbody>
</table>
5. For continuous infusions, the dose should be written in mcg/kg/min, mcg/kg/hour (or mcg/hour), or mg/kg/hour (or mg/hour). Continuous infusion orders written only in cc/hour will not be accepted. Bolus doses from continuous infusions should also be written in mg/kg (or mg) or mcg/kg (or mcg). Bolus doses written only in cc/kg will not be accepted. This excludes maintenance or bolus IV fluids.

6. Pediatric medication orders that do not specify the patient’s weight in grams (g) or kilograms (kg) will be considered incomplete and will not be processed. The pharmacist must contact the nurse or prescriber to clarify the medication order.

7. An order clarification with the patient’s current weight and the dosing parameters will then be documented in the patient’s medical record either by the prescriber, the house staff on-call, the nurse, or the pharmacist.
Appendix 3

OPERATIONAL DEFINITION

MEASUREMENT: OCHSPS Hospital Score by HAC

I. Description and Rationale

This measure answers the question: What improvement stage is the hospital in for a particular HAC? And, what is the overall status of improvement for all 10 HACs (Hospital summary)

OCHSPS utilized the IHI scoring system in addition to specific objective criteria related to the National Network deliverables.

II. Population Definition

The population is all 10 HACs for each of the network hospitals.

III. Data Source(s)

Each hospital will self-report utilizing the attached scoring system. (Appendix A)

IV. Sampling and Data Collection Plan

Hospitals will report data for the month which their data is reported.

V. Calculation

Hospital Summary

Numerator = Sum of OCHSPS score for each HAC

Denominator = Total number of HACs

VI. Data Quality Audit Procedures

Hospitals should develop their own procedures for auditing data quality until quality auditing procedures are suggested by the network.

VII. Notes

N/A

VIII. Experts/Resources

N/A

IX. Attachments

IHI Adapted Scoring – Appendix A
# APPENDIX A

<table>
<thead>
<tr>
<th>Assessment Score</th>
<th>Description</th>
<th>OCHSNS Network Definition (adapted from IHI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Start</td>
<td>- No Change</td>
</tr>
<tr>
<td>0.5</td>
<td>Building Alignment</td>
<td>- Hospital has signed up to participate in HAC improvements.</td>
</tr>
<tr>
<td>1</td>
<td>Forming Team</td>
<td>- Team or individual assigned&lt;br&gt;- Define charter&lt;br&gt;- Population Defined&lt;br&gt;- Lit Review, Evidence, Visit Sharepoint&lt;br&gt;- Operational definition adopted</td>
</tr>
<tr>
<td>1.5</td>
<td>Planning for the project has begun</td>
<td>- Team Formed&lt;br&gt;- Initial AIM Statement &amp; Key Driver Diagram defined&lt;br&gt;- Data Collection begun &amp; validated&lt;br&gt;- Project Work Plan</td>
</tr>
<tr>
<td>2</td>
<td>Activity, but no changes</td>
<td>- Work Plan Adopted&lt;br&gt;- Goals Adopted (Annual and Quarterly)&lt;br&gt;- Key Driver Diagram Adopted (including bundle validated)&lt;br&gt;- Baseline established&lt;br&gt;- PDSSAs planned</td>
</tr>
<tr>
<td>2.5</td>
<td>Changes tested, but no improvement</td>
<td>- Active PDSSA Cycles started (improve bundle reliability)&lt;br&gt;- No improvement to process/outcome measures</td>
</tr>
<tr>
<td>3</td>
<td>Modest Improvement</td>
<td>- Centerline shifts for bundle/process at ≥ 90% reliability</td>
</tr>
<tr>
<td>3.5</td>
<td>Improvement</td>
<td>- Bundle/process sustained at ≥ 90% reliability&lt;br&gt;- Centerline for outcome measure at least 50% of goal</td>
</tr>
<tr>
<td>4</td>
<td>Significant Improvement</td>
<td>- Bundle/process sustained at ≥ 90% reliability&lt;br&gt;- Centerline shifts for outcome measures at goal</td>
</tr>
<tr>
<td>4.5</td>
<td>Sustainable Improvement</td>
<td>- Bundle/process sustained at ≥ 90% reliability&lt;br&gt;- Outcome measures centerline sustains at goal without special cause</td>
</tr>
<tr>
<td>5</td>
<td>Outstanding sustainable results</td>
<td>- Outcome measures equals best in class and sustained</td>
</tr>
</tbody>
</table>
References


