

## Clinical Excellence Series

# Eliminating Adverse Drug Events at Ascension Health

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This article is the ninth of a series, which charts the journey of one health care system, Ascension Health, toward the clinical transformation of inpatient care and no preventable injuries or deaths.

In 2002, Ascension Health, the largest Catholic and nonprofit health care system in the United States, articulated a call to action with a commitment to provide 100% access to safe, effective care. As part of its Healthcare That Is Safe strategy, an interdisciplinary rapid design team identified eight priorities for action in September 2003, one of which was adverse drug events (ADEs).<sup>1</sup> Following systemwide adoption of the July 2008 Clinical Excellence goal in December 2003,<sup>1</sup> each Ascension Health hospital began new initiatives, tailored to their patient population and existing ADE data, in an effort to markedly reduce and eventually eliminate harm from ADEs, as measured by the Institute for Healthcare Improvement (IHI) ADE Trigger Tool.<sup>2</sup>

The ADE priority for action did not use “alpha sites,” in which standardized best practices, such as for pressure ulcers<sup>3</sup> or falls,<sup>4</sup> are identified at one or more hospitals and then spread to the remaining hospitals. Instead, Ascension Health sought to concentrate and expand the existing ADE reduction goals at each hospital in an effort to discover pockets of success in harm reduction *that could later be deployed to the other hospitals*. The reason was the variation among the 65 hospitals in terms of their pharmacy process sophistication, automation, and monitoring capabilities. In addition, all hospitals had ongoing projects aimed at reducing harm from ADEs already in place from which we did not want to detract attention. This article describes two hospitals’ efforts to reduce harm from ADEs.

## Article-at-a-Glance

**Background:** In 2003, as part of its Healthcare That Is Safe strategy, Ascension Health sought to concentrate and expand the existing adverse drug event (ADE) reduction goals at each hospital to discover pockets of success in harm reduction that could be deployed to the other hospitals.

**Implementation:** Our Lady of Lourdes Memorial Hospital (Binghamton, New York) and Saint Thomas Hospital (Nashville, Tennessee) used the ADE Trigger Tool to make significant changes to prevent, detect, and mitigate harm from ADEs in the medication use process.

**Results:** At Our Lady of Lourdes, ADEs per 100 patient days have not statistically changed from the baseline mean of 1.39 (November 2003–October 2004) to a mean of 1.11 (October 2006–June 2007). At Saint Thomas, ADEs per 100 patient days decreased from a baseline mean of 3.04 (November 2003–October 2004) to a mean of 1.21 (October 2006–June 2007), representing a 60% reduction. ADE Trigger Tool results have not shown a consistent reduction in ADEs across Ascension Health.

**Discussion:** The decreased harm rate from ADEs reflected not the types of standardization and process changes typically thought of as being effective means of reducing ADEs but rather the hospital becoming more proactive at addressing potential ADEs, leveraging education through the use of new technology and developing a new mindset on how these events are viewed in the hospital.

The Institute of Medicine (IOM) 2006 Report *Preventing Medication Errors* conservatively estimated that, on average, a hospital patient was at risk of at least one medication error per day<sup>5</sup> and also described wide variation in reported error rates, primarily because of issues related to culture (often discouraging accurate reporting) and the varied means of obtaining ADE data. Patient harm occurs across the spectrum of ADEs, adverse drug reactions (ADRs), and some medication errors. Although the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)<sup>6</sup> provides a helpful method to differentiate the degree of harm across any number of event types, Ascension Health considered *any* harm associated with medication use to be an opportunity for improvement. As such, the conventional boundaries of improvement had to be stretched to include all ADEs, regardless of whether they are associated with error. This perspective expanded the scope of improvement to include not only traditional efforts to prevent medication errors but also efforts to develop new strategies to detect the risk of ADEs earlier and to mitigate harm as soon as it could be detected.

## Implementation

### USING THE ADE TRIGGER TOOL

When this priority for action was established, most Ascension Health hospitals had voluntary event reporting systems in place, in addition to other methods of detecting potential ADEs (such as automated target-drug monitoring.) Voluntary event reporting systems are widely recognized as unreliable because of a number of cultural, work flow, and similar processes that impede their effectiveness. In fact, one study by Cullen et al., found that only 6% of ADEs were ever reported.<sup>7</sup> In addition, automated target-drug reporting systems (1) often cannot detect events that do not require a reversal agent or have a measurable blood level denoting toxicity and (2) require a more sophisticated pharmacy system than some of our hospitals at the time had in place.

To determine progress toward the goal to eliminate preventable injuries and deaths from ADEs, Ascension Health chose the IHI ADE Trigger Tool measurement system, which does not require a common information system or database among hospitals. Although the ADE Trigger Tool was designed to identify opportunities for

improvement and chart outcomes over time within a single facility, it cannot replace operational and clinical measures like those noted in Table 1 (page 529), which may be crucial to sustaining system improvement. In addition, it was designed to produce reliable results within, but not between, hospitals and should not be used to compare results across institutions.<sup>2</sup>

ADE Trigger Tool-based audits, starting in July 2003 at Our Lady of Lourdes Memorial Hospital (Our Lady of Lourdes), a 267-bed acute care hospital in Binghamton, New York, and in October 2003 at Saint Thomas Hospital (Saint Thomas), a 541-bed tertiary care hospital in Nashville, Tennessee, identified processes, medications, or situations that are likely related to harm. Although the tool draws attention to high-risk medications, interventions designed to prevent high-risk medication-related ADEs also commonly result in more “global” improvements to the systems of patient assessment, prescribing, dispensing, administration, and monitoring in a way that may be applied across many other drug categories. For example, after harm related to the extravasation of a dopamine infusion was detected, review of the ADE scenario resulted in systematic deployment of a broad new policy to address the prevention, early detection, and mitigation of extravasation, which applies to all parenteral drug formulations. The two hospitals also used their ADE Trigger Tool findings to enhance and inform existing quality improvement (QI) projects or to investigate new opportunities for quality improvement. For example, existing work to tightly control hyperglycemia in postoperative patients was broadened to include new measures to prevent the risk of hypoglycemia associated with discontinuation of insulin infusions on the patient's transfer to the floor, a finding detected by the ADE Trigger Tool.

### EDUCATION PROCESS

Ascension Health's medication safety advisory council used a series of IHI-developed tool kits with an accelerated improvement methodology for hospitals to employ in ADE reduction activities. Several computer-based training modules offering strategies for reducing harm associated with the use of anticoagulants, insulin, and narcotic/sedative agents were developed and released via the Web-based Ascension Health Learning Center. A module also

Table 1. Examples of Key Measures for the Medication Safety System Evaluation\*

| Operations (Process) Measure Examples |   |   |                       |                     |                    |
|---------------------------------------|---|---|-----------------------|---------------------|--------------------|
| Intervention                          | Rationale   | Key Measure   | Baseline Performance  | Current Performance | Change             |
| Override rate                         | Overrides, accessing medications prior to independent (usually pharmacist) verification, increase the risk of medication related harm.  | Percent of medications removed via the override function                                | 9.8%                  | 0.9%                | Rate improved 91%  |
| Do-Not-Use abbreviations rate         | The use of these abbreviations increases the risk of order misinterpretation.   | Percent of orders without these abbreviations   | 45.5%                 | 99.8%               | Rate improved 120% |
| Transcription errors                  | Transcription errors accounted for 29% of all ADEs and near misses prior to the implementation of eMAR.   | Percent of errors due to transcription  | 29%                   | 0%                  | Step eliminated    |
| Medication reconciliation             | Medication reconciliation is a proven method of reducing adverse drug events.   | Percent unreconciled medications on admission   | 12.5%                 | 1.5%                | Rate improved 89%  |
| Clinical Metric Examples              |   |   |                       |                     |                    |
| Intervention                          | Rationale   | Key Measure   | Baseline Performance  | Current Performance | Change             |
| Insulin-related ADE                   | Perioperative hyperglycemia is an independent risk factor contributing to morbidity and mortality. However, decreasing hyperglycemia should occur without contributing to hypoglycemia. | Percent WBG in target range (70–150 mg/dL), with no increase in hypoglycemia occurrence | 72%                   | 82%                 | Rate improved 14%  |
| Anticoagulation-related ADE           | ADEs caused by anticoagulant therapy have significant risk of causing patient harm when they do occur.  | Percent of anticoagulant ADEs per 100 patient days                                      | 2.9%                  | 0.5%                | Rate improved 83%  |
| Warfarin clinics                      | Outpatient monitoring of INR to decrease ED visits and admissions related to warfarin ADE   | Percent of patients seen with INR within the established target range                   | No baseline available | 69%                 | n/a                |

\* ADE, adverse drug event; eMAR, electronic medication administration record; WBG, whole blood glucose; INR, international normalized ratio; n/a, not applicable (no baseline); ED, emergency department.

provided additional training on consistent and reliable use of the ADE Trigger Tool.

**GOALS**

Beginning in July 2005 all Ascension Health hospitals were expected to achieve the following two goals:

1. Track hospitalwide improvements as observed by the ADE Trigger Tool
2. Implement changes to reduce by at least 30% ADEs

related to at least one of four high-risk medication categories: insulin, anticoagulants, narcotics/sedatives, and medication reconciliation

Improvements were to be tested in a pilot unit and spread throughout the hospital. Recognizing change is incremental; Ascension Health defined initial success as a minimum of 60% of acute care hospitals achieving a 30% reduction in harm specific to the medication category of focus on the pilot unit. This first goal was an attempt to

develop a “gold standard” within Ascension for measuring the “true” rate of ADEs, as described by Rozich, Haraden, and Resar,<sup>2</sup> and to reduce factors that contribute to underreporting of ADEs. After the ADE Trigger Tool data were collected at each facility, teams aggregated and reviewed their findings to identify opportunities for improvement. The pursuit of these goals at Our Lady of Lourdes and Saint Thomas is described in the following sections.

### ACHIEVING GOAL 1: OUR LADY OF LOURDES

For many years, Our Lady of Lourdes tracked medication errors and ADEs using conventional methods of voluntary reporting and targeted monitoring for medications such as the anti-emetic ondansetron. Although these methods enabled the identification of specific events, they did not produce generalizable opportunities for improvement across different categories of medication or different parts of the medication use process. For instance, audits would identify the use of ondansetron; however, there may be no discernable patient harm to be found, especially in high-risk populations, where much anti-emetic use can be prophylactic. Conducting such audits produced little actionable data and did little to improve patient care. However, with the implementation of the ADE Trigger Tool, the use of an anti-emetic may be discovered in conjunction with another trigger such as abrupt cessation of a medication like morphine, and a pattern of at-risk narcotic usage was revealed in certain patient populations. These findings were forwarded to a pain committee, and methods were developed to address high-risk patient populations earlier and possibly avoid the ADE.

Our Lady of Lourdes’ use of the ADE Trigger Tool (Figure 1, page 531) in July 2003—two years before Ascension Health set its ADE goals—reflected its participation in an IMPACT series with IHI for ADE reduction that used the trigger tool.<sup>8</sup> Initially, the ADE baseline rate revealed no opportunities for improvement; no ADEs were detected in the sample charts reviewed. Recognizing the unlikelihood of such a result, the team examined the way that the ADE Trigger Tool was initially used. It identified a need for greater education in the tool’s proper use, including retraining to reduce the likelihood of personal bias (detected when different reviewers, looking at the same sample chart, found different events). The team met

over time and discussed discrepancies until consensus was developed. Initial discussion at these meetings centered on whether or not an error had precipitated the event; if it had not, the event was excluded. Yet this is not the intended use of the ADE Trigger Tool, which detects harm irrespective of the existence of an error. Over time, the number of reviewers was decreased and competency in use of the tool improved with additional training. The ideal review team should be limited to three or four consistent participants, when possible, and include multiple disciplines (pharmacist, nurse, and physician). By October 2003, once the new team was assigned and new training for a computerized version of the ADE Trigger Tool was completed, data began to reveal many new opportunities for improvement, beginning with anticoagulation therapy.

Training was also redesigned to decrease frequent sources of bias by providing examples of its occurrence and discussing the rationale for including and excluding event types in a more consistent manner.

In January 2004, an ADE team was established that consisted of a senior leader, frontline nurses, pharmacists, and a physician champion to tackle the difficult day-to-day work of implementing changes to practice. To address anticoagulation, the team began to use a specialized or “drill down” version of the ADE Trigger Tool geared specifically to assess anticoagulation; the following triggers (Ts) are deployed:

- T1 Vitamin K (Aqua-mephyton)
- T10 Partial prothrombin time (PPT) > 100 seconds
- T11 International normalized ratio (INR) > 6 or < 1.5
- T18 Abrupt cessation of a medication
- T20 Cerebrovascular accident (CVA)
- T21 Hematocrit (HCT) drop  $\geq 4$
- T22 Bleeds
- T23 Emboli

The team, meeting weekly to review progress using accelerated improvement methodologies, focused on the standardization of key systems, such as medication reconciliation and heparin- and warfarin-ordering protocols, and gained financial backing for hospital- and community-based warfarin clinics. As the team became proficient at implementing changes in care, it expanded its efforts to other areas of opportunity, such as narcotics and insulin, still using the ADE Trigger Tool as the organizational gold standard to measure the outcomes.

## Adverse Drug Event (ADE) Trigger Tool Used by Our Lady of Lourdes

### Trigger Tool For Measuring Adverse Drug Events

ADE Patient Record Review Sheet

Patient Identification Number (MR#) \_\_\_\_\_ Acct# \_\_\_\_\_

Admission Date \_\_\_\_\_ Patient's Age \_\_\_\_\_

Discharge Date \_\_\_\_\_ Current Date \_\_\_\_\_

(Two-day minimum hospital stay required)

Length of Stay \_\_\_\_\_

- |   |   |
|---|---|
| <b>T1</b> Diphenhydramine   | <b>T9</b> <i>C. difficile</i> positive stool          |
| <b>T2</b> Vitamin K (Aqua-mephyton)   | <b>T10</b> PPT > 100 seconds                          |
| <b>T3</b> Flumazenil (Romazicon)  | <b>T12</b> WBC < 3,000                                |
| <b>T4</b> Anti-emetics (Inapsine, Zofran, Phenergan, Vistaril, Tiglan, Kytril, Compazine, Reglan) | <b>T13</b> Platelet count < 50,000                    |
| <b>T5</b> Naloxone (Narcan)   | <b>T14</b> Digoxin level > 2 mg/ml                    |
| <b>T6</b> Anti-diarrheals (Lomotil, Loperamide/Imodium, Kaopectate)                               | <b>T15</b> Rising serum creatrine                     |
| <b>T7</b> Sodium polystyrene (Kayexalate)   | <b>T16</b> Oversedation, lethargy, falls, hypotension |
| <b>T8</b> Serum glucose <50   | <b>T17</b> Rash                                       |
|   | <b>T18</b> Abrupt cessation of a medication           |
|   | <b>T19</b> Transfer to a higher level of care         |

| Triggers Found                      | ADE Found? |    | Harm Category* | Description of ADE |
|-------------------------------------|------------|----|----------------|--------------------|
|                                     | Yes        | No |                |                    |
|                                     |            |    |                |                    |
|                                     |            |    |                |                    |
|                                     |            |    |                |                    |
|                                     |            |    |                |                    |
|                                     |            |    |                |                    |
| <b>Total ADEs for this patient:</b> |            |    |                |                    |

\* 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

**Figure 1.** Our Lady of Lourdes began using the ADE Trigger Tool in July 2003—two years before Ascension Health set its ADE goals. *C. difficile*, Clostridium difficile; PPT, partial prothrombin time; WBC, white blood cell count.

### ACHIEVING GOAL 2: SAINT THOMAS

At Saint Thomas, all interventions were facilitated by the medication safety team—which consists of the medical director of pharmacy and therapeutics committee, the chief quality officer, the patient safety officer, the medication safety officer [K.B.], the associate chief nursing officer, frontline nurses, the director of pharmacy services, the manager of pharmacy operations, the manager of clinical pharmacy services, an information technology clinical pharmacist, and a critical care nurse practitioner from the

rapid response team.

The team's review of three-month aggregate ADE Trigger Tool data in December 2003 revealed opportunities for improvement for traditional high-risk medications, including anticoagulants, insulin, narcotics, and sedatives. Improvement initiatives were developed in an effort to standardize care, and new system measures (both operational and clinical) were established; some examples of these initiatives and measures are provided in Table 1 (page 529).



**Standardizing Care and Establishing New Metrics.** As events were detected, further chart review, interviews with caregivers, and review of current practices were examined to describe more clearly the root causes for patient harm relative to ADE. For example, for hypoglycemia (which was detected by the trigger tool), it was discovered that the cardiovascular patient population seemed to be particularly prone. When patients were moved from the intensive care unit to the floor, they were rapidly transitioned from intravenous (IV) infusions of insulin to subcutaneous intermittent injections. Because both hypoglycemia and hyperglycemia in this population are known risks to patient safety,<sup>9</sup> a standardized insulin transition protocol was developed. The key system metrics were then revised to include both hyperglycemia and hypoglycemia, and the retrospective interviewing process was made concurrent with the institution of a “debriefing” form for all patients suffering from hypoglycemia following arrival to telemetry to capture more clearly the preceding course of events. Once efficacy was demonstrated in the cardiovascular patient subset, the insulin transition protocol began deployment across other areas. The incidence of hyperglycemia declined from 28% of patients with total blood glucose > 150 mg/dL to 18%, with no increase in hypoglycemia occurrence.

New processes and protocols have also been developed to promote best practices in prescribing, dispensing, administering, and monitoring for anticoagulants, narcotics, and sedatives and the process of medication reconciliation. A description of these and many other approaches to reducing risk associated with the targeted medications are described elsewhere.<sup>10</sup> However, even with the improvements in the measures associated with new processes of care, the rate of harm from ADEs did not significantly decline. New event types occurred that were unforeseen, such as those involving cardiovascular medications, look-alike/sound-alike drugs, infusion-pump programming, and recent formulary additions. Therefore, by March 2005, the team began to consider the ADE Trigger Tool data more as a measure of outcomes rather than as a predictor of harm, as it had been used. The team then began to look for opportunities to become more proactive in addressing ADE-related harm.

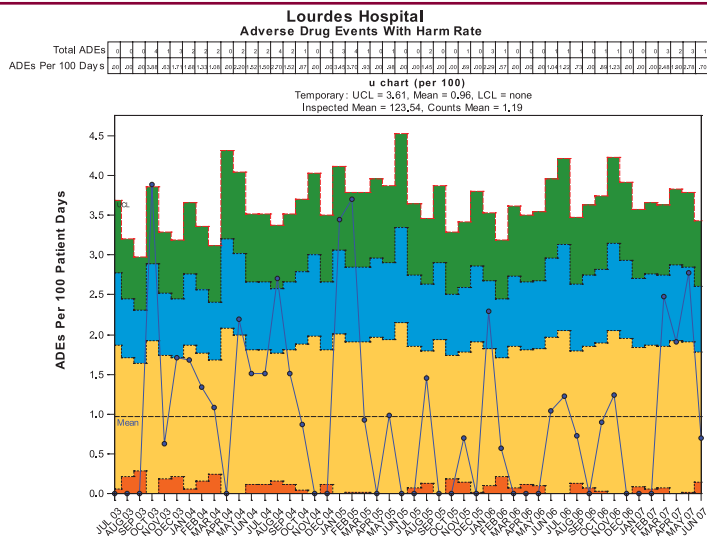
**Leveraging External Data Sources to Become Proactive.** In March 2005, the medication safety team reviewed ways

to become more proactive in managing the medication system. To eliminate ADEs, the team determined that there was a critical need to better anticipate harm by more effectively leveraging the available medication safety data from external data benchmarks and data sources. The committee adopted a new approach, the 360-Degree Agenda, to achieve this. This agenda retained all the previous internal sources of data—the ADE Trigger Tool audit results, event-reporting system aggregate and trend reports, and key metrics measures such as those described in Table 1—but added external data sources such as the Institute for Safe Medication Practice’s (ISMP) Quarterly Action Agendas<sup>11</sup> and the IHI’s 5 Million Lives Campaign How-To Guides.<sup>12</sup> For each recommended practice, the team completed a gap analysis. When approaches are not found or where deployment in key areas is lacking, system gaps are identified and new approaches developed in an effort to prevent, detect, or mitigate a harmful event before its occurrence. The monthly 360-Degree Agenda also includes management’s and administration’s response to each voluntarily reported incident so the medication safety team can review the consistency of follow-up with frontline staff on voluntary reports. This also serves to validate leadership’s commitment to maintaining the culture of safety. Root cause analysis results are also reported when medication processes may be affected.

In conducting the gap analysis, it was not uncommon that a policy might address only a small part of the overall issue, which necessitates expanding the policy’s scope to fill the practice gap completely. For example, regarding the risk of extravasation associated with promethazine,<sup>13</sup> the gap analysis revealed one systematic approach to managing extravasation for vasopressors and another for addressing extravasation of cytotoxins. We developed a single new policy to address extravasation of any parenteral agent to include not only promethazine but also hyperosmotic drugs and nonphysiologic pH drugs. We also added new recommendations on the prevention, earlier detection, and management of all extravasations. Such proactive efforts have also led to the development of new protocols to screen additions to the formulary of error-prone medications and formulations.

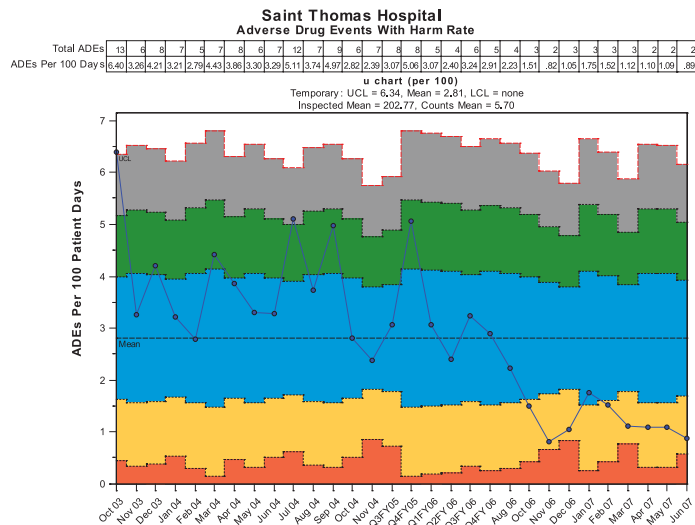
In January 2006, pharmacists (director and medication safety pharmacist) from another pharmacy department at another local Ascension Health hospital officially joined

## Our Lady of Lourdes Adverse Drug Event (ADE) Trigger Tool Results, July 2003–June 2007



**Figure 2.** The data indicated do not demonstrate a statistically significant change in ADE rate as measured by the ADE Trigger Tool. The colored areas represent 1, 2, and 3 standard deviations from the mean. UCL, upper control limit; LCL, lower control limit.

## Saint Thomas Hospital Adverse Drug Event (ADE) Trigger Tool Results, October 2003–June 2007



**Figure 3.** ADEs per 100 patient days decreased by 60% from the baseline mean of 3.04 (November 2003–October 2004) to a mean of 1.21 (October 2006–June 2007). The colored areas represent 1, 2, and 3 standard deviations from the mean. UCL, upper control limit; LCL, lower control limit.

our medication safety team to share their own experiences to help it develop more generalized and consistent approaches to the eventual elimination of harm.

**Using Technology to Support Work Flow and Communication.** In July 2006 an electronic medication administration record (eMAR) was implemented at Saint Thomas, replacing a handwritten medication administration record. This deployment dramatically improved the medication safety team's ability to rapidly communicate key alerts and process changes to the frontline staff. A number of key system measures, such as medication cabinet override rates, reconciliation rate, use of do-not-use abbreviations, and transcription errors showed significant improvement (Table 1). The time needed to provide education on safety initiatives also decreased significantly as an eMAR made it possible to provide education closer to the point of care. Changes that were previously very difficult to inculcate (such as "do not crush" medications) were implemented more efficiently.

### Results

At Our Lady of Lourdes, ADEs per 100 patient days have not statistically changed from the baseline mean of 1.39 (November 2003 through October 2004) to a mean of 1.11 (October 2006 through June 2007; Figure 2, page 533). At Saint Thomas, ADEs per 100 patient days decreased from a baseline mean of 3.04 (November 2003 through October 2004) to a mean of 1.21 (October 2006 through June 2007), representing a 60% reduction in the ADE rate (Figure 3,

page 533). As of March 2007, ADE Trigger Tool results did not show a consistent reduction in ADEs across Ascension Health.

## Discussion

Only some Ascension Health hospitals, as described in this article in the case of Saint Thomas, showed significant reductions in ADEs. However, the experience of those hospitals suggests that the following three key program elements are needed to eliminate ADEs:

- Adherence to the recommended practices in handling high-risk medications to include improvements in both operational and clinical practice
- Adoption of a more proactive approach in setting medication safety agendas, with gap analysis as a key component
- Expansion of the scope of intervention

### ADHERENCE TO RECOMMENDED PRACTICES

After using the ADE Trigger Tool data for a number of months, neither Our Lady of Lourdes nor Saint Thomas saw a sustained reduction in ADE rate. While this was discouraging, both facilities kept working, continuously developing and deploying new strategies to prevent recurrent ADE-related harm as identified by the ADE Trigger Tool. Many new practices targeting high-risk medications began to show measurable improvement. New programs, such as medication reconciliation, multidisciplinary anticoagulation services, and standardization of common ordering and dispensing functions were instituted. Operational improvements were made in key areas such as automated dispensing machine overrides, unit-of-use dosage distribution, double independent verification for high-alert medications, and new methods to better engage patients in the medication reconciliation process were implemented. Most of these improvements were later expanded to include new steps to detect potential ADEs earlier and to mitigate harm, when applicable and as explained in the IHI How-To Guides.<sup>11</sup> Only after deployment and sustained improvement for these and many other interventions were coupled with proactive assessment, however, did Saint Thomas begin to see a decline in ADE-related harm.

### ADOPTION OF A PROACTIVE APPROACH

The introduction of gap analysis as a means to leverage the expertise of external data sources has facilitated our ability to improve systems before harm can take place in our patient base. As new medications and new methods of using older medications are continually introduced, new sources of patient harm arise. Therefore, it is increasingly important that the medication safety system evaluation process stay proactive to sustain and improve reductions in overall ADE-related harm as we pursue elimination of preventable injury and death from medication use. Saint Thomas's 360-Degree Agenda has enabled it to systematically detect flaws and gaps in the process before a patient has been subjected to the opportunity of injury.

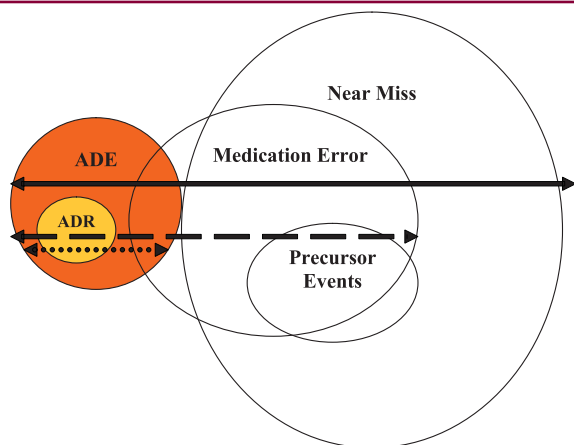
### EXPANSION OF THE SCOPE OF INTERVENTION

Before the ADE Trigger Tool was mandated at Ascension Health, most of the hospitals' methods to detect and, when possible, eliminate flaws in the medication use system were geared toward identifying error rather than harm as a way to pare down reported events. For example, some of those methods were based on preventability indices such as the Naranjo, Busto, and Sellers algorithm.<sup>14</sup> Ascension Health's goal of excellent clinical care with no preventable injuries or deaths and use of the ADE Trigger Tool as the primary means of measuring outcomes forced a shift from only preventing error to also managing harm. This shift in mindset was challenging operationally, as the traditional view of ADEs and error caused some practitioners to wonder if the ADE Trigger Tool produced sparse or inconsistent data, much of which was viewed as reflecting nonpreventable events. It became necessary to place much more emphasis on a broader scope of intervention—specifically, detection and mitigation of (sometimes unpreventable) harm while still continuing efforts to prevent ADEs. This redefined perspective, as reflected in the model in Figure 4 (page 535), was critical in addressing some initial resistance to using the ADE Trigger Tool as a sole source of outcomes data.

As an example of a standardized approach to detecting foreseeable events that might occur subsequent to drug administration but before the patient exhibits harm, increased end tidal carbon dioxide may be monitored in a patient receiving a continuous infusion of narcotics. Mitigation strategies lie only within ADEs and ADRs



## A Model for on Adverse Drug Events (ADEs) and Medication Errors



**Figure 4.** This model on ADEs and medication error is driven by a focus on reducing patient harm (depicted in the shaded areas). The arrows reflect the intervention types to consider: prevention, detection, and mitigation. Prevention strategies are represented by the solid line and transect the entire system—from near misses through ADE. Whereas prevention strategies do not affect ADRs or precursor events, detection strategies transect both of these areas, as indicated by the dashed line. Mitigation strategies are depicted by the dotted line.

(Figure 4)—where harm has occurred but can be mitigated before worsening. A standardized approach to mitigate an event may prevent a later ADE from inadequate, inappropriate, or overzealous mitigation strategies. For example, overzealous mitigation, such as the administration of phytonadione (Vitamin K) in higher than necessary doses or intravenously to reverse minimal bleeding with an elevated international normalized ratio (INR), may unnecessarily predispose a patient to further harm. Further, intravenous (IV) administration of phytonadione may unnecessarily increase the risk of harm. If given in too high a dose, it is very difficult to re-anticoagulate, potentially for several days. The intervention in this case—a standardized mitigation strategy for INR reversal—would facilitate making the right choices at each of these opportunities for “unforeseeable” harm. Similarly, a nurse-initiated extravasation-reversal protocol can limit harm in patients with misplaced or displaced IV catheters. The bidirectional

arrows (Figure 4, at left) represent the potential for the strategies’ overall impact to the medication system, despite the fact that the events are detected retrospectively (by the ADE Trigger Tool) or prospectively (through gap analysis as identified through external sources).

While this model continues to evolve, it has been instrumental in helping us describe the need for a broader scope of intervention in our quest for zero preventable injuries.

### Summary and Conclusion

Improvement in ADE rate did not occur at either hospital with any one particular intervention, or even after several conventional interventions had time to take effect. Instead, instituting many simultaneous system changes, proactively assessing risk, and expanding the scope of intervention were each essential to sustaining the described reductions in harm.

The next step toward eliminating ADEs requires simultaneous communication across systems in a way that is manageable, approachable, and adaptable, and that supports the elements of change. A system of mutually informed processes—from medication selection and entry through preparation and dispensing, administration, monitoring, and reconciliation—should result in safe, patient-centered, reliable, and efficient medication use. In March 2007, Ascension Health, drawing on the work described in this article, began developing such a system. **J**

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