



Program Brief Network of Patient Safety Databases



Driving Improvement in Medication Safety: Patient Safety Organization Approaches

This educational brief shares approaches taken by patient safety organizations (PSOs) engaged in reducing medication errors and improving medication safety. In particular, the brief highlights how PSOs use medication safety event data reported by member hospitals and other providers to drive improvement in medication-related processes and outcomes.

The Patient Safety and Quality Improvement Act of 2005 facilitates the reporting, analysis, and discussion of safety events between providers and PSOs by making the information privileged and confidential. The information presented in this brief is from discussions in fall 2014 between PSOs that are part of the Agency for Healthcare Research and Quality (AHRQ) PSO program and Network of Patient Safety Databases researchers.

Four PSOs volunteered to be interviewed about their activities:

- Medication Management Research Network PSO¹
- Wake up Safe PSO²
- The PSO Advisory³
- Institute for Safe Medication Practices PSO⁴

Background: The Importance of Medication Safety

A medication-related patient safety event is frequently called an adverse drug event (ADE).⁵ An ADE arises from an act of commission or omission in health care delivery at any step along the continuum that includes:

- Prescribing medication,
- Transcribing the prescription,
- Dispensing the product,
- Administering it to the patient, and
- Monitoring the patient who received the medication.

Clinicians have access to a vast array of more than 10,000 prescription medications, and nearly one-third of adults in the United States take five or more medications. The population's broad exposure to pharmaceutical products and the many daily care delivery transactions that involve pharmaceuticals make medication error an important patient safety problem to target.

¹The Medication Management Research Network was first listed as a PSO in January 2010. It is a component PSO of the University at Buffalo and is primarily affiliated with the Department of Pharmacy Practice. Farzia Kaufman, Administrative Coordinator, and Jeff Lombardo, Patient Safety Officer, were interviewed in October 2014.

²Wake up Safe was first listed as a PSO in December 2008. It is a component PSO of the Society for Pediatric Anesthesia. Donald Tyler, Executive Director, was interviewed in September 2014.

³The PSO Advisory was first listed as a PSO in May 2010. William Smith, President, was interviewed in September 2014.

⁴The Institute for Safe Medicine Practices was first listed as a PSO in November 2008. Mike Cohen, President, was interviewed in September 2014.

⁵An adverse drug event can be either a medication error or an adverse drug reaction with no apparent incorrect action involved.



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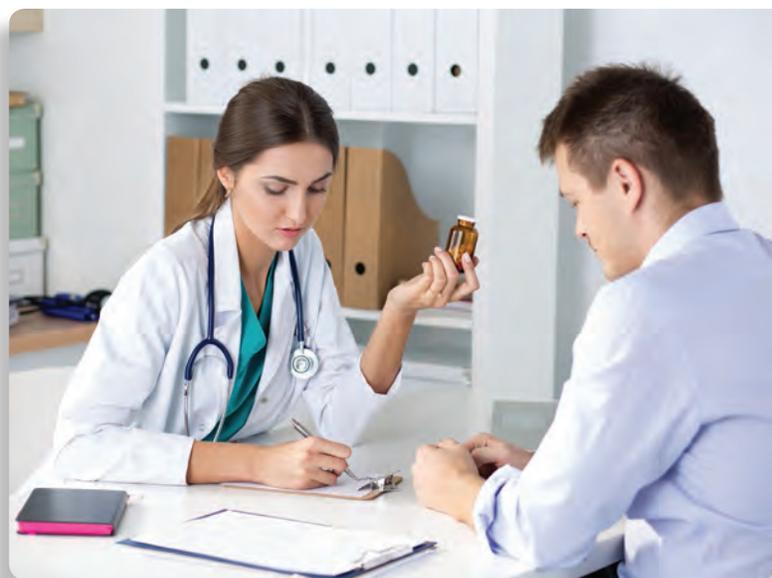


The Federal Government recently established a National Action Plan for the prevention of ADEs as part of its commitment to medication safety for the U.S. population.⁶ They developed the plan to align Federal agency efforts in reducing patient harm from common, preventable, and measurable ADEs that have been identified as priorities. The three initial targets are:

- Anticoagulants (bleeding is the primary concern),
- Diabetes agents (hypoglycemia is the primary concern), and
- Opioids (accidental overdose, oversedation, or respiratory depression are the primary concerns).

The Centers for Medicare & Medicaid Services (CMS) Hospital Engagement Network (HEN) program conducts multifaceted quality improvement work to prevent patients from getting injured or sicker in the health care system. As the HEN program has been extended, the three target ADEs were added to the core set of preventable harms that participants are required to address.⁷

Regardless of the type of provider entity or setting, events that involve medications often account for a sizable share of the total number of safety events. An analysis of unsafe medical care in inpatient settings estimated that among seven categories of events, ADEs had the highest incidence (five percent) in high-income countries.⁸ For the United States, AHRQ estimated a rate of 40.3 ADEs per 1,000 adult hospital discharges in 2013; ADEs accounted for the largest share of hospital-acquired conditions contributing to the overall rate.⁹ Within one established State program of patient safety event reporting, medication errors (within the prescribing-to-administering continuum and not including adverse drug reactions) accounted for 21 percent of safety events reported from acute-level facilities.¹⁰



A variety of approaches aim to reduce medication errors. The remainder of this brief describes different approaches that PSOs are using in their effort to improve medication safety:

- High-Risk Medication Management: Targeting Patients and Developing Infrastructures To Prevent Serious Adverse Events
- Pediatric Anesthesiology: Improving Processes, Visiting Peers, and Educating Other Medical Professionals
- Analytics for Community Pharmacy Chains and Other Corporations: Finding Repeated Errors, Setting Benchmarks, and Using the PSO Network
- Affecting National Safety: Building a Case for Change by Manufacturers and National Organizations

⁶U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. National Action Plan for Adverse Drug Event Prevention. 2014. <http://www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf>

⁷Centers for Medicare & Medicaid Services. Hospital Engagement Network (HEN) 2.0 Solicitation, Section C, Description/ Specifications/Work Statement. Solicitation Number RFP-CMS-APP150491-2014. February 11, 2015. https://www.fbo.gov/index?s=opportunity&mode=form&id=260576871760e4476c6cecf2e809a10c&tab=core&_cvview=1 .

⁸Jha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, Bates DW. The global burden of unsafe medical care: analytic modeling of observational studies. *BMJ Quality and Safety*. 2013;22(10):809–815.

⁹Unpublished estimates based on Agency for Healthcare Research and Quality, Medicare Patient Safety Monitoring System, 2010–2013; Center for Disease Control and Prevention, National Healthcare Security Network, 2010–2013; and Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2010–2012.

¹⁰Pennsylvania Patient Safety Authority. 2013 Annual Report. April 30, 2014. <http://patientsafetyauthority.org/PatientSafetyAuthority/Documents/Annual%20Report%202013.pdf>. Note: in 2013, reports from hospitals accounted for 98 percent of acute facility types.

High-Risk Medication Management: Targeting Patients and Developing Infrastructures To Prevent Serious Adverse Events

As it gears up for full implementation, the Medication Management Research Network (MMRN) PSO is building a system to support a tailored approach to help client sites—largely ambulatory care sites and specialty pharmacies—improve medication safety through prevention activities.

Targeting Patients. The target population is patients on medications that pose high risks, such as patients taking oncology drugs that are cytotoxic or have a narrow therapeutic range for safe administration. The MMRN is involved with other high-risk clinical conditions that include diabetes, infectious diseases such as HIV and hepatitis C, and cardiometabolic diseases. This PSO aims to make each client site aware of potential medication risks to patients and to recommend evidence-based practices for reducing those risks.

Under their service model, the MMRN advises on patient groups in aggregate (e.g., patients on drug regimens that are known for heart-related toxicity) through group education activities and seminars. The MMRN may advise clients to develop or review policies and procedures related to high-risk medications.

Developing Infrastructures. The PSO is developing a system to support high-risk medication management. Client sites submit deidentified data to the PSO for the selected populations. Using this information, the PSO will identify and educate providers about at-risk groups. To alleviate the need for sites to manually submit data, the PSO also is building a platform that can take data from different electronic medical record systems and export them to the PSO in a de-identified format. This information is then organized into dashboards that are analyzed by the PSO. Improved reporting by health care providers allows for a dialogue with the PSO about trends in care and future therapeutic implications.

The MMRN PSO encourages clients to tell the PSO how information is being used and will hold monthly roundtable discussions for feedback on how best to serve patients and providers.

Pediatric Anesthesiology: Improving Processes, Visiting Peers, and Educating Other Medical Professionals

Another PSO, Wake up Safe, is actively engaged in patient safety improvement interventions and various forms of education for its 26 pediatric hospital members and for anesthesiologists from academia and private practice. Anesthesiologists are the only physicians who both draw up and administer a patient's medication. Focusing on serious ADEs allows the PSO to isolate anesthesia complications from surgical complications. Data about these events in patients under age 21 are collected via an online system and supplemented by electronic billing data to create event rates per procedure.

Improving Processes. The PSO initiated a project among member institutions to improve labeling of drug names and concentrations on medication syringes. Anesthesiologists from each institution measured how often syringes were correctly labeled, and the group learned that institutions with the best accuracy provided the anesthesiologist with preprinted labels containing the necessary information. However, after the PSO encouraged the anesthesiologists to adopt the practice, remeasurement revealed barriers at the institution level. In response to these barriers, the initiative changed methods to strengthen member education and seek institutional buy-in. Wake up Safe also selected a second improvement intervention regarding meaningful double-



checks to manage infusion pump dosages and rates; this intervention does not require institutional support.

Visiting Peers. Borrowing a practice from other industries, peer-to-peer visits bring anesthesiologists from other institutions or the PSO to observe and critique processes of care in the operating room of a single institution. To date, the PSO has organized 10 of these 1-day visits. Reports of findings about what is done well (for example, morning huddles) and what can be improved have given anesthesiology chiefs leverage within institutions to support their improvement efforts. In one case, the institution received data from the PSO about reported events that involved handoffs, a risk factor that was frequently observed during the visit. The findings, which are protected as patient safety work products (PSWPs), can also be shared anonymously with other PSO members.



Educating Other Medical Professionals. The PSO's educational outreach about risks and process improvements has extended to the broader health care community through publications in journals of other medical professions. For example, the PSO member anesthesiologists reasoned that a long-understood problem related to transfusion continued to occur because blood banks are not sufficiently aware of the risk associated with transfusion of old blood (i.e., blood with

higher potassium concentration) in small infants. Wake up Safe published an article in the blood bank journal *Transfusion* that reviewed the literature for case reports and clinical studies about risk factors—including the age of red blood cells and potassium levels—for pediatric cardiac arrest during massive transfusion.¹¹

Analytics for Community Pharmacy Chains and Other Corporations: Finding Repeated Errors, Setting Benchmarks, and Using the PSO Network

Providing actionable reports to corporate safety officers at pharmacy organizations, such as national and regional chains, is a core activity of The PSO Advisory. The goal is to identify the root cause of any errors. Corporate clients may set up monitoring projects or interventions based on the information provided by the PSO. A project might involve tracking errors for a group of high-risk medications from one 6-month period to the next to determine their trends, or tracking errors before and after the introduction of a new pharmacy system.

Finding Repeated Errors Across Client Systems.

Because reports of actual events come from client-specific systems, The PSO Advisory uses sophisticated import routines to identify and map to the relevant field before evaluating the reported events. For example, the PSO may compare the prescribed drug and dosing to the dispensed product. Close calls or “near-misses” that occur before the consumer receives the medication can be detected by a provider’s pharmacy system.

Depending on the data record for the reported error, the PSO may be able to look for errors related to similar medications. When an emerging error is identified, such as when a pharmacist confuses two drugs because he or she relied on faulty memory instead of a pharmacy decision support system, the PSO can look for a similar error in a different client’s database. The PSO Advisory also uses multiple databases for analytic purposes.

Setting Benchmarks on Safety Reporting and Rates of Error.

For corporate clients that desire store-level feedback to share with field managers, the PSO provides dashboard reports with benchmark-like information. The content may include trends of whether pharmacies

¹¹Lee AC, Reduque LL, Luban NL, Ness PM, Anton B, Heitmiller ES. Transfusion-associated hyperkalemic cardiac arrest in pediatric patients receiving massive transfusion. *Transfusion*. 2014;54(1):244–254.

are reporting and what they are reporting, as well as comparisons with a blinded aggregate. Rates are the focus: either errors per million prescriptions dispensed for pharmacies or errors per 1,000 patient days for hospitals. Furthermore, based on event and outcome data provided by the client, The PSO Advisory can develop a client-specific risk score for each drug category (e.g., seizure disorder medications) to prioritize prospectively the items they want to address with a client.

Using the PSO Network To Spread Safety. The PSO Advisory's role as subject matter expert on medication errors for nonpharmacy organizations, including hospitals and other PSOs, provides a recent example of the power of both data analytics and collaboration. As a contractor to Quantros Patient Safety Center PSO, The PSO Advisory detected repeated occurrences of a pharmacy error from different clients and with different outcomes. The cause was the dispensing of the wrong insulin pump device with preprogrammed and preset dose levels (20, 30, or 40 units, depending on the device). This error led to hypo- or hyperglycemic events, some of which involved intervention in intensive care units. Quantros PSO issued a safety advisory in late December 2014 and notified other major PSOs. The Institute for Safe Medication Practices (ISMP) PSO put a notice in their January newsletter and also brought the issue to the attention of the U.S. Food and Drug Administration (FDA), which had approved the device.

Affecting National Safety: Building a Case for Change by Manufacturers and National Organizations

One model for widespread improvement of medication safety is to work with Federal agencies, manufacturers, and other national entities (such as standards organizations) to effect change, particularly with regard to risks identified in patient safety event reports. Although accounting for a minor portion of the PSO's activities, interacting with these audiences is an influential role played by the ISMP PSO.

Getting the Story. The ISMP PSO accepts PSWP reports of medication errors through their Web site.¹² All providers reporting to the ISMP PSO give a narrative



description of what went wrong or could go wrong and the causes or contributing factors. They also report how the event or condition was discovered or intercepted and the actual or potential outcome of the involved patient. Specific information such as product name, form, dose, strength, and manufacturer is collected where possible.

The ISMP PSO focuses on getting the complete story behind the report to learn as much as possible from the experience and contribute to a system of learning. After receiving and reviewing an event report, ISMP may ask additional questions to clarify what happened and why. Insights about patient safety improvement that are gleaned from one or more event reports are then put into the public domain. Examples of information dissemination vehicles include a newsletter geared toward consumers, a newly developed newsletter for long-term care providers, and reports on the ISMP Web site.

Working With Stakeholders. ISMP communicates with FDA and product vendors (when applicable) about medication safety issues identified in reports. Vendors may be informed about labeling, packaging, or nomenclature designs that contribute to errors. For example, in response to an event analysis and report by ISMP, Roxane Laboratories revised their packaging and labeling of a high-potency oral morphine sulfate solution in 2010 to minimize the risk of accidental overdosing.

¹²Institute for Safe Medication Practices (ISMP). ISMP Medication Error Reporting Program. ISMP Web site; 2015. <https://www.ismp.org/reporterrors.asp>

Also, after a 2008 ISMP hazard alert, Brookstone Pharmaceuticals initiated a nationwide voluntary recall of certain concentrated acetaminophen drop containers that might be confused with lower concentration liquids. The PSO also presents programs to and stimulates discussions with staff at FDA and the Centers for Disease Control and Prevention on various topics.

Conclusion

The activities of a variety of PSOs show different ways analysis of patient safety medication-related event data can help prevent future medication errors. Although the nature and complexity of the data analysis varies across the PSOs, they use similar data elements in addition to the currently available AHRQ Common Formats to carry out their specific approach to medication safety improvement. The upcoming release of a beta version of Common Formats for Retail Pharmacy is an important development regarding structured data about events involving medications. Another common feature across the PSOs is the use of individual event reports to facilitate learning. Future briefs will provide more information about this and other types of PSO activities.

To learn more about PSOs, visit www.pso.ahrq.gov. Topics covered there include the following:

- Providers can learn about how to work with and choose a PSO.
- Organizations can learn more about how to become a PSO.
- Users can access a full directory of AHRQ-listed PSOs.

This program brief was prepared under Contract No. HHS A290201200003 TO#3 for the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Suggested Citation: Driving Improvement in Medication Safety: Patient Safety Organization Approaches. Network of Patient Safety Databases Brief. Rockville, MD: Agency for Healthcare Quality and Research; December 2015. AHRQ Publication No. 15(16)-0013-5-EF.



AHRQ Pub. No. 15(16)-0013-5-EF
December 2015