Drug Shortages: A Patient Safety Crisis That Affects Everyone

BY ALLEN VAIDA, PHARMD, FASHP, EXECUTIVE DIRECTOR, INSTITUTE FOR SAFE MEDICATION PRACTICES

Sporadic shortages of critical medications have occurred over the last decade, but according to reports from the Food and Drug Administration (FDA) and the American Society of Health-System Pharmacists (ASHP), the number of drugs in short supply has tripled since 2006. There were 211 newly reported drug shortages in 2010 alone.1

From January through September 15, 2011, the University of Utah Drug Information Service reported 210 new drug shortages, compared to 74 shortages in all of 2005 and 70 in 2006.2 Unfortunately, most of these unavailable drugs are ones deemed medically necessary, such as:

- Chemotherapeutic agents
- Anesthetics
- Analgesic agents
- Electrolytes used in preparing nutritional formulas

Media coverage has focused on the effect of these shortages on healthcare systems and, most importantly, on patients.

Exploring the extent of the problem
In late summer 2010, the Institute for Safe Medication Practices (ISMP) conducted a national survey of more than 1,800 healthcare providers. The survey identified at least 1,000 errors and adverse patient outcomes due to drug shortages over the preceding 12 months.3

In response, ASHP, ISMP, the American Society of Anesthesiologists (ASA), and the American Society of Clinical Oncology (ASCO) convened a national summit in the fall of 2010.4 Invited stakeholders from industry, the FDA, group purchasing organizations, and frontline practitioners met to identify the causes of drug shortages and to develop recommendations for addressing the problem. Since that meeting, ASHP, ISMP, ASA, ASCO, and the American Hospital Association (AHA) have formed work groups to address the issues.

Premier, a large group purchasing organization, recently estimated that buying alternative medications or turning to other therapies can cost providers at least an extra $200 million per year.5 ASHP also conducted a survey with the University of Michigan Health System that estimated the cost of time and labor required to manage shortages across the US at $216 million annually.6

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How are drug shortages affecting hospitals?
The AHA surveyed its members in June 2011. Of the 820 hospitals that responded, nearly 100% reported at least one drug shortage in the last 6 months and nearly half reported 21 or more drug shortages.

The survey also revealed that in the first half of 2011:

- 82% of hospitals had delayed treatment, and more than half were not always able to provide patients with the recommended treatment because of drug shortages.
- 69% of hospitals reported that patients got a less effective drug because the most effective drug was unavailable.
- Hospitals experienced drug shortages across all treatment categories.
- 77% of hospitals rarely or never received advance notification of drug shortages, and 67% were rarely or never informed about the cause of the shortage.
- Most hospitals reported increased drug costs as a result of drug shortages, and had purchased more-expensive alternative drugs.7

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Why are drug shortages occurring?
There are numerous reasons for drug shortages, including:

- Quality issues at pharmaceutical plants
- Limited redundancies in the manufacturing of many critical drugs
- A shortage of raw ingredients
- The FDA's decision to require a New Drug Application (NDA) for drugs developed prior to 1938, unless the manufacturer can demonstrate that the drug is "generally recognized as safe and effective" or that the current version of the drug is identical to the pre-1938 version and therefore should remain "grandfathered"\(^8\)
- Marketplace consolidation, such as decisions by pharmaceutical companies to discontinue certain medications due to low profit margins or new business strategies
- A lack of sufficient FDA resources to handle the scope of the crisis

Sometimes there may be a single cause for a given drug shortage, but most often a combination of factors leads to a shortage.

What are the patient safety implications?
Several of the most pressing problems with drug shortages are limited supply or unavailable medication in major drug categories such as:

- Neuromuscular blocking agents (NMBAs)
- Oncologics (anti-cancer drugs)
- Electrolytes

Current shortages of injectable calcium gluconate and phosphates are causing major concerns for patients who require these substances as a component of intravenous nutrition therapy. These substances are extremely critical in newborns; their shortage has forced hospitals to restrict therapy and to prepare guidelines on using oral supplements in adults for phosphate therapy.

Managing these shortages takes cooperation among healthcare professionals treating affected patients, along with time to prepare the guidelines. One valuable resource is the ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems, which is freely available online.\(^9\)

There are also shortages of injectable vitamins, trace elements, and other nutrients used in the treatment of hospitalized patients. Shortages of succinylcholine, a neuromuscular blocking agent, have caused significant changes in the anesthesia community, especially in the treatment of pediatric and obstetrical patients.

Shortages of oncologic medications have caused ethical dilemmas in cases where the number of patients for whom the drug would be the most effective therapy exceeds the available supply of the drug. Also, patients who have begun a course of treatment may need to delay further therapy or receive lower doses of medications as a result of shortages.

There is now a shortage of almost all anthracyclines, drugs used to treat a variety of cancers. There are no alternatives for many oncologic medications, and where alternatives are available, they are more expensive, may have more numerous or more serious side effects, and most importantly, may not be as effective as the unavailable drug for the disease being treated.

Another issue is the “gray market”—specialty distributors that offer medications in short supply at extremely inflated prices. Hospitals are often put in the difficult position of having to work with these distributors to address medication needs despite their questionable pedigree. Many times, the provenance of the drug can’t be assured unless the state has a pedigree law—which not all states do.\(^10\)

What is the government doing?
The US government is taking steps to deal with issues surrounding drug shortages. At the federal level, there are legislative proposals that would:

- Require pharmaceutical companies to give notice before leaving the marketplace
- Ease requirements for importation of medications
- Increase FDA resources for dealing with the problem...

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**Notes:**

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\(^2\) Resources to Report and Track Drug Shortages

The FDA has an online resource at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm. This includes information on:

- Current drug shortages
- Resolved drug shortages
- How to report a drug shortage
- Drugs to be discontinued
- Frequently asked questions about drug shortages

The ASHP has a drug shortage resource center at http://www.ashp.org/shortages, maintained by the University of Utah Drug Information Service. The ASHP site tracks all medications, not just those deemed medically necessary, relying on information supplied by hospitals.

The FDA web site relies on information it receives from manufacturers to predict when a shortage may end and may not be as current as the ASHP web site.
On May 25–27, patient safety professionals, advocates, and champions from around the globe gathered in Washington, DC, for the 13th Annual NPSF Patient Safety Congress. “Cultivating Patient Safety—It’s in Our Hands: Sharing Accountability and Responsibility” drew more than 1,000 attendees and featured a multidisciplinary faculty of presenters.

Pre-Congress program
The conference was preceded by 4 concurrent full-day workshops that offered a diverse range of learning experiences:

- **Leadership Day** was designed for C-suite and board-level attendees. Using a case-study approach, presenters addressed organizational barriers to accountability, outlined strategies for aligning incentives in organizations to reward patient safety efforts, and described best practices to create meaningful, sustainable culture change.

- **Measurement Boot Camp**, a hands-on workshop, provided attendees with critical training and skills for evaluating the effectiveness of patient safety efforts. Presenters also addressed how to target areas for improvement and how to learn from publicly reported data.

- **Patient Safety 101** was designed for professionals with less than 2 years of experience in patient safety or for those in operations or administrative departments seeking to learn patient safety fundamentals. Using case studies as illustrations, presenters outlined the elements of an effective patient safety management program, including factors that drive human performance and how theories of human factors engineering can be applied to improve care.

- **Community Engagement Day** offered perspectives and ideas to support engaging healthcare consumers in patient safety work. Presenters described their efforts at forging patient–provider partnerships and addressed the importance of informed and involved decision making by patients and families. Participants critiqued a community engagement toolkit under development.

Learning and Simulation Center
Following last year’s success, the 2011 Congress reprised the transformation of the exhibit hall into a Learning and Simulation Center that ran scenarios at intervals throughout the 2-day conference. Two simulated episodes showed transitions through the continuum of care.

1. A simulated emergency department featured advanced cardiac life support and the use of therapeutic hypothermia. The simulation depicted the emergency medical technicians’ handoff of the “patient” to the ED team and the transition to the intensive care unit.

2. A labor and delivery room simulation focused on a young mother with level-1 postpartum hemorrhage. The patient-mannequin was transferred to the operating room for more-aggressive treatment.

Both simulations included in-depth debriefing sessions, designed to offer learning opportunities for the audience.

Lucian Leape Institute Town Hall
The opening plenary featured members of the Lucian Leape Institute at the National Patient Safety Foundation (LLI) in a town hall format to discuss their work in the context of recent developments in patient safety. Dr. Leape opened the program with a review of recent studies suggesting that medical errors remain a significant issue in the US healthcare system.

Given how important the healthcare professions are and how gratifying it can be to help people regain their health, Dr. Leape said medical professionals “ought to be ecstatic,” but in large part, they are not. The discussion focused largely on finding joy and meaning in work and ensuring the safety of the healthcare workforce, 2 of the 6 transforming concepts to significantly advance patient safety that the Institute has been addressing.

LLI member Julianne Morath summarized the results of roundtable meetings held with expert panels convened by the institute in 2010 and 2011:

- Although many healthcare organizations espouse the belief that “our staff is our most important asset,” they...
have not made the physical and psychological safety of frontline staff a priority.

- **Success in improving patient safety is not possible without an aligned staff.** All members of the team need to be engaged as problem solvers.
- **Multiple studies have linked disruptive behavior (or non-teamwork-promoting behavior) to medical error.**

LLI member Paul O’Neill suggested that reporting of errors and workplace injuries needs to become more efficient and transparent. “Either organizations are habitually excellent or they’re not,” he said. Publicly reporting adverse events as well as workforce injuries would represent a clear statement from leadership about the seriousness of its commitment to making improvements in this area.

O’Neill said healthcare leaders should ensure that all of their workers can answer “yes” to 3 questions:

1. Are you treated with dignity and respect every day by everyone you encounter?
2. Are you given the tools and training you need to make a personally meaningful contribution to the organization?
3. Are you recognized for what you do?

**The Music Paradigm**

NPSF brought back Roger Nierenberg and his acclaimed program, The Music Paradigm, which had been presented at the 2010 Congress, as the second plenary session for 2011. Maestro Nierenberg led the Washington, DC–based National Symphony Orchestra in his presentation, which focuses on using an orchestra as a metaphor for other dynamic organizations.

Through a series of exercises designed to complement the program, and with the musicians seated in groups among the audience, Nierenberg illustrated parallels between the way an orchestra works and how other types of organizations perform. The program revealed multiple lessons for healthcare professionals:

- **Accountability.** Nierenberg observed, “If there is a difference between what we idealize and what we are producing, it is our job to fix it.” In health care, the work product may take time to be fully realized. If healthcare professionals want their audience—their patients—to experience the best care they can provide, they need to be accountable for the entire process.

- **Leadership.** Nierenberg invited 2 members of the audience to join him at the podium and experience the “eyes and ears” of the conductor. Both participants found that perspective to be completely different than what they experienced from their seats. The exercise showed that leaders may be the only ones who can really see an organization’s scope. Great things can be accomplished by individuals or by groups, but it’s the leader’s job to ensure that they mix effectively to achieve a higher level of success for the whole organization.

- **Organizational dysfunction.** Nierenberg pointed out that most organizations are good at remedying dysfunction that is causing chaos. Sometimes it is much more difficult to tackle insidious dysfunction. Many organizations invest in technical expertise, but they may lose sight of the overall performance quality. Leaders need to determine whether problems reside in a particular place or within the system as a whole.

“**If there is a difference between what we idealize and what we are producing, it is our job to fix it.”** —Maestro Roger Nierenberg

- **Disruptive behavior.** This can occur when an individual “pushes up the pitch.” Nierenberg suggested that disruptive behavior is not always malicious, but it can change an organization’s agenda. Disruptive behavior from the leader—being too controlling or too remote—may result in an alienated or disengaged workforce and less-than-ideal work environment and work product.

- **Importance of effective communication.** Nierenberg ended the program with reflections on the conductor’s baton. Like all good leadership tools, he said, it is simple. Yet, as one member of the audience observed: “The movement of the baton is directly attached to the ear. The whole thing is about listening.”

In essence, the technical expertise of the musicians (or the staff) is not enough to get the job done. There needs to be strong leadership that supplies appropriate direction and organizational vision, enables the staff (the musicians) to
Pros and Cons of Federal Reporting in Patient Safety

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Overview of federal reporting

While significant progress has been made toward improving patient safety and quality of care, much work remains to be done.1 To this end, the Agency for Healthcare Research and Quality (AHRQ) will continue to lead the federal government’s initiatives to improve provider performance, measurement utility, and quality of care delivery.

Federal patient safety reporting initiatives involve multiple efforts across different agencies, such as the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and AHRQ. Each agency’s program covers different topics and serves different purposes. For example, FDA collects adverse event reports on drugs, medical devices, and biologics currently on the market; CDC collects information on healthcare-acquired infections; CMS monitors safety information on care delivered to Medicare beneficiaries; and AHRQ synthesizes healthcare incident data collected by providers and submitted to Patient Safety Organizations (PSOs). Reporting programs may be voluntary or mandatory, and may be based on submissions by facilities, providers, or manufacturers. Protection of and access to data also can vary by agency.

Healthcare providers use multiple methods and sources of data to facilitate detection and reporting of adverse events (see Figure 1). Providers may recognize an adverse event at the time it occurs and actively draft a patient safety report. As providers review patient discharge data, they may discover that an event occurred. With the adoption of health information technology (HIT), events are increasingly detected via triggers and alerts incorporated into clinical decision support applications and electronic medical records.

AHRQ’s PSO Program

The Patient Safety and Quality Improvement Act of 20052 provided the legislative means for fundamentally expanding and enhancing AHRQ’s capabilities to synthesize safety data derived from clinical care delivery. Key provisions of the act established the PSO program (administered by AHRQ), created the Network of Patient Safety Databases (NPSD), and authorized development and use of Common Formats for reporting patient safety events. Seventy-eight PSOs are currently listed by AHRQ, representing 31 states and the District of Columbia.3

Figure 1. Detection of patient safety events and reporting: Multiple methods and sources of data

The overarching goal of the act is to improve patient safety by establishing a protected space for learning from adverse events. Providers can submit reports to PSOs without fear of malpractice litigation or inadequate protection by state laws. The act also addressed the inability to share and aggregate data on a larger scale. The act includes strict restrictions and fines against disclosure of information from PSOs.

The role of PSOs was defined clearly in the act. PSOs are expected to be organizations with substantial expertise in the identification, analysis, and elimination of threats to the safety and quality of patient care. PSOs function as “consultants” to providers. Providers send patient safety and quality data to their respective PSO for analysis, confidentiality, and privilege protection. Data sent to PSOs are not limited to adverse event reports and may also include reports of near misses and unsafe conditions. In turn, PSOs send provider data to the Network of Patient Safety Databases for national aggregation. AHRQ’s Common Formats standardize vocabulary and data elements for national aggregation. The data flow of information from providers through PSOs to the NPSD for various reports is depicted in Figure 2.

Provider participation in PSOs is voluntary. Providers are not assigned to a PSO but may select the organization of their preference. PSOs receive no federal funding, and their

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activities are not directed by the federal government. Furthermore, PSO data is not tied to reimbursement: data are not sent to CMS or other payers.

The Common Formats incorporate the NQF Serious Reportable Events. Sample Common Formats and aggregate reports can be found in the online PSO Privacy Protection Center established by AHRQ. De-identified data from the PSOs will be aggregated and sent to the Network of Patient Safety Databases. Reports will be available for public viewing. AHRQ will include NPSD data in the National Healthcare Quality and Disparities Annual Reports.

Benefits of PSOs
There are several benefits of working with a PSO (see Table 1). First, PSOs offer a nationally supported, provider-driven patient safety and quality improvement system. Providers retain control of their patient safety data. The protected space provided by PSOs fosters a culture where reporting is encouraged and safe. Physicians, nurses, pharmacists, and any licensed healthcare provider or facility can participate. Second, providers working with PSOs gain access to patient safety expertise. They receive federally mandated confidentiality and privilege protections, including that for analyses beyond the initial report (eg, root cause analysis). The PSO enables a shared learning environment within the provider’s system and other PSOs. NPSF

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<tr>
<th>Benefits</th>
<th>Downsides</th>
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<tr>
<td>Available to all healthcare providers</td>
<td>Data release and non-identification</td>
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<tr>
<td>Applies to all settings of health care—hospital, skilled nursing facilities, etc.</td>
<td>Numerator data only (voluntary reporting)</td>
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<tr>
<td>Applies to quality and patient safety data</td>
<td>New program – PSOs just getting started</td>
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<tr>
<td>Consistent minimum confidentiality and privilege protection across all states</td>
<td>No funding</td>
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<tr>
<td>Any quality or patient data developed and sent to a PSO</td>
<td>Concerns about duplicate reporting</td>
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<td>National aggregation of data</td>
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<td>Local, regional, and PSO to PSO</td>
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<td>Aggregate reports available to public through NPSD</td>
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<td>Voluntary</td>
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<td>Strict limits on data release and nonidentification requirements</td>
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<td>PSOs provide feedback to local healthcare providers</td>
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Table 1. Benefits and downsides of PSOs

Common Format for federal reporting
Standardized data elements and reporting formats are essential components of a national adverse incident reporting system. Both are necessary to aggregate data, analyze results, and compare organizations and practices over time. AHRQ’s Common Format enables standardization and aggregation of PSO data at the local, regional, state, and national levels. Most importantly, it accelerates the ability to identify and disseminate information about safety problems and evidence-based solutions, which is of great benefit to patients and providers. This also accelerates widespread adoption of best practices that are tied directly to improved patient care and better health outcomes. Data aggregation also serves as an important resource to inform AHRQ’s research agenda.

The AHRQ Common Format supports standardized reporting of all patient safety concerns, including incidents, near misses, and unsafe conditions. All types of events can be captured (eg, common and rare, discrete modules for blood, devices [including those involving health information technology]), falls, healthcare-acquired infections, medications, perinatal, pressure ulcer, surgery and anesthesia) across multiple provider settings (eg, hospital, nursing home).

Currently, a federal interagency collaborative is working on development of the Common Formats (common definitions and reporting standards).
The Government Accountability Office (GAO) is also conducting a study on the drug shortage crisis. (Personal communication with the offices of Senators Casey, Blumenthal, and Harkin; May 4, 2011.)

The FDA held a public workshop on September 26, 2011. The workshop was intended to provide information for, and to gain additional insight from, professional societies, patient advocates, industry, consumer groups, healthcare professionals, researchers, and other interested parties about the causes and impact of drug shortages, and possible strategies for preventing or mitigating drug shortages. There were 47 speakers, including panel members who participated in the proceedings. A discussion led by Nancy Davenport-Ennis of the National Patient Advocate Foundation presented the patient's perspective on the issues. A collective response from healthcare professionals is key

What can healthcare professionals, especially patient safety officers, do while the drug shortage crisis continues?

- Everyone in healthcare needs to be aware of drug shortages' potential to harm patients. Rationing, making changes in therapy, using alternative medications, continually educating employees, and updating procedures, policies, and IT systems will be commonplace. Healthcare providers should work collaboratively with the pharmacy and with established medication committees such as their state's Pharmacy and Therapeutics (P&T) committee.

- Processes may need to be changed. Prescribers, nurses, pharmacists, respiratory therapists, and others involved in drug therapy must be aware of the different medications that may be used for a given indication and their dosing, preparation, administration, and monitoring requirements.

- Electronic prescribing systems, dispensing cabinets, smart pumps, medication administration records, and pharmacy systems will need constant updating. Many changes and decisions will need to be made without much lead time.

- Everyone must be aware of the extra labor necessitated by drug shortages.

- Hospital ethics committees may need to help decide who receives treatment with first-line agents or alternative medications when available.

The drug shortage crisis affects everyone, and healthcare professionals need to strongly consider different courses of action when making therapeutic decisions. NPSF

References
employ their individual artistry, and engenders cooperation and support throughout all levels of the organization.

Healthcare Simulation Live on Stage
The final plenary featured a live healthcare simulation introduced and facilitated by Jeff Cooper, PhD, and Haru Okuda, MD. As Cooper began the presentation, a member of the audience took ill—or so it appeared. The patient was taken to the “emergency room” set up on stage, where he was treated by Jared, a nurse with 1 week of work experience after completing nursing orientation.

In the scenario, Jared gave the patient aspirin, following the protocol for chest pain, but he failed to ask about allergies. The patient was allergic to aspirin and began to show signs of an anaphylactic reaction. Two attending physicians and nurses responded to the case, identified the problem, stabilized the patient, and had him transferred to the coronary care unit for further treatment.

Although the simulation depicted a medical error, it became a story about disclosure. The team called in the patient safety officer after stabilizing the patient. The patient safety officer assessed the situation and recommended that the attending physicians disclose the error to the family.

In live voting by the audience:
• 85% agreed an apology was necessary in this case.
• 65% said simulation had not been used at their institutions to practice disclosure.

The program included a debriefing of the initial clinical encounter, then one of the disclosure, followed by a question-and-answer period.

In closing, Cooper emphasized that simulation “is a technique, not a technology.” The program showed that simulation can be used to practice any skill—but that the key to learning from simulation is to conduct a thorough debriefing.

With the help of the dedicated efforts and expertise of its planning committee and faculty, the generosity of its sponsors, and the enthusiastic engagement of participants, the NPSF Annual Congress provides a valuable resource for the patient safety community. As the field of patient safety expands in scope and complexity, the NPSF Congress will continue to evolve in this role. To learn more about the NPSF Congress, visit npsfcongress.org.

NPSF Recognizes Members of the AHA-NPSF Comprehensive Patient Safety Leadership Fellowship

The AHA-NPSF Comprehensive Patient Safety Leadership Fellowship, now in its eleventh year, is a transformational learning experience dedicated to preparing the next generation of patient safety, quality, and performance improvement leaders. The Fellowship is a year-long program culminating with the completion of an Action Learning Project demonstrating the Fellow’s ability to apply the concepts learned.

In 2011, program co-sponsors the American Hospital Association (AHA) and the National Patient Safety Foundation (NPSF) adapted the curriculum to include components identified by the NPSF Lucian Leape Institute as critical to efforts to improve the safety and quality of the healthcare system. The redesigned curriculum extends the program’s traditional focus on core patient safety knowledge, while also providing greater focus on emerging topics and realities driven by changes in the healthcare environment.

Details on the 2012–2013 Fellowship will be available later this autumn. For more information, visit www.ahafellowships.org.

Reference

Patient Safety Awareness Week 2012: Be Aware for Safe Care

Join healthcare organizations and communities across the country and around the world in celebration of Patient Safety Awareness Week March 4–10, 2012. NPSF offers tools and resources designed to help you make the most of the week.

This year’s theme, Be Aware for Safe Care, emphasizes the need for every member of the healthcare team, from patients to providers, to understand the importance of patient safety and to recognize the range of efforts being made to improve health safety in the US and internationally. The campaign seeks to make patients, providers, and the public aware of the ways they can participate in these efforts and partner to improve patient safety.

To learn more about the event and how you can get involved, go to www.npsf.org/hp/psaw/.

Members of the American Society of Professionals in Patient Safety (ASPPS) receive a discount on Patient Safety Awareness Week Toolkits and items on the NPSF Store. Members of the NPSF Stand Up for Patient Safety program receive a free toolkit as a benefit of membership.

For the first time, NPSF is offering co-branding opportunities for the promotional posters and educational brochure that are included with the toolkit. If you would like more information about this opportunity, please contact Sara Reardon at sreardon@npsf.org or 617-391-9906.

NPSF Offers CME-Accredited Educational Module on Reducing Diagnostic Errors

The National Patient Safety Foundation has released a new CME-accredited Educational Module: Reducing Diagnostic Errors.

Diagnostic errors are a serious concern in the patient safety field, but these errors have received relatively little attention and are difficult to detect and to study. Healthcare organizations need a more systematic approach for identifying diagnostic errors and educating clinicians on strategies for reducing the prevalence of these errors.

Compiled by experts in the field, the module provides a diverse set of tools and resources designed to educate healthcare professionals on diagnostic errors, including basic principles, common theories, and key strategies for reducing these errors at both the individual practice and system levels. In addition, the module provides a dedicated set of materials to engage patients and families in the prevention of diagnostic errors.

The module includes:

- A Primer for Clinicians
- Educational PowerPoint presentations
- Pre-recorded lectures by industry experts
- Sample workshop curriculum for teaching medical learners
- Case studies for discussion and practice
- Suggested readings and references
- Practice quiz
- Patient and family tools and resources
- Ask Me 3™ checklist: Good Questions for Getting the Right Diagnosis

For more information, visit www.npsfstore.com/categories/Education-Modules/.