

focus on Patient Safety

A NEWSLETTER FROM THE NATIONAL PATIENT SAFETY FOUNDATION

NPSF Announces Patient Safety Research and Development Agenda

In May, the NPSF approved an Agenda for Research and Development in Patient Safety, establishing the organization's strategy and tactics for its early years. "This agenda is important because it describes the landscape of patient safety research," says Jeffrey B. Cooper, Ph.D., chair of the NPSF Research Program, which prepared the agenda. "It identifies the large issues that need to be examined so we can better understand the problems in patient safety — and the kinds of solutions we can use to ameliorate them."

"We define patient safety as the avoidance, prevention, and improvement of adverse outcomes or injuries stemming from the processes of health care," says Dr. Cooper. These events include *errors*, *deviations* and *accidents*.

"Safety emerges from the interaction of the system's components; it does not reside in a person, device or department," he explains. "Improving safety depends on learning how safety emerges from interactions of the components. Patient safety is a subset of health care quality."

"The agenda offers investigators and funding agencies a big-picture view and good examples of where research is most needed. It will guide us in our decisions about where to put our energies and resources," says Dr. Cooper. "We trust that other agencies will add their support in funding research in the areas we have defined because it is so important to all of us who use the health care system."

NPSF's agenda defines two broad categories of issues needing research: safety problems — superficial characteristics, and underlying mechanisms — more generic, deeply rooted characteristics of the health care system. Efforts to improve patient safety must attack both categories. Improvement requires understanding technical work, identifying organizational factors that influence the safe work conduct, and identifying new vulnerabilities resulting from interventions.

"Solutions should not be implemented without assessing how they will work in the real world," says Dr. Cooper.

"Safety research must examine how changes may alter error

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tolerance, how operators detect and recover from failures in the initial stage, and how unintended side effects create new paths to failure."

Understanding the nature of technical work includes learning about the basis for expertise, success and challenges. Learning about underlying systemic factors influencing performance includes:

- Learning about when incidents and accidents occur;
- Anticipating new areas of concern as change occurs;
- Finding deeper and more generic patterns in failures; and
- Developing, prototyping, and evaluating new approaches to safety.

Interventions that may improve safety performance or help solve patient safety problems include:

- Improving mechanisms of patient identification;
- Using computerized drug order entry systems;
- Bar code scanning of blood products;
- Addressing language barriers and cultural differences that may lead to poor provider/patient communications;
- Regulating physician work hours;
- Designing new systems of safety reporting; and
- Using new training modalities, such as simulation.

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Which issues are *not* priorities for patient safety? Examples: problems that are not generally preventable, anticipated complications of medical treatment, known side-effects of drugs or procedural interventions, agendas much broader than safety, reducing malpractice claims or tort reform, non-serious injuries or quality of care alone, patient satisfaction, and reducing the cost of care.

NPSF defines *research* as encompassing development of techniques and interventions in addition to acquiring new knowledge. Research and development are needed to:

- Reveal the existence of and/or determine the frequency and magnitude safety problems;
- Evaluate the contribution of underlying human or system characteristics to safety problems;
- Assess the prevalence of underlying human or system characteristics in health care analogous to those known to be important arbiters of safety in other hazardous industries;
- Develop, pilot, and evaluate techniques or approaches to modify human or system characteristics (e.g., safety reporting, education and training, modified procedures for drug order entry); and
- Develop, pilot, and evaluate techniques or approaches to maintain patient safety efforts as integral to the culture of health care delivery. NPSF must also promote the development of a cadre of experts in this area.

All forms of research must be considered, including quantitative and qualitative methods. Innovation is especially important. New methods for understanding basic mechanisms, new measurements, and new ways to test interventions are needed. To do that, it is important to understand the “stories” that describe failures and to dig deeper into the issues essential to creating solutions.

For now, we advise against the NPSF itself being a research agency rather than one that supports others to do research. Conducting research would drain the NPSF’s limited administrative resources and requires competitively low overhead expenses that would be difficult to achieve. Furthermore, every decision to fund targeted research must recognize that NPSF overhead will be required to manage the project with the necessary oversight.

The following strategies are the basis for the agenda for NPSF-sponsored research:

- Foster and encourage investigator-initiated research;
- Target one or two special areas likely to achieve positive results in a few years; and
- Leverage NPSF’s resources by convincing other funding sources of the importance and scientific validity of patient safety research topics.

Priority should be given to projects that:

- Have high leverage, e.g., large output for small input;
- Have a broad impact on the population;
- Improve understanding of what is generally referred to as preventable problems, especially those brought about by human error and system failures;
- Propose innovative and creative methods of study or solutions to problems;
- Involve interdisciplinary research teams; and
- Do not have other sources of funding.

While it’s difficult to measure the success of a research program objectively, indicators will include publications reporting the results of NPSF-funded research, the use and implementation of that research, and how the information from NPSF-funded studies is used elsewhere. NPSF also hopes to facilitate the expansion of priorities of federal agencies and private foundations as part of its research goals. Ultimately, the impact on front-line providers will be a very good sign that the program is successful. [NPSF](#)

**NPSF gratefully acknowledges
the efforts of the Research
Program members:**

Jeffrey B. Cooper, PhD, Chair
Joan Fitzmaurice, RN, PhD
David Gaba, MD
Larry Goldman, MD
Kenneth Kern, MD
Bryan Liang, MD, PhD, JD
Denise Martin-Sheridan, CRNA, EdD
Michael Ragan, DMD, JD
Matthew Rice, MD, JD
Karlene Roberts, PhD
Jane Takeuchi, PhD
Albert Wertheimer, PhD
David Woods, PhD

our thanks

How Does Cultural Competence Affect Patient Safety?

BY CARRIE CAMERON, PH.D.

Carrie Cameron, Ph.D.,
is senior consultant with
Multicultural Health Care
Solutions, Houston TX.

The following scenario is based on actual events occurring in Houston, Texas:

A 25-year old Latina mother brings her three-year-old daughter in to the clinic for treatment for an intestinal disorder. The symptoms she reports are fever, vomiting, and diarrhea. In uncertain English, she describes the illness as 'empacho' but doesn't know how to translate that word. 'Empacho' doesn't mean anything to the 43-year-old Anglo physician, so she moves on. The physician prescribes antibiotics, Tylenol, and Pedialyte, and tells the mother to report back after three days.

Three days later, the mother comes back in to the clinic reporting no change, so the physician prescribes a different antibiotic. After this visit the mother doesn't report back. When she brings her daughter in four months later for an immunization, the physician reviews the chart and inquires about the outcome of the stomach illness. The mother smiles politely and mumbles, "It was okay." The little girl seems slightly lethargic and inattentive.

At first glance, nothing particularly remarkable has happened in this incident. But a closer examination, illuminated by some basic cultural information, reveals a more disturbing picture. 'Empacho' is an everyday illness category held among many traditional Latinos. It is described as an intestinal or stomach obstruction resulting from a clump of food attaching itself to the stomach or intestinal wall. What the physician doesn't know is that the mother has been treating her child's empacho with a traditional home remedy known as greta — lead powder with up to 99% concentration. It is one of a number of treatments that may be given for empacho. Greta is, unfortunately, effective — at least temporarily — in relieving the symptoms of empacho.

Several factors at work in this incident underscore the need for cultural competence in health care. The most obvious: health care professionals need a working knowledge of the more common traditional health practices among various ethnicities. Few of these practices pose a health threat, but even where they do not, their use may lead to misunderstandings with serious consequences.

For example, many traditional Southeast Asians practice

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coining, a form of dermal abrasion used to release 'bad wind' (what mainstream Americans might identify as cold symptoms). A coin is rubbed vigorously on the skin, leaving a bruise. The practice is harmless — but there have been instances of clinicians, unaware of the nature of the marks, interpreting them as evidence of physical abuse and contacting child-protection authorities.

Other patient safety issues include use of prescription drugs, available at flea markets, not followed by a physician; modification of dosages at home to alleviate side-effects; and avoidance even of urgent care due to lack of trust in health care professionals.

Equally as important as learning about the beliefs and practices of non-mainstream groups is developing cross-cultural skills. A culturally adept provider uses good communication techniques, is able to recognize cultural influences on the encounter, and can find creative compromises to reach a solution satisfactory to all. Culturally competent care is patient-centered care.

Some skills useful for a health care professional in a cross-cultural situation include:

- Having a plan for rapidly contacting an interpreter and/or culture broker when necessary and having informational materials on other cultures close at hand;
- Using good rapport-building skills to help the patient or family members develop a sense of trust and comfort with the physician;
- Attending carefully and respectfully to informal or folk diagnoses and following up by exploring customary

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First Do No Harm

A Practical Guide to Medication Safety and JCAHO Compliance

EDITED BY ??

REVIEWED BY PAMELA M. BARNARD, MSLS, AHIP

book review

First Do No Harm, (1999, ISBN: ????????????) the third book on medication safety reviewed in this newsletter, offers a practical guide to medication safety and JCAHO compliance.

As the book's introduction states, "if medical treatment can't always make patients better, it certainly should not make them worse, ... and medication is often the reason why [it does]."

Medication errors can be expensive — in human lives and dollars alike. When it comes to tracking the exact costs, it is easier for the health care industry, as well as society at large, to blame individuals and institutions. But the underlying systems are the real problem.

The purpose of *First Do No Harm* is to show how the way we think about safety and accountability in health care is starting to transform the culture in which health care operates. By providing details on relevant programs and initiatives in medication safety, the book can be a springboard for change.

The book's five chapters follow a natural progression, first placing the new approach to error prevention in the context of the overall magnitude of the problem. The authors then provide more detail on how the systems approach can be applied with new technologies and processes to improve the safety of drug treatment. Next, it discusses how to perform a root-cause analysis, "health care's newest technique for responding to adverse events," and how to design and implement improvement proposals. The book ends by discussing JCAHO accreditation standards for medication use and offering compliance tips.

While acknowledging the difficulty of assessing actual death, injury, and error rates for medication use, Chapter 1 strongly supports the belief that a new approach is needed to significantly improve medication safety. This new approach has to do with admitting that preventing all adverse drug events (ADEs) is probably not possible, nor is eliminating human error by health care professionals. Admitting these two points begins to create an atmosphere where problems are identified through error-reporting, which can lead to system improvements. This theme echoes the previously reviewed

title, *Medication Use: A Systems Approach to Reducing Errors*, edited by Diane Demichelle Cousins, RPh.

Other "high-risk" industries such as aviation approach the challenge of safety improvement in similar ways. Chapter 1 shows how the Aviation Safety Reporting System (ASRS) has been working since 1975 to provide reporting incentives as well as to "strengthen the foundation of human factors safety research in aviation." In that system, information on reported incidents is shared through a database to supplement safety publications and to support policy-making and research on aviation safety.

Incident-reporting is also important in health care because compiling actual error data can help identify risk points along the medication-use continuum. This is much more important in a systems-analysis approach than an isolated identification of specific details about a particular event.

Chapter 1 outlines how the search for error patterns can lead beyond what researchers such as Lucian Leape, David Bates and David Cullen call "proximal causes." These are the "apparent 'reason' [an] error was made" — but not the root cause. Looking at an aggregate of the types of causes can point out underlying similarities, such as a breakdown in access to information. Chapter 1 concludes with graphic displays of both proximal causes of errors in one real-life study of medication error, and the underlying root causes or flawed and deficient systems behind those proximal causes.

All the chapters have helpful suggested further readings from prominent books and journals.

A basic knowledge of how humans interact with their surroundings underlies the redesign of systems to reduce the potential for errors. Chapter 2 begins by discussing human factors research and how researchers such as James D. Reason are beginning to develop a framework for explaining how, why, and when people err. The core idea: You can design systems that make it harder to commit errors, as well as "more difficult for mistakes to go undetected long enough to harm a patient."

While unit-dose distribution of medication adopted by most U.S. hospitals takes a step in the right direction "by ensuring

that a number of skilled people are involved in medication use," there is still much room for error. Standardized procedures and equipment can leave less to chance and take the burden off the health care professional's human tendencies to follow habit and previous patterns.

The author sounds a warning call in Chapter 2, acknowledging that the use of technology to "help ensure quality and accuracy during high-risk activities — like medication use — is less pervasive in health care than it is in other industries."

The book's discussion of specific technologies involving computerized prescribing and bar coding systems will be helpful to health care professionals looking for concrete ways to take advantage of the new technologies. Computer applications have even been taken as far as robotic drug dispensing at the University of Wisconsin Hospital and Clinics. Robots "don't get bored or tired, can't be distracted, and won't lose focus ... and won't be fooled by look-alike and sound-alike labels."

While technology can be helpful, the chapter concludes with an emphasis on humans — specifically pharmacists. William Kelly, PharmD, advocates the increased involvement of pharmacists in treatment decisions. Kelly argues that the costs involved in maintaining a larger, more clinically active pharmacy staff are small compared to the potential savings in prevention of medication errors.

Chapters 3 and 4 include the most practical aspects of the book. They offer actual how-to descriptions of gathering, presenting, and analyzing data for root-cause analysis, as well as designing and implementing improvement proposals.

The book presents a brief discussion of the JCAHO sentinel event policy with clear examples of a sentinel event ("an unexpected occurrence or variation involving death or serious physical or psychological injury, or the risk thereof"). This leads to a discussion of the root-cause analysis process, including:

- How to assemble a team.
- How to make teams and analyses effective.
- What makes a root-cause analysis thorough and credible.
- How to conduct an analysis, including how to identify "late-stage variations" (referred to in Chapter 2 as "proximal causes).
- How to use appropriate tools to support the root-cause analysis.

This section gives an especially useful basic description of the tools used in root-cause analysis. Examples include information-gathering tools such as interviews and surveys,

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as well as information-analysis tools such as flow charts, cause-and-effect diagrams, Pareto charts and decision matrices. It might have been even more helpful to include examples of actual options (or courses of action) as well as the criteria spelled out in the sample decision matrix.

Chapters 3 and 4 focus on the practical. Two case studies highlight an actual root-cause analysis performed at an unidentified West Coast facility, and a data-driven quality improvement initiative to reduce risks and costs of drug toxicity at University Community Hospital in Tampa, Florida.

Chapter 4 explains how once the root causes are identified, the next step is setting an action plan for improvement. The method used to design, test, and implement an action plan is called the FOCUS PDCA method: **Plan, Do, Check, and Act**. This method, based on early work by Walter Shewart and W. Edwards Deming, is also known as "The Deming Cycle." The authors outline the need for careful consideration of the team's composition and its tools to design and implement a quality improvement plan.

The difference between root-cause analysis and quality improvement is, in part, a reactive versus a proactive stance. Reactive root-cause analysis is needed after a sentinel event; proactive quality-improvement initiatives help prevent future events. Both involve identifying an actual or potential problem and then peeling away "causal layers to reveal the flaws in a system, process, policy, or procedure that are to blame." Both processes present challenges to health care organizations, but they can be made easier with more experience and by sharing the lessons learned.

The final chapter details the need to improve medication safety — not only to improve patient safety and thus

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Pamela M. Barnard, MSLS, AHIP, is a Senior Knowledge Consultant, Information Services, at Allina Health Systems in Minneapolis. She is a member of the Academy of Health Information Professionals and the Medical Library Association.

To order a copy of *First Do No Harm*, call Opus Communications at ????????

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book review

health-care quality — but to comply with relevant JCAHO standards.

The authors review JCAHO standards affecting medication use, including

- Care of patients (TX)
- Improving organization performance (PI)
- Managing information (IM)
- Education (PF)
- Patient assessment (PE)
- Human resource management (HR)
- Medical staff (MS)

The authors discuss “hot-button” compliance issues identified by JCAHO surveyors as posing problems for accredited organizations, and outline compliance strategies. The

publisher will offer updates to the list of relevant standard numbers on its Web site (www.opuscomm.com) as the JCAHO releases them.

This final chapter will be especially useful to organizations getting ready for an upcoming survey. Neither of the previously reviewed titles included such detailed discussions of medication use in the JCAHO process.

Although it would have been helpful to know the precise authorship of each chapter in *First Do No Harm*, the individuals listed in the acknowledgments include physicians, pharmacists, nurses, academicians and industry executives. This diverse array of authors contributes to the depth, detail, and practical outlook offered in this useful book on medication safety and JCAHO compliance. [NPSF](#)

Cultural Competence

CONTINUED FROM PAGE 3

treatments and ideas about the causes and course of illness, etc., to help anticipate the patient's or family's possible behaviors and attitudes;

- Identifying vague responses, such as described in the earlier incident, as possibly concealing information the patient or family does not feel comfortable disclosing. It is very unlikely that patients or families will volunteer information they feel the provider will not approve of, whether non-compliance with medication regimens, use of traditional or alternative therapies, or any other information likely to be dismissed or chided;
- Showing high levels of tact and respect when reacting to the patient's concerns, to develop necessary trust; and
- Never dismissing, patronizing, or ridiculing a patient's or family member's traditional methods of health care. While education may be necessary, keeping the relationship comfortable is also crucial.

For more information on cultural issues in health care, please visit the following Web sites:

- EthnoMed: eber.u.washington.edu/~ethnomed/emedhp.htm
- Diversity Rx: www.diversityrx.org;

‘Equally as important as learning about the beliefs and practices of non-mainstream groups is developing cross-cultural skills. Culturally competent care is patient-centered care!’

- Office of Minority Health Resource Center: www.omhrc.gov
- *AM News*: This American Medical Association publication has an archive of cultural competence articles: www.ama-assn.org/public/journals/amnews/amnnav
- Australian Transcultural Mental Health Network: ariel.its.unimelb.edu.au/~atmhn [NPSF](#)

Correction

In the Summer issue of *Focus on Patient Safety*, we reported that the Foundation had announced five \$100,000 research grants. There were actually four grants totaling \$350,000. The editors regret the error.

Confronting the Risks of Medical Products: An FDA Perspective

BY DEBBIE HENDERSON

"Patient Safety: A Growing Community," an article in the spring issue of this newsletter, describes the 1998 Annenberg Conference on Patient Safety. In this brief feature, Lorri Zipperer of the NPSF highlights the patient community's critical role in enhancing the safety of medicine. Perhaps most notably, the 1998 conference elicited broad consensus that a "sea change is needed if the health care system is to become a safer place for patients."

A book review in the previous issue of this newsletter also focuses on a systems approach to improving the safety of health care. In the book *Medication Use: A System Approach to Reducing Errors*, the authors concur that preventing medication errors requires not only a look at the obvious players in the drug delivery chain — e.g., the doctor who prescribes, the pharmacist who dispenses and the nurse who administers — but an examination of the entire system of health care delivery from prescriber to patient.

The Food and Drug Administration (FDA) echoes this call for a systems approach to improving patient safety in its recent report "Managing the Risks from Medical Product Use." Unlike the above-mentioned reports that primarily focus on preventing the harm caused by medication errors, the FDA report examines the full range of risks associated with medical products. In addition to medication errors, these risks include:

- Product defects
- Known side-effects
- Remaining uncertainties after a medical product is marketed (e.g., unexpected side effects)

Even when used appropriately, the adverse effects linked to medical product use are associated with alarming morbidity and mortality. Like the NPSF reports, the FDA report's primary conclusion is that the Agency as well as the many other participants in health care delivery must work together in a systems framework to plan effective risk-management strategies. Our common goal of maximizing benefits while minimizing risks of medical product use can only be achieved if the system is fully understood, with roles and responsibilities clearly defined and well-integrated.

Medical products are developed and used within an elaborate system that has evolved over the years to ensure their safety. Manufacturers develop and extensively test medical products in both animal and clinical trials and submit data

'Our common goal of maximizing benefits while minimizing risks of medical product use can only be achieved if the system is fully understood, with roles and responsibilities clearly defined and well-integrated!'

to the FDA to support applications for marketing approval. The FDA thoroughly reviews the data submitted, and grants marketing approval only if the product's benefits for the population studied are judged to outweigh the known risks. A key goal of the FDA's pre-market review is to assure that appropriate information about the product's known risks and benefits, as well as instructions for use, are accurately communicated in the product's labeling. The FDA as well as the product manufacturers maintain active post-marketing surveillance programs. However, once an approved product enters the marketplace, responsibility for managing the risks and benefits of that product in use rests primarily with health care providers (the prescribing physician and, to varying degrees, other health care delivery personnel).

While the FDA determines the risk/benefit ratio of a medical product for a certain study population, it is the health care provider, in concert with the individual patient, who assumes responsibility for determining and managing the balance between the benefits and risks of any given therapeutic option that patient. The FDA's role in minimizing risks in the individual patient setting has been primarily to assure that accurate and adequate information is available to the health care provider.

For many decades, patients received personal and individualized medical care from a single physician. A single corner pharmacist dispensed a fairly limited array of prescription drugs, the community hospital received local patients, and a well-established insurance company footed the bills. Today's health care is delivered in the context of managed

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Debbie Henderson is the director of the Executive Operations Staff at the Center for Drug Evaluation and Research, Food and Drug Administration.

Focus on Patient Safety (ISSN 1097-0673) is the official quarterly publication of the not-for-profit National Patient Safety Foundation (NPSF) at the AMA, in Chicago, IL. The NPSF represents an unprecedented initiative to improve health care safety by studying why errors in the health care system occur and implementing safeguards to prevent such failures from injuring patients. NPSF board members represent every major segment of the health care system, as well as employers, medical ethicists, public health advocates and distinguished scientific research institutions.

The opinions expressed in this publication are not necessarily those of the National Patient Safety Foundation or of its board of directors.

To submit articles to, or publications for possible review in, Focus, please direct materials to: Lorri Zipperer, Managing Editor, Focus on Patient Safety, National Patient Safety Foundation at the AMA, 515 N. State Street, Chicago, Illinois 60610. Materials, inquiries and subscription requests for the publication will be accepted electronically at npsf@ama-assn.org or via fax at 312-464-4154.

Executive Director: Martin Hatlie
Managing Editor: Lorri Zipperer
Editor: Susan Raef, WordPower Communications, Inc., Chicago

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care and third-party payers, with multiple requirements layered on both the quality and cost of that care. Today's educated consumers also demand a more active role in making health care decisions and require increasingly more information and interaction with the health care delivery system. This changing environment, the dramatic rise in the number and complexity of available therapeutic options, and the ever increasing use of prescription, over-the-counter, and "alternative" medicines, combine to challenge the traditional system of managing the risks associated with the use of medical products.

Ensuring patient safety remains among the highest priorities for the medical product development and delivery system. All players in the system, from product manufacturers through product consumers, hold a large stake in assuring that the overall risk management system is working as efficiently and effectively as it can. In this changing environment, the FDA believes the time is right for all stakeholders to evaluate the strengths and weaknesses of the current system. Our mutual goal: to develop an improved strategy for managing medical product-associated risk. **NPSF**

National Patient Safety Foundation
515 North State Street
Chicago, Illinois 60610