Advancing the Science of Patient Safety

Paul G. Shekelle, MD, PhD; Peter J. Pronovost, MD, PhD; Robert M. Wachter, MD; Stephanie L. Taylor, PhD; Sydney M. Dy, MD, MSc; Robbie Foy, MSc, MBChB; Susanne Hempel, PhD; Kathryn M. McDonald, MM; John Ovretveit, PhD; Lisa V. Rubenstein, MD, MSPH; Alyce S. Adams, PhD; Peter B. Angood, MD; David W. Bates, MD; Leonard Bickman, PhD; Pascale Carayon, MD; Sir Liam Donaldson, MD; Naihua Duan, PhD; Donna O. Farley, PhD; Trisha Greenhalgh, MD; John Haughom, MD; Eileen T. Lake, PhD, RN; Richard Lilford, PhD; Kathleen N. Lohr, PhD; Gregg S. Meyer, MD, MSc; Marlene R. Miller, MD, MSc; Duncan V. Neuhauser, PhD; Gery Ryan, PhD; Sanjay Saint, MD, MPH; Kaveh G. Shojania, MD; Stephen M. Shortell, PhD; David P. Stevens, MD; and Kieran Walshe, PhD

Despite a decade's worth of effort, patient safety has improved slowly, in part because of the limited evidence base for the development and widespread dissemination of successful patient safety practices. The Agency for Healthcare Research and Quality sponsored an international group of experts in patient safety and evaluation methods to develop criteria to improve the design, evaluation, and reporting of practice research in patient safety. This article reports the findings and recommendations of this group, which include greater use of theory and logic models, more detailed descriptions of interventions and their implementation, enhanced explanation of desired and unintended outcomes, and better description and measurement of context and of how context influences interventions. Using these criteria and measuring and reporting contexts will improve the science of patient safety.

Ann Intern Med. 2011;154:693-696. www.annals.org
For author affiliations, see end of text.

In the decade since the Institute of Medicine published *To Err Is Human: Building a Safer Health System* (1), patient safety has assumed an important role in health care. Accreditation standards are stricter, most U.S. states now require serious medical errors to be reported, and Medicare will no longer pay for certain complications and outcomes of in-hospital care. Despite substantial changes (2) and isolated and heartening success stories (3, 4), evidence that these activities have improved patient outcomes is not entirely convincing (5, 6). The science of patient safety undoubtedly needs to mature.

Considering this background, the Agency for Healthcare Research and Quality (AHRQ) convened a panel of international experts in patient safety who reviewed the literature and discussed how to improve the conduct and reporting of patient safety interventions.

Researchers in patient safety face substantial challenges. Interventions are usually multifactorial and complex, target multiple persons (including patients, clinicians, care teams, and leaders), and use various incentives and levers (social, economic, and work redesign). For example, a checklist cannot work if individuals choose not to use it or the required supplies are unavailable, or the interface of a computer system may compromise its potential safety benefits.

The setting matters, as well. Although an intravenous medication that is effective in a 600-bed teaching hospital is also likely to be effective in an 80-bed rural hospital, a safety intervention may produce vastly different results in these 2 settings.

Study Design in the Evaluation of Patient Safety Practice

Experts debate what constitutes rigor in the design of studies on patient safety (7–10). Some investigators say that we do not need a randomized, controlled trial to determine whether parachutes work (11). This is certainly true, yet reflecting on why it is true is instructive. Strong theory supports the association between using the parachute and preventing death if a person jumps from an airplane; a parachute is a relatively standardized intervention; failures of implementation are obvious; we expect the intervention to be relatively insensitive to such contexts as the kind of airplane used and the height, weight, genetics, and personality of the jumper; the outcome is immediate and unambiguous; and the causal link between what the intervention is trying to prevent (hitting the ground) and the outcome (death) is direct.

Few patient safety interventions share these characteristics, and how best to evaluate the validity of patient safety interventions remains contested (8–10). We therefore focused on why and how we evaluate safety interventions and make causal inferences about their effectiveness. The reasons for this focus are 4-fold: 1) to help organizations judge whether an intervention shown to be effective elsewhere is likely to work in their setting; 2) to propose cointerventions, such as those designed to improve culture or leadership, that can support the successful implementation of a given practice; 3) to suggest to regulators and accreditors that an effective practice should not be required if the effectiveness varies widely across health care settings depending on key contextual elements; and 4) to evaluate whether the costs and unintended harms of an intervention may outweigh its benefits.

Table 1 shows the most important of these additional key evaluation issues that merit measurement and reporting.

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Table 1. **Recommendations for Evaluating the Effectiveness of Patient Safety Practices**

Explicitly describe the theory behind the chosen intervention components or an explicit logic model for why this patient safety practice should work
Describe the patient safety practice in sufficient detail that it can be replicated, including the expected effect on staff roles
Measure high-priority contexts in the 4 domains described in Table 2
Detail the implementation process, the actual effects on staff roles, and how the implementation or intervention changed over time
Assess the effect of the patient safety practice on outcomes and possible unexpected effects, including data on costs, when available
For studies with multiple intervention sites, assess the influence of context on the effectiveness of intervention and implementation

Describe the Theory

An explanation of the theory or logic model (that is, why should this patient safety practice work?) places the results of the evaluation in the context of previous knowledge. Most clinical intervention trials are based on voluminous molecular and physiologic science that establishes expectations as to why the intervention, such as a pill or a surgical procedure, should work; evaluations of patient safety practices require this intellectual scaffolding as well. However, the "basic science" supporting safety interventions is diverse and draws on clinical medicine, engineering, and social sciences.

For example, the media largely attributed the decrease in bloodstream infections associated with central venous lines to the use of a checklist. In reality, the intervention also involved measurement and feedback of infection rates and interventions to improve culture and teamwork. Such a multifaceted approach attempts to mitigate the technical and adaptive barriers, including those that are social, emotional, cultural, and political, to change clinician behavior (12). Qualitative and quantitative research methods are often needed to provide meaningful insights.

Describe Patient Safety Practices in Detail

A second key evaluation issue is describing the patient safety practice in sufficient detail for others to replicate it. Although this suggestion seems self-evident and has been recommended by other authors (13, 14), we found in our review of studies reporting several prominent patient safety practices that these descriptions were limited to a few sentences.

Detail the Implementation Process

The third key evaluation issue is detailing the implementation process. Reporting the challenges encountered and addressed as the implementation evolves is critically important. As with many complex interventions, the core intervention may be hard to distinguish from efforts to implement it, and these aspects sometimes blend over time. For example, one effort to reduce bloodstream infections recognized the importance of leadership support and a collaborative safety culture; as such, the investigators packaged these factors together as the safety practice (3, 15). Many experts even believe that it may not be possible or meaningful to disentangle the collection of co-interventions, or implementation, from the safety intervention.

Assess the Outcomes and the Influence of Context

Finally, an assessment of the outcomes that includes possible unintended effects is standard in most investigations of new clinical interventions (for example, evaluation of adverse effects in clinical trials) but is often ignored in evaluations of safety practices, even though such effects may outweigh any benefits (16, 17). Assessing the influence of context on effectiveness for evaluations with multiple intervention sites is conceptually similar to the analyses measuring the heterogeneity of treatment effects in studies of clinical interventions. Doing this in safety studies will both establish the degree to which a particular patient safety practice is context-sensitive and build the evidence base for understanding the role of context in general. For example, intensive care units without a director and intensivist or hospitalist staff experienced difficulties in implementing safety interventions to reduce health care–associated infections (Pronovost PJ. Personal communication.).

The Role of Context

Context is important in the successful implementation of patient safety practices. Although the definition of "context" may vary depending on the purpose of the study, one way that context can be thought of is as characteristics of the organization and its environment that influence the implementation and effectiveness of the patient safety practice. The influence of context may be one reason why interventions that carry the same "label" (for example, computerized order entry for medications) achieve different outcomes when they are implemented in different settings (18, 19). Although most authorities agree on the importance of context, the evidence base for context is minimal; moreover, agreement is lacking on what elements of context are most influential and therefore most in need of measurement and reporting in evaluations of patient safety practice.

On the basis of theory and the limited evidence available, we propose that high-priority contexts be grouped into 4 domains (**Table 2**). First, external factors are the environment in which the health care organization resides. This domain includes whether a regulatory authority or

Table 2. **High-Priority Contexts to Include in Reports of Patient Safety Research**

External factors, such as regulatory requirements, public reporting or pay-for-performance, and local sentinel events
Organization structural characteristics, such as size, complexity, and financial status or strength
Teamwork, leadership, and patient safety culture
Management tools, such as training resources, internal organization incentives, audit and feedback, and quality improvement consultants

accreditor, such as the Joint Commission, requires the safety practice; the existence of public reporting or pay-for-performance programs; or the occurrence of a sentinel event (for example, a wrong-site surgery) that garnered media attention. External contextual factors are generally not under the influence of the organization itself, although they may be influenced by policymakers or payers.

Second, organization structural characteristics include size, location, academic status, financial status, and the more challenging factor of organization complexity. These features are mostly fixed; the organization can influence them only slowly, if at all.

Third, teamwork, leadership, and patient safety culture are interrelated concepts that are likely to influence whether and how well the organization can implement and sustain an intervention. Over time, organizations can change these factors; the literature on the role of specific efforts to improve safety culture and teamwork (20) is hopeful, but opinions on the subject are mixed.

Finally, the presence of management tools is easily influenced by the organization. Examples include using internal audit and feedback, training, offering financial incentives, designating a local champion or coach, or hiring an external consultant.

Although all 4 contextual domains may not apply equally to all attempts to implement patient safety practice, evaluators should consider all domains to be potentially applicable. The full AHRQ report (21) includes more specific recommendations for assessing and reporting context measurement, including examples obtained from a diverse and representative sample of specific patient safety practices. As the evidence base for context matures, we expect that these domains and recommendations may change to reflect new findings.

Conclusions and Future Directions

Over the past decade, the toll of preventable adverse events and associated public awareness has led to powerful and diffuse pressures to improve. This pressure is deserved and needed, yet science must guide the way. Health care systems and providers must learn the right practice or set of practices to prevent harm.

Only in retrospect is it obvious how immature the science of patient safety was when the Institute of Medicine report on this subject was published. Even the well-meaning hospital chief executive officer, physician, or nurse who wished to prevent patient harm would have found (and often still does find) gaps in the literature. Knowing the right practices to implement (or, in the case of accreditors or regulators, to require [22]) or determining which adverse events are sufficiently preventable to merit public reporting or payment penalties depends on robust research evidence. As with all high-risk industries, we must weigh the costs of the safety interventions in medicine against the benefits (23).

Over the past few years, research has emerged that points the way to safer practices. Without high-quality research, an appreciation of the role of context, or reporting standards that allow all stakeholders to determine the applicability of study results to their own settings, there is a substantial risk that research results will be misinterpreted and misapplied. We urge researchers to measure and report on the recommendations that we have outlined here and advocate that editors and persons who fund research encourage such measurement and reporting when promoting and disseminating the results of safety-oriented research.

From RAND Health, Santa Monica, California, and Pittsburgh, Pennsylvania; Veterans Affairs Greater Los Angeles Healthcare System, Los Angeles, California; The Johns Hopkins University, Baltimore, Maryland; University of California, San Francisco, San Francisco, California; University of Leeds, Leeds, United Kingdom; Stanford University, Stanford, California; Karolinska Institutet, Stockholm, Sweden; Kaiser Permanente, Oakland, California; National Quality Forum, Washington, DC; Harvard Medical School and Massachusetts General Physicians Organization, Boston, Massachusetts; Vanderbilt University, Nashville, Tennessee; University of Wisconsin–Madison, Madison, Wisconsin; Department of Health and University College London, London, United Kingdom; New York State Psychiatric Institute, New York, New York; PeaceHealth, Bellevue, Washington; University of Pennsylvania School of Nursing, Philadelphia, Pennsylvania; University of Birmingham, Birmingham, United Kingdom; RTI International, Research Triangle Park, North Carolina; Case Western Reserve University, Cleveland, Ohio; University of Michigan, Ann Arbor, Michigan; University of Toronto, Toronto, Ontario, Canada; University of California, Berkeley, Berkeley, California; Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, New Hampshire; and The University of Manchester, Manchester, United Kingdom.

Disclaimer: The findings and conclusions in this article are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the AHRQ. Therefore, no statement in this report should be construed as an official position of the AHRQ or the U.S. Department of Health and Human Services.

Acknowledgment: The authors thank Lauren Carr, MPH; Breanne Johnsen, MPH; Patricia Smith; and Aneesa Motala.

Grant Support: By the AHRQ (contract HHSA-290-2009-10001C).

Potential Conflicts of Interest: Forms can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M10-2776.

Requests for Single Reprints: Paul G. Shekelle, MD, PhD, RAND Corporation, 1776 Main Street, Santa Monica, CA 90401; e-mail, shekelle@rand.org.

Current author addresses and author contributions are available at www.annals.org.

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Current Author Addresses: Drs. Shekelle, Taylor, Hempel, and Ryan: RAND Corporation, 1776 Main Street, Santa Monica, CA 90401.
Dr. Pronovost: The Johns Hopkins University, Second Floor, 1209 Thames Street, Baltimore, MD 21231.
Dr. Wachter: University of California, San Francisco, Box 0120, San Francisco, CA 94143-0120.
Dr. Dy: Health Services Research and Development Center, The Johns Hopkins University, 624 North Broadway, Room 609, Baltimore, MD 21205-1901.
Dr. Foy: Leeds Institute of Health Sciences, University of Leeds, Charles Thackrah Building, 101 Clarendon Road, Leeds, Yorks LS2 9LJ, United Kingdom.
Ms. McDonald: Stanford University, 117 Encina Commons, Stanford, CA 94305.
Dr. Ovretveit: Medical Management Centre, Floor 5, Berzelius Väq 3, Karolinska Institutet, Stockholm, SE-171 77, Sweden.
Dr. Rubenstein: Veterans Affairs Greater Los Angeles Healthcare System, Sepulveda Campus, 16111 Plummer Street, North Hills, CA 91343.
Dr. Adams: Division of Research, Kaiser Permanente, 2000 Broadway, Oakland, CA 94612.
Dr. Angood: National Quality Forum, 601 13th Street NW, Suite 500 North, Washington, DC 20005.
Dr. Bates: Division of General Internal Medicine, Brigham and Women's Hospital, 1620 Tremont Street, 3rd Floor, Boston, MA 02115.
Dr. Bickman: Vanderbilt University's Peabody College, Peabody #151, 230 Appleton Place, Nashville, TN 37203-5721.
Dr. Carayon: Department of Industrial & Systems Engineering, College of Engineering, University of Wisconsin–Madison, 3126 Engineering Centers Building, 1550 Engineering Drive, Madison, WI 53706.
Sir Donaldson: National Patient Safety Agency, 44 Butler's and Colonial Wharf, London SE1 2PX, United Kingdom.
Dr. Duan: Division of Biostatistics, New York State Psychiatric Institute, 1051 Riverside Drive, Unit 48, New York, NY 10032.
Dr. Farley: RAND Institute, 4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213.
Dr. Greenhalgh: Healthcare Innovation and Policy Unit, Centre for Health Sciences, Blizard Institute, Barts and The London School of Medicine and Dentistry, Abernethy Building, 2 Newark Street, London E1 2AT, United Kingdom.
Dr. Haughom: PeaceHealth, 14432 SE Eastgate Way, Suite 300, Bellevue, WA 98007-6412.
Dr. Lake: University of Pennsylvania School of Nursing, Room 302 Fagin Hall, 418 Curie Boulevard, Philadelphia, PA 19104-4217.
Dr. Lilford: Birmingham Clinical Research Academy, Room 110, 90 Vincent Drive, University of Birmingham, Edgbaston, Birmingham B15 2TT, United Kingdom.
Dr. Lohr: RTI International, 3040 Cornwallis Road, PO Box 12194, Research Triangle Park, NC 27709-2194.
Dr. Meyer: Massachusetts General Physicians Organization, 55 Fruit Street, Boston, MA 02114.
Dr. Miller: The Johns Hopkins University, 200 North Wolfe Street, Baltimore, MD 21287.
Dr. Neuhauser: Department of Epidemiology and Biostatistics, Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH 44106.
Dr. Saint: University of Michigan, 300 NIB, Room 7E08, Ann Arbor, MI 48109-0429.
Dr. Shojania: Sunnybrook Health Sciences Center, University of Toronto, Room H468, 2075 Bayview Avenue, Toronto, Ontario M4N 3M5, Canada.
Dr. Shortell: School of Public Health, University of California, Berkeley, 50 University Hall, Berkeley, CA 94720.
Dr. Stevens: Dartmouth Institute for Health Policy and Clinical Practice, 30 Lafayette Street, Lebanon, NH 03766.
Dr. Walshe: Harold Hankins Building-Room 6.36, Manchester Business School, The University of Manchester, Manchester M13 9PL, United Kingdom.

Author Contributions: Conception and design: P.G. Shekelle, P.J. Pronovost, R.M. Wachter, S.L. Taylor, R. Foy, K.M. McDonald, L.V. Rubenstein, A.S. Adams, P.B. Angood, D.W. Bates, L. Bickman, T. Greenhalgh, J. Haughom, E.T. Lake, R. Lilford, K.N. Lohr, G.S. Meyer, M.R. Miller, D.V. Neuhauser, G. Ryan, S. Saint, K.G. Shojania, S.M. Shortell, D.P. Stevens, K. Walshe.
Analysis and interpretation of the data: P.G. Shekelle, P.J. Pronovost, S.L. Taylor, S.M. Dy, R. Foy, S. Hempel, J. Ovretveit, L.V. Rubenstein, P.B. Angood, L. Bickman, D.O. Farley, J. Haughom, E.T. Lake, G.S. Meyer, M.R. Miller, D.V. Neuhauser, S. Saint, K.G. Shojania, S.M. Shortell.
Drafting of the article: P.G. Shekelle, P.J. Pronovost, S.M. Dy, R. Foy, J. Ovretveit, L. Bickman, G.S. Meyer, G. Ryan, K. Walshe.
Critical revision of the article for important intellectual content: P.G. Shekelle, P.J. Pronovost, R.M. Wachter, S.M. Dy, R. Foy, S. Hempel, K.M. McDonald, N. Duan, D.O. Farley, L.V. Rubenstein, A.S. Adams, P.B. Angood, D.W. Bates, T. Greenhalgh, J. Haughom, E.T. Lake, R. Lilford, K.N. Lohr, G.S. Meyer, M.R. Miller, G. Ryan, S. Saint, K.G. Shojania, D.P. Stevens, K. Walshe.
Final approval of the article: P.G. Shekelle, P.J. Pronovost, R.M. Wachter, S.L. Taylor, S.M. Dy, R. Foy, S. Hempel, K.M. McDonald, J. Ovretveit, L.V. Rubenstein, N. Duan, D.O. Farley, A.S. Adams, P. Carayon, L. Donaldson, P.B. Angood, D.W. Bates, L. Bickman, T. Greenhalgh, J. Haughom, E.T. Lake, R. Lilford, K.N. Lohr, G.S. Meyer, M.R. Miller, G. Ryan, S. Saint, K.G. Shojania, S.M. Shortell, D.P. Stevens.
Provision of study materials or patients: P.J. Pronovost, L.V. Rubenstein.
Statistical expertise: P.J. Pronovost, N. Duan, D.V. Neuhauser.
Obtaining of funding: P.G. Shekelle, P.J. Pronovost, R. Foy, L.V. Rubenstein.
Administrative, technical, or logistic support: P.J. Pronovost, S.L. Taylor, L. Donaldson.
Collection and assembly of data: P.G. Shekelle, P.J. Pronovost, S.L. Taylor, S.M. Dy, S. Hempel, J. Ovretveit, L.V. Rubenstein, G.S. Meyer, M.R. Miller, S.M. Shortell.