

The National Patient Safety Foundation

Agenda for Research and Development in Patient Safety

This document sets forth the strategy and tactics for research and development that will be pursued by the National Patient Safety Foundation (NPSF) in its early years. Together, these constitute an “agenda” for research and development in patient safety. No formula exists that could be applied to setting this agenda. The problem of patient safety begins with the lack of a common definition, the disparate views of the topic, and the lack of a systematic process for collecting and analyzing scientific data from which to set an agenda objectively. Yet, to effect real change—especially in the underlying culture of the system that delivers health care—and improves clinical outcomes, a strategy complete with tactics is needed. Absent scientific data, an informed intuitive process was used to establish the agenda, with success to be measured by the product judged as having face validity by the Board of Directors of the NPSF. The agenda will be modified over time to incorporate new understanding and concepts.

We begin by examining the definition of patient safety and set boundaries of the general areas that should have the attention of the NPSF. We then consider the kinds of information from which an agenda can be formed. We present the general nature of the safety issue. The agenda is then set in some broad and some specific terms.

The broad questions we address are:

- A. What is patient safety and what is patient safety research?
- B. What are the goals of research concerning patient safety?
- C. How much should the NPSF’s research agenda be driven by a targeted agenda versus the independent ideas of investigators?
- D. How much should research focus on underlying mechanisms of unsafe systems versus the development and testing of remedies for specific safety problems?

- E. What methodologies are appropriate for research in patient safety?
- F. By what processes should the research strategy and agenda of the NPSF be developed, maintained, and updated so that it is consistent with contemporaneous needs of the patient safety movement and the NPSF?
- G. By what measures will we know if our goals are being achieved?

A. What is Patient Safety?

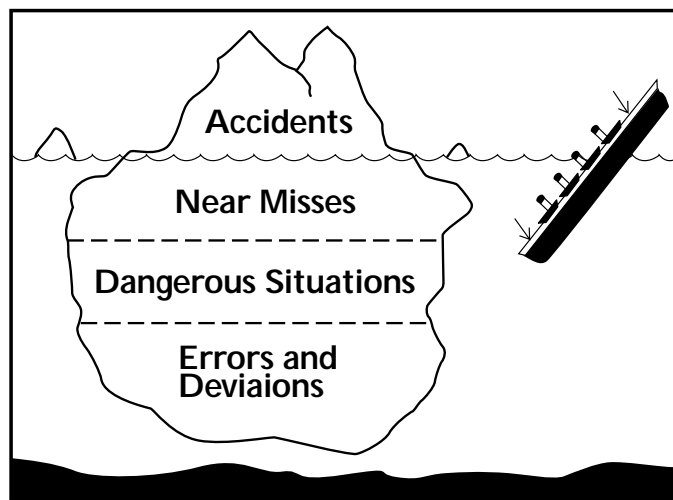
Background

The term “patient safety” is becoming widely used. As does the term “safety” alone, it means different things to different people. Those who formed the National Patient Safety Foundation had in mind some concept, individually and collectively, of what is patient safety. Yet, until now, no one has articulated what constitutes the spectrum of issues to which the NPSF should give its attention. Where does safety end and quality begin? What problems are better addressed in a context of medical complications or public health? What should be the boundaries of patient safety in which the NPSF operates its research and other programs?

Defining Characteristics of Patient Safety

Based on these materials, patient safety can be defined as incorporating the following points:

1. Patient safety has to do primarily with the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care itself. It should address events that span the continuum from what may be called “errors” and “deviations” to “accidents” (See model below).
2. Safety emerges from the interaction of the components of the system. It is more than the absence of adverse outcomes and it is more than avoidance of identifiable “preventable” errors or occurrences. Safety does not reside



Battles JB, Kaplan HS, van der Schaaf TW, Shea CE. The attributes of medical event-reporting systems. *Arch Pathol Lab Med.* 1998;122:231-238.

in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components.

3. Patient safety is related to “quality of care”, but the two concepts are not synonymous. Safety is an important subset of quality. To date, activities to manage quality, such as quality assurance, continuous quality improvement, total quality management, etc, have not focused sufficiently on patient safety issues.

Using several information-gathering processes conducted by the NPSF, coupled with historical materials about safety in other domains, the outlines of patient safety can be defined. These processes are:

1. The request for Letters of Intent (LOI) to apply for grant funding from the NPSF.
2. The criteria resulting from the NPSF Research Program’s deliberations on which LOIs to invite to submit full proposals.
3. The survey of Program members regarding possible topics to be considered as relevant and important to patient safety.
4. The topics addressed in abstracts submitted to the 1998 conference on patient safety.
5. The presentations at the 1997 Workshop on Assembling the Scientific Basis for Progress on Patient Safety and position papers statements by experts participating in that conference.

Note: The NPSF published a 1998 monograph on the results of this workshop entitled A Tale of Two Stories: Constrasting Views of Patient Safety. This document is available on its web site at www.npsf.org.

Continuum of Patient Safety

Patient safety research efforts span a continuum from understanding the roots of system and individual failure, through developing interventions to mitigate those failures, to assessing the effect of implementation of error reduction processes.

Examples on the continuum are:

| <i>Epidemiology of Error</i> | <i>Error Mechanisms</i> | <i>Developing Interventions</i> | <i>Implementation of Error Reduction Processes</i> |
|--|-----------------------------|---|---|
| Observational studies of error incidence | Analysis of technical work | Creation and trial of experimental reporting system | Effectiveness testing of broadscale reporting system |
| Descriptive studies of error typology | Analysis of error processes | Creation and trial of error reduction process | Effectiveness testing of simulation for improving performance |

Efforts to improve safety are needed at all points along this continuum. Furthermore, improvement requires an understanding of technical work, of organizational factors that influence the safe conduct of that work and, especially, of new vulnerabilities that are introduced whenever an

intervention is made. It is not sufficient to suggest implementing solutions to identified safety problems without assessing how they will work in the real world. Safety research must examine how changes may alter error tolerance, support detection and recovery from incipient failure and recognize and address unintended side effects that create new paths to failure.

Patient safety research can be defined in two broad categories of problems: safety problems and underlying mechanisms. Below is a definition of this rubric of patient safety and some examples of issues that are in need of attention.

Safety Problems: Failures in specific health areas. Some refer to these as “phenotypes,” ie, the superficial characteristics of the system as opposed to underlying mechanisms:

- Prevalence and cause of medication errors by health care personnel in all settings;
- Surgery or procedure on wrong part of body;
- Errors in performance of hazardous activities (surgery, anesthesia, radiation therapy, etc);
- Misdiagnosis;
- Selection of inappropriate treatment; and
- Nosocomial infection.

Underlying Mechanisms for Safety Problems: Often called “genotypes” because they are more generic, deeply rooted characteristics of health care systems:

- Latent failure in organizational structure or processes;
- Safety culture and the blame processes;
- Safety reporting, eg, incident reporting and other mechanisms for learning about systemic vulnerabilities;
- Organizational learning processes and barriers;
- Production pressure;
- Fundamental human limitations-performance shaping factors;
- Fatigue and sleep deprivation;
- Stress;
- Human factors design in devices and systems;
- Coordination and cooperation across people and boundaries (coordination infrastructure);
- Education and training processes for safe procedures; and
- Special problems of sectors that are severely resource-limited.

Elements of Research

1. One of the most important approaches to patient safety research is to understand the nature of technical work, including:

- The basis for expertise and success;
- The factors that challenge expertise and success; and
- Balancing a view of the practitioner's world with a view of the various aspects of human performance that play out in that setting.

2. This work goes beyond the surface characteristics to discover underlying patterns of systemic factors that influence performance. Developing this understanding supports:

- Learning about systemic vulnerabilities when incidents and accidents occur;
- Anticipating new areas of concern as change occurs;
- Finding deeper and more generic patterns in failures;
- Developing, prototyping, and evaluating new approaches; and
- Linking the patterns in these to specific health care contexts.

3. Among the interventions that may improve safety performance or ameliorate patient safety problems are (some of which are related to issues above):

- Improving mechanisms of patient identification;
- Computerized drug order entry;
- Bar code scanning of blood products;
- Regulation of physician work hours;
- Changes in health care culture;
- Reorganization of health care;
- Language barriers and cultural differences that may lead to poor provider/patient communications;
- New systems of safety reporting; and
- Use of new training modalities, eg simulation.

For some of these, research is needed to prove efficacy; for others, research is needed to test implementation or effectiveness.

4. The following are examples of issues that are not priorities for patient safety:

- Problems that are not generally preventable;
- Anticipated complications of medical treatment, known side effects of drugs or of procedural interventions;
- An agenda that is much broader than safety;
- Reducing malpractice claims or tort reform*;
- Involving non-serious injuries or quality of care alone;
- Patient satisfaction*;
- Reducing the cost of care*

* These items could have a priority when they have a direct connection to patient safety or we have defined it.

B. What are the Goals of Research Concerning Patient Safety?

The patient safety movement and the NPSF have many goals in addressing the issues of patient safety. Research is an important component of a broader strategy to improve safety. The term “research” encompasses “development” of techniques and interventions in addition to the acquisition of new knowledge. In particular, research is needed to:

1. Reveal the existence of and/or determine the frequency and magnitude of the occurrence of known or new safety problems (broadly interpreted this could be considered as questions of epidemiology);
2. Assess the contribution of underlying human or system characteristics to safety problems;
3. Assess the prevalence of underlying human or system characteristics in health care that are analogous to those known to be important arbiters of safety in other hazardous industries;
4. Develop, pilot test, and evaluate techniques or approaches to modify human or system characteristics including such items as safety reporting, education and training, modified procedures for drug order entry, etc; and
5. Develop, pilot test, and evaluate techniques or approaches to maintain patient safety efforts as an integral part of the culture of health care delivery, similar to what exists in the aviation and nuclear power industries.

Beyond adding to the actual knowledge and techniques generated by patient safety research support, we must seek to encourage and support research in patient safety to promote the development of a cadre of experts and expertise in this area.

C. Targeted vs. Investigator-initiated Research

There are several ways to address the support of research. Two basic strategies include:

1. Rely on proposals initiated by investigators, and
2. Target support to topics deemed important in the research agenda.

These strategies are not mutually exclusive. There are advantages and disadvantages to each. In addition, the decision on which strategies to pursue, and to what degree, will be dependent on the financial resources of the Foundation at a given time. Currently, the funds available to support research are modest, and the field of research in patient safety is in its infancy. Thus, the Foundation’s most important role will be as a catalyst, providing seed money for innovative work at the “pilot” stage, rather than definitive funding for projects likely to achieve definitive, dramatic results. Success is likely to come from some surprising directions rather than “obvious” solutions.

1. Investigator-initiated Research Support

Relying on investigator-initiated proposals has many advantages. Investigator-initiated research is the central core of most biomedical research. Programs that allow for individual investigators to define the scope of their projects solicit ideas from the broadest source possible.

This minimizes the risk of missing important and novel ideas due to pre-existing prejudices within the NPSF. It invites participation at the earliest stages from those in the best position to carry out the work. It is the most powerful way to develop a cadre of investigators active in this arena, since it is likely that even investigators who are unsuccessful in receiving funding from this source will seek funding elsewhere. It lends itself to the solicitation of innovation and pilot work that, by necessity, appears to be the NPSF's most likely current focus.

The main disadvantage of relying on investigator initiation is that investigators may not have the same view of the importance of topics as does the Foundation itself through its officers and Research Program. To the extent that NPSF perceived critical topics are not addressed by investigators' proposals, research on these topics will be missed.

2. Targeted Support

Targeted support has advantages. To the extent that particular topics or issues can be agreed upon as critical, targeted support can guarantee solicitation of proposals to address them. Further, targeted support may be more likely to bring forward the full spectrum of investigators and organizations able to address a particular area. A specific target also may lead to higher public visibility and be the nucleus for raising funds, possibly allowing more funds to be addressed to the targeted area than to the diversity of ideas generated by individual investigators.

The disadvantages of targeted support are: one, that it presumes that the critical topics or approaches can be articulated; two, that it may tend to promote a parochial view of the broad issues of patient safety; and three, that its very advantages in visibility and fund-raising may tend to squeeze out investigator-initiated support that may have a benefit in the long run. Indeed, in a field as young as patient safety, targeting research may artificially narrow the innovative and creative processes necessary to develop a sustainable patient safety effort.

Among the topics and areas that should be considered for targeted support when resources are available include:

- Incident reporting systems;
- Medication error;
- Safety culture;
- Patient handoffs and discontinuities in care;
- Missed diagnosis;
- Misdiagnosis;
- Medical device design;
- Coordination of medical work;
- Understanding of the nature of expertise; and
- Analyses of technical work.

3. Other Avenues of Research and Development

Independent of these two strategies, there are other avenues by which the NPSF may pursue R&D related to patient safety.

One is to collaborate with other agencies in supporting projects that appear likely to serve the research and development goals of the NPSF (regardless of where those projects are initiated). This approach has the advantage of leveraging NPSF support via collaboration. Conversely, it runs the risk of funding projects that will already be funded while leaving unfunded novel ideas that, largely for bureaucratic reasons, have not attained funding by another source.

Another useful strategy is to foster within other agencies the desire to provide research support themselves for projects that would otherwise be within the purview of the NPSF.

4. Research conducted directly by or under the administration of the NPSF

Opportunities will arise for research to be conducted directly by or managed by the staff or others directly affiliated with NPSF. That is, the NPSF could be considered a research agency rather than merely an agency that supports research. We counsel against that at the current time since it would drain the very limited administrative resources of the NPSF and would require unachievable overhead to be a competitive research organization.

D. Research on Basic Mechanisms vs. Identified Safety Problems

Being a characteristic of systems, patient safety is a complex phenomenon. The health care systems in place today have the characteristics they do because of a complicated interaction of organizational, economic, legal, social, and technical factors. These systems evolved into their current state and no portion of them can be altered easily even if data were available to show unequivocally the need for change.

Just as in research on diseases, an agenda for patient safety research and development must achieve a balance between research and development that addresses specific avenues to attack currently identified problems versus research on the fundamental underlying mechanisms that lead to the sub-optimal safety. Ultimately the research on underlying mechanisms can be more powerful since it can, in theory, show what characteristics of the system must be changed to achieve fundamental alterations in the processes of care. However, such research is difficult, will take a long time to achieve any measurable results, will by its nature travel down some blind alleys, and is likely to involve some contentious political issues.

Research along these lines would focus on such things as organizational structure and process in health care, especially in comparison to principles of high reliability organizations. These lines of inquiry would try to delineate

exactly what characteristics of the health care system(s) promote errors or adverse outcomes, which of these characteristics are amenable to modification, and outline the potential side effects of any modifications. It is likely that this kind of research will involve comparisons of health care to other high-hazard activities in society, and it will be important to determine in what ways health care is different intrinsically and irrevocably from other industries.

However, just as medical science does not give up finding new treatments for cancer as it attempts to understand the basic processes of the disease, it is prudent to investigate the surface level of identified problems and to study reasonable approaches already available to deal with them. Examples of these abound, but medication errors and procedures on the wrong body part are two examples that readily come to mind. While a full understanding of how such events occur (and continue to occur despite the industry's awareness of the problems) will require a more complete understanding of underlying mechanisms, reasonable approaches exist that may be expected to ameliorate these problems, if admittedly not to completely eradicate them.

In assessing the proper balance of these activities for the NPSF, we should be cognizant that existing agencies are more likely to fund research concerning currently identified problems, whereas there are few funding agencies to deal with the longer term research on underlying mechanisms. For example, research on medication errors may well be funded by organizations involved in the manufacture, distribution, and regulation of pharmaceuticals. These same organizations are less likely to fund "basic" research on the mechanisms of error and error propagation in complex organizations. Therefore, the Foundation should be careful not to lean too heavily in the direction of research on currently available avenues to attack currently identified problems, especially if in doing so it would reduce its ability to fund research on fundamental mechanisms with a longer time horizon, but with more profound potential implications.

E. Methodologies for Patient Safety Research

Because catastrophic outcomes are rare and measures of preventable outcomes are difficult to establish, research in patient safety does not easily fit into conventional quantitative models. Thus, all forms of research must be considered, including those that are quantitative and qualitative. Innovation is especially important. Research and development are needed in all areas, including the development of new methods for understanding of basic mechanisms, new measurements and ways to test interventions. Understanding the "stories" that describe failures and digging into the deeper issues that are essential to creating solutions are important.

F. How to Develop and Update the Research Agenda

The agenda must be set based on a set of research strategies. The agenda itself is a set of tactics to achieve the strategy. The problems encompassed in patient safety are so large and diffuse as to resist formation of a hard agenda, ie a set of projects that will meet some goal of reducing patient injuries from presumably preventable events. Implementation of tactics will be molded both by the resources available in any year, as well as by opportunities that present themselves.

The following strategies are the criteria for the agenda for NPSF-sponsored research.

1. Foster and encourage investigator-initiated research. This will secure the broadest base of research ideas with a constant (yearly) update of the most novel and important techniques and concerns while fostering the development of a research cadre. Funded ideas will yield results. Many unfunded ideas will acquire funding from other sources. In the first years, NPSF should give priority to proposals that have a more direct path to implementation in patient care, but also support research on more underlying mechanisms where the other funding criteria are strongly met.
2. Target one or two special areas that are likely to achieve positive results in the time frame of a few years. The topics may arise from unsolicited proposals to the NPSF or from ideas brought forward by members of the NPSF Board of Directors, programs or committees.
3. Leverage the resources of the NPSF by convincing other funding sources of the importance and scientific validity of patient safety research topics.

The general basis on which to judge support of projects from any source should be to give priority to those that:

1. Have high leverage, eg, large output for small input.
2. Have a broad impact on the population.
3. Improve understanding of what is generally referred to as preventable problems, especially those brought about by human error and system failures.
4. Propose innovative and creative methods of study or solutions to problems.
5. Involve inter-disciplinary research teams.
6. Work towards understanding or solving problems for which there are not other sources of funding.

The following tactics will implement this strategy:

1. Support investigator-initiated research projects meeting the general criteria for research and development funding. At current levels of funding for the research program, no less than two grant awards should be made to purely investigator-initiated projects. This investigator-initiated research would go through the standard grant cycle review.
2. If the Executive Committee of the Foundation believes that one particular topic in any year is of sufficient importance to warrant a special call for

proposals within the current grants program, a sub-solicitation within the overall request for proposals (RFP) can be devoted to that topic. Proposals for that topic would be evaluated separately from the general investigator-initiated proposals. The research evaluation of proposals submitted under the sub-solicitation should be conducted under the auspices of the Research Program, with special guidance for priorities given by the Executive Committee, if necessary.

3. If funding permits, special RFPs can be generated for specific topics. This will be especially advantageous in situations where the nature of the topic can allow sufficient funds to be raised to support more complex studies and interventions.
4. The Research Program will develop and maintain a list of currently recognized problems for which the Program and the Foundation's Executive Committee may decide to solicit targeted applications, or for which opportunities to collaborate with other organizations may seem particularly advantageous. This list should not be seen as an exhaustive definition of critical issues in patient safety.
5. The Foundation should be ready to respond to inquiries from other agencies about potential collaboration on projects that meet the joint goals of the agencies. It would be advisable to maintain contingency funding available for these "targets of opportunity." When such inquiries are received by the NPSF, an ad hoc committee drawn from the members of the Research Program should be appointed and convened by the Chair of the Research Program to assess whether (1) the inquiry is within this document's framework with regard to patient safety; and (2) whether the substantive proposal is technically feasible. If the Research Program Chair determines that expertise from the Research Program cannot adequately assess the proposal, eg, the proposal requires assessment by experts in and/or familiar with other industries, then the Chair will obtain the relevant expertise by accessing the NPSF National Health Care Safety Council. The ad hoc committee will then provide substantive comments on the proposal with a recommendation as to whether the Board of Directors and Executive Committee should proceed based upon the proposal's fit with the themes in this document and the project's technical rigor.
6. The NPSF should initiate meetings with other biomedical and social research funding agencies, both private and governmental, to publicize the need for research on patient safety issues as an important part of a comprehensive strategy of research to improve the health of the nation's citizens.
7. Both investigator-initiated and targeted programs should seek a balance between research on underlying mechanisms and interventions addressed to currently identified problems. On a continuing basis, the Research Program shall assess the projects supported to date in terms of this balance for guidance for its own deliberations and those of the Executive Committee.

G. How Will the Success of the Research Agenda Be Measured?

Success is relative. On one level, success should be measured by the information generated by the grant program. Substantive information gained from projects funded by NPSF will be an important measure as to the direct effects of the grant program. Thus, publications reporting the results of NPSF-funded research will be an important method of measuring the success of the research agenda.

The use and implementation of such work also are important considerations in measuring success: Has the information from the NPSF grant funded studies been put to use elsewhere? Have others obtained similar results in their systems? Have others used the study information in expanded and extended work? These assessments can be accomplished through a determination of citations of studies using NPSF funds.

A broader goal of the NPSF is education of the public regarding patient safety. Is the NPSF successful in providing such education? Newsclips, media coverage, survey data and public recognition of such activities are measures of the NPSF's success in delivering its message. To enhance its probability of success, NPSF must work with other organizations to educate the public regarding patient safety. Mere recognition of NPSF does not constitute success.

Another related goal is the ability for NPSF to increase the visibility of patient safety amongst other organizations. Thus, for example, expansion of priorities of federal agencies and private foundations to include patient safety efforts in their own agendas would be an important measure of success of the NPSF agenda.

Finally, and most difficult, the NPSF should attempt to determine whether the efforts in its grant program and educational activities has an impact upon front line providers. The best systems and reporting mechanisms in the world are ineffective if providers do not recognize them as important, if they are not accessible to providers, and if they are not used by providers. Survey data that accesses hospital, managed care organization, and private practice administrator and provider (including resident physician) knowledge and implementation of patient safety work is essential in assessing success. This subject may be a relevant topic for NPSF grant funding.

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For more information, contact the NPSF at 312-464-4848 or visit the web site at www.npsf.org