Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety and Quality Improvement Act of 2005

AHRQ
Agency for Healthcare Research and Quality

Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety and Quality Improvement Act of 2005

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Contents

Tables

Figures

Preface

As required by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act),[a] the Secretary of the Department of Health and Human Services (HHS) has prepared this Final Report to Congress on effective strategies for reducing medical errors and increasing patient safety in consultation with the Director of the Agency for Healthcare Research and Quality (AHRQ). It includes measures determined appropriate by the Secretary to encourage the appropriate use of effective strategies for reducing medical errors and increasing patient safety, including use in federally funded programs. As the Patient Safety Act also required, a draft of this report was made available for public comment and submitted for review to the Institute of Medicine, now the National Academy of Medicine. This Final Report, which is required to be submitted to Congress no later than December 21, 2021, includes updates and additions made to address feedback received from members of the public and the National Academy of Medicine.

Executive Summary

The report begins with an overview of the impetus for and objectives of the Patient Safety Act, its key provisions, and some milestones in its implementation. Currently, as a result of the Patient Safety Act, over 90 patient safety organizations (PSOs) are working with thousands of healthcare providers across the country to improve patient safety and the quality of healthcare delivery.[b] This legislation also required the Secretary to facilitate the creation of and maintain a network of patient safety databases (NPSD), which can leverage data contributed by these healthcare providers and PSOs into a valuable national resource for improving patient safety.[c] The work of PSOs and providers under the Patient Safety Act serves as a national learning system for patient safety improvement.

The report reviews some of the principles and concepts underlying effective patient safety improvement, many of which stem from approaches to safety that grew in industries unrelated to healthcare. It includes an overview of research and measurement in patient safety. The effectiveness of a given patient safety improvement strategy or practice must be measured over time as it is implemented in various healthcare settings. Measuring effectiveness in patient safety is complex because the problems and solutions are multifaceted and often context-dependent. Given this complexity, applying traditional evidence-based medicine approaches to evaluating the effectiveness of patient safety improvement strategies presents some unique challenges.

The strategies and practices for reducing medical errors and increasing patient safety presented in this report are those reviewed in AHRQ's Making Healthcare Safer reports, published in 2001, 2013, and March 2020 (the latest edition reviewed literature published between 2008 and 2018, prior to the onset of the COVID-19 pandemic). Together, these reports reviewed the existing evidence for the effectiveness of more than 100 patient safety strategies and practices used in hospitals, primary care practices, long-term care facilities, and other healthcare settings. These include cross-cutting strategies and topics such as patient and family engagement and teamwork training; safety topics specific to particular clinical interventions, such as medications and surgery; a variety of tools and processes, such as rapid response teams and antimicrobial stewardship; and practices that target prevention of specific harms, such as healthcare-associated infections and pressure injuries. Hyperlinks lead to the full text of the evidence review and to later updates regarding the assessment of evidence for the effectiveness for each strategy and practice. Scarcity of evidence at a given point in time does not necessarily equal lack of effectiveness. Conversely, the weight and direction of the evidence base can change as more studies

are conducted in different settings, the field's understanding of patient safety expands, and new research is published.

AHRQ, other Federal agencies, and nongovernmental organizations are important sources of tools, resources, and initiatives that encourage the use of effective patient safety improvement strategies. Moving effective patient safety improvement strategies into practice requires an understanding of the contextual factors that might hinder or facilitate implementation. It must also take into account the needs of the patients and healthcare providers who will be affected; the work structures, support systems, and organizational culture surrounding them; and the local resources and circumstances. The report describes an approach that has a track record of success in encouraging the use of evidence-based practices within a thoughtfully designed implementation framework that supports and improves safety culture, teamwork, and communication.

Several measures could accelerate progress in improving patient safety and encouraging the use of effective improvement strategies:

▸ Patient safety research, measurement, and practice improvement should encompass analytic approaches that support learning from how and why things go right and how to monitor risk [d,e,f] without losing sight of the importance of addressing specific adverse events and harms.

▸ There is a continuing need for more research to develop the patient safety evidence base because safety is an important aspect of care for every patient in all healthcare disciplines, specialties, settings, and modes of healthcare delivery. Expanding the use of research methodologies that explore and capture the complexity of patient safety problems and solutions will also advance the evidence base. [g, h, i]

▸ Translating evidence-based practices into real-world settings requires the development of clinically useful tools and infrastructure and often foundational changes in organizational culture, leadership and patient engagement, teamwork, and communication. Implementation must be designed with and from the perspectives of the people who will be most affected and should extend across the wide range of stakeholders who intend to support patient safety.

▸ Encouraging the development of learning health systems that integrate continuous learning and improvement in their day-to-day operations can speed the application of the most promising evidence to improve care. The concept of learning health systems can also facilitate the integration of patient safety practices with functions necessary to achieve other priorities, including the effectiveness, timeliness, efficiency, patient-centeredness, and equity of healthcare.

▸ The National Action Plan[j] put forth by the National Steering Committee for Patient Safety has the potential to advance and align efforts to encourage the use of effective patient safety strategies. Many recommendations throughout the plan focus on ensuring that foundational factors are in place and sufficiently robust to enable the successful deployment and use of strategies and practices for reducing medical error and increasing patient safety.

The work of federally listed PSOs and healthcare providers to reduce medical errors and increase patient safety in various clinical settings and specialties is highly valued, successful, and thriving. A study of a sample of Medicare-participating acute-care hospitals conducted by the Office of the Inspector General of the U.S. Department of Health and Human Services[k] in 2018 concluded that of hospitals that work with a PSO, nearly all (97 percent) find it valuable, and half rated it as very valuable. Among the most

important reasons why hospitals choose to work with a federally listed PSO, according to the study, are the opportunity to improve patient safety (94 percent cited this as very important in their decision to work with a PSO); the opportunity to learn from PSOs' analysis of patient safety data (87 percent cited this as very important); and the privilege and confidentiality protections (83 percent cited this as very important). The study also noted that a majority (80 percent) of hospitals that work with a PSO reported that feedback and analysis on patient safety events had helped prevent future events, and nearly three-quarters reported that such feedback had helped them understand the causes of events.

To date, PSOs have voluntarily submitted over 2 million records to the NPSD, which is the data infrastructure aspect of the Patient Safety Act. However, the NPSD's ability to publicly release data is constrained by limitations in the mechanisms currently available for data collection and the need to accumulate a sufficient volume of data prior to public release in order to protect confidentiality. The voluntary nature of the system and corresponding need to minimize the burden of data submission affects the nature, volume, and quality of the data available to the NPSD. Existing technology that might permit remote collaboration between and among a broad array of networks without actually transferring data, such as distributed data networks,[i] has the potential to resolve some of these limitations. Future advances in machine learning may enable evolution of the NPSD into a system that can accept unstructured or differently-structured data. Should any such new approaches to data infrastructure and transmission become feasible, progress in building the NPSD into a more comprehensive national patient safety learning system could be accelerated.

Considering the voluntary nature of the Patient Safety Act, the number and diversity of providers and PSOs who choose this framework for patient safety improvement confirm the significance of this law and its successful application. PSOs are making valuable contributions to the providers they work with, the safety of their patients, and the development of the NPSD as a resource for shared national learning about patient safety. The landmark Patient Safety and Quality Improvement Act of 2005 created a unique and powerful framework that is supporting patient safety and quality improvement work across the United States. That framework stands ready to support the collaborative national effort needed to make further progress in improving the safety and quality of healthcare.

Appendix A of this report addresses the specific recommendations made by the National Academy of Medicine, which reviewed the December 2020 Draft Report as required by 42 U.S.C. § 299b-22(j)(1). Appendix B describes the actions taken by HHS to meet the statutory requirements for development and review of this report and provides an overview of comments on the December 2020 Draft Report received from members of the public.

Endnotes

[a] The requirement for the Draft Report can be found at 42 U.S.C. § 299b-22(j)(1); for the Final Report, 42 U.S.C. § 299b-22(j)(2).
[b] Agency for Healthcare Research and Quality. Patient safety organization (PSO) program: Federally-listed PSOs. https://pso.ahrq.gov/listed. Date accessed October 29, 2020.
[c] Agency for Healthcare Research and Quality. NPSD: Network of patient safety databases. https://www.ahrq.gov/npsd/index.html. Date accessed October 29, 2020.
[d] Stevens JP, Levi R, Sands K. Changing the patient safety paradigm. J Patient Saf. 2019 Dec;15(4):288-289. doi: 10.1097/PTS.0000000000000394. PMID: 28691972.
[e] Fairbanks RJ, Wears RL, Woods DD, Hollnagel E, Plsek P, Cook RI. Resilience and resilience engineering in health care. Jt Comm J Qual Patient Saf. 2014 Aug;40(8):376-83. doi: 10.1016/s1553-7250(14)40049-7. PMID: 25208443.
[f] Braithwaite J. Changing how we think about healthcare improvement. BMJ. 2018 May 17;361:k2014. doi: 10.1136/bmj.k2014. PMID: 29773537; PMCID: PMC5956926.

[g] Davidoff F. Improvement interventions are social treatments, not pills. Ann Intern Med. 2014 Oct 7;161(7):526-7. doi: 10.7326/M14-1789. PMID: 25285545.

[h] Webster CS. Evidence and efficacy: time to think beyond the traditional randomised controlled trial in patient safety studies. Br J Anaesth. 2019 Jun;122(6):723-725. doi: 10.1016/j.bja.2019.02.023. Epub 2019 Apr 4. PMID: 30954239.

[i] Dixon-Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q. 2011 Jun;89(2):167-205. doi: 10.1111/j.1468-0009.2011.00625.x. PMID: 21676020; PMCID: PMC3142336.

[j] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement. http://www.ihi.org/SafetyActionPlan. Date accessed October 29, 2020.

[k] Office of the Inspector General of the Department of Health and Human Services. Patient safety organizations: hospital participation, value, and challenges. OEI-01-17-00420. September 2019. https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf

[l] Curtis LH, Brown J, Platt R. Four health data networks illustrate the potential for a shared national multipurpose big-data network. Health Aff (Millwood). 2014 Jul;33(7):1178-86. doi: 10.1377/hlthaff.2014.0121. PMID: 25006144.

Chapter 1.
The Patient Safety and Quality Improvement Act of 2005: Overview of the Statute and Its Implementation

1.1.   Impetus for and Objectives of the Patient Safety Act

Recommendations made by the Institute of Medicine (IOM, now the National Academy of Medicine) in its landmark report *To Err Is Human: Building a Safer Health Care System*[1] (referred to here as the IOM Report) were the impetus for the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).[2] The IOM Report brought attention to the problem of adverse events in the U.S. healthcare system, and it issued a call to action to incorporate safety principles used in other high-risk industries to make healthcare safer.

The IOM Report encouraged the promotion of voluntary reporting by healthcare providers but also noted that fear of legal discovery was a significant barrier. Because existing laws offered limited protection for information related to patient safety and quality improvement efforts and often did not apply when such information was shared beyond a single institution, action was needed to "encourage health care professionals and organizations to identify, analyze, and prevent errors without increasing the threat of litigation and without compromising patients' legal rights."[3] The IOM Report therefore included a recommendation that "Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality."[4]

Consistent with this recommendation, the Patient Safety Act created a framework for the development of a voluntary patient safety event reporting system to advance patient safety and quality of care across the Nation.[5] Without limiting patients' rights to their medical information, the law created Federal legal privilege and confidentiality protections for patient safety work product; that is, information that would be exchanged between healthcare providers and organizations specializing in patient safety and quality improvement, called patient safety organizations (PSOs). The law charged PSOs with analyzing and using this information to provide feedback and assistance to help providers minimize patient risk and improve the safety and quality of their care.

In addition to creating a protected legal environment where healthcare providers can share information and learning for improvement purposes beyond organizational and State boundaries, Congress also envisioned and created the potential for aggregating and analyzing patient safety data on a national scale. This part of the Patient Safety Act, the network of patient safety databases (NPSD), is a

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[1] Institute of Medicine (US) Committee on Quality of Health Care in America. To Err Is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000. PMID: 25077248.

[2] Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424, codified at 42 U.S.C. sections 299b–21 through 299b–26.

[3] Institute of Medicine (US) Committee on Quality of Health Care in America. To Err Is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000;112. PMID: 25077248.

[4] Institute of Medicine (US) Committee on Quality of Health Care in America. To Err Is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000;111. PMID: 25077248.

[5] H.R. Rep. No. 109–197. Patient Safety and Quality Improvement Act of 2005. 2005;9. https://www.congress.gov/109/crpt/hrpt197/CRPT-109hrpt197.pdf

mechanism that can leverage data contributed by individual healthcare providers and PSOs across the United States into a valuable national resource for improving patient safety.

The Patient Safety Act has been compared to programs that perform specified safety reporting and improvement functions for an entire industry or national healthcare system, such as the Aviation Safety Reporting System (ASRS) and the VA National Center for Patient Safety. Such systems operate under a single national directive that applies uniformly to all participants and have a single, centralized locus for receipt and analysis of all reports. In the case of ASRS, reports are submitted directly by individual personnel. The Patient Safety Act created a very different structure for supporting national learning and improvement. Unlike such centralized safety reporting systems, Congress designed the Patient Safety Act national learning system using a market-based approach that works by "allowing the healthcare industry to voluntarily avail itself of this framework in the best manner it determines feasible.[6] PSOs are neither funded nor controlled by the Federal Government; this is a learning system that "…allows the marketplace to be the principal arbiter of the capabilities of each PSO."[7] It is shaped by the diverse expertise, creativity and business plans of the entities that seek PSO listing and the providers they serve, the particular patient safety and quality improvement services they offer, and the healthcare providers that choose to engage particular PSO services that would not be undertaken without the Patient Safety Act protections. Across the country, PSOs are receiving, analyzing, and aggregating patient safety work product from the providers they serve and are engaging in patient safety improvement work with them, often across settings. The nature of the data they generate depends on the nature of the data providers (typically entities rather than individual healthcare personnel) choose to submit and the particular focus of the improvement work undertaken by the PSO and its reporting providers. PSOs that work with providers using the AHRQ Common Formats may volunteer to contribute nonidentified data to populate the NPSD, but they are not required to do so.

1.2. Key Provisions of the Patient Safety Act
This section provides an overview of the statutory structure and content for reference and to provide context for the report.

1.2.1. Definitions (Codified at 42 U.S.C. § 299b-21)
Several of the definitions in this section, unique to the statute, are central to understanding how it operates; for example, patient safety work product, patient safety activities, patient safety evaluation system, and provider.

1.2.2. Privilege and Confidentiality Protections (Codified at 42 U.S.C. § 299b-22)
The confidentiality and privilege protections afforded by the Patient Safety Act only apply when a provider works with a federally listed PSO. Notwithstanding any other provision of Federal, State, or local law, information that meets the definition of patient safety work product is privileged and confidential and may only be disclosed consistent with an applicable statutory exception. Civil money penalties may be imposed for knowing or reckless violations of the confidentiality requirements. Individuals are protected from adverse employment actions by providers for having made a good faith report intended for a patient safety organization, and providers that take advantage of the confidentiality provisions are protected from certain adverse actions by accrediting bodies. The

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[6] Department of Health and Human Services. 42 CFR Part 3: Patient Safety and Quality Improvement. Notice of Proposed Rulemaking. 73 FR 8111; February 12, 2008, at 8114. https://www.federalregister.gov/documents/2008/02/12/E8-2375/patient-safety-and-quality-improvement
[7] Department of Health and Human Services. 42 CFR Part 3: Patient Safety and Quality Improvement. Notice of Proposed Rulemaking. 73 FR 8111; February 12, 2008, at 8126. https://www.federalregister.gov/documents/2008/02/12/E8-2375/patient-safety-and-quality-improvement. Date accessed August 27, 2021.

Department of Health and Human Services' (HHS) Office for Civil Rights has been delegated certain authorities under the Patient Safety Act, including the authority "to make decisions regarding interpretation and enforcement of the privilege and confidentiality protections…" of the Patient Safety Act.[8]

The Patient Safety Act includes a Rule of Construction that makes it clear that the Act does not limit the application of laws that provide greater privilege or confidentiality protections or affect any Federal, State, or local laws pertaining to information not protected under the Patient Safety Act. The Rule of Construction also explicitly states that the Patient Safety Act does not preempt or affect State laws that require providers to report information that is not patient safety work product or affect or limit any Food and Drug Administration (FDA) reporting requirements. Clarification is provided on how the Health Insurance Portability and Accountability Act's confidentiality regulations apply to PSOs and patient safety activities conducted under the Patient Safety Act. Another provision clarifies that there is no prohibition on conducting an additional analysis of the same or similar issues that were reported to or assessed by a PSO or patient safety evaluation system.

1.2.3. Network of Patient Safety Databases (Codified at 42 U.S.C. § 299b-23)

The Patient Safety Act requires the Secretary of HHS to create and maintain a network of patient safety databases (NPSD) that provides an interactive, evidence-based resource for providers, PSOs, and other entities with the capacity to accept, aggregate, and analyze nonidentifiable patient safety work product voluntarily reported by PSOs, providers, and other entities. The statute also addresses data standards and use of data. It authorizes the Secretary to develop common formats, including common and consistent definitions, so that data collected from different sources can be aggregated for analysis of national and regional statistics, including trends and patterns of healthcare errors. Information resulting from the analyses is available to the public.

1.2.4. Patient Safety Organization Certification and Listing (Codified at 42 U.S.C. § 299b-24)

The Patient Safety Act establishes the process for entities to be certified and listed as PSOs, which is implemented by the Agency for Healthcare Research and Quality (AHRQ). The statute details the types of entities excluded from becoming listed as a PSO and the requirements an entity must meet to become a PSO, or to form a component PSO, and to maintain its Federal listing. For initial listing, the entity must certify that it has policies and procedures to perform defined patient safety activities and must meet certain criteria. To maintain listing, the PSO must certify every three years that it is performing each of the patient safety activities and is complying with the specified criteria. For example, the entity's mission and primary activity must be to conduct activities that improve patient safety and quality of healthcare delivery, and it must have an appropriately qualified workforce, including licensed or certified medical professionals. During its period of listing, a PSO must meet additional requirements, such as certifying within specified timeframes that it has at least two bona fide contracts with providers. The statute specifies the process the Secretary must follow in making listing decisions, addressing PSO deficiencies, and when necessary, revoking a PSO's listing. It also addresses public notice requirements and issues related to disposition of protected data when a PSO is no longer listed.

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[8] US Department of Health and Human Services. Office for Civil Rights. The Patient Safety and Quality Improvement Act of 2005; Delegation of Authority. 71 FR 28701; May 17, 2006. https://www.federalregister.gov/documents/2006/05/17/06-4578/office-for-civil-rights-the-patient-safety-and-quality-improvement-act-of-2005-delegation-of. Date accessed August 27, 2021.

1.2.5. Technical Assistance (Codified at 42 U.S.C. § 299b-25)

The Patient Safety Act authorized the Secretary to provide technical assistance to PSOs, including convening annual meetings to discuss methodology, communication, data collection, or privacy concerns.

Patient Safety and Quality Improvement Final Rule

42 CFR PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT

Subpart A: General Provisions

Subpart B: PSO Requirements and Agency Procedures

Subpart C: Confidentiality and Privilege Protections for Patient Safety Work Product

Subpart D: Enforcement Program

1.3. Implementation of the Patient Safety Act: 2005 to Present

HHS was able to begin work on implementing some of its responsibilities under the Patient Safety Act immediately upon enactment. Operationalizing the NPSD, which depended in large part on the business plans and choices made by PSOs and providers, including choices about voluntary event reporting, needed to evolve over time.

1.3.1. Development of Common Formats

The first step in making it possible to aggregate patient safety data for analysis and learning at the national level was to create a standardized form of data collection. In 2005, AHRQ began creating an inventory of private and public sector patient safety reporting systems to establish an evidence base for developing what are now known as the AHRQ Common Formats for Event Reporting (CFER). AHRQ also defined a systematic process for creating, implementing, and updating the Common Formats. The process includes input from the Federal Patient Safety Workgroup and review by an expert panel convened by the National Quality Forum (NQF), a nonprofit organization focused on healthcare quality. The NQF also assists AHRQ with gathering and analyzing public comment and feedback on the Common Formats. AHRQ released the first version of Common Formats for Event Reporting for Hospitals (CFER-H) in September 2008, in time for use by the PSOs that would soon be approved and listed. Since the initial release, the CFER-H has been updated three times. AHRQ is continuously assessing the feasibility of developing new types of Common Formats. CFER for Nursing Homes and Community Pharmacies have been released, and work is underway on a CFER for Diagnostic Safety (CFER-DS). The CFER-DS will be the first to be used across all settings of care. Release is anticipated sometime in late 2021 or early 2022.

In 2014, AHRQ developed the Common Formats for Surveillance (CF-S). AHRQ uses the term ''surveillance'' in this context to refer to retrospective review of medical records using a tool designed to improve detection of patient safety events with this methodology.[9] The CF-S will enable calculation of adverse event rates in populations reviewed and facilitate collection of comparable performance data over time and across populations of patients. These formats are designed to provide information that is complementary to that derived from event reporting systems.

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[9] The CFER-S should not be confused with systems designed to detect potential patient safety risks and adverse events using real-time surveillance of electronic medical records. See, for example, Sammer C, Miller S, Jones C, Nelson A, Garrett P, Classen D, Stockwell D. Developing and Evaluating an Automated All-Cause Harm Trigger System. Jt Comm J Qual Patient Saf. 2017 Apr;43(4):155-165. doi: 10.1016/j.jcjq.2017.01.004. Epub 2017 Feb 16. PMID: 28325203 and Escobar GJ, Liu VX, Schuler A, Lawson B, Greene JD, Kipnis P. Automated Identification of Adults at Risk for In-Hospital Clinical Deterioration. N Engl J Med. 2020 Nov 12;383(20):1951-1960. doi: 10.1056/NEJMsa2001090.

1.3.2. Notice of Proposed Rulemaking and Final Rule
On February 12, 2008, HHS published the proposed Patient Safety and Quality Improvement Rule. The Final Rule, codified at 42 CFR Part 3, was published November 21, 2008, and became effective January 19, 2009.

1.3.3. Certification and Listing of Patient Safety Organizations and Technical Assistance
With few exceptions, the statute permits any entity to become a federally listed PSO if it can meet the requirements. The requirements include that the entity must submit certain certifications to HHS. The initial and continued listing process is based primarily on self-attestation by the PSO's authorized official. The statutory framework and regulatory approach to PSO listing are designed to minimize burden and maximize protection of the confidential reporting relationship between PSOs and the providers they serve. PSOs are encouraged to provide limited additional information about themselves and about their reporting providers on the voluntary annual PSO Profile form.[10] However, other than in the context of a compliance assessment or identified deficiency,[11] PSO listing does not require the submission of such additional information or documentation. If the Secretary accepts the entity's certifications, the entity becomes a federally listed PSO.

AHRQ began listing PSOs in 2008, and by July 2009, there were 65 PSOs in 26 States and the District of Columbia.[12] Because PSOs may work with any provider in any State, the location of the PSO does not necessarily reflect the location of the providers it serves. Over time, new entities seek initial listing and some PSOs delist, most often voluntarily for various business reasons, so the number of listed PSOs at any given time has been fairly steady. Between 2009 and 2013, the number of listed PSOs ranged from 73 to 79; between 2014 and 2021, the number of listed PSOs ranged from 81 to 96.[13]

AHRQ makes available numerous web-based resources and provides direct technical assistance to help PSOs and entities seeking to become a PSO understand the requirements for listing. AHRQ is joined by the Office for Civil Rights when technical assistance is needed on topics under its authority. AHRQ hosts a PSO annual meeting, periodic webinars, and other opportunities for PSO collaboration and education. AHRQ also responds to inquiries about the Patient Safety Act from healthcare providers and others. In 2020 alone, AHRQ logged 631 technical assistance encounters.

1.3.4. Development and Launch of the NPSD
After the Common Formats became available, providers could begin sending data to PSOs in a standardized format suitable for submission to the NPSD. However, AHRQ needed to take additional steps before the NPSD could accept data. AHRQ created the PSO Privacy Protection Center (PSOPPC), which through a contractor maintains the Common Formats and assists PSOs that choose to volunteer data for the NPSD with the submission process. The PSOPPC receives the patient safety data,

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[10] The PSO Profile form and related information can be found at https://www.psoppc.org/psoppc_web/publicpages/psoProfileDataSubmission. Date accessed June 21, 2021.

[11] See, for example, 42 CFR 3.110 and 3.108(a)(3)

[12] Government Accountability Office. Patient Safety Act: HHS is in the process of implementing the act, so its effectiveness cannot yet be evaluated. GAO Publication No. GAO-10-281. Washington, DC; January 2010.

[13] Agency for Healthcare and Research Quality. Patient Safety Organization Program. Federally-listed PSOs. https://pso.ahrq.gov/listed. Date accessed October 29, 2020.

implements the processes required to render the data nonidentifiable,[14] and then submits the data to the NPSD.[15]

The NPSD needed a critical mass of data before it could become operational. The NPSD achieved this threshold and launched in June 2019. The time it has taken for this to happen is the result of several factors:

▸ Federally listed PSOs did not exist prior to 2008. These new entities had to develop systems for receiving and analyzing data, recruiting providers, waiting for providers to submit data, and in some cases, building systems compliant with or able to map data to the Common Formats before they could contemplate contributing data to the NPSD. All the costs of getting data to the entry point for submission to the NPSD are borne by PSOs and the providers they work with. There is no Federal funding for their operations.

▸ Patient safety event reporting for learning and improvement purposes is voluntary at all levels and often requires information beyond that available in medical records. Providers choose whether to work with a PSO, whether to use the AHRQ Common Formats, and which data they would like to report to the PSO. Even if providers are willing to collect and report data in the Common Formats to a PSO, PSOs are not required to submit the data to the NPSD.

▸ Federally listed PSOs and the providers they work with address many different kinds of quality/safety issues in a variety of care settings. NPSD data are derived from reports of all types of patient safety incidents, near misses, and unsafe conditions. The NPSD strives to make data publicly available at a level of detail that is useful for learning about patient safety, but it must do so without compromising the confidentiality of patients, providers, and reporters. For this reason, in addition to checking data quality, the NPSD must accumulate a sufficient volume of data for each data element to meet the nonidentification requirements before it can be presented to the public. Given the voluntary nature of participation and tremendous diversity of PSO specialties, activities and types of data collected, the time from collection to public display in the NPSD is unpredictable.

Currently, the NPSD website publicly displays the following interactive "dashboards" (also a downloadable "Chartbook") that present patient safety data derived from the CFER-H:

Data Submission Dashboard
The Data Submission Dashboard includes overall data about reports on patient safety concerns submitted to the PSOPPC. The dashboard charts detail reports submitted by Common Formats version by year, completeness of reports submitted by version, percentage of reports by version, percentage of reports by report type, and percentage of events by event type and version.
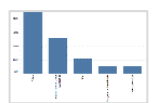
Generic Dashboard
The Generic Dashboard is based on general information gathered from reports of patient safety concerns associated with at least 1 of 10 specific event types. The dashboard charts detail event type, report type by event type, extent of harm by event type, event type by extent of harm, and extent of harm.

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[14] Agency for Healthcare Research and Quality. PSO Privacy Protection Center. https://www.psoppc.org/psoppc_web/publicpages/about. Date accessed October 29, 2020.
[15] Agency for Healthcare Research and Quality. NPSD: Network of patient safety databases. https://www.ahrq.gov/npsd/index.html. Date accessed October 29, 2020.
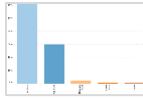
Blood and Blood Product Dashboard

The Blood and Blood Product Dashboard details the extent of harm due to blood or blood products, type of blood product involved, type of blood product by patient harm, stage of process where the event originated, and stage of process where the event originated by patient harm.

Device or Medical/Surgical Supply, Including Health Information Technology Dashboard

The Device or Medical/Surgical Supply Dashboard also includes health information technology (HIT). It details the extent of harm due to devices; type of device; type of device by patient harm; device defect, failure, or user error; device defect, failure, or user error by patient harm; type of HIT device in HIT-related report, and type of HIT device in HIT-related report by patient harm.
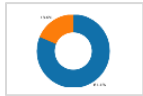
Falls Dashboard

The Falls Dashboard details the extent of harm due to falls, the presence of fall assistance, the presence of fall assistance by patient harm, the type of fall injury, and fall location.
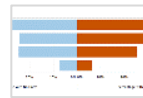
Medication or Other Substance Dashboard

The Medication or Other Substance Dashboard details the extent of harm due to medication incidents, incorrect action taken, incorrect action by patient harm, type of incorrect dose, type of incorrect dose by patient harm, stage of process where event originated, and stage of process where event originated by patient harm.
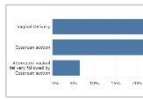
Perinatal Dashboard

The Perinatal Dashboard details the extent of harm to a mother, fetus(es), and/or neonates(s) as a result of perinatal incidents, and whether originated during either the birthing process or an intrauterine procedure.
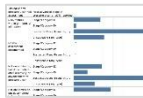
Pressure Ulcer Dashboard

The Pressure Ulcer Dashboard details the extent of harm due to a newly-developed or worsening pressure ulcer, including suspected deep tissue injury (sDTI); the documentation of increased risk for pressure ulcer following a risk assessment; and the timing of the first risk assessment for reported pressure ulcers or sDTIs.

The NPSD currently includes more than 2 million records. Voluntary patient safety event reports, as currently operationalized, are unable to produce a representative sample of the underlying provider or patient populations. For this reason, NPSD data cannot currently be used to calculate incidence or prevalence rates. As more providers work with federally listed PSOs to contribute data to the NPSD and new methodologies and modes of analysis become feasible, the volume and types of patient safety information that can be made available to the public will expand.

1.4. The Patient Safety Act: A National Learning System

A "learning health system" systematically integrates internal data with external evidence to develop and put into practice new knowledge to improve the quality, safety, and efficiency of care. The work of PSOs and providers under the Patient Safety Act serves as a national learning system for patient safety improvement (figure 1).

Figure 1. The Patient Safety and Quality Improvement Act of 2005: A National Learning System

Notes: NPSD = network of patient safety databases; PSO = patient safety organization; PSOPPC = PSO Privacy Protection Center

Federally listed PSOs undertake an impressive array of patient safety and quality improvement activities with different types of healthcare providers in a variety of settings across the United States. Each PSO serves as a resource to the healthcare providers it serves, aggregating their data with that of other PSO clients, analyzing data to develop new and innovative patient safety improvement approaches, and facilitating the development and application of evidence-based patient safety improvement strategies and practices such as those presented later in this report. PSOs work one-on-one with individual providers and health systems to tailor the implementation of improvement strategies to their particular needs and often work collaboratively with groups of their reporting providers and with other healthcare providers. These PSOs and the providers they work with demonstrate their commitment to a culture of continuous learning and improvement by capturing, analyzing, and using a vast amount and variety of patient safety and quality information for the purpose of improving care. Providers and PSOs willing to contribute data play an essential role in growing the NPSD into an ever-more-robust national resource for patient safety and quality improvement. The data acquired through this national learning system offer the potential to aid all providers in their efforts to reduce medical errors and increase safety for every patient.

Chapter 2.
Strategies for Reducing Medical Errors and Increasing Patient Safety

2.1. Scope and Terminology

This chapter begins with background information about some of the principles and concepts that underlie effective patient safety improvement; provides an overview of patient safety research, which is how patient safety strategies and practices are designed and tested; and includes examples of different approaches to measuring their effectiveness in reducing medical errors and increasing patient safety.

The Patient Safety Act's specific directive to HHS is for a report on effective strategies for reducing medical error and increasing patient safety that could be encouraged for use, including use in any federally funded programs. This requirement has been met by incorporating content from AHRQ's *Making Healthcare Safer* reports, which provide an analysis of effective strategies and practices for reducing medical error and increasing patient safety. Tables in section 2.5 list all the existing and emerging strategies and practices for reducing medical errors and increasing patient safety reviewed for evidence of effectiveness in AHRQ's *Making Health Care Safer* series. The methodology used to assess effectiveness is described in section 2.5.1. Hyperlinks in the tables in section 2.5.2 lead to the full evidence review for each patient safety strategy and practice.

As noted below, agencies within HHS as well as other Federal agencies have large portfolios of patient safety work. That work is reflected in the effective strategies in section 2.5 of this report if it was represented in the literature reviewed in the *Making Healthcare Safer* series. Section 3.2.2. includes an overview and a few examples of patient safety improvement resources Federal agencies make available to healthcare providers.

This report generally combines or treats the terms "strategies and practices" as interchangeable because many, if not most, effective patient safety improvement efforts combine specific practices with more generic strategies. The concepts used in the statute, "reducing medical errors" and "increasing patient safety," are also considered interchangeable. The strategies and practices presented target the reduction of medical error and work to increase patient safety simultaneously. As the IOM Report noted, "Human beings, in all lines of work, make errors. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing."[16] Effective strategies to reduce error are those that build safeguards into the systems surrounding patients and their healthcare providers to increase safety and prevent harm.

This report does not address mechanisms for setting, incentivizing, and/or enforcing compliance with patient safety-related standards or requirements, or for holding providers accountable, such as professional licensing and discipline and healthcare facility licensing and certification. The report also does not encompass regulatory activities pertaining to public health or to regulation of the safety of drugs, medical devices, or radiation-emitting products. These activities play a critical role in protecting patient safety but are not within the scope of this report. Consistent with the framework and purpose of

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[16] Institute of Medicine (US) Committee on Quality of Health Care in America. To Err Is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, editors. Washington (DC): National Academies Press (US); 2000; ix. PMID: 25077248.

the Patient Safety Act, this report addresses strategies to be encouraged for use in voluntary patient safety improvement activities conducted by, with, and/or for healthcare providers.

2.2. The Foundation for Effective Strategies: Some Fundamental Safety Principles and Concepts

Many strategies and practices that have successfully improved patient safety stem from scientific approaches to safety that grew in industries unrelated to healthcare. For example, commercial aviation, nuclear power, and railway industries have long implemented safety strategies using a systems approach, human factors engineering, and the concept of high-reliability organizations.[17] This section briefly introduces some of these interrelated frameworks.

2.2.1. Systems Approach to Managing Safety

Studies of several accidents in high-risk industries made it clear that error could only be completely understood within the context of the surrounding system. The basic premise of a systems approach[18] to safety is that accidents and errors stem from a combination of human and system failures. While humans are fallible, the systems in which they operate can either contribute to or help prevent human error and associated harm. The key to prevention, then, is to identify and address factors in the system that contribute to or fail to prevent adverse events or to mitigate harm when adverse events do occur. Applied to healthcare, the systems approach expands the focus of analysis beyond the provider when an adverse event occurs to include an examination of flaws in the surrounding system that facilitated or failed to prevent the adverse event. A well-functioning safety culture, including a clear and just process for distinguishing between unintentional errors and blameworthy conduct, is a core component of the systems approach and high reliability.[19]

Professor James Reason's "Swiss cheese model" of accident causation illustrates how small flaws or weaknesses in different parts of a system can compromise the system's integrity. According to the model, a system can have multiple layers of defenses, barriers, and safeguards (akin to the slices of Swiss cheese), but when small weaknesses (the holes in the cheese, although these holes are constantly opening, closing, and shifting) line up across multiple layers, their alignment creates an opening through which hazards can pass and cause harm.

Two factors account for system weaknesses: active failures and latent conditions. In the healthcare context, active failures refer to the lapses, mistakes, and other actions of the people who are in direct contact with the patient. Latent conditions are flaws or weaknesses in the surrounding system that make active failures more likely to happen. Within an organization, these may be conditions such as time pressures, design deficiencies in the physical environment or equipment, leadership and workplace culture issues, and unworkable policies or procedures. Latent conditions may exist for many years before an active failure happens and triggers an accident. Active failures are typically unpredictable, but a proactive approach to safety can identify and address risky latent conditions to reduce the potential for adverse events. Models of the systems approach have continued to evolve,[20,21] but understanding

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[17] Bogner MS. Introduction. Human Error in Medicine. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994.

[18] Unless otherwise noted, all content in this section is from: Reason J. Human error: models and management. BMJ. 2000 Mar 18;320(7237):768-70. doi: 10.1136/bmj.320.7237.768. PMID: 10720363; PMCID: PMC1117770.

[19] Chassin MR, Loeb JM. High-reliability health care: getting there from here. Milbank Q. 2013 Sep;91(3):459-90. doi: 10.1111/1468-0009.12023. PMID: 24028696; PMCID: PMC3790522.

[20] Reason J, Hollnagel E, Paries, J. European Organization for the Safety of Air Navigation, EUROCONTROL Experimental Centre. Revisiting the Swiss cheese model of accidents. 2006-017EEC, Note 2006/13; October 2006. https://www.eurocontrol.int/publication/revisiting-swiss-cheese-model-accidents

[21] Bogner MS. Stretching the search for the "why" of error: the systems approach. J Clin Eng. 2002;27(2):110-115.

that multiple underlying factors influence both the likelihood an adverse event will occur and the potential for related harm is essential to developing effective solutions.

2.2.2. Human Factors Engineering

A basic premise of human factors engineering (HFE) is that well-designed systems capitalize on human capabilities and compensate for human limitations. HFE applies "knowledge of how we see, hear, think, and physically function to the design of tools, products, and systems that are conducive to human task performance and protective of human health and safety."[22] Errors and accidents result when the sensory and cognitive functions inherent to being human intersect with imperfect tools, machines, or systems. Using HFE design principles and processes can help prevent these types of errors and accidents. For example, some vehicles warn us when we leave the headlights on; others anticipate we will forget and automatically turn them off. HFE considers the component tasks of activities and takes into account factors such as the physical demands, skill demands, mental workload, team dynamics, and aspects of the work environment (e.g., visual display, lighting, distractions). In essence, HFE focuses on how tools and processes work for real people in the real world and attempts to design tools and processes that optimize safety, minimize the risk of error, and mitigate potential harm when error cannot be prevented or intercepted.[23] Initially applied in industries outside healthcare—such as aviation—HFE analyzes various components of the systems in which workers operate to identify, prevent, or remedy vulnerabilities and enhance usability.

2.2.3. High-Reliability Organizations

Organizations that consistently avoid accidents despite operating in complex, high-risk environments are described as "high-reliability organizations (HROs)."[24] Industries that exemplify high reliability include commercial aviation and nuclear power. These industries share several characteristics that help them maintain safety. Among them is a preoccupation with failure. Because they operate in environments where inattention to safety threats can have catastrophic effects, HROs are exceptionally vigilant, always scanning the environment for any sign of a problem. They treat every incident and close call as an opportunity to learn, and they encourage reporting of errors.

Another common characteristic of HROs is a reluctance to simplify their understanding of work processes and how and why things succeed or fail. They understand that the work is complex and dynamic and seek underlying rather than surface explanations. Rather than accepting seemingly obvious but superficial explanations of why an incident occurred, HROs take time to analyze each incident to fully understand why it happened and what may have contributed to it. By seeking different points of view and challenging assumptions, HROs avoid the risks associated with complacency.

HROs are also resilient. They appreciate the unpredictable nature of system failures and prepare for the unexpected by learning how to identify threats early and practicing methods of containing or recovering from such threats. Recent developments in the application of resilience engineering to healthcare emphasize a focus on resilience in approaches to patient safety improvement.[25]

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[22] Federal Aviation Administration, Human Factors Division. FAA Human Factors Awareness Course: Introduction – Foundations - What "Human Factors" is. https://elmscontent.dot.gov/elms/faa/ato/to/hfwebtraining/Intro/Foundation1.htm. Date accessed November 2, 2020.

[23] Agency for Healthcare Research and Quality. PSNet Patient safety primer: human factors engineering. https://psnet.ahrq.gov/primer/human-factors-engineering. Last reviewed September 7, 2019.

[24] Unless otherwise noted, all content in this section is from: Agency for Healthcare Research and Quality. PSNet Patient safety primer: High reliability. https://psnet.ahrq.gov/primer/high-reliability. Last reviewed September 7, 2019.

[25] Fairbanks RJ, Wears RL, Woods DD, Hollnagel E, Plsek P, Cook RI. Resilience and resilience engineering in health care. Jt Comm J Qual Patient Saf. 2014 Aug;40(8):376-83. doi: 10.1016/s1553-7250(14)40049-7. PMID: 25208443.

Sensitivity to operations is another defining characteristic of HROs. Workers in HROs strive to maintain an overall awareness of the situation as they operate and constantly assess how the current state might support or threaten safety. This awareness keeps team members at all levels able to identify and address small issues that could have a cascading effect on other operations and compromise system safety.

Finally, when analyzing a situation, HROs defer to the individuals who are most knowledgeable about the situation at hand. Those with the most knowledge or direct experience are considered the experts, regardless of their seniority or place in the organizational hierarchy. In action, this practice means leadership defers to expertise and uses it to inform improvement.

2.3. Designing and Testing the Strategies: Patient Safety Research

Ongoing research is necessary for the successful adaptation of safety strategies from other industries and the design of new patient safety practices that will be effective in the ever-changing, complex world of healthcare. As early as the 1970s, physicians and researchers aimed to better understand the causes of preventable patient harms by investigating trends and patterns in frequently occurring anesthesia-related incidents.[26] These studies were among the first to systematically analyze "critical incidents" in healthcare through the lens of human factors and design engineering principles.[27] Identification of the underlying causes of anesthesia-related incidents paved the way for developing and testing strategies for their prevention and detection.[28]

Patient safety gained further attention among the medical profession and healthcare communities in 1991 after publication of the Harvard Medical Practice Study.[29] In 1994, Dr. Lucian Leape, an author of that study who subsequently worked on the IOM Report, published a groundbreaking paper calling for the integration of safety science concepts from other disciplines into healthcare.[30] AHRQ's official designation as the Federal lead in patient safety began when the Healthcare Research and Quality Act of 1999 was signed into law. It required AHRQ to "conduct and support research and build private-public partnerships to: (1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry."[31] AHRQ's Patient Safety Research Portfolio is described briefly in the text box.[32]

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[26] Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: a study of human factors. Anesthesiology. 1978 Dec;49(6):399-406. doi: 10.1097/00000542-197812000-00004. PMID: 727541.

[27] Small SD, Barach P. Patient safety and health policy: a history and review. Hematol Oncol Clin North Am. 2002 Dec;16(6):1463-82. doi: 10.1016/s0889-8588(02)00066-7. PMID: 12512178.

[28] Cooper JB, Newbower RS, Kitz RJ. An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection. Anesthesiology. 1984 Jan;60(1):34-42. doi: 10.1097/00000542-198401000-00008. PMID: 6691595.

[29] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991 Feb 7;324(6):370-6. doi: 10.1056/NEJM199102073240604. PMID: 1987460.

[30] Leape LL. Error in medicine. JAMA. 1994 Dec 21;272(23):1851-7. PMID: 7503827.

[31] Healthcare Research and Quality Act of 1999, Pub. L. No. 106-129, section 912(c). https://www.congress.gov/106/plaws/publ129/PLAW-106publ129.pdf

[32] Agency for Healthcare Research and Quality. Funding opportunity announcement (FOA) guidance. https://www.ahrq.gov/funding/policies/foaguidance/index.html. Last reviewed July 2021.

> **AHRQ's Patient Safety Research Portfolio**
>
> AHRQ encourages investigators to conduct interdisciplinary research that is grounded in a safety science or theoretical framework, such as organizational theory, human factors, industrial engineering, facilities design, education, and other disciplines. Researchers may address topics such as the surveillance, measurement, detection, and reporting of patient safety events; the impact of human performance, work flow, and working conditions on patient safety; the patient's role and contribution to patient safety; healthcare safety culture, leadership, communication, teamwork, and simulation; prevention and control of healthcare-associated infections; diagnostic safety and quality; the safe use of medical devices and medications, including safely prescribing opioids; the role of PSOs; and the challenges inherent in transitions of care between settings and handoffs between healthcare providers. The resulting portfolio is both broad in scope and deep in content.

In the years following release of the IOM report, AHRQ, in conjunction with its Federal partners and non-Federal stakeholders, began accelerating research efforts to better understand patient safety challenges and effective solutions. By the end of 2000, Congress directed $50 million to AHRQ to support patient safety research and improvement activities.[33] Over the next 20 years, AHRQ developed a research agenda and awarded patient safety-related research grants supporting every phase of the learning and improvement continuum.[34] Research studies have focused on identifying risks and harms associated with healthcare delivery; designing, implementing, and evaluating interventions to prevent such harms; and developing methods for promoting uptake and adoption of effective improvement strategies.

Early Research Efforts. Between 2001 and 2003, AHRQ patient safety initiatives focused on six program areas as follows:[35]

▸ Centers of Excellence for Patient Safety Research and Practice Developmental Centers for Evaluation and Research in Patient Safety

▸ Improving Patient Safety: Health System Reporting, Analysis, and Safety Improvement Research Demonstrations

▸ Clinical Informatics to Promote Patient Safety

▸ Effect of Working Conditions on Quality of Care and Patient Safety

▸ Patient Safety Research Dissemination and Education

The evidence generated by these grants provided the foundation for the Partnerships in Implementing Patient Safety (PIPS) grant program. AHRQ announced the PIPS funding opportunity in fiscal year 2005 and awarded 17 grants totaling more than $9 million. These grants focused on implementation and evaluation of evidence-based safe practice interventions. Though awardees tested implementation in one setting, such as an acute care hospital, they were encouraged to collaborate with other awardees so the practice could be tested in more than one facility. For example, an intervention that effectively reduced adverse events in a small hospital might be scaled for implementation in a larger hospital with a greater number of high-risk patients. These collaborations were an important step toward assessing whether the practice could achieve the same results when adapted for use in other organizations. AHRQ

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[33] Agency for Healthcare Research and Quality. Advancing patient safety: a decade of evidence, design, and implementation. https://www.ahrq.gov/patient-safety/resources/advancing.html. Last reviewed October 2018.

[34] Agency for Healthcare Research and Quality. Funding opportunity announcement (FOA) guidance. https://www.ahrq.gov/funding/policies/foaguidance/index.html. Last reviewed July 2021.

[35] U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. Partnerships in implementing patient safety. RFA Number RFA-HS-05-012; 2004. https://grants.nih.gov/grants/guide/rfa-files/RFA-HS-05-012.html

emphasized the importance of thoroughly documenting implementation procedures and challenges for purposes of assessing the feasibility of implementing the practice and achieving the same outcomes across different organizations. This work led to the development of a number of different resources that have been widely disseminated and used to improve patient safety such as the Re-Engineered Discharge Toolkit, which can help to reduce hospital readmissions,[36] and the Preventing Hospital-Associated Venous Thromboembolism: A Guide for Effective Quality Improvement.[37]

Examples of AHRQ-Funded Research Underlying Effective Patient Safety Strategies. Some of the most significant improvements in patient safety have resulted from AHRQ-funded research on the prevention of healthcare associated infections (HAIs). For example, with funding from an early career development grant, Dr. Peter Pronovost developed and tested what later came to be known as the Comprehensive Unit-based Safety Program (CUSP).[38] CUSP focuses on improving safety culture, teamwork, and communication, together with a set of evidence-based technical interventions, such as a checklist. In 2004, AHRQ funding supported a statewide demonstration in intensive care units (ICUs) across the State of Michigan that used CUSP to prevent deadly central line-associated blood stream infections (CLABSIs). AHRQ later funded nationwide implementation of CUSP, which led to a 41 percent reduction in CLABSI between 2008 and 2012. CUSP makes its tools relevant to clinicians by putting them in the context of a hospital environment at the unit level and promoting safety culture. The effectiveness of this approach has since been demonstrated in various care settings and is discussed in more detail later in this report.

A public-private partnership among AHRQ, the Centers for Disease Control and Prevention (CDC), and the Hospital Corporation of America led to REDUCE-MRSA, a landmark AHRQ-funded study in ICUs, the results of which were published in the *New England Journal of Medicine* in 2013.[39] This study demonstrated that universal decolonization—cleansing bacteria from all ICU patients' bodies with an antiseptic bathing solution and nasal antibiotic ointment—was effective in reducing transmission of methicillin resistant staphylococcus aureus (MRSA), a healthcare-associated infection, and preventing bloodstream infections caused by any bacteria. To spread the proven benefits of REDUCE-MRSA to ICUs that did not participate in the study, AHRQ developed and posted on its website a toolkit, known as an Enhanced Protocol, that enables other ICUs to use the universal decolonization strategy with their patients. AHRQ subsequently extended its support to studies of broad application of decolonization in healthcare settings beyond the ICU.

The Department of Defense (DoD) Patient Safety Program and AHRQ collaborated on research that resulted in Team Strategies and Tools to Enhance Performance and Patient Safety, known as

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[36] Jack B, Greenwald J, Forsythe S, O'Donnell J, Johnson A, Schipelliti L, Goodwin M, Burniske GM, Hesko C, Paasche-Orlow M, Manasseh C, Anthony D, Martin S, Hollister L, Jack M, Jhaveri V, Casey K, Chetty VK. Developing the Tools to Administer a Comprehensive Hospital Discharge Program: The ReEngineered Discharge (RED) Program. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 3: Performance and Tools). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. PMID: 21249944.

[37] Maynard G. Preventing hospital-associated venous thromboembolism: a guide for effective quality improvement, 2nd ed. Rockville, MD: Agency for Healthcare Research and Quality; August 2016. AHRQ Publication No. 16-0001-EF. https://www.ahrq.gov/sites/default/files/publications/files/vteguide.pdf

[38] AHRQ Grantee Profile. Making health care safer for patients: Peter Pronovost, M.D., Ph.D. https://www.ahrq.gov/funding/grantee-profiles/grtprofile-pronovost.html. Last reviewed February 2021.

[39] Huang SS, Septimus E, Kleinman K, Moody J, Hickok J, Avery TR, Lankiewicz J, Gombosev A, Terpstra L, Hartford F, Hayden MK, Jernigan JA, Weinstein RA, Fraser VJ, Haffenreffer K, Cui E, Kaganov RE, Lolans K, Perlin JB, Platt R; CDC Prevention Epicenters Program; AHRQ DECIDE Network and Healthcare-Associated Infections Program. Targeted versus universal decolonization to prevent ICU infection. N Engl J Med. 2013 Jun 13;368(24):2255-65. doi: 10.1056/NEJMoa1207290. Epub 2013 May 29. Erratum in: N Engl J Med. 2013 Aug 8;369(6):587. Erratum in: N Engl J Med. 2014 Feb 27;370(9):886. PMID: 23718152.

TeamSTEPPS.[40] TeamSTEPPS® is an evidence-based curriculum and training program that has been implemented in many care settings, nationally and internationally, to improve communication and teamwork skills among healthcare professionals. The first version of TeamSTEPPS® was released in 2006, following 3 years of research and development. DoD and AHRQ convened experts in team training, healthcare, human factors, and change management to conduct a comprehensive review of the research literature and assess evidence regarding the role of teamwork in patient safety. Based on that research and the study of Crew Resource Management protocols in aviation, the experts identified essential competencies of effective teams and created the TeamSTEPPS® curriculum for developing those competencies among healthcare teams.

In 2014, AHRQ launched a new research funding opportunity announcement and portfolio of grants entitled Advancing Patient Safety Implementation Through Safe Medication Use Research. These grants supported research on safe medication use across all healthcare settings and transitions. The grants emphasized engagement of patients in funded research and addressed a broad array of issues related to medication safety, such as medication management for patients with multiple chronic conditions; the role of labeling, packaging, and distribution of medications in patient safety; and improved communication among patients, family members, physicians, and pharmacists.[41] Findings from these grants helped inform the development of the Six Building Blocks program, which provides primary care teams with evidence-based tools and resources for improving management of patients on chronic opioid therapy.[42]

To address gaps in research related to patient safety in ambulatory care settings (such as doctors' offices and clinics) and long-term care (LTC) facilities, AHRQ launched a multiyear initiative beginning in 2015 that focused on these settings, where most of the healthcare in the United States takes place. [43] Research stemming from this initiative included Project RedDE (Reducing Diagnostic Errors in Pediatric Primary Care), which focused on reducing diagnostic errors in primary care pediatric practices. Conducted in collaboration with the American Academy of Pediatrics' Quality Improvement Innovation Networks, this research resulted in development of the toolkit for Reducing Diagnostic Errors in Primary Care Pediatrics.[44]

AHRQ-Funded Simulation Grants. Simulations are valued for their ability to create seemingly realistic conditions in controlled situations or environments that optimize learning. Elements of difficult procedures can be selectively practiced to the point of expertise, and how to respond to uncommon but life-threatening situations can be practiced without compromising patient safety. In 2006 and 2007, AHRQ funded approximately $10 million in grants for research on how simulation can improve patient safety across disciplines and settings. Since then, AHRQ has continued to fund simulation studies to evaluate the use and effectiveness of various simulation approaches. Areas of research include technical skills, team performance, system performance, methodological issues, education and training, and

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[40] King HB, Battles J, Baker DP, Alonso A, Salas E, Webster J, Toomey L, Salisbury M. TeamSTEPPS™: Team Strategies and Tools to Enhance Performance and Patient Safety. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 3: Performance and Tools). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. PMID: 21249942.

[41] US Department of Health and Human Services. Advancing patient safety implementation through safe medication use research (R18). Grant overview information. https://grants.nih.gov/grants/guide/pa-files/PA-14-002.html.

[42] Agency for Healthcare Research and Quality. About the Six Building Blocks program. https://www.ahrq.gov/professionals/prevention-chronic-care/improve/six-building-blocks.html. Last reviewed February 2020.

[43] US Department of Health and Human Services. FOA Number PA-15-339. AHRQ Health Services Research Projects: Making health care safer in ambulatory care settings and long term care facilities (R01). Grant overview information; 2015. https://grants.nih.gov/grants/guide/pa-files/PA-15-339.html

[44] Agency for Healthcare Research and Quality. Reducing diagnostic errors in primary care pediatrics toolkit. https://www.ahrq.gov/professionals/quality-patient-safety/diagnostic-safety/toolkit.html. Last reviewed November 2018.

accreditation and certification. For example, researchers at the University of Texas, Arlington, received an AHRQ grant to improve physician and nurse communication. The intervention they created enables users to experiment with and learn more effective communication skills and behaviors through practice and feedback.[45,46]

AHRQ's Patient Safety Learning Laboratories. Many interdependent factors converge to influence safety in healthcare delivery. Promoting a better understanding of these interdependencies and their potential effects on patients and providers is a key challenge facing patient safety researchers today. AHRQ's patient safety learning laboratories (PSLLs) address the challenge by bringing together cross-disciplinary teams and using systems engineering—defined as "the science of how to design and manage complex human-centered systems"—to identify and reduce potential sources of patient harm.[47] Between 2014 and 2019, AHRQ awarded 30 PSLL grants targeting a broad array of patient safety issues, such as medication use and adverse drug events, communication and coordination across primary and specialty care, diagnostic errors, care transitions, alarm fatigue, and perinatal morbidity and mortality.

Several PSLL studies focus on diagnostic errors. For example, the project Re-engineering for Accurate, Timely, and Communicated Diagnosis of Cardiovascular Disease in Women (known as DREAM Lab) studies the factors that compromise accurate diagnosis of cardiovascular disease in women. The research team aims to reduce diagnostic errors and improve clinical management of cardiovascular disease by developing and testing human-centered solutions in simulated environments, followed by pilot testing in clinical settings.

Another ongoing PSLL project is working to reduce diagnostic delays that can result in negative health outcomes in the primary care setting, where many factors can prevent patients and providers from following up on recommended diagnostic tests or referrals. This project is using systems engineering methods to design, develop, and refine highly reliable closed loop systems for diagnostic tests and referrals to ensure appropriate follow-up occurs within clinically and patient-important timeframes.

Several PSLL projects focus on special populations, such as older adults and pediatric patients, who are at elevated risk for one or more types of patient safety harms. For example, when the Partnership in Resilience for Medication Safety (known as PROMIS) Learning Lab was first funded in 2019, it tested methods for reducing preventable medication-related harms among patients 65 and older, who are particularly vulnerable to adverse drug effects. Another PSLL project is working to reduce healthcare-associated harms and hospital readmissions among older patients following discharge from hospital emergency departments. Other population-specific PSLL projects are working to prevent healthcare-associated harms among children with chronic conditions, reduce harms in neonatal intensive care units, and reduce perinatal morbidity and mortality among mothers and infants.

In addition to AHRQ's role in funding patient safety research, the National Institutes of Health (NIH) supports and conducts patient safety research, with a focus on disease- and condition- specific, as well as population health research, in the United States and internationally. These research studies address a broad range of patient safety topics across health care settings, examining issues such as hospital safety performance including diagnostic errors, staff training protocols, perioperative adverse event

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[45] US Department of Health and Human Services, National Institutes of Health. Advances in patient safety through simulation research (R18) Grant announcement overview https://grants.nih.gov/grants/guide/pa-files/PA-14-004.html.

[46] Agency for Healthcare Research and Quality. Improving patient safety through simulation research: funded projects. https://www.ahrq.gov/research/findings/factsheets/errors-safety/simulproj11/index.html. Last reviewed November 2018.

[47] Agency for Healthcare Research and Quality. Overview of patient safety learning laboratory (PSLL) projects. https://www.ahrq.gov/patient-safety/resources/learning-lab/index.html. Last reviewed April 2021.

reduction, control and prevention of healthcare-associated infections, and adverse drug reactions; as well as building, designing, and testing informational systems for patient safety. NIH-supported research expands the evidence base for the development, implementation, and evaluation of effective strategies that enhance patient safety.

Responding to New Challenges. Research is underway to understand and address the challenges to patient safety and healthcare quality introduced to all healthcare settings by SARS-CoV-2. Less than 3 months after the first known case of COVID-19 was confirmed in the United States, HHS, through AHRQ, announced plans to award $5 million in fiscal year 2020 to support studies that evaluate the responsiveness of healthcare delivery systems, professionals, and the overall U.S. healthcare system to the pandemic.[48] AHRQ funded 14 new research projects and provided supplemental funding for 14 existing projects to refocus on COVID-19. These projects are examining how COVID has impacted delivery of care in and across various healthcare settings.[49]

One of the existing projects to receive supplemental funding was PROMIS, the Learning Lab initially focused on supporting safe medication use among patients age 65 and older.[50] [51] In 2020, the project team received supplementary funding to investigate how SARS-CoV-2 related disruptions to primary care, such as increased use of telehealth, disproportionately affect underserved populations. The findings will inform clinical practice guidelines to support primary care clinics in responding to unique challenges posed by the pandemic.

New research projects on COVID-19 focus on evolving safety challenges related to telehealth, nursing homes, home-based care, health information technology, and dialysis. One study is evaluating the shift to telehealth for delivering behavioral, primary, and prenatal healthcare services to vulnerable patients living in rural and urban communities.[52] Another project is examining challenges to providing safe home-based long-term services and supports to older adults and individuals with disabilities during the pandemic. The study aims to identify threats to the health and safety of the home care workforce, and to improve delivery of quality home health care through enhanced education and training of workers, patients and their families.[53]

In addition to these research projects, AHRQ has partnered with the University of New Mexico's ECHO Institute and the Institute for Healthcare Improvement (IHI) to establish a national nursing home COVID-19 Action Network. The network provides nursing homes with free training and mentorship to implement safety protocols that can protect residents and staff against COVID-19.[54]

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[48] Agency for Healthcare Research and Quality. HHS to award $5 million for health services research related to COVID-19. https://www.ahrq.gov/news/newsroom/press-releases/funding-opportunity-covid.html. Last reviewed May 2020.

[49] Agency for Healthcare Research and Quality. COVID-19 Research Grant Awards. https://www.ahrq.gov/coronavirus/grants.html. Last reviewed January 2021.

[50] Agency for Healthcare Research and Quality. Overview of Patient Safety Learning Laboratory (PSLL) Projects. https://www.ahrq.gov/patient-safety/resources/learning-lab/index.html. Last reviewed April 2021.

[51] US Department of Health and Human Services, National Institutes of Health. PROMIS Learning Lab: Partnership in Resilience for Medication Safety. https://reporter.nih.gov/search/alg_rvY10E2nzvWFu4eMMg/project-details/10016289. Date accessed August 19, 2021.

[52] US Department of Health and Human Services, National Institutes of Health. Quality, Safety, Value: Impact of sudden shift to telehealth due to COVID-19 within Nurse-led care models located in Colorado rural and urban communities. https://reporter.nih.gov/search/iv0nc0cfwUeu_kXibfsqAw/project-details/10189368. Date accessed August 19, 2021.

[53] US Department of Health and Human Services, National Institutes of Health. Care and Safety Practices during the COVID-19 Pandemic in Home-Based Long term Services and Supports. https://reporter.nih.gov/search/HDImP-DcvEO1bBwTR6tn5w/project-details/10193969. Date accessed August 19, 2021.

[54] Agency for Healthcare Research and Quality. AHRQ ECHO National Nursing Home COVID-19 Action Network. https://www.ahrq.gov/nursing-home/index-old.html. Date accessed August 19, 2021.

Research and development of patient safety interventions is essential, but not sufficient, to fully assess the effectiveness of an intervention or its component parts. Measuring the effectiveness of a patient safety strategy across different clinical settings presents unique challenges. The following section describes some current and potential future approaches to measuring and monitoring the effectiveness of patient safety strategies.

2.4.   Assessing the Effectiveness of Strategies: Measurement in Patient Safety

Medical research is a complex endeavor, but the approach to designing a study to evaluate a medical treatment is fairly straightforward: The focus is typically a specific, well-defined diagnosis; the participating patients share a set of characteristics specified by the researchers; the intervention is a specific drug or other clearly defined, tangible intervention; and the study can be designed to minimize factors that could confound the results. Similar studies can be replicated and generate large volumes of data that can be analyzed systematically.

In patient safety, the problems and the solutions are multifaceted. Numerous variables (known and not yet known) can influence the success or failure of an intervention. Whether a patient safety improvement strategy is effective might be measured by looking at the adverse events or harms that occurred or were prevented; the presence or absence of factors that promote safer healthcare delivery;[55]or the relationship between and among such variables. The level at which effectiveness can be assessed also varies, from one or more units within a single healthcare setting, the entire facility, or multiple facilities in a healthcare system; across multiple healthcare systems; across regions; and at the national level. Context has been found to influence effectiveness of a patient safety practice in important ways; this is one reason patient safety strategies found to be effective in one research study may not produce the same results in a different setting.[56]

Given this complexity, applying traditional evidence-based medicine approaches to evaluating the effectiveness of patient safety improvement strategies presents some unique challenges. Complex organizational interventions that are more typical in patient safety cannot always be analyzed in the same way as medical interventions,[57]although there are study designs that can help researchers better understand their effects.[58] [59] Extensive research may not be needed to decide whether to implement what seems to be a low-risk, common-sense strategy for improving safety; however, action without evidence of effectiveness can waste resources and result in unintended consequences.[60]

To date, the effectiveness of patient safety improvement efforts is typically assessed by measuring how they affect the occurrence of adverse events and/or harm. Examples of this approach include methods such as retrospective review of medical records, automated surveillance of electronic health records using "trigger tools" or other instruments or approaches, systematic reporting systems such as CDC's

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[55] Hollnagel E. Is safety a subject for science? Safety Science. 2014 Aug; 67:21-24.

[56] Taylor SL, Dy S, Foy R, Hempel S, McDonald KM, Ovretveit J, Pronovost PJ, Rubenstein LV, Wachter RM, Shekelle PG. What context features might be important determinants of the effectiveness of patient safety practice interventions? BMJ Qual Saf. 2011 Jul;20(7):611-7. doi: 10.1136/bmjqs.2010.049379. Epub 2011 May 26. PMID: 21617166.

[57] Davidoff F. Improvement interventions are social treatments, not pills. Ann Intern Med. 2014 Oct 7;161(7):526-7. doi: 10.7326/M14-1789. PMID: 25285545.

[58] Webster CS. Evidence and efficacy: time to think beyond the traditional randomised controlled trial in patient safety studies. Br J Anaesth. 2019 Jun;122(6):723-725. doi: 10.1016/j.bja.2019.02.023. Epub 2019 Apr 4. PMID: 30954239.

[59] Dixon-Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q. 2011 Jun;89(2):167-205. doi: 10.1111/j.1468-0009.2011.00625.x. PMID: 21676020; PMCID: PMC3142336.

[60] Shojania KG, Duncan BW, McDonald KM, Wachter RM. Safe but sound: patient safety meets evidence-based medicine. JAMA. 2002 Jul 24-31;288(4):508-13. doi: 10.1001/jama.288.4.508. PMID: 12132985.

National Healthcare Safety Network (NHSN), and metrics derived from administrative claims data using tools such as the AHRQ Patients Safety Indicators.

Strategies for measuring factors that promote safety or indicate risk (as opposed to the occurrence of adverse events and harm) are less common. Tools designed to measure attributes of high reliability have been developed for healthcare organizations.[61] AHRQ has developed tools for measuring safety culture in various healthcare settings, known as the AHRQ Surveys on Patient Safety Culture™ (SOPS®).[62] These surveys enable healthcare organizations to assess how their providers and staff perceive various aspects of patient safety culture in several settings, including hospitals, medical offices, ambulatory surgery centers, nursing homes, and community pharmacies. Users of SOPS® surveys have the option of incorporating additional questions, known as supplemental items, to customize their questionnaires, and to contribute their data to the national SOPS® Databases, central repositories for survey data from each of the SOPS® surveys. For example, AHRQ recently released a Diagnostic Safety supplemental item set for use with the Medical Office Survey on Patient Safety Culture. This item set is designed to be used in conjunction with the core Medical Office SOPS® to help medical offices assess the extent to which their organizations support the diagnostic process, accurate diagnoses, and communication around diagnoses. [63]

Using the mechanisms described below, AHRQ tracks adverse events and longitudinal trends in patient safety at the national level and is working to advance our ability to better measure patient safety at all levels.

The Medicare Patient Safety Monitoring System (MPSMS). In 2001, the Centers for Medicare & Medicaid Services (CMS) developed MPSMS to measure rates of specific adverse events and create a baseline to assess the impact of national patient safety initiatives. MPSMS is a medical record review-based surveillance system containing 21 measures of adverse events.[64] Trained abstractors have used the MPSMS software tool to review a sample averaging over 20,000 inpatient records each year from hospitals across the country.[65] CMS discontinued MPSMS after the 2007 data year; the program restarted in 2009 with funding from AHRQ and has been an AHRQ-CMS effort for data years 2009–2019. The final 2019 data will be analyzed through CY 2020 and 2021.

The Quality and Safety Review System (QSRS). Much has changed in the patient safety landscape since the MPSMS was first developed nearly two decades ago. To keep pace with these changes and capitalize on advances in patient safety measurement and health IT, AHRQ developed the QSRS to replace MPSMS. MPSMS was retired after the 2019 data year, and QSRS is now the system that will be used to develop national estimates of adverse events going forward. The QSRS is capable of electronically importing Admit, Discharge, and Transfer files standardized according to CMS billing definitions. Over

[61] Veazie S, Peterson K, Bourne D. Evidence brief: implementation of high reliability organization principles. Washington (DC): Department of Veterans Affairs (US); 2019 May. PMID: 31233295.

[62] Agency for Healthcare Research and Quality. Surveys On Patient Safety Culture™ (SOPS®). https://www.ahrq.gov/sops/index.html. Date accessed October 29, 2020.

[63] Agency for Healthcare Research and Quality. Diagnostic Safety Supplemental Items for Medical Office SOPS®. https://www.ahrq.gov/sops/surveys/medical-office/supplemental-items/diagnostic-safety.html. Last reviewed June 2021.

[64] Wang Y, Eldridge N, Metersky ML, Verzier NR, Meehan TP, Pandolfi MM, Foody JM, Ho SY, Galusha D, Kliman RE, Sonnenfeld N, Krumholz HM, Battles J. National trends in patient safety for four common conditions, 2005-2011. N Engl J Med. 2014 Jan 23;370(4):341-51. doi: 10.1056/NEJMsa1300991. PMID: 24450892; PMCID: PMC4042316.

[65] Classen DC, Munier W, Verzier N, Eldridge N, Hunt D, Metersky M, Richards C, Wang Y, Brady PJ, Helwig A, Battles J. Measuring Patient Safety: The Medicare patient safety monitoring system (past, present, and future). J Patient Saf. 2016 Oct 20. doi: 10.1097/PTS.0000000000000322. Epub ahead of print. PMID: 27768654.

time, it will incorporate data from electronic health records, such as prescriptions and laboratory test results, relevant to patient safety events. [66]

Like the MPSMS, the QSRS generates adverse event rates and can be used to trend performance at the national level through abstraction of medical records. However, the QSRS expands on what the MPSMS currently collects. New measures include those related to opioid administration and adverse events, surgical site infections, other surgical and anesthesia-related events, and obstetric and neonatal adverse events, with the goal of coming as close as possible to capturing and measuring "all-cause harm."[67] QSRS also has the capability to track hospitalized patients who were admitted to the hospital with COVID-19 or who tested positive for COVID-19 during their hospital stay. This will allow for special analysis of patient safety events to determine whether or not patients with COVID-19 experience similar or different adverse events.

AHRQ National Scorecard on Hospital-Acquired Conditions. Many of the patient safety initiatives launched in the last decade target adverse events referred to as hospital-acquired conditions (HACs). They are common, they can cause significant harm, and they are often preventable. AHRQ estimated the rate of HACs using data from the MPSMS, the AHRQ Patient Safety Indicators, and CDC's NHSN data and publishes the findings in the AHRQ National Scorecard on Hospital-Acquired Conditions. From 2014 to 2017, HACs fell by 13 percent, averting approximately 20,700 deaths and saving about $7.7 billion in healthcare costs.[68]

National Healthcare Quality and Disparities Reports and Chartbooks. The annual National Healthcare Quality and Disparities Reports (QDR) present findings on the quality of healthcare received by the general U.S. population and disparities in care experienced by different racial and socioeconomic groups. Patient safety is one of six priorities considered in the QDR. A related report, the *Chartbook on Patient Safety,*[69] summarizes trends across selected patient safety measures over time.

The body of research focused on measuring the effectiveness of strategies for reducing medical error and increasing patient safety is significant and growing. The AHRQ *Making Healthcare Safer* (MHS) series has used a systematic approach for reviewing this literature at three points during the last 20 years, most recently in 2020. The links to each Summary of Evidence and Update for the strategies and practices for improving patient safety are presented in the next section. This information illustrates progress as well as opportunities for improvement in the field's ability to generate new research about patient safety improvement strategies and to use this knowledge base to assess their effectiveness.

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[66] Agency for Healthcare Research and Quality. AHRQ Quality and Safety Review System (QSRS): improved patient safety monitoring. https://www.ahrq.gov/patient-safety/resources/qsrs/index.html. Last reviewed January 2021.

[67] Classen DC, Munier W, Verzier N, Eldridge N, Hunt D, Metersky M, Richards C, Wang Y, Brady PJ, Helwig A, Battles J. Measuring patient safety: the Medicare patient safety monitoring system (past, present, and future). J Patient Saf. 2016 Oct 20. doi: 10.1097/PTS.0000000000000322. Epub ahead of print. PMID: 27768654.

[68] Agency for Healthcare Research and Quality. AHRQ national scorecard on hospital-acquired conditions. https://www.ahrq.gov/hai/pfp/index.html. Last reviewed July 2020.

[69] National Healthcare Quality and Disparities Report chartbook on patient safety. Rockville, MD: Agency for Healthcare Research and Quality; October 2019. AHRQ Pub. No. 19(20)-0070-2-EF. https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/2018qdr-patsaf-chartbook.pdf. Date accessed November 3, 2020.

2.5. Existing and Emerging Strategies for Reducing Medical Error and Increasing Patient Safety

2.5.1. Introduction

The strategies and practices presented in this section are defined as "discrete and clearly recognizable structures and/or processes used during the provision of care that are intended to mitigate the effects" of various threats to patient safety.[70] All were evaluated for effectiveness based on the quality and extent of the evidence as published in peer-reviewed journals and other relevant literature in one or more of AHRQ's three MHS reviews, published in 2001, 2013, and 2020. This body of work has collected, critically reviewed, and in 2013 and 2020, provided selected updates on the existing evidence base for many of the strategies and practices that are in use to reduce medical error and increase patient safety. These reports, while not all-inclusive, together create a compendium that captures many of the patient safety strategies and practices that are in use and provides an assessment of the evidence regarding their effectiveness.

Each report used a slightly different approach to topic selection and/or methodology, but all used standard methods for assessing the quality and weight of the available evidence and the risk of bias. For the first edition of MHS in 2001, experts from the University of California at San Francisco (UCSF)–Stanford University Evidence-based Practice Center (referred to as the Board) developed an initial list of domains and topics with input from patient safety experts, clinician–researchers, AHRQ, and the National Quality Forum (NQF) Safe Practices Committee. Teams of researchers searched bibliographic databases and grey literature for safety practices associated with each topic and evaluated the available evidence using specific criteria provided by the Board. A safety practice was considered for inclusion in the review if it could be applied in the hospital setting or at the interface between inpatient and outpatient settings and it applied to a broad range of health care conditions or procedures. Practices were excluded if the only available evidence came from observational studies without controls and the measured outcomes could not be directly tied to observed errors, laboratory results, adverse events, morbidity or mortality. The resulting list of practices was reviewed by the Board and a six-person Advisory Panel to identify gaps in coverage and assess justifications for excluding a given practice. Any disagreements over whether a practice met the inclusion or exclusion criteria were resolved by the MHS Editors. AHRQ and the NQF Safe Practices Committee reviewed the final list, which included 79 practices.[71]

MHS II (2013) focused much more broadly. Editors started with the 79 practices identified in MHS I and added several practices identified by other entities (such as the National Quality Forum and the Joint Commission) and advisors, including a 21-member Technical Expert Panel (TEP). The editorial team then narrowed the topics by excluding those that were too early in their development, practices relating to medical approaches no longer widely used, and practices more related to quality than safety. They further narrowed the list through "team triage," group discussion, and TEP votes. Those practices that remained were "judged likely to be most helpful to providers, policymakers, and patients."[72] Editors

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[70] Hall KK, Shoemaker-Hunt S, Hoffman L, Richard S, Gall E, Schoyer E, Costar D, Gale B, Schiff G, Miller K, Earl T, Katapodis N, Sheedy C, Wyant B, Bacon O, Hassol A, Schneiderman S, Woo M, LeRoy L, Fitall E, Long A, Holmes A, Riggs J, Lim A. Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020; Mar. Report No.: 20-0029-EF. PMID: 32255576: Methods-1.

[71] Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. Evid Rep Technol Assess (Summ). 2001;(43):i-x, 1-668. PMID: 11510252; PMCID: PMC4781305.

[72] Shekelle PG, Wachter RM, Pronovost PJ, Schoelles K, McDonald KM, Dy SM, Shojania K, Reston J, Berger Z, Johnsen B, Larkin JW, Lucas S, Martinez K, Motala A, Newberry SJ, Noble M, Pfoh E, Ranji SR, Rennke S, Schmidt E, Shanman R, Sullivan N, Sun F, Tipton K, Treadwell JR, Tsou A, Vaiana ME, Weaver SJ, Wilson R, Winters BD. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. Evid Rep Technol Assess (Full Rep). 2013 Mar;(211):1-945. PMID: 24423049; PMCID: PMC4781147: ES-4.

noted that "The evidence supporting the effectiveness of many patient safety practices has improved substantially over the past decade…Twenty-two patient safety practices are sufficiently well understood, and health care providers can consider adopting them now."[73]

In terms of healthcare settings, the scope of MHS III, published in 2020, was broader still. The introduction notes that "AHRQ is seeking to support a culture of safety across the healthcare continuum, including in nursing homes, home care, outpatient, and ambulatory settings, and during care transition."[74] The project report team developed a new conceptual framework that put the patient in the center. The framework included harms that could occur between settings as well as patient risks resulting from existing vulnerabilities and disparities.

Figure 2. Framework for Making Healthcare Safer III Report
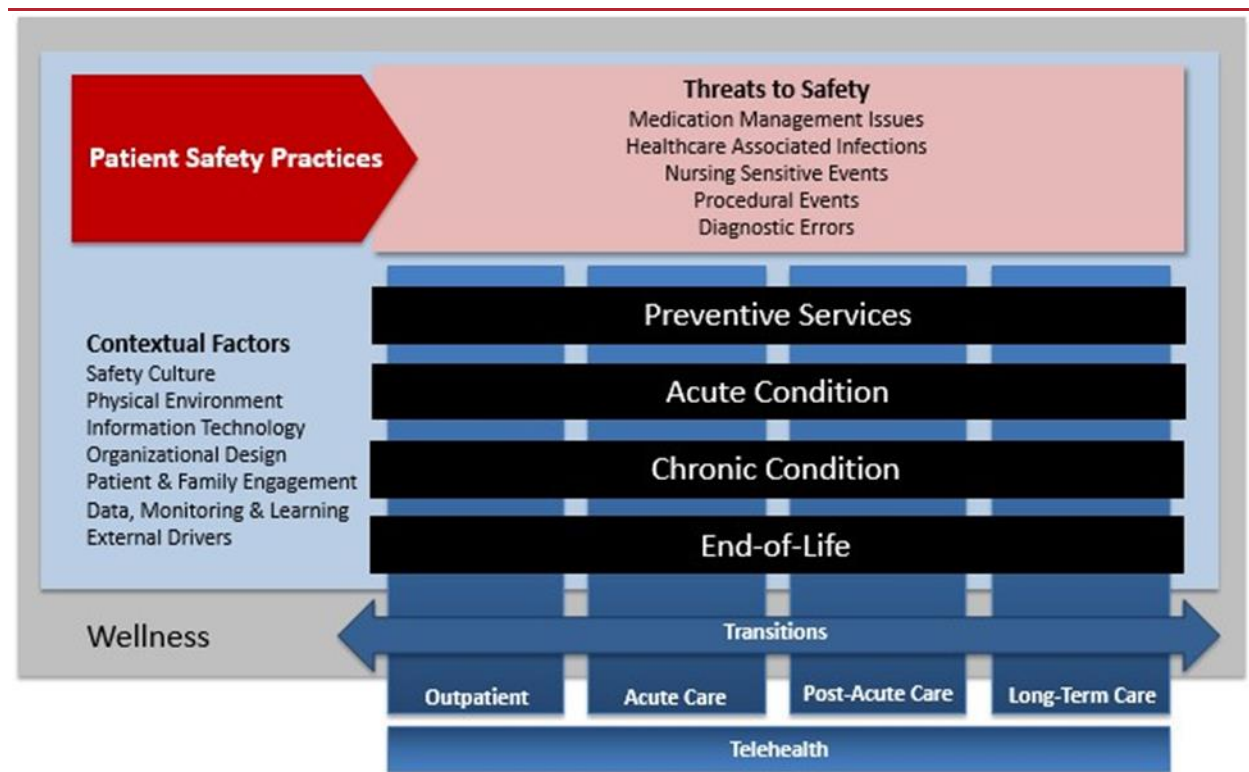
Similar to the approach taken by MHS II, the MHS III project team conducted an environmental scan to identify topics for the evidence review. Sources for the scan included AHRQ's PSNet, the National Quality Strategy, the Joint Commission's National Patient Safety Goals, the National Quality Forum's 2015 Patient Safety Report, the Centers for Medicare & Medicaid Services Hospital Value-Based Purchasing Program and Partnership for Patients, ECRI Institute's 2017 and 2016 Top 10 Patient Safety Issues briefs, and Becker's Hospital Review 10 Top Patient Safety Issues for 2018. Based on these

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[73] Shekelle PG, Wachter RM, Pronovost PJ, Schoelles K, McDonald KM, Dy SM, Shojania K, Reston J, Berger Z, Johnsen B, Larkin JW, Lucas S, Martinez K, Motala A, Newberry SJ, Noble M, Pfoh E, Ranji SR, Rennke S, Schmidt E, Shanman R, Sullivan N, Sun F, Tipton K, Treadwell JR, Tsou A, Vaiana ME, Weaver SJ, Wilson R, Winters BD. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. Evid Rep Technol Assess (Full Rep). 2013 Mar;(211):1-945. PMID: 24423049; PMCID: PMC4781147: x.

[74] Hall KK, Shoemaker-Hunt S, Hoffman L, Richard S, Gall E, Schoyer E, Costar D, Gale B, Schiff G, Miller K, Earl T, Katapodis N, Sheedy C, Wyant B, Bacon O, Hassol A, Schneiderman S, Woo M, LeRoy L, Fitall E, Long A, Holmes A, Riggs J, Lim A. Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020 Mar. Report No.: 20-0029-EF. PMID: 32255576: ES-1.

sources and the list of topics reviewed in MHS I and II, the team identified eight broad and 74 specific harm areas. An Advisory Group narrowed the list down to 67 topics, after concluding that seven listed topics were outside the scope of the report.

Members of a Technical Expert Panel (TEP) and the Advisory Group (AG) rated each of the 67 topics to determine which ones warranted inclusion in the evidence review. The rating system included two parts: a five-point Likert scale where 1=low priority and 5=high priority and a reason for the rating if a topic rated 3 or higher on the priority scale. Raters could choose from the following list of reasons: (1) the harm has not been adequately addressed in the past, (2) this is a newer harm area, or (3) this harm should be examined in a new healthcare setting.

Fifteen members of the TEP and AG participated in the rating exercise. An average priority score was calculated for each topic, and any topic with a score of 2.5 or lower was excluded. After the results were presented to AHRQ, some new topics were added, resulting in a final list of 17 harm area topics. Next, the team identified specific patient safety practices for review. Members of the TEP and AG were asked to vote on inclusion or exclusion of patient safety practices associated with the following areas: harms related to diagnostic error and failure to rescue, infection-related harms, transitions of care, medication management, and nursing-related events. AHRQ reviewed the results and identified seven additional patient safety practices for inclusion in the report, resulting in the final list of 47 patient safety practices.[75]

The list of strategies and practices for reducing medical errors and increasing patient safety for which there is evidence of effectiveness is growing and will continue to grow. Scarcity of evidence at a given point in time does not necessarily equal lack of effectiveness. Conversely, the weight and direction of the evidence base can change as more studies are conducted in different settings and new research is published. Change is a constant in healthcare, and advances in medicine and technology are ongoing.

Designing research to measure effectiveness in patient safety is uniquely challenging; the breadth and diversity of potential topics and settings is vast. One clear and consistent finding is that many factors influence the success of any patient safety practice, as will be discussed further in chapter 3. The importance of context that takes into account real-world constraints for successful uptake and use of patient safety strategies and practices cannot be overstated.

2.5.2 Strategies and Practices for Reducing Medical Errors and Increasing Patient Safety Organized by Topic: The State of the Evidence
Tables 1 to 28 contain a consolidated list of all strategies and practices for reducing medical errors and increasing patient safety reviewed for effectiveness in all three MHS editions, organized by topic area.[76]

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[75]Hall KK, Shoemaker-Hunt S, Hoffman L, Richard S, Gall E, Schoyer E, Costar D, Gale B, Schiff G, Miller K, Earl T, Katapodis N, Sheedy C, Wyant B, Bacon O, Hassol A, Schneiderman S, Woo M, LeRoy L, Fitall E, Long A, Holmes A, Riggs J, Lim A. Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020 Mar. Report No.: 20-0029-EF. PMID: 32255576: ES-3 and Methods, 6-7.

[76] The tables that follow are adapted from Comparison Tables for Making Healthcare Safer Reports available at https://www.ahrq.gov/research/findings/making-healthcare-safer/comparison.html. Within all the tables, MHS stands for the series Making Healthcare Safer.

Table 1. Adverse Drug Events: General Medication Topics

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Computer Adverse Drug Event (ADE) Detection and Alerts	Summary of Evidence	(Not reviewed)	(Not reviewed)
Unit-Dose Drug Distribution Systems	Summary of Evidence	(Not reviewed)	(Not reviewed)
Automated Medication Dispensing Devices	Summary of Evidence	(Not reviewed)	(Not reviewed)
Computerized Physician Order Entry with Clinical Decision Support Systems	Summary of Evidence	Update	(Not reviewed)
The Clinical Pharmacist's Role in Preventing Adverse Drug Events	Summary of Evidence	Update	(Not reviewed)
Protocols for High-Risk Drugs: Reducing Adverse Drug Events Related to Anticoagulants	Summary of Evidence	Update	(Not reviewed)
The Joint Commission's "Do Not Use" List	(Not reviewed)	Summary of Evidence	(Not reviewed)
Medication Reconciliation Supported by Clinical Pharmacists	(Not reviewed)	Summary of Evidence	(Not reviewed)

Table 2. ADEs: Harms due to Anticoagulants

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Single Provider	(Not reviewed)	(Not reviewed)	Summary of Evidence
Nomograms	(Not reviewed)	(Not reviewed)	Summary of Evidence
Medication Reconciliation and Handoffs	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 3. ADEs: Harms due to Diabetic Agents

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Standardized Insulin Protocols	(Not reviewed)	(Not reviewed)	Summary of Evidence
Teach-Back	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 4. ADEs: Reducing Adverse Drug Events in Older Adults

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Deprescribing	(Not reviewed)	(Not reviewed)	Summary of Evidence
Use of STOPP Criteria	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 5. ADEs: Harms Due to Opioids

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Opioid Stewardship	(Not reviewed)	(Not reviewed)	Summary of Evidence
Medication-Assisted Treatment	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 6. ADEs: Infusion Pumps/Medication Error

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Smart Pumps and Other Protocols for Infusion Pumps	(Not reviewed)	Summary of Evidence	(Not reviewed)
Structured Process Changes/Workflow Redesign	(Not reviewed)	(Not reviewed)	Summary of Evidence
Staff Education and Training	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 7. Alarm Fatigue

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Safety Culture	(Not reviewed)	(Not reviewed)	Summary of Evidence
Alarm Risk Assessment	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 8. Care Transitions

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Interventions To Improve Care Transitions at Hospital Discharge	(Not reviewed)	Summary of Evidence	(Not reviewed)
BOOST: Better Outcomes for Older Adults through Safe Transitions	(Not reviewed)	(Not reviewed)	Summary of Evidence
CTI: Care Transition Intervention	(Not reviewed)	(Not reviewed)	Summary of Evidence
TCM: Transitional Care Model	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 9. Cross-cutting: Teamwork Training

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Crew Resource Management and its Applications in Medicine	Summary of Evidence	(Not reviewed)	(Not reviewed)
Teamwork and Team Training	(Not reviewed)	Summary of Evidence	Update

Table 10. Cross-cutting: Health Information Technology

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Information Transfer	Summary of Evidence	(Not reviewed)	(Not reviewed)
Clinical Decision Support	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 11. Cross-cutting: Other Topics

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
"Closed" Intensive Care Units and Other Models of Care for Critically Ill Patients	Summary of Evidence	(Not reviewed)	(Not reviewed)
Fatigue, Sleepiness, and Medical Errors	Summary of Evidence	(Not reviewed)	(Not reviewed)
Nurse Staffing, Models of Care Delivery, and Interventions	Summary of Evidence	Update	(Not reviewed)
Human Factors and Medical Devices	Summary of Evidence	Update	(Not reviewed)
Promoting a Culture of Patient Safety	Summary of Evidence	Update	Update
Staff Education and Training (Simulation)	Summary of Evidence	Update	Update
Limiting Individual Provider's Hours of Service	(Not reviewed)	Summary of Evidence	(Not reviewed)
Monitoring Auditing and Feedback	(Not reviewed)	Summary of Evidence	Update

Table 12. Delirium

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Prevention of Delirium in Older Hospitalized Patients	Summary of Evidence (Also listed under Safety Practices for Hospitalized or Institutionalized Elders)	Update (Also listed under Safety Practices for Hospitalized or Institutionalized Elders)	(Not reviewed)
Screening and Assessment	(Not reviewed)	(Not reviewed)	Summary of Evidence
Staff Education and Training	(Not reviewed)	(Not reviewed)	Summary of Evidence
Non-Pharmacologic Intervention Programs	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 13. Diagnostic Error

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Patient Safety Practices Targeted at Diagnostic Errors	(Not reviewed)	Summary of Evidence	(Not reviewed)
Clinical Decision Support	(Not reviewed)	(Not reviewed)	Summary of Evidence
Performance Review and Feedback	(Not reviewed)	(Not reviewed)	Summary of Evidence
Result Notification Systems	(Not reviewed)	(Not reviewed)	Summary of Evidence
Staff Education and Training	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 14. Failure to Rescue

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Rapid Response Systems	(Not reviewed)	Summary of Evidence	Update
Patient Monitoring Systems	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 15. General Clinical Topics

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Safety During Transport of Critically Ill Patients	Summary of Evidence	(Not reviewed)	(Not reviewed)
Nutritional Support	Summary of Evidence	(Not reviewed)	(Not reviewed)
Pneumococcal Vaccination Prior to Hospital Discharge	Summary of Evidence	(Not reviewed)	(Not reviewed)
Pain Management	Summary of Evidence	(Not reviewed)	(Not reviewed)
Prevention of Clinically Significant Gastrointestinal Bleeding in Intensive Care Unit Patients	Summary of Evidence	Update	(Not reviewed)
Inpatient Intensive Glucose Control Strategies To Reduce Death and Infection	(Not reviewed)	Summary of Evidence	(Not reviewed)
Tubing Misconnections	(Not reviewed)	Summary of Evidence	(Not reviewed)
Identifying Patients at Risk for Suicide	(Not reviewed)	Summary of Evidence	(Not reviewed)

Table 16. Infection Control: Carbapenem-Resistant Enterobacteriaceae

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Transmission-based Precautions: Contact Precautions, Patient Isolation, Dedicated Staff	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 17. Infection Control: Central Line-Associated Bloodstream Infections

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Prevention of Central Line-Associated Bloodstream Infections	(Not reviewed)	Summary of Evidence	(Not reviewed)
Interventions To Allow the Reuse of Single-Use Devices	(Not reviewed)	Summary of Evidence	(Not reviewed)

Table 18. Infection Control: Clostridioides difficile Infection

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Impact of Changes in Antibiotic Use Practices on Nosocomial Infections and Antimicrobial Resistance, *Clostridium difficile*, and Vancomycin-Resistant Enterococcus (VRE)	Summary of Evidence (Also listed in Vancomycin-resistant Enterococcus under Miscellaneous section)	(Not reviewed)	(Not reviewed)
Antimicrobial Stewardship	(Not reviewed)	(Not reviewed)	Summary of Evidence
Testing	(Not reviewed)	(Not reviewed)	Summary of Evidence
Surveillance	(Not reviewed)	(Not reviewed)	Summary of Evidence
Hand Hygiene	(Not reviewed)	(Not reviewed)	Summary of Evidence
Environmental Cleaning & Decontamination	(Not reviewed)	(Not reviewed)	Summary of Evidence
Multicomponent Prevention Interventions	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 19. Infection Control: Infections Due to Other Multi-Drug-Resistant Organisms

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Hand Hygiene	(Not reviewed)	(Not reviewed)	Summary of Evidence
Surveillance	(Not reviewed)	(Not reviewed)	Summary of Evidence
Minimize Use of Devices	(Not reviewed)	(Not reviewed)	Summary of Evidence
Chlorhexidine Bathing	(Not reviewed)	(Not reviewed)	Summary of Evidence
Communication of MDRO Status	(Not reviewed)	(Not reviewed)	Summary of Evidence
Environmental Cleaning & Disinfection	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 20. Infection Control: Miscellaneous Topics

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Impact of Changes in Antibiotic Use Practices on Nosocomial Infections and Antimicrobial Resistance - *Clostridium Difficile* and Vancomycin-resistant Enterococcus (VRE)	Summary of Evidence (Also listed in Clostridium Difficile Infection)	(Not reviewed)	(Not reviewed)
Prevention of Ventilator-Associated Pneumonia	Summary of Evidence	Update	(Not reviewed)
Practices to Improve Handwashing Compliance	Summary of Evidence	Update	See CDI and MDROs chapters
Impact of Barrier Precautions in Reducing the Transmission of Serious Nosocomial Infections	Summary of Evidence	Update	See MDROs and CRE chapters

Table 21. Infection Control: Urinary Tract Infection

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Prevention of Nosocomial Urinary Tract Infections	Summary of Evidence	Update	(Not reviewed)
Reducing Unnecessary Urinary Catheter Use and Other Strategies to Prevent Cather-Associated Urinary Tract Infections	Summary of Evidence	Update	(Not reviewed)

Table 22. Patient and Family Engagement

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Advance Planning For End-of-Life Care	Summary of Evidence	(Not reviewed)	(Not reviewed)
Other Practices Related to Patient Participation	Summary of Evidence	(Not reviewed)	(Not reviewed)
Obtaining Informed Consent From Patients	Summary of Evidence	Update	(Not reviewed)
Ensuring Documentation of Patients' Preferences for Life-Sustaining Treatment	(Not reviewed)	Summary of Evidence	(Not reviewed)
Person and Family Engagement	(Not reviewed)	Summary of Evidence	Update
Cultural Competency	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 23. Patient Identification Errors

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Prevention of Misidentifications	Summary of Evidence	(Not reviewed)	(Not reviewed)
Operating Room/Surgery-Specific Practices	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 24. Radiological

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Reducing Errors in the Interpretation of Plain Radiographs and Computed Tomography Scans	Summary of Evidence	(Not reviewed)	(Not reviewed)
Interventions To Prevent Contrast-Induced Acute Kidney Injury	Summary of Evidence	Update	(Not reviewed)
Preventing Patient Death or Serious Injury Associated With Radiation Exposure From Fluoroscopy and Computed Tomography	(Not reviewed)	Summary of Evidence	(Not reviewed)

Table 25. Safety Practices for Hospitalized or Institutionalized Elders

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Multidisciplinary Geriatric Consultation Services	Summary of Evidence	(Not reviewed)	(Not reviewed)
Geriatric Evaluation and Management Units for Hospitalized Patients	Summary of Evidence	(Not reviewed)	(Not reviewed)
Prevention of Falls in Hospitalized and Institutionalized Older People	Summary of Evidence	Update (all patients)	(Not reviewed)
Prevention of Pressure Ulcers in Older Patients	Summary of Evidence	Update (all patients)	(Not reviewed)
Prevention of Delirium in Older Hospitalized Patients	Summary of Evidence (Also listed under Delirium)	Update (Also listed under Delirium)	Specific PSPs in Delirium chapter

Table 26. Sepsis Recognition

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Screening Tools and Algorithms	(Not reviewed)	(Not reviewed)	Summary of Evidence
Patient Monitoring Systems	(Not reviewed)	(Not reviewed)	Summary of Evidence

Table 27. Surgery, Anesthesia, and Perioperative Medicine

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Localizing Care to High-Volume Centers	Summary of Evidence	(Not reviewed)	(Not reviewed)
Learning Curves for New Procedures - the Case of Laparoscopic Cholecystectomy	Summary of Evidence	(Not reviewed)	(Not reviewed)
Prevention of Surgical Site Infections	Summary of Evidence	(Not reviewed)	(Not reviewed)
Ultrasound Guidance of Central Vein Catheterization	Summary of Evidence	Update	(Not reviewed)
Prevention of Surgical Items Being Left Inside Patient	Summary of Evidence	Update	(Not reviewed)
Pre-Anesthesia Checklists To Improve Patient Safety	Summary of Evidence	Update	(Not reviewed)
The Impact Of Intraoperative Monitoring On Patient Safety	Summary of Evidence	(Not reviewed)	(Not reviewed)
Beta-blockers and Reduction of Perioperative Cardiac Events	Summary of Evidence	Update	(Not reviewed)
Use of Report Cards and Outcome Measurements To Improve Safety of Surgical Care: American College of Surgeons National Surgical Quality Improvement Program	(Not reviewed)	Summary of Evidence	(Not reviewed)
Operating Room Integration and Display Systems	(Not reviewed)	Summary of Evidence	(Not reviewed)

Table 28. Venous Thromboembolism

Patient Safety Practices	MHS I (2001)	MHS II (2013)	MHS III (2020)
Prevention of Venous Thromboembolism	Summary of Evidence	Update	(Not reviewed)
Post-Surgical Prophylaxis using Aspirin	(Not reviewed)	(Not reviewed)	Summary of Evidence

Chapter 3.
Encouraging the Use of Effective Strategies for Reducing Medical Errors and Increasing Patient Safety

Encouraging the use of effective strategies for reducing medical errors and increasing patient safety requires a clear understanding of the factors that influence their adoption and the resources needed to facilitate their uptake. This chapter provides an overview of some of the concepts underlying effective implementation and how they have been applied in patient safety; examples of resources Federal agencies make available to encourage healthcare providers to use effective patient safety strategies; work underway to align patient safety improvement efforts across public and private sectors; and potential future directions for efforts to encourage the use of effective patient safety strategies.

3.1. Moving Patient Safety Strategies Into Practice: Key Concepts Supporting Effective Implementation

3.1.1. Learning Health Systems

Every day, clinical encounters generate data pertaining to healthcare procedures and patient outcomes. When these data are systematically collected and analyzed, the results can point to risks and hazards in healthcare delivery and contribute to the evidence on safe practices. In a learning health system, that evidence is aligned with safety culture and the mission of healthcare organizations to drive improvements in clinical practice. Figure 2 illustrates the continuous feedback loop wherein data generates evidence, evidence informs practice, and ongoing research supports the cycle of improvement.

Figure 3. Learning Health Systems

Learning health systems share several defining characteristics. They have leaders who are committed to a culture of continuous learning and improvement. They have systems in place to gather and apply evidence in real time to guide care. They have the capacity to share new evidence and support clinician

decisionmaking using HIT. Learning health systems consider patients vital members of the learning team and analyze patient and provider care experiences along with other data to improve care. Finally, learning health systems continually assess outcomes and refine processes and training to create a dynamic feedback cycle for learning and improvement.[77] Although the concept of a learning health system is relatively new, it may be an important driver to encourage use of effective patient safety strategies. The learning health systems perspective provides a blueprint for integrating data and evidence into clinical practice with the goal of achieving safer, higher quality care. It may also help to reinforce that safety is an attribute of the entire healthcare system and the first responsibility of every participant, rather than a discrete program or silo of activities.[78] PSOs can play an important role in supporting the evolution of health systems into learning health systems.

3.1.2. Strategies for Effective Implementation

Translation of research into practice is a complex endeavor. Evidence-based patient safety practices are not one-size-fits-all, "off the shelf" or "plug and play" products that are ready to operate consistently across different environments and users. Encouraging the use of effective strategies requires an understanding of the contextual factors that might hinder or facilitate the implementation process and its outcomes.[79]

Once potential barriers and facilitators are identified, appropriate plans can be designed to adapt the strategy or practice to the particular healthcare organization or service. Engaging stakeholders at multiple levels is essential to anticipating and addressing implementation barriers and identifying and supporting facilitators. However, implementers must ultimately understand how to strike the right balance between adaptation of an evidence-based strategy or practice and fidelity to its core components. Making too many changes can compromise its effectiveness, or worse, result in problematic unintended consequences.[80]

Identifying ways to find that balance is one of the goals of implementation science. Several models guide implementers in identifying adaptations that may be needed to enhance the adoption, implementation, and sustainability of evidence-based practices. Implementation strategies include developing stakeholder interrelationships and tailoring the practice or set of practices to fit the local context. Effectively encouraging the use of effective strategies often requires the ability to provide interactive assistance throughout implementation, such as educational outreach or learning collaboratives and other kinds of practical support. Finally, financial strategies and changes to infrastructure may be needed to support implementation and sustainability of evidence-based practices. Using many strategies to address barriers at different levels and capitalize on existing strengths is critical to effective implementation.

3.2. Federal Resources That Support the Use of Effective Patient Safety Strategies

Federal agencies are a major source of funding for the research and development of patient safety strategies and practices and the tools, initiatives, and other resources used to implement them.

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[77] Agency for Healthcare Research and Quality. About learning health systems. https://www.ahrq.gov/learning-health-systems/about.html. Last reviewed May 2019.

[78] Agency for Healthcare Research and Quality. Learning health systems. AHRQ Pub. No. 19-0052-1. https://www.ahrq.gov/sites/default/files/wysiwyg/lhs/lhs_case_studies_overview.pdf. Last reviewed April 2019.

[79] Hull L, Athanasiou T, Russ S. Implementation science: a neglected opportunity to accelerate improvements in the safety and quality of surgical care. Ann Surg. 2017 Jun;265(6):1104-1112. doi: 10.1097/SLA.0000000000002013. PMID: 27735828.

[80] US Department of Health and Human Services, National Institutes of Health. Implementation science at a glance: a guide for cancer control practitioners. https://cancercontrol.cancer.gov/IS/docs/NCI-ISaaG-Workbook.pdf. Date accessed October 29, 2020.

3.2.1. AHRQ Patient Safety Resources

As the principal Federal agency working to improve patient safety, AHRQ conducts and supports much of this work through its Center for Quality Improvement and Patient Safety (CQuIPS). In addition to implementing the Patient Safety Act, CQuIPS manages grant funding for patient safety research, reports on and disseminates research findings and other new developments in patient safety, and develops tools and resources to support and promote implementation, adoption, and timely diffusion of evidence-based patient safety practices among clinicians and across healthcare settings and systems.

AHRQ has multiple mechanisms to encourage healthcare providers to implement evidence-based patient safety practices. As discussed earlier in this report, AHRQ-funded research typically generates practical resources such as toolkits that AHRQ makes freely available on its website.[81] For example, AHRQ's Healthcare-Associated Infections program supported the research that informed the development of the CUSP toolkit. CUSP methods underlie the successful implementation of several patient safety programs, such as AHRQ's Safety Program for Improving Antibiotic Use. The Safety Program adapts principles of CUSP to improve antibiotic prescribing, engaging bedside clinicians through the use of the Four Moments of Antibiotic Decision Making – an innovative approach to antibiotic stewardship that enables clinicians to be stewards of their own antibiotic prescribing. Results from the acute care cohort of the Safety Program were published in JAMA Open February 26, 2021. Antibiotic use in the Program was reduced in over 400 hospitals by 30.3 days of therapy per 1000 patient days over the 1-year period (p=0.008). The incidence rate of hospital-onset C. difficile rates was reduced by 19.5% (p=0.03). [82] [83]

Another notable web-based resource for healthcare providers and others working on improving patient safety is the AHRQ Patient Safety Network (PSNet), launched in 2005, which now includes AHRQ Morbidity and Mortality Rounds on the Web (WebM&M), launched in 2003. PSNet offers weekly updates of the latest patient safety literature, news, tools, innovative practices, and learning opportunities (Current Issue) and carefully annotated links to important research and other information on patient safety (The Collection). Supported by a robust patient safety taxonomy and web architecture, AHRQ PSNet provides powerful searching and browsing capability and offers users the ability to customize searches to their interests. AHRQ WebM&M includes expert analysis of cases, interactive learning modules available for continuing medical education credit, and commentaries written by patient safety experts. These resources enable AHRQ to disseminate the latest evidence on patient safety to help healthcare providers quickly respond to new challenges, including those confronting healthcare providers responding to the COVID-19 pandemic.

AHRQ investments in research on diagnostic safety across inpatient and outpatient settings have resulted in a series of issue briefs available for download on the agency website.[84] One of the issue briefs reviewed research on the use of health information technology tools, such as patient portals, mobile text messaging, and smartphone apps, to improve patient engagement in the diagnostic process when patients seek emergency care. Another brief addressed the complexities and advances associated with operational measurement of diagnostic safety. Three additional briefs focused on quality and

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[81] Agency for Healthcare Research and Quality. AHRQ Patient Safety Tools and Resources. https://www.ahrq.gov/patient-safety/resources/pstools/index.html. Last reviewed May 2021.

[82] Tamma PD, Miller MA, Dullabh P, Ahn R, Speck K, Gao Y, Scherpf E, Cosgrove SE. Association of a Safety Program for Improving Antibiotic Use With Antibiotic Use and Hospital-Onset Clostridioides difficile Infection Rates Among US Hospitals. JAMA Netw Open. 2021 Feb 1;4(2):e210235. doi: 10.1001/jamanetworkopen.2021.0235. PMID: 33635327; PMCID: PMC7910818.

[83] Agency for Healthcare Research and Quality. AHRQ Safety Program Helps Hospitals Decrease Antibiotic Use and Reduce Infections, Study Finds. https://www.ahrq.gov/news/newsroom/press-releases/antibiotic-stewardship-hospital.html. Last reviewed February 2021.

[84] Agency for Healthcare Research and Quality. AHRQ Papers on Diagnostic Safety Topics. https://www.ahrq.gov/patient-safety/reports/dxsafety-issuebriefs.html. Last reviewed June 2021.

safety of telediagnosis for acute conditions, the efficacy of using checklists to improve diagnostic reasoning, and how organization leaders can be engaged in diagnostic improvement.

Research shows that when patients are engaged in their healthcare, it can lead to measurable improvements in safety and quality. Table 22 in this report includes links to syntheses of the research on several aspects of patient and family engagement in patient safety. AHRQ has developed a number of resources and tools to help patients, families and healthcare providers put this kind of research into practice. "Questions Are the Answer" compiles videos and other resources that patients can use to plan for upcoming visits, become more comfortable asking questions about their treatment, and learn how they can help to prevent medical errors.[85] The resource includes a free mobile app that allows patients to select questions they would like answered or pictures they want to share with their care team.[86]

AHRQ has also developed resources to help both hospitals and primary care settings promote patient engagement. The Guide to Patient and Family Engagement in Hospital Quality and Safety is a tested, evidence-based resource to help hospitals work as partners with patients and families to improve quality and safety.[87] The Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families[88] is composed of four evidence-based strategies that promote meaningful engagement with patients and families in ways that affect safety. It contains practical materials to support adoption of the interventions, including strategy-specific implementation and evaluation guidance, training materials and job aids, and materials for patients. The Toolkit to Engage High-Risk Patients in Safe Transitions Across Ambulatory Settings help staff actively engage high risk patients and their care partners to safely transition to a new ambulatory-care provider after their visit. It includes an interactive pre-assessment toolkit that provides specific recommendations in response to an organization's patient and family engagement practices.[89]

In addition to toolkits and other resources for improving safety, AHRQ makes resources available to encourage honest communication with patients when things go wrong. The Communication and Optimal Resolution (CANDOR) process is designed to assist healthcare institutions and practitioners to respond to patients and families in a timely, thorough, and just way when unexpected events cause harm. AHRQ has posted a toolkit based on the CANDOR process to assist hospitals in implementing communication and optimal resolution programs.[90]

Federal agencies other than AHRQ also develop and make important resources for improving patient safety available to healthcare providers. The resources listed in the following sections include just a few examples. AHRQ collaborates with its Federal partners regularly, formally and informally, on specific projects and cross-cutting issues. For example, DoD's Patient Safety Program collaborated with AHRQ to develop TeamSTEPPS,® a powerful tool for improving communication, teamwork, and safety culture. CDC's NHSN, the nation's most comprehensive and established system to capture and analyze

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[85] Agency for Healthcare Research and Quality. Questions are the answer. https://www.ahrq.gov/questions/index.html. Date accessed August 25, 2021.

[86] Agency for Healthcare Research and Quality. QuestionBuilder App. https://www.ahrq.gov/patient-safety/question-builder/index.html. Last reviewed November 2020.

[87] Agency for Healthcare Research and Quality. Guide to patient and family engagement in hospital quality and safety. https://www.ahrq.gov/patient-safety/patients-families/engagingfamilies/guide.html. Last reviewed December 2017.

[88] Agency for Healthcare Research and Quality. Guide to improving patient safety in primary care settings by engaging patients and families. https://www.ahrq.gov/patient-safety/reports/engage/strategies.html. Last reviewed April 2018.

[89] Agency for Healthcare Research and Quality. Toolkit to Engage High-Risk Patients in Safe Transitions Across Ambulatory Settings. https://www.ahrq.gov/hai/tools/ambulatory-care/safe-transitions.html. Last reviewed December 2017.

[90] Agency for Healthcare Research and Quality. Communication and Optimal Resolution (CANDOR). https://www.ahrq.gov/patient-safety/capacity/candor/index.html. Last reviewed April 2018.

healthcare-associated infection (HAI) data, is an essential component of the AHRQ HAI-prevention initiatives that use the CUSP approach. AHRQ is working with the Health Resources and Services Administration (HRSA) and other partners in the Alliance for Innovation on Maternal Health (AIM) to integrate resources for improving teamwork and communication with AIM's maternal safety bundles. AHRQ mechanisms for interagency collaboration include the Patient Safety Work Group, an important component of the AHRQ Common Formats development process, and the Federal Interagency Workgroup on Improving Diagnostic Safety and Quality in Health Care.

3.2.2. Examples of Patient Safety Resources From Other HHS Agencies

CDC. One of the many resources CDC has developed, the Targeted Assessment for Prevention (TAP) framework, aims to help healthcare organizations reduce HAIs.[91] TAP uses the NHSN, CDC's HAI tracking system, to identify and support facilities and units with an excess burden of HAIs. Another CDC resource is support for perinatal quality collaboratives, which are State or multistate networks of teams working to improve the quality of care for mothers and babies. Members of these collaboratives identify healthcare processes that need improvement and use the best available methods to make changes as quickly as possible.[92]

CMS. CMS funds Quality Innovation Network-QIOs (QIN-QIOs) that serve regions of two to six states each. They bring Medicare beneficiaries, providers, and communities together in data-driven initiatives that increase patient safety, make communities healthier, better coordinate posthospital care, and improve clinical quality. The program structure maximizes learning and collaboration in improving care; enhances flexibility; supports the spread of effective new practices and models of care; helps achieve the priorities of the National Quality Strategy and the goals of the CMS Quality Strategy; and delivers program value to beneficiaries, patients, and taxpayers.[93]

FDA. FDA's Center for Devices and Radiological Health launched the Medical Product Safety Network (MedSun), which works collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. MedSun researchers work with facility representatives to clarify and understand a problem and share reports and lessons learned with the clinical community and the public, without facility and patient identification, so clinicians nationwide may take necessary preventive actions.[94] The Division of Medication Error Prevention and Analysis, within FDA's Center for Drug Evaluation and Research, collaborates with external stakeholders, regulators, patient safety organizations, standard setting organizations such as the U.S. Pharmacopeia, and researchers to understand the causes of medication errors and the effectiveness of interventions to prevent them and address broader safety issues that contribute to medication errors.[95] Some novel approaches for safety surveillance and improvement used by FDA to carry out regulatory responsibilities, such as the MDEpiNet Coordinated Registry Networks[96] and the Center for Devices and Radiological Health's Patient

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[91] Centers for Disease Control and Prevention. The targeted assessment for prevention (TAP) strategy. https://www.cdc.gov/hai/prevent/tap.html. Last reviewed March 11, 2021.

[92] Centers for Disease Control and Prevention. Perinatal quality collaboratives. https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm. Last reviewed May 7, 2021.

[93] Centers for Medicare & Medicaid Services. Quality improvement organizations. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs. Last reviewed February 11, 2020.

[94] US Food and Drug Administration. MedSun: medical product safety network. https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network. Last reviewed December 16, 2020.

[95] US Food and Drug Administration. Medication errors related to CEDR-regulated drug products. https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products. Last reviewed November 2, 2020.

[96] The Medical Device Epidemiology Network (MDEpiNet). Coordinated Registry Networks. https://www.mdepinet.net/coordinated-registry-networks. Last reviewed September 28, 2021.

Science and Engagement Program[97], may have implications for the future development of patient safety improvement strategies for use by providers.

HRSA. HRSA's Maternal and Child Health Bureau funds several initiatives that assist providers with patient safety improvement, including the Alliance for Innovation on Maternal Health Program, which provides patient safety tools, including maternal safety "bundles," technical assistance, and implementation support. The bundles are a set of small, straightforward evidence-based practices, which when implemented collectively and reliably have improved outcomes and reduced maternal mortality.[98]

Office of the National Coordinator for Health Information Technology (ONC). ONC maintains a website with a number of resources to help providers strengthen patient safety efforts and reduce medical errors through the effective use of HIT. Through this site, interested stakeholders can learn more about selecting, upgrading, implementing, and using HIT to support more satisfying work experiences for clinicians and staff that help them deliver safer, higher value care to patients.[99] The website also includes information that can be helpful to providers in addressing patient safety issues related to establishing and maintaining interactions between HIT systems and their users. The complete set of the Safety Assurance Factors for EHR Resilience (SAFER) Guides,[100] which help health care organizations conduct self-assessments to ensure EHRs are implemented using best practices to promote patient safety, are also available through the website.

3.2.3. *Examples of Patient Safety Resources From Other Federal Agencies*
Patient safety programs in the Military Health System of the Department of Defense and the Veterans Health Administration of the Department of Veterans Affairs develop and promote services, tools, training, and other resources for reducing medical errors and increasing patient safety for providers within their respective systems. Some of their resources are also made publicly available for use by other healthcare providers.[101]

In addition to the PSOs created as a result of the Patient Safety Act, many State, local, and nongovernmental organizations are instrumental in developing effective patient safety strategies and play a leadership role in encouraging their use.

3.3. The National Steering Committee for Patient Safety: Working to Align Efforts to Encourage the Use of Effective Patient Safety Strategies
Coordinating efforts among all stakeholders, public and private, could significantly advance efforts to encourage the use of effective patient safety strategies. The Institute for Healthcare Improvement (IHI) convened the National Steering Committee for Patient Safety (NSC) in May 2018 to advance the goal of the National Patient Safety Foundation's[102] vision for a coordinated public health framework to address preventable harm in healthcare. The NSC is cochaired by P. Jeffrey Brady, M.D., M.P.H., Director of

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[97] US Food and Drug Administration. CDRH Patient Science and Engagement Program. https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-science-and-engagement-program. Last reviewed September 28, 2021.
[98] Health Resources and Services Administration. Maternal/Women's Health. https://mchb.hrsa.gov/maternal-child-health-topics/maternal-and-womens-health. Last reviewed May 2021.
[99] HealthIT.gov. Health IT safety. https://www.healthit.gov/topic/health-it-safety. Last reviewed March 14, 2018.
[100] HealthIT.gov. SAFER Guides. https://www.healthit.gov/topic/safety/safer-guides. Last reviewed November 28, 2018.
[101] U.S. Department of Defense. Military health system. Patient safety products & services. https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Quality-And-Safety-of-Healthcare/Patient-Safety/Patient-Safety-Products-And-Services. Date accessed October 29, 2020. U.S. Department of Veterans Affairs. VHA National Center for Patient Safety. Medical professionals: Patient safety and you. https://www.patientsafety.va.gov/professionals/. Date accessed October 29, 2020.
[102] The NPSF has since merged with the IHI.

AHRQ's Center for Quality Improvement and Patient Safety, and Tejal K. Gandhi, M.D., M.P.H., CPPS, Senior Fellow, IHI and Chief Safety and Transformation Officer, Press Ganey Associates LLC. The NSC includes 27 members who span the healthcare delivery, quality and safety, policy, regulatory, and advocacy communities. In September 2020, the NSC released Safer Together: A National Action Plan to Advance Patient Safety along with an Implementation Resource Guide and Self-Assessment Tool. [103]The National Action Plan makes recommendations to guide patient safety efforts across the United States in four foundational, interdependent areas:

National Action Plan: 17 Recommendations to Advance Patient Safety[104]

Culture, Leadership, and Governance

1. Ensure safety is a demonstrated core value.
2. Assess capabilities and commit resources to advance safety.
3. Widely share information about safety to promote transparency.
4. Implement competency-based governance and leadership.

Patient and Family Engagement

5. Establish competencies for all health care professionals for the engagement of patients, families, and care partners.
6. Engage patients, families, and care partners in the co-production of care.
7. Include patients, families, and care partners in leadership, governance, and safety and improvement efforts.
8. Ensure equitable engagement for all patients, families, and care partners.
9. Promote a culture of trust and respect for patients, families, and care partners.

Workforce Safety

10. Implement a systems approach to workforce safety.
11. Assume accountability for physical and psychological safety and a healthy work environment that fosters the joy of the health care workforce.
12. Develop, resource, and execute on priority programs that equitably foster workforce safety.

Learning System

13. Facilitate both intra- and inter-organizational learning.
14. Accelerate the development of the best possible safety learning networks.
15. Initiate and develop systems to facilitate interprofessional education and training on safety.
16. Develop shared goals for safety across the continuum of care.

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[103] The Implementation Resource Guide and Self-Assessment Tool (www.ihi.org/SafetyActionPlan) includes case examples and resources related to four foundational areas of patient safety: Culture, Leadership, and Governance; Patient and Family Engagement; Workforce Safety; Learning System.
[104] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement. (http://www.ihi.org/SafetyActionPlan). Date accessed October 29, 2020.

17. Expedite industry-wide coordination, collaboration, and cooperation on safety.

3.4. Encouraging Effective Patient Safety Improvement: What Works?

Successful implementation of a new patient safety strategy or practice requires thoughtful planning and a multifaceted approach. It must take into account the needs of the patients and healthcare providers who will be affected; the work structures, support systems, and organizational culture surrounding them; and the local resources and circumstances.

A review of interdisciplinary implementation frameworks suggests a dynamic series of coordinated steps that are critical to achieving the intended effects of an intervention.[105]The implementation process is cyclical and typically begins with understanding the target setting and assessing resources, fit, capacity and need for adaptation. Developing an implementation plan, establishing teams to enact that plan, providing technical assistance, training, and a means to evaluate the implementation process are also critical. Building in a feedback loop fosters learning throughout implementation, which in turn, supports efforts to scale the intervention or apply it to another setting. In addition to these steps, effective implementation requires attention to collaboration, teamwork, communication, and culture.

As discussed earlier in this report, Dr. Peter Pronovost and colleagues at Johns Hopkins developed a highly successful approach to encouraging the use of effective patient safety strategies based on these principles with funding from AHRQ. Known as the Comprehensive Unit-based Safety Program (CUSP), it was first applied to prevent central line-associated bloodstream infections (CLABSIs) in patients in ICUs. Over time, it evolved into a model to address other kinds of patient safety issues in a variety of clinical settings, including catheter-associated urinary tract infections (CAUTI) in acute care and long-term care settings; improving surgical safety; promoting antibiotic stewardship to improve antibiotic use; and improving perinatal safety.

The next section describes CUSP in more detail, followed by two examples of successful AHRQ-funded projects that used this approach. The CUSP projects are presented to highlight the complexity of effectively moving research into practice. They are intended as examples, to illustrate that it takes thoughtful planning informed by implementation science principles to effectively encourage the use of evidence-based patient safety strategies. As with any approach, the success of CUSP will vary because implementation is always context-dependent. The key to encouraging the use of effective patient safety strategies is to recognize that "…because improvement impacts people, it must not simply work from an evidence-based standpoint; the change itself must also be workable for the people affected by and implementing that change."[106]

3.4.1. The Approach

CUSP is based on the recognition that effective safety improvement requires frontline staff to be empowered and provided with the resources needed to identify and address risks; performance and culture are unit-specific; and improvement can be accelerated by facilitating connections between unit staff and senior leadership and among professional colleagues.[107] The approach combines strategies that

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[105] Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. Am J Community Psychol. 2012 Dec;50(3-4):462-80. doi: 10.1007/s10464-012-9522-x. PMID: 22644083.

[106] Hilton K, Anderson A. IHI Psychology of Change Framework to Advance and Sustain Improvement. IHI White Paper. Boston, MA: Institute for Healthcare Improvement; 2018. Available at: http://www.ihi.org/resources/Pages/IHIWhitePapers/IHI-Psychology-of-Change-Framework.aspx.

[107] Pronovost, PJ, Marsteller, JA, Wu AW, Holzmueller CG, Thompson, DA, Lubomski, LH, Paine LA, Hobson DH, Sawyer MD, Wyskiel RM, Aboumatar H, Needham DM, Goeschel CA, Winters BD, Pham JC, Sapirstein A, Romig M, Mendez-Tellez, PA, Gurses, AP, Rosen, MA, Weaver SJ, Austin, JM, Latif, A, Berenholtz, SM. Advancing the Science of Patient Safety and Quality Improvement to the Next Level. In: Battles, JB, Cleeman, JI, Kahn, KL, Weinberg, DA, editors. Advances in the Prevention and Control of HAIs. Rockville (MD): Agency for Healthcare Research and Quality; June 2014. https://www.ahrq.gov/sites/default/files/publications/files/advancesinhai.pdf.

improve safety culture, teamwork, and communication with evidence-based practices that are translated into clear, simple checklists and other carefully designed tools. The multifaceted CUSP framework has five components:

- ▶ Engage executive leaders.
- ▶ Educate staff in the science of safety.
- ▶ Identify system defects that can lead to patient harm.
- ▶ Learn from defects.
- ▶ Implement teamwork tools.

Elements of AHRQ's approach to CUSP implementation in national projects follow:

- ▶ Engagement of frontline clinicians and institutional senior leadership
- ▶ Education in the science of safety and application of its principles
- ▶ Assessment of safety culture and infection control policies and procedures
- ▶ Regional consortia of stakeholders
- ▶ Expert coaching, consultation, and technical assistance
- ▶ Peer support
- ▶ Educational materials, tools, and webinars
- ▶ Data collection and feedback for performance monitoring
- ▶ Patient and family engagement

The CUSP projects develop toolkits encompassing all the educational interventions to extend the impact of the projects beyond their duration. CUSP differs from other change models by combining behavioral elements—with an emphasis on safety culture, teamwork, and communication—with clinical elements, such as the checklist of proven practices, to create a powerful tool for promoting the adoption of evidence-based patient safety strategies.

Studies of this approach in the original CLABSI prevention projects revealed commonalities in implementation among hospitals successful in reducing and maintaining low infection rates.[108] Facility leadership (executive and clinical) committed to and communicated the goal (in this case, zero CLABSIs) and their belief it was attainable. They demonstrated their support for the goal and for frontline clinicians by creating and supporting a cross-departmental team that served as the supporting infrastructure. This cross-departmental team provided project management and coordination, timely data collection, analytics and reports, clinical and improvement science expertise, and assistance with training needs. They provided important support for the clinician-led unit-level CUSP teams, which worked to engage their colleagues in the improvement work and benefit from their insights about harm prevention. They helped to connect units with others working toward the same goal to support peer

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[108] Unless otherwise cited, all related content in this section is from: Pronovost PJ, Weaver SJ, Berenholtz SM, Lubomski LH, Maragakis LL, Marsteller JA, Pham JC, Sawyer MD, Thompson DA, Weeks K & Rosen MA. Reducing preventable harm: observations on minimizing bloodstream infections. J Health Organ Manag. 2017 Mar 20;31(1):2-9. doi: 10.1108/JHOM-10-2016-0197. PMID: 28260406.

learning and coaching. The coordinating teams also facilitated data tracking and reporting, from the front line to the board, and shared accountability for the results.

In a related analysis of the model, the authors cautioned that the complexity of effective implementation is often oversimplified and misunderstood. Evaluation of how to encourage the use of an effective improvement strategy requires an analysis of what actually happened, as opposed to what was originally planned. Their analysis attributed the success of this approach in part to organizations having perceived this as the right thing to do and wanting to join others in improving performance; combining "bottom up" and "top down" methods; facilitating the development of a networked community that encouraged collaboration between and among healthcare professionals; and in other ways, helping to "shape a culture of commitment to doing better in practice."[109]

3.4.2. Application of the Approach: Examples of Projects

On the CUSP: Stop BSI
CUSP was first deployed on a large scale between 2003 and 2005 in over 100 Michigan ICUs with funding from AHRQ and the Michigan Health and Hospital Association (MHA) Keystone Center for Patient Safety and Quality.[110] The MHA Keystone ICU project reduced CLABSI in the first 18 months by 66 percent. The median CLABSI rate was 2.7 at baseline and dropped to a median of 0.0 in that period. Subsequent analyses showed the significant reductions achieved in the initial phase of the project were sustained for up to 10 years.[111]

Based on the success of the initial MHA Keystone ICU project, AHRQ replicated the approach nationally in partnership with several other organizations, starting with at least 10 hospitals in each of 10 States. The contract was expanded in fall 2009 to offer participation to all 50 States, the District of Columbia, and Puerto Rico. Project partners included the Health Research and Educational Trust (HRET), the Armstrong Institute, MHA Keystone, and State and regional hospital associations, which in turn partnered with hospitals and units they recruited into the program. The national project team was composed of staff from HRET, the Armstrong Institute, and MHA Keystone.

A total of 6 cohorts from 44 States, the District of Columbia, and Puerto Rico participated including, collectively, more than 1,000 hospitals and 1,800 hospital units. Again, the CUSP approach succeeded. Nationwide, participating adult ICUs reduced their rate of CLABSIs from a baseline of 1.915 infections per 1,000 line days to a rate of 1.133 infections, or a relative reduction of 41 percent. ICUs that started with low CLABSI rates achieved additional improvements, again demonstrating that "getting to zero" was possible. Non-ICU and pediatric units had similar, impressive reductions in CLABSI rates.

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[109] Dixon-Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q. 2011 Jun;89(2):167-205; 167. doi: 10.1111/j.1468-0009.2011.00625.x. PMID: 21676020; PMCID: PMC3142336.

[110] Unless otherwise cited, all related content in this section is from: Health Research & Educational Trust, Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality and Michigan Health & Hospital Association Keystone Center for Patient Safety & Quality. Eliminating CLABSI, a national patient safety imperative: final report on the national On the CUSP: Stop BSI Project. October 2012. Publication: 12-0087-EF. https://www.ahrq.gov/sites/default/files/publications/files/clabsifinal.pdf

[111] Pronovost PJ, Watson SR, Goeschel CA, Hyzy RC, Berenholtz SM. Sustaining reductions in central line-associated bloodstream infections in Michigan intensive care units: a 10-year analysis. Am J Med Qual. 2016 May;31(3):197-202. doi: 10.1177/1062860614568647. Epub 2015 Jan 21. PMID: 25609646.

The AHRQ Safety Program for Long-Term Care: HAIs/CAUTI

CAUTI[112] is costly and potentially life threatening for LTC residents. This project, funded by AHRQ and conducted by and in partnership with a number of other Federal, State and nongovernmental partners, set out to adapt CUSP to the LTC setting with a goal of reducing CAUTI rates. The evidence-based interventions used in this project primarily targeted unnecessary use of urinary catheters and adherence to infection-prevention measures for catheter insertion and maintenance. As in all CUSP projects, other interventions focused on empowering frontline staff; identifying and reducing barriers to implementing the interventions; and promoting safety culture, teamwork, leadership, and resident and family engagement.

HRET was the lead for this AHRQ-funded project, in partnership with Abt Associates, the Association for Professionals in Infection Control and Epidemiology, Baylor College of Medicine, Qualidigm, the Society of Hospital Medicine, and the University of Michigan. In addition to the national project team, other program partners coordinated, promoted, and coached facility teams as they implemented the interventions. These included State hospital associations, State-based and professional organizations, national partners from LTC corporations, State and regional organizations with expertise in quality improvement, and the VA. AHRQ and HRET also worked with CDC and CMS.

Nursing homes from 48 States, the District of Columbia, and Puerto Rico participated in this national implementation project. Significant reductions in CAUTI rates occurred among the 404 community-based nursing homes that participated, along with decreases in the number of inappropriate urine cultures collected. Overall, there was a 54 percent reduction in the CAUTI rate as measured by the number of CAUTIs per 1,000 catheter days.[113] Catheter utilization did not decrease significantly, likely in part because utilization rates were low at the start.

Project participants who were later interviewed observed that strategies implemented as a result of the program other than those focused on catheter utilization may have had a positive effect on infection rates: increased hand hygiene, reducing inappropriate urine cultures, facility-wide education about CAUTI, walking rounds, better monitoring, and random auditing to ensure adherence to best practices for urinary catheter insertion and maintenance. They noted the possibility that staff learning about standard definitions and best practices improved infection surveillance overall. Interviewees described cultural shifts as a result of the program, such as nursing staff feeling more empowered to speak with physicians and senior leadership about not requesting unneeded urine cultures.

Interviewees noted that relationships were extremely important among the organizational leads, the facilities, and the faculty coaches. Having someone at the State or national level to contact when they had issues, or to share successes, was a benefit for some facilities, particularly those without a large corporate support structure. Feedback provided by the facility team leads interviewed was unanimous: they described their organizational leads and national project team contacts as proactive, responsive, helpful, and knowledgeable. Relationships among the LTC facility team members were also key to program success. During qualitative interviews, facility team leads indicated that strong staff relationships led to more excitement and support among the staff participating in the program, while

[112] Unless otherwise noted, all content in this section is from: Health Research and Educational Trust. Final report on the AHRQ safety program for long-term care: preventing CAUTI and other HAIs. Prepared for Agency for Healthcare Research and Quality, US Department of Health and Human Services. May 2017; AHRQ Publication No. 16(17)-0003-1-EF. https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/quality-resources/tools/cauti-ltc/modules/final-report.pdf

[113] Mody L, Greene MT, Meddings J, Krein SL, McNamara SE, Trautner BW, Ratz D, Stone ND, Min L, Schweon SJ, Rolle AJ, Olmsted RN, Burwen DR, Battles J, Edson B, Saint S. A national implementation project to prevent catheter-associated urinary tract infection in nursing home residents. JAMA Intern Med. 2017 Aug 1;177(8):1154-1162. doi: 10.1001/jamainternmed.2017.1689. PMID: 28525923; PMCID: PMC5710434.

weak or nonexistent relationships meant staff would not participate in the same way. The relationships among participating facilities were also beneficial with respect to teams' ability to learn from peers.

As the preceding examples illustrate, to successfully encourage the use of effective patient safety strategies, it is essential to engage the insights of clinicians at the front lines of care and provide a method that works from their perspective. The team that developed the CUSP approach to promoting the use of evidence-based improvement strategies described this as "the importance of the spirit of humble inquiry."[114] Reflecting on what made their approach so effective, they observed: "Throughout our efforts, we had profound respect for the wisdom of health care workers, especially caregivers; sought to integrate researchers with operational safety practitioners; and used the frontlines of clinical care as our laboratory to harness the wisdom of clinicians, test tools and interventions, measure performance and evaluate success, and acquire new knowledge."[115]

3.5. Encouraging the Use of Effective Patient Safety Strategies

3.5.1. Measures to Encourage the Development and Use of Effective Strategies

This report has provided an overview of strategies and practices for reducing medical error and increasing patient safety; a link to a discussion of the state of the evidence for the effectiveness of each; and an overview of "measures determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in federally funded programs."[116] To summarize—

▶ Concepts and principles from disciplines other than medicine underlie many of the strategies known to be effective in reducing medical errors and increasing patient safety. Exploring innovative ways to facilitate collaboration between and among safety experts in clinical and nonclinical disciplines has the potential to advance the development and use of effective patient safety strategies.[117] Patient safety research, measurement, and practice should encompass existing and emerging analytic approaches that support learning from how and why things go right and how to monitor risk [118, 119,120] without losing sight of the importance of addressing specific adverse events and harms.

▶ Since 2001, the AHRQ *Making Healthcare Safer* series has reviewed and/or updated the evidence of effectiveness for more than 100 patient safety strategies and practices in areas that span multiple clinical and safety topics and settings. There is a growing body of research as well as a growing need for more, as safety is an important aspect of care for every patient in all healthcare disciplines, specialties, settings, and modes of healthcare delivery. Expanding the use

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[114] Sood G, Caffrey J, Krout K, Khouri-Stevens Z, Gerold K, Riedel S, McIntyre J, Maragakis LL, Blanding R, Zenilman J, Bennett R, Pronovost P. Use of implementation science for a sustained reduction of central-line-associated bloodstream infections in a high-volume, regional burn unit. Infect Control Hosp Epidemiol. 2017 Nov;38(11):1306-1311;1309. doi: 10.1017/ice.2017.191. Epub 2017 Sep 13. PMID: 28899444.

[115] Pronovost, PJ, Marsteller, JA, Wu AW, Holzmueller CG, Thompson, DA, Lubomski, LH, Paine LA, Hobson DH, Sawyer MD, Wyskiel RM, Aboumatar H, Needham DM, Goeschel CA, Winters BD, Pham JC, Sapirstein A, Romig M, Mendez-Tellez, PA, Gurses, AP, Rosen, MA, Weaver SJ, Austin, JM, Latif, A, Berenholtz, SM. Advancing the Science of Patient Safety and Quality Improvement to the Next Level. In: Battles, JB, Cleeman, JI, Kahn, KL, Weinberg, DA, editors. Advances in the Prevention and Control of HAIs. Rockville (MD): Agency for Healthcare Research and Quality; June 2014; 8. https://www.ahrq.gov/hai/patient-safety-resources/advances-in-hai/hai-article1.html

[116] 42 U.S.C. § 299b-22(j).

[117] For example, see Carayon P, Wooldridge A, Hose BZ, Salwei M, Benneyan J. Challenges and opportunities for improving patient safety through human factors and systems engineering. Health Aff (Millwood). 2018 Nov;37(11):1862-1869. doi: 10.1377/hlthaff.2018.0723. PMID: 30395503; PMCID: PMC6509351.

[118] Stevens JP, Levi R, Sands K. Changing the patient safety paradigm. J Patient Saf. 2019 Dec;15(4):288-289. doi: 10.1097/PTS.0000000000000394. PMID: 28691972.

[119] Fairbanks RJ, Wears RL, Woods DD, Hollnagel E, Plsek P, Cook RI. Resilience and resilience engineering in health care. Jt Comm J Qual Patient Saf. 2014 Aug;40(8):376-83. doi: 10.1016/s1553-7250(14)40049-7. PMID: 25208443.

[120] Braithwaite J. Changing how we think about healthcare improvement. BMJ. 2018 May 17;361:k2014. doi: 10.1136/bmj.k2014. PMID: 29773537; PMCID: PMC5956926.

of research methodologies that can explore and capture the complexity of patient safety problems and solutions will also advance the evidence base.[121,122,123]

▸ The key to encouraging the use of effective strategies for improving patient safety is to use a multifaceted approach. Translating evidence-based practices into real-world settings requires the development of clinically useful tools and infrastructure and often foundational changes in organizational culture, leadership and patient engagement, teamwork, and communication. Implementation must be designed with and from the perspectives of the people who will be most affected, and this deliberate engagement should extend across to the wide range of stakeholders who intend to support patient safety.

▸ Encouraging the development of learning health systems that integrate continuous learning and improvement into their day-to-day operations can speed the application of the most promising evidence to improve care. PSOs can play an important role in supporting the growth and development of learning health systems. In addition to serving as a practical model for evidence-based operational improvement, the concept of learning health systems can also facilitate the integration of patient safety practices with functions that are necessary to achieve other priorities, including the effectiveness, timeliness, efficiency, patient-centeredness, and equity of healthcare.

▸ Many different governmental and nongovernmental organizations make evidence-based patient safety resources available for use in patient safety and quality improvement work. The National Action Plan put forth by the National Steering Committee for Patient Safety, which supports coordination and alignment of efforts among all stakeholders, public and private, could significantly advance and help to align efforts to encourage the use of effective patient safety strategies. Many recommendations throughout the plan focus on ensuring that prerequisite foundational factors are in place and sufficiently robust to enable the successful deployment and use of strategies and practices for reducing medical error and increasing patient safety.

3.5.2. *Role of the Patient Safety Act and PSOs: Future Directions and Opportunities*
The framework created by the Patient Safety Act can serve as the linchpin for a national learning system for patient safety. The NPSD, which is the data infrastructure aspect of the Patient Safety Act, launched in 2019 with a publicly available set of dashboards, with plans to update them annually or as otherwise deemed appropriate. As the volume of data submitted to the NPSD increases, it will become possible to release new dashboards with additional data that can be used for national learning about how to improve patient safety. However, the ability to release more NPSD data is constrained by limitations in the mechanisms currently available for data collection and the need to accumulate a sufficient volume of data prior to public release in order to protect confidentiality. These limitations are interrelated with the voluntary nature of the system. At this time, advancement of the NPSD depends entirely on the willingness and ability of federally listed PSOs and the providers with whom they work to volunteer to take on the burden and expense of data submission. The need to minimize this burden affects the nature, volume, and quality of the data available to the NPSD. Existing technology that might permit remote collaboration between and among a broad array of networks without actually transferring data,

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[121] Davidoff F. Improvement interventions are social treatments, not pills. Ann Intern Med. 2014 Oct 7;161(7):526-7. doi: 10.7326/M14-1789. PMID: 25285545.

[122] Webster CS. Evidence and efficacy: time to think beyond the traditional randomised controlled trial in patient safety studies. Br J Anaesth. 2019 Jun;122(6):723-725. doi: 10.1016/j.bja.2019.02.023. Epub 2019 Apr 4. PMID: 30954239.

[123] Dixon-Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: developing an ex post theory of a quality improvement program. Milbank Q. 2011 Jun;89(2):167-205. doi: 10.1111/j.1468-0009.2011.00625.x. PMID: 21676020; PMCID: PMC3142336.

such as distributed data networks,[124] has the potential to resolve several of these limitations. Future advances in machine learning may enable evolution of the NPSD into a system that can accept unstructured or differently-structured data. Should any such approaches to data infrastructure and transmission become feasible, progress in building the NPSD into a more comprehensive national patient safety learning system could be accelerated.

The aspect of the statutory framework regarding the conduct of patient safety activities between individual PSOs and the providers with whom they work is highly valued, successful, and thriving. The Office of the Inspector General of the Department of Health and Human Services (OIG)[125]conducted a study that included a sample of general acute-care hospitals participating in Medicare in 2018 and reported that of the 59 percent that work with a federally listed PSO, nearly all (97 percent) find it valuable, and half rated it as very valuable. The study found that among the most important reasons why hospitals choose to work with a federally listed PSO are the opportunity to improve patient safety (94 percent cited this as very important in their decision to work with a PSO); the opportunity to learn from PSOs' analysis of patient safety data (87 percent cited this as very important); and the privilege and confidentiality protections (83 percent cited this as very important). Among the hospitals that work with PSOs, 80 percent found feedback and analysis on patient safety events had helped prevent future events, and 72 percent reported such feedback had helped them understand the causes of events.

3.5.3. Conclusion: The Patient Safety Act at 15 Years and Beyond
With the Patient Safety Act, Congress created a solution to the dilemma of limited and varying state protections that can hinder patient safety and quality improvement work as well as an innovative blueprint for national learning. Over the last 15 years, that blueprint has been used to build a strong foundation and framework for a national learning system. HHS is proud of the infrastructure it has built, the robust participation by many providers and PSOs, and the contributions the implementation of this legislation have made to the larger patient safety movement. Considering the voluntary nature of the Patient Safety Act, the number and diversity of providers and PSOs who choose this framework for patient safety improvement confirm the significance of this law and its successful application. More than 90 federally listed PSOs are working with thousands of healthcare providers across the country to reduce medical errors and increase patient safety in various settings and clinical specialties, including but not limited to anesthesiology, dentistry, emergency care, general and specialty medical care in various settings, home health and hospice, long-term care, mental health, pediatrics, pharmacy, radiology, rehabilitation, renal dialysis, and surgery. They are making valuable contributions to the providers they work with, the safety of their patients, and to the development of the NPSD as a resource for shared national learning about patient safety.

Operationalization of the NPSD was a significant milestone necessary to realize the full potential of the Patient Safety Act in creating a national learning system. The volume of data being contributed to the NPSD is growing and, in turn, more data is being made available to the public through the NPSD's data reporting tools. The NPSD is a unique source of data supporting national learning into the "how" and "why" patient safety events are occurring by providing valuable insight into areas such as contributing factors. While it is not possible for the federal government to address all impediments to data

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[124] Curtis LH, Brown J, Platt R. Four health data networks illustrate the potential for a shared national multipurpose big-data network. Health Aff (Millwood). 2014 Jul;33(7):1178-86. doi: 10.1377/hlthaff.2014.0121. PMID: 25006144.
[125] Office of the Inspector General of the Department of Health and Human Services. Patient safety organizations: hospital participation, value, and challenges. OEI-01-17-00420. September 2019. https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf

submission to the NPSD, AHRQ continues to seek new ways to make reporting easier and is exploring the potential for future evolution of strategies for NPSD data submission and analysis.

AHRQ has worked to increase hospitals' awareness of the Patient Safety Act and its value to participants. AHRQ is also making concerted efforts to cultivate new and stronger relationships with stakeholders who can help educate others about the Patient Safety Act and welcomes ideas for future opportunities to expand outreach. AHRQ continues to support and shape the patient safety research agenda in response to the important questions that patients, clinicians, and others have about how to prevent healthcare harm. The results are disseminated to healthcare professionals, PSOs, and others ready to apply this knowledge.

The availability of federally listed PSOs and the NPSD are significant achievements that comprise one part of the infrastructure needed to support a larger national mission: to build a 21st-century healthcare system that delivers high-quality, safe, equitable, high-value care. PSOs and the providers they work with play an important role in this mission, but they cannot accomplish it alone. All stakeholders must work in harmony to drive major advances in patient safety. The National Action Plan to Advance Patient Safety provides momentum and clearer direction for working in a collaborative way across organizations and sectors to keep patients and those who care for them free from harm. The landmark Patient Safety and Quality Improvement Act of 2005 created a unique and powerful framework that is supporting patient safety and quality improvement work across the United States. That framework stands ready to support the collaborative national effort needed to make further progress in improving the safety and quality of healthcare.

Appendix A: Recommendations from the National Academy of Medicine

A.1. Introduction

As required by 42 U.S.C. § 299b-22(j)(1), the December 16, 2020 draft of this report was submitted to the National Academy of Medicine (NAM) for review.

The contract AHRQ executed with the National Academy of Sciences specified that NAM's review was to address the following questions:

1. Are there effective strategies or practices for reducing medical errors and increasing patient safety not mentioned in the draft that the reviewers believe should be considered for addition to the final report?

2. Is there any significant additional or new evidence regarding the effectiveness of particular strategies or practices for reducing medical errors and increasing patient safety that the reviewers believe should be considered for adding to the final report?

3. Are there any methods for encouraging effective adoption and sustained implementation of effective strategies for reducing medical errors and increasing patient safety not mentioned in the draft that the reviewers believe should be considered before the report is final?

4. Are there any technical comments or corrections regarding any of the content in the draft report?

The National Academies of Sciences, Engineering and Medicine Health and Medicine Division convened a committee of four physician subject matter experts with experience in clinical patient safety, patient safety research, health information technology, safety science, clinical medicine, and implementation to conduct the review. Based on their interpretation of Congressional intent in enacting the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), the committee members concluded that the "question before Congress and the authors of the draft AHRQ report[126] is whether the creation of PSOs and the NPSD has significantly enabled major advances in patient safety."[127] They further stated that this report to Congress should include "an assessment of the degree to which these functions have been achieved, areas in which they have not, and steps that could be taken to address any barriers that are identified,"[128] while also noting that much of this information is contained in the 2019 report on a study of PSOs conducted by the HHS Office of the Inspector General (OIG).[129]

NAM published its report, entitled "Peer Review of a Report on Strategies to Improve Patient Safety," on April 19, 2021, and it is publicly available on NAM's website.[130] HHS is grateful for NAM's review, which

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[126] The Preface to the NAM review states that the Patient Safety Act required AHRQ to produce the Report to Congress, and this report is described as the "AHRQ Report" throughout the NAM review. The Patient Safety Act requires the Secretary of HHS to prepare the Draft Report, in consultation with the AHRQ Director. *See* 42 U.S.C. § 299b-22(j)(1).

[127] National Academies of Sciences, Engineering, and Medicine. 2021. Peer review of a report on strategies to improve patient safety. Washington, DC: The National Academies Press. https://doi.org/10.17226/26136, page 1.

[128] National Academies of Sciences, Engineering, and Medicine. 2021. Peer review of a report on strategies to improve patient safety. Washington, DC: The National Academies Press. https://doi.org/10.17226/26136, page 12.

[129] Office of the Inspector General of the Department of Health and Human Services. Patient safety organizations: hospital participation, value, and challenges. OEI-01-17-00420. September 2019. https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf

[130] National Academies of Sciences, Engineering, and Medicine. 2021. Peer review of a report on strategies to improve patient safety. Washington, DC: The National Academies Press. https://doi.org/10.17226/26136.

highlighted and emphasized the major national significance and value of the Patient Safety Act. The NAM review offered important insights that expanded our thinking. A number of points raised by the NAM review resulted in additions and revisions that strengthened this report. While some concepts raised by NAM's review were not within context for this report, they will inform AHRQ's planning for ongoing and future patient safety programming and research. Other ideas presented in the NAM review may be particularly intriguing to the greater patient safety community. Of note, NAM's recommendation for an updated, comprehensive evaluation of the effectiveness of the Patient Safety Act, including recommendations for changes, if appropriate, would be welcome and clearly of major significance to HHS, to Congress, and to the Nation. Although this Final Report to Congress will not meet the NAM Committee's expectations for a such an evaluation, HHS appreciates NAM's overall vision as well as its specific feedback. We also welcome this opportunity to have NAM share its perspectives about patient safety with Congress, other policymakers, and members of the public.

In light of the richness of NAM's review, this appendix includes the summary of NAM's overall suggestions and recommendations as outlined in the Summary and Conclusion sections of its review. Below, we present each item together with HHS' reflections and/or information that may be of assistance to stakeholders reviewing this report and interested in exploring these ideas to move the patient safety field forward together.

A.2. The NAM Recommendations

The numbered items below in bold font are copied from the bulleted list that appears in the Conclusion section of the NAM review. The same items can be found in the Summary section of the NAM review in a slightly different order.

1. **Fund demonstration projects and communicate compelling evidence of the benefits of PSOs and the NPSD, both to client organizations and to patient safety researchers. Highlight the benefits of transparency and the utility of analyzing data from multiple, similar organizations for benchmarking and learning.**

   An existing (and previous) AHRQ Funding Opportunity Announcement (FOA) invites Large Research Demonstration and Dissemination (R18) Project applications that focus on AHRQ's mission and/or any aspect of its specific priority areas. FOA Number PA-18-793[131] includes the following language in the section describing the priority area "Research to Improve Health Care Patient Safety":

   "Projects may address important topics such as: the surveillance, measurement, detection, and reporting of patient safety events; the impact of human performance, work flow, and working conditions on patient safety; the patients' role and contribution to patient safety; health care safety culture, leadership, communication, teamwork, and simulation; prevention and control of healthcare-associated infections (HAIs); diagnostic safety and quality; the safe use of medical devices and medications, including safely prescribing opioids**; the role of Patient Safety Organizations**; and the challenges inherent in transitions of care in the same setting and between settings and handoffs between health care providers." (emphasis added).

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[131] US Department of Health and Human Services. AHRQ Health Services Research Demonstration and Dissemination Grants (R18). Grant overview information. https://grants.nih.gov/grants/guide/pa-files/PA-18-793.html. Date accessed August 26, 2021.

2. **Communicate clear guidance about the legal protections afforded data submitted to PSOs and the NPSD, including privacy protecting procedures. Where protections are deemed insufficient to address health care organizations' concerns, strategies for encouraging further regulatory or legislative actions may be required.**

   Since the 2019 OIG Report, AHRQ has renewed efforts with the HHS Office for Civil Rights (OCR) to identify opportunities to improve stakeholder awareness of privilege and confidentiality protections of the PSQIA and its implementing regulation, the Patient Safety Rule. OCR has developed a slide deck for a one hour presentation on the Patient Safety Rule's privilege and confidentiality provisions and enforcement. OCR plans to use the slide deck for dedicated outreach presentations to healthcare providers, including hospitals. Separately, OCR has developed Patient Safety Rule slide content to be included in presentations made by OCR staff across the nation as part of OCR's routine outreach to health care providers on OCR's work relating to health information privacy.

3. **Increase the use of Common Formats (e.g., definitions, data elements) as a critical intermediary step to shared learning and benchmarking. Explore inclusion of Common Formats use as part of the certification criteria for PSOs. Explore the use of natural language processing as an adjunct to gathering patient-safety information from free-text fields.**

   AHRQ appreciates NAM's recognition that use of the Common Formats is a critical intermediary step to shared learning about how to improve patient safety. Goals for increasing use of the Common Formats must take into account that the data submitted to PSOs is determined by each unique provider-PSO relationship. The nature and type of data collected may vary considerably based on provider choice and the particular clinical setting and specialty targeted, the focus of the patient safety or quality improvement activities to be undertaken, the particular improvement targets and PSO services provided, and the individual PSO's platform(s) for data collection and analysis.

   AHRQ is actively exploring natural language processing as an adjunct to gathering and analyzing patient safety information from free-text fields.

   Consistent with the full extent of HHS' statutory authority, the Patient Safety Rule requires PSOs to collect patient safety work product in a standardized manner that permits valid comparisons of similar cases among similar providers, with limited exceptions.[132]Careful analysis of the potential advantages, disadvantages, and unintended consequences should be conducted before considering the pursuit of authority to impose further mandates on PSOs and providers. Technological solutions discussed in section 3.5 of this report that could reduce burden and accelerate data collection and analysis, should they become feasible, would be the preferred approach to accelerating opportunities for shared learning at the national level.

4. **Expand the coverage of Common Formats into ambulatory care and specialty care.**

   Currently, both active versions of the CFER-Hospital allow for capture of events and unsafe conditions in any "outpatient care area" location that is part of a hospital.[133] On June 1, 2021,

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[132] 42 U.S.C. § 299b-24(b)(1)(F) and 42 CFR 3.102(b)(2)(i)(F), (b)(2)(ii), and (b)(2)(iii).

[133] See item 2.2.11 in the Generic Event Description: AHRQ Common Formats for Event Reporting – Hospital Version 2.0 available at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0; and item 2.2.10 in the HERF, PIF and SIR Event Description, AHRQ Common Formats for Event Reporting – Hospital Version 1.2. https://www.psoppc.org/psoppc_web/publicpages/supportingDocsV1.2.

AHRQ made available for public comment the draft Common Formats for Event Reporting (CFER) for Diagnostic Safety (CFER-DS), which is designed for use in all healthcare settings and specialties.[134] When the development process is complete, the CFER-DS and related technical specifications and supporting documents will be publicly available for use.

AHRQ is exploring further expansion of the Common Formats, accepts suggestions from members of the public, and considers other enhancements on an ongoing basis. AHRQ also invites and welcomes collaboration with PSOs and others who are willing to have AHRQ adapt for national use elements from event reporting formats that are widely recognized and used in particular specialty areas. The CFER - Community Pharmacy, released in 2016,[135] is an example of such an adaptation.

5. **Explore incentives and technical strategies to facilitate automated transmission of patient-safety data from electronic health record systems to PSOs to reduce the costs and burden of reporting. Include attention to data quality and completeness.**

This recommendation appears to focus on the transmission of electronic health record (EHR) data between providers and the PSOs they voluntarily choose to engage. As mentioned in this report,[136]automated transmission of EHR data and other modes of real-time clinical data capture and analysis for risk prediction and surveillance, early detection, and prevention of adverse events are currently being employed as frontline patient safety strategies. Emerging patient safety strategies involving such data transmission, artificial intelligence, machine learning, and the use of other innovative technologies such as sensors hold great promise, and AHRQ intends to explore the evidence supporting their effectiveness as part of its program activities. As discussed generally in section 2.4 and in a recent review specific to such technologies,[137]patient safety strategies deserve careful evaluation of the evidence for their safety, accuracy, and effectiveness.

Currently, unrelated to PSO participation, individual providers determine whether and how to configure their EHRs and their internal patient safety and quality improvement-related data systems to reduce internal and/or external reporting burdens. AHRQ is interested in, and actively exploring ways to facilitate, learning more from PSOs and health information technology vendors on best practices for supporting PSOs and providers in obtaining the information they need from EHRs. New technologies should also be explored to better support PSOs and providers in obtaining the information they need from sources other than medical records to identify, analyze, and address the myriad human factors and systems issues that contribute to patient safety hazards.

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[134] Department of Health and Human Services, Agency for Healthcare Research and Quality. Common Formats for Patient Safety Data Collection, Notice of Availability: New Common Formats. 86 Fed. Reg. 29263 (June 1, 2021). See also https://www.qualityforum.org/Common_Formats_for_Patient_Safety_Data.aspx

[135] Department of Health and Human Services, Agency for Healthcare Research and Quality. Common Formats for Reporting on Healthcare Quality and Patient Safety. Notice of Availability - New Common Formats. 81 Fed. Reg. 92816 (December 20, 2016), 06/08 available at: https://www.govinfo.gov/content/pkg/FR-2016-12-20/pdf/2016-30604.pdf. *See also* Common Formats for Event Reporting - Community Pharmacy Version 1.0. PSO Privacy Protection Center. https://www.psoppc.org/psoppc_web/publicpages/commonFormatsCPV1.0

[136] See section 1.3.1, footnote 9.

[137] Bates DW, Levine D, Syrowatka A, Kuznetsova M, Craig KJT, Rui A, Jackson GP, Rhee K. The potential of artificial intelligence to improve patient safety: a scoping review. NPJ Digit Med. 2021 Mar 19;4(1):54. doi: 10.1038/s41746-021-00423-6. PMID: 33742085; PMCID: PMC7979747.

6. **Explore the use of artificial intelligence (e.g., machine learning, natural language processing) to enhance the value of the insights from large, multi-organizational datasets and to potentially reduce the burden of data collection and normalization.**

   This echoes the recommendation made by the HHS OIG in 2019. AHRQ concurs[138] with the recommendation to explore the use of advanced technologies that might, in the future, make it possible for the NPSD to accept and further analyze unstructured and differently-structured data. AHRQ is committed to monitoring the development of the science to determine when the viability and accuracy of methods supporting such technology is sufficiently mature to consider for application in the specific situation of the NPSD. As stated in section 3.5.2. of this report, "Existing technology that might permit remote collaboration between and among a broad array of networks without actually transferring data, such as distributed data networks, has the potential to resolve several of these limitations. Future advances in machine learning may enable evolution of the NPSD into a system that can accept unstructured or differently-structured data. Should any such approaches to data infrastructure and transmission become feasible, progress in building the NPSD into a more comprehensive national patient safety learning system could be accelerated."

7. **Explore payer or regulatory incentives for reporting safety data to PSOs in a standardized format as a strategy to increase voluntary reporting that facilitates return benefits to both the reporting organizations and the systematic enhancement of patient safety for the nation.**

   With limited exceptions, all PSOs are required to collect patient safety work product in a standardized format,[139] so it appears the focus of the incentives described in this recommendation would be to encourage providers to work with a PSO. Existing regulatory incentives relating to working with a PSO, in whole or in part, include section 1311(h) of the Affordable Care Act, which requires, in part, a qualified health plan to contract with a hospital with greater than 50 beds only if it utilizes a patient safety evaluation system as described in the Patient Safety Act;[140] and 42 U.S.C. § 280j-3, which requires HHS to make available a program for eligible hospitals to improve their readmission rates through the use of PSOs. HHS looks forward to future internal and external discussions on the feasibility of providing additional incentives.

8. **Include results of additional studies related to the Comprehensive Unit-Based Safety Program (CUSP) in which CUSP may not have been effective, as well as studies of approaches that can help struggling hospitals improve patient safety.**

   Additions have been made in section 3.4 of this report to clarify that the CUSP projects are provided as examples, intended to illustrate the complexity of implementing patient safety strategies in the real world; and that as with any approach, the success of CUSP will vary because implementation is always context-dependent. Consistent with this reality, it is not unexpected that studies that adapted the CUSP approach[141] or which faced infrastructure

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[138] Office of the Inspector General of the Department of Health and Human Services. Patient safety organizations: hospital participation, value, and challenges. OEI-01-17-00420. September 2019. https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf, p. 35.

[139] 42 CFR 3.102(b)(2)(i)(F), (b)(2)(ii), and (b)(2)(iii).

[140] See also 45 CFR § 156.1110, Establishment of patient safety standards for QHP issuers.

[141] Dixon-Woods M, Leslie M, Tarrant C, Bion J. Explaining Matching Michigan: an ethnographic study of a patient safety program. Implement Sci. 2013 Jun 20;8:70. doi: 10.1186/1748-5908-8-70. PMID: 23786847; PMCID: PMC3704826.

challenges and focused less on the adaptive elements of the CUSP model[142] might have different outcomes, or that the VA could achieve success using a more streamlined program model. To illustrate the potential influence of contextual factors, as the authors of the VA study cited by NAM[143] observed, their approach was likely facilitated by a longstanding culture of performance measurement and quality improvement and clear lines of authority within the VA.

The key point is that successful implementation of evidence-based patient safety improvement strategies -- and sustained success -- requires attention to implementation science principles as well as program designs that respect and are workable for clinicians at the front line. Implementation is complex and the results will always be context-dependent.

9. **Explore high visibility implementation strategies from other national patient safety organizations, programs, and initiatives—such as the Veterans Health Administration National Center for Patient Safety, the U.S. Food and Drug Administration (FDA) Adverse Event Reporting System, the FDA Sentinel Initiative, the Vaccine Adverse Event Reporting System, the Centers for Disease Control and Prevention Epicenters Program, the Institute for Healthcare Improvement, and The Joint Commission, and appropriate international examples.**

With one exception,[144] work from the agencies, organizations, programs, and/or initiatives cited in this recommendation is referenced in various places in this report. Studies conducted by researchers affiliated with some of these partners in patient safety improvement are included among the literature assessed in the *Making Healthcare Safer* reviews that comprise section 2.5 of the report. AHRQ will consider additional future opportunities for exploring relevant implementation strategies used by these partners in patient safety.

10. **Update AHRQ's responses to the OIG report recommendations with any subsequent results.**

The specific tasks AHRQ committed to doing in response to the OIG's recommendations can be found in the original letter from the AHRQ Director incorporated in the OIG report as Appendix B.[145] AHRQ has completed some; others are in progress.

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[142] Meddings J, Greene MT, Ratz D, Ameling J, Fowler KE, Rolle AJ, Hung L, Collier S, Saint S. Multistate programme to reduce catheter-associated infections in intensive care units with elevated infection rates. BMJ Qual Saf. 2020 May;29(5):418-429. doi: 10.1136/bmjqs-2019-009330. Epub 2020 Jan 6. PMID: 31911543; PMCID: PMC7176547.

[143] Render ML, Hasselbeck R, Freyberg RW, Hofer TP, Sales AE, Almenoff PL; VA ICU Clinical Advisory Group. Reduction of central line infections in Veterans Administration intensive care units: an observational cohort using a central infrastructure to support learning and improvement. BMJ Qual Saf. 2011 Aug;20(8):725-32. doi: 10.1136/bmjqs.2010.048462. Epub 2011 Apr 2. PMID: 21460392.

[144] This report does not include content related to the Vaccine Adverse Event Reporting System (VAERS).

[145] Office of the Inspector General of the Department of Health and Human Services. Patient safety organizations: hospital participation, value, and challenges. OEI-01-17-00420. September 2019. https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf.

Appendix B: Development of the Draft Report and Public Comments

B.1. Introduction

The Draft Report to Congress (Draft Report) released on December 16, 2020 contained three chapters. In this Final Report, Chapters One through Three have been updated and revised in part to address feedback received from members of the public and from the National Academy of Medicine (NAM). This new Appendix B has been added to the Final Report to describe the actions taken by the Department of Health and Human Services (HHS) to meet the statutory requirements for development and review of this report and to provide an overview of comments received from members of the public.

Development and Review of the Draft Report. The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) specified that the Draft Report be developed and made available for public comment and review by the Institute of Medicine (now NAM) no later than 18 months after the Network of Patient Safety Databases (NPSD) became operational. The NPSD was operationalized on June 21, 2019. The Draft Report was prepared, and the Notice of Opportunity to Comment was published in the Federal Register on December 16, 2020 with an original deadline for public comment of February 16, 2021.[146] The Notice of Opportunity to Comment included background information on the Patient Safety Act with links to additional information on the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Organizations (PSO) and NPSD websites;[147] an overview of the Draft Report; and instructions for accessing the Draft Report and submitting comments. AHRQ publicized the Notice of Opportunity to Comment on the PSO program website[148] and via email to subscribers of the Patient Safety Organizations bulletin. A blog post published on February 12 encouraged readers to submit their comments before the end of the public comment period on February 16. On the same date, the weekly issue of AHRQ News Now[149] directed readers to the blog post and the draft report. On March 18, AHRQ published a second notice in the Federal Register that extended the public comment period through April 5.[150] An announcement about the extended public comment period was included in the AHRQ PSNet Weekly Issue on March 31, 2021.[151]

On December 15, 2020, AHRQ and the National Academy of Sciences executed a contract for a review of the Draft Report to meet the statutory requirement. The NAM review and public comment period were roughly concurrent. NAM independently conducted its review, finalized its report, and sent an embargoed copy of the completed report to AHRQ on April 5, 2021. NAM conducted a briefing for AHRQ

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[146] Department of Health and Human Services, Agency for Healthcare Research and Quality. Notice of Opportunity to Comment on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine. 85 Fed. Reg. 81478 (December 16, 2020). https://www.federalregister.gov/documents/2020/12/16/2020-27589/notice-of-opportunity-to-comment-on-strategies-to-improve-patient-safety-draft-report-to-congress. Date accessed August 27, 2021.

[147] AHRQ PSO website: https://pso.ahrq.gov/. AHRQ NPSD website: https://www.ahrq.gov/npsd/index.html. Date accessed May 17, 2021.

[148] Draft Report to Congress Required by the Patient Safety Act, Patient Safety Act Resources webpage. Date accessed May 17, 2021. https://pso.ahrq.gov/resources/act.

[149] Agency for Healthcare Research and Quality. New AHRQ Views Blog Posts. Issue Number 751.https://www.ahrq.gov/news/newsletters/e-newsletter/751.html. Date accessed August 26, 2021.

[150] Department of Health and Human Services, Agency for Healthcare Research and Quality. Public Comment Period Extended for Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine. 86 Fed. Reg. 14752 (March 18, 2021). https://www.federalregister.gov/documents/2021/03/18/2021-05605/public-comment-period-extended-for-strategies-to-improve-patient-safety-draft-report-to-congress-for. Date accessed August 27, 2021.

[151] Agency for Healthcare Research and Quality. Public comment period extended for strategies to improve patient safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine. March 31, 2021. https://psnet.ahrq.gov/issue/public-comment-period-extended-strategies-improve-patient-safety-draft-report-congress-public. Date accessed. August 26, 2021.

staff on April 12, 2021 and published its report, entitled "Peer Review of a Report on Strategies to Improve Patient Safety," on April 19, 2021.[152]

General Overview of Public Comments. AHRQ received 37 comments from members of the public between December 18, 2020 and April 5, 2021. Most were submitted by or on behalf of entities, including health systems and other healthcare providers; patient safety organizations and related entities; and associations, membership organizations, and businesses. The entities that submitted comments focus on various aspects of patient safety and healthcare quality and/or related technologies, health policy, and/or health information transparency. Others were from organizations that focus on one or more particular patient populations or clinical specialties. Some members of the public submitted comments that referenced their experience as healthcare personnel; others submitted comments based on their personal experiences as patients.

B.2. Themes in the Comments

The comments received regarding the Draft Report are available for review at https://www.pso.ahrq.gov/resources/act.[153] Below, we provide an overview of themes that emerged across the entire set of comments as well as some examples. HHS and AHRQ are thankful to the public for providing thoughtful comments that have expanded our thinking on implementation of the Patient Safety Act and beyond.

B.2.1. Specific Clinical and Patient Safety Issues

Many public comments suggested specific aspects of patient safety, clinical patient safety risks and/or risk mitigation strategies, and healthcare settings for further emphasis or addition in national patient safety efforts. Others highlighted patient populations with particular vulnerabilities and noted patient safety risks related to shortcomings in care planning. Some suggested attention to particular patient safety strategies and technologies. Feedback regarding clinical and patient safety issues of interest and concern to members of the public will be particularly helpful to AHRQ in considering future program directions.

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[152] National Academies of Sciences, Engineering, and Medicine. 2021. Peer review of a report on strategies to improve patient safety. Washington, DC: The National Academies Press. https://doi.org/10.17226/26136.

[153] A PDF of the public comments is available via a link on this page, see the bullet stating, "Access a copy of the public comments (PDF 5.2 MB) on the draft report." Agency for Healthcare and Research Quality. Patient Safety Organization Program. Patient Safety Act. https://www.pso.ahrq.gov/resources/act. Last accessed September 28, 2021.

Clinical and Related Patient Safety Issues: Examples of Topics Raised in Public Comments

Cross-Cutting Strategies	Specialties and Settings	Areas of Emphasis	Specific Safety Topics
• Nurturing safety culture at the organizational leadership level • Early clinical training in patient safety for physicians and other health care professionals • Proactive learning employing resiliency science • Artificial intelligence and predictive analytics to predict or detect and prevent clinical deterioration	• Pediatrics and children's hospitals • Perinatal and neonatal care and reducing maternal morbidity and mortality • Women's health • Ambulatory care, including community-based medical practice, primary care, clinics, home health, and community pharmacies	• How social determinants of health influence patient harm and the effectiveness of patient safety practices • Health disparity metrics and work towards achieving health equity • Individuals with serious illnesses and other vulnerabilities	• Diagnostic safety • Health information technology • Medication (including opioids) safety; incorporating pharmacogenomics • MRI and radiation/radiology • Implants such as those used in joint replacement • Environmental and equipment sanitation

B.2.2. Centrality of the Patient and Family in Patient Safety

Some comments from the public emphasized that patient safety efforts require recognition of the centrality of patients and families in patient safety and the need to effectively support patients when things go wrong. Comments included encouragement for:

▶ Patient and family engagement being front and center in patient safety improvement efforts. Patient safety should go to the source - patients - in deciding courses of action.

▶ Education about effectively engaging with patients - for example, issues such as trusting patients' self-assessments, bedside manner, and responding to patient complaints - should be emphasized in medical school.

▶ More mechanisms that enable patients to give voice to their valuable experiences.

B.2.3. Transparency, Confidentiality and Privilege

The Patient Safety Act was carefully designed to protect patients' rights to their medical information while providing protections that could effectively facilitate patient safety improvement. Some comments reflected varying perspectives about how best to balance the inevitable tension between transparency and confidentiality in the area of patient safety, for example:

▶ Several emphasized that the confidentiality and privilege protections for quality and safety improvement information created by the Patient Safety Act are essential to promote learning and improvement. They observed that these Federal protections have increased voluntary reporting and have also fostered informal sharing, discussions, and learning among healthcare providers. Much of that success can be attributed to the teamwork between the healthcare provider and the PSO as they endeavor to build and maintain strong and just learning cultures that support teamwork and communication based on the overriding goal of patient safety improvement. Several emphasized the value of "safe tables" organized by PSOs to encourage providers to share safe practices utilizing the Patient Safety Act protections. One noted that

Congress designed the Patient Safety Act protections to break silos that had been created due to the erosion of state peer review laws and thereby create a national system of sharing and learning for the benefit of patients.

▶ Others urged a focus on increasing the transparency and sharing of safety data, with a focus on system failures instead of individual blame. Some emphasized accountability to the public and opined that confidentiality and privilege protections can allow unsafe providers or practices to go unaddressed.

▶ Commentors also encouraged continuing attention to the privacy of patients' medical information with the increasing use of electronic systems for patient record sharing.

B.2.4. *Suggestions for AHRQ*

Some comments from the public offered specific suggestions unrelated to implementation of the Patient Safety Act that AHRQ could take into consideration, for example:

▶ Offering a webinar to provide an overview of the Final Report.

▶ Updating the status of software development related to the AHRQ Quality and Safety Review System (QSRS).[154]

▶ Actively engaging the assistance of professional organizations to increase implementation of patient safety strategies as they can help to synthesize, target, and push information to healthcare team members most in need of a certain tool or strategy and many also have the means to promote research. Several working in the area of medication safety expressed interest in working with AHRQ to identify the most effective communications strategies to disseminate the relevant *Making Healthcare Safer* evidence syntheses to their audiences.

▶ Keeping *Safer Together: A National Action Plan to Advance Patient Safety*[155] and its recommendations before patient safety advocates and leaders, including patient safety personnel in hospitals, health systems, long-term care facilities, pharmacies, and other settings.

▶ Developing safety culture surveys for telemedicine, behavioral health clinics, assisted living, radiology and others healthcare sectors that do not have setting-specific safety culture surveys.

B.2.5. *Policy Recommendations*

Some of the feedback offered perspectives about patient safety health policy issues and recommendations pertaining to various government agencies and functions, for example:

▶ How research conducted or supported by AHRQ is adopted by or influences the Centers for Medicare and Medicaid Services (CMS) and other Federal agencies, such as the Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), the Health Resources and Services Administration (HRSA), and the Department of Veterans Affairs (VA).

▶ One commenter opined that the goals of healthcare organizations, clinicians, payors, and patient needs are misaligned and expressed concerns about moving care to settings lacking outcomes and safety transparency, reporting, or incentives to drive quality and safety.

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[154] Agency for Healthcare Research and Quality. AHRQ Quality and Safety Review System (QSRS). https://www.ahrq.gov/patient-safety/resources/qsrs/index.html. Page last reviewed January 2021.
[155] National Steering Committee for Patient Safety. Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement. http://www.ihi.org/SafetyActionPlan. Date accessed May 13, 2021.

▸ One commenter opined that a voluntary system cannot function effectively as a national learning system for patient safety improvement and stated a belief that regulatory authority and government enforcement are needed to ensure that safety processes are truly in place, that government oversight supports a transparent culture of safety and learning in healthcare, and that Federal oversight modeled after the Federal Aviation Administration and National Transportation Safety Board would help link disparate data from across all the existing agencies and establish the structure needed to ensure accountability so that the same adverse events do not continue to reoccur.

▸ One commenter noted that they believed there is growing published evidence of how little overall progress has been made in reducing patient harm and warned that the Report risks misleading Congress and fumbling a major opportunity to improve our nation's current approach. The commenter further criticized the voluntary nature of activities under the Patient Safety Act; a lack of transparent public reporting; the NPSD; the absence of a discussion of emerging "evidence of systematic gaming of our safety reporting and measurement systems"; and the absence of a diagnosis to help Congress understand how to fix the gaps and a comparison to the federal safety system for transportation.

▸ Other commenters cautioned that consumers in our data-driven culture may mistakenly be led to believe that the high performing hospitals that invest heavily in safe systems and safety culture provide lower quality and value of care – which then punishes the high performing providers and correspondingly punishes patients. This commenter noted that incident reports are not an indicator of quality or value and therefore cannot be used for consumers to decide upon the quality or value of healthcare. The commenter also made the point that collection of incident reports allows for more learning and a higher quality of care.

▸ It was suggested that there is a need to identify targets for substantial federal funding in safety sciences to address new system threats, such as COVID-19, and to develop a roadmap for the path forward to overcome challenges and greatly accelerate efforts to improve patient safety, including in proactively identifying and eliminating health disparities across racial, ethnic, and socioeconomic groups. The commenter emphasized that AHRQ's role in health services and primary care research is critical and unique to make compelling arguments for the additional research resources needed to make care safer as healthcare continues to be transformed.

▸ One commenter suggested that States should consider adding a Medication Risk Reduction Model to enhance their Medicaid Drug Utilization Review (DUR) and/or Medicaid Medication Therapy Management Programs to bend the health care cost curve associated with adverse drug events.

▸ Concern was expressed by a commenter that HIPAA does not provide sufficient privacy protections, especially with respect to electronic systems for patient record sharing, health insurance systems that require online usage, other for-profit companies hired by hospitals, for example, to facilitate record keeping, and access by attorneys without patient consent.

B.2.6. Comments Regarding Patient Safety Organizations, AHRQ Common Formats, and the NPSD

Some members of the public suggested ways to encourage more participation in patient safety activities conducted under the Patient Safety Act and ways to improve the AHRQ Common Formats and/or the NPSD, for example:

▶ Several commenters encouraged the development of incentives for PSOs to submit data to the NPSD, to increase both the volume and diversity of submitters and sources of data. Commenters noted that PSOs receive no government funding, make substantial financial investments to operate and staff their patient safety work, and that the primary revenue stream for many is from the data collected and work product produced. Recent financial losses and other stressors on the healthcare system and PSOs add to the challenges to reporting to the NPSD. Financial incentives or funding for PSOs to collect and report data would allow them to better update their information technology systems to sync with the NPSD, enable regular updates to the most current versions of the AHRQ Common Formats, and afford more PSOs the opportunity to contribute.

▶ One commenter observed that as many organizations vary in size, readiness, and resources, a one size-fits-all approach would be detrimental. Reporting is burdensome to clinicians, even for organizations with advanced EHR and reporting infrastructure in place. Making reporting easier for clinicians will be key to effective adoption. Resources are needed to support data submission and automation; next steps should ensure a plan that does not add more regulations or impose structures, but rather guides a diverse landscape of organizations to success.

▶ Some urged emphasis on PSOs' function as a learning network that supports national hospital learning systems. For example, one PSO provides a network function for 60 children's hospitals across the country, enabling the knowledge collected, analyzed, and assembled within the network to further accelerate learning to improve patient care beyond the PSO to outside organizations. PSOs make it possible for healthcare providers to deliberate about protected information with their colleagues. Many PSOs make their findings available to the entire healthcare community.

▶ Several of the comments sought to promote and emphasize the role of PSOs in understanding and eliminating patient harm. One opined that meetings of healthcare providers and PSOs referred to as "safe tables" prevent the same events from happening in different facilities and enable PSOs to share innovative programs, data analysis results, and quality improvement success, similar to approaches taken in the aviation industry. Another opined that unlike aviation, healthcare is varied, complex and multi-faceted as there are many modes, facilities and systems of care as well as many specialties of clinical practice, medical devices, pharmaceuticals and digital devices used in patient care as opposed to a single focus -- aircraft -- which involves little decision-making beyond the operations manual.

▶ Commenters indicated that PSOs – despite being relatively new market entrants lacking defined funding models – have become more recognized as useful vehicles for hospitals to improve safety as evidenced by the Office of Inspector General report. PSOs vary as to providers and patient populations served, but they all play a part in national solutions and deploying the latest principles in safety science toward these efforts. The flexibility of the Patient Safety Act framework enables PSOs to bring robust quality improvement to specialties, settings and modes of health care that traditionally faced high barriers to implementing such programs.

▶ One commenter expressed interest in advancing patient safety by reporting and aggregating data (both internally and on a national level) pertaining to how adverse events are prevented.

▶ One commenter opined there are unintended limitations on the ability to share protected information among and between entities operating within an organized health care system and with entities external to a health system but involved in the provision of its healthcare services and encouraged AHRQ and HHS to explore solutions.

▶ Several commenters offered suggestions to improve the Common Formats and increase contributions to the NPSD by leveraging technology and machine learning:

- Existing technologies create an important opportunity to further develop a national infrastructure for information exchange, analysis, research, and surveillance to improve patient safety.

- One PSO opined that modifications are needed to make the Common Formats more conductive to collecting information needed to develop actionable insights for providers to improve care.

- Technologies such as natural language processing, distributed data networks, artificial intelligence (AI), and machine learning (ML) could improve and increase contributions to the NPSD while relieving the burden of data collection and reporting at the frontline of care, and noted that the FDA Sentinel Initiative (as mentioned in the Report) and the CDC National Syndromic Surveillance Program (NSSP) offer examples of how HHS agencies can leverage technologies and advanced data analytics to streamline and automate data collection. Suggestions for encouraging the use of such emerging data collection technologies by federally-listed PSOs included either: (a) update the PSO certification guidelines to create standards for using autonomous data collection technology with AI/ML analytics; or (b) provide a standard set of data analytic tools and technologies that the PSOs could adopt through the technical assistance AHRQ provides to the PSOs. This is similar to how the FDA provides IT tools to the data owners in the FDA Sentinel Initiative, and it is similar to how the CDC provides data analytic tools to the public health community in the NSSP program.

AHRQ and HHS are grateful to the members of the public who took the time to share feedback on the Draft Report and their insights and concerns about patient safety. Some of that feedback is reflected in this Final Report; much will be used by AHRQ to inform program planning. While some sought content beyond the scope of the statutory mandate specific to this report,[156]members of the public have provided HHS and Congress with valuable information and perspectives about important issues related to patient safety.

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[156] See 42 U.S.C. § 299b-22(j). See also section 2.1 of the Draft Report: Scope and Terminology: "This report does not address mechanisms for setting, incentivizing, and/or enforcing compliance with patient safety-related standards or requirements, or for holding providers accountable, such as professional licensing and discipline and healthcare facility licensing and certification. The report also does not encompass regulatory activities pertaining to public health or to regulation of the safety of drugs, medical devices, or radiation-emitting products. These activities play a critical role in protecting patient safety but are not within the scope of this report."