

From: [Joanne Lynn](#)
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: a modest request of the Patient Safety Report
Date: Saturday, February 13, 2021 11:20:27 PM

I applaud the report overall.

I do wish that the report always took notice of the risks to patient safety by not making comprehensive care plans, at least for people facing serious illnesses. It is a serious breach of patient safety, for example, to have done CPR on a patient who would have refused, if anyone had asked – or even had volunteered the information, but did not have it known or honored by the emergency respondents.

Or a person who is mildly demented and homeless who is discharged from a hospital or ER without a plan for supportive care.

Even if you cannot actually deal with errors like this, the report might acknowledge them and explicitly say that they will not be dealt with – that the report only deals with conventional threats to patient safety as ordinarily considered by physicians in medical (mostly hospital) settings.

Joanne Lynn

Joanne Lynn, MD

Policy Analyst | Center for Eldercare Improvement

ALTARUM | Washington, DC

C [REDACTED]

[@ALTARUM](#) | altarum.org

[@medicaring](#) | medicaring.org

MediCaring Communities: Getting What We Want and Need in Frail Old Age at an Affordable Cost – at <http://medicaring.org/book>



CHILDREN'S
HOSPITAL
ASSOCIATION

600 13TH ST., NW, SUITE 500
WASHINGTON, DC 20005
p | 202-753-5500
f | 202-347-5147

16011 COLLEGE BLVD., SUITE 250
LENEXA, KS 66219
p | 913-262-1436
f | 913-262-1575

WWW.CHILDRENSHOSPITALS.ORG

February 16, 2021

Paula DiStabile
Patient Safety Organization Division
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
Department of Health and Human Services
Submitted electronically to PSQIA.RC@ahrq.hhs.gov

Re: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Dear Ms. DiStabile,

The Child Health Patient Safety Organization (Child Health PSO) appreciates the opportunity to provide comments on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine (draft report). We believe the draft report should highlight the vital networking role of patient safety organizations (PSOs), make recommendations to improve the Common Format to benefit patient care, include a focus on children and the providers that care for them, promote and emphasize the role of well-established PSOs, and encourage more funding opportunities for research in diagnostic safety measurement and interventions while ensuring their applicability to pediatric hospital care.

Child Health PSO is the only federally registered PSO dedicated to children's hospitals by the Agency for Healthcare Research and Quality (AHRQ). Our mission is to improve the safety and quality of child health care delivery by creating a secure environment where clinicians and health care organizations collect, aggregate, and analyze data that will identify and reduce the risks and hazards associated with patient care. Child Health PSO draws case experience from 60 children's hospitals across the nation, whose combined inputs are analyzed to guide the PSO's activities. Since 2012, Child Health PSO has released 16 Patient Safety Action Alerts to improve pediatric safety and reduce patient harm. Child Health PSO also recently released the "Improving Communication to Enhance Diagnostic Safety Toolkit", which provides strategies to make patient safety improvements through better communication and referenced several AHRQ resources. The toolkit's release reached over 100 organizations concerned with improving pediatric safety, including many outside the Child Health PSO.

We provide a few comments on the draft report below for your consideration.

The draft report should highlight the vital networking role of Patient Safety Organizations

We urge AHRQ to recognize the important network function that PSOs provide. The draft report acknowledged the works of PSOs under the Patient Safety and Quality Improvement Act and described them as serving as a national learning system for patient safety improvement. The draft report should also highlight the PSOs' function

Champions for Children's Health

as a learning network supporting the national and hospital learning system. The Child Health PSO, for instance, provides a network function for 60 children's hospitals across the country, which is important because the knowledge and expertise in patient safety within the network can be collected, analyzed and assembled, to further accelerate learning to improve patient care at children's hospitals and beyond the PSO to outside organizations.

The draft report should make recommendations to improve the Common Format to benefit patient care

We appreciate the updates to the Common Format and the network of patient safety databases (NPSD) but encourage additional work to improve patient care and creating opportunities to enable providers and PSOs to efficiently participate, such as leveraging technology and machine learning. While the standardization of data collection was well-intentioned and contributed to the development of PSOs, 42% of pediatric cases reported to the Child Health PSO via the Common Format fall in the "other" category. As a result, the Child Health PSO had to adopt a modified classification system more conducive for actionable insights for providers to improve care. Child Health PSO intends to contribute to national learning as part of the NPSD, but based on experiences with the Common Format, it is unclear if the effort outweighs the attempt for broader adoption.

The draft report should include a focus on children and the providers who care for them

While the draft report appropriately highlights the complexities and opportunities with measurement for complex learning systems, the draft report focuses on systems supporting Medicare. In doing so, the draft report neglects populations that are not covered by Medicare, such as children. This diminishes the draft report's impact and offers little benefit for providers that serve the pediatric population such as children's hospitals. Children are not small adults and there are significant – and meaningful – differences between the delivery of health care services for adult and pediatric patients. While there are undoubtedly lessons that can be shared, a narrow focus on Medicare risks ignoring the unique needs of children. Therefore, we urge the draft report to expand its scope to include a pediatric perspective to help pediatric providers deliver care to children.

The draft report should promote and emphasize the role of well-established PSOs

We suggest that the draft report promote and emphasize the role of well-established PSOs in understanding and eliminating patient harm. We believe highlighting their activities could be another accelerator opportunity. As relatively new market entrants lacking defined funding models, PSO's have recently become more recognized as useful vehicles for hospitals to improve safety as evidenced by the 2018 Office of Inspector General report¹. The promotion of PSOs will also raise industry awareness and position PSOs to strengthen their support of AHRQ's vision for the 21st century. PSOs can vary on 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.

¹ 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>

The draft report should encourage more funding opportunities for research in diagnostic safety measurement and intervention while ensuring their applicability to pediatric hospital care

AHRQ's safety agenda has been valuable to the health care industry, particularly the web-based tools which more broadly apply across care settings, including pediatric care. However, more is needed in patient safety research, measurement and practice improvement, and proactive learning employing resiliency science. More funding opportunities for research is necessary to develop the evidence needed in patient safety science and frontline practical tools. In addition to funding opportunities already listed in the draft report, we urge the draft report to recommend more funding in diagnostic safety measurement and interventions and to ensure their applicability to pediatric hospital care.

We thank you for the opportunity to provide comments and look forward to continuing to work with you to improve the delivery of children's health care. Please contact Kate Conrad at [REDACTED] should you need more information.

Sincerely,

[REDACTED]
Kate Conrad

Vice President, Delivery System Transformation



February 16, 2021

David Meyers, M.D.
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Meyers:

AcademyHealth welcomes the opportunity to provide input to the Agency for Healthcare Research and Quality (AHRQ) on the draft report on effective strategies for reducing medical errors and increasing patient safety. We are the professional home of health services researchers, policy experts, and practitioners, and we strongly support the production, dissemination, and use of evidence to inform policy and practice. Our membership is highly engaged with AHRQ, and we recognize and support AHRQ's mission to make healthcare safer, while also improving quality, equity, and affordability. We appreciate that AHRQ has asked for comments from the community on a draft of the report required by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).

General Comments on the Report

Overall, this draft report does a good job of summarizing the development of effective strategies for patient safety in response to the Patient Safety Act, and the importance of health services research and primary care research in delivering better value care that prioritizes patient safety. The RAND Corporation released a [report](#) in 2020 as called for by the Consolidated Appropriations Act of 2018, which identified AHRQ as “the only agency that has statutory authorizations to generate HSR and be the home for federal PCR, and the unique focus of its research portfolio on systems-based outcomes (e.g., making health care safer, higher quality, more accessible, equitable, and affordable) and approaches to implementing improvement across health care settings and populations in the United States.” This draft report should build on the 2020 RAND report and highlight the value that AHRQ brings in supporting HSR, including examples of potential future patient safety projects that Congress can direct new funding towards.

While substantial progress has been made in recent decades to improve patient safety, with AHRQ leading the charge, there still [remains](#) a significant frequency of preventable harm in the health system. While the report highlights some of the legal, cultural, policy and practice reasons why avoidable harm occurs, more needs to be said to build a compelling case to garner the necessary attention from Congress and other leaders in the public and private sectors. The report should not only discuss the past achievements and challenges, but also lay 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. In essence, AHRQ should use this opportunity to be more forward looking. This would provide the new administration a solid platform to create needed additional investments in patient safety.

The report should provide a more comprehensive analysis of the challenges facing patient safety reforms. For example, there was not a discussion of safety areas that have been resistant to change and improvement efforts, nor why so little progress has been achieved. Additionally, it would be helpful and informative to discuss grants and programs that were not successful in improving patient safety, that had



unanticipated undesired consequences, or could not generalize outside of their initial development setting. Not all efforts are successful, and the audience could learn from greater transparency about how to better design interventions and grants. It is important to know what types of patient safety concerns are the most and least amenable to reforms, as this can give the field some direction on areas to focus “implementation-ready” change efforts and where new approaches, including research and development, are necessary.

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

Chapter One provides a comprehensive overview of the rationale for, components of, and implementation of the Patient Safety and Quality Improvement Act of 2005. It summarizes the key objectives of the Patient Safety Act and presents a perhaps optimistic picture of how the Statute was implemented. While the report acknowledges barriers to participation, it does not explicitly discuss the advantages to individual practices that may choose to become patient safety organizations (PSOs), or barriers to the success of a PSO. The report should specify how many US hospitals and health systems work with PSOs, including a discussion about how to increase that number. The report can also discuss [examples](#) of what we have learned from partnerships with PSOs, including what insights are available from aggregated data and how Common Formats are being used by US health systems.

Additionally, while a network of patient safety databases (NPSDs) is a hallmark achievement of the Patient Safety Act, this report does not clearly articulate how these data are to be accessed and used by health systems and individual providers to improve the quality and safety of patient care. The report should discuss if there are research projects underway using NPSD that show early evidence of impact.

Chapter Two, Strategies for Reducing Medical Errors and Increasing Patient Safety

Chapter Two is effectively framed by the discussion of fundamental safety principles and concepts, specifically systems thinking, human factors engineering, and attributes of high-reliability organizations. The report discusses several successful examples of AHRQ-funded efforts to improve patient safety through systems-based approaches, specifically the Comprehensive Unit-based Safety Program (CUSP), REDUCE-MRSA effort, Project RedDE, DREAM lab, PROMIS Learning Lab, and others. It also highlights how knowledge from these and other AHRQ-funded grants were broadly and publicly disseminated through efforts like the AHRQ Enhanced Protocol, Department of Defense TeamSTEPPS curriculum, primary care-focused Six Building Blocks program, Reducing Diagnostic Errors in Primary Care Pediatrics toolkit, and others. Further description of wider adoption and implementation of these principles, programs, tools, and resources would be useful as the Agency has the opportunity to do more to demonstrate its impact. This chapter should also discuss AHRQ funded work on other emerging safety concerns, such as on discovering the striking [frequency](#) of outpatient diagnostic errors or health information technology and electronic health records [safety](#) issues.

The report indicates that there will be a discussion of how interventions to improve patient safety can be evaluated, but it does not provide that framework. There is a discussion on systems that were previously or currently are in place for safety event reporting, such as the Medicare Patient Safety Monitoring System, the Quality and Safety Review System, the AHRQ National Scoreboard on Hospital-Acquired Conditions, and the National Healthcare Quality and Disparities Reports and Chartbooks. The report does not describe whether and how any of these systems facilitated the evaluation of quality/safety improvement efforts and whether this led to the ultimate improvement at scale of patient safety and health outcomes. For example, this discussion could further explore how the QSRS is currently being used or could be used in the future as a measurement mechanism to assess effectiveness of strategies. The report could also include a section that is dedicated to the implementation of the described strategies, including

on the state of evidence of their uptake in US organizations. This could include a discussion on what AHRQ can and should do to foster [relationships](#) with health care organizations to increase implementation and accelerate their journey towards becoming high performing learning health systems.

The report also helpfully summarized AHRQ funding initiatives and their products and deliverables, which clarifies the return on investment in terms of meaningfully reducing patient harm and improving the safety of healthcare delivery. This explanation clearly showcases the strong benefit-cost analysis in AHRQ funding, and that AHRQ's role in health services and primary care research is critical and unique. Expanding on this section further can make compelling arguments for the additional HSR resources that are needed to make care safer in the next decade and beyond as healthcare continues to be transformed.

The report also illustrated how AHRQ responded to the COVID-19 pandemic, using its grants mechanism to support research on the quality, safety, and equity of care delivered during the pandemic, with an additional focus on how digital health innovations contributed to health system responses to COVID-19. We have seen the deep racial and ethnic inequities both within and beyond healthcare as people of color are disproportionately contracting COVID-19, suffering worse outcomes, having less access to diagnostics, vaccinations, treatments, and are dying at higher rates. These disparities are not only a health systems crisis, but are also a spotlight on the need to identify and eliminate racial and ethnic disparities in patient safety, or indeed whether disparities linked to a patient's race or racism are themselves a source of unsafe healthcare. This is a subject AHRQ can and should be a leader on. New [system](#) threats, such as COVID-19, illustrate why we must continually keep investing substantial resources in safety sciences. AHRQ is one of the few organizations that has a multidisciplinary knowledge and talent to do that, as evidenced by the recent RAND Corporation [study](#). This report should more clearly make this argument.

The tables at the end of Chapter Two are highly informative, and the links to the AHRQ Making Healthcare Safer series were helpful.

Chapter Three, Encouraging the Use of Effective Strategies for Reducing Medical Errors and Increasing Patient Safety

This was an informative chapter and reinforces the scope, breadth, and depth of AHRQ-supported efforts to improve patient safety. It was also helpful to review efforts of other federal agencies. For providers, health systems, and nonprofits new to the field, this is a helpful overview of where to start in their efforts to support patient safety and high-quality care. This section could provide additional explanations on how research conducted or supported by AHRQ is adopted by or influences CMS and other federal agencies, such as FDA, ONC, HRSA, and the VA.

AcademyHealth appreciates the work that AHRQ undertook in developing this deeply informative document. For further comment, clarification, or inquiry, please email Josh Caplan at

████████████████████



April 5, 2021

VIA ELECTRONIC MAIL
PSQIA.RC@ahrq.hhs.gov

David Meyers, M.D.
Acting Director
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, Maryland 20857

Re: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review

Dear Dr. Meyers:

On behalf of AdventHealth, we appreciate the opportunity to comment on the Agency for Healthcare Research and Quality (AHRQ) and Alliance for Quality Improvement and Patient Safety (AQIPS) report titled "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine." Our system includes more than 50 hospital facilities located across nine states. AdventHealth provides inpatient, outpatient and emergency room care to more than four million patients each year. We also operate a Patient Safety Organization (PSO) that provides quality and patient safety improvements for our health system.

AdventHealth commends the AHRQ for its efforts to improve patient safety nationwide and the strategies outlined in the report referenced above. In this same report, the AHRQ mentions that "the ability to release more National Patient Safety Database (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."¹ We recognize that there are concerns with respect to the quantity of data reported from PSOs to the NPSD. As an operator of a PSO, we realize the challenges that PSOs face when seeking to report such data to the NPSD and wish to shed light on those difficulties, which include the following:

¹ [Strategies to Improve Patient Safety](#): Draft Report to Congress for Public Comment and Review

1. *Financial restraints:* PSOs make substantial financial investments to operate and staff their patient safety initiatives and yet receive no federal funding for those initiatives or the collection and reporting of data. This lack of funding limits the ability of PSOs to report data to the NPSD.
2. *Network capabilities and syncing of data:* PSOs handle a large amount of data that is not always compatible with the format used by the NPSD. This can strain sharing capabilities across different information technology platforms when reporting to the NPSD.
3. *The COVID-19 pandemic:* Patients delaying medical care as a result of COVID-19 could also be a contributing factor to less patient safety events being reported to the NPSD.

Due to these challenges, we encourage the AHRQ to consider providing financial incentives to PSOs for the collection and reporting of data. This funding will allow PSOs to better update their information technology systems to sync with the NPSD and enable regular updates to the most current versions of the AHRQ Common Formats to sustain robust data collection. We believe this incentive-based approach will afford more PSOs the opportunity to report to the NPSD, ultimately providing more robust datasets.

We strongly discourage the adoption of any mandatory data reporting by PSOs or providers as this would result in such data losing the protections granted under the Patient Safety and Quality Improvement Act (Patient Safety Act). The Act states: “If patient safety work product is disclosed as provided for in subsection (c)(2)(B) [relating to disclosure of nonidentifiable patient safety work product], the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.”² Section 921, Part C, (7)(B)(iii)(II) also states that if information is reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes it will no longer be patient safety work product. Because of these provisions, should mandatory reporting be pursued and the reported data become public domain, the protected legal environment afforded to PSOs and providers will no longer apply. This would run contrary to the intent of the Act, which was to create a national culture of patient safety by providing confidentiality protections for the reporting and analysis of

² Patient Safety and Quality Improvement Act

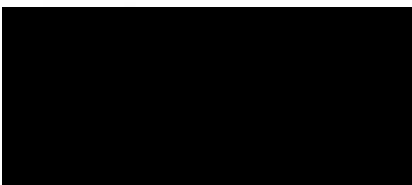
patient safety events. This voluntary reporting cultivates a national learning system for patient safety improvement that leads to the prevention of future medical errors.

Multiple studies also indicate that voluntary reporting systems may be more effective at getting providers to report errors, weaknesses and improve safety.³ If event information cannot be designated as patient safety work product because it is required for reporting to an agency, it will no longer be afforded the protection of the Patient Safety Act and providers will be inclined to decrease the quantity and quality of data they contribute. Concerns about legal action, risk to reputation or negative media attention could result in some PSOs and providers becoming more selective about the information reported. This will ultimately inhibit the advancement of AHRQ's mission of supporting research designed to improve the quality of health care.

Conclusion

AdventHealth welcomes the opportunity to discuss further the recommendations provided above. We appreciate the opportunity to provide feedback on PSOs reporting data to the NPSD and patient safety improvement efforts. If you have any questions or would like additional information, please do not hesitate to contact Julie Zaiback-Aldinger, Executive Director of Community Advocacy and Health Equity, at [REDACTED].

Sincerely,



Michael E. Griffin

Vice President, Advocacy and Public Policy
AdventHealth

³ Journal of Patient Safety. [Developing an Error Reporting System to Improve Patient Safety](#)



10000 Cedar Ave. | Cleveland, Ohio 44106 | [REDACTED]

February 15, 2021

Marquita N. Cullom
Associate Director
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Ln #7
Rockville, MD 20857

Re: "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," Document No. 2020-27589

Dear Associate Director Cullom:

I am writing to request that the "Strategies to Improve Patient Safety Report to Congress" consider adding avoidable radiation exposure for patients and health care workers to the reporting system currently included in the network of patient safety databases and the national resource that is used in developing effective strategies for increasing patient safety. There are technologies and measures that can be taken to ameliorate this risk that correlates with harm to patients, physicians and health care workers.

Among the highest risks of harm from avoidable radiation exposure is fluoroscopic imaging, used in many types of minimally-invasive surgeries and treatments. It uses repeated doses of X-rays and contrast dyes to visualize the inside of the body. The radiation from X-rays is known as ionizing radiation, meaning it carries enough energy to turn neutral atoms or molecules into much more reactive ions, leading to mutations that can cause cancer. Fluoroscopic radiation can also cause skin burns in patients, and increases cancer risk for doctors, nurses, technicians, and anyone else in the room where the procedure is performed. The radiation can also cause cataracts and increase the risk of stroke. In addition, the contrast dyes used are typically iodine based and toxic to the kidneys. In the worst cases, patients can end up with renal failure requiring dialysis. Fluoroscopy is used in a wide range of procedures including treating cardiovascular disease with stents, guiding catheters in urological procedures, and navigating needles to diagnose cancer. However, while the fundamental technology of fluoroscopy has not changed in many decades, other image guidance technologies have been developed to achieve the same medical or surgical goals while eliminating or reducing the need for ionizing radiation.

The Food and Drug Administration (FDA) is aware of this patient safety issue. On September 9, 1994, the FDA issued a warning for physicians and other health care professionals regarding "reports of

occasional but at times severe radiation-induced burns to patients from fluoroscopically-guided, invasive procedures.”¹ This report also highlights the risk of longer term or late effects from these procedures, including “radiation-induced cancers in other tissues and organs.” The report states, “The potential for such late effects should not be disregarded in risk/benefit considerations, especially for individuals with many decades of expected life remaining.”

The FDA raises concerns for health care workers, not just patients in this report. It points to the “increased occupational exposure” for medical professionals and concludes that any reduction in the exposure to patients will also result in reductions in exposure to the medical professionals conducting these procedures. Cardiologists, in particular, are at high risk, according to several studies.² For women in their childbearing years, the radiation carries risks of birth defects, which is an unacceptable risk to ask the female workforce to take in order to care for patients.³ Moreover, some data even suggest that the radiation can impair a doctor's brain function.⁴

With the increased proliferation of fluoroscopy in modern medicine, it is important to effectively manage radiation exposure. That is why avoidable radiation exposure in health care should be reported and serve as a part of this national data gathering system to inform patient safety strategies. We cannot take meaningful steps to address this problem unless we have the data. This can inform better understanding of the factors that affect patient doses and enable greater use of new protocols and technologies that reduce or eliminate radiation exposure without compromising image quality or the ability of the health care professional to provide the best care possible. Effective management of radiation exposures with proper use of equipment, adequate training of fluoroscopic operators, frequent quality control, and use of new tools for fluoroscopy can all contribute to an overall reduction in patient and personnel exposures, thus improving patient safety and health outcomes.

In conclusion, the Journal of Vascular Surgery, a leading journal in this field, published a review article that effectively summarized this issue by stating, “every effort should be made to decrease radiation exposure.... Attempts must be directed towards maximizing the operator’s awareness, welcoming new imaging technology emitting less radiation, and shifting to follow-up strategies that require minimal or no radiation.”⁵

Thank you for your consideration. We hope that you will address patient safety relating to avoidable radiation exposure in the “Strategies to Improve Patient Safety Report to Congress” and determine avoidable radiation exposure be considered appropriate for inclusion in the network of patient safety databases. Without the ability to report avoidable radiation exposure, the development of strategies to

¹ FDA Avoidance of Serious X-Ray-Induced Skin Injuries to Patients During Fluoroscopically-Guided Procedures, <https://www.fda.gov/media/74894/download>

² Reduction of Radiation Risk to Interventional Cardiologists and Patients during Angiography and coronary Angioplasty, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5643866/>

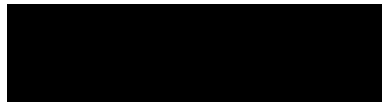
³ Radiation and Pregnancy, <https://www.marchofdimes.org/pregnancy/radiation-and-pregnancy.aspx>

⁴ Role of Ionizing Radiation in Neurodegenerative Diseases, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5963202/>

⁵ Radiation Exposure in Endovascular Repair of Abdominal and Thoracic Aortic Aneurysms, [https://www.jvascsurg.org/article/S0741-5214\(15\)01203-3/pdf](https://www.jvascsurg.org/article/S0741-5214(15)01203-3/pdf)

improve patient safety will be missing an important factor that the FDA has reported as linked to severe burns and radiation-induced cancers.

Sincerely,



Vikash Goel
Founder and Chief Technology Officer
Centerline Biomedical, Inc.




April 1, 2021

Greetings,


Tabula Rasa HealthCare (TRHC) is eager to join AHRQ in submitting our comments to Congress for improving patient safety. At TRHC, we are dedicated to addressing medication-related risks at the source, which is why we work closely with patients and their providers to prospectively address risks and optimize regimens. By addressing and mitigating adverse drug events, the third leading cause of death in the U.S., we believe healthcare organizations can vastly improve the safety of their patients.

As efforts to improve patient safety progress, TRHC continues to promote the role of pharmacists in medication safety programs, prioritize research related to medication safety, and advocate for legislation that promotes medication safety.

Thank you,



Jacques Turgeon, PhD, BPharm
Chief Scientific Officer
Tabula Rasa HealthCare



Brian J Litten, JD
Strategic Growth Officer
Tabula Rasa HealthCare

I. Tabula Rasa HealthCare (TRHC) Overview

Tabula Rasa HealthCare (TRHC) provides clinical solutions that enhance the safe and efficacious use of medications. These solutions empower healthcare professionals to optimize medication regimens in patients with polypharmacy. They also aid healthcare professionals in targeting and reducing medication-related risk (i.e., risk associated with adverse drug events). Healthcare professionals, both internal and external to TRHC, use TRHC's proprietary science-based technology to improve patient outcomes, reduce hospitalizations and emergency room visits, and lower total cost of care. TRHC also offers an extensive clinical telepharmacy network across the U.S. (comprised of seven clinical call centers and a network of over 18,000 local community pharmacies). Our solutions are trusted by health systems, health plans, provider groups, and pharmacies nationwide to help drive patient safety.

TRHC solutions support more than 100 million patients across the U.S. In 2020, through TRHC's 800 clinical providers and our expanding local community pharmacy network, TRHC completed over 400,000 individual, person-to-person Comprehensive Medication Reviews and Medication Safety Reviews™ and completed more than 4.7 million interventions to address medication-related problems that, if left unaddressed, could have contributed to deaths and increased utilization.

a. Mission/Vision

Our mission: To optimize the safe use of medications for people everywhere.

Our vision: To be the world's most trusted solution for the safe use of medications.

b. Precision Pharmacotherapy Research & Development Institute

TRHC's Precision Pharmacotherapy Research & Development Institute (PPRDI) is committed to the development of proprietary products, as well as their validation and recognition by the scientific and regulatory communities to optimize medication regimen to improve patient outcomes, reduce utilization of various healthcare services, lower healthcare costs, and manage risk. The PPRDI's research vision expands with the emerging research initiatives that include bioinformatics, biomedical engineering systems, nanoscale science, patient-specific information, data-driven technologies and solutions, and translational research. PPRDI faculty conduct research using pharmacokinetics and pharmacodynamics modelling, computer simulations, and computational modelling using healthcare data from large databanks. The overall objective of this research group is to maintain, update, and develop new products associated with medication risk mitigation and medication risk stratification. The PPRDI provides a unique opportunity for highly qualified individuals in pharmacokinetics, simulation and modelling, machine learning, and programming, as well as for candidates seeking non-conventional post-doctoral positions.





The goal of TRHC's PPRDI is to innovate and redefine the science of medication safety to optimize medication use. The institute's charter includes:

- Maintenance, update, and development of TRHC's current technology products (e.g., Matrix, Medication Risk Score)
- New products based on pharmacokinetics/pharmacodynamics/pharmacogenomics (PK/PD/PGx), including transporter and receptor genes
- Publications related to PK/PD/PGx science

- Research, such as drug-induced Long QT Syndrome, pharmacogenomics and phenoconversion, disease states and enzyme activity, peer-reviewed funded research, contract research organization funded initiatives

c. Relationships with National Professional Pharmacy Associations

- TRHC has developed key relationships with national associations that are dedicated to improving the quality and safe use of medications; the chart below briefly describes the joint activity

Association	TRHC Relationship
	Contracted for multi-faceted collaboration, including the exploration of opportunities to advance MedWise use in the Long-Term Care setting and, generally, among senior care pharmacists. ASCP is a licensed reseller of MedWise.
	Contracted for multi-faceted collaboration, including the exploration of the best settings of patient care for use of MedWise in hospitals. ASHP is a licensed reseller of MedWise.
	Evaluating introduction of the Certified MedWise Advisor credential into Pharmacy Profiles platform
	Collaborating to evaluate the use of MedWise among pharmacy school faculty and students in MedWise.

II. Description of Tool/Science

a. MedWise®

MedWise is our unique software platform that identifies accumulative multi-drug interactions to help manage patients' medication risk for adverse drug events. Our science-backed approach to medication safety focuses on reducing trial-and-error prescribing, assuring appropriate time of day administration to avoid the competitive inhibition type multi-drug interactions and making recommendations to prescribers to reduce adverse drug event risk.

MedWise:

- Serves as a clinical/medication decision support system, not only a drug-drug interaction software
- Enables clinicians to establish rational clinical judgements and associated action plans for patients with polypharmacy
- Analyzes multiple drugs concomitantly in a drug regimen
- Considers drug characteristics from literature search, NDA, and drug monograph

- Identifies pharmacokinetic and pharmacodynamic drug interactions
- Predicts drug interactions that have not been reported yet using specific drug characteristics:
- Provides a quantitative assessment of required dose adjustments
- Considers dose, time, and sequence of administration
- Analyzes inter- and intra-individual variables
- Enables rich pharmacogenomic (PGx) insights

A systematic approach to medications where each medication (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) is individually assessed to confirm that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended.

More about MedWise can be found at: https://www.carekinesis.com/wp-content/uploads/2016_Turgeon_Clinical_decision_support_systems.pdf

MedWise as an advanced clinical decision support system comprises the following functions and support tools:

- *The Medication Risk Mitigation Matrix™* considers pharmacokinetic (drug absorption, distribution, metabolism, excretion) and pharmacodynamic risks (mechanisms of action, effects).
- *The Wind Rose* evaluates potential events which may occur in a patient and which maps out the risk of each potential factor.
- *The Bullseye* that indicates a patient's highest risk areas based on individual risk factors considered to estimate the MedWise Risk Score™.

b. The MedWise Risk Score

Our MedWise technology calculates a MedWise Risk Score on a scale of 0 to 53. Patients with high-risk scores have higher overall healthcare costs and poor clinical outcomes. Risk scores will be used to prioritize Medication Safety Reviews. This proprietary MedWise Risk Score is a personalized indicator of potential adverse drug events based on individual risk factors and include: anticholinergic burden, sedative burden, competitive inhibition burden, and several other factors. TRHC's team of certified MedWise Advisor™ pharmacists manage medication safety and patient concordance (which is a critical factor to medication adherence) through a scientific approach that addresses each safety factor in detail. Typically, our recommendations decrease risk scores by four to six units, which can equate to \$4,000 to \$6,000 per year in avoided medical costs per patient.

c. Real-time Analytics

TRHC's medication risk identification and reduction technologies, including MedWise and RxCompanion™, maintain over 1,000 clinical algorithms that identify opportunities to improve medication safety, cost, and care gaps. Every time a patient receives a prescription or is supposed to receive a prescription for a chronic medication, their medication list is run against the clinical algorithm included in the program. Algorithms are developed using pre-clinical and clinical

information: drug biophysical characteristics, pharmacokinetics, pharmacodynamics, and pharmacogenetics (>150 factors considered).

d. Notable Publications

Clinical decision support systems

- Turgeon J, Michaud V. Clinical decision support systems: Great promises for better management of patients' drug therapy. *Expert Opinion on Drug Metabolism & Toxicology*. 2016 Mar 23;12(9):993-995. <https://doi.org/10.1517/17425255.2016.1171317>.

Medication risk stratification/risk scoring

- Cicali B, Michaud V, Knowlton C, Turgeon J. Application of a novel medication-related risk stratification strategy to a self-funded employer population. *Benefits Quarterly*. 2018;34:49-55. https://www.carekinesis.com/wp-content/uploads/2018/Cicali_B_Benefits_Q_Application_of_a_novel_medication-related_risk_stratification_strategy.pdf
- Bankes D, Jin H, Finnel S, Michaud V, Knowlton C, Turgeon J, Stein A. Association of a novel medication risk score with adverse drug events and other pertinent outcomes among participants of the Programs of All-Inclusive Care for the Elderly. *Pharmacy*. 2020 May 15;8(87). <https://doi.org/10.3390/pharmacy8020087>
- Ratigan AR, Michaud V, Turgeon J, Bikmetov R, Villarreal GG, Anderson HD, Pulver G, Pace WD. Longitudinal association of a medication risk score with mortality among ambulatory patients acquired through electronic health record data. *Journal of Patient Safety*. 2021. [Accepted for publishing]

III. Use of MedWise in Practice

a. Clients

Who we serve:

- Chain and community pharmacies
- Health insurers
- Health systems and hospitals
- Provider groups
- Employer groups

Payers and pharmacies:

- 100 million patients served
- More than 350 payers supported
- More than 18,000 community pharmacies supported
- More than 270 hospitals/health systems supported

PACE:

- 50,000 patients served
- More than 90 percent of PACE programs supported

b. Adoption

Full-service solution

In this model, clients entrust TRHC's board-certified pharmacists to provide their patients with Medication Safety Reviews through TRHC clinical call centers. TRHC's pharmacy serves the targeted, risk stratified population as a full-service solution.

Software as a Service

TRHC offers MedWise as a standalone software solution for healthcare organizations who are looking to enhance their medication management programs with advanced medication decision support. The software platform can also be implemented as a hybrid option, utilizing TRHC's clinical providers and clients' in-house providers, to coordinate care and support an efficient and effective medication management program.

Pharmacies adopt MedWise into their workflow setting to identify high-risk patients and use the medication decision support tools to mitigate risks.

Hybrid solution

In a hybrid solution, clients use MedWise to identify patients at high risk for medication-related problems leading to adverse drug events. Clients refer patients to TRHC's MedWise-certified pharmacists, who facilitate interventions and provide recommendations for risk mitigation.

Pharmacies that use a hybrid solution adopt MedWise into their workflow setting to identify high-risk patients and refer them to TRHC's MedWise-certified pharmacists.

c. Professional Collaboration

TRHC collaborates with clients to ensure patient safety. TRHC works with patients' healthcare teams, including doctors and nurses, to optimize patient medication regimens.

After Medication Safety Reviews, patients' prescribers receive faxed action plans with recommendations to optimize patient medication regimens.

d. Legislation

Medicaid Medication Risk Reduction Model

In New Jersey, legislation is advancing that would require State Medicaid to contract with a third-party entity to apply a risk reduction model to medications. The bill (Senate No. 887) has passed the State Senate and awaiting final action in the General Assembly. New Jersey Governor Murphy indicated his support for the measure in his FY2022 Budget-in-Brief book.

Purpose: Establish a medication risk reduction model that leverages the clinical expertise of pharmacists to reduce cost by:

- Identifying simultaneous, multi-drug medication-related risk
- Leveraging pharmacokinetic and pharmacodynamic sciences
- Coordinating with local community pharmacies
- Reducing adverse drug events
- Enhancing quality of care and improve health-related outcomes
- Reducing total cost of care

IV. Recommendations

a. Secure an Integral and Reimbursed Role of Pharmacists as the Medication Expert on the Healthcare Team

In all medication risk identification and reduction programs, whether they be traditional Medication Therapy Management, Comprehensive Medication Management, or more innovative outcome-focused models (like MedWise programs) require the inclusion of pharmacist on the healthcare team.¹ Pharmacists have acquired specific knowledge making them uniquely able to use advanced clinical decision support systems (CDSS) to analyze pharmacokinetic and pharmacodynamic drug properties, multi-drug interactions, pharmacogenetics, efficacy, and toxicity of each active drug ingredient to improve overall regimen safety. Therefore, pharmacists are often the best prepared member of the healthcare team to provide these services. Further, to ensure the fully-engaged involvement of pharmacists, appropriate levels of reimbursement must be attached to the clinical services they provide.

b. Support Continued Research Related to Medication Safety

Continued research is critical to ensure continuous quality improvement in the approach to medication safety.

Pharmacogenomics (PGx) is an area that needs specific research focus and investment. There is a great need to adopt systematic inclusion and approaches to the use of PGx information in medication safety evaluation, especially for patients with polypharmacy. Use of PGx in the context of acute care for patients with a limited number of diseases and limited number of drugs is of value and easier to manage. Such programs have been implemented in academic centers and hospital settings with success; for instance, identification of somatic mutations in patients with cancer to guide drug selection. The value of PGx in patients with multiple chronic diseases and polypharmacy requires the development of much greater inter-connectivity between different healthcare systems and providers to obtain and transfer the information. Especially, it requires much advanced knowledge and detailed consideration of various factors prior to making a valuable clinical recommendation.

c. Advocate for Comprehensive Medication Safety Studies in Drug Discovery and Discovery and Development Process

Comprehensive data on metabolism and transport of medications is inconsistently available on drug package inserts. Information about metabolism and transport impacts patient safety, particularly when patients are on multiple medications. This data can be obtained in Phase I studies utilizing simulation and/or *in-vitro* methods. AHRQ should support a requirement for inclusion of complete metabolism and transport studies for all new drugs and this information should be provided to the Food and Drug Administration (FDA) as part of New Drug Applications (NDA) and included on all drug package inserts.

¹ McInnis T, Webb E, and Strand L. The patient-centered medical home: Integrating comprehensive medication management to optimize patient outcomes, patient centered primary care collaborative. June 2012. Available at <https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>

d. Advocate for Legislation to Support Medication Safety as a Primary Goal

States should consider adding a Medication Risk Reduction Model to enhance their Medicaid Drug Utilization Review (DUR) program and/or Medicaid MTM program to bend the cost curve associated with health care costs associated with ADEs.

Pharmacist prospective DUR process should include enhanced clinical decision support tools that go beyond a one-to-one drug interaction and provide a simultaneous multi-drug analysis and a risk score that assesses a patient potential risk for ADEs. This would allow the pharmacist to efficiently and effectively identify and prevent potential adverse drug events. Proper alignment of payment for this service needs to be aligned by the state to recognize this clinical service at the pharmacy and allow for designated pharmacy staff to provide medication safety reviews. This DUR process should include patient use of vitamins, dietary supplements, natural products, and over the counter products

Prescription Drug Monitoring programs are limited in scope as they do not fully identify patients at risk for adverse drug events related to opioid use. PDMPs should include a risk score assessment that identifies a patient risk for an ADE associated with the combination of medications that interact with the opioid medication.

States that have legalized marijuana should consider policies that raise awareness of how marijuana use can interact with a patient medication regimen and cause harm/ADEs, especially for Medicaid populations.



ALLIANCE FOR PATIENT MEDICATION SAFETY

2530 Professional Road Suite 200 North Chesterfield, VA 23235

Phone: (804) 285-4431 | Fax (804) 612-6555 | www.medicationsafety.org

April 5, 2021

Agency for Healthcare Research and Quality
Center for Quality Improvement and Patient Safety
Patient Safety Organization Division
5600 Fishers Lane
Rockville, Maryland, 20857

Transmitted via Email: PSQIA.RC@ahrq.hhs.gov

RE: The Alliance for Patient Medication Safety's comments on AHRQ's draft report "Strategies to Improve Patient Safety: Draft Report to Congress and Review by the National Academy of Medicine".

Dear AHRQ,

The Alliance for Patient Medication Safety (APMS), a listed Patient Safety Organization (PSO) since 2008, values the opportunity to review and comment on the draft report, "Strategies to Improve Patient Safety: Draft Report to Congress and Review by the National Academy of Medicine".

This report provides information on the landmark Patient Safety and Quality Improvement Act of 2005 and some of the subsequent activities that AHRQ and PSOs have achieved to support patient safety and quality improvement work across the country and identifies additional strategies and improvements that are needed to continue the patient safety progress journey in the future.

The privilege and confidentiality protections afforded by the Patient Safety Act have increased voluntary reporting as well as 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. PSO's have developed innovative strategies such as "safe tables" and created ways to encourage and share safe practices utilizing the Patient Safety Act protections that could be highlighted in the report.

The APMS PSO, a 501 c 3 organization, contracts with community pharmacy practice sites across the country to help them continue to build and improve their medication-safety continuous quality improvement programs. Our funding comes from fees that are generated by contracts with our client pharmacies. The pharmacies track their patient safety metrics on a PSO developed dashboard; one that provides them a variety of visual tools, charts, and graphs. We provide education, guidance, and feedback to our clients on how to utilize their information to build robust learning-cultures and transform lessons learned into corrective actions and strategies that result in safer care. Medication Safety tips, continuing education, and medication safety articles are created and shared via social media and/or distributed to the pharmacy community.

We appreciate the opportunity to provide comments on this important report. We look forward to continuing to work with the dedicated AHRQ PSO staff and with our community pharmacies to improve medication safety and patient care.

Respectfully submitted,

Tamarie Modisett
Executive Director
Alliance for Patient Medication Safety PSO



April 5, 2021

Transmitted Electronically: PSQIA.RC@ahrq.hhs.gov

Agency for Healthcare Research and Quality
Patient Safety Organization Division
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
5600 Fishers Lane, Mailstop 06N100B
Rockville, Maryland 20857

RE: The Alliance for Quality Improvement and Patient Safety (AQIPS) Additional Comments on AHRQ's draft Report "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine". Docket No. AHRQ_FRDOC_0001_0853 (Extended Comment period ends April 5, 2021)

Dear AHRQ:

The Alliance for Quality Improvement and Patient Safety (AQIPS)¹ appreciates AHRQ extending the comment period and providing additional opportunity for PSOs to submit comments on the draft Agency for Healthcare Research and Quality (AHRQ) report entitled "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine." Many of AQIPS members are providing their own comments on this report. Additional examples of innovative strategies developed by PSOs and healthcare providers to improve patient safety and the quality of patient care using the protections of the Patient Safety and Quality Improvement Act of 2005² (Patient Safety Act, commonly referred to as the National Peer Protections) are attached in a paper entitled "Frameworks for Providing Feedback on Interfacility/Interoperability Patient Safety Information to Improve the Reliability of Patient Care." The frameworks discussed in the paper are examples of how PSOs/healthcare providers address harm from a coordinated care perspective following the patient throughout their journey through the healthcare system.

As discussed in Congressional hearings for the Patient Safety Act, PSO were established as the National Transportation Standards Board (NTSB) for healthcare. Unlike aviation, the system of healthcare is varied, complex and multi-faceted as there

¹ AQIPS is the premier non-profit, national professional association composed of over 50 Patient Safety Organizations (PSOs) and their participating providers throughout the healthcare continuum and throughout the United States. AQIPS mission is to foster the ability of PSOs to improve the delivery of patient care through the privilege and confidentiality protections afforded in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, et seq.

² 42 U.S.C. § 299b-21 et seq.

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 aircraft with very little decision-making beyond the operations manual. Congress gave PSOs broad protections to create systems that collect a variety of quality information and allow broad investigation as well as safety communication to occur among and between healthcare providers for the purpose of improving the delivery of patient care. ("To encourage provider reporting of sensitive patient safety information, Congress saw a need for strong privilege and confidentiality provisions that continue to apply downstream even after disclosure..." See 73 Fed. Reg. 70787). Sensitive patient safety information used to improve the quality of patient care would not be developed if that information could be used to harm healthcare providers and patients. To illustrate by example, making public numbers of incident reports is deceiving to patients because high reliability systems – those healthcare providers who foster a strong safety and learning culture and who encourage incident reporting - will have more events to analyze and evaluate to achieve consistent high-quality care. Hospitals with a weaker safety culture will have a lower number of events not because events are not occurring, but because these incidents are not being reported and likely will not be reported even if reporting is mandatory. As a result, health care 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. 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. Indeed, the more incident reports that are collected, the more learning can be accomplished and a higher quality of care can be achieved. As illustrated in AQIPS comments, PSOs and healthcare providers have created many innovative programs that improve the quality of patient care delivery. In addition, during the past decade, PSOs have created extensive distribution systems for learnings developed by PSOs and healthcare providers to reach and be implemented by other providers to raise the reliability of care throughout the healthcare system.

The PSO community is excited to continue work in a public-private partnership with the AHRQ PSO program. Please let me know should you have any questions or require additional information, please contact me at

[REDACTED]

Sincerely yours,

Peggy Binzer

Executive Director
Alliance for Quality Improvement and
Patient Safety

Frameworks for Providing Feedback on Interfacility/Interoperability Patient Safety Information to Improve the Reliability of Patient Care

Joe Schneider M.D., Susan Saik, M.D., Lisa Mead, RN, Shelley Boden, RN, Barbara Pon, and Peggy Binzer, J.D.

Confidential sharing of interfacility patient safety information and best practices is becoming increasingly expected. Protected interfacility communications are more imperative as the healthcare community prepares for potential unintended consequences of electronic health record (EHR) interoperability. Incorrect medical information created or introduced at one facility may cause confusion or patient harm in other facilities as the patient and their medical information make their journey through multiple healthcare organizations. The healthcare community has been developing several methods for healthcare professionals to confidentially share and address interfacility patient safety events as well as prepare for the unintended consequences of EHR interoperability using the Patient Safety and Quality Improvement Act of 2005 privilege and confidentiality protections (hereinafter “National Peer Protections”).ⁱ National Peer Protections permit protected sharing of quality and clinical performance information among unaffiliated licensed healthcare professionals and facilities, ancillary clinicians and those individuals otherwise authorized under state law to provide healthcare servicesⁱⁱ to implement protected safety culture and to create a continuous learning system for the benefit of patients.

This paper identifies several examples of interfacility/interoperability events and protected frameworks that healthcare professionals have successfully implemented to create interoperability of quality and clinical improvement information to provide feedback on clinician performance, share learnings with other healthcare professionals, facilitate full disclosure to the patient and continuously improve the quality of care across the care continuum. This article is not advocating for new law to be created to address the lack of communication about interfacility information among healthcare providers but discusses how current law can be used to reduce the barriers that prevents the sharing of such information for the benefit of patients.

Reimagining Interoperability of Patient Safety Information Across the Healthcare Continuum

Interfacility/interoperability patient safety information (IPSI) may relate to system processes and workflows, quality improvement, performance improvement, or providing feedback to healthcare professionals across organizations. IPSI may include:

- Patient safety events³ that occur repeatedly at different facilities with no coordinated response among the healthcare organizations and clinicians to readdress the underlying problem(s);

³ A Patient Safety Event, as defined in a footnote in the preamble to the Department of Health and Human Services (HHS) proposed rules on Patient Safety and Quality Improvement,³ means an incident that occurred during the delivery of a health care service and that harmed, or could have resulted in harm to, a patient. A patient safety event may include an error of omission or commission, mistake or malfunction in patient care processes; it may also involve an input to such processes (such as a drug or device) or the environment in which such process occurs. The term patient safety event is used in place of the more limited concept of medical error to describe the work that organizations and clinicians and Patient Safety Organizations may undertake, reflects the evolution in the field of patient safety. It is increasingly recognized that important insights can be derived from the study of patient care processes

- Sharing best practices, clinical protocols and other practice information that improve the delivery of patient care or minimize patient harm, such as synchronizing alerts and order sets across competitive hospitals in a city where clinicians see inpatients in more than one hospital system;
- A patient safety event discovered by a clinician providing care in a subsequent healthcare facility when the event originated in a previous facility and the ultimate patient harm, if any, is not known to previous clinicians who cared for the patient, including a diagnosis of a condition that was missed at one facility and was correctly identified at a subsequent facility;
- Evaluating transfers from one healthcare organization to another. Healthcare facilities that transfer patients can conduct a gap analysis and evaluating systems failures among facilities that frequently transfer patients proactively to mitigate the risk of care going wrong.
- Monitoring patient outcomes across healthcare organizations. In some cases, after a patient safety event occurs and is addressed by a healthcare organization, that organization may need to follow the patient through the healthcare continuum to monitor the effectiveness of their response and the patient's outcome. Following a patient's outcome with complete care and outcome

and their organizational context and environment in order to prevent harm from patients. This term also encompasses the safety of a person who is a subject in a research study conducted by a health care provider. In addition, the flexible concept of a patient safety event is applicable in any setting in which health care is delivered: A health care facility that is mobile (e.g., ambulance), fixed and free standing (e.g., hospital), attached to another entity (e.g., school clinic), as well as the patient's home or workplace,

information can give organizations much-improved insights into improving the delivery of care.

- System evaluations. Oftentimes a surgical center, emergency department or other clinical setting may have better outcomes than other similar departments, either within the same organization or across organizations. Analyses to determine the differences between the systems that are responsible for the better outcomes can be instrumental to improving surgical checklists and other process improvements.

IPSI includes digital activities that contribute to patient safety events. For example, when incorrect information (e.g., wrong patient matching or data entry errors) created or introduced in one facility is discovered or causes patient harm in another facility as a patient makes their journey throughout the healthcare continuum, a mechanism for sending corrections to the organization where the event occurred and for that organization to act on them needs to be facilitated. Unintended consequences of the limited interoperability that currently occurs have been realized in electronic medical records (EMRs) and health information exchanges (HIEs). As interoperability is being adopted on a nationwide scale and patient information will be moving among multiple clinicians and organizations, the unintended consequences will be more difficult to correct and the risk of patient harm will increase.

Without the use of the National Peer Protections, patient safety events and best practices are typically carefully guarded within a healthcare facility. IPSI is rarely shared outside of an organization or discussed in practice without privilege and confidentiality protections. Current barriers to sharing include legal, administrative, cultural, and

practical obstacles. Indeed, the National Peer Protections were established to remove long-recognized impediments to implementing safety culture “to accelerate the development of new, voluntary provider-driven opportunities for improvement.”ⁱⁱⁱ The National Peer Protections increase the ability of health care clinicians and organizations to share quality and clinical information peer-to-peer to learn for the benefit of patients. Indeed, according to a recent Office of the Inspector General (OIG) investigation 99.3% of acute care hospitals find the National Peer Protections important.^{iv}

The National Peer Privilege and Confidentiality Protections Advance the Sharing of Interfacility/Interoperability Patient Safety Information

Healthcare professionals are on the front line of sharing IPSI. The national peer privilege is not limited to data concerning patient safety events, indeed, the national protections extend to clinical causal analysis, peer collaborations, clinical audits and any other effort to improve healthcare delivery. The National Peer Protections “enable health care organizations and clinicians to protect their internal deliberations and analysis of patient safety information.”^v Therefore, healthcare professionals are also sharing how to overcome barriers to improving the quality of patient care. Many healthcare facilities have successfully addressed interfacility patient safety events using the national peer privilege. Toward this end, below are innovative frameworks for sharing interfacility information implemented by healthcare professionals using the national peer privilege.

Protected Peer-to-Peer Safety Culture (Confidential Communications among Healthcare Professionals):

The National Peer privilege and confidentiality protections permit healthcare facilities or clinicians to confidentially disclose information to other organizations and clinicians to improve patient safety and the quality of healthcare delivery. The protections empower clinicians to contact their peers to share outcomes, discuss potential missed diagnosis, inquire whether their patients are experiencing certain adverse events and/or to share clinical interventions. In other words, health care professionals can use protected internal and external transparency to share clinical information in a protected safety culture without fear of liability or professional reputational harm.

Safe-Tables are another example of how organizations and clinicians facilitate peer-to-peer learning in a confidential environment. Providers use Safe-Tables to bring together healthcare professionals—either in person or using a virtual platform—to candidly discuss efforts to improve the quality of healthcare delivery, share interventions and collaborate on solutions.^{vi}

Another tool that healthcare systems have employed are "Interfacility Event Committees". Such committees engage in protected conversations about patient safety events that may occur throughout a health system so a coordinated approach can be taken to resolve the problems. Such a centralized approach allows proactive action to be taken to prevent similar events from occurring throughout the health system rather than each hospital working on similar events separately. The National Peer Protections allow health

systems to share information across state lines, which is not permitted under state peer review laws.

Similar to interfacility event committees are “Service-Line Safe Collaboratives”. Service Line Safe Collaboratives convene all members of a service line together to discuss clinical performance, including technical skills, clinical quality improvement and excellence. Similar to safe collaboratives, clinical performance audits are another activity that can be performed under the national peer privilege. In many health systems medical directors cannot review records of their service-line staff and evaluate their clinical performance because of the limitations of state peer protections. Under the National Peer Protections, medical directors can audit their clinicians’ performance to maximize the reliability of patient care.

National Improvement Healthcare Collaboratives are not new but the National Peer Protections permit unaffiliated healthcare organizations and universities to share information that otherwise would not be shared because of fear of harm to the healthcare facilities.

PSO Feedback to Individual Clinicians/Organizations

The goal of a Patient Safety Organization (PSO) is to foster the ability of healthcare professionals to improve the delivery of patient care and patient outcomes by sharing information through a “safety culture” and to ensure accountability by raising standards

for continuous quality improvement in healthcare. Today, over half (59%) of acute care hospitals are members of PSOs. Nearly all hospitals (97%) find working with a PSO to be valuable to prevent patient harm and save lives.⁸ These hospitals found peer-to-peer learning to be very valuable and PSO feedback and analysis made a measurable improvement in their patient care.

With respect to sharing IPSI, if the healthcare professionals are members of a PSO, the clinicians can work with the PSO to close the loop among them to develop protocols to prevent future harm. To illustrate by example, healthcare organizations and clinicians have reached out to PSOs to address diagnostic errors or delay of treatment. With respect to missed diagnosis, a doctor notified a PSO of a missed diagnosis by a previous clinician that was reported to the doctor by his patient. The PSO contacted the clinician and the clinician's facility to provide feedback concerning the missed diagnosis and worked with both hospitals to develop clinical protocols that would prevent future similar patient safety events. Regarding delayed treatment, patient harm can occur years after the original contribution by the initial treating physician and the subsequent organizations and clinicians may not think to close the loop and make the information about the patient's outcome known to those original caregivers. Using the National Peer Protections, the causal analysis and changes to clinical processes can be shared with appropriate health care professionals to ensure patient care is more reliable. Without the national privilege and confidentiality protections, knowledge of interfacility information through peer-to-peer learning that would not otherwise be available to healthcare professionals throughout the healthcare continuum.

Importantly, the National Peer Protections do not hide poor performance. The process includes learning and reeducation so that the learning is prospective and patient harm can be prevented. However, when there is reckless behavior, the protected information can be used by the provider for any purpose including in credentialing, disciplinary action, and peer review.^{vii} Therefore, the National Peer Protections can be used to root out those who may need education or, if necessary, disciplinary action under principles of “Just Culture.”

Patient Disclosure

The PSO community supports the disclosure of a serious error to a patient with an explanation as to why the error occurred, how the error's effects will be minimized and the steps the physician (and organization) will take to prevent recurrences.

To this end, the greater information, investigation and analysis conducted under the National Peer Protections means that not only can more robust information be shared with the patient, but also greater resolution to prevent the same patient harm from being repeated across the healthcare system. Additionally, the PSO community encourages patient representatives to be included in the causal evaluation process (e.g., root cause analysis) under the National Peer Protections. Therefore, the protections can include greater patient engagement than would occur without the protections.

Conclusion

The National Peer Protections were established to permit healthcare professionals to candidly discuss, develop, and share information to evaluate efforts to improve the quality of healthcare delivery in a protected safety culture. This evaluation system permits interoperability of improved quality and clinical practice information throughout the healthcare continuum. The evaluation system supports self-improvement programs that reinforce professionalism for the benefit of patients.^{viii} Through the use of the National Peer Protections, healthcare professionals are modernizing the patient safety movement through peer-to-peer collaboration to improve the delivery of care. The National Peer Protections break the silos of patient safety information, break the silence of clinicians who may have knowledge of a potential harm, and thereby continuously improve the reliability of healthcare delivery for the benefit of patients.

ⁱ The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21, et seq. (PSQIA)

ⁱⁱ 42 U.S.C 299b-21(8)(Provider)

ⁱⁱⁱ Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8114 (Feb 12, 2008)

^{iv} OIG Report Patient Safety Organizations: Hospital Participation, Value, and Challenges 11 OEI-01-17-00420

^v 42 U.S.C. 299b-21(7)(A)(ii); Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8113 (Feb. 12, 2008)

^{vi} Safe-tables are committee meetings that occur within the providers or PSOs Patient Safety Evaluation System.

^{vii} The PSQIA does not limit uses of privileged information by a provider. Patient Safety and Quality Improvement, Final Rule, 73 Fed. Reg. 70732, 70779 (Nov. 21, 2008).

^{viii} The National peer privilege supports self-regulatory, self-improvement programs that encourage innovation in improving patient safety and quality of patient care delivery. The program is not funded nor controlled by the Federal Government. Patient Safety and Quality Improvement, Proposed Rule, 73 Fed. Reg. 8114 (Feb. 12, 2008). OIG report on Patient Safety Organizations at 11.

February 16, 2021

Transmitted Electronically: PSQIA.RC@ahrq.hhs.gov

Agency for Healthcare Research and Quality
Patient Safety Organization Division
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
5600 Fishers Lane, Mailstop 06N100B
Rockville, Maryland 20857

RE: The Alliance for Quality Improvement and Patient Safety (AQIPS) Comments on AHRQ's draft Report "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine". Docket No. AHRQ_FRDOC_0001_0853 (Comment period ends February 16, 2021)

Dear AHRQ:

The Alliance for Quality Improvement and Patient Safety (AQIPS)¹ appreciates the opportunity to comment on the draft Agency for Healthcare Research and Quality (AHRQ) report entitled "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine." AQIPS applauds AHRQ's leadership in its strategies for improving the quality of patient care, including its nationwide Patient Safety Organization (PSO) collaborative to collect and learn from information surrounding COVID-19 patient safety and quality related events² and its encouragement of the PSO community to develop innovative strategies to improve patient safety.³ AQIPS comments to this report:

- Highlight examples of innovative strategies developed by PSOs and healthcare providers to improve patient safety and the delivery of patient care using the protections (commonly referred to as the National peer protections) of the Patient Safety and Quality Improvement Act of 2005⁴ (Patient Safety Act); and

¹ AQIPS is the premier non-profit, national professional association composed of over 50 Patient Safety Organizations (PSOs) and their participating providers throughout the healthcare continuum and throughout the United States. AQIPS mission is to foster the ability of PSOs to improve the delivery of patient care through the privilege and confidentiality protections afforded in the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, et seq.

² AHRQ PSO Meeting 2019.

³ The scope of the PSO program is to improve patient safety and the quality of the delivery of patient care (42 U.S.C. §299b-21(5)(A)).

⁴ 42 U.S.C. § 299b-21 et seq.

- Propose national strategies as a collaborative public-private partnership with AHRQ to use the National Patient Safety Database (NPSD) to reduce medical errors and encourage a culture of safety.

PSOs Create Innovative Strategies to Reduce Medical Errors and Improve Patient Safety

PSOs are a voluntary private sector self-improvement innovation program for all healthcare providers and all healthcare settings. PSOs host a variety of programs to meet the needs of their healthcare community. “The Patient Safety and Quality Improvement Act is flexible ‘to accelerate the development of new, voluntary provider-driven opportunities for improvement’ and to ‘set the stage for breakthroughs in our understanding of how best to improve patient safety.’⁵ As correctly noted in the AHRQ report, PSOs are bringing robust quality improvement and peer review programs to specialties, settings and modes of health care that traditionally faced high barriers to implementing such programs.⁶ AQIPS concurs with AHRQ’s report that “[t]he 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.”⁷ PSOs and healthcare providers are using quality information between facilities and providers following patients throughout the healthcare system to improve the coordination and quality of patient care. Healthcare providers are also disclosing and deliberating upon protected information with their colleagues through the provider-to-provider disclosure permission⁸ to create a culture of safety and learning. Congress designed the National peer protections to break the silos that had been created due to the erosion of state peer review laws, and thereby create a national system of sharing and learning with the goal of improving the quality and safety of patient care for the benefit of patients. The National peer protections have proven to be successful.

Healthcare providers and facilities, such as hospitals, who work with PSOs are high performing healthcare providers and systems, which aim to provide the highest quality healthcare in the nation. The providers who work with PSOs use the National peer protections to implement continuous quality improvement and coordinate care throughout the healthcare continuum. In an evaluation of the effectiveness of PSO strategies, the majority of hospitals reported that PSOs are effective in improving safety culture and preventing medical errors.⁹

PSOs make substantial financial investments to operate and staff their patient safety initiatives and strategies. According to one PSO, a peer review program costs approximately \$800,000/year to operate. PSOs receive no money from the government to collect and analyze data or produce quality improvement innovation. For many PSOs,

⁵ Patient Safety and Quality Improvement Proposed Rule, 73 Fed. Reg. 8112, 8113 (Feb 12, 2008).

⁶ Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine, AHRQ (Feb. 2021) at 7.

⁷ *Id.* at iii.

⁸ 42 C.F.R. § 3.206(4)(i).

⁹ OIG Report “Patient Safety Organization: Hospital Participation, Value, and Challenges” OEI-01-17-00420, Sept. 2019.

the data collected and work product produced is their primary revenue stream. Hospitals also make considerable investments in their quality improvement strategies using the National peer protections.

Moreover, PSOs, hospitals, medical groups, physician management companies and other healthcare entities have experienced significant financial losses in 2020. Two studies report that hospitals alone have lost \$323.1 billion through the end of 2020.¹⁰ These financial losses and struggles to reopen the healthcare system will continue into 2021 and beyond. Given that many patients have decided not to seek medical care during COVID-19 shut-down and postponed elective medical procedures, patient safety events reports have subsided. As reported in the press, the healthcare community is bracing for undiagnosed conditions and delayed treatment of others once patients elect to obtain medical care. Hence, financial and other stressors on the healthcare system and PSO community adds to the challenges to reporting to the NPSD.

PSOs Develop Effective Evidence Based Strategies Based on the IOM Report *To Err is Human: Building a Safer Health System* (1990) Recommendation to Adopt Strategies from Other Complex High-Risk Industries.¹¹

The PSO community and healthcare providers who work with them implemented the IOM's recommendation to adopt strategies from other complex high risk industries, including aviation and nuclear energy.¹² The National peer protections are spurring collaboration to improve healthcare delivery throughout the healthcare continuum. AQIPS member PSOs have focused on several strategies, including the following, to accelerate learning and improvement.

1. Protected Safety Culture Strategies

Healthcare providers use the National peer protections to foster safety culture, which is unrestrained communication among healthcare providers about safety and quality.¹³ Improving the culture of safety within healthcare is an essential component to preventing and reducing medical events and improving overall healthcare.¹⁴ High risk industries, such as aviation and nuclear power, adopt a culture of safety to encourage communication about safety to move toward becoming high-reliability organizations. The National peer protections addressed long-recognized barriers that prevent physicians and other providers from sharing and reviewing others care by providing confidentiality protections for the identifiable conversations, information and analysis for the benefit of patients.

¹⁰ Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVID-19 (June 2020).

¹¹ See 73 Fed. Reg. 8113. See S. Rep. No. 108-196, at 2.

¹² 73 Fed. Reg. 8113 (February 12, 2008) citing Institute of Medicine, *To Err is Human: Building a Safer Health System*, 1999 at 75.

¹³ Safety Culture is defined, in pertinent part, as communication and collaboration across rank and disciplines to seek solutions to patient safety problems. Culture of Safety Primer (Sept. 2019). PSNET/ahrq.gov/primer/culture-safety.

¹⁴ *Id.*

Congress wanted physicians, not only within a hospital, but also outside of the hospital's narrow confines, e.g., throughout the country, to be able to freely communicate on matters involving patient safety and quality improvement following a serious medical event.¹⁵ Hence, the National peer protections were created to provide protections to promote "a learning environment ... to move beyond the existing culture of blame and punishment ... to a 'culture of safety' that focuses on ... the prevention of future medical errors," to improve patient safety outcomes."¹⁶

PSOs encourage physicians and other healthcare providers to disclose protected quality information (known as Patient Safety Work Product (PSWP)) to other physicians and medical groups outside of their facility using the disclosure permissions of the Patient Safety Act¹⁷ to learn how to prevent patient harm, to determine whether a problem is occurring throughout healthcare or to review care to improve performance. Physicians learn from each other through stories; including case studies about how harm occurred, how to improve practice and how to adopt successes and implement new protocols. "If we can't talk about these mistakes, how can we change things, make them better?"¹⁸ Sharing information among hospitals, medical groups and physicians in this manner has never been done before because of the lack of protections. PSOs are the only means to permit health care providers to investigate how they are providing patient care and how they can do a better job without fear of litigation or harm to professional reputation. Many quality and safety programs look only at the *what*, whereas a PSO can help health care professionals figure out the *how*, in an environment that reinforces professionalism and learning, to the benefit of patients. Therefore, PSOs encourage what is really needed in healthcare; that is, a learning culture where where real-world learning is protected to enable practical solutions to be shared and implemented at the bedside for the benefit of patients. Indeed, healthcare providers who participate in PSO programs not only operate a "learning health system" but also participate in a "learning healthcare continuum" by making quality information interoperable throughout the healthcare continuum.

High risk industries also implement "just culture." The Patient Safety Act mandates provider protection from blame for the fact of reporting a patient safety or quality related event and confidential reporting to create just culture.¹⁹ Just culture establishes a blame free environment where individuals are able to report errors or near misses without fear of reprimand or punishment for the fact of reporting.²⁰ Implementing safety culture, just culture and learning culture results in greater information reported to hospitals and other provider facilities and to

¹⁵ See 73 Fed. Reg. 8113. See S. Rep. No. 108-196, at 2.

¹⁶ S. Rep. No. 108-196, at 3.

¹⁷ Provider-to-Provider disclosure, 42 C.F.R. §3.206(4)(i).

¹⁸ Quote from Martin Markey, M.D., "Too often, the Health-care system silences people around a problem. CNBC.com, Feb. 22, 2018.

¹⁹ 42 U.S.C. §299b-22(e).

²⁰ Culture of Safety Primer (Sept 2019). AHRQ Patient Safety Network. www.psnet.ahrq.gov/primer/culture-safety.

PSOs. Therefore, high performing hospitals that provide the highest quality of patient care may have the most patient safety and quality related event reports in their learning systems. Healthcare is bloated with data about patient care, but are starved for wisdom on how to use that data to improve the quality of patient care. PSOs, researchers and AHRQ provide that wisdom.

The National peer protected learning system provides greater accountability for healthcare professionals under “Just Culture,” because such professionals are accountable for quality, systems and performance improvement. Reckless care and intentional harm can be identified in Nationally peer protected PSWP/peer review and used in disciplinary actions to root-out substandard care; and thereby, fostering continued quality improvement of healthcare delivery.²¹

Peer-to-Peer Innovative Collaboration Strategies

Healthcare researchers have called for self-improvement programs focusing on prospective peer-to-peer collaboration following nuclear safety programs.²² Healthcare providers have embraced collaborative improvement strategies. To illustrate by example, one exceedingly successful strategy is for large hospitals with strong quality programs to review the improvement systems of small and rural hospitals to improve quality improvement processes. Similarly, some PSO programs focus on professionals reviewing other professionals clinical work or root cause analysis for improvement purposes. Peer review strategies by unaffiliated providers are proven effective to improve reliability in procedures, to identify quality and technical errors and to share highly successful treatment protocols.

PSOs and healthcare providers have borrowed from the aviation industry the practice of conducting confidential meetings - PSOs and providers call safe-tables - to communicate information, conduct joint peer review, as well as to develop solutions and best practices to solve interfacility events. The OIG in its report stated that hospitals found communication strategies like safe-tables very valuable and that such strategies improve culture and reduce patient harm.²³

One of the main conclusions of the IOM report was that the majority of medical errors do not result from individual recklessness or the actions of a particular group rather, most errors are caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent adverse events.²⁴ The National peer protections and patient safety activities were designed to focus on improving systems, action and accountability. PSOs are encouraging providers

²¹ Patient Safety and Quality Improvement, Final Rule, 73 Fed. Reg. at 70779.

²² P. Pronovost, “Improving healthcare quality through organizational peer-to-peer assessment: lessons from the nuclear power industry.” *BMJ Qual Saf.*, 2012 Oct. 21(10). 872-875.

²³ OIG Report “Patient Safety Organization: Hospital Participation, Value, and Challenges” OEI-01-17-00420, Sept. 2019 at 11.

²⁴ Institute of Medicine. “*To Err is Human: Building a Safer Health System*” 1999. At 49 -66 (see Patient Safety and Quality Improvement, 73 Fed. Reg. 8112, 8113 (February 12, 2008).

to implement approaches like Root Cause Analysis and Action²⁵ using the National PSO protections to improve the systems of care.

PSOs are creating innovative programs using information and communication that would not otherwise be collected or transferred without the National peer protections for the benefit of patients. Successful communication strategies, including safe-tables and peer-to-peer review programs, occur because of the National peer protections. The protections lower barriers to quality improvement and thereby save lives.

Strategies with PSOs, AHRQ, Patient Safety Experts and Researchers to Improve Patient Safety and the Quality of Healthcare Delivery as a Public-Private Partnership

The AHRQ PSO program is a public-private partnership. PSOs share innovative programs, data analysis results, and quality improvement success with AHRQ at the annual AHRQ PSO meeting and data through voluntary reporting to the NPSD. We applaud AHRQ and the reporting PSOs for making the NPSD operational. When there is a plane crash in the U.S., the tragedy often yields important lessons for the aviation industry. The industry hosts confidential meetings with pilots, experts, and government representatives who have no regulatory responsibilities to discuss how to improve aviation safety in a blame-free environment. The medical community hosts similar meetings referred to as “safe-tables” so that the same preventable mistakes are not made over and over again in different facilities in the healthcare system. Most PSO conduct evidence based safe-tables using experts in the field of medicine, researchers, and exhaustive literature searches. Under the Patient Safety Act, PSOs do not simply collect data; PSOs and providers have a duty to solve problems and ensure the solutions are effective.²⁶ Many PSOs make their findings available to the entire healthcare community.²⁷ Because of this excellent patient safety work, AQIPS would like to propose several public-private partnership patient safety strategies with AHRQ PSO Program, including National Safe-Tables and Safety Culture Surveys.

National Safe-Tables

AHRQ has made the NPSD operational. Therefore, the data contained within the NPSD is ample to gain a better understanding of how to improve the delivery of patient care. Moreover, PSOs and healthcare providers have analyzed, reviewed the evidence, created evidence-based solutions, shared these solutions with providers, and, in some case, monitored implementation and assessed their efficacy in solving the problems.

²⁵ RCA² type approaches were discussed in Congressional Hearings during the development of the Patient Safety and Quality Improvement Act in 2003 and 2005. The PSO's Patient Safety Activities were designed to focus on action and accountability (see 42 U.S.C § 299b-21(5)(D)).

²⁶ See 299b-21(5) Patient Safety Activities

²⁷ www.ECRI.org; www.rmfi.harvard.edu/About-CRICO/Our-Community/AMC-PSO-home-page/AMCPSO-newsletters.

Therefore, it makes sense for AHRQ and the PSO community to come together in a safe-table to discuss evidence-based solutions and adopt standards for the healthcare community. Toward this end, AQIPS PSOs have created a committee to develop National Safe Tables to facilitate this public-private partnership. Again, experts, researchers, patient representatives, and certain government officials who have no regulatory responsibilities, can participate in these forums for improvement. Further, PSOs are a great resource to distribute best practice standards resulting from such National Safe-Tables to all provider types. Traditionally, AHRQ has had a difficult time reaching many types of providers, including primary care. PSOs are trusted within the healthcare community and are strategically positioned to distribute best practices.

Safety Culture Surveys

Many healthcare sectors have created Patient Safety Act programs focused on encouraging safety culture and improving patient care delivery but have no appropriate surveys to assess safety culture. AQIPS is developing a PSO committee to work with AHRQ to develop safety culture surveys for telemedicine, behavioral health clinics, assisted living, radiology and other healthcare sectors that do not have common safety culture surveys. Some PSOs have created safety culture surveys for their own participating providers. We applaud these initiatives but would like to be able to consistently assess the culture across provider types. This public-private partnership program will permit AHRQ to develop tools to support the PSO program, including a means to measure the PSO community's effectiveness in encouraging safety culture.

Conclusion

AQIPS and AQIPS member PSOs look forward to working with AHRQ on creating nationwide PSO safe-tables and creating safety culture surveys for providers who lack such surveys or lack common surveys. We expect the NAS comments will be made public in the docket created for this report and the final AHRQ report will be available for public comment prior to submission to Congress. Should you have any questions or require additional information about AQIPS comments, please contact me at [REDACTED]

Respectfully submitted,

[REDACTED]
Margaret (Peggy) Binzer



Ascension

Marquita Cullom
Associate Director
Attn: Patient Safety Organization Division
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

VIA EMAIL: PSQIA.RC@ahrq.hhs.gov

February 16, 2021

Re: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Dear Ms. Cullom:

Ascension appreciates the opportunity to submit comments on the draft report entitled *Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine* (the “draft report”).¹

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2020, Ascension provided \$2.4 billion in care of persons living in poverty and other community benefit programs. Ascension includes more than 160,000 associates and 40,000 aligned providers. The national health system operates more than 2,600 sites of care – including 145 hospitals and more than 40 senior living facilities – in 19 states and the District of Columbia, while providing a variety of services including clinical and network services, venture capital investing, investment management, biomedical engineering, facilities management, risk management, and contracting through Ascension’s own group purchasing organization.

Given our broad and diverse footprint, Ascension has prioritized standardization of clinical quality measures and thus recognizes the importance of data collection, reporting, and analysis to generate learnings and best practices. We offer the following comments from this perspective and appreciate your consideration of our input to the Agency for Healthcare Research and Quality (AHRQ). As a general matter, the draft report highlights the success of the

¹ Accessed via: <https://psa.ahrq.gov/resources/act>

network of patient safety databases (NPSD). Of note, the draft report states that the “NPSD needed a critical mass of data before it could become operational. The NPSD achieved this threshold and launched in June 2019.”² However, while the NPSD generally collects good data, which could ultimately be helpful, Ascension’s experience is that our organization and related entities submit much of, if not the majority of, such data—rendering the NPSD unhelpful to our facilities for purposes of drawing comparisons or learnings. We encourage AHRQ and the Department of Health and Human Services (HHS), broadly, to consider how best to promote more reporting across more entities, while also working to increase the diversity of submitters and sources of data. One option might include providing an incentive for Patient Safety Organizations (PSOs) to report. While we recognize that this report does not address mechanisms for setting, incentivizing, and/or enforcing compliance with patient safety-related standards or requirements, as these are outside the scope of the report, we do believe this is an important aspect of patient safety data quality and its usefulness for which AHRQ and HHS should give further consideration.

The draft report also explains that the Medicare Patient Safety Monitoring System (MPSMS) will be replaced with the Quality and Safety Review System (QSRS) and says QSRs software will be made available to hospitals and health systems as a tool they may use to monitor, identify, and measure adverse events at the local level. We appreciate AHRQ and HHS taking steps to provide QSRs software and are working to prepare for this transition. However, we strongly encourage AHRQ and HHS to provide a public update on the status of pilot testing and anticipated timing of the QSRs software release. In the current environment, we have found that some vendors appear to be capitalizing on the vacuum of information regarding the QSRs software status through retail of private alternative products. If AHRQ and HHS could provide a public update on the status of QSRs software development and timing of its availability, this would allow for better informed decision making by reporting entities with respect to our current and future needs.

Finally, while this comment may fall outside the scope of the draft report, we would also raise for AHRQ’s consideration that the current regulatory framework creates unintended limitations on the ability to share certain data within and across related organizational functions. In particular, it has been our experience that, at times, qualification as a Component PSO within an organization makes it difficult to share Patient Safety Work Product (PSWP) with the “Parent” organization. As healthcare entities have increasing amounts of operational functions directed by a “Parent” organization, it becomes increasingly important to be able to share PSWP among an entity’s parent and subsidiary organizations. We have also experienced increased challenges arising out of the requirement that entities can only be “participants” if they are licensed entities. For example, if an organization has a travel nurse entity that is not a department of a licensed hospital, there arise limitations with respect to how the travel nurse entity and its parent or sister entities can share PSWP, since the travel nurse entity isn’t eligible to be a PSO participant (*i.e.*, is not a licensed entity). We encourage AHRQ and HHS to consider providing blanket authorizations that permit the sharing of PSWP among and between entities operating within an organized health care system.

² Draft Report at 5.

Conclusion

We sincerely appreciate your consideration of these comments. If you have any questions, or if there is any additional information we can provide, please do not hesitate to contact Mark Hayes, Senior Vice President for Policy and Advocacy for Ascension, at [REDACTED] or [REDACTED].

Sincerely,

[REDACTED]

Peter M. Leibold
Chief Advocacy Officer
Ascension

February 15, 2021

Marquita N. Cullom Associate Director
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services 5600 Fishers Ln #7
Rockville, MD 20857

Re: "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," Document No. 2020-27589

Dear Associate Director Cullom:

Thank you for your commitment to improving the safety and quality of health. We applaud the efforts of the Agency for Healthcare Research and Quality to reduce adverse events and improve the safety of our healthcare system.

As a national biomedical and healthcare network, the American Society of Pharmacovigilance's mission is to reduce the high rate of suffering and mortality due to adverse drug events. Adverse drug events (ADEs) are the fourth leading cause of death in the United States and contribute annually account for more than 3.5 million physician office visits¹, an estimated 1 million emergency department (ED) visits², and approximately 125,000 hospital admissions each year.² Since genetic variation has been estimated to account for 20–95% of the variation in individual responses to medications³, a key objective of the Society is to charter the development of personalized medicine practices that benefit the public health.

For those reasons, we are writing to request that the Draft Report address adverse drug events by developing strategies that utilize pharmacogenomics to optimize medication therapy as appropriate. Pharmacogenetic testing combined with clinical decision support can significantly reduce adverse drug reactions and improve health outcomes.

Enhancing Genetics Literacy and Engagement

A recent report indicated personalized medicines accounted for more than one of every four drugs the agency (FDA) has approved in the past six years.⁴ As medicine continues to become more personalized and targeted towards specific therapies geared to the individual's genetic type, the explanations of diagnoses and treatment options becomes more complex. Drug labels often include references to specific biological markers to help guide decision-making, and that process requires more time from the provider and greater understanding for the recipient of health care services and caregivers. Consequently, patients need to have access to information about how genetics affects their health and considerations in which treatments to pursue. Approaches are needed to engage diverse participant populations in conversations about genetics and its impact on medication responses.

¹ Bourgeois FT, Shannon MW, Valim C, Mandl KD. Adverse drug events in the outpatient setting: an 11-year national analysis. *Pharmacoepidemiol Drug Saf.* 2010;19(9):901-10.

² CDC, unpublished data. Updated numbers for: Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL. National surveillance of emergency department visits for outpatient adverse drug events. *JAMA.* 2006;296(15):1858-66.

³ Wang L, McLeod HL, Weinshilboum RM. Genomics and drug response. *N. Engl. J. Med.* 364(12), 1144–1153 (2011).

Identifying Underlying Causes of Adverse Drug Events by Enabling Pharmacogenomics Reporting

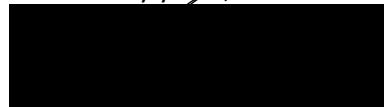
Determining common formats and consistent definitions for the reporting of patient safety events to enable analysis of trends and patterns of adverse events is *critical* to identifying problems and developing best practices. Since the impact of genetic variation on drug response is a key factor underlying many adverse drug reactions, pharmacogenomics should be included in the common formats and consistent definitions for the reporting of patient safety events. Without a concerted effort to identify the genetic correlation to adverse drug events, the root cause of many adverse events will remain unknown, unresolved and contribute to continued patient harm. Including pharmacogenomics in the network of patient safety databases (NPSD) and as a specific measure used to improve patient safety is an urgent unmet need.

Pharmacogenomics Provides Important Information

Pharmacogenomics can help identify safer medications or optimal dose selections for many commonly prescribed medications by considering a patient's unique genetic information. Since genetic predisposition to drug response is not a routine consideration in care, adverse drug reactions continue to be a major contributor to high adverse drug event rate. The STRIPE Collaborative Community, an ASP Initiative, was formed in 2020 to bring together stakeholders in a continuing forum of private- and public- sector members, including FDA, to address key challenges related to pharmacogenetics testing.⁵ With multi-stakeholder collaboration, pharmacogenetics testing can be used to improve access to safe, accurate and reliable information about a patient's medication and gene-drug interactions to reduce adverse drug events, decrease costs and improve patient outcomes. Since the Patient Safety Act works in concert with FDA laws to promote patient safety, please consider supporting ongoing national initiatives aimed at solving shared challenges and leveraging collective opportunities to improve patient safety across stakeholder groups.

New ways of thinking and new strategies are needed to enhance patient and provider genetics literacy, foster understanding of all factors that affect drug response, including pharmacogenomics, and encourage collaborative efforts in these areas. Thank you for your consideration.

Sincerely yours,



Benjamin Brown

Executive Director



Sara Rogers, PharmD, BCPS

Director of Clinical Affairs

⁴ Personalized Medicine Coalition, Personalized Medicine at FDA: The Scope & Significance of Progress in 2019.

⁵ Center for Devices and Radiological Health. "Collaborative Communities: Addressing Health Care Challenges Together." U.S. Food and Drug Administration, FDA, www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together.

From: [Ken Segel](#)
To: [PSQIA.RC \(AHRQ/CQuIPS\)](#)
Subject: Comment Submission - "Strategies to Improve Patient Safety: Draft Report to Congress"
Date: Saturday, March 27, 2021 7:51:49 AM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.png](#)

March 27, 2021

Dear AHRQ and NAM leaders,

I am writing to offer public comment on your draft report "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine."

I am a co-founder and CEO of Value Capture, a mission-driven trusted advisory firm that supports safety-focused performance transformations, primarily in health systems. We have been privileged to support several of the leading examples of dramatic safety improvement across American healthcare. Safety pioneer Paul O'Neill served as our non-executive chairman until his passing last year. Paul was CEO of Alcoa, US Treasury Secretary, Co-Chair of the Pittsburgh Regional Healthcare Initiative (where I served as founding director), and a member of several National Academy of Medicine (NAM) panels.

When helping others to effect dramatic, systemic changes, Mr. O'Neill often offered a key piece of wisdom – "Do not confuse a lot of well-intentioned activity with outcomes." Unfortunately, this draft report, as written, does just that.

- The draft report ignores the growing published evidence of how little overall progress we have made in reducing patient harm since the Patient Safety and Quality Improvement Act was passed in 2005, and offers no broader systemic analysis of the remaining significant structural gaps in the national approach instigated by the Act and the clear steps that might remedy them. In fact, it does the opposite. The body of the report states that the Act created an effective national learning system and asserts that the key players -- especially prominent in the report are AHRQ and the Patient Safety Organizations (PSOs)-- are doing an invaluable job. The draft cites no summary outcomes data (results) to justify such conclusions, just a PSO customer satisfaction survey and a few AHRQ supported or guided projects (activity).
- The hints of what remains structurally broken that have prevented an effective national learning system from emerging are left as passive hints. These include the voluntary nature of participation by healthcare organizations, the lack of transparent public reporting, and a focus on creating a national database which is riven by political and technical challenges and is mis-designed to have impact where it counts, on the front line. Other major gaps, such as the emerging evidence of systematic gaming of our safety reporting and measurement systems, are not cited at all.
- Without a diagnosis, simple clear comparisons which might be made to Congress to help

them understand how to fix the gaps are not provided. These include the dramatically more effective (outcomes) federal safety system for transportation, anchored by the National Transportation Safety Board, an entity and “ground rules” which if translated to heal the gaps in our healthcare safety system might dramatically improve our pace of change.

In sum, the body of the report in this draft reads as defensive, a justification by current funded players, versus the sober national assessment, analysis, and courageous hypothesis generation that every American, each of us so vulnerable to medical error, expects from NAM and AHRQ.

Without significant revisions that shift the overall message, the draft report risks misleading Congress and fumbling a major opportunity to improve our nation’s current approach. However, with changes, that opportunity may still be captured.

With respect,

Kenneth T Segel
CEO and Managing Director
Value Capture



Ken Segel
Value Capture, LLC
CEO & Managing Director



Profound change. Sustainable results.

valuecapturellc.com |



[Join the important discussion at VacciNexus](#) - Share your COVID Vaccination process improvements and learn from others. #SeeSolveShare.

From: [Robert Ferguson](#)
To: [PSQIA.RC \(AHRQ/CQuIPS\)](#)
Subject: Comments on "Strategies to Improve Patient Safety: Draft Report to Congress"
Date: Monday, April 5, 2021 9:48:25 PM

Dear Ms. DiStabile:

We agree that existing technologies, such as distributed data networks, AI, and Machine Learning, can help to create a more comprehensive Network of Patient Safety Databases (NPSD) while relieving the burden of data collection and reporting at the frontline of care. 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.

There are also promising examples related to collecting data about adverse events. One of the AHRQ-certified Patient Safety Organizations (PSOs), Pascal Metrics, developed a real-time patient safety surveillance system that extracts EHR data, uploads the data to a cloud, identifies the IHI Global Triggers, applies AI predictive analytics and clinically validated algorithms to identify and anticipate adverse safety events, and displays the information through dashboards (<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0728>).

To spread this type of data collection technology across the AHRQ-certified PSOs, AHRQ could either: (a) update its 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.

With the technologies and data that exist today, there is an important opportunity to further develop a national infrastructure for information exchange, analysis and research, and surveillance related to adverse events. With this in place, our nation will be positioned to understand why adverse events continue to occur and to issue recommendations to prevent these adverse events from re-occurring.

Thank you for considering these comments.

Sincerely,
Robert

Robert Ferguson
Chief Policy Officer
Jewish Healthcare Foundation
EQT Plaza
625 Liberty Ave, Ste. 2500
Pittsburgh, PA 15222



Unauthorized use or distribution of this email is prohibited and may be unlawful.

Unauthorized use or distribution of this email is prohibited and may be unlawful.

From: [Carol Cronin](#)
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Cc: [Carol Cronin](#)
Subject: Comments on Draft Report
Date: Tuesday, February 16, 2021 10:29:39 AM

To Whom It May Concern,

I would like to briefly comment on the report: Strategies to Improve Patient Safety.

While the report does a good job providing background on patient safety to date, I would note that a factor that has changed since the passage of the law in 2005 is the growing awareness within the public, patient/family world and the media of the extent of patient harm and medical errors in healthcare.

Given this, I was struck again in reading the report by the degree to which much of patient safety work occurs behind doors closed to the public under the sanctioned auspices of "confidentiality and privilege". I searched the document for the word "transparency" and it only appears once. I, along with many patient, consumer and family advocates are now much more savvy about both the extent of harm, the extent of secrecy, and the limitations of the "trust us" culture that permeates health care and medicine.

As a patient/public member of a hospital patient safety committee, I understand and respect the need to develop safe ways to share information in order to learn and improve. I understand the problems with the "blame and shame" culture, but I also collect stories about hospitals and physicians that are harming patients and allowed to continue given the culture of silence. Until the health care industry and professions truly acknowledge and address egregious behavior within their ranks, it will be difficult to truly address patient safety and quality.

And I would note, that despite the infrastructure set up for patient safety under these acts, the actual outcomes of care are still pretty dismal for the US compared to other countries (as well as being very expensive). The recent COVID epidemic, for example, laid bare the woeful work on patient safety in nursing homes (Disclosure - I volunteered to help create system to track COVID data in long term care facilities for the COVID Tracking Project).

I would urge authors of the report to think and write more deeply about the issues related to transparency and accountability to the public.

Thank you.

Carol Cronin, M.S.G., M.S.W.

Executive Director

Informed Patient Institute

<https://protect2.fireeye.com/v1/url?k=1dac0cda-4237340e-1dac3de5-0cc47a6d17cc-1127e981736382a1&q=1&e=9fb3483a-5150-47fe-8a92-460f64a0bba3&u=http%3A%2F%2Fwww.informedpatientinstitute.org%2F>

Chair

Medical Board Roundtable

Patient Safety Action Network

<https://protect2.fireeye.com/v1/url?k=7f63a0ce-20f8981a-7f6391f1-0cc47a6d17cc-9270f6ef17d6ae89&q=1&e=9fb3483a-5150-47fe-8a92-460f64a0bba3&u=https%3A%2F%2Fwww.patientsafetyaction.org%2Fmedical-board-round-table>

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: Comments: HRQ Draft Report to Congress about Improving Patient Safety
Date: Tuesday, February 16, 2021 11:13:57 PM

Dear Dr. Brady and Ms. Timashenka,

Re. Patient Safety

I just this evening learned about your Draft Report and invitation to comment on it.

Since I was made aware of this report just now, I was not able to not invest as much time as your report deserves nor in order to formulate a precise analysis, but since the deadline for feedback is tonight, I am submitting the following feedback and thoughts. I very much appreciate your invitation to comment, at a time where I feel my voice as a victim of the LACK of patient care, has been dismissed over and over again.

I am eager to see a major change where health care becomes patient-focused, where patient care wins over the focus of profit, and where non-profit patient advocacy groups exist, are accessible, and are in place at every health care facility.

In reading your report I am left with these areas of concern:

- **The report is physician-focused.** It should focus much more on **the enlisting of patients** and their families. In an industry that does not ultimately support patients who are victims of carelessness or malpractice, we need to establish patient advocacy. In my experience, the industry is organized to protect physicians, pharmaceutical and insurance companies. Patient Safety should go to the source (ie PATIENTS) in deciding courses of action.

-Establishing **mandatory, non-profit patient advocacy entities** that are easily accessible and ideally located in each healthcare provider practice or hospital should be a priority. Although the report details implementing education that might better support patient safety, it ultimately states (if I read correctly) that reporting of patient suffering is *elective*, still suppressing the voices of those victims of ill care and malpractice. Under "Patient and Family Engagement" you list crucial steps, and it is these very steps that should take the front stage in your efforts.

-**Education** about patient care (how to handle medical errors, trusting patients' self-assessments, bedside manner, protocol for complaints, etc.) needs to be central to studies in medical school- long before physicians get enlisted into practices that are not bound to any accountability. I do believe patients are great educators to their providers. Unfortunately the lack of education around patient handling, patient 'special cases' (medication allergies, for example), pressures of time placed on physicians, does not allow them to really hear their patients, and patients have no portal for voicing their valuable experience.

-As for the implant industry and patient safety in this relatively unregulated industry, there needs to be a **law requiring ALL patients to be tested** for metals and cement hypersensitivity BEFORE being sold implants.

-As for **patient privacy**, there really is none. I learned HIPAA does NOT protect the rights of patients. With e-systems for patient record sharing, health insurance systems that require

online usage, and other for-profit companies that are hired by hospitals for example to facilitate record keeping, there is no privacy. I learned lawyers can access patient records without patient consent. This is a very real challenge we face today. I do not know of a solution, but to believe patient privacy and rights exist, is to be oblivious. Can we reverse this state?

We need accessible patient advocacy groups IN PLACE to help bridge positive communication between patients and their providers. I understand this appears to be in conflict with efforts of the for-profit health industry, but in reality a positive and interdependent relationship can be built, but it requires integrity.

My hope is your continued efforts will help create an industry where patients feel safe, feel heard, and are recognized as individuals who put their trust in doctors in their efforts to feel well and contribute positively. Profit simply cannot trump patient safety.

In providing a very brief summary of my medical history that 'qualifies' me to provide educated feedback relative to your report, please note the following:

I will summarize in brief, what has been a long, painful, stressful, eye-opening, and devastating series of events prompted by the total knee replacement surgery I was convinced by a surgeon to 'purchase' in [REDACTED].

I was a very athletic and [REDACTED] when my knee pain led me to seek advice. I did my research, and still was convinced by a 'reputable' orthopedic surgeon to have TKR surgery. He failed to provide a safe and acceptable surgery, leaving me nearly completely bed ridden and in horrific chronic pain. To date I continue to suffer horrific pain and physical disability, even after a painful and necessary revision was performed.

After the initial failed surgery, I was completely abandoned by the surgeon and the industry. My pain was dismissed. Doctors refused to seriously investigate my immobility and pain; they said they could not afford to invest the time, lab test, etc. to help me. My reasonable and polite efforts to seek help yielded not even replies from the surgeon who left me 'ruined,' CEOs, Board Members or the like. I learned the Board of Medicine, the hospital and practice administrators, and the surgeon were completely aligned to protect doctors but not patients. Even finding a surgeon to provide the corrective surgery took nearly a year, as many physicians refused to provide care that might place them in opposition to their professional peer. Ultimately I found 3 surgeons who explained the failed surgery (placed incorrectly, tilted backwards, any sizes too large, etc.). I endured another excruciating surgery; a TKR revision at great pain and expense. The damage was not fully repaired, and I continue to suffer severely.

Feeling I had no other options, having lost my ability to work, and suffering severely, I attempted to enlist legal help. All 35 lawyers I contacted claimed I had a valid, strong case of malpractice but would not represent me as they, "...don't earn enough profit on malpractice cases due to low caps." To date not only have I not been refunded for the failed surgery, but I have had no financial assistance though I have been left physically disabled.

I took the humbling route of applying for disability. There, too, I was refused solely due to the

fact that my husband earns more (barely) than \$3k per month, the basis by which Disability apparently determines compensation. As you can imagine, it is difficult to support a family on one teacher's salary. My family depended on my income and now, for nearly 6 years, I have been unable to provide financially.

I continue to live in chronic pain and have immobility issues. Pursuing diagnoses and help has become cost prohibitive even with the health insurance I pay for every month, at great expense.

I am a reasonable, educated, fair person who has friends and family members who are physicians. I understand human error exists. My journey to get well could have been progressive had my surgeon simply accepted responsibility and helped me along the path. Instead he was not required to help me, did not apparently want to help me, and I still, to date, have found no advocacy groups nor any other means of support, other than patient discussion groups that include people who have also suffered. it is all very traumatizing.

Thank you for taking the time to hear my story. I ultimately hope it helps you in your efforts to build better pro-safety processes.

Sincerely,

A solid black rectangular box used to redact the signature of the sender.



April 5, 2021

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Re: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Dear Colleagues,

ASHP (American Society of Health-System Pharmacists) is pleased to submit comments to the Agency for Healthcare Research and Quality (AHRQ) regarding the document “Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine”. ASHP represents pharmacists who serve as patient care providers in a wide variety of settings, including hospitals, health systems, clinics, community pharmacies, and pharmacists in academia and research. The organization’s nearly 58,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

Since the passage of the Patient Safety and Quality Improvement Act of 2005, the accomplishments of AHRQ listed in Chapter 2 and Tables 1-28 are notable. We commend AHRQ for these accomplishments and the extensive resources accessible to healthcare practitioners that enable improvement in the care and safety of their patients. ASHP also has an extensive library of consensus-based patient safety and best practice resources available for our members and important safety initiatives such as Standardize 4 Safety that are available to the public. These resources are designed to assist our healthcare system in improving the health and health outcomes of our patients.

Medication adverse events remain a serious patient safety issue with significant morbidity and mortality. The recent updated data reported by Watanabe and colleagues indicates annual emergency room visits of 500,000 and hospitalizations of 100,000 because of medication-associated problems, with a cost estimated to be \$528 billion.¹ Despite the tremendous effort to date, further analysis and understanding of the current patient safety landscape and a continued concerted effort to improve patient safety, especially for medications is necessary. We steadfastly agree with the report statement that patient safety is a “complex and multifaceted problem.” In order to develop implementable and successful solutions and unravel the complex ontology of medication related problems, a multifaceted approach that garners the insight and knowledge of a team that includes all stakeholders is required.

Chapter 3 of the report discusses the need for a coordinated effort among all stakeholders for dissemination and implementation of the many known and effective patient safety strategies. ASHP agrees with the approach outlined, including adopting a learning health-systems strategy and adoption of organizational cultures that have safety focused leadership and engagement of patients and frontline workforce. We would suggest there is a potential missing and advantageous step for effective dissemination and implementation - the inclusion of professional organizations into the process. Even ASHP, with staff dedicated to medication and patient safety,

ASHP Comments to Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

April 5, 2021

Page 2

was unfamiliar with several tools and initiatives listed in the report. Thus, it seems highly unlikely that the average healthcare practitioner charged with organizational safety initiatives would have the time to sift and prioritize the voluminous safety strategies with this report and found elsewhere. Consequently, items of value sit unseen or unread. In our experience, practitioners will often turn to their professional organizations and associated virtual communities for assistance. Such organizations can synthesize, target, and push information to the healthcare team member most in need of a certain tool or strategy. The communities of likeminded individual providers, embedded in most professional organizations, can organically assist each other in implementation strategies. A substantial number of communities exist within ASHP, aligned by practice setting and specialty area, that engage and collaborate regularly. Additionally, ASHP is committed to using the wide range of educational tools and communication mechanisms from podcasts, webinars, web-based resource pages, meetings, etc., to assist and educate members and amplify matters of national importance. Most professional organizations also have means to promote research as ASHP has with the ASHP Foundation. Unique to ASHP is the establishment of the ASHP Innovation Center dedicated to new and emerging science and system development that advance safety and quality of patient care, such as promoting and assisting in adoption of a learning health system. Utilizing the resources and reach of professional organizations is an untapped method of facilitating dissemination and implementation of patient safety initiatives.

ASHP appreciates AHRQ's consideration of our comments, and we look forward to continuing to work collaboratively to achieve the goals set forth in the Patient Safety and Quality Improvement Act. We recognize this may require a higher level of collaboration than currently exists. We encourage AHRQ to take this opportunity to collaborate with ASHP and other professional organizations, and to act as a facilitator for strengthening the healthcare team by engaging siloed professions through their respective organizations to achieve the common goal of patient safety.

Sincerely,

A solid black rectangular box used to redact the signature of Mary Ann Kliethermes.

Mary Ann Kliethermes, BS. Pharm., Pharm.D., FAPhA, FCIOM
Director of Medication Safety and Quality

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: Covi 19
Date: Wednesday, December 30, 2020 11:41:07 PM

Hi my name is [REDACTED] and I want the you know the real-life I been living .. This year in January a friend the she works for [REDACTED] she ask me what's up in my arm and tell her I have psoriasis and she said I looks very bad .. and I said yes . and she is me if she can take a picture and said yes .3 weeks after my order fried hi said go look in Facebook and it was a post with my arm and my house it was on Facebook said the I have the Corona Virus and I got that well I call her and she was tell me the I was crazy and we stop talking eacheder and since that day my life star getting worst and I'm sad because now people belive that the city of Burbank and Los Angeles make my life miserable lawyers Banks repast state IRS loan companies and stores transportation and single families they are on me and they been cruel the same with social media they haven't stop attacking I want to request to have fiasco exam and mental I feel good but my situation it is very complicated and very sad I live in a free Country with free speech and I can complain to the Human Rights and the UNITED NATION AND I hope you can help me my house is ver important because it is a lot memories a lot probles I found out the my house have life insurance and the IRS They tell if don't pay the \$ 9000 they are going to take my house and. I don't want to lost my house the government needs to pame my money the soon it is possible

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: Draft Report Consideration
Date: Tuesday, February 16, 2021 11:06:05 PM

Hello, I would like to bring attention to the need for better standardized protocol for patient care locations to begin more performance improvement measures through the process of benchmarking cleanliness of not only EVS jurisdiction in cleaning but also include the footprints regarding medical equipment and facility management equipment and structures outside EVS responsibilities. The current CDC focus has been with housekeeping jurisdiction and these efforts only represent 1/3 of the total environmental hygiene control efforts to allow safer conditions to lower the transmission risks through the environment. When sampling environments, we can not keep focusing on cleanliness levels on only EVS responsibilities. Without monitoring all hazardous conditions then how can we begin to control environmental workspaces for the staff as well? It makes no sense to only include EVS practices and we are not only fighting drug resistant organism but also a pandemic situation. We must begin to understand a much larger environmental footprint instead of 1/3 of the full spectrum. It is almost criminal to be leaving out the medical equipment and facility management equipment in patient care environments.

From: [REDACTED]
To: [PSQIA.RC \(AHRQ/CQuIPS\)](#)
Subject: Draft Report to Congress about Improvement of Patient Safety
Date: Friday, February 12, 2021 3:55:15 PM

AHRQ Patient Safety Team,
I recommend also offering a webinar with an overview or update on your Report as it has been 15 years since the initial PSO legislation.

[REDACTED]

[REDACTED]
[REDACTED]
+ [REDACTED] | e: [REDACTED]

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: Draft Report to Congress for Patient Safety
Date: Saturday, February 13, 2021 8:45:36 PM

As a former researcher on the Partnership for Patients Project I have thoroughly reviewed your current project. It is good that you have continued to do research on patient safety and your project looks well researched. However, I continue to see a need that is missing in the community that you are greatly missing for research in the future.

I continue to see that you focus on hospitals and never look at the community physician. Having worked in home health and outpatient clinics, as well as having a medical error myself in the community practice twice this would be a concern for research in the future.

I would be happy to share my personal experiences with you and my concerns for future research.

Please feel free to email me for further information anytime.

[REDACTED]

PUBLIC SUBMISSION

As of: December 29, 2020
Received: December 20, 2020
Status: Pending_Post
Tracking No. 1k4-9kr8-76km
Comments Due: February 16, 2021
Submission Type: API

Docket: AHRQ_FRDOC_0001
Recently Posted AHRQ Rules and Notices.

Comment On: AHRQ_FRDOC_0001-0853
Opportunity to Comment on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Document: AHRQ_FRDOC_0001-DRAFT-0144
Comment on FR Doc # 2020-27589

Submitter Information

Name: Brian Dummett
Address: [REDACTED]
Email: [REDACTED]
Organization: Kaiser Permanente

General Comment

Patient monitoring systems and dedicated, out of the count, proactive rounding rapid response systems are effective as proven by large scale implementation of Automated Identification of Adults at Risk for In-Hospital Clinical Deterioration. In describing the summary of the evidence, there was no convincing evidence of reduced mortality until now. Please mention the extensive and ongoing work being done to address unrecognized deterioration. The lessons learned from the literature, can be applied widely.
<https://www.nejm.org/doi/full/10.1056/NEJMsa2001090>

Attachments

escobar et al

April 5, 2021

Paula DiStabile
Patient Safety Organization Division
AHRQ Center for Quality Improvement and Patient Safety
5600 Fishers Lane
Rockville, MD 20857
Email: PSQIA.RC@ahrq.hhs.gov

RE: Comments on Strategies to Improve Patient Safety: Draft Report to Congress

The undersigned organizations representing pharmacists and other pharmacy personnel who work across multiple patient care settings appreciate the opportunity to review and comment on the draft report to Congress as required in the Patient Safety and Quality Improvement Act of 2005 (PSA). This report contains a substantive review of historical, current and future patient safety strategies and programs across multiple federal agencies. As such, it should provide those both in and out of government with important guidance on progress that has been made since the PSA was signed into law. It also identifies that additional improvements in the delivery of health care are needed to meet our goals for patient safety.

Of particular note and importance are the 28 evidence tables contained in Section 2.5.2 in the report. We note that a number of these are highly germane to safe medication use, including those associated with transitions of care. We believe our members would be extremely interested in these compilations of evidence. Our organizations are committed to working with AHRQ's Patient Safety Organization Division or another relevant staff group to identify the most effective communications strategies to disseminate this information to our audiences.

It is especially timely for the report to include reference to the September 2020 *Safer Together: A National Action Plan to Advance Patient Safety* report containing 17 recommendations in four specific categories. Given how disruptive the COVID-19 pandemic has been across all settings of care, we recommend that AHRQ and other federal entities identify a variety of communication strategies to keep this report 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.

Despite a decades-long commitment to improving patient safety within both the public and private sectors, it has been estimated that the U.S. may now be experiencing over \$500 billion annually as the cost of not managing medication use optimally¹. The resulting utilization of additional, and likely highly avoidable, health services and resources that accounts for this huge cost could be avoided if pharmacists were more fully integrated with functional interprofessional care teams. Empowering pharmacists to apply their knowledge and skills as providers of medication management and other health-related services will improve patient outcomes, reduce long-term costs and address health inequities.

Throughout the pandemic a national network of pharmacy associations has worked in a highly coordinated fashion to identify the many ways our pharmacist, student pharmacist, and pharmacy

¹ Watanabe JH, McInnis T, Hirsch JD. Cost of Prescription Drug-Related Morbidity and Mortality. *Annals of Pharmacotherapy* 2018;52:829-37.

technician members could work to prevent the spread of the virus and treat those afflicted with COVID-19 in our communities, our long-term care facilities, our emergency departments and our ICUs.

Pharmacists have led the effort in vaccine deployment and monoclonal antibody treatments to stop the spread of the disease. Nowhere is this more apparent than in the expanding accessibility of pharmacy-based immunization locations and COVID mass vaccination centers that are utilizing pharmacy personnel. However, the expanded role of pharmacists to combat COVID-19 was only possible due to the Public Readiness and Emergency Preparedness (PREP) Act and public health emergency declaration. We remain concerned that barriers to patient access and care will be reimposed following the COVID-19 pandemic. We believe that the success pharmacists had in providing care, consulting and expertise could be used to tackle long lingering health inequities, if these barriers were permanently removed. We ask that AHRQ consider examining how an expanded role for pharmacists could benefit patient care, public health and the overall healthcare delivery system.

Again, we appreciate the opportunity to provide comments on this important report and we stand ready to assist AHRQ in disseminating this critical research to practitioners providing medication management services to American families.

Sincerely,

Lucinda L. Maine, AACP EVP and CEO
[On behalf of the following signing organizations]

Academy of Managed Care Pharmacy
American Association of Colleges of Pharmacy
American College of Apothecaries
American College of Clinical Pharmacy
American Pharmacists Association
Accreditation Council for Pharmacy Education
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
College of Psychiatric and Neurologic Pharmacists
Hematology/Oncology Pharmacy Association
National Alliance of State Pharmacy Associations
National Association of Specialty Pharmacists
National Community Pharmacists Association
National Pharmaceutical Association
Pharmacy Quality Alliance

From: [PSQIA.RC \(AHRO/CQuIPS\)](mailto:PSQIA.RC (AHRO/CQuIPS))
To: [REDACTED]
Subject: FW: abusing dogs and cats in research which has no relevance to human use
Date: Thursday, March 18, 2021 1:44:32 PM

From: [REDACTED]
Sent: Thursday, March 18, 2021 1:25 PM
To: [REDACTED]; PSQIA.RC (AHRQ/CQuIPS) <PSQIA.RC@ahrq.hhs.gov>
Subject: Re: abusing dogs and cats in research which has no relevance to human use

public comment on federal register

patient safety is non-existent. so many come out of hospitals dead or worse than they went in. i went in for breast cancer and came out with breast cancer and lymphedema, which is turning my body into a round ball and that will cause my heart to stop pumping from all the swelling from lymph fluid that does not circulate through the body as it should. that is an example of happening to millions of American women. why is it allowed. is it because women get less time to have safe results from operations. i think so.

it is a true example of the horror that is done to women, who far too often get far less time and attention from the male world.

this comment is for the public record please receipt. [REDACTED]

On Thu, Mar 18, 2021 at 10:05 AM [REDACTED] > wrote:

[Federal Register Volume 86, Number 51 (Thursday, March 18, 2021)]
[Notices]
[Pages 14752-14753]
From the Federal Register Online via the Government Publishing Office
[\[www.gpo.gov\]](http://www.gpo.gov)
[FR Doc No: 2021-05605]

=====

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

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of extension in comment period.

SUMMARY: As required by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), the Secretary of HHS (the Secretary) is making this draft report on effective strategies for reducing medical errors and increasing patient safety available to the public for review and comment. Through this notice the comment period is extended. The subject matter content remains unchanged from the original notice which was published on 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>).

DATES: Submit comments on or before April 5, 2021.

ADDRESSES: The draft report, Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine, can be accessed electronically at the following HHS website: <https://psa.ahrq.gov/legislation/act>. Comments on the draft report must be submitted by email to PSOIA.RC@ahrq.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Paula DiStabile, Patient Safety Organization Division, Center for Quality Improvement and Patient Safety, AHRQ; telephone (toll free): (866) 403-3697; telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; email: PSOIA.RC@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Secretary, in consultation with the Director of AHRQ, has prepared a draft report on effective strategies for reducing medical errors and increasing patient safety as required by the Patient Safety Act. The report includes measures determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The draft report is now available for public comment and has been submitted to the National Academy of Medicine for review. The final report is required to be submitted to Congress no later than December 21, 2021. The specific provision describing these requirements can be found at 42 U.S.C. 299b-22(j).

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. 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 exchanged between healthcare providers and organizations listed by the Secretary that specialize 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. More information about the Patient Safety Act, its implementing regulation, and PSOs can be found at <https://psa.ahrq.gov/>.

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 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. Congress required the draft report that is the subject of this Notice to be made available for public comment and submitted to the Institute of Medicine (now the National Academy of Medicine) no later than 18 months after the NPSD became operational. The NPSD became operational on June 21, 2019. More information about the NPSD

[[Page 14753]]

can be found at <https://www.ahrq.gov/npsd/index.html>.

Overview of the Draft Report

The draft report contains three chapters. It begins with an overview of the impetus for and objectives of the Patient Safety Act, its key provisions, and some milestones in its implementation. Chapter 2 reviews some of the principles and concepts underlying effective patient safety improvement, provides an overview of research and measurement in patient safety, and presents the strategies and practices for reducing medical errors and increasing patient safety reviewed in AHRQ's Making Healthcare Safer reports, published in 2001,

2013, and 2020. 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. They 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 in the draft report 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. The final chapter in the draft report begins with an overview of learning health systems and concepts underlying effective implementation of patient safety strategies. It provides examples of resources Federal agencies make available to encourage healthcare providers to use effective patient safety strategies and describes "Safer Together: A National Action Plan to Advance Patient Safety," recently released by the National Steering Committee for Patient Safety that was convened by the Institute for Healthcare Improvement. The draft report concludes by describing an approach that has a track record of success in encouraging providers to use effective practices to improve patient safety and outlines measures that could accelerate progress in improving patient safety and encouraging the use of effective patient safety improvement strategies.

Where To View the Draft Report and How To Submit Comments

The draft report is posted on the AHRQ PSO Program website at <https://pso.ahrq.gov/legislation/act>. The website contains a link to the email address for submitting comments on the draft report, which is PSOIA.RC@ahrq.hhs.gov.

Dated: March 15, 2021.
Marquita Cullom,
Associate Director.
[FR Doc. 2021-05605 Filed 3-17-21; 8:45 am]
BILLING CODE 4160-90-P

From: [Jean Salera-Vieira](#)
To: [PSQIA.RC \(AHRQ/CQUIPS\)](#)
Subject: FW: AHRQ Views Blog: Comments Welcome on Draft Report About Improving Patient Safety
Date: Tuesday, February 16, 2021 11:09:16 AM
Attachments: [image003.jpg](#)

Thank you for the opportunity to review and comment on the Draft Report About Improving Patient Safety. This response may be considered the organizational response from the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN).

The Draft Report is very thorough and does include brief mentions of the safety work in the neonatal and perinatal spheres of practice, including the formation of perinatal quality collaboratives and reduction of CLABSI in the NICU. There is a large body of intra- and interorganizational patient safety work across the US, including the incorporation of the CUSP and Team Training principles, care bundles, and required safety drills and simulations. We would recommend inclusion of these topics in the tables highlighting the important patient safety work to improve maternal morbidity and mortality. Tables 9, 11 or 15 might include topics such as team training and the application to the obstetric setting or the response to The Joint Commission new Perinatal Care Core Measures that requires simulation and interprofessional training.

Again, thank you for the opportunity to review and comment. Please let me know if there are any questions to our review and recommendations.

Sincerely,

Jean Salera-Vieira, DNP, APRN-CNS, RNC

Director of Clinical Program Development
Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)
1800 M Street, N.W. Suite 740 South Washington, D.C. 20036

t [REDACTED] | e [REDACTED]

-



We are pleased to introduce a new series, "Read Between the Lines: Live FHM Strip Review Series." Expand your clinical skills with these one-hour webinar series featuring leading thought-leaders working in perinatal care. Kicking off the series, the "Understanding the Variable Deceleration" session will take place on February 23, 2020, at 2 pm Eastern. [Register today.](#)

From: Agency for Healthcare Research and Quality (AHRQ) <updates@subscriptions.ahrq.gov>
Sent: Friday, February 12, 2021 4:48 PM
To: Jean Salera-Vieira [REDACTED] >
Subject: AHRQ Views Blog: Comments Welcome on Draft Report About Improving Patient Safety

[Warning!!] This email message is from the external user. Please treat this email with caution when opening attachments or clicking links!

[View as a webpage](#)



AHRQ Welcomes Your Comments

on Draft Report to Congress About Improving Patient Safety

A new AHRQ Views blog post highlights the success of Patient Safety Organizations (PSOs) while encouraging feedback on a draft report to Congress that is intended to accelerate national efforts to keep patients safe from harm. The report, "[Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine](#)," was mandated by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act). Authors of the blog post—Jeff Brady, M.D., M.P.H., director of AHRQ's Center for Quality Improvement and Patient Safety, and Andrea Timashenka, J.D., director of AHRQ's PSO program—describe the unique role of AHRQ-listed PSOs in boosting safety and note that the draft report is aimed at advancing patient safety as a national priority. Comments on the report are due by Feb. 16.

[Read the Full Blog Post](#)



Agency for Healthcare Research and Quality

Subscriber Services:

[Change Your Profile](#) | [Unsubscribe](#) | [Help](#)

Stay Connected:

[Contact Us](#) | [Social Media](#)

From: [PSQIA.RC \(AHRQ/CQuIPS\)](#)
To: [REDACTED]
Subject: FW: Comment on draft "Strategies to Improve Patient Safety"
Date: Thursday, March 18, 2021 12:59:42 PM
Attachments: [pastedImagebase640.png](#)

From: Floyd J. Roberts MD [REDACTED] >
Sent: Thursday, March 18, 2021 10:27 AM
To: PSQIA.RC (AHRQ/CQuIPS) <PSQIA.RC@ahrq.hhs.gov>
Cc: [REDACTED]
[REDACTED]
Subject: Comment on draft "Strategies to Improve Patient Safety"

Thank you for the opportunity to comment upon the current draft of "Strategies to Improve Patient Safety" [Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine \(ahrq.gov\)](#).

[Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine - Home | PSO](#)

Preface . The Secretary of the Department of Health and Human Services welcomes public comment on this draft report on effective strategies for reducing medical errors and increasing patient safety, prepared in

www.pso.ahrq.gov

The document is well done and includes terrific work, reporting, and summaries. However, it seems to be missing a clear focus on what is the true foundational element upon which success in improving the quality, safety, reliability, and equability of patient care depends: Culture of Safety.

The draft is effective in outlining key concepts of Patient Safety Science, but it is weak on the Culture of Safety. A discussion of the role of PSOs in fostering and sustaining a Culture of Safety in participating institutions should lead off Chapter 2 in advance of the sections focused on the current concepts of Patient Safety Science. Without a healthy Culture of Safety, the principles of Patient Safety Science will not find fertile ground to become established, sustained, and bear fruit. The focus on the necessity for organizational leadership to be focused upon and committed to a Culture of Safety should be emphasized. In addition, the protections of the PSQIA that create a non-punitive protective space within the organization

as well as within the wider legal and regulatory milieu is crucial to the long-term goal of attaining High Reliability through an established, robust, and sustained Culture of Safety.

Elsewhere, AHRQ has focused upon Culture of Safety such as in the document [Culture of Safety | PSNet \(ahrq.gov\)](#). However, I do not see that this document is referred to, and I do not see its principles recapitulated in the Strategies to Improve Patient Safety.

There is, in fact, a thread touching upon Culture of Safety weaving through the document as noted below with relevant pages noted:

Learning Health Systems

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. (p ii)

My note here: Learning Systems exist within the framework of an organization's culture and will not be effective unless that culture is in fact a Culture of Safety, where team members feel confident that the reporting of errors or near misses will not subject themselves or co-workers to an unnecessary punitive response. In this Culture of Safety, those who work on the front line come to realize their value as the essential "early warning system" of the Learning System. Once they feel valued within the overall processes, enthusiasm for learning builds, work satisfaction improves, and burnout is minimized.

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 in 2018 concluded that of hospitals that work with a PSO, nearly all (97 percent) find it valuable... the privilege and confidentiality protections (83 percent cited this as very important) (p iii)

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 (p 1)

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. They use evidence-based patient safety improvement strategies and practices such as those presented later in this report; develop new and innovative patient safety improvement approaches; and work one-on-one with individual providers and health systems to tailor the implementation of improvement strategies to their particular needs. 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. (p 7)

Once again, many thanks for the opportunity to comment upon the draft. My request is that Culture of Safety be given a clear and highlighted focus in the document. Such a focus can be very helpful as we continue to develop the necessary commitment to Culture of Patient Safety at the organizational leadership level, without which commitment we have limited hope for success.

FJR

Floyd "Flip" Roberts, MD, FACP, FCCP

Executive Director/Medical Director

Louisiana Alliance for Patient Safety PSO

9521 Brookline Ave. | Baton Rouge, LA 70809

██████████ | Fax: ██████████ | Cell: ██████████ | ██████████



This e-mail message, including any attachments, is for the sole purpose of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

From: [PSQIA.RC \(AHRO/CQuIPS\)](#)
To: [REDACTED]
Subject: FW: Comments on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine
Date: Monday, March 22, 2021 7:38:25 AM

From: [REDACTED] >
Sent: Sunday, March 21, 2021 6:54 AM
To: PSQIA.RC (AHRO/CQuIPS) <PSQIA.RC@ahrq.hhs.gov>
Subject: Comments on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Respectfully, I submit that most of these strategies are hospital-centric. While that is admirable, the reality is that patient care should be viewed as longitudinal not episodic. One of the prime members that should be involved in transitions/handoffs and patient history is the community pharmacist. The report touches very tangentially on this. This setting is key is both patient education related to medication regimens (compliance) as well as physician education as to why a patient may not be able to adhere to a prescribed medication regimen. The community pharmacist, as the liaison between patient and primary care provider, can appropriately question medication regimens and assist patients both in education around appropriately compliance and also helping to obtain medications via grants and at discounted prices.

I urge the committee to address this in future iterations of the report.

Regards,

[REDACTED]

February 16, 2021

Via Electronic Submission: PSQIA.RC@ahrq.hhs.gov

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

RE: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Masimo welcomes the opportunity to provide comments on “Strategies to Improve Patient Safety” draft report. We appreciate your dedication to exploring options and effective strategies for reducing medical errors and increasing patient safety.

Masimo is a global medical technology company that develops and produces a wide array of industry-leading monitoring technologies, including innovative measurements, sensors, patient monitors, and automation and connectivity solutions. Our mission is to increase patient safety, improve patient outcomes and reduce the cost of care.

Preventable medical errors are tragedies that devastate patients, families, providers and consumers. They also cost taxpayers trillions of dollars. In fact, a large percentage of every dollar in healthcare is spent addressing medical errors, making this is an estimated \$1.26 trillion issue. In the United States, numerous Medicare patients will suffer harm or die from a condition acquired during their time in a hospital.

We applaud your goal to accelerate progress in improving patient safety and encouraging the use of effective improvement strategies and urge you to explore the ways that medical technology can keep patients safe.

AHRO’s Patient Safety Research strategy to safely prescribe opioids
The Dangers of Opioid-Induced Respiratory Depression

Prescription opioids can have dangerous side effects, *even when taken exactly prescribed by a physician*. Today, more people die from breathing complications caused by opioid use than from automobile accidents. 97% of deaths caused by opioid-induced respiratory depression are preventable. Further, advanced age, COPD, sleep apnea and obesity increase the risk of death or severe brain damage from opioid-induced respiratory depression.

Recognizing the serious nature of OIRD, the Joint Commission and the Centers for Medicare and Medicaid Services (CMS) have issued alerts to draw attention to OIRD as a national problem and to urge hospitals to take actions to prevent opioid-related adverse events by increasing the frequency of patient monitoring.

Inpatient Dangers: In spite of the calls to address failure to rescue for postoperative respiratory depression, a high percentage of post-surgical patients on opioids are not monitored continuously. This

lack of a systematic approach to prevent failure to rescue from postoperative respiratory depression poses significant patient safety, quality, and cost of care implications.

Continuous physiologic monitoring provides an ongoing picture of the patient's condition rather than typical monitoring by a staff member, which measures only episodically without the ability to trend data. As a result, some early deterioration signals can be missed as they occur between the times that the staff measures the patient's vital signs.

Outpatient Dangers: Opioid analgesics are associated with adverse effects and cause respiratory depression in a significant number of patients, even after they have left the hospital.

Opioids are potent respiratory depressants and can cause shallow and decreased respiration rate and decreased blood oxygen saturation. In older adults with a higher risk of cognitive impairment, opioids may result in further deficiency of cognition and decision making function,ⁱ and there is a risk of death from these drugs due to opioid-induced respiratory depression.ⁱⁱ

Older adults (>65 years old) are more sensitive to the sedating effects of opioidsⁱⁱⁱ and are at increased risk for respiratory depression.^{iv} Further, advanced age, in combination with other risk factors that are common in older adults such as obstructive sleep apnea,^v chronic obstructive pulmonary disease (COPD), chronic kidney disease,^{vi} cardiac disease, and neurological disease^{vii} increase the risk of opioid-induced respiratory depression. Advanced age, coupled with coexisting COPD, necessitates greater vigilance in monitoring older patients who are at greatest risk for serious consequences if respiratory function is compromised from anesthesia and postoperative analgesia.^{viii}

Clinicians face difficult challenges in monitoring patients taking prescribed opioids. Due to concerns regarding post-surgery opioid-related adverse events particularly among older patients, hospitals have integrated risk assessment tools to identify high risk patients and adjust their prescription and/or monitoring efforts, in an effort to minimize the likelihood opioid induced respiratory events and adverse events.^{ix}

Further, over 12 million Americans over age 65 live alone,^x where there may not have an available caregiver to provide medical assistance in emergencies, and major health emergencies can be overlooked as "age-related changes" (general weakness, dizziness, and upset stomach) when in fact the person is experiencing respiratory depression.^{xi} Without someone else in the home or the availability of remote physiologic monitoring, older adults may lack the ability to notify emergency medical assistance.

Fortunately, technology exists today that can meet those challenges by enabling physicians to prescribe the medications that they feel are appropriate to manage pain and keep their patients safe from opioid-induced respiratory depression, catastrophic permanent injury, and death.

Remote Physiologic Monitoring Saves Lives:

Continuous physiological electronic monitoring can save lives. Technology available today will enable seniors to wear a device that can be worn continuously to monitor oxygen saturation, pulse rate, and respiratory rate, transmit that data to a smart phone or remote view station, send alerts based on device alarms through an escalation protocol, and offer healthcare providers to use remote viewing stations that enable real-time monitoring of devices, and communication with device and connected smart phones associated with the device. This alarm system can create a true safety net for elderly patients, with will decrease anxiety and save lives.

Researchers at Dartmouth-Hitchcock Medical Center, over a ten year period, found improved outcomes following installation of continuous postoperative monitoring in a post-orthopedic unit. Specifically, researchers were able to eliminate preventable deaths and brain damage due to opioid overdose in post-surgical units^{xii} as well as reduce rapid rescue events by 60%,^{xiii} ICU transfers by 50%,^{xiv} and cost by an estimated \$7 million annually.^{xv}

This technology can provide earlier identification of a patient's deteriorating condition which will increase the chance of a positive outcome.

In order to ensure that life-saving remote physiologic monitoring technology is available to patients and providers, the federal coverage and reimbursement structure must be sustainable and equitable. In the past, reimbursement policies and restrictions have impeded patient access to available breakthrough remote monitoring technologies. We urge AHRQ to support the elimination of these restrictions and increased coverage and reimbursement of remote monitoring technologies that will increase access, decrease costs, and save lives.

We appreciate the opportunity to share this feedback, and we look forward to working with the Agency for Healthcare Research and Quality on policies to address the challenges we face in keeping patients safe. If you have any questions or would like to address any aspects of our comments, please feel free to contact Kaye Meier at [REDACTED], or via email at [REDACTED].

Sincerely,

[REDACTED]
Paul Ordal
Vice President, Government Relations and Public Policy

ⁱ Schiltenswolf M, Akbar M, Hug A, et al. Evidence of specific cognitive deficits in patients with chronic low back pain under long-term substitution treatment of opioids. *Pain Physician*. 2014;17(1):9-20.

ⁱⁱ Bonnie, Richard J., Morgan A. Ford, Jonathan K. Phillips, The Opioid Epidemic Balancing Societal and Individual Benefits and Risks of Prescription Opioid use; Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse; Board on Health Sciences Policy; Health and Medicine Division; National Academy of Sciences, Engineering and Medicine. 2017. Pg. 54.

ⁱⁱⁱ Reducing Adverse Drug Events Related to Opioids Implementation Guide; Copyright ©2015 by Society of Hospital Medicine. Pg. 25.

^{iv} ACPA Resource Guide To Chronic Pain Management An Integrated Guide to Medical, Interventional, Behavioral, Pharmacologic and Rehabilitation Therapies; 2018 Edition; Pg. 77. https://www.theacpa.org/wp-content/uploads/2018/03/ACPA_Resource_Guide_2018-Final-v2.pdf.

^v Reducing Adverse Drug Events Related to Opioids Implementation Guide; Copyright ©2015 by Society of Hospital Medicine. See also: Lynn LA, Curry JP. Threshold monitoring, alarm fatigue, and the patterns of unexpected hospital death. *APSF Newsletter*. 2011;26(2):32-35.

^{vi} Conway BR, Fogarty DG, Nelson WE, Doherty CC. Opiate toxicity in patients with renal failure. *BMJ* 2006; 332:345-346.

^{vii} Kapil Gupta, Arun Prasada, Mahesh Nagappab, Jean Wonga, Lusine Abraham, and Frances F. Chunga; "Risk factors for opioid-induced respiratory depression and failure to rescue: a review." *www.co-anesthesiology.com* Volume 31; Number 1; February 2018; pg. 115-116.

^{viii} Jarzyna D, Jungquish CR, Pasero C, et al. American Society for Pain Management nursing guidelines on monitoring for opioid-induced sedation and respiratory depression. *Pain Manag Nurs*. 2011;12:118-145.

^{ix} <http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?year=2019&index=15&absnum=1077><http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?year=2019&index=15&absnum=1077>.

^x <https://www.apa.org/monitor/2016/05/numbers#:~:text=12%20million,by%20the%20Pew%20Research%20Center>.

^{xi} ACPA Resource Guide To Chronic Pain Management; An Integrated Guide to Medical, Interventional, Behavioral, Pharmacologic and Rehabilitation Therapies; 2018 Edition. Pg. 11. https://www.theacpa.org/wp-content/uploads/2018/03/ACPA_Resource_Guide_2018-Final-v2.pdf.

^{xii} McGrath S et al. *J Patient Saf*. 2020 14 Mar. DOI: 10.1097/PTS.0000000000000696.

^{xiii} McGrath S et al. *The Joint Commission Journal on Quality and Patient Safety*. 2016 Jul;42(7):293-302.

^{xiv} McGrath S et al. *The Joint Commission Journal on Quality and Patient Safety*. 2016 Jul;42(7):293-302.

^{xv} Taenzler A et al. *Anesthesia Patient Safety Foundation Newsletter*. Spring-Summer 2012.

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](mailto:PSQIA.RC@AHRO/CQuIPS)
Subject: MRI safety is left out
Date: Friday, January 29, 2021 6:05:15 PM

To whom it may concern,

There are multiple safety issues with MRI and they are not discussed.

First I personally am a victim of a full thickness burn on my face from MRI. Burns happen and more than reported.

Second MRI contrast gadolinium is a toxic metal that causes NSF and toxicity to humans, animals and the environment. It causes extreme harm and causes mitochondria damage. The increase in autoimmune disorders are directly related to this toxic metals very frequent use now. I know I have NSF from gadolinium.

Hearing damage is the most common injury because these machines can reach 105 decibels and even with ear protection the vibration can cause hearing loss itself.

Please include MRI and MRI contrast in your safety warning.

Thank

[REDACTED] [REDACTED]

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: MRI Safety
Date: Friday, January 29, 2021 4:00:05 PM
Attachments: [Alternate Fig 1 - FDA MRI Accident Rate Table w 2019 data.jpeg](#)
[minnies logo finalist 150.jpg](#)

Ladies & Gentlemen,

I write to you today to call your attention to an omission within radiology / radiological patient safety practices.

While ionizing radiation exposure has been markedly reduced in diagnostic settings through the effective combination of improved technologies and more informed practices, the same is not true for MRI safety-related risks. Over the past 20 years (concurrent with the marked reduction in ionizing radiation risks from diagnostic medical sources), MRI related risks have increased at rates greater than 2x the rate of utilization increase.

The chart below depicts 20 years of data for both MRI-classified adverse event reports to the US FDA (red line) and total US MRI procedure volume (blue line). To be able to effectively compare these two values over time, this chart uses the year 2000 as a baseline for both, and maps the percentage change from the year-2000 values.



It is also worth noting that the 'red line' data in the chart above only counts adverse events categorized under the FDA's MRI product code (product code "LNH"), and does *not count* adverse events in which an MRI had a negative interaction with another medical device or implant for which the adverse event was classified under the non-MRI medical device / implant (which is the case for nearly all of these negative-interaction events). Said plainly, the number and percentage change of all reported directly MRI-related adverse events, including significant injuries and deaths, is even greater than this "LNH" data indicates in the above. The 'top line' data that quantifies MRI adverse events - as alarming as it is - fails to capture significant number of device interaction adverse events.

MRI hazards, accidents, and injuries have been highlighted in previous ECRI top-10 healthcare hazard lists, FDA alerts and warnings, Joint Commission Sentinel Event Alert #38, multiple guidance documents from the American College of Radiology, and dozens and dozens of academic papers. I am far from the first to highlight this particular patient safety issue. Despite this, throughout the past two decades of MRI safety warnings, alerts, guidances and academic papers, the number of reported adverse events continues to climb!

Studies of causation of MRI injury accidents regularly point to the effectiveness that existing best practices *could have* if they were more widely and consistently adopted. As a professional community radiology has the information to prevent nearly all MRI injury accidents, but the will to do so has been absent.

MRI accidents are on an unsustainable growth-trajectory. There are many contributing factors - from stronger and faster MRI scanners, to vast expansions in the clinical applications of MR imaging (and the patient co-morbidities that have been included in those clinical expansion applications), to greater variety and proliferation of implants with MRI-safety concerns or

contraindications, to cost-reductions and throughput pressures arising from reduced reimbursement rates - to the growth in MRI adverse events. In short, the majority of technical, clinical, patient cohort, and financial changes that have occurred in MRI in the past two decades have all sought to incrementally increase risks to MRI patients.

Adding MRI to the radiological patient safety practices category of the AHRQ report would not only be appropriate based on the distinct and increasing risks the modality presents as compared to the declining risks of ionizing radiation for diagnostic modalities, but the evident 'correct-ability' of MRI injury accidents with existing best practices demonstrates how the added attention from the inclusion within the AHRQ report, alone, could positively affect patient safety.

I implore you to add MRI to your identified list of radiological patient safety practices to direct much needed attention to this correctable problem before another high-profile fatality occurs in the United States. Given the current trajectory, that appears to be more of a question of when, and not if.

If I can provide you with any information to support consideration of the requested action, I would be honored to be of service.

Respectfully,

[REDACTED]

--

[REDACTED]

Mobile: [REDACTED] (USA Central Time Zone)

[REDACTED]



PUBLIC SUBMISSION

As of: December 29, 2020 Received: December 16, 2020 Status: Pending_Post Tracking No. 1k4-9kod-zux3 Comments Due: February 16, 2021 Submission Type: API
--

Docket: AHRQ_FRDOC_0001
Recently Posted AHRQ Rules and Notices.

Comment On: AHRQ_FRDOC_0001-0853
Opportunity to Comment on Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Document: AHRQ_FRDOC_0001-DRAFT-0143
Comment on FR Doc # 2020-27589

Submitter Information

Name: [REDACTED]
Address: [REDACTED]
Email: [REDACTED]
Organization: OCAKABOSCO

General Comment

<http://ocakabosco.simplesite.com>
<http://ocakabosco.eventbrite.com>

From: [REDACTED]
To: [PSQIA.RC \(AHRO/CQIPs\)](#)
Subject: Patient Safety and Quality Improvement Act of 2005 (July 2005) - Public Comment
Date: Tuesday, February 2, 2021 11:49:33 AM
Attachments: [image001.jpg](#)
[image002.jpg](#)
[image003.jpg](#)

Dear Sir / Madam,

Upon review of the most recent PSIA Draft Report it appears that there is no section dealing with proper direction surrounding hospital / medical facility access control / hazard notification standardization recommendations. One example is the Magnetic Resonance Imaging static magnetic field hazard and the inconsistent manner in which healthcare facilities provide notification and process access restriction to the extremely strong and potentially dangerous magnetic field. This magnetic field can not be sensed by anyone accessing the area and reliance for proper notification or access restriction is haphazardly applied. There are other radiation containing locations of medical facilities that would require some direction on this matter as well. Certainly from an infectious control standpoint – proper notification and access control recommendations to surgical areas, etc. would warrant this similar recommendation.

There are automated solutions that address this notification recommendation and access control process management that many facilities have utilized and many more could benefit from. Automated “caution barriers” are recommended by the American College of Radiology – 2020 White Paper on MR Safe Practices – at the entrance to MRI rooms – which could effectively be applied to the other areas of concern raised above. It is critical to provide standardized, preferably automated (to reduce Human Error Factors) methodology to safeguarding patients and untrained or uniformed staff from accessing these unique environments within the healthcare facility.

Best regards,
Joseph Barwick

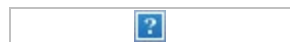
Joseph Barwick

AEGYS FOUNDER

p: [REDACTED]

e: [REDACTED]

[aegysgroup.com](mailto:jbarwick@aegysgroup.com)





April 1, 2021

Dear Secretary Becerra,

Congratulations on your recent confirmation as our newly appointed Secretary of Health and Human Services. We look forward to working closely with you to improve patient safety.

We appreciate the opportunity to provide feedback on the draft report, "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine" and have feedback on the aforementioned report which we hope is helpful as you settle into your new role as Secretary.

We applaud the efforts taken since the establishment of the Patient Safety Act but, even over the past two decades since the "To Err is Human" report was published by the Institute in Medicine, there has been significant effort to improve patient safety and we haven't seen results as quickly as we all hoped. Everyone involved in healthcare truly wants to do the right thing, but despite all of their hard work over the years, preventable medical error continues to harm millions of patients each and every year. For this reason the Patient Safety Movement Foundation is calling for a Patient Safety Moonshot™- ZERO preventable harm and death in healthcare by 2030 - because we've been working on this problem for far too long without a sense of urgency and without meaningful change to our healthcare system, here nationally and beyond. We have several topics we would like to bring to your attention to strengthen the Strategies to Improve Patient Safety.

1. Lack of Safety Data Transparency

Current patient safety data are only estimates of the harm and death patients experience in our healthcare system and we don't really know how many people are affected each year because we don't have an accurate method for measurement. There is no requirement that the frequency and severity of all medical errors, or the resulting patient outcomes, is reported to the public. Organizations and clinicians are often fearful to be transparent with patients and families about medical errors that have occurred due to fear of litigation or blame. Programs like CANDOR which AHRQ has supported have produced positive patient outcomes, saved money, and built stronger health systems. Death certificates do not include "preventable medical error" as either a secondary or primary cause of death, and are solely focused on the diagnosis and the physical causes, such as "cardiac arrest" or "sepsis". A focus on system failures instead of individual blame and transparency of all patient harm and death is key. *The word transparency is only mentioned once in your 51 page report, we believe it deserves much more attention.*

We realize that this report does not address mechanisms for "setting, incentivizing, and/or enforcing compliance with patient safety-related standards or requirements..." as is stated on page 8 of the report. However, we believe they are so crucial to improving patient safety that we would like to share our perspective on how they will greatly impact patient safety.



2. Lack of Region-Appropriate Regulatory Oversight

Regulatory oversight and legislation to improve patient safety has increased in many countries over the past two decades, but is still not sufficient to capture the reporting, investigation, and learning required on a national or regional level. A regulatory authority similar to aviation and transportation safety boards who investigate errors, and government administrations who provide enforcement, is necessary to ensure that organizations truly have safety processes in place and can learn from each other. This type of oversight also helps to support a transparent culture of safety in healthcare. While PSOs are helpful sources of voluntary information the learnings from PSOs have not translated into function effectively together as a “national learning system for patient safety improvement.” So, we are calling for a Federal Healthcare Agency, similar to the Federal Aviation Administration, and a National Provider & Patient Safety Authority, modeled after the National Transportation Safety Board. These agencies will help link disparate data from across all the existing agencies and will establish the structure needed to ensure accountability so that the same adverse events do not continue to reoccur. We would love to work with you to see how we might make this a reality.

3. Misaligned Incentives

There is misalignment between the goals of healthcare organizations, clinicians, payors, and patients. Healthcare is a very patriarchal industry, so care is more clinician-focused than patient-focused. Our current care delivery model was designed to provide care for existing disease, not wellness and prevention of illness. Healthcare organizations and clinicians are generally paid according to the volume of hospitalizations, visits, and procedures completed, rather than by quality and safety patient outcomes. While there has been some success around outcomes like CLABSI and CAUTI these are just the tip of the iceberg. Despite the best intentions of those on the frontline, we will never eliminate harm in healthcare until financial incentives for healthcare organizations are aligned with the needs of the patient. Care and procedures (e.g. hip and knee replacements) are rapidly moving to ambulatory settings where there is no outcomes transparency, reporting or incentives in place to drive quality and safety. The same is true for children’s hospitals. The public has no insight into which of these facilities are safe.

We kindly ask for you to consider how to put even more emphasis on patient and family input and feedback into the system. We also ask for your support in helping to drive reporting outcomes and providing incentives outside of acute care hospitals as the healthcare landscape changes.

Many health care systems, their leadership and boards, are striving to develop high reliability organizations that will provide a safe environment for patients and staff. They have appointed safety officers with safety and quality committees. “Zero Harm” is highlighted on posters and computers to keep it in front of staff and patients. Preventable errors are publicized in these systems and measures put in place to prevent repeated events. Many of these “Best Practices” have been developed by the Patient Safety Movement Foundation and are available to all virtually through educational events. We are seeing local improvements in safety and quality but we need



your help in moving this to a national level where all the preventable errors and solutions are registered in a public database and available to all to review. This transparency must be in place together with incentives to put in place the best practice and penalties if this is not done. We believe the high quality healthcare systems will embrace this action as they truly want to reach Zero Harm and Zero Preventable Deaths but need your help to get there.

We thank you for providing us the mechanism to comment on the draft report and hope that you find our perspectives helpful as you finalize your national strategy. Please feel free to contact us anytime.

Sincerely,

[Redacted signature block]

David B. Mayer, MD
Chief Executive Officer

[Redacted contact information]

[Redacted signature block]

Michael A.E. Ramsay, MD, FRCA
Chairman of the Board

[Redacted contact information]

From: [Timashenka, Andrea \(AHRO/CQuIPS\)](#)
To: [Timashenka, Andrea \(AHRO/CQuIPS\)](#)
Subject: Some feedback re. the draft report
Date: Tuesday, June 22, 2021 10:50:30 AM

From: [REDACTED] >
Sent: Friday, December 18, 2020 10:51 AM
To: Brady, Jeff (AHRO/CQuIPS) [REDACTED] >
Subject: Some feedback re. the draft report

Jeff,

I hope you are doing well.

I just took a quick look at the excellent draft document:

Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

There is a lot of great material in this document. I realize that many aspects of patient safety can be covered in only a cursory manner, even across the current 42 pages of this document. I have a few comments that might be useful as you finalize this draft document.

1. **P. 3**

"In 2014, AHRQ developed the Common Formats for Surveillance (CF-S). AHRQ uses the term "surveillance" in this context to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will facilitate collection of comparable performance data over time and across populations of patients. These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems."

-

I am thinking that you might want to add some language in the CF-S section related to **information that is assembled through concurrent electronic health record data use for measuring and reducing harm.** The terminology "retrospective review of medical records" is a bit confusing. Does it include concurrent/real time electronic health record data mining ala the type of capability that Don Berwick and others argued 3 years ago in the ***Annals of Internal Medicine***?

I am sure you are familiar with that article. The last line in the commentary continues to be as relevant in 2020 as it was when Berwick wrote it in 2017:

“All hospitals should use their EHRs to measure harm and better guide and monitor the real effect of their patient safety efforts.”

[Measuring Patient Safety in Real Time: An Essential Method for Effectively Improving the Safety of Care | Annals of Internal Medicine \(acpjournals.org\)](https://www.acpjournals.org)

Don Berwick was not calling on everyone to do traditional EHR data mining — which suggests highly retrospective analysis and activity — but to use EHR data while patients are receiving care, and to improve in a more timely way. That’s the point.

This also illustrates a nuance the field often misses, namely that retrospective data are not all of equal value. Yes, EHR data that are retrospective by minutes remain highly valuable for *concurrent* intervention, whereas EHR data that are retrospective by weeks or months are not. There is an opportunity for AHRQ to help the field understand that referring only to retrospective versus predictive is a false dichotomy; the third category between the two is concurrent, which is technically retrospective but offers a clinical relevance and utility that traditional safety refers to as “retrospective” (i.e. weeks or months) does not.

Finally, this is not simply a theoretical distinction. Major health systems, including BSWH where I started this work with Pascal Metrics in 2015, have now operationalized EHR-based harm identification and reduction methodologies capitalizing on concurrent intervention and improvement, moving practice well beyond trigger-based research that for many years remained just that. AHRQ would be well served to make sure that the broader health care community understands what is happening in the field.

Surveillance in most contexts connotes a timeliness. If so, this might be better framed as analysis or mining of EHR data, instead of “surveillance.” I am not aware of any health systems that have operationalized this taxonomy and are using it at scale (e.g. dozens of hospitals).

2. **On page 12 “six” program areas are apparently supposed to be listed, but the list includes five (unless 2 are counted within one of the bullets).**

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

- **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”

-

3. P. 17.

“In 2014, AHRQ developed the Common Formats for Surveillance (CF-S). AHRQ uses the term “surveillance” in this context to refer to the improved detection of events and calculation of adverse event rates in populations reviewed that will facilitate collection of comparable performance data over time and across populations of patients.

-

These formats are designed to provide, through retrospective review of medical records, information that is complementary to that derived from event reporting systems.”

I think that admixing automated surveillance of EHRs with these other methods of the assessment of the effectiveness of patient safety improvement efforts might be misplaced.

As you appreciate much better than I do, voluntary reporting systems capture only a very small percentage of all patient safety events. The reality, as Berwick described 3 years ago in the **AIM** article, is that several health care systems are making substantial progress with EHR-based adverse event data mining for operational improvement purposes to reduce patient harm and improve financial performance, not in a research context. As one example, Baylor Scott & White Health (BSWH) has been doing this for more than 5 years since I started this operational improvement work across BSWH with Pascal Metrics in 2015.

The second and third full paragraphs on page 17 do not capture what is happening in the field across large health systems. While it is true that EHR-based methods to generate validated outcomes or the NHSN are used to identify all-cause harm and infections with a high level of fidelity, respectively (PSI-90s have to be done, but would not be chosen to drive operations, absent the reimbursement risk), it is not correct that the utility of EHR-based outcomes are used only to identify the incidence of harm. Health systems using the EHR-based outcomes method identify not only events, but also patterns of harm in the other 95% of events missed by event reporting (i.e. which captures only about 5% of harm based on the evidence). Consequently, providers who are using this method have much expanded opportunity to improve by conducting RCAs on many more events and patterns (of the other 95%) versus conducting RCAs on patterns within the 5% identified by event reporting. This results in a more accurate understanding of the risk of harm and more actionability in reducing the **risk** of harm in a more timely fashion — moving well beyond what long cycles of safety / organizational culture assessments are able to deliver.

Finally, with respect to promoting safety: the optimal approach is to understand what “my” patients are suffering, where, when, how, and at what severity. EHR-based outcomes enable health systems to tailor safety & reliability programs to target just that versus looking to e.g. the Joint Commission to tell us what harm we should focus on this year — which may have no correlation to how my patients are suffering. Targeting and reducing harm that my patients are suffering — and showing progress with reliable data and robust measurement — is one of the best ways to show that we are

serious about patient safety.

Thanks for your ongoing leadership of our national patient safety efforts.

Best wishes,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From: [Amy Bennett](#)
To: [PSQIA.RC \(AHRO/CQuIPS\)](#)
Subject: Strategies to Improve Patient Safety Draft Comments
Date: Friday, February 5, 2021 11:57:53 AM

To Whom It May Concern:

The American Academy of Neurology (AAN), an association of more than 36,000 neurologists and neuroscience professionals, appreciates the opportunity to comment on the draft report, "Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine". The AAN supports the recommendations, and suggests including links to resources for each of the 17 recommendations.

Regards,

Amy Bennett, JD

Pronouns: she/her

Associate Director, Quality Improvement

American Academy of Neurology

201 Chicago Avenue

Minneapolis, MN 55415

Ph: [REDACTED] Fax: [REDACTED]
www.aan.com

Connect with the AAN:

[Facebook](#) | [Twitter](#) | [LinkedIn](#) | [Instagram](#) | [YouTube](#)

AAN 2021 Annual Meeting • April 17-22



[April 17-22 • Register now!](#)

AAN Vision: To be indispensable to our members.

AAN Mission: To promote the highest quality patient-centered neurologic care and enhance member career satisfaction.

Legal Notice: This message may contain confidential or legally privileged information intended only for the use of the addressee(s) named above. Unauthorized use,

disclosure, distribution, or copying is prohibited. If you have received this message in error, please reply to the sender and delete the original message. Thank you.



UnityPoint Health

Government & External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266

February 16, 2021

Marquita Cullom, Associate Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

RE: Strategies to Improve Patient Safety published in Vol. 85 (242) Federal Register 81478-81479 on December 16, 2020.

Submitted electronically via email to PSQIA.RC@ahrq.hhs.gov

Dear Associate Director Cullom:

UnityPoint Health appreciates the opportunity to provide input in response to the Health & Human Services Agency for Healthcare Research and Quality's Strategies to Improve Patient Safety Draft Report to Congress. With more than 400 physician clinics, 40 hospitals, 16 home health locations, 7 Community Mental Health Centers and 4 accredited colleges, UnityPoint Health is one of the nation's most integrated health care systems. Our more than 32,000 employees provide care throughout Iowa, western Illinois, and southern Wisconsin. UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 7.9 million patient visits annually.

UnityPoint Health respectfully offers the following comments.

Strategies to Improve Patient Safety Draft Report

In accordance with the Patient Safety and Quality Improvement Act (Patient Safety Act), the Secretary of Health and Human Services (HHS) seeks comment on the draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report includes measures determined appropriate by the Secretary to encourage the appropriate use of such strategies.

Comment: UnityPoint Health has a strong focus on patient safety and is encouraged to see HHS taking active steps to ensure patient safety across the nation. We agree with the overall concepts addressed in this report and are in support of a national safety committee and safety plan. That said, as a complex integrated health system, we recognize the importance of addressing safety across the continuum of care. UnityPoint Health also recognizes the importance of positive influence on learned behaviors early in clinical training. With this backdrop, **we encourage HHS to consider missed opportunities outlined below.**

The report does not adequately address safety in the ambulatory setting. Research indicates over 12 million Americans suffer a diagnostic error each year in a primary care setting, of which 33% result in serious or permanent damage or death. (*Singh H, et al. The frequency of diagnostic errors in outpatient care. BMJ Qual Saf 2014;23:737-731*) As presented, the report primarily focuses on the hospital setting. Without addressing patient safety in the ambulatory setting, many health care systems risk serious safety events for patients outside the hospital, spanning from misdiagnosis to missed routine care. By merely placing focus on the hospital setting, hefty assumptions are made around the safety of clinics. In fact, it has been noted that more than 30 percent of safety issues for hospital patients originate before admission. (*Kaplan M, The Time Has Come to Improve Safety in Ambulatory Care. IHI 2016*) The risks are potentially greater on the ambulatory side if communication is missed or misdiagnosis occurs.

The report does not address early clinical training for safety. In the academic arena, physicians and clinicians are rarely trained in patient safety core principles, such as just culture and continuous learning and improvement. Since early learning behaviors often occur through this academic procurement, it's vital to build foundations of patient safety into curriculum. By elevating the importance and priority of patient safety in clinical training, learned behaviors begin to form around acceptability and encouragement of reporting safety concerns, risks, and medical errors. This is absent from training programs today and therefore presents challenges in gaining buy-in from providers and clinicians, the workforce vital in making an effective patient safety culture.

The report is unclear on benefits of PSO participation. Participation in a Patient Safety Organization (PSO) needs clear benefits for participants, specifically for organizations already successful in building a strong culture of patient safety. It's clear that interoperability plays an important role in supporting a culture of patient safety and is key to keeping the costs down for such support. However, aside from the National Patient Safety Database, it's unclear how an organization can benefit from PSO participation. A one-size-fits-all approach will be detrimental, as many organizations vary in size, readiness, and resources. Reporting in the PSO database today is burdensome to clinicians, even for organizations with advanced EHR and reporting infrastructure in place. An understanding of how this reporting for clinicians can be made easier will be key to effective adoption. As the Agency for Healthcare Research and Quality (AHRQ) moves towards PSO standards, AHRQ should continue to evolve the resources needed to support data submission and automation.

As an addition to this draft report, we encourage AHRQ to consider expanding focus on the ambulatory and other non-hospital-based settings as well as promoting additional education for physician and clinicians during their academic training. Overall, we strongly urge AHRQ to undertake a thoughtful evaluation of next steps ensuring a plan that does not add more regulations or impose structures, but rather guides a diverse landscape of organizations to success.

UPH is pleased to provide input on this draft report. To discuss our comments or for additional information, please contact Stephanie Collingwood, Government & External Affairs at [REDACTED] or [REDACTED].

Sincerely,

[REDACTED]
Kendra Gustafson, MPA, BSN, RN, CPXP, CPPS
System Executive Director, Clinical Excellence & Safety

[REDACTED]
Stephanie A. Collingwood, CA, Epic Systems Certified
Government & External Affairs Specialist

March 30, 2021

Re: Strategies to Improve Patient Safety: Draft Report to Congress for Public Comment and Review by the National Academy of Medicine

Submitted electronically via: PSQIA.RC@ahrq.hhs.gov

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 18 hospitals with approximately 4,900 staffed beds, 21 outpatient Family Health Centers, 11 ambulatory surgery centers, and numerous physician offices. Cleveland Clinic employs over 4,600 salaried physicians and scientists. Last year, our system cared for 2.4 million unique patients, including 8.7 million outpatient visits and 273,000 hospital admissions and observations.

Cleveland Clinic has embraced a safety culture across the organization, adopting initiatives such as Just Culture Training and High Reliability. The Cleveland Clinic Alliance for Patient and Caregiver Safety Patient Safety Organization (CC APCS PSO) provides an important part of our safety culture framework by applying national peer protections to create a safe place where providers can learn and share patient safety and quality related information. These protections allow Cleveland Clinic to operate as a “learning health system” and to focus on improving systems where errors may occur.

CC APCS PSO has used the national peer protections provided by the Patient Safety and Quality Improvement Act of 2005 to become more collaborative in regards to patient safety activities across state lines and across the healthcare continuum. We regularly convene quality and safety representatives from our Ohio and Florida hospitals to share and discuss outcomes and lessons from safety events. For example, we recently were able to share our experiences regarding a device related issue to all of hospitals within our system to ensure our clinicians understood the issues and what was being communicated to the manufacturer.

CC APCS PSO appreciates the opportunity to comment on the AHRQ’s draft report to Congress, “Strategies to Improve Patient Safety.”

2.4 Assessing the Effectiveness of Strategies: Measurement in Patient Safety

A critical gap we have identified in the report is meaningful discussion around measuring and reducing the magnitude of patient harm in socially vulnerable populations as an overall strategy, not just as it relates specifically to COVID-19. Organizations should be looking at the impact of social determinants of health (SDOH) on patient harm, focusing on health disparity metrics, and working towards achieving health equity. Taking into account SDOH adds much needed contextual information that can influence effective patient safety practices. We recommend explicitly addressing the role and impact of SDOH on patient safety in this report.

3.5.2 Role of the Patient Safety Act and PSOs: Future Directions and Opportunities

CC APCS PSO appreciates the transparency of patient safety data the AHRQ provides via the Network of Patient Safety Databases (NPSD) dashboards. However, CC APCS PSO is very interested in advancing patient safety reporting (both internally and on a national level) by not just determining how often safety events occur but also by aggregating data to assess how events are prevented.

Healthcare providers are all too familiar with the financial and administrative burden that collecting and reporting countless data entail. During a time of so much uncertainty in healthcare, added financial pressures may be unbearable for some institutions. We appreciate the recognition of the need to minimize burden around data submission in the report and look forward to seeing how the NPSD evolves to improve efficiencies in the safety reporting system. We encourage AHRQ to continue collaborating with healthcare providers to improve the NPSD.

We'd like to add that an effective vehicle for improving patient safety reporting is through forums called Safe Tables. A Safe Table provides a protected environment that fosters open and frank discussions on a range of patient safety topics which in turn can encourage more safety reporting. Cleveland Clinic and its PSO are pleased to see the scope of the Safe Tables experience expanded at the national level and eager to contribute through active participation in the AQIPS PSO National Safe Table Committee.

PSOs play a critical role implementing a voluntary patient safety event reporting system by enhancing learning environments and promoting patient safety robustly across the nation. We believe this report serves as vital resource to Congress that underscores the value PSOs have in addressing and improving patient safety.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues and for your consideration of this information. Should you need any further information, please do not hesitate to contact me or Melissa Myers, Senior Director of Policy, at [REDACTED]

Sincerely,

[REDACTED]
Leslie M. Jurecko, MD, MBA
Chief Safety and Quality Officer