

## WHITE PAPER

# National Patient Safety Board

### Abstract

Since the Institute of Medicine's 1999 report *To Err is Human*, it has been known that upwards of 100,000 deaths due to preventable medical errors occur each year.<sup>1</sup> In the twenty years since then, little progress has been made in the way of reducing the number of these deaths and estimates now suggest between 200-440,000 Americans are dying preventably each year.<sup>2</sup> One major component many believe is lacking in the United States is a national agency that focuses on responsibility and accountability for patient safety. The goal of this paper is to explore the value and feasibility of achieving that objective by establishing a National Patient Safety Board, modeled after successful regulation in the aviation industry and lessons learned in the patient safety movement over the past 20 years.

### Introduction

#### The Current State of Patient Safety

Accountability in patient safety is currently handled in the United States by a number of segmented organizations and governing bodies in both the public and private sector. There is no single entity that accounts for or tracks the safety of all patients in the country or tracks death or harm caused by medical error.<sup>2</sup> Two of the main organizations that currently set patient safety standards are The Joint Commission and Centers for Medicare and Medicaid Services (CMS).<sup>3,4</sup> Both of these organizations have power to enforce standards or leverage improvement, but neither focus exclusively on patient safety, so regulations and standards can be diluted in the larger obligations of function.<sup>3,4</sup>

The Joint Commission is a non-profit organization that accredits over 20,000 health care facilities and programs. In order to receive Medicare and Medicaid reimbursements, most state governments require accreditation from The Joint Commission.<sup>3</sup> While The Joint Commission is the main accreditation organization in the United States, there are several others like it, which leads to the issue of fragmented patient safety measures and accountability. Additionally, it has been shown that the accreditation process does not indicate greater patient safety.<sup>3</sup>

The CMS partners with state governments to administer Medicare, Medicaid, CHIP, and health insurance standards. The other responsibilities of CMS include maintaining quality and privacy standards in hospitals, long-term care facilities, and laboratories.<sup>4</sup> While the CMS upholds regulations and mandatory reporting practices, critics believe the organization does not do enough in the realm of patient safety because of its broad scope of responsibilities.

Another concern is the availability of data and reporting systems currently present in the healthcare system. As it is with the problem of accountability, error reporting and data collection is fragmented and uncoordinated across the country. The Centers for Disease Control and Prevention (CDC), a sister agency

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of CMS under the Department of Health and Human Services (DHHS) umbrella, tracks causes of death but does not recognize medical error as a reportable category. The CMS sets rules about what types of occurrences must be reported, but even so there are numerous errors in various types of healthcare facilities that go unreported completely, or are severely underreported.<sup>5</sup> This is also because most of the current reporting systems are voluntary. Hospital reporting systems also vary from organization to organization, capturing only a fraction of the true number of events experienced by patients, estimated as low as 14 percent.<sup>4</sup> Several States also have reporting requirements, which vary from jurisdiction to jurisdiction. Many states also use dated machines and methods of collecting and compiling data on medical error which often, when released publicly, is between 12-24 months old.<sup>4</sup> In combination, these factors lead to a major gap in data collection and understanding of the breadth and possible solutions for preventable medical error.

Another major issue with the current state of patient safety practices is the lack of sharing and access to knowledge regarding preventable medical error. When errors are reported and issues are found within a particular hospital or healthcare facility, the problems investigated and their ensuing solutions are typically shared only with the members of the particular facility or health group where they occurred.<sup>6</sup> Despite over 20 years of calls to action for transparency and heroic efforts to spread knowledge through voluntary learning collaboratives across organizations, lessons learned from medical errors are currently not used systemically or comprehensively as a learning method to prevent further harm and improve patient safety.<sup>6</sup>



## Existing Models

### Strengths and Weaknesses

One effective innovation for tackling patient safety accountability has been developed in the private sector by The Leapfrog Group. A nonprofit organization started 20 years ago by a consortium of large employers, the Leapfrog Group focuses on transparency in healthcare and uses safety and quality data to evaluate facilities using a Safety Grade ranging from A to F. The letter grade evaluations allow consumers to directly review and assess a hospital's level of safety and care.<sup>8,9</sup> This is a major strength of the model, because consumers are able to determine the best facility for their own care. Additionally, The Leapfrog Group is funded by a variety of stakeholders outside of the healthcare industry, including Business Roundtable and The Commonwealth Fund.<sup>8</sup> According to CEO Leah Binder, this transparency model works best because it incentivizes hospitals to earn better Safety Grades in order to attract the most consumers (L. Binder, Aug 04, 2020). Critics point out that The Leapfrog Group underutilize both patients and healthcare professionals in their process.<sup>7</sup> Another challenge is that significant data used to compile its Safety Grade come from CMS, CDC or other government data sources that lag in time, or voluntary surveys that may not completely report all safety and quality related events.<sup>7</sup>

Another existing model is represented by the Agency for Healthcare Research and Quality (AHRQ). The AHRQ is a government agency also under the Department of Health and Human Services (DHHS) umbrella, the mission of which is to compile data and produce evidence to improve the safety and quality of healthcare in the United States.<sup>10</sup> Although the AHRQ has no regulatory power to enforce standards, it oversees the Network of Patient Safety Databases (NPSD), which collects non-identifiable data from Patient Safety Organizations (PSOs) around the country.<sup>12</sup> This model helps track patterns and reoccurring issues in patient safety using aggregate data. In turn, these patterns can be used to learn how to mitigate patient safety risks in healthcare facilities

and reduce patient harm.<sup>12</sup> A major downside of this model however, is that the data is disjointed and difficult to compile because it comes from so many different sources with different data collection systems.<sup>11</sup> Because of this, the trends that are published by the AHRQ are often outdated due to the time it takes to complete analysis. Finally, this model also does not utilize patients and individual consumers in their process.<sup>11</sup>

Two existing agencies that function on a state level are the Pennsylvania Patient Safety Authority (PPSA) and the Oregon Patient Safety Commission (OPSC). The PPSA is an independent state agency that collects information on patient safety events in Pennsylvania healthcare facilities. In Pennsylvania, all incidents of harm or incidents with potential for harm must be reported.<sup>13</sup> Using these reports, the PPSA creates educational material for patients and providers, resources and consultations, and safety alerts for facilities in the state to be made aware of incidents of error and harm.<sup>14</sup> The OPSC functions similarly. It is a semi-independent state agency that collects information on patient safety events in the state and uses reported data to create a learning network to mitigate patient safety risks.<sup>14</sup> The main difference is that reporting is voluntary, not mandatory in Oregon.<sup>15</sup> Although slightly different in their form and structure, the PPSA and OPSC provide a strong model for what a patient safety agency could look like if it were independent but received government funding. The drawbacks of these models is that if reporting is not made mandatory, then many incidents of harm or potential harm may go unreported. Additionally, all reporting comes directly from healthcare facilities with little to no patient reports and representation.<sup>15</sup>

Arguably the best existing safety model for healthcare is regulation of the aviation industry, which is widely credited for effectively managing risk and saving passenger and crew lives. First, the Federal Aviation Administration (FAA) sets standards and regulations for all commercial and private entities to follow. Most of these regulations are federally enforced, with the FAA also providing some suggested guidelines and advisories to further help with safety.<sup>16</sup> The FAA has an Aviation Safety Information Analysis and Sharing (ASIAS) system in place. The ASIAS collects a wide array of data from various sources that are not only electronic and automatic, but in some cases voluntary and from individuals themselves.<sup>17</sup> These data are then broadly shared in order to learn and improve aviation safety. The next layer in aviation safety comes from a source entirely independent from the FAA and Department of Transportation - the National Transportation Safety Board (NTSB). The NTSB investigates safety incidents in aviation, the railroad industry, and ship and marine affairs. The agency uses its findings to make recommendations, create learning materials, and assist victims of accidents.<sup>18</sup> The major strength of the NTSB is that it is an independent agency that focuses primarily on investigating safety incidents and disseminating recommendations and information that can help avoid future mistakes.<sup>19</sup> The model of information analysis and sharing for learning purposes has shown to significantly improve safety. The weakness of the FAA is that it is not entirely independent and is dependent upon Congress for continued support and funding.<sup>19</sup> Another piece of the aviation safety solution is the Aviation Safety Reporting System (ASRS), which creates a pathway for anyone in the industry to confidentially report a "near miss" event or other safety concern and protects reporters from being disciplined. The ASRS was designed and is operated by NASA (National Aeronautics and Space Administration), an independent federal agency that stands at arms length from the FAA and is seen as a neutral 3rd party not influenced by FAA politics or the leverage of the airline industry.<sup>24</sup>

Another informative model is the patient safety infrastructure embedded in the United Kingdom's National Health Service (NHS). The NHS comprises each of the publicly funded healthcare systems of the four countries in the UK.<sup>20</sup> Under the general umbrella of the NHS, England has a National Reporting and Learning System (NRLS). The NRLS is a central database where all patient safety

incident reports are collected and analyzed to identify patient safety risks in order to make improvements.<sup>20</sup> The NRLS data is organized into three official statistic outputs: national patient safety incident reports (NaPSIR), organization patient safety incident reports (OPSIR), and monthly summary data.<sup>20</sup> NaSPIR provides an overview of patient safety along with their characteristics, including the type of incident, type of care facility, and degree of harm.<sup>21</sup> NaSPIR collects data from the largest group of care settings that include dental, mental health, pharmacy, therapy, and optometry services in addition to hospitals, nursing homes, and ambulatory care facilities.<sup>23</sup> The OPSIR clusters organizations by type and allows for comparisons to be made between similar facilities and makes it easier to track trends within each cluster of organizations.<sup>21</sup> Finally, the monthly summaries include timely, key data to encourage consistent reporting. This model's strength lies in the breadth and depth of reporting and data collection, as well as its provision of consistent opportunities for learning with each set of published reports on the NHS website.<sup>23</sup> The main weakness is that although consistent reporting is encouraged by the NRLS, reporting of patient safety incidents is only voluntary for most facilities.<sup>20</sup>



## Creating a National Patient Safety Board

### Challenges

Some of the main challenges in creating a National Patient Safety Board are related to the weaknesses of the existing models previously mentioned. One such challenge is incorporating a variety of stakeholders in the structure of an NPSB, without allowing special interests from any one group to take over. Often there are a few parties left out of the picture with little to no representation, such as patients and families, who have actually experienced harm in a healthcare setting.<sup>1,2</sup> An NPSB must also use data to inform recommendations and investigate incidents of potential harm. However, data collection is difficult to consolidate across the nation due to the wide range of reporting practices, lack of clear reporting guidelines, and outdated and disjointed data collection systems in different parts of the healthcare system.<sup>12</sup> Another issue with data collection is the voluntary aspect of current reporting practices. Many healthcare facilities push for reporting to remain voluntary in order to avoid repercussions of higher reported incidents of harm or potential harm.<sup>11</sup> Without mandatory reporting, data collection cannot be complete and accurate assessments of patient safety risks cannot be made. Finally, the influence of money from healthcare organizations, the government, lobbyists, and policy makers all greatly impact the potential to create an NPSB.<sup>2</sup> The interests of these groups rarely align with optimizing patient safety, because the current system focuses on profits rather than individuals.

### Recommendations

The value of a national patient safety agency based on the aviation model has been discussed rhetorically for more than 20 years.<sup>25</sup>

The Patient Safety Movement Foundation believes that the creation of an independent, transparent, and data-driven National Patient Safety Board could significantly reduce patient harm and preventable deaths in healthcare facilities. The proposed NPSB would be an independent agency that focuses on collecting information on patient safety events, investigating patient harm in facilities, and using findings from data to make recommendations and facilitate learning. We invite other patients, safety advocates and people interested in health policy to join us in assessing readiness and feasibility of the National Patient Safety Board as a solution NOW, rather than waiting another 20 years and experiencing hundreds of thousands more preventable deaths annually while we wait.

The first step in executing an effective NPSB would be to standardize reporting practices. Currently, reporting is only sometimes mandatory, and the agencies that healthcare facilities report to are often different and require different reporting documents and technology.<sup>6</sup> With an NPSB in place, all the different reporting agencies would need to submit required information to the NPSB in order for the data to be compiled.

The data collection and compilation would be the next step in executing an effective NPSB. The NPSB would use up-to-date, available technologies to compile existing data coming from agencies like CMS, The Joint Commission, and state patient safety agencies. Additionally, the NPSB would collect data from facilities and areas that may not currently have mandated reporting practices through another agency, using the standardized reporting practices mentioned above. Patient reporting would also be utilized in data collection practices. This compiled data would then be used to track trends in patient safety and investigate any incidents of serious harm to patients.

Next, the investigation aspect of the NPSB would be very similar to the process used by the NTSB.<sup>13</sup> The NPSB would investigate serious instances of patient harm to determine what mistakes and underlying factors led to an adverse outcome. The healthcare facilities, providers, and medical groups involved would all be part of the investigation to get a thorough understanding of what problems emerged. Based on the findings of an investigation, the NPSB would then move on to the recommendation and learning phase.

After completing the investigation, the NPSB would use the investigative findings to create consumable materials for healthcare facilities, providers, and patients to review. These materials would aim to be transparent in relaying what issues were found in the investigation, without breaching privacy of the entities involved. The NPSB would issue a report on the preventative measures that could be taken in the future to avoid a similar adverse patient safety event. In addition to the report, resource documents for patients and healthcare providers would be made publicly available online. These resources will provide helpful information on how to prevent and avoid adverse patient safety events in the future.<sup>14, 15</sup>



## Acknowledgements

This issue surfaced as a priority idea for the Patient Safety Movement Foundation in January 2019, when we convened a meeting of more than 60 patients, family members and their advocates at our 7th Annual World Patient Safety, Science & Technology Summit. When asked to identify the biggest challenge to progress in patient safety, their overwhelming response was that safety incentives and accountability were fractured because there is no entity in charge. During the summer of 2019 PSMF further engaged this group and others, from the United States and beyond, in a planning effort to think through what a national patient safety agency solution would look like, what it should do and how it could be structured. We take this opportunity to acknowledge all who contributed to that planning process.

This paper and the research behind it would not have been possible without the help of our interviewees. Their enthusiasm, knowledge, and expertise made it possible for The Patient Safety Movement Foundation to thoroughly assess patient safety policy and the potential for creating a National Patient Safety Board.

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## References

1. Institute of Medicine; Committee on Quality of Health Care in America; Kohn L.T., Corrigan, J.M., Donaldson, M.S. (1999, November 29). To Err Is Human: Building a Safer Health System. doi: 10.17226/9728
2. Van Den Bos, J., Rustagi, K., Gray, T., Halford, M., Ziemkiewicz, E., & Shreve, J. (2011, April 01). The \$17.1 Billion Problem: The Annual Cost Of Measurable Medical Errors. doi: 10.1377/hlthaff.2011.0084
3. Roberts, J.S., Coale, J.G., Redman, R.R. (1987, August 21). A History of the Joint Commission on Accreditation of Hospitals. doi:10.1001/jama.1987.03400070074038
4. Hennessy, S., Leonard, C.E., Palumbo, C.M., Newcomb, C., Bilker, W.B. Quality of Medicaid and Medicare Data Obtained Through Centers for Medicare and Medicaid Services (CMS), *Medical Care*: (2007, December) doi: 10.1097/MLR.0b013e318148435a
5. Mattie, A.S., Webster, B.L. Centers for Medicare and Medicaid Services' "Never Events": An Analysis and Recommendations to Hospitals, *The Health Care Manager*: (2008, October-December) Volume 27, Issue 4, p 338-349. doi: 10.1097/HCM.0b013e31818c8037
6. Karsh, B., Escoto, K. H., Beasley, J. W., & Holden, R. J. (2005, September 22). Toward a theoretical approach to medical error reporting system research and design. doi: 10.1016/j.apergo.2005.07.003
7. Galvin, R. S., Scanlon, J. M., Furukawa, M. F., Sepulveda, M. J., Galvin, R. S., Nichols, L. M., . . . O'Malley, A. S. (2005, February). Has The Leapfrog Group Had An Impact On The Health Care Market? Doi: 10.1377/hlthaff.24.1.228
8. Birkmeyer, J. D., & Dimick, J. B. (2004, June 01). Potential benefits of the new Leapfrog standards: Effect of process and outcomes measures. doi: 10.1016/j.surg.2004.03.004
9. Milstein, A., Galvin, R.S., Deblanco, S.F., Salber, P., Buck, C.R. (2000, November-December). Improving the Safety of Health Care: The Leapfrog Initiative. *Effective Clinical Practice*. 6:313-316.
10. Harrison, K., Perrow, C., Reason, J., Weick, K. E., Zohar, D., Frankel, A. S., . . . Olsen, E. (1970, January 01). Multilevel psychometric properties of the AHRQ hospital survey on patient safety culture. doi: 10.1186/1472-6963-10-199
11. Owens, D. K., Lohr, K. N., Atkins, D., Treadwell, J. R., Reston, J. T., Bass, E. B., . . . Helfand, M. (2009, July 11). AHRQ Series Paper 5: Grading the strength of a body of evidence when comparing medical interventions-Agency for Healthcare Research and Quality and the Effective Health-Care Program. doi: 10.1016/j.jclinepi.2009.03.009
12. Fu, R., Gartlehner, G., Grant, M., Shamliyan, T., Sedrakyan, A., Wilt, T. J., . . . Trikalinos, T. A. (2011, April 07). Conducting quantitative synthesis when comparing medical interventions: AHRQ and the Effective Health Care Program. doi: 10.1016/j.jclinepi.2010.08.010
13. Da Silva, B. A., & Krishnamurthy, M. (2016, September 07). The alarming reality of medication error: A patient case and review of Pennsylvania and National data. doi: 10.3402/jchimp.v6.31758
14. Clarke, J. R., Lerner, J. C., & Marella, W. (2007, September 01). The Role for Leaders of Health Care Organizations in Patient Safety. doi: 10.1177/1062860607304743
15. Rosenthal, J., Booth, M. (2004, October). State Patient Safety Centers: A new approach to promote patient safety. *The Flood Tide Forum*. National Academy for State Health Policy.

16. Friedberg, W., Copeland, K., Duke, F.E., O'Brien III, K., Darden Jr., E.B. (1999, December 01). Guidelines and Technical Information Provided by the US Federal Aviation Administration to Promote Radiation Safety for Air Carrier Crew Members, Radiation Protection Dosimetry. Volume 86, Issue 4, 1, p 323-327. doi: 10.1093/oxfordjournals.rpd.a032966
17. Stolzer, A. J. (2009). Aviation Safety Information Analysis and Sharing -- General Aviation (ASIAS -- GA). , (). Retrieved from <https://commons.erau.edu/publication/121>
18. Marcus J.H., Rosekind M.R. (2007). Fatigue in transportation: NTSB investigations and safety recommendations. Injury Prevention. doi: 10.1136/injuryprev-2015-041791
19. Denham, C.R., Sullenberger, C.B., Quaid, D.W., Nance, J.J. (2012, March). An NTSB for Health Care – Learning From Innovation: Debate and Innovate or Capitulate. Journal of Patient Safety. Volume 8, Issue 1, p 3-14. doi: 10.1097/PTS.0b013e3182446c51
20. Aksu, C., & Gunter, S. I. (2002, April 27). An empirical analysis of the accuracy of SA, OLS, ERLS and NRLS combination forecasts. doi: 10.1016/0169-2070(92)90005-T
21. Healey F., Scobie S., Oliver D. (2008, November). Falls in English and Welsh hospitals: a national observational study based on retrospective analysis of 12 months of patient safety incident reports. BMJ Quality & Safety. doi: 10.1136/qshc.2007.024695
22. Howell A.M., Burns E.M., Bouras G., Donaldson L.J., Athanasiou T., Darzi A. (2015, November 15). Can Patient Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National Reporting and Learning System Data. PLoS ONE Volume 10, Issue 12. doi: 10.1371/journal.pone.0144107
23. Mitchell I., Schuster A., Smith K. (2016, January 18). Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human.'BMJ Quality & Safety. doi: 10.1136/bmjqs-2015-004405
24. The National Aeronautics and Space Administration. (2019, July). ASRS - Aviation Safety Reporting System - Program Briefing. [https://asrs.arc.nasa.gov/docs/ASRS\\_ProgramBriefing.pdf](https://asrs.arc.nasa.gov/docs/ASRS_ProgramBriefing.pdf)
25. Hatlie, M. J., & Sheridan, S. E. (2003, July-August). The Medical Liability Crisis Of 2003: Must We Squander The Chance To Put Patients First? Health Affairs. 22:4, 37- 40. doi:10.1377/hlthaff.22.4.37

## About the Patient Safety Movement Foundation

Each year, more than 200,000 people die unnecessarily in U.S. hospitals. Worldwide, 4.8 million lives are similarly lost. The Patient Safety Movement Foundation (PSMF) is a global non-profit on a mission to eliminate preventable patient deaths from medical errors. PSMF uniquely brings patients and patient advocates, healthcare providers, medical technology companies, government, employers, and private payers together under the same cause. From our Actionable Patient Safety Solutions and industry Open Data Pledge to our World Patient Safety, Science & Technology Summit and more, PSMF won't stop fighting until we achieve zero. For more information, please visit [www.patientsafetymovement.org](http://www.patientsafetymovement.org).