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Leveraging Patient Safety Research: Efforts Made Fifteen Years Since *To Err Is Human*

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Abstract

Despite U.S. federal agencies increasing their investment since 1999's release of To Err Is Human, recent reports suggest there is a lack of measurable outcomes in patient safety research. The present study sought to explore the associations between federal incentives of patient safety research and the outcomes from 1995 to 2014, in which the two historical events – the release of To Err Is Human and the American Recovery and Reinvestment Act – were considered in the analysis. We employed Poisson distribution models to provide a longitudinal picture of (1) how the federal incentives drove sponsored research projects; (2) how hot research topics changed over time. Our findings suggested a positive outcome in patient safety research. We also found trending health information technology (HIT) related topics including "natural language processing", "user-computer interface", and "clinical decision support systems" that are prevalent approaches to patient safety research.

Keywords:
Patient Safety, Medical Errors, Quality of Health Care

Introduction

Patient safety is the first priority for healthcare quality. Its significance had been lost for a long period of time in the public and healthcare professions' attention until the release of the Institute of Medicine's (IOM) report *To Err Is Human* on November 29, 1999 [1]. The report disclosed 44,000 to 98,000 patient deaths of medical errors every year. Nevertheless, errors that resulted in patient harm are preventable, to a great extent [2].

Nationwide collaboration is key to patient safety. Immediately after the IOM's report, several collaborations among hospitals, research institutes, and healthcare organizations were called on. Among these collaborations, patient safety research was an integral component [3]. Meanwhile, financial incentives were offered to motivate the systematic study of better understanding patient safety challenges and solutions. At the direction of Congress and the Agency for Healthcare Research and Quality (AHRQ), strategies were made during the first decade since the IOM's report to (1) develop a solid evidence base, (2) develop useful strategies and tools, and 3) implement the strategies and tools. These efforts made notable progress and were highlighted in a number of AHRQ reports and scholarly publications [4,5].

In 2009, the American Recovery and Reinvestment Act (ARRA) became another notable factor that triggered an influx of research awards to spur patient safety research. Because of this economic stimulus, the National Institute of Health (NIH) received a total of $10.4 billion in funds for patient safety research [6].

Despite the federal government and institutions making more investments than ever, there are recent reports on worsening patient safety [2,7]. Most of the critiques come directly from the statistics of patient harm in the hospitals. As of 2013, the annual patient deaths of preventable medical errors increased to 210,000 ~ 440,000 [2]. Patient safety still poses serious challenges nationwide.

Measuring the efforts and progress of patient safety plays a vital role in the framework of patient safety research [8]. A wide variety of measurements have been used for such a purpose, including clinical study, literature review, and survey on patient safety culture [5]. However, there is a missing perspective on how the activities and outcomes of patient safety research changed under the influence of federal incentives. The awareness of such an association is necessary to sustain the improvement of patient safety. Recommended by IOM, patient safety research was included in the national collaboration on enhancing the knowledge about safety and developing tools for reducing medical errors. Among many other efforts, research is one of the most supported efforts by the federal government and stakeholders.

We investigated the activities of patient safety research in the U.S. from 1995 to 2014, which consisted of fifteen years since *To Err Is Human* and five years before it as a baseline. Data of federally sponsored research projects and publications on health sciences were used as the gauge for the national priority, research activities, and outcomes of patient safety [3]. We included two remarkable events, *To Err Is Human* and ARRA, in the data analysis to assess their influence in a longitudinal view. Specifically, we developed Poisson regression models to provide longitudinal pictures of (1) how federal incentives drove sponsored research projects, reflected in the quantity and cost of grants and the quantity of publications; (2) how hot research topics changed over time.

Methods

Data sources

To track federal funding in patient safety research, we used the Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) provided by NIH to download research projects funded by U.S. national institutions. These projects were archived in the ExPORTER format. The data underlying

RePORTER contains detailed information for each project. See Table 1 for a dictionary of the data we used. We retrieved the projects from the fiscal year (Oct. 1 – Sep. 30) 1995 to 2014. Note that data for the cost of projects are not available before 1999. To track the publications affiliated with the sponsored projects, we performed a literature search in the Medline database from 1995 to 2014 via PubMed. To extract hot topics of sponsored patient safety publications, we incorporated MeSH major topics and PMID in the search of RePORTER and Medline.

Table 1 – RePORTER data dictionary

RePORTER Database	RePORTER Entity	Definition
Project Data	Application_ID	A unique identifier of the funded project.
	Activity	A 3-character code identifying the funded project.
	FY	The fiscal year appropriation from which project funds were obligated.
	Project_Terms	Prior to the 2008 fiscal year, terms are assigned by NIH CRISP indexers. From the 2008 fiscal year, terms are mined from the project's title, abstract, and specific aims using an automated text mining tool.
	Project_Title	Title of the funded project.
	Total_Cost	Total project funding from NIH for a given fiscal year.
Project Abstracts	Application_ID	A unique identifier of the funded project.
	Abstract_Text	An abstract of the research being performed in the project.
Publication Link Tables	PMID	A PubMed unique identifier.
	Core Project_Num	An identifier of the research project either cited in the publications' acknowledgements section or reported to have provided support in the NIH Public Access manuscript submission system.

Data analysis

Identification of thesaurus terms related to patient safety

Five domain experts developed a list of thesaurus terms related to patient safety. Thereafter, these terms were used to retrieve sponsored projects on patient safety. The decision-making process took three criteria into account: (1) terms that had been documented to determine the patient safety literature were used as a pool of candidates [3], (2) the NIH Computer Retrieval of Information on Scientific Projects (CRISP) thesaurus (1972 – 1995) were used as a source of candidate terms, and (3) MeSH terms were used to substitute candidate terms identified by criteria (1) and (2) when available. We used CRISP because it was a long-lasting database of NIH funded projects before the implementation of RePORTER in 2009.

Finally, we compiled a list of terms: "medical errors" (MeSH ID: D019300), "medical mistakes" (MeSH entry term of "medical errors"), "surgical errors" (MeSH entry term of "medical errors"), "medication errors" (MeSH ID: D008508), "drug use errors" (MeSH entry term of "medication errors"), "patient safety" (MeSH ID: D061214), "patient harm" (MeSH ID: D064406), "iatrogenic disease " (MeSH ID: D007049), and "diagnostic errors" (MeSH ID: D003951).

Trend analysis: Change of grants in patient safety over time

The trend analysis was intended to disclose the change in the number and cost of patient safety grants over time. Within a timeframe from 1995 to 2014, we assumed two historical events may remarkably impact the trend. The first event denotes the release of *To Err Is Human* in 1999. The second event denotes ARRA enacted in 2009.

Sponsored patient safety projects were retrieved by searching the project data from ExPORTER using the thesaurus terms. Table 1 shows the definitions of the fields in ExPORTER we used. We searched in the selected fields of project data consisting of Project_Title, Project_Terms, and Abstract_Text. A project is labeled as a patient safety project if the text in any of these fields contains one or more terms.

We constructed Poisson regression models to evaluate the trends of grant number and cost in patient safety on a longitudinal scale. In the Poisson regression models, two interventions corresponded to the two events [9]. These models accounted for the instant effect and the lasting effect of the interventions. The model for the number and cost of patient safety grants is:

$$\log(Patient\ safety\ grant\ number\ (or\ cost)) = \beta 1 + \beta 2 * time\ + \beta 3 * intervention1 + \beta 4 * time\ after\ intervention1 + \beta 5 * intervention2 + \beta 6 * time\ after\ intervention2 + e$$

where $time$ denotes the year of a grant; $intervention1$ and $intervention2$ are dummy variables denoting the events of *To Err Is Human* and ARRA, respectively; $time\ after\ intervention1$ denotes the year of a grant since *To Err Is Human*; $time\ after\ intervention2$ denotes the year of a grant since ARRA; $\beta 1 \sim 6$ and e are coefficients.

Trend analysis: Change of publications in patient safety over time

Similarly, we accommodated two historical events in the analysis. In the Medline database via PubMed, we retrieved all articles from January 1, 1995 to December 31, 2014, by specifying the following query:

> "Medical errors"[mh:noexp] OR "Medication errors"[mh:noexp] OR "Patient safety"[mh:noexp] OR "Patient harm"[mh:noexp] AND (("1995/01/01"[PDAT] : "2014/12/31"[PDAT]) AND "humans"[MeSH Terms] AND English[lang])

To model the trend of quantity of patient safety publication, we included the number of Medline documented publications per quarter, obtained from Medline Trend [10], and the number of Medline documented patient safety publications per quarter for analysis. The model is:

$$\log(Patient\ safety\ publication\ number) = \beta 1 + \beta 2 * time\ (quarter) + \beta 3 * intervention1 + \beta 4 * time\ after\ intervention1 + \beta 5 * intervention2 + \beta 6 * time\ after\ intervention2 + e$$

Lag effect

To evaluate the possible lag effect of the number of patient safety publications in acknowledgement of the number of

patient safety grants, we assumed the lag time could be 0 ~ 4 year(s). For example, a 2009 grant would start to show its impact on the number of publications in 2012, which indicates 3 years of lag time. We compared the Bayesian Information Criterion (BIC) by applying these candidate lag times [11]. BIC is a measure of the relative quality of models given the existing data. Higher BIC value refers to a better fit of the model.

Hot topic tracking: Change of MeSH major topics in patient safety publications over time

We identified hot topics of the publications sponsored by funded patient safety projects. The MeSH major topics (i.e., MeSH major headings and MeSH major subheadings) were used to track the hot topics since they were designed to identify focusing research subjects, methodologies, fields of interest, etc. To extract MeSH major topics from the patient safety publications, we followed these procedures: (1) we identified PMIDs of publications associated with the patient safety projects in the RePORTER, (2) we retrieved bibliographical information of these publications by searching the PMIDs in Medline, and (3) we extracted MeSH major topics from the bibliographical data.

Results

Identification of patient safety grants and publications

We identified 3,358 (0.28%) patient safety-related projects in a total number of 1,208,188 documented projects from the RePORTER between the fiscal year 1995 and 2014. We identified 21,441 (0.16%) patient safety publications from 13,278,113 publications documented in Medline between January 1, 1995 and December 31, 2014.

Trend of patient safety grants

Table 2 shows the estimated coefficients of the Poisson regression model are statistically significant, which indicates a good fit of the model to the actual number of patient safety grants.

Table 2 – Model parameters for the number of safety grants

Effect	λ	95% CI	z
Time	0.040	[0.026, 0.054]	5.63**
Intervention1	1.280	[1.129, 1.432]	16.58**
Intervention2	0.158	[0.049, 0.262]	2.83*
Time after intervention2	-0.054	[-0.081, -0.027]	-3.93**

* $p < 0.01$; ** $p < 0.001$

Table 3 shows the estimated coefficients of the Poisson regression model are statistically significant, which indicates a good fit of the model to the actual cost of patient safety grants.

Table 3 – Model parameters for the cost of safety grants

Effect	λ	95% CI	z
Time	0.1870	[0.1870, 0.1871]	13000.00**
Intervention2	0.2434	[0.2432, 0.2436]	2847.02**
Time after intervention2	-0.2173	[-0.2174, -0.2173]	-9578.03**

* $p < 0.01$; ** $p < 0.001$

Figure 1 shows the number of grants reveals an overall ascending trend from 1995 to 2014. We observed two rapid momentums in 1999 and 2009, respectively. A similar pattern was observed on the project cost.

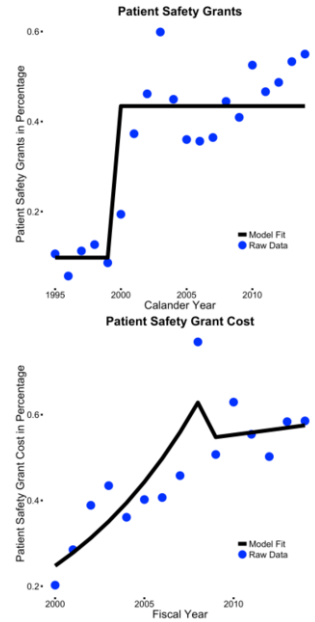

Figure 1 – Trends of patient safety project number (top) and grant cost (bottom)

Furthermore, we categorized the number and cost of awarded projects, respectively, by NIH research award activity codes. Figure 2 shows there is a significant effect on the number of the awarded projects ($F(17,342) = 43.57$, $p < .05$). NIH Research Projects increased by 10.1% ($p < .001$), leading to a significant contribution to the number and cost of the awarded projects.

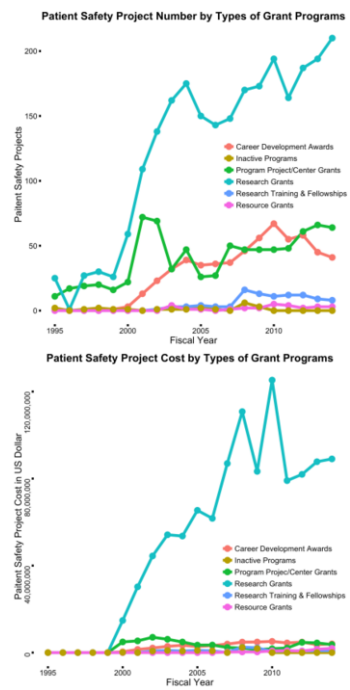

Figure 2 – Trends of patient safety project number (top) and cost (bottom) by NIH activity codes

We presented 24 major MeSH topics that have the highest frequency of occurrences out of 6,472 in total from 1995 to

2014 (see Figure 3). MeSH terms that were used for identifying publications were excluded since they naturally occur in every publication. Due to the limited space, we only demonstrated the hot research topics in 1999 and 2009, respectively, in Table 4.

Figure 3 – Frequencies of hot research topics in the publications of sponsored patient safety projects over time

Table 4 – Examples of hot research topics and frequencies

1999 Hot topics	*f.*	2009 Hot topics	*f.*
Risk Management/ *methods	19	*Safety Management	101
Malpractice/ *legislation & jurisprudence	13	Safety Management/ *organization & administration	93
*Drug-Related Side Effects and Adverse Reactions	10	Safety Management/ *methods	41
Medication Systems, Hospital/*standards	8	*Quality Assurance, Health Care	31
*Quality of Health Care	7	*Attitude of Health Personnel	29
*Clinical Pharmacy Information Systems	6	*Clinical Competence	28
*Truth Disclosure	6	Drug Prescriptions/ *standards	27
*Patient Care Team	6	*Medication Systems, Hospital	24
Nursing Staff, Hospital/*legislation & jurisprudence	6	*Quality of Health Care	24
*Attitude of Health Personnel	6	*Safety	24

The two historical events are associated with the trends of research topics. Notably, we observed an immediate increase of a research topic, "hospital mortality trends", following the release of *To Err Is Human*, suggesting that hospital mortality was one of the earliest research foci since 1999. Immediately following are "adverse drug reaction reporting systems", "needs assessment", "safety management", "quality improvement", "natural language processing", "electronic health records", "medical order entry systems", and "user computer interfaces". Among these topics, health information technology (HIT) related techniques received increasing attention. This finding is in line with the complex origins of HIT-related errors [12,13]. "Natural language processing", "electronic health records", "user computer interfaces", and "medical order entry systems" have maintained a relatively high frequency through the release of ARRA. Research topics such as "quality of healthcare", "computer simulation", and "artificial intelligence" did not show a clear upward trend until the release of ARRA.

Trend of patient safety publications

The estimated coefficients are statistically significant in the model for the number of publications, indicating a fit for the actual data (Table 5). Patient safety publications revealed a similar pattern as compared to the number and cost of patient safety grants, where two rapid momentums were observed in 1999 and 2009 on an ascending trend (Figure 4). The baseline increase was 8.6% by quarter. After the release of the IOM report, patient safety publications instantly increased 11.8% by quarter, and 2.6% thereafter. After the release of ARRA, publications instantly increased 74.5% by quarter, and 0.8% thereafter.

Table 5 – Model parameters for patient safety publications

Effect	λ	95% CI	*z*
Time	1.086	[1.079, 1.093]	24.68**
Intervention1	1.118	[1.035, 1.207]	2.83*
Time after intervention1	0.940	[0.934, 0.947]	-17.99**
Intervention2	1.745	[1.648, 1.848]	18.99**
Time after intervention2	0.982	[0.972, 0.992]	-3.56**

* $p < 0.01$; ** $p < 0.001$

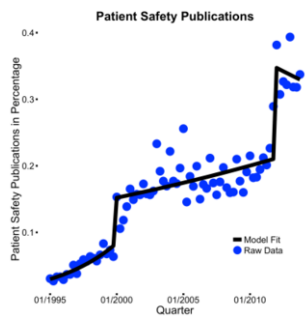

Figure 4 – The trend of patient safety publications

We calculated the BIC for 0 - 4 years of lag time. BIC peaked (BIC = -11.4) when the lag time was 3 years, indicating the trend of patient safety publications has a three-year lag of time as compared to the trend of patient safety grants (Table 6).

Table 6 – Bayesian Information Criterion values

Lag time (year)	0	1	2	3	4	5
BIC	-15.18	-30.37	-13.64	-11.40	-17.26	-13.39

Discussion

Building on a data-driven approach, this study underscores how patient safety research has evolved since 1999. The efforts during the fifteen years since the release of *To Err Is Human* have shown an ascending trend in patient safety research reflected in the volume and cost of federally sponsored projects and scholarly publications. This finding can serve as one of the measurable outcomes that gauges the nationwide endeavor on patient safety research over two decades. It also implies a positive change of priority and cultural attitude toward patient safety. Our findings also confirmed the prominent influence of *To Err Is Human* and ARRA on patient safety research.

The change in topics of patient safety research has provided important insights. One observation is research interests have advanced from the general assessment of preventable medical errors to specific domains (e.g., HIT) that may contribute to errors in the US hospitals. The "hospital mortality trends" was the first topic that caught the researchers' attention since 1999 because hospital mortality rate has been a common measure of healthcare quality. Soon after, researchers started to focus on adverse drug reaction and clinical or patient safety educational needs assessment. Notably, IOM has now identified adverse drug events and medication errors as a national priority in the U.S. [14].

The other observation pertains to the emergence of novel methods. There has been an increasing number of patient safety studies on exploring new knowledge from electronic health records (EHR) [15]. Researchers have identified Human-computer interaction (HCI) as a crucial contributing factor to data quality and data entry during event reporting [16,17]. Natural language processing (NLP) has also emerged in many studies because patient safety event reports consist of considerable free text data [18]. In our view, health informatics is a promising future direction along with new data challenges. Recent studies have shown the application of advanced data analytics, e.g., machine learning, to address the ever-increasing volume of patient safety event reports [19,20].

Our findings need to be discussed in light of limitations. First, our data sources provided only a few facets of patient safety research. *To Err Is Huamn* has led to actions from many governmental agencies and professional groups that were not included in this paper. In 2000, the U.S. congressional hearings directed $50 million funds to establish a patient safety center at AHRQ. Additionally, our study paradigm may be used to gauge efforts on patient safety research in Europe, Asia, etc. when data is available. Secondly, our findings are not intended to explain the latest estimate of increasing patient deaths, between 210,000 and 400,000 [2]. The proliferation of patient safety research and measurable clinical outcomes are separate processes. Nonetheless, we believe the ultimate goal for patient safety research is to reduce preventable deaths. Future studies are needed to investigate the translational outcomes of patient safety research that make measurable changes to patient harm.

Conclusions

We have identified an ascending trend of activities of patient safety research during the 15 years since *To Err Is Human*. We also identified trending research topics in which shifts of research foci, challenges, and future directions were discussed.

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References

[1] L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, To err is human: Building a safer health system, National Academies Press, Washington, DC, 2000.

[2] J.T. James, A new, evidence-based estimate of patient harms associated with hospital care, *J Patient Saf* **9** (2013) 122–128.

[3] H.T. Stelfox, S. Palmisani, C. Scurlock, E.J. Orav, and D.W. Bates, The "To err is human" report and the patient safety literature, *Qual Saf Heal Care* **15** (2006) 174–178.

[4] L.L. Leape and D.M. Berwick, Five years after to err is human: What have we learned?, *JAMA* **293** (2005) 2384–2390.

[5] P.J. Pronovost, M.R. Miller, and R.M. Wachter, Tracking progress in patient safety: An elusive target, *JAMA* **296** (2006) 696–699.

[6] H.R. Clinton and B. Obama, Making patient safety the centerpiece of medical liability reform, *N Engl J Med* **354** (2006) 2205–2208.

[7] J.R. Edwards, K.D. Peterson, Y. Mu, et al., National healthcare safety network (NHSN) report: Data summary for 2006 through 2008, *Am J Infect Control* **37** (2009) 783–805.

[8] P.J. Pronovost, C.A. Goeschel, J.A. Marsteller, et al., Framework for patient safety research and improvement, *Circulation* **119** (2009) 330–337.

[9] D. Posada and T.R. Buckley, Model selection and model averaging in phylogenetics: Advantages of akaike information criterion and bayesian approaches over likelihood ratio tests, *Syst Biol* **53** (2004) 793–808.

[10] A.D. Corlan, Medline trend: Automated yearly statistics of PubMed results for any query, (2004). http://Dan. Corlan.net/Cgi-Bin/Medline-Trend (accessed in 2016).

[11] M.A. Makary and M. Daniel, Medical error - The third leading cause of death in the US, *BMJ* **353** (2016) i2139.

[12] D.F. Sittig and H. Singh, Defining health information technology-related errors: New developments since to err is human, *Arch Intern Med* **171** (2011) 1281–1284.

[13] H. Kang, J. Wang, B. Yao, S. Zhou, and Y. Gong, Toward safer health care: A review strategy of FDA medical device adverse event database to identify and categorize health information technology related events, *JAMIA Open* (2018).

[14] P. Aspden, J.A. Wolcott, J.L. Bootman, et al., Preventing medication errors, National Academies Press, Washington, DC, 2007.

[15] D.F. Sittig and H. Singh, Electronic health records and national patient-safety goals, *N Engl J Med* **367** (2012) 1854.

[16] Y. Gong, H.Y. Song, X. Wu, and L. Hua, Identifying barriers and benefits of patient safety event reporting toward user-centered design, *Saf Heal* **1** (2015) 7.

[17] Y. Gong, Data consistency in a voluntary medical incident reporting system, *J Med Syst* **35** (2011) 609–615.

[18] C. Liang, Patient safety narratives as a key to promoting quality measurement, *J Heal Med Informat* **8** (2017) 2.

[19] C. Liang and Y. Gong, Automated classification of multi-labeled patient safety reports: A shift from quantity to quality measure., *Stud Health Technol Inform* **245** (2017) 1070–1074.

[20] C. Liang and Y. Gong, Predicting harm scores from patient safety event reports, *Stud Health Technol Inform* **245** (2017) 1075–1079.

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