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# Law, Technology, and Patient Safety

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## Recommended Citation

Kathryn Zeiler & Gregory Hardy, *Law, Technology, and Patient Safety*, 68 DePaul L. Rev. (2019)

Available at: <https://via.library.depaul.edu/law-review/vol68/iss2/15>

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# LAW, TECHNOLOGY, AND PATIENT SAFETY

*Kathryn Zeiler\* and Gregory Hardy\*\**

## INTRODUCTION

The Institute of Medicine's frequently cited report, *To Err is Human*, brought to light the high rate of patient injuries from medical errors in hospitals throughout the United States.<sup>1</sup> The report estimated that the number of deaths resulting from medical error in 1997 was as high as 98,000.<sup>2</sup> Despite efforts over the nearly two decades since the report was published, the medical error rate remains a pervasive problem. In 2016, Makary and Daniel ranked medical error as the third leading cause of death in the United States, estimating that approximately 250,000 deaths from medical error occur annually.<sup>3</sup> The Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) estimated that 27% of Medicare beneficiaries experienced adverse events during hospital stays in 2008.<sup>4</sup> Other studies have demonstrated similar adverse event rates in non-Medicare populations.<sup>5</sup>

Various regulatory agencies require reporting of adverse events. The Centers for Medicare and Medicaid Services (CMS), for example,

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1. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000). The report defined "adverse events" as "medical errors resulting in injury." *Id.* at 1–2.

2. *Id.*

3. Martin A. Makary & Michael Daniel, *Medical Error—A Leading (but Hidden) Cause of Death*, 353 *BRIT. MED. J.* 236, 237 (2016).

4. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OEI-06-09-00090, *ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES 15–20* (2010) [hereinafter *ADVERSE EVENTS IN HOSPITALS*]. Approximately 268,000 beneficiaries experienced an adverse event, 13.5% experienced lasting harm, and 13.5% experienced temporary harm. "Adverse event" is defined as "harm to a patient as a result of medical care . . ." *Id.* at i.

5. See David C. Classen et al., '*Global Trigger Tool*' Shows that Adverse Events in Hospitals May Be Ten Times Greater than Previously Measured, 30 *HEALTH AFF.* 581, 581 (2011) [hereinafter Classen et al., '*Global Trigger Tool*'] (reporting that "adverse events occurred in one-third of hospital admissions").

requires participating hospitals to “measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.”<sup>6</sup> About half the states run systems to collect adverse event reports from hospitals.<sup>7</sup>

Adverse event counts using data from such collection and reporting systems are wildly inaccurate. While tracking and reporting is required, compliance relies mostly on providers’ voluntary reports. In addition, sanctions for failing to report adverse events seem to be quite weak.<sup>8</sup>

In 2005, in an effort to reduce adverse event rates, Congress proposed a list of “never events”—adverse events, such as wrong-site surgery, that should never occur in hospitals—and authorized CMS to refuse payment for care required following such events. CMS has since pushed for further regulation, “such as putting more payment at risk, increasing transparency, increasing frequency of quality data reviews, and stepping up media scrutiny.”<sup>9</sup> Evidence suggests these public reporting and pay-for-performance initiatives compel hospitals to manipulate reports, and in some cases patient treatment, to conceal adverse events.<sup>10</sup>

The purpose of this Article is to consider how we might use law coupled with technological advances to increase adverse event count accuracy. On the technology front, three advances are particularly relevant. First, digitization of medical records, billing data, and other sources of germane information has made collecting large amounts of data easier than ever. Second, current adverse event counters employ powerful computer algorithms, and we are likely moving towards detecting adverse events through analysis of large datasets using artificial intelligence. Third, governmental entities have started to team up with computer scientists who use cryptographic techniques to collect sensitive data in ways that protect the anonymity of data producers.<sup>11</sup> We explore how law might harness the power of these technological developments to increase adverse event count accuracy without creat-

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6. 42 C.F.R. § 482.21(a)(2) (2018).

7. Kaitlin Sheedy et al., *2014 Guide to State Adverse Event Reporting Systems*, NAT’L ACAD. FOR ST. HEALTH POL’Y (Feb. 1, 2015), <https://nashp.org/2014-guide-state-adverse-event-reporting-systems/>.

8. See Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 452–53 (2012) [hereinafter Furrow, *Adverse Events and Patient Injury*].

9. *Id.* at 447–49.

10. See *infra* Part II.

11. See *infra* Part III.

ing incentives for providers to hide data or alter treatment practices in harmful or wasteful ways.

Efficiently decreasing adverse event rates is impossible without accurate adverse event counts. Without accurate counts, estimating the costs and benefits of methods that might help lower adverse event rates is difficult.<sup>12</sup> In addition, lack of access to accurate counts makes judging the efficacy of efforts to improve patient safety impossible.<sup>13</sup>

We are not the first to consider legal reforms related to adverse event counts. Since the Institute of Medicine's 2000 report, experts have considered how the law might improve counts. Barry Furrow, for example, has repeatedly suggested that the government mandate hospitals to report adverse events and patient outcomes.<sup>14</sup> Furrow has also argued that payer reimbursements should account for safety performance.<sup>15</sup> Most recently, Furrow proposed a new federal agency to regulate patient safety.<sup>16</sup> Furrow's Patient Safety Commission would mandate safety-data collection, computerized detection tool use, public adverse event disclosure, and compensation for injured patients. Maxine Harrington, on the other hand, has warned that, given data unreliability, patient safety efforts should not focus on adverse event counting.<sup>17</sup> Rather, she suggests shifting our efforts towards mandating practices that have been shown to benefit patient safety, such as monitoring hand washing to decrease the incidence of hospital-based infections. We build on this literature by considering how the law might take advantage of recent technological advances to both improve data reliability and increase patient safety.

The Article is organized as follows. Part I describes current methods used by hospitals, CMS, and researchers to count adverse events. It also attempts to explain the wide disparities in counts produced by

12. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 447 ("Systematic data collection will spur improved safety practices . . . Improved methods of adverse event detection also allow the evaluation of various patient-safety initiatives, reducing their evaluation cost and helping to develop a reliable arsenal of safety tools.").

13. *Id.*

14. Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 *HOUS. J. HEALTH L. & POL'Y* 181, 216–17 (2003).

15. Barry R. Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 *WIDENER L. REV.* 1, 37–38 (2005). *But see* Amy Chaho, *To Pay or Not to Pay: Medicare and the Preventable Adverse Event: A Rational Decision or Dangerous Philosophical Change?*, 22 *J.L. & HEALTH* 91, 134–36 (2009) (disagreeing with Furrow's focus on reimbursement and asserting that cooperation, not coercion through non-payment, is the best means of improving patient safety).

16. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 447–49.

17. Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made a Measurable Difference?*, 15 *HEALTH MATRIX: J. LAW-MEDICINE* 329, 331–32 (2005).

various counting methods. A close look at count disparities illuminates two problems with today's methods. First, the most reliable count estimates are not generalizable. Second, evidence suggests that providers act to shroud true counts, sometimes in ways that put patients at risk. Part II suggests that recent technological advances might make it possible to use law to improve the accuracy of adverse event counts. In particular, we explore the law's possible annexing of three technological advances—digitized patient data, artificial intelligence, and cryptography—to assemble a state-of-the-art adverse events dataset that could make it possible for policymakers, in conjunction with providers, to take well-informed steps towards increasing patient safety. Part III discusses a number of possible hurdles and concludes.

## I. MODERN METHODS FOR COUNTING ADVERSE EVENTS

Since the Institute of Medicine published *To Err is Human* in 2000, policymakers and researchers have worked to improve patient safety in hospitals by developing various systems for estimating the incidence of adverse events throughout the country. These systems vary widely, not only in how they operate, but also in the adverse event counts they produce. This Part explores a number of adverse event counting systems and demonstrates a trend toward accuracy and efficiency in counting.

### A. Hospital Incident Reporting

Incident reporting is the adverse event counting system that hospitals most commonly use.<sup>18</sup> CMS requires all participating hospitals to report adverse events through incident reporting. In 2003, the HHS promulgated a regulation requiring hospitals to implement programs to “track medical errors and adverse patient events,” as a condition of participation in Medicare.<sup>19</sup> The Joint Commission and other hospital accreditors survey hospitals to evaluate compliance with CMS's adverse event reporting standards.<sup>20</sup> Although regulations require hospitals to report adverse events, hospital incident reporting systems are essentially voluntary because they rely on provider decisions about

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18. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 454 (“[Incident reporting] is still the dominant approach in most hospitals.”).

19. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OEI-06-09-00091, HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM 3 (2012) [hereinafter HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM].

20. *Id.*

whether and when to report an injury as one caused by medical error.<sup>21</sup>

Hospital incident reporting systems vary in design and functionality.<sup>22</sup> Many hospitals have no clear standards regarding how and when to document harm.<sup>23</sup> In 2009, HHS's Agency for Healthcare Research and Quality (AHRQ) attempted to address these issues by creating the Common Formats. These guidelines advise providers to report "patient safety events that reached the patient, whether or not there was harm involved."<sup>24</sup> The guidelines also provide a list of adverse events that fall within this definition,<sup>25</sup> and provide guidance about information that reports should include.<sup>26</sup>

Despite these efforts, hospital incident reporting systems are thought to be highly inaccurate. While hospital incident reporting systems estimated that 1% of hospitalizations resulted in an adverse event, in 2011, Classen et al. found that alternate counting methods produce substantially higher counts.<sup>27</sup> In 2012, the OIG found that hospital incident reporting captures a small fraction of all adverse events.<sup>28</sup> The OIG used a sample of 293 adverse events taken from a prior OIG adverse event study.<sup>29</sup> They surveyed the hospitals in which these events occurred to determine which events had been detected

21. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 454 (describing hospital incident reporting as a voluntary system).

22. For example, Hamilton et al. describe two adverse event reporting systems. In the first, providers submit electronic forms to report adverse events to a "risk manager." In the second, providers anonymously fill out handwritten cards, place them in boxes throughout the hospital, and each week, a committee reviews these cards. See Emma C. Hamilton et al., *Are We Missing the Near Misses in the OR?—Underreporting of Safety Incidents in Pediatric Surgery*, 221 J. SURGICAL RES. 336, 337 (2016); see also Donna O. Farley et al., *Adverse-Event-Reporting Practices by US Hospitals: Results of a National Survey*, 17 QUALITY & SAFETY HEALTH CARE 416 (2008).

23. HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM, *supra* note 19, at 12.

24. *Common Formats*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <https://www.pso.ahrq.gov/common> (last visited Mar. 19, 2018).

25. For example, the surgery category lists "[i]ncorrect surgical or invasive procedure" and "retained surgical item" as adverse events that hospitals should report using the Common Formats system. See *Common Formats and Event Reporting - Hospital Version 2.0*, PSO PRIVACY PROTECTION CTR., [https://www.psoppc.org/psoppc\\_web/publicpages/commonFormatsHV2.0](https://www.psoppc.org/psoppc_web/publicpages/commonFormatsHV2.0) (last visited Mar. 19, 2018) (providing links to lists of adverse events detected using the Common formats tool).

26. For example, the Common Formats suggests that hospitals focus on three areas: "information describing the event, information describing the impact on the patient, and summary and contributing factor information." HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM, *supra* note 19, at 5.

27. See Classen et al., '*Global Trigger Tool*', *supra* note 5, at 584.

28. HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM, *supra* note 19, at 12.

29. *Id.* at 7.

by the hospitals' incident reporting systems.<sup>30</sup> They determined that hospitals reported only 14% of the 293 events.<sup>31</sup> Similarly, in 2017, Khan et al. estimated that hospital incident reporting detected approximately 10% of adverse events related to the treatment of hospitalized children.<sup>32</sup> Hospital incident reporting detected only 7 adverse events out of the 71 the researchers detected.

### B. Medicare Algorithms

In addition to developing incident reporting regulations, HHS has explored other strategies for improving patient safety. In 2001, for example, HHS developed the Patient Safety Task Force and charged it with the goal of improving existing patient safety systems.<sup>33</sup> The task force developed the Medicare Patient Safety Monitoring System (the MPSMS), designed as “a national surveillance project aimed at identifying the rates of adverse events within the Medicare population.”<sup>34</sup>

The MPSMS uses algorithms to produce counts. The algorithms are “discrete, self-contained modules” and do not require clinical expertise or opinion.<sup>35</sup> Only events that fall into one of twenty-one event types are counted.<sup>36</sup> For many of the twenty-one event types, including blood infections and pressure ulcers, trained abstractors first use medical chart data to determine if a condition signaling an adverse event was present on admission and therefore, not an adverse event that occurred in the hospital.<sup>37</sup> These are excluded.<sup>38</sup> Next, the ab-

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30. *Id.*

31. *Id.* at 12.

32. See Alisa Khan et al., *Families as Partners in Hospital Error and Adverse Event Surveillance*, 171 JAMA: PEDIATRICS 372, 377 (2017).

33. See David C. Classen et al., *Measuring Patient Safety: The Medicare Patient Safety Monitoring System (Past, Present, and Future)*, J. PATIENT SAFETY, Oct. 20, 2016, at 2, [https://journals.lww.com/journalpatientsafety/Abstract/publishahead/Measuring\\_Patient\\_Safety\\_\\_The\\_Medicare\\_Patient.99576.aspx](https://journals.lww.com/journalpatientsafety/Abstract/publishahead/Measuring_Patient_Safety__The_Medicare_Patient.99576.aspx) [hereinafter Classen et al., *Measuring Patient Safety*].

34. *Id.*

35. See David R. Hunt et al., *Fundamentals of Medicare Patient Safety Surveillance*, in 2 AGENCY FOR HEALTHCARE RESEARCH & QUALITY, ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 105, 114 (James B. Battle et al. eds., 2005).

36. These events include: inpatient falls, pressure ulcers, antibiotic-associated clostridium difficile, bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, femoral artery punctures, contrast nephropathy, mechanical complications associated with central lines, postoperative cardiac events (cardiac surgical cases), postoperative cardiac events (non-cardiac surgical cases), events associated with hypoglycemic agents, events associated with low molecular weight Heparin, events associated with Warfarin, events associated with IV Heparin, postoperative pneumonia, postoperative venous thromboembolic events, events associated with Digoxin, methicillin-resistant staphylococcus aureus, and vancomycin-resistant enterococcus. Yun Wang et al., *National Trends in Patient Safety for Four Common Conditions, 2005–2011*, 370 NEW ENG. J. MED. 341 app. at 7–28 (2014).

37. *Id.*

structors work through a flow chart of questions based on clinical diagnoses and test results from patient chart data to determine which remaining patients experienced adverse events.<sup>39</sup> Unlike hospital incident reporting, the MPSMS is considered an “involuntary” adverse event counting system because it reviews data retrospectively and does not rely on provider reports. This is thought to increase count accuracy.

The AHRQ is currently upgrading the MPSMS. The upgrade will build on the successes of the MPSMS but will incorporate the Common Formats to capture a wider range of harms than the list of twenty-one adverse event types that the system was initially designed to count.<sup>40</sup> The AHRQ is currently testing ways to automate the system.<sup>41</sup>

The MPSMS detects more adverse events than hospital incident reporting. MPSMS’s most recent adverse event count, based on a sample of roughly 33 million discharges from 2014, estimates that 12% of hospitalizations result in an adverse event.<sup>42</sup> In comparison, recall that Classen et al. found that hospital incident reporting estimates that 1% of hospitalizations result in adverse events.<sup>43</sup> The system’s accuracy, however, has not been independently evaluated. Some have called it into question.<sup>44</sup>

### C. Non-Governmental Researcher Methods

Non-governmental researchers have developed their own adverse event counting methods. The Harvard Medical Practice Study reports one of the first counts by academic researchers.<sup>45</sup> The study’s primary purpose was to estimate the percentage of adverse events that resulted in medical malpractice claims.<sup>46</sup> This required estimating the

38. *Id.*

39. *Id.*

40. For example, “[m]ajor additions include additional adverse drug events[,] . . . surgical site infections[,] and . . . obstetric and neonatal adverse events.” See Classen et al., *Measuring Patient Safety*, *supra* note 33, at 6.

41. *Id.*

42. *Saving Lives and Saving Money: Hospital-Acquired Conditions Update*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY 9 (Dec. 2016), <https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/2014finalhacreport-cx.pdf>.

43. See Classen et al., ‘Global Trigger Tool’, *supra* note 5, at 584.

44. See Richard Kronick et al., *Improving Safety for Hospitalized Patients: Much Progress but Many Challenges Remain*, 316 JAMA 489, 489 (2016) (noting that AHRQ’s estimates have not been subjected to peer review).

45. A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 245 (1991).

46. The study defined “adverse event” as harm caused by negligent medical care. *Id.*

number of negligently-caused adverse events that occurred during the period under study among a sample of patients randomly drawn from fifty-one hospitals across the state of New York. The researchers employed a highly labor-intensive data collection method. Specially trained nurses, medical record administrators, and licensed physicians performed detailed, manual reviews of patient medical charts to identify negligently-caused adverse events.

More recent efforts have focused on reducing the labor required to count. In 2003, for example, the Institute for Healthcare Improvement, a non-profit research group, developed the Global Trigger Tool (GTT), a guided chart review counting system based on Classen et al.'s automated adverse drug event detection system.<sup>47</sup> Like the MPSMS, the GTT is an involuntary system and does not rely on provider reports.<sup>48</sup> The system utilizes the expertise of trained nurses, who review information in closed patient charts, including "discharge codes, discharge summaries, medications, lab results, operation records, nursing notes, physician progress notes, and other notes or comments."<sup>49</sup> The information is used to identify "triggers," which are indications that an adverse event may have occurred.<sup>50</sup> If a chart contains a trigger, the reviewers flag it for additional review.<sup>51</sup> During the second stage, reviewers search the patients' records for evidence of unintended harm to determine if an adverse event occurred.<sup>52</sup> A physician must sign off on all identified adverse events.<sup>53</sup>

Some adverse events are easy to identify based solely on diagnoses. For example, diagnosed pressure ulcers, preventable injuries that result from prolonged pressure on the skin, are counted as adverse events if not present upon admission. Other adverse events require looking beyond an initial diagnosis. In some cases, a diagnosis might be followed by a surgical procedure that necessitates follow-up treatment to address avoidable complications. A hip osteoarthritis diagno-

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47. Lee Alder et al., *Global Trigger Tool: Implementation Basics*, 4 J. PATIENT SAFETY 245, 245 (2008).

48. See Classen et al., '*Global Trigger Tool*', *supra* note 5, at 582.

49. See *id.*

50. See *id.*

51. See *id.*

52. Frances A. Griffin & David C. Classen, *Detection of Adverse Events in Surgical Patients using the Trigger Tool Approach*, 17 QUALITY & SAFETY HEALTH CARE 253, 253-54 (2008) ("For example, transfusion of blood products is a positive trigger. If blood loss during or following an operative procedure was within expected limits, then this trigger has not resulted in identification of an adverse event; in contrast, the documentation of extensive intraoperative or postoperative bleeding or an unexpected number of transfusions means that an adverse event has occurred.").

53. See Classen et al., '*Global Trigger Tool*', *supra* note 5, at 582.

sis, for example, might lead to a total hip arthroplasty (or hip replacement).<sup>54</sup> If the patient's medical records indicate a later diagnosis of stiffness or deep periprosthetic joint infection, the records will be flagged for further review.

Unlike the MPSMS, GTT counts are not limited to the closed list of twenty-one adverse event types. The GTT is designed to detect any harm that constitutes an "unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death."<sup>55</sup>

The GTT is thought to be less labor intensive than the methods used in the Harvard Study, and researchers are working to improve efficiency by automating the counting process. The recently developed Risk Trigger Monitoring (RTM) system has been designed to detect adverse events in real time by compiling data extracted from electronic medical records.<sup>56</sup> Like the GTT, the RTM system uses triggers to flag charts.<sup>57</sup> Sammer et al. automated the chart review process, eliminating the need for manual evaluation.<sup>58</sup> RTM continues to require manual review of chart data to determine which triggers indicate hospital-caused adverse events.<sup>59</sup>

In 2011, using the GTT, Classen et al. estimated that 33% of hospital admissions resulted in a serious adverse event.<sup>60</sup> From the study's sample of 795 patient charts from three hospitals, the GTT detected 354 adverse events.<sup>61</sup> This rate is substantially higher than the counts produced by either hospital incident reporting (1%) or the MPSMS (12%).

#### D. What Explains the Variation?

Several factors account for the variations in estimates, including data collection methods, pay-for-performance incentives, populations

54. See e.g., Hans Rutberg et al., *Adverse Events in Orthopedic Care Identified Via the Global Trigger Tool in Sweden – Implications on Preventable Prolonged Hospitalizations*, 10 PATIENT SAFETY SURGERY 23 (2016).

55. FRANCES A. GRIFFIN & ROGER K. RESAR, IHI GLOBAL TRIGGER TOOL FOR MEASURING ADVERSE EVENTS 5 (2d ed. 2009), <http://www.ihl.org/resources/Pages/IHIWhitePapers/IHIGlobalTriggerToolWhitePaper.aspx>.

56. Christine Sammer et al., *Developing and Evaluating an Automated All-Cause Harm Trigger System*, 43 JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 155, 156 (2017).

57. *Id.*

58. *Id.*

59. *Id.* at 157–58.

60. See Classen et al., 'Global Trigger Tool', *supra* note 5, at 584.

61. *Id.* at 583–84 (noting that the three hospitals were all tertiary care hospitals, part of large health systems, and "had developed extensive patient safety programs.").

from which samples are drawn, and varying definitions of “adverse event.”

### 1. *Data Collection Methods*

Hospital incident report estimates are lower than MPSMS and GTT estimates because incident reporting systems are voluntary, while the MPSMS and the GTT are involuntary.<sup>62</sup> Although hospitals participating in Medicare are required to report adverse events through incident reporting,<sup>63</sup> these systems rely on individual providers to report the occurrence of patient harm. Several forces drive provider underreporting. Examples include fear of medical malpractice claims and negative reputation effects,<sup>64</sup> staff misunderstandings about conditions that trigger reporting requirements,<sup>65</sup> the high cost of investigating and reporting,<sup>66</sup> and weak sanctions for failure to report.<sup>67</sup>

### 2. *Pay-for-Performance Incentives*

Pay-for-performance incentives tied to adverse event detection encourage providers to underreport adverse events to optimize patient safety metrics.<sup>68</sup> This sort of manipulation can impact all three types of counts but has the most severe impact on hospital incident reporting and MPSMS counts. Counting methods like the GTT and RTM do not rely on self-reporting and focus on a broader set of adverse events. This makes them more likely to capture events that evade detection by other methods.

Perhaps more concerning, in addition to underreporting adverse events, providers might manipulate the way they practice medicine to

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62. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 454; *supra* text accompanying note 21.

63. See *id.*

64. See Furrow, *Adverse Events and Patient Injury*, *supra* note 8, at 455–56 (observing that communication and resolution programs are designed in part to encourage reporting of adverse events); see also Emily R. Carrier et al., *High Physician Concern About Malpractice Risk Predicts More Aggressive Diagnostic Testing in Office-Based Practice*, 32 HEALTH AFF. 1383, 1389 (2013) (observing that no evidence of changes in reporting practices prompted by these programs exists).

65. HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM, *supra* note 19, at 2.

66. See generally Bonnie B. Blanchfield et al., *The Hidden Cost of Regulation: The Administrative Cost of Reporting Serious Reportable Events*, 44 JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 212 (2018).

67. See FUITOW, *Adverse Events and Patient Injury*, *supra* note 8, at 452–53.

68. See OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., OEI-01-15-00320, CMS VALIDATED HOSPITAL INPATIENT QUALITY REPORTING PROGRAM DATA, BUT SHOULD USE ADDITIONAL TOOLS TO IDENTIFY GAMING 1 (2017) [hereinafter CMS VALIDATED HOSPITAL INPATIENT QUALITY REPORTING PROGRAM DATA].

avoid detection. Examples include both “overculturing” and “underculturing.”<sup>69</sup> Overculturing involves performing unnecessary diagnostic tests to render false positives.<sup>70</sup> A false positive allows a provider to bill for a condition that was contracted in the hospital but falsely diagnosed as present upon admission. Underculturing is the practice of not conducting necessary diagnostic tests throughout hospital stays in order to avoid acknowledging adverse events in billing codes.<sup>71</sup> In some cases, hospital administrators override physician decisions to report adverse events in an effort to avoid financial penalties or detection.<sup>72</sup> Methods that are unable to detect this sort of manipulation will result in lower counts.

### 3. Populations

The MPSMS and GTT use data from different populations that face different health risks. The MPSMS uses data derived from the treatment only of Medicare patients.<sup>73</sup> The GTT, on the other hand, is not limited to these populations. It is, however, severely limited in other ways. Classen et al. drew their sample from the set of “all adults” who received care at three high-quality tertiary care hospitals.<sup>74</sup> Drawing general inferences from data based only on the Medicare population is impossible. Similarly, drawing general inferences from GTT counts is impossible given the high levels of variation across hospitals in quality, types of patients, and types of care provided.

### 4. “Adverse Event” Definitions

All three counting methods define adverse events differently. Not only do hospitals apply a variety of definitions, producing cross-hospital variation, but evidence also suggests that staff members of the same hospital apply varying definitions, which leads to within-hospital variation.<sup>75</sup> Differences in MPSMS and GTT counts likely are at least partly attributable to the use of varying definitions. In addition, while the MPSMS detects harms confined to a list of twenty-one adverse

69. *Id.* at 6.

70. *Id.*

71. *Id.*

72. *Id.*

73. See Classen et al., *Measuring Patient Safety*, *supra* note 33, at 2. Medicare patients include adults over the age of 65, individuals with certain disabilities, and individuals with end-stage renal disease. 42 U.S.C. § 1395(c) (2012).

74. Classen et al., ‘Global Trigger Tool’, *supra* note 5, at 583 (“We randomly selected study patients from all adult (age on admission greater than eighteen years) inpatients . . .”).

75. See CMS VALIDATED HOSPITAL INPATIENT QUALITY REPORTING PROGRAM DATA, *supra* note 68, at 1.

events, the GTT is not limited to this list.<sup>76</sup> The GTT detects any harm that constitutes an “unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death.”<sup>77</sup> Classen et al. suggest that such differences in definition at least partially explain count variation.<sup>78</sup> The GTT’s broader definition of adverse events likely contributes to the system’s higher adverse event estimates.

We turn now to a number of technological advances the law can capitalize on to improve counts.

## II. USING LAW AND TECHNOLOGY TO IMPROVE COUNTS

Part II highlighted two main objectives in our quest for a better counting system. First, we need a way to efficiently collect data that we can use to produce generalizable adverse event count estimates. Second, we need to find a way around unintended, indirect incentives for providers and administrators to avoid adverse event detection. In this Part, we discuss three technological advances policymakers might consider when designing methods aimed at achieving these objectives.

### A. *Electronic Medical Records and Digitized Claims Data*

The use of electronic medical records systems by hospitals and physicians is now widespread.<sup>79</sup> While electronic medical records (EMRs) have been around for some time, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 and the Affordable Care Act led to an increase in the use of EMRs.<sup>80</sup> When an entity moves to participate in Medicare as an Accountable Care

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76. See *supra* text accompanying note 55.

77. Griffin & Resar, *supra* note 55, at 5.

78. Classen et al., ‘Global Trigger Tool’, *supra* note 5, at 586 (“[O]ur study used a broader definition of adverse events and did not require that these events either be judged preventable or lead to major disability, as in prior studies.”); see also J. Matthew Austin & Peter J. Pronovost, “Never Events” and the Quest to Reduce Preventable Harm, 41 JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 279, 282 (2015).

79. Spencer S. Jones et al., *Health Information Technology: An Updated Systematic Review with a Focus on Meaningful Use*, 160 ANNALS INTERNAL MED. 48 (2014); Joseph Conn, *Hospitals Achieve 96% EHR Adoption Rate; Data Exchange Still Needs Work*, MODERN HEALTHCARE (May 31, 2016), <http://www.modernhealthcare.com/article/20160531/NEWS/160539990>; Mathematica Policy Research et al., *Health Information Technology in the United States: Better Information Systems for Better Care* (July 8, 2013), <https://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf406758>.

80. Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 230 (2009); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2702, 124 Stat. 119, 318–19 (2010).

Organization, it is required to coordinate care through EMRs.<sup>81</sup> HHS gives grants to providers to adopt, implement, upgrade, and demonstrate meaningful use of EMRs.<sup>82</sup> While hospitals clearly have not optimized meaningful use, the percentage of practitioners that use them continues to grow.<sup>83</sup>

Hospitals have also made great strides towards digitizing information used to obtain reimbursements from payers (i.e., claims data). Payers, such as private insurers and CMS, require disclosure of a vast amount of information required to verify that goods and services they have promised to cover and billed for have, in fact, been provided to the payers' enrollees. These data include diagnoses; procedures performed; number and type of prescriptions dispensed; patient demographics; and service, admission, and discharge dates.<sup>84</sup> Some states have adopted the use of all-payer claims databases to aggregate claims data that can be used to answer policy and research questions related to cost, quality, and access to medical care.<sup>85</sup>

The move toward digitized information allows for less labor-intensive methods to count adverse events.<sup>86</sup>

### B. Computer Algorithms and Machine Learning

The second important advancement is the use of computer algorithms and machine learning. Computer algorithms allow for automation of otherwise labor-intensive processes.<sup>87</sup> Computers have the

81. Taylor Burke, *Law and the Public's Health: Accountable Care Organizations*, 126 PUB. HEALTH REP. 875, 875–78 (2011).

82. U.S. Dep't of Health & Human Servs., *HHS Awards \$125 Million to Support Community Health Center Quality Improvement* (Aug. 15, 2018), <https://www.hhs.gov/about/news/2018/08/15/hhs-awards-125-million-support-community-health-center-quality-improvement.html>.

83. Eric J. Lammers & Catherine G. McLaughlin, *Meaningful Use of Electronic Health Records and Medicare Expenditures: Evidence from a Panel Data Analysis of U.S. Health Care Markets, 2010–2013*, 52 HEALTH SERVS. RES. 1364, 1378–81 (2017). While the use of electronic medical records is on the rise, the quality of the information in the records and the use of them have been scrutinized. *Id.*; see also Julia Adler-Milstein, *Achieving the Right Balance: Safer Care Through HIT and Avoiding Safety Failures from HIT*, 68 DEPAUL L. REV. 197 (2019); Ross Koppel, *Uses of the Legal System that Attenuate Patient Safety*, 68 DEPAUL L. REV. 273 (2019).

84. *Inventory and Prioritization of Measures to Support the Growing Effort in Transparency Using All-Payer Claims Databases: Data Evaluation of All-Payer Claims Databases*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/apcd/backgroundreport/data.html> (last visited Apr. 2017).

85. Patrick B. Miller et al., *All-Payer Claims Databases: An Overview for Policymakers*, ALL-PAYERS CLAIM DATABASE COUNCIL (May 2010), [http://www.statecoverage.org/files/SCI\\_All\\_Payer\\_Claims\\_ReportREV.pdf](http://www.statecoverage.org/files/SCI_All_Payer_Claims_ReportREV.pdf).

86. See Mindy K. Ross et al., "Big Data" and the Electronic Health Record, 9 INT'L MED. INFORMATICS ASS'N YEARBOOK MED. INFORMATICS 97, 99 (2014).

87. For an application in medicine, see William E. Trick et al., *Computer Algorithms to Detect Bloodstream Infections*, 10 EMERGENCY INFECTIOUS DISEASES 1612, 1619 (2004).

capacity to perform sets of procedures many times faster than humans. Machine learning involves the use of computers to automate discovery of useful patterns in data.<sup>88</sup> These technologies are being put to widespread use in medicine, including in biomedical research,<sup>89</sup> genomic medicine,<sup>90</sup> and cancer diagnosis and detection.<sup>91</sup>

During the last few decades, computer technology has been used to design advanced adverse event detection methods.<sup>92</sup> The Risk Trigger Monitoring System described *supra* is an example of a patient safety tool that has capitalized on both digitization of medical records and computer algorithms. Other researchers are moving towards the use of machine learning-based systems to predict the presence of adverse events caused by the treatment of cardiac conditions.<sup>93</sup> Machine learning has been employed to identify and collect adverse drug events to improve drug safety.<sup>94</sup> Researchers are currently experimenting with IBM's Watson to design a method to detect adverse events stemming from misuse of pharmaceuticals.<sup>95</sup> As described by Chen et al.,

[T]he current capability of Watson to read and extract relationships from text is being applied to pilot research projects in pharmacovigilance. A few research projects with large pharmaceutical companies have involved the application of Watson to reading both published journal articles and adverse event case reports to evaluate whether Watson can assist the drug safety process through faster recognition and coding of adverse events out of text. In this case, Watson may be used to augment existing drug safety personnel

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88. SHAI SHALEV-SHWARTZ & SHAI BEN-DAVID, UNDERSTANDING MACHINE LEARNING: FROM THEORY TO ALGORITHMS 22 (2014).

89. Andreas Holzinger & Igor Jurisica, *Knowledge Discovery and Data Mining in Biomedical Informatics: The Future Is in Integrative, Interactive Machine Learning Solutions*, in INTERACTIVE KNOWLEDGE DISCOVERY AND DATA MINING IN BIOMEDICAL INFORMATICS: STATE-OF-THE-ART AND FUTURE CHALLENGES 1–18 (2014).

90. Michael K. K. Leung et al., *Machine Learning in Genomic Medicine: A Review of Computational Problems and Data Sets*, 104 PROC. IEEE 176 (2016).

91. Joseph A. Cruz & David S. Wishart, *Applications of Machine Learning in Cancer Prediction and Prognosis*, 2 CANCER INFORMATICS 59, 69 (2006).

92. David W. Bates et al., *Detecting Adverse Events Using Information Technology*, 10 J. AM. MED. INFORMATICS ASS'N 115, 116 (2003); Barry R. Furrow, *Searching for Adverse Events: Big Data and Beyond*, 27 ANNALS HEALTH L. 149, 150 (2018) (discussing the use of modern data analysis and adverse event detection tools in liability claims).

93. Evanthia E. Tripoliti et al., *Heart Failure: Diagnosis, Severity Estimation and Prediction of Adverse Events Through Machine Learning Techniques*, 15 COMPUTATIONAL & STRUCTURAL BIOTECHNOLOGY J. 26, 35 (2017).

94. Harsha Gurulingappa et al., *Extraction of Potential Adverse Drug Events from Medical Case Reports*, 3 J. BIOMEDICAL SEMANTICS 15 (2012).

95. Ying Chen et al., *IBM Watson: How Cognitive Computing Can Be Applied to Big Data Challenges in Life Sciences Research*, 38 CLINICAL THERAPEUTICS 688, 696 (2016).

to speed their work and support timely reporting of adverse events to U.S. and European regulatory agencies.<sup>96</sup>

While researchers have come a long way in the use of technology to detect adverse events, their results are not especially useful for regulators tasked with generating comprehensive counts. The most obvious problem is the lack of generalizability. Researcher results cannot be used to estimate the total number of adverse events, even within a subspecialty of medicine or within a geographic region. Research studies generally collect data from a small number of providers, oftentimes just one, and from narrow geographic areas. Given variation in patient populations, treatment methods, and levels of medical care provided by hospitals from which samples are drawn, attempting to generalize from the results of research studies is futile.

Although regulators are unable to generalize from the results of published studies, they are able to put to use the methods that researchers employ to detect and count adverse events. Despite researcher adoption of recent technological advances, however, regulators generally continue to use hospital incident reporting systems that rely on voluntary disclosure to produce comprehensive adverse event counts.<sup>97</sup> These counts are highly unreliable given the system's voluntary nature. Hospitals might be reluctant to report all adverse events out of fear of facing medical malpractice claims or hits to their reputations. Weak sanctions for underreporting make matters worse. Misunderstandings about reporting requirements might at least partially explain the low counts.

To avoid these issues, regulators should move away from relying on regulated entities' self-reports. Ideally, external counters should be given access to all necessary data to detect and count adverse events and make use of technological advances to efficiently wade through the undoubtedly vast amounts of information. This is not all that is required, however. HHS's experience with provider reactions to their counting methods—specifically, provider changes in diagnosis and treatment methods designed to artificially reduce adverse event counts—illuminates the need to address predictable data manipulation behaviors.

The following Section introduces a third technological advance and argues that it can be used to weaken incentives to underreport and to otherwise game the system while, at the same time, change patient

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96. *Id.*

97. A counterexample is Medicare's use of technology to detect never events. These counts, however, cannot confidently be used to generalize to non-Medicare and Medicaid populations.

safety regulatory culture from one emphasizing negative reinforcement to one focused instead on collaboration.

### C. *Cryptography*

Most recently, policymakers have started to take advantage of technological advancements in cryptography to collect sensitive data in ways that protect the anonymity of entities that submit the data.<sup>98</sup> Results are produced using data sent over the web by entities that are allowed to remain anonymous. The technology not only protects submitter identities but can also ensure that the data never leave the submitters' computer servers. Extractors receive only aggregated information that is untraceable to any submitter. Web-based secure multi-party computation allows information from multiple submitters to be combined to produce results while ensuring that none of the information can be tracked back to any particular submitter.

Regulators are already making use of this technology in other arenas. In 2014, then-Mayor Thomas Menino created the Boston Women's Workforce Council. By 2016, the Council had secured more than 50 employers as signatories to the 100% Talent: The Boston Women's Compact (Compact).<sup>99</sup> As part of the agreement, the companies' CEOs promised to provide wage data that would be used to produce a report on the wage gap. Inside legal counsel and human resources personnel, however, advised against it due to concerns over revealing payroll data. Working with researchers, the Council proposed the use of secure multi-party computation to gather the data. Following a pilot run, in 2016, the Council was able to convince 69 Boston employers employing over 112,000 workers to sign on to the Compact and to make their data available for aggregation by the computation program.<sup>100</sup> Unsurprisingly, the invisible data revealed a gender gap. Covering 114 employers and nearly 167,000 workers, the 2017 report revealed not only a gender wage gap but also a race wage gap.<sup>101</sup> While it is impossible to verify the gap estimates, these early efforts have helped to shine light on the issue and to get employer

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98. Andrei Lapets et al., *Web-based Multi-party Computation with Application to Anonymous Aggregate Compensation Analytics* (Aug. 15, 2015) (Technical Report BUCS-TR-2015-010), <https://www.cs.bu.edu/techreports/pdf/2015-009-mpc-compensation.pdf>.

99. Andrew Thurston, *Calculating Gender Pay Equity in Boston*, MEDIUM (July 12, 2016), <https://medium.com/boston-university-pr/calculating-gender-pay-equity-in-boston-dcc00607e0d1>.

100. *Boston Women's Workforce Council Report 2016*, BOSTON.GOV, [https://www.boston.gov/sites/default/files/bwwc\\_report\\_final\\_january\\_4\\_2017.pdf](https://www.boston.gov/sites/default/files/bwwc_report_final_january_4_2017.pdf) (last visited Nov. 20, 2018).

101. *Boston Women's Workforce Council Report 2017*, BOSTON.GOV, [https://www.boston.gov/sites/default/files/document-file-01-2018/bwwc\\_2017\\_report.pdf](https://www.boston.gov/sites/default/files/document-file-01-2018/bwwc_2017_report.pdf) (last visited Nov. 20, 2018).

leadership into the same room to collaborate about ways to make progress towards eliminating the gaps.

This technology might prove useful in moving us towards the collection of more accurate data on adverse events arising from medical care. We know of no instances of regulators using anonymous data collection techniques to collect adverse event data.<sup>102</sup> Researchers, however, have started to do so.<sup>103</sup> White et al. accepted anonymously reported adverse events data when studying injuries caused by acupuncture.<sup>104</sup> Suresh et al. took steps they claimed ensured anonymity by collecting data related to medical errors made giving neonatal intensive medical care using an Internet-based system.<sup>105</sup> They did not collect information about the reporting individual, and they ensured that “no record of the IP address of the submitting computer was stored at the central reporting site.”<sup>106</sup> Seiden and Barach developed an anonymous Internet-based reporting site to collect data on injuries caused by “[w]rong-side/wrong-site, wrong-procedure, and wrong-patient errors. . . .”<sup>107</sup>

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102. Some have argued the benefits of allowing health care providers to report adverse events anonymously. See, e.g., Bill Runciman et al., *Improving Patients' Safety by Gathering Information*, 323 BRIT. J. MED. 298, 298 (2001). The U.S. Veterans Health Administration explored but finally abandoned an anonymous adverse event data collection that was modeled after a system designed by the National Aeronautics and Space Administration. See William B. Weeks & James P. Bagian, *Developing a Culture of Safety in the Veterans Health Administration*, 6 EFFECTIVE CLINICAL PRAC. 270, 273–74 (2000); Debbie Chase & Douglas McCarthy, *Case Study: Sustaining a Culture of Safety in the U.S. Department of Veterans Affairs Health Care System*, COMMONWEALTH FUND, <https://www.commonwealthfund.org/publications/newsletter-article/case-study-sustaining-culture-safety-us-department-veterans-affairs> (last visited Jan. 20, 2019). Government agencies have funded research projects that study anonymous reporting systems. See Wilson D. Pace et al., *Database Design to Ensure Anonymous Study of Medical Errors: A Report from the ASIPS Collaborative*, 10 J. AM. MED. INFORMATICS ASS'N 531, 531 (2003). In 2005, Congress passed the Patient Safety and Quality Improvement Act, 42 U.S.C. § 299b-21 *et seq.*, to provide “legal protections around reporting and analysis of patient safety events when reported” which ensures confidentiality but not anonymity. Peter L. Elkin et al., *Improving Patient Safety Reporting with the Common Formats: Common Data Representation for Patient Safety Organizations*, 64 J. BIOMEDICAL INFORMATICS 116, 117 (2016).

103. Private actors have also made use of this approach. See e.g., Paul Conlon et al., *Using an Anonymous Web-Based Incident Reporting Tool to Embed the Principles of a High-Reliability Organization*, in 1 AGENCY FOR HEALTHCARE RESEARCH & QUALITY, *ADVANCES IN PATIENT SAFETY: NEW DIRECTIONS AND ALTERNATIVE APPROACHES* 1, 5 (Kern Henriksen et al. eds., 2008).

104. Adrian White et al., *Adverse Events Following Acupuncture: Prospective Survey of 32 000 Consultations with Doctors and Physiotherapists*, 323 BRIT. J. MED. 485 (2001).

105. Gautham Suresh et al., *Voluntary Anonymous Reporting of Medical Errors for Neonatal Intensive Care*, 113 PEDIATRICS 1609 (2004).

106. *Id.* at 1610.

107. Samuel C. Seiden & Paul Barach, *Wrong-Side/Wrong-Site, Wrong-Procedure, and Wrong-Patient Adverse Events*, 141 ARCHIVES SURGERY 931, 934 (2006).

Regulator use of anonymous data collection techniques could generate a number of positive side effects. For example, anonymity might encourage collaborative approaches to reducing the number of adverse events that occur in hospitals.<sup>108</sup> More importantly, though, the promise of anonymity might reduce potentially harmful forms of data manipulation. Providers generally assume that adverse events reflect poorly on them and could potentially harm their reputations and possibly hurt their bottom lines. When data can be traced back to the source, providers have incentives to choose to withhold information to avoid detection of adverse events.

In addition, and perhaps more troubling, evidence suggests hospitals employ a number of tactics to avoid adverse event detection. As discussed *supra*, both overculturing and underculturing expose patients to potential harm and increase the cost of care. To the extent unnecessary diagnostic tests increase the risk of harm to patients, overculturing increases the number of injuries. Underculturing is also potentially harmful. For example, when hospitals avoid diagnostics to get around reporting requirements related to hospital-acquired infections, doctors treat conditions in the absence of important information. Consequently, doctors prescribe broad-spectrum antibiotics, which might lead to negative social outcomes such as antibiotic resistance.<sup>109</sup>

Providers might react to mandated information disclosure in other sorts of perverse ways. Some argue that adverse event reporting requirements compel providers to cherry-pick patients. Rubin, for example, suggests that evaluating physician quality based on patient outcomes generates incentives to turn away patients based on socioeconomic status or health issue complexity.<sup>110</sup> This sort of reaction to reporting requirements might put the most vulnerable patients at risk.

Others point to “upcoding” as a possible response. Bastani et al. employ a clever identification strategy to measure the prevalence of upcoding in Medicare claims reporting.<sup>111</sup> They define “upcoding” as “the practice of biasing claims reports towards higher-paying diagno-

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108. Harrington, *supra* note 17, 376–77 (suggesting that more collaborative methods might increase the efficacy of patient safety initiatives).

109. See CMS VALIDATED HOSPITAL INPATIENT QUALITY REPORTING PROGRAM DATA, *supra* note 68, at 6.

110. Rita Rubin, *How Value-Based Medicare Payments Exacerbate Health Care Disparities*, 319 JAMA 968, 969 (2018).

111. Hamsa Bastani et al., *Evidence of Upcoding in Pay-for-Performance Programs 1–4* (July 13, 2015) (Research Paper) (on file with Stanford University Graduate School of Business), <https://www.gsb.stanford.edu/faculty-research/publications/evidence-upcoding-pay-performance-programs>.

ses, rather than taking steps to reduce the true rate of [hospital acquired conditions],” a category of adverse events defined by Medicare. Bastani et al. find evidence that, in Medicare billing data, physicians classify infections acquired in the hospital as present-upon-admission to avoid taking a hit on reimbursement from Medicare for medical care necessary to treat an adverse event.

Some have reported evidence of early discharge of hospital patients to avoid financial penalties triggered by adverse events. For example, Andrew Ryan discusses provider decisions to discharge patients as soon as possible after admission to avoid getting penalized for an adverse event, such as a hospital-borne infection.<sup>112</sup> Research suggests that hospitals discharged a large number of patients too early, only to readmit them shortly after. Readmission triggers another Medicare reimbursement, a profitable outcome for the hospital. When Medicare discovered that its penalty structure resulted in increased costs, it instituted a penalty for readmissions within thirty days of discharge.<sup>113</sup>

While it might be possible to develop ways to detect manipulation, any detection method will be costly and likely not foolproof given the methods providers use to avoid detection. Anonymous data collection along with a collaborative approach to error reduction might soften or even eliminate incentives to manipulate the data.

### III. DISCUSSION AND CONCLUSION

We argue that regulators should consider taking advantage of three recent technological advances to improve health care quality: (1) the shift of the industry towards implementing electronic medical records and claims data, (2) the use of algorithms and machine learning, and (3) the use of cryptography to protect the identities of entities that disclose sensitive information. Although electronic data and machine-driven automation currently are making it easier to collect information about adverse events, non-anonymous data collection techniques have been found to encourage providers to manipulate the data and, more importantly, to provide substandard medical treatment. The addition of cryptography to ensure anonymity might lead to more accurate counts and overall better information about medical errors. Better information, coupled with a more cooperative approach to solutions, holds promise as an avenue to improved patient safety.

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112. Andrew M. Ryan, *Improving Patient Safety Through Policy: Is Payment Reform Up to the Task?*, 68 DEPAUL L. REV. 333 (2019).

113. Julia James, *Medicare Hospital Readmissions Reduction Program*, HEALTH AFF. (NOV. 12, 2013), <https://www.healthaffairs.org/doi/10.1377/hpb20131112.646839/full/>.

Our proposal is not free from potential hurdles. Three hurdles are worth mentioning. First, the U.S. Supreme Court recently held that the Employee Retirement Income and Security Act (ERISA) limits the ability of state regulators to require self-insured insurance plans to disclose claims data—presumably anonymously or otherwise.<sup>114</sup> Prior to the Court's decision, sixteen states required all payors, including private insurers, to report claims data for purposes of gathering information on medical care utilization and spending. These states can no longer require self-insured employer plans to disclose their claims data. These self-insured employer plans constitute over 60% of private health insurance plans.<sup>115</sup> To the extent that collecting claims data from insurers as opposed to providers is optimal, *Gobeille* erects a hurdle for states hoping to gather a complete set of information from insurers. Two developments, however, suggest the hurdle might not be a major cause for concern. First, the Court's ruling cannot prevent the U.S. Department of Labor from mandating information disclosure, and there has been some movement in this direction.<sup>116</sup> Second, some insurers continue to disclose data even though states can no longer require them to do so.<sup>117</sup> It's quite possible that voluntary participation might spur more cooperative problem-solving by industry actors.

A second potential hurdle is the questionable usefulness of anonymously gathered data. While anonymity might dampen the reluctance to hand over data, regulators will not be able to determine which providers have the highest incidence of medical errors, experience increases in medical error rates, and cause the most serious types of harm to patients. This makes it impossible to target regulations designed to decrease errors to specific providers. Despite this, the collection of anonymous data will generate more efficient targeting of resources by allowing the tracking of aggregate time trends, the study of effects of state or regional interventions, the development of protocols to reduce medical error rates, and the analysis of costs and benefits. In addition, to the extent that anonymity helps to move the industry towards a more cooperative stance, tying errors back to particular providers is unnecessary. Relative to current data collection

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114. *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 946 (2016).

115. Gregory D. Curfman, *All-Payer Claims Databases After Gobeille*, HEALTH AFF. BLOG (Mar. 3, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170303.058995/full/>; see also Edward A. Zelinsky, *ERISA Preemption After Gobeille v. Liberty Mutual: Completing the Retrenchment of Shaw*, 34 HOFSTRA LAB. & EMP. L.J. 301 (2017).

116. Curfman, *supra* note 115.

117. *Id.*

methods, which have yet to prove successful in decreasing medical error rates, anonymous data collection has some promise.

A third hurdle is the possibility that data manipulation might continue despite anonymity. To the extent that reporters do not trust the promise of anonymity or continue to be driven by incentives to get regulators off their backs, promised anonymity might not succeed in wringing data manipulation out of the system. This, of course, is most problematic when the methods of manipulation put patients at risk. Regulators, however, can take additional steps to dampen incentives to manipulate. First, they can use the data in ways that encourage desirable behavior. Formulating regulations to function as carrots instead of sticks might be one way to achieve this. Second, regulators can take steps to facilitate cooperation by industry actors in the search for solutions. The city of Boston's success in facilitating cooperative efforts to reduce the gender wage gap provides a useful model.<sup>118</sup>

The time seems right for a paradigm shift in the regulation of medical errors. Traditional methods grounded in mandatory information disclosure have failed to deliver. Technological advances hold promise for moving us in a new direction.

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118. See *supra* notes 99–101 and accompanying text.

