Annals of Health Law

Volume 27
Issue 2 *Summer 2018*

Article 5

2018

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Barry R. Furrow

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Recommended Citation

Barry R. Furrow *Searching for Adverse Events: Big Data and Beyond*, 27 Annals Health L. 149 (2018).
Available at: https://lawecommons.luc.edu/annals/vol27/iss2/5

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Searching for Adverse Events: Big Data and Beyond

Barry R. Furrow[*]

INTRODUCTION.

Big Data is coming to health care, albeit slowly.[1] The widespread diffusion of electronic health records into the health care industry means that huge quantities of data can now be generated and stored in data warehouses for use.[2] The benefits of data analytics are potentially groundbreaking for the health care industry.[3]

First, the ability to identify high-risk patients may reduce emergency department costs by using predictive analytics to reduce the number of ER visits by identifying high-risk patients and offering them customized, patient-centric care.[4]

Second, hospitals can use predictive analytics to analyze admission rates over short periods, thereby assigning staff based on those predictions to allow for more accurate and cost-effective staffing.[5] This will reduce hospital costs and waiting times and yield immense benefit to a high-cost, low-margin industry.[6]

Third, big data analytics can prevent and protect healthcare institutions from the risks of security breaches and fraud; the healthcare industry is particularly vulnerable to increased attacks, given the value of patient personal data.[7] The healthcare industry is particularly vulnerable to increased attacks, given the value of patient personal data.[8]

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* Professor of Law and Director, the Health Law Program, Thomas R. Kline School of Law at Drexel University. I would like to thank my research assistant Elizabeth Bertolino for her able research assistance on this article.

1. Ryan Ayers, *5 Ways the Healthcare Industry Could Use Big Data—and Why It's Not*, DATACONOMY (Aug. 7, 2017), http://dataconomy.com/2017/08/5-ways-healthcare-big-data/.
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.*
6. *Id.*
7. *Id.*
8. Daniel R. Levinson, U.S. DEP'T OF HEALTH AND HUM. SERV., OFF. OF INSPECTOR GEN., A-01-13-00510, THE FRAUD PREVENTION SYSTEM IDENTIFIED MILLIONS IN MEDICARE SAVINGS, BUT THE DEPARTMENT COULD STRENGTHEN SAVINGS DATA BY IMPROVING ITS

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Fourth, patient outcomes might be improved through wearable devices and other analytical tools that monitor and track patient data and progress.[9]

Finally, and central to my discussion in this article, the use of data analytics enhances institutional provider power to spot anomalies, such as a doctor's high rate of patients with post-operative infections or hospital readmission.[10] Analytical tools can also spot adverse drug events ("ADEs"), common problems in a complex health care institution.[11] Software systems can reduce ADEs by scanning patient records for medications prescribed outside standard treatment.[12]

Vendors, such as Oracle, Sparx, IBM, Allscripts, and Verisk Analytics, market the tools of Big Data with enthusiasm.[13] Some of the largest hospitals and health care networks use these tools already, but in general, hospitals and health systems have been slow to adopt them, despite vendor enthusiasm.[14] Sluggish adoption by hospitals has many explanations. First, computer data systems suffer from lack of interoperability; too often, systems of competing vendors usually do not work well together.[15]

Second, although the Health Insurance Portability and Accountability Act ("HIPAA") provides some uniformity in the privacy landscape, confidentiality laws vary across the fifty states. Today, as hospitals consolidate into much larger multi-state systems, software systems must comply and master these inter-state intricacies.[16]

Third, cost presents a significant barrier to easy adoption. Many institutions have developed their own custom datasets, hindering data sharing.[17] Health care is an expensive industry, and health care institutions are cautious about large investments, particularly considering their other equipment and building costs and the costs of acquiring skilled IT personnel to adopt new data analytic systems in a tight IT labor market.[18]

Data mining — the endpoint of data analytics, once data is scrubbed, organized and sorted — permits an organization to convert, collate and digest

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PROCEDURES, (2014); *see also id.*

9. Ayers, *supra* note 1.

10. *See* Carney, *infra* note 159.

11. *Id.*

12. *Id.*

13. Tom Hardy, *Significant Benefits of Big Data Analytics In Healthcare Industry*, BUILT IN L.A. (Jan. 12, 2016), https://www.builtinla.com/blog/significant-benefits-big-data-analytics-healthcare-industry.

14. Mona Lebied, *9 Examples of Big Data Analytics in Healthcare That Can Save People*, DATAPINE (May 24, 2017), https://www.datapine.com/blog/big-data-examples-in-healthcare/.

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

a vast amount of complex, disparate patient-related data from many sources for a range of uses.[19] A leading textbook by Charu Aggarwal defines it as follows:

> Data mining is the study of collecting, cleaning, processing, analyzing, and gaining useful insights from data. . . . In the modern age, virtually all automated systems generate some form of data either for diagnostic or analysis purposes. . . . [D]ata mining analysts use a pipeline for processing, where the raw data are collected, cleaned, and transformed into a standardized format. The data may be stored in a commercial database system and finally processed for insights with the use of analytical methods.[20]

This article will focus on hospital adverse events, broadly defined, and the use of data analytics tools to reduce those adverse events. I will first examine the advantages of data mining and the necessity for its adoption as federal reimbursement policy moves further toward "pay for performance" and data analytic tools gain in power. Second, I will consider the complex environment of hospital adverse events – their possible causes and uses. Third, I will look at existing tools for detecting adverse events. Fourth, I will reflect on several court cases that have used varieties of data mining to spot adverse events due to the activities of particular physicians. Fifth, I will contemplate the tapestry of state peer immunity statues and federal statues, and the expansion of physician vulnerability for adverse detection that falls outside peer immunity protections. Finally, I will ponder the legal implications of the adoption as a standard practice in hospitals of full-blown data analytics programs that can, among other things, detect a range of hospital-acquired conditions and adverse events. This includes the negative implications for physicians and medical staff or employees within large health care systems.

I. PATIENT SAFETY IN HOSPITALS: THE DETECTION PROBLEM

Since the ancient Greek physicians practiced medicine, physicians have caused harm to patients.[21] Adverse events are as old as medicine itself, and just as medicine progresses technologically, adverse events grow in complexity.[22] The production of adverse events has shifted from individual

19. Ragupathy Veluswamy, *Golden Nuggets: Clinical Quality Data Mining in Acute Care*, 34(3) THE PHYSICIAN EXEC. 48, 48–53 (2008).

20. CHARU C. AGGARWAL, DATA MINING: THE TEXTBOOK 1–2 (Springer Int'l Publ'g) (2015).

21. BARRY FURROW ET AL., HEALTH LAW 243, (West Publ'g Co. 2015) [hereinafter, HEALTH LAW].

22. *Id.*

physicians to complex health care institutions where the most invasive high-risk care is delivered.[23]

Complexity in modern medicine produces more adverse events and errors than ever before.[24] Errors in drug prescribing,[25] physicians who practice medicine contrary to best practice, and adverse events resulting from complex system interactions continue to be major sources of patient harm.[26] Despite substantial evidence of patient injury, progress in reducing the volume of patient harms remains slow.[27] Patients who suffer adverse events, even severe ones, often do not realize what has happened, are rarely told about the adverse event, and seldom file a claim for compensation.[28]

Patients continue to suffer preventable injury or death in hospitals in surprisingly high numbers.[29] They either die, suffer surgical injury, become infected, are disabled, are readmitted with problems, lose time from work, or otherwise experience "adverse events," the sometimes lethal byproducts of health care.[30] These adverse events happen for a multiplicity of reasons –

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23. *Id.*; *see*, e.g. Barry R. Furrow, *Adverse Events and Patient Injury: Coupling Detection, Disclosure, and Compensation*, 46 NEW ENG. L. REV. 437, 440–41 (2012) [hereinafter, *Furrow 1*]; Barry R. Furrow, *The Patient Injury Epidemic: Medical Malpractice Litigation as a Curative Tool*, 4 DREXEL L. REV. 41, 65 (2011) [hereinafter, *Furrow 2*]; Barry R. Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PENN. L. REV. 1727, 1728 (2011) [hereinafter, *Furrow 3*]; Barry R. Furrow, *Patient Safety and the Fiduciary Hospital: Sharpening Judicial Remedies*, 1 DREXEL L. REV. 439, 458 (2009) [hereinafter, *Furrow 4*]; Barry R. Furrow, *Data Mining and Substandard Medical Practice: The Difference Between Privacy, Secrets, and Hidden Defects*, 51 VILLANOVA L. REV. 803, 810 (2006) [hereinafter, *Furrow 5*].

24. HEALTH LAW, *supra* note 21, at 244; *Mark* R. Chassin & Jerod M. Loeb, *The Ongoing Quality Improvement Journey: Next Stop, High Reliability*, 30 HEALTH AFF. 559, 563 (2011).

25. HEALTH LAW, *supra* note 21, at 244; *see, e.g.*, Thomas T. Tsai et al., *Contraindicated Medication Use in Dialysis Patients Undergoing Percutaneous Coronary Intervention*, 302 JAMA 2458, 2463 (2009) (discussing that in a study of 22,778 hemodialysis patients undergoing percutaneous coronary interventions ("PCI") such as angioplasty, the authors found that 46.7% were administered enoxaparin, 64.1% were administered eptifibatide, and 10.9% received both medications – yet the use of both is contraindicated in dialysis patients due to excessive bleeding risk).

26. HEALTH LAW, *supra* note 21, at 244; *see* William B. Borden et al., *Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention*, 305 JAMA 1882, 1886 (2011) (stating, "[l]ess than half of patients undergoing PCI are taking [optimal medical therapy ("OMT")] before their procedure, despite the guideline-based recommendations to maximize OMT and the clinical logic of doing so before PCI so that the need for additional symptom relief from revascularization can be appreciated.").

27. HEALTH LAW, *supra* note 21, at 244.

28. *Id.*; *Furrow 1*, *supra* note 23 at 440; Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 THE LANCET 309, 309 (1997) ("Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% of the 1047 patients made claims for compensation.").

29. HEALTH LAW, *supra* note 21, at 243.

30. *Id.*

staff errors, system failures of coordination and management, drug mismanagement, and a hundred others.[31] The causes are hard to detect in busy hospitals – many patient injuries are not reported in hospital records as required – especially when the main person responsible for the error is a physician.[32] Without systematic detection of adverse events, their causes cannot be eliminated.[33] In an attempt to quantify the patient deaths due to adverse events or errors in hospitals, the 2000 Institute of Medicine report, *To Err Is Human* ("IOM Report"), projected almost 100,000 patient deaths annually due to medical errors.[34] The IOM report – with its extrapolation of high levels of patient harms – spurred the development of the Patient Safety Movement, which intensified the search for adverse events and means of preventing them.[35]

A. Adverse Events.

The IOM Report defines an adverse event as "an injury caused by medical management rather than the underlying condition of the patient," and defines a medical error as "the failure of a planned action to be completed as intended. . . or the use of a wrong plan to achieve an aim. . . ."[36] Adverse events occur at even higher levels than the IOM Report estimated.[37] The Office of the Inspector General estimated in 2010 that around 13.5% of hospitalized Medicare beneficiaries suffered an adverse event, with an equal

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31. *Id.*

32. *Id.;* Lori Andrews, *Studying Medical Error in Situ: Implications for Malpractice Law and Policy*, 54 DEPAUL L. REV. 357, 357–58 (2005). (Attempting to evaluate the extent of errors and injuries, after recognizing the gaps in the Institute of Medicine report discussed infra).

33. *See* Andrews, *supra* note 32 at 358 (discussing the need "to identify, remedy, and prevent medical errors"); *see also* Eric Nalder & Cathleen F. Crowley, *Patients Beware: Hospital Safety's a Wilderness of Data*, CHRON (Mar. 22, 2010, 5:30 AM), http://www.chron.com/news/article/Patients-beware-Hospital-safety-s-a-wilderness-1702575.php (illustrating that hospitals often underreport adverse events, and showing that in some instances, hospitals have missed cases where patients were killed).

34. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 31 (Linda T. Kohn et al. eds., 2000) [hereinafter, IOM REPORT] (suggesting a range from 44,000 to 98,000 individuals); Andrews, *supra* note 32 at 357.

35. HEALTH LAW, *supra* note 21, at 243.

36. IOM REPORT, *supra* note 34 at 28; AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, GLOSSARY, https://psnet.ahrq.gov/glossary (last visited May 22, 2018) (defining an adverse event as "any injury caused by medical care," essentially the same as the IOM's definition).

37. Compare IOM REPORT, *supra* note 34 (listing 44,000 to 98,000 patients) with Daniel R. Levinson, U.S. DEP'T OF HEALTH AND HUM. SERV., OFF. OF INSPECTOR GEN., OEI-06-09-00090, ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES (2010) (estimating that 13.5 percent of almost 1 million patients or approximately 135,000 patients experienced adverse events).

percentage experiencing temporary harm.[38] A 2011 study concluded that 1 in 3 admitted patients suffer adverse events.[39] John James' study of adverse events in 2013 concluded that incidents of premature death due to preventable adverse events could total more than 400,000 per year.[40]

The Patient Safety Movement aims to reduce the level of such adverse events.[41] The Patient Protection and Affordable Care Act of 2010 ("ACA") added several patient safety reforms and granted the Secretary of the Department of Health and Human Services authority to expand patient safety initiatives.[42] As part of comprehensive quality management programs, private firms and hospitals are developing patient safety compliance programs.[43] The tools for making modern health care safer are developing in tandem with the increased power of modern medicine to harm, as well as to cure, patients.[44]

B. Sentinel Events and the Joint Commission.

The Joint Commission accredits U.S. hospitals,[45] and data has always been central to its hospital accreditation process. The Joint Commission Accreditation Manual has included quality assurance requirements since the 1960s; the Joint Commission was an early leader in pushing hospitals to

38. Levison, *supra* note 37.

39. 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).

40. John T. James, *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, 9 J. PATIENT SAFETY 122, 122 (2013).

41. Lucian L. Leape, *Scope of Problem and History of Patient Safety*, 35 OBSTETRICS AND GYNECOLOGY CLINICS N. AM.1, 8 (2008); *see generally* CHARLES VINCENT, PATIENT SAFETY (Wiley Blackwell, 2nd ed. 2010); Stephen D. Small & Paul Barach, *Patient Safety and Health Policy: A History and Review*, 16 HEM. ONCOL. CLINICS. N. AM. 1463, 1480 (2002); Robert M. Wachter, *Understanding Patient Safety,* 29 J. OF LEGAL MED. 561, 561 (2008).

42. *See* 42 U.S.C. § 299b–31(f) (2010) (stating that the Secretary can develop and update "provider-level outcome measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary"); *see generally Furrow 3*, *supra* note 23 (examining a wide range of regulatory initiatives in the ACA and providing an overview of the ACA's patient-safety provisions).

43. *See* THE HANDBOOK OF PATIENT SAFETY COMPLIANCE: A PRACTICAL GUIDE FOR HEALTHCARE ORGANIZATIONS (Fay A. Rozovsky & James R. Woods, Jr., eds. 2005); *see generally* ECRI INST., www.ecri.org (last visited May 22, 2018) (illustrating the offerings of the ECRI Institute, including a Healthcare Risk Control System for provider subscribers that gives risk and quality management strategies).

44. HEALTH LAW, *supra* note 21, at 244.

45. *See About the Joint Commission,* THE JOINT COMMISSION, https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (last visited May 22, 2018).

develop continuous quality improvement programs.[46] Its ORYX initiative aims to integrate data-driven, continuous quality performance measurement systems into the Joint Commission hospital accreditation program as a supplement to traditional standards-based assessments.[47]

The Joint Commission adopted the perspective of the IOM Report in its Sentinel Event Policy, which had developed hospital risk management into a more effective tool for analyzing adverse events.[48] The Joint Commission defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof."[49] The Joint Commission chose the word "sentinel" to "signal the need for immediate investigation and response."[50] Hospitals accredited by the Joint Commission may, but are not mandated to, report serious events.[51] Sentinel event reporting to the Joint Commission, therefore, is certain to understate the level of sentinel events in hospitals. It suffers from the limitations of all adverse event detection systems based on voluntary reporting by health care providers.

Hospitals that are not Joint Commission accredited and nonetheless participate in the Medicare program must comply with the Medicare Conditions of Participation, which also require that the hospital have a quality assurance program.[52] Nursing homes that participate in the Medicare or Medicaid programs must also have a quality assessment and assurance committee, which must meet quarterly to identify quality issues and to develop and implement plans to correct quality deficiencies.[53] In addition, a number of states have adopted explicit statutes or regulations requiring hospitals to have risk management or quality assurance programs as a condition of licensure.[54] Quality assessment depends on data, and the

46. HEALTH LAW, *supra* note 21, at 227.

47. *Id*; *Performance Measurement,* FACTS ABOUT ORYX VENDORS, https://www.jointcommission.org/facts_about_oryx_performance_measurement_systems/ (last visited May 22, 2018).

48. *Sentinel Event Policy and Procedures,* THE JOINT COMMISSION (June 29, 2017), https://www.jointcommission.org/sentinel_event_policy_and_procedures/.

49. *Sentinel Events (SE),* COMPREHENSIVE ACCREDITATION MANUALS FOR HOSP., THE JOINT COMMISSION (2013) https://www.jointcommission.org/assets/1/6/CAMH_2012_ Update2_24_ SE.pdf.

50. *Id.*

51. However, if they do not and the Joint Commission learns of the events from a third party, the hospital must conduct a root cause analysis or risk loss of accreditation. *Id.*

52. 42 C.F.R. § 482.21 (2018).

53. 42 U.S.C. § 1395i–3(b)(1)(B) (2014); 42 U.S.C. § 1396r(b)(1)(B) (2011); HEALTH LAW, *supra* note 21, at 228.

54. U.S. GOV'T ACCOUNTABILITY OFF., HEALTH CARE: INITIATIVES IN HOSPITAL RISK MANAGEMENT 1, 20–37 (1989); ECRI INSTITUTE, *Risk Management, Quality Improvement and Patient Safety*, https://www.ecri.org/components/HRC/Pages/RiskQual4.aspx (last visited May 22, 2018).

mandate to collect data by hospitals is intensifying.[55]

C. Other Reporting Requirements: Hospital Acquired Conditions and "Never Events."

Much of the regulatory response to the 1998 Institute of Medicine study—identifying medical errors as a leading cause of illness and death in the United States—stemmed from the work of the National Quality Forum.[56] The National Quality Forum ("NQF"), a not-for-profit organization "created to develop and implement a national strategy for health care quality measurement and reporting," identified 27, now 29, "serious reportable conditions," including events such as hospital acquired conditions, wrong-site and wrong-patient surgeries, foreign object retention post-surgery, and discharge of an infant to the wrong person.[57] Initially termed "Never Events," they were later renamed "serious reportable events."[58] State regulators saw the value of the list of adverse events, given the recognized impartiality of the NQF and the obvious nature of the harms described by "never events."[59] A number of states used these events to create their own reporting systems.[60] This was a major regulatory step forward, as it forced hospitals to disclose adverse outcomes on the list to the responsible state agency, with an ultimate goal of improving their operations.[61] The reporting allowed for data analysis and pattern identification, for feedback to hospitals, and could be provided to consumers.[62] However, the reporting mechanisms still tend overwhelmingly to be voluntary.

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55. 42 C.F.R. § 482.21 (2018); 42 U.S.C. § 1395i–3(b)(1)(B) (2014); 42 U.S.C. § 1396r(b)(1)(B) (2011); ECRI INSTITUTE, *supra* note 54.

56. HEALTH LAW, *supra* note 21, at 245.

57. *National Quality Forum (NQF),* AGENCY FOR HEALTHCARE RES. & QUALITY (Feb. 2015), https://www.ahrq.gov/professionals/quality-patientsafety/talkingquality/resources/initiatives/nqf.html.

58. *Never Events,* AGENCY FOR HEALTHCARE RES. & QUALITY (June 2017), https://psnet.ahrq.gov/primers/primer/3/never-events. Leapfrog appears to continue to use "serious adverse events" primarily, while seeming to treat it as identical to Never Events. See LEAPFROG FACTSHEET: NEVER EVENTS, LEAPFROG GROUP (Apr. 1, 2016) http://www.leapfroggroup.org/sites/default/files/Files/Never%20Events%20Fact%20Sheet.pdf. For an analysis of Never Events and now they compare to NQF adverse events, *see* John Crist, *Never Say Never: "Never Events" in Medicare*, 20 HEALTH MATRIX 437 (2012).

59. *Id.*

60. CARRIE HANLON, KAITLIN SHEEDY, TAYLOR KNIFFIN, JILL ROSENTHAL, 2014 GUIDE TO STATE ADVERSE EVENT REPORTING SYSTEMS 3 (2015) (finding 27 adverse event reporting systems in place, with one ended and one new one implemented, bringing the total to 28); HEALTH LAW, *supra* note 21, at 245 (discussing that twenty-three states created reporting systems).

61. *Id.*

62. *See Adverse Health Events in Minnesota*, (Minn. Dep't of Health. 9th eds., Jan. 2013); HEALTH LAW, *supra* note 21, at 245. Only certain states permitted disclosure of the information to consumers.

The Leapfrog Group ("Leapfrog") is a nonprofit organization that also sought to leverage the Never Events to improve quality.[63] Large businesses wanted quality metrics to improve the quality of care.[64] Leapfrog, comprised of a group of private companies that purchased health care for their employees, developed a hospital focused policy as early as 2006 to improve hospital quality based finding and handling serious adverse events.[65] However, this policy is voluntary and not all hospitals use the Leapfrog list as a metric for measuring their adverse events.[66]

D. Federal Reporting Requirements

1. Health Care Quality Improvement Act of 1986

The Health Care Quality Improvement Act of 1986 ("HCQIA") required institutional providers to collect information on physicians in conjunction with granting physician staff privileges.[67] The HCQIA established the National Practitioner Data Bank ("Data Bank") to collect information about physicians all over the country and to monitor the credentialing of physicians by hospitals and states.[68] Hospitals must register to be eligible to provide information and to access the registry. They are mandated to report disciplinary actions and malpractice settlements to the Data Bank.[69]

The NPDB is an information clearinghouse created by Congress which aims to improve health care quality, protect the public, and reduce health care fraud and abuse. The NPDB collects information on medical malpractice payments and certain adverse actions and discloses that information to eligible entities to facilitate comprehensive reviews of the credentials of health care practitioners, entities, providers, and suppliers.

It serves as a flagging system to help institutional providers spot incompetent practitioners,[70] alerting the users that they may have to undertake a more comprehensive review of the qualifications and

63. *See Mission and Vision*, THE LEAPFROG GROUP, http://www.leapfroggroup.org/about/mission-and-vision (last visited May 22, 2018).

64. HEALTH LAW, *supra* note 21, at 245.

65. *See Mission and Vision*, *supra* note 63.

66. *Never Events*, THE LEAPFROG GROUP, http://www.leapfroggroup.org/influencing/never-events (last visited May 22, 2018).

67. 42 U.S.C.A. § 11135 (West 1986). NPBD GUIDEBOOK APRIL 2015, NAT'L PRACTITIONER DATA BANK (Apr. 2015), https://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf.

68. *See* 42 U.S.C.A. § 11101 (West 1986); *About Us*, NAT'L PRACTITIONER DATA BANK, https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp (last visited May 22, 2018).

69. Michael Benson et al., *Hospital Quality Improvement: Are Peer Review Immunity, Privilege, and Confidentiality in the Public Interest?* 11 NW. J. L. & SOC. POL'Y. 1, 1 (2016).

70. NAT'L PRACTITIONER DATA BANK, *supra* note 68; HEALTH LAW, *supra* note 21, at 211.

background of a health care practitioner, entity, provider, or supplier. NPDB information is intended to be used in combination with information from other sources in making determinations on employment, affiliation, clinical privileges, certification, licensure, or other decisions. The physician's record must, therefore, accurately reflect all Data Bank information.[71] The record must also be constantly updated to reflect malpractice settlements and disciplinary actions taken against physicians, which must be reported to the Data Bank.[72] Reporting entities are responsible for the accuracy of information they report to the NPDB and for keeping information reported to the NPDB up to date.[73] Kristen Madison, an advocate of quality reporting, argues that effective quality reporting will allow the monitoring of physician practice patterns and thereby improve health care delivery.[74]

The Data Bank has generated hundreds of thousands of reports on medical malpractice and even more reports on licensure, hospital privileges, and other forms of peer review.[75] However, the Data Bank has been criticized for massive underreporting, with estimates that thousands of hospitals have failed to report to the NPDB.[76] It is clear that physicians also engage in strategic underreporting to avoid the NPDB.[77] The volume of reporting by hospitals to the NPDB needs to be improved by a range of reforms to current practices.[78]

2. Patient Safety and Quality Improvement Act

Congress enacted the Patient Safety and Quality Improvement Act ("Patient Safety Act") in 2005 to encourage the expansion of voluntary, provider-driven initiatives to improve the quality and safety of health care.[79]

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71. HEALTH LAW, *supra* note 21, at 211.

72. Benson et. al., *supra* note 69.

73. NPBD GUIDEBOOK, *supra* note 67.

74. *See* Kristen M. Madison, *From HCQIA to the ACA: The Evolution of Reporting as a Quality Improvement Tool*, 33 J. LEGAL MED. 63, 92 (2012) (illustrating "Governmental health Care Quality Reporting" through examples of state and federal based reporting in various states).

75. *See* DIV. OF PRACTITIONER DATA BANKS, U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L PRACTITIONER DATA BANK 2012 ANNUAL REPORT 5 (2014) ("The information contained in the NPDB is intended to direct discrete inquiry into, and scrutiny of, a practitioner's licensure, clinical privileges, professional society memberships, and medical malpractice payment history.").

76. ALAN LEVINE & SIDNEY WOLFE, HOSPITALS DROP THE BALL ON PHYSICIAN OVERSIGHT FAILURE OF HOSPITALS TO DISCIPLINE AND REPORT DOCTORS ENDANGERS PATIENTS, PUBLIC CITIZEN (May 27, 2009).

77. William M. Sage et al., *Bridging the Relational-Regulatory Gap: A Pragmatic Information Policy for Patient Safety and Medical Malpractice,* 59 VAND. L. REV. 1263, 1299 (2006) (finding that "[m]any providers simply refuse to participate").

78. See LEVINE & WOLFE, *supra* note 76.

79. Patient Safety and Quality Improvement, 70 Fed. Reg. 70,732 (Nov. 21, 2008) (to be

The Patient Safety Act promotes cooperation between health care providers and patient safety research entities to improve patient safety.[80] The Patient Safety Act provides legal protections for sharing information related to safety and thus encourages providers to collect and report safety information.[81] The goal is to minimize patient care errors in the United States health system through improved error data analysis.[82]

Patient Safety Organizations ("PSOs") are the primary entities responsible for aggregating and analyzing provider error data.[83] They work with clinicians and health care organizations to identify, analyze, and reduce the risks and hazards associated with patient care.[84] PSOs are responsible for compiling and examining error information provided by health care providers.[85] PSOs can then make recommendations to providers on how to avoid errors in health care practice.[86] PSOs provide their collected data on a national level through the Network of Patient Safety Databases ("NPSD").[87] These database networks then analyze error trends on both a national and regional level, recommending strategies for the U.S. health care system as a whole.[88]

The Patient Safety Act also creates a federal privilege for error reports designated "Patient Safety Work Product" ("PSWP"), preempting states' laws governing civil or administrative procedures that would otherwise require health care providers to disclose information to a certified PSO.[89] With this privilege in place, providers may report all errors confidentially to a certified PSO.[90] Such work products are not subject to discovery, disclosure under the Freedom of Information Act, admissibility in any Federal, state or local government proceeding or disciplinary proceeding under state law.[91] They are also confidential and may not be disclosed.[92]

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codified at 42 C.F.R. pt. 3); s*ee also* Patient Safety and Quality Improvement Act of 2005 42 U.S.C.A. §§ 299b-21–299b-26 (West 2005).

80. *See* Frederick Levy et al., T*he Patient Safety and Quality Improvement Act of 2005: Preventing Error and Promoting Patient Safety*, 31 J. LEGAL MED. 397, 407 (2010) (describing the Act's purposes and goals); HEALTH LAW, *supra* note 21, at 246.

81. Levy et al., *supra* note 80; HEALTH LAW, *supra* note 21, at 246.

82. Levy et al., *supra* note 80.

83. *Id.*; HEALTH LAW, *supra* note 21, at 246.

84. Levy et al., *supra* note 80, at 408.

85. *Id.*; HEALTH LAW, *supra* note 21, at 246.

86. *See* 42 U.S.C. § 299b–23(c) (2006) (providing for the use of data collected).

87. *See* 42 U.S.C. § 299b–23 Network of patient safety databases (defining the capacity of patient safety networks).

88. *Id.*

89. 42 U.S.C.A. §§ 299b-22(c) (West 2005).

90. *Id.*

91. 42 U.S.C.A. §§ 299b-22(a) (West 2005).

92. 42 U.S.C.A. §§ 299b-22(b) (West 2005).

II. ADVERSE EVENT DETECTION: IMPROVED TOOLS

Current approaches to tracking adverse events, including reporting systems attached to the Joint Commission's Sentinel Events and the NQF's Never Events, are largely dependent on voluntary reporting systems that fail to detect most adverse events.[93] The tools of detection are however rapidly improving as electronic health records ("EHRs") have moved into full use in U.S. hospitals.[94] As of 2016, U.S. hospitals had achieved a 96 percent adoption rate of EHRs.[95] The existence of such electronic patient records in U.S. hospitals allows the systematic use of data analytics to data mine hospital records and employ automated detection to identify adverse events.[96]

A. Measurement Tools

Most current approaches to adverse event detection may be viewed as first-generation tools.[97] Relying on voluntary reporting and tracking of errors leads to the reporting of only 10 to 20 percent of errors, and most reported errors did not result in patient harm.[98] Computer-driven data collection is the next, second generation of adverse event collecting,[99] and continues to develop rapidly.[100] EHRs provide much promise in the second generation of

93. *See* Robert Lowes, *Most Adverse Events in Hospitals Go Unreported*, MEDSCAPE (Jan. 6, 2012), https://www.medscape.com/viewarticle/756540 ("Roughly 86% of patient mishaps in hospitals never make it into the database of incident reporting systems designed to improve the quality of care . . .").

94. *See generally* Joseph Conn, *Hospitals Achieve 96% EHR Adoption Rate; Data Exchange Still Needs Work,* MOD. HEALTHCARE (May 31, 2016), http://www.modernhealthcare.com/article/20160531/NEWS/160539990 (finding that out of 96% of hospitals that adopted the EHR system, 82% of those hospitals demonstrated basic inter-exchange of data).

95. *Id.*

96. *See* M. K. Ross et al., *"Big Data" and the Electronic Health Record*, IMIA YEARBOOK OF MED. INFORMATICS 97, 99 (2014) ("[C]linical information from EHRs can augment signal detection from adverse event reporting databases . . . .").

97. *See* Jonathan Pearce, *The Four Generations of Analytics Tools*, SINGLE TRACK ANALYTICS (Jan 1, 2014, 1:52 PM), http://www.singletrackanalytics.com/blog/14-01-01/four-generations-analytics-tools (discussing the four generations of analytics tools).

98. GRIFFIN F. A. RESAR, INST. FOR HEALTHCARE IMPROVEMENT, IHI GLOBAL TRIGGER TOOL FOR MEASURING ADVERSE EVENTS 1 (2nd ed. 2009).

99. *See* LEIGHANNE OLSEN & J. MICHAEL MCGINNIS, INST. OF MED, REDESIGNING THE CLINICAL EFFECTIVENESS RESEARCH PARADIGM: INNOVATION AND PRACTICE-BASED APPROACHES WORKSHOP SUMMARY 250 (2010) ("Registries can improve data quality by adjudicating adverse events and implementing a monitoring process to ensure data registry."); *see generally* Pearce, *supra* 97 (defining "second generation" analytics as having the ability to filter data).

100. See Wullianallur Raghupathi & Viju Raghupathi, *Big Data Analytics in Healthcare: Promise and Potential*, 6 HEALTH INFO. SCI. & SYS. 1, 7 (2014) ("In the future we'll see the rapid, widespread implementation and use of big data analytics across the healthcare organization and the health care industry.").

adverse event collection and detection; EHRs can be subjected to multiple and parallel adverse event detection methods, including the automatic analysis of (1) administrative coding measures, (2) treatment details, and (3) a range of data mining strategies.[101]

Eight distinct methods have traditionally been used to discover adverse events: morbidity and mortality conferences and autopsies; malpractice claims analysis; error reporting systems; administrative data analysis; chart review; electronic medical records; observation of patient care; and clinical surveillance.[102] When used individually, these methods are largely incapable of indicating rates of adverse events, due to their imprecision.[103] Combining approaches in different ways will maximize detection because each approach has its own advantages and disadvantages.[104] Chart review, often a favored measure, is hard to apply because it requires agreement among multiple reviewers to ensure accuracy.[105] Other identified problems include how to measure rates due to the infrequency of many adverse events; limits on surveillance methods, and the need for effective methodologies.[106]

Medical-record-trigger tools are a newer approach to record review.[107] Hundreds of hospitals across the world monitor adverse event rates by using

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101. *See id.* at 4 (noting that data mining, statistical approaches, algorithms, visualization techniques, parallel computing and "divide and process" techniques are necessary in healthcare's big data analytics).

102. *See* Eric J. Thomas & Laura A. Petersen, *Measuring Errors and Adverse Events in Healthcare*, 18 J. GEN. INTERNAL MED. 61, 62 (2003) (providing eight methods to measure errors and adverse events); *see also* Harvey J. Murff et al., *Detecting Adverse Events for Patient Safety Research: A Review of Current Methodologies*, 36 J. BIOMED. INFORMATICS 131, 141 (2003) (providing other methods to identify errors and adverse events).

103. Thomas & Petersen, *supra* note 102, at 65 ("They are incapable of providing error or adverse event rates because they are imprecise, primarily because of the various factors that influence whether an error or adverse event leads to a claim incident report, or autopsy. Therefore, they should be used sparingly, if at all, to assess the efficacy of interventions to improve patient safety.").

104. *See generally Furrow 1*, *supra* note 23, at 455–56.

105. *See* Alan J. Forster, et al., *Reliability of the Peer-Review Process for Adverse Event Rating,* 7 PLOS ONE 1, 5 (2012) ("Because agreement defines accuracy, there is a need to consider it when selecting reviewers for an adverse event study.").

106 *See* Peter J. Pronovost et al., *Tracking Progress in Patient Safety: An Elusive Target*, 296 JAMA 696, 696 (2006) ("A prime challenge in measuring safety is clarifying indicators that can be validly measured as rates. Most safety parameters are difficult or impossible to capture in the form of valid rates for several reasons: (1) events are uncommon (serious medication errors) or rare (wrong-site surgical procedure); (2) few have standardized definitions; (3) surveillance systems generally rely on self-reporting; (4) denominators (the populations at risk) are largely unknown; and (5) the time period for exposure (patient day or device day) is unspecified. All of these may introduce bias. Creating measurement systems that are relatively free of such bias would be costly and complex.").

107 *See generally* RESAR, *supra* note 98 (providing general information about the advancement of trigger tools).

the IHI Global Trigger Tool (the "Global Trigger Tool").[108] The Global Trigger Tool uses close chart review, examining discharge codes and other entries to find a "trigger" in the chart, such as an abnormal lab result.[109] The trigger then leads to further investigation about the adverse event,[110] which leads to the uncovering of more adverse events.[111] However, the limitations of such trigger tools have been noted.[112]

More sophisticated record reviews are being developed, leveraging data analytics and data sets.[113] For example, one study concluded that triangulation through data linkage was a workable balance between chart review (an effective, but expensive method to carry out) and a readily available, if imperfect, data set.[114]

B. Data Mining for Adverse Events

This process of digging through data to discover hidden connections and predict future trends is not new. At the heart of this process is statistical analysis of data to gain understanding of a phenomenon.[115] Statistical tools go back at least as far as the 800s, when the Islamic mathematician Al-Kindi developed frequency analysis for breaking cryptographic codes.[116] In the late 1880s, Florence Nightingale, a major figure in the development of modern

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108. James M. Naessens et al., *Measuring Hospital Adverse Events: Assessing Inter-Rater Reliability and Trigger Performance of the Global Trigger Tool*, 22 INT'L J. QUALITY HEALTH CARE 266, 272 (2010) ("The trigger methodology appears to be a promising approach to the measurement of patient safety. However, automated processes could make the process more efficient in identifying adverse events and has a greater potential of improving care delivery and patient '*outcomes*'.").

109. *See generally* J.D. Rozich et al., *Adverse Drug Event Trigger Tool: A Practical Methodology for Measuring Medication Related Harm*, 12 BMJ QUALITY & SAFETY 194, 194 (2003) ("In this system, specific events—including the ordering of certain drugs, orders for antidotes, certain abnormal laboratory values, and abrupt stop orders—serve as sentinels or "triggers" to initiate a more detailed concurrent chart audit.").

110. *Id.*

111. *Id.* at 198.

112. *See e.g.,* Lina Lander et al., *A Trigger Tool Fails to Identify Serious Errors and Adverse Events in Pediatric Otolaryngology*, 143 OTOLARYNGOLOGY–HEAD & NECK SURGERY 480, 484 (2010) ("Some aspects of surgical admissions may be inherently too complex for a pure trigger tool methodology to detect [errors and adverse events].").

113. *See e.g.,* Jennifer A. Taylor et al., *Triangulating Case-Finding Tools for Patient Safety Surveillance: A Cross-Sectional Case Study of Puncture/Laceration*, 17 BMJ INJ. PREVENTION 388 (2011) ("This study investigated four tools for detecting potential patient safety events, identified the overlap among them and ascertained that multiple data sources and case-finding tools were necessary to maximise [sic] potential patient safety event surveillance.").

114. *Id.*

115. *Id.*

116. FAMOUS INVENTORS: AL-KINDI, http://www.famousinventors.org/al-kindi (last visited May 22, 2018).

public health epidemiology, applied statistical analysis to health problems.[117]

Despite statistics' long history, the term 'data mining' was only recently coined in the 1990s.[118] Early data pioneers, using the metaphor of early gold mining techniques of hand panning for gold in streams, sought the "golden nuggets" to match to evidence-based medicine, allowing a physician to use this new information to influence practice behavior changes.[119] Data mining links three scientific disciplines: (1) statistics: the study of data relationships using numbers; (2) artificial intelligence: the use of software and/or machines that display human-like; and (3) machine learning: algorithms learning from data to make predictions.[120] Data mining technology has become central to most large enterprises as they struggle to keep pace with the masses of big data generated by affordable computing power.[121] Data mining is the use of automated tools to discover patterns and causes in large quantities of data.[122] Data mining is a problem-solving tool that analyzes existing data in large databases, through patterns represented in structures, patterns, or clusters that can be used to inform future decisions.[123] It extracts predictive information from these large databases, finding hidden patterns that may lie outside viewer expectations or be invisible on a case-by-case basis.[124] It uses specialized software tools based on advanced search algorithms, multiprocessor computers, and massive databases to discover knowledge that is often unexpected.[125]

The burgeoning field of data analytics offers the prospect of a fully automated detection system, without any form of manual review. Intra-operative monitors, inpatient-fall monitors, and other programs can match and improve upon chart review.[126] Such tools are exemplified by patient fall detection programs that use natural language processing of the electronic

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117. *See generally* Edwin W. Kopf, *Florence Nightingale as Statistician*, 15 PUBLICATIONS AM. STAT. ASS'N 388 (1916) (emphasizing seven primary tabulation elements of hospital sickness statistics in her paper on Hospital Statistics and Hospital Plans).

118. *Data Mining: What it is and Why it Matters*, SAS INST. https://www.sas.com/en_us/insights/analytics/data-mining.html (last visited May 22, 2018) [hereinafter, SAS].

119. Veluswamy, *supra* note 19.

120. SAS, *supra* note 118.

121. *Id.*

122. IAN H. WITTEN ET AL., DATA MINING: PRACTICAL MACHINE LEARNING TOOLS AND TECHNIQUES 5 (3rd ed. 2011).

123. *Id.*

124. *Id.*

125. *Dating Ming Concepts*, ORACLE, https://docs.oracle.com/cd/B28359_01/ datamine.111/b28129/process. htm#DMCON002 (last visited May 22, 2018).

126. Harvey J. Murff et al., *Detecting Adverse Events for Patient Safety Research: A Review of Current Methodologies*, 36 J. BIOMEDICAL INFORMATICS 131, 138 (2003).

medical record to detect inpatient falls.[127] These tools search all inpatient radiology reports, excluding those performed during the first two days of an admission, to identify those that had been requested as a result of a fall.[128] The tool could then determine when a fracture was diagnosed.[129] The fall rates detected through this fully automated tool are similar to fall rates reported within the medical literature.[130] Similar tools could be used for finding drug adverse events using powerful analytic techniques.[131] My primary focus, here, is leveraging the data analytics and datasets to discover adverse events in order to repair the system in which they occur.[132]

Computer processing power and speed have increased in leaps and bounds, replacing slow manual practices with far quicker automated data analysis.[133] As data sets have thereby grown much more complex, faster processing allows for the discovery of relevant insights about adverse events.[134] Health care is an obvious candidate for such tools, given the complexity and multiplicity of data sources, the management of complex diseases, and the linkage of government reimbursement to outcomes.

Data mining has proven to be powerful in uncovering Hospital Acquired Conditions ("HACs").[135] CMS imposes financial penalties on hospitals that perform poorly with regard to HACs. Hospitals need to reduce certain types of HACs to lower potential penalties from the Centers for Medicare and Medicaid Services ("CMS").[136] Data mining allows clinicians to identify potential HACs before they occur, resulting in improved care to patients and better financial outcomes for the hospital.[137] Data mining has been a key tool

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127. *See e.g.,* Genevieve B. Melton & George Hripcsak, *Automated Detection of Adverse Events Using Natural Language Processing of Discharge Summaries*, 12 J. AM. MED. INFO. ASS'N 448, 452 (2005) ("Natural language processing was an effective method for automated adverse event detection, with the reported system outperforming traditional and previous automated adverse event detection methods.").

128. *Id.*

129. *Id.*

130. *Id.*

131. *See e.g.*, Callie Federer et al., *Big Data Mining and Adverse Event Pattern Analysis in Clinical Drug Trials*, 14 ASSAY & DRUG DEV. TECH. 557, 558 (2016) (utilizing proportional reporting ratio to compare selected small molecule kinase inhibitors and adverse events).

132. John McQuaid, *To Fight Fatal Infections, Hospitals May Turn to Algorithms*, SCIENTIFIC AM. (Feb. 13, 2018), https://www.scientificamerican.com/article/to-fight-fatal-infections-hospitals-may-turn-to-algorithms/?itx[idio]=5816636&ito=792&itq=0f076e71-6c9a-47d6-aa48-8bcd9e2dbebe.

133. *Id.*

134. *Id.*

135. CONDUENT BUSINESS SERVS., HEALTH CARE ANALYTICS: HOW DATA IS CHANGING EVERYTHING 12 (2017) (eBook).

136. *Id.*

137. *Id.*

in reducing the causes of HACs since 2008.[138]

Such tracking efforts will increase as hospitals adopt data analytics and federal pay-for-performance programs which condition a fraction of a hospital's reimbursement on performance standards for readmissions and infections.[139] Data analytics can aid clinicians in eliminating adverse events and resulting excessive costs.[140] It can also assist clinicians in determining care plans, for example, based on estimating disease trajectories of cancer patients from unstructured, free text in EHRs.[141]

According to the software company Oracle, "[d]ata mining is accomplished by building models."[142] Oracle explains, "[a] model uses an algorithm to act on a set of data [with] [t]he notion of automatic discovery refer[ring] to the execution of data mining models."[143] Although both data analytics and data mining extract data from its raw state to a result, data mining takes a statistical approach to pattern identification, while data analytics focuses on using the intelligence gain to solve problems.[144] As Health IT Analytics editor Jennifer Bresnick writes, "Data mining is about the discovery of patterns previously undetected in a given dataset. Once those patterns are discovered, they can be compared to other patterns in order to generate an insight. That is big data analytics."[145]

Data mining is especially appropriate for health care data, which exists in vast quantities in an unstructured format.[146] Patterns discovered with the data

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138. *Id.*

139. *See id.* at 18 (helping organizations know where their money is being spent and where to focus their attention).

140. *See e.g.*, *id.* (In the context of hospital-acquired conditions, "[l]everaging machine-learning, analytics can identify emerging complications and alert clinicians to prevent serious harm to patients, excessive costs and long-term healthcare needs.").

141. Kasper Jensen et al., *Analysis of Free Text in Electronic Health Records for Identification of Cancer Patient Trajectories*, SCI. REPS. (2017), https://www.nature.com/articles/srep46226 ("By using these disease trajectories, we predict 80% of patient events ahead in time. By control of confounders from 8326 quantified events, we identified 557 events that constitute high subsequent risks (risk > 20%), including six events for cancer and seven events for metastasis. We believe that the presented methodology and findings could be used to improve clinical decision support and personalize trajectories, thereby decreasing adverse events and optimizing cancer treatment.").

142. *Id.*

143. *Id.*

144. Jennifer Bresnick, *Data Mining, Big Data Analytics in Healthcare: What's the Difference?,* HEALTH IT ANALYTICS (2017), https://healthitanalytics.com/news/data-mining-big-data-analytics-in-healthcare-whats-the-difference.

145. *Id.*

146. Dan LeSeuer, *5 Reasons Healthcare Data is Unique and Difficult to Measure*, HEALTH CATALYST 1–2 (2017), http://www.healthcatalyst.com/wp-content/uploads/2014/08/5-Reasons-Healthcare-Data-Is-Unique-and-Difficult-to-Measure.pdf (discussing unstructured data).

can then be used to frame queries digging deeper into why and how those patterns occur, what they mean in relation to a particular case or decision-making need. Companies, such as Conduent's Midas Care Performance Platform,[147] ACS's MIDAS+ DataVision,[148] and IBM's SPSS Inc.'s data mining software,[149] provide software products to health care companies to allow them to mine large volumes of data and harvest risk-related results and outcome comparisons.[150]

Technological advances in data analytics have manifested through increased computing power through distributed processing; new computer systems based on advanced machine learning and probabilistic reasoning (for example, IBM's "Watson");[151] and new ways to visualize data, such as the BioMosaic mapping program being developed by the Centers for Disease Control.[152] Increases in computing and processing power have also advanced natural language processing. One study found that a program called MedLEE tripled the number of detected events without effects on clinicians' workflow.[153] Processing of documents takes only second per document and provides that processing as documents are created as contrasted to retrospective manual detection and voluntary reporting, which require time spent on clinician decision making.[154] The search for adverse events and substandard medical practice has advanced because of these improvements in data analytics, making the use of these tools much more effective.[155]

Data mining moves from tracking a particular patient, or physician, to an overview of the whole population of a hospital over time. It can search

147. Conduent, *Midas Health Analytics Solutions*, CONDUENT, https://www.conduent.com/solution/healthcare-provider-solutions/midas-health-analytics-solutions/ (last visited May 22, 2018).

148. *Midas+ DataVision: Full Spectrum Data Management Services*, MIDAS PLUS SOLUTIONS (2011), http://www.midasplus.com/pages/newsandevents/public/executivesummary_datavision.pdf.

149. *IBM SPSS Software*, IBM, https://www.ibm.com/analytics/data-science/predictive-analytics/spss-statistical-software (last visited May 22, 2018).

150. *Id.*

151. *IBM Watson Analytics,* IBM, https://www.ibm.com/us-en/marketplace/watson-analytics (last visited May 22, 2018) ("Watson Analytics is a smart data analysis and visualization service you can use to quickly discover patterns and meaning in your data – all on your own. With guided data discovery, automated predictive analytics and cognitive capabilities such as natural language dialogue, you can interact with data conversationally to get answers you understand.").

152. U.S. GOV'T ACCOUNTABILITY OFFICE (GAO), REPORT TO CONGRESSIONAL ADDRESSEES, DATA AND ANALYTICS INNOVATION: EMERGING OPPORTUNITIES AND CHALLENGES 85 (2016).

153. Melton & Hripcsak, *supra* note 127.

154. *Id.*

155. *Id.*

databases to investigate particular problems.[156] IBM cites the benefits of its DB2 Intelligent Miner with an example of a Florida hospital where its data mining program revealed that pneumonia patients who were not given medication immediately upon admittance suffered significantly worse outcomes than those who were.[157] At another facility, data mining showed that patients with cardiovascular disease were not always prescribed beta-blockers because the discharge process did not include a crucial step to ensure the prescription was ordered; an easy solution, to change work processes, was implemented.[158]

Mandated data mining of hospital and provider records will allow hospitals to detect more adverse events than existing voluntary reporting mechanisms. Everything from surgeons' infection rates to adverse events caused by drugs and medical devices can be tracked; such data mining can then spot anomalous findings like a doctor's high infection rate in patients after surgery.[159] However, this tracking and monitoring will ultimately shift the meaning of "adverse event" away from a specific example of patient harm via provider mistake or negligence; instead, "adverse event" will eventually come to mean substandard care as measured against a benchmark of acceptable rates. This change prompts the question of whether each hospital, as a "silo," sets its own acceptable rate, or whether a national standard should be available, such as for hospital readmission rates.

III. CORPORATE NEGLIGENCE AND DATA DETECTION: THE BATTLE FOR THE SOUL OF THE HEALTH CARE INSTITUTION

Liability doctrines, such as hospital corporate negligence, will inevitably evolve to include modern adverse event detection tools as the standard of care. Given the magnitude of adverse events, hospitals and other health care institutions have legal and fiduciary obligations to find and reduce adverse events that cause patient suffering and death.

A. Corporate Negligence Doctrine

As established in *Cronic v. Doud,* hospitals have a duty to know the qualifications and standard of performance of physicians who practice on their premises.[160] This means it is a hospital's duty to restrict the clinical

156. *Furrow 5*, *supra* note 23, at 818.

157. *Id.*

158. *Id.*

159. Interview with Dr. Sharon Carney, Chief Medical Officer, Mercy Health Systems, (Jan. 22, 2018) (discussing her system's use of data analytics to spot problems in their hospitals, including infection hotspots).

160. Cronic v. Doud, 523 N.E.2d 176,178 (Ill. App. Ct. 1988), *appeal denied* 530 N.E.2d 242 (Ill. 1988) (citing Pickle v. Curns, 435 N.E. 2d 887, 881 (1982)).

privileges of staff physicians who it knows are not qualified to handle certain procedures and to detect concealment of medical errors by a staff doctor.[161] While some courts have limited this duty to only those situations where a hospital has learned of physician insufficiencies,[162] others have talked of "negligent supervision" in terms of an affirmative duty to detect problems.[163]

The duty imposed on hospitals to know the performance of its physicians serves as a precursor to the proposed uses for data analytics today. However, this data use is driven by hospital administrative recordkeeping rather than medical staff committee actions.[164] Such regularized data collection, gathered not solely in preparation for specific committee meetings, but as a routine part of administrative data gathering, has become the new normal.[165] Sorting through medical error data gathered from the data collection is invaluable to hospitals trying to reduce their adverse events.[166] It is also invaluable to a plaintiff's lawyer under a range of malpractice theories.[167] Moreover, courts are beginning to wrestle with a tangle of state peer immunity statutes that protect the confidentiality of committee discussion, their relationship to PSO data accumulate and data protection.[168]

1. The Hospital Standard of Care.

The corporate negligence doctrine, accepted in many American jurisdictions, defines a hospital's duties in four different areas: (1) reasonable care in maintaining safe and adequate facilities and equipment; (2) selection and retention of competent physicians; (3) oversight of all those who practice medicine within the hospital's walls; and (4) creation, adoption and enforcement of policies adequate to ensure quality care for patients.[169] Consider a patient who undergoes surgery in hospital X performed by Dr. Smith. After the surgery, he suffers a severe infection that proves hard to treat and leaves him with respiratory impairments. The hospital had run data analytics that produced surgical infection data profiles for all surgeons on the medical staff, and Dr. Smith is at the very bottom of the staff profile.[170] The patient-plaintiff may reasonably argue that the

161. Corleto v. Shore Mem. Hosp., 350 A.2d 534, 537 (N.J. Super. Law Div. 1975).
162. Albain v. Flower Hosp., 553 N.E.2d 1038, 1045 (Ohio 1990).
163. Oehler v. Humana, Inc. 775 P.2d 1271, 1272 (Nev. 1989).
164. HEALTH LAW, *supra* note 21, at 212.
165. *Id.*
166. *Furrow 5, supra* note 23, at 812.
167. HEALTH LAW, *supra* note 21.
168. Levy et al., *supra* note 80, at 402.
169. *See, e.g.,* Thompson v. Nason Hosp., 591 A.2d 703, 707 (Pa. 1991) (listing elements of corporate negligence doctrine).
170. *See* Doud, 523 N.E.2d at 178–79 (showing case where unnecessary surgery by physician should have been detected by hospital through utilization review, because it had

hospital was negligent in failing to scrutinize this doctor's performance during his re-credentialing for retention on the medical staff. Corporate negligence arguably would apply where the hospital fails to use its detailed risk information on its physicians to limit or revoke their staff privileges, or to improve support where deficiencies occur.[171]

Does current tort law require a health care provider to gather such information carefully? The standard of care for credentialing and retaining physicians has long required hospitals to check on physician performance. It follows, then, that the standard of care applied in negligence actions is evolving to require the systematic data collection of outcomes, and to monitor regularly the outcomes of individual physicians. A data mining system will go beyond individual observational reports to data as to unnecessary procedures, high readmissions, infection rates, and other data that can easily be compared with peers in the institution. Some courts have talked of "negligent supervision" in terms of an affirmative duty to detect problems.[172] A system approach aims to design systems by which adverse events are reduced by design, rather than a checklist approach to reduce human errors.[173]

In 2010, the Joint Commission issued standards on medical staff governance that prescribe the relationship between the medical staff, the medical staff's Executive Committee, and the hospital's Board.[174] These standards have intensified the institutional focus on prospective monitoring of physician quality.[175] One of the standards, for example, specifically provides that the hospital must establish a system for collecting, recording, and addressing individual reports of concerns about individual physicians.[176] The Joint Commission also requires a period of focused review for all new and all renewal privileges for existing providers.[177] The standard requires the medical staff to develop criteria for evaluating the performance of practitioners.[178] It also includes examples of triggering events, such as

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data to put it on notice of problem).

171. *See Furrow 5*, *supra* note 23, at 822 (describing how a plaintiff can prevail against a hospital on a corporate negligence claim for failing to use information on their physicians).

172. Oehler v. Humana, Inc., 775 P.2d 1271, 1272 (Nev. 1989) (discussing what is necessary to prove negligent supervision).

173. *Furrow 5*, *supra* note 23, at 822.

174. HEALTH LAW, *supra* note 21, at 1, 187.

175. *Id.*

176. *Id.*; THE JOINT COMMISSION, STANDARDS BOOSTERPAK FOR FOCUSED PROFESSIONAL PRACTICE EVALUATION/ONGOING PROFESSIONAL PRACTICE EVALUATION (FPPE/OPPE) [hereinafter, PROFESSIONAL PRACTICE] (2011), http://www.mc.vanderbilt.edu/documents/CAPNAH/files/Forms/Competency%20Evaluation%20Forms/TJC%20Booster%20Pack%20FPPE-OPPE.pdf.

177. PROFESSIONAL PRACTICE, *supra* note 176, at 2.

178. *Id.* at 21.

"infection rates, sentinel events, complaints, or other events that are not sentinel events."[179]

Federal requirements also changed hospital-staff relations. For example, under the Medicare Conditions of Participation, federal law requires among other things that hospital bylaws reflect the accountability of the medical staff to hospital governing board or "governing body for the quality of care provided to patients."[180] In addition, the Medicare Improvement for Providers and Patients Act, enacted in 2008, removed the provision which had allowed hospitals to receive permanent "deemed" status the Joint Commission; instead, hospitals are required to periodically reapply for deemed status.[181] This reapplication mandate gives CMS more power to push the Joint Commission to improve its standards for quality improvement.[182]

Hospitals are increasingly under pressure from multiple sources to track and prevent adverse event creation.[183] The universality of EHRs, and the availability of data analytics tools, gives hospitals tools to track and prevent adverse event creation. The ubiquity of these tools is changing the landscape of adverse events. The adverse event universe is now populated by adverse drug events, variations in the mortality rates of particular surgical teams, and problems that are not just physician-created but are structural in staff assignments, and even architectural flaws that may increases the risks of surgical accidents and fires.

2. Data Mining Power and Medical Staff Discipline: Adverse Events for Internal Uses.

Three decades ago, the prevailing judicial view of hospital power vis-à-vis physicians was described in *Albain v. Flower Hospital* as follows: "Nor is a hospital required to constantly supervise and second-guess the activities

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179. *See id.* (describing the standard that includes performance issues, which include "small number of admissions or procedures over an extended period of time that raise the concern of continued competence; a growing number of longer lengths of stay than other practitioners; returns to surgery; frequent or repeat readmission suggesting possibly poor or inadequate initial management/treatment; patterns of unnecessary diagnostic testing/treatments; failure to follow approved clinical practice guidelines; frequent or repeat readmission; patterns of unnecessary diagnostic testing/treatments; and failure to follow approved clinical practice guidelines and whether the variance is justified.").

180. 42 C.F.R. § 482.12(a)(5) (2001).

181. *See id.* (To be "deemed" hospitals must "meet or exceed Medicare and Medicaid requirements"); *Facts about Deemed Status*, THE JOINT COMMISSION, https://www.jointcommission.org/facts_about_federal_deemed_status_and_state_recognition / (last visited May 22, 2018).

182. *Id.*

183. David W. Bates et al., *Big Data in Health Care: Using Analytics to Identify and Manage High-Risk and High-Cost Patients*, 33 HEALTH AFF. 1123, 1124 (2014); *see* Ziad Obermeyer and Ezekiel J. Emanuel, *Predicting the Future – Big Data, Machine Learning, and Clinical Medicine*, 375 N. ENG. J. MED. 1216, 1217 (2016).

of its physicians, beyond the duty to remove a known incompetent."[184] Peer review processes, including mortality and morbidity conferences, were designed to make physician incompetence known, primarily through human observation.[185] However, peer review was less equipped to spot hard-to-recognize causes of adverse events, such as errors with system design, poor architecture in the surgical suite, and physicians who demoralized staff.[186]

A survey of cases from the late 1990s highlights hospitals' early use of statistical analyses either to spot otherwise hidden problems or to compare hospital physicians' performance and set a performance benchmark. The first example is *Unnamed Physician v. Board of Trustees of Saint Agnes Medical Center*.[187] The hospital used a Midas data mining program as a part of the reappointment process, which generated a statistical analysis of outliers in the hospital physicians' performance, including infection rates flagging outlier physicians.[188] From January 1, 1999 to September 30, 1999, one physician had a 14% infection rate from one procedure and a 7.9% overall infection rate, quadruple the national rate for physicians in his specialty.[189] His charts were reviewed by an outside reviewer and his staff privileges were limited.[190] The Midas program had identified charts that generated a statistical red flag.[191]

Lo v. Provena Covenant Medical Center provides a second example.[192] In reviewing patient statistics from the hospital's cardiovascular-surgery program, the hospital found that Dr. Lo, one of two cardiovascular surgeons on the medical staff, had a high rate of patient mortality.[193] Specifically, his mortality rate was 5.3 percent compared to national norms of 3%.[194] Furthermore, his complication and readmission rates were high, when compared to the national standard.[195] Moreover, the plaintiff's patient mortality rate was consistent: 5.3 percent in 2000, 5 percent in 2001 and 5

184. Albain, 553 N.E.2d at 1046.

185. *Id.* at 1045–46.

186. *Id.* at 1045.

187. Unnamed Physician v. Bd. of Trs. of Saint Agnes Med. Ctr., 113 Cal. Rptr. 2d 309 (Cal. Ct. App. 2001).

188. *Id.* at 317. ACS's Midas+ Comparative Performance Measurement System was a performance improvement software application that provides comparative data to over 250 hospitals nationally at the time of this case, with large databases housing over fourteen million encounters. *Id.*

189. *Id.* at 313.

190. *Id.*

191. *Id.* at 324.

192. Lo v. Provena Covenant Med. Ctr.,796 N.E.2d 607 (Ill. App. Ct. 2003).

193. *Id.* at 611.

194. *Id.*

195. *Id.*

percent in 2002.[196] Meanwhile, by contrast, the national rate of mortality for open-heart surgery was 3 percent in 2000 and 2.3 percent in 2001.[197] *Lo v. Provena Covenant Medical Center* highlights the use of a statistical approach to spotting staff variation, and the court's recognition of a hospital's inherent power to suspend clinical privileges "to prevent an imminent danger to patients."[198] The court held that if danger to patients is genuine and imminent, the hospital governing board has a duty to protect patients by summarily suspending the privilege of a physician when data shows that a mortality rate is well above the norm.[199]

A third example is *Nugent v. Saint Agnes Medical Center*, where the hospital used statistical analysis to compare Dr. Nugent's infection rate to that of his hospital peers.[200] The hospital found deficiencies in Dr. Nugent's treatment of ten hospital patients.[201] The doctor had a high patient infection rates for orthopedic surgeries between January 1, 1999 and September 30, 1999: 7.8 percent for all orthopedic surgeries and 14 percent for lumbar laminectomy/fusion procedures.[202] No other St. Agnes physicians, including all other St. Agnes orthopedists, exceeded 4 percent.[203] The physician had been unaware of his infection rates.[204] Upon learning of his above-average infection rates, he made changes in his hospital practices so that his infection rate for his patients dropped to zero.[205] The court upheld the decision of the hospital's Judicial Review Committee, over that of the appeals committee and hospital, which found that Dr. Nugent had adequately cured the problem of high infection rate.[206]

Sokol v. Akron General Medical Center provides a fourth example of the use of data analytics.[207] Sokol was a cardiac surgeon on staff at Akron General.[208] The Medical Council at Akron General received information in the mid–1990's that Sokol's patients had an excessively high mortality

196. *Id.*
197. *Id.*
198. *Id.* at 615 (internal citation omitted). In support of the hospital's power, the Court stated that "the chief executive officer can impose a summary suspension on the authority of the hospital board. *Id.*
199. *See id.* at 614 (finding that "hospital has inherent right to summarily suspend the clinical privileges of a physician whose continued practice poses immediate danger to patients").
200. Nugent v. Saint Agnes Med. Ctr., 2004 WL 2953326, at *1 (Cal. Ct. App. 2004).
201. *Id.*
202. *Id.* at *23.
203. *Id.*
204. *Id.* at *23–*24.
205. *Id.* at *24.
206. *Id.* at *8.
207. Sokol v. Akron General Medical Center, 173 F.3d 1026, 1028 (6th Cir. 1999).
208. *Id.*

rate.[209] In response to Sokol's high mortality rate, the Medical Council created the coronary artery bypass surgery ("CABG") Surgery Quality Task Force.[210] The Task Force hired Dr. Pine, a former practicing cardiologist with expertise in statistical risk assessments.[211] Dr. Pine identified Sokol as having a mortality rate of 12.09%, a "high risk-adjusted rate, while the predicted mortality rate for his CABG patients was 3.65%.[212] Pine found that Sokol's "high mortality rate was of great concern and warrants immediate action."[213]

Akron General limited Sokol's privileges and Sokol appealed.[214] The magistrate judge ruled against the Medical Council's decision to limit Sokol's privileges on the grounds that its decision was arbitrary because Akron General lacked a fixed, baseline mortality rate before it limited plaintiff's privileges.[215] However, the court disagreed.[216] The court believed the magistrate's reasoning was too narrow and risked preventing hospitals from limiting privileges in the future, even in if physicians demonstrated a 100 percent mortality rate.[217] The arbitrary inquiry only required the hospital to treat medical staff with like outcomes in a similar fashion.[218] Though the court held Akron General could "base its decision upon a statistical overview of a surgeon's cases,"[219] the case points to the need for a fixed standard as a general rule, as the magistrate judge had proposed.

Several conclusions can be drawn from this overview. First, courts are prepared to grant substantial deference to a hospital and its trustees, recognizing a hospital's "inherent" power to suspend a substandard physician until he remedies the problem or is removed from the staff. Second, the medical staff also has a heavier burden to determine whether doctors fall within patterns of practice and harms connected to them.[220]

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209. *Id.*
210. *Id.*
211. *Id.*
212. *Id.*
213. *Id.*
214. *Id.* at 1029.
215. *Id.* at 1031–32.
216. *Id.* at 1032.
217. *Id.* at 1031–32.
218. *Id.* at 1032.
219. *Id.* at 1031. The court also stated, "We are in no position to say that one sort of evidence of a surgeon's performance—a statistical overview—is medically or scientifically less accurate than another sort of evidence—the case-by-case study plaintiff suggests we require of Akron General."
220. Skip Freedman, *Peer Review: Best Practices for Enhancing Quality*, PATIENT SAFETY & QUALITY HEALTHCARE (Jan./Feb. 2007) ("Looking at the trends for every doctor in the hospital and seeing whether they fall within the standards that the hospital has set establishes quality patient care consciousness and adjusts the process when needed. Reasons for doctors falling outside the norm must be understood also. Those who do fall outside the

Third, the use of comparative physician data by hospitals raises fundamental questions of what the acceptable range of patient risks is, and what hospitals should be doing to improve physician treatment patterns and repair the problem. Consider the problem of preventable blood clots. Preventable blood clots – known as venous thromboembolism ("VTE") – are a chronic problem in hospitals, with between 350,000 and 650,000 people developing VTEs per year, and as many as 200,000 deaths per year resulting from VTE.[221] Such clots are highly preventable if patients with risk factors get the right medications.[222] In fact, this standard of care is well established and reflected professional society guidelines.[223] Yet rates of appropriate prophylaxis are surprisingly low for at-risk patients.[224] A government report concluded, "[an] international study of almost 70,000 patients in 358 hospitals found that appropriate prophylaxis was administered in only 58.5 percent of surgical and 39.5 percent of medical inpatients at risk for VTE; another U.S. registry found only 42 percent of patients with hospital-associated DVT received prophylaxis within 30 days prior to diagnosis."[225] In other words, physician implementation of this medication practice is substandard per evidence-based guidelines.

Health care data analytics could provide a benchmark to review physician performances, by providing an aggregate picture of the performance of their peers. In practice, hospitals could use data analytics to generate physician report cards, computer reminders to prescribe evidence-based medicines, or even clinical-decision support tools to help them assess patient risks for blood clots. Upon compiling the data, hospitals will be forced to develop new strategies of adverse event reduction, from support tools to ways of penalized physicians who continue to be poor performers. Only once poor performers can be identified will the duty to act on that information solidify.

B. Data Mining Power and Medical Liability: The Growing Tension Between Data Use and Peer Protection Statutes

State peer review statutes raise a question of whether these statutes

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norm may need to upgrade their skills. In addition, not only are the trends in the individual hospital important to know, but physician performance outside the hospital in other institutions is well worth knowing, too. This knowledge can help a hospital maintain its quality of care.").

221. Greg Maynard G., *Preventing Hospital-Associated Venous Thromboembolism: A Guide For Effective Quality Improvement*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (Aug. 2016), https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/vtguide/index.html.

222. *Id.*

223. *Id.*

224. *Id.*

225. *Id.*

preclude corporate negligence actions based on negligent credentialing. Courts generally have held that negligent credentialing is little more than an extension of common law negligence, for which institutions have always had liability.[226] By contrast, a minority of courts conclude that state peer review statutes bar such claims.[227]

Even if peer review statutes do not prohibit corporate negligence litigation, the statutes impose substantial discovery limitations that may impede bringing any such case against a hospital. All states currently have statutes extending at least some protection to peer review participants in health care institutions.[228] First, these statutes make information generated by the quality assurance peer review processes confidential, usually insulating such information from discovery in litigation and from introduction in evidence.[229] Second, the statutes protect both peer review decision makers and those who provide information to them from civil liability claims brought by persons who receive negative reviews in the quality assurance process.[230] Finally, a small number of statutes explicitly protect risk management documents from discovery or risk managers from liability.[231]

Nevertheless, risk management programs and the information they generate are unlikely to be immunized from discovery and use in many situations. First, hospital employees typically generate risk management incident reports as a matter of course. Incident reports are common in business generally and in hospitals in particular; they are not usually protected from discovery in other contexts. Incident reports are also often among the best available sources of information as to what happened to cause an adverse event.

When a plaintiff seeks discovery of incident reports, rather than committee proceedings, the policy considerations are somewhat different. State peer review statutes that protect committee proceedings from discovery and use

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226. *See, e.g.,* Larson v. Wasemiller, 738 N.W.2d 300, 306 (S.C. Minn. 2007) (concluding that "the tort of negligent credentialing is inherent in and the natural extension of well-established common law rights" and noting that more than half of the state courts have adopted the tort, which is based on Restatement (Second) Tort sections such as section 320 and 411). *See also* Lake Cumberland Reg'l Hosp. v. Adams, 536 S.W.3d 683, 689 (Ky. 2017), *rehearing denied* (Feb. 15, 2018).

227. *See* Kauntz v. HCA-Healthone, LLC, 174 P.3d 813, 817 (Colo. App. 2007) (holding that a professional review body was immune from damages in any civil action brought against it with respect to its participation in a professional peer review proceeding); Smith v. Pratt, No. M2008-01540-COA-R9-CV, 2009 WL 1086953, at *5 (Tenn. Ct. App. 2009).

228. HEALTH LAW, supra note 21, at 228.

229. *Id.*

230. *Id.*

231. *Id.*; *see* Benson et al., *supra* note 72 (providing a full overview of state peer immunity statutes).

in negligence proceedings less frequently protect incident reports, and courts have been less willing to immunize incident reports from discovery.

Courts have also denied discovery and confidentiality protections to root cause investigations done in compliance with Joint Commission guidelines. For example, in *Reyes v. Meadowlands Hospital Medical Center*, the defendant hospital argued that its root cause analysis of a sentinel event under Joint Commission guidelines should be protected from discovery.[232] The court was skeptical, holding that "the Sentinel Event Policy invoked by defendant Meadowlands Hospital does not create a self-critical analysis privilege, insulating any and all discussions and statements made, and conclusions reached by the participants therein and actions taken by the Hospital pursuant thereto not subject to the Civil Rules of Discovery."[233]

Courts have also struggled in recent medical malpractice litigation with the proliferation of ad verse event reporting obligations and their poor fit with state peer immunity statutes. In *Nielson v. SwedishAmerican Hospital*, the defendant SwedishAmerican Hospital refused to produce three quality control reports ("QCRs") pertaining to surgery performed on the plaintiff Connie F. Nielson and was held in contempt.[234] Defendant argued that the QCRs were privileged under the Illinois Medical Studies Act.[235] They were submitted to a quality-assurance committee by the committee's designees, pursuant to the committee's standing request for such information whenever a defined "medical occurrence" has taken place.[236] Swedish American's medical staff bylaws provided for various committees, including the Quality Assurance/Improvement committee.[237] The Hospital's Quality and Safety Plan for Improving Organizational Performance stated: "The members shall monitor and evaluate objectively and systematically the quality, safety, and appropriateness of patient care provided by members of the Medical Staff. They *** shall receive and evaluate reports from individual quality and safety subcommittees and provide a forum for interdepartmental discussions."[238]

The cour"t noted that "[a] document that 'was initiated, created, prepared, or generated by a peer-review committee' is privileged under the Act, 'even though it was later disseminated outside the peer-review process."[239] The court noted however that the reverse is not true.[240] The court stated:

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232. Reyes v. Meadowlands Hosp. Med. Ctr, 809 A.2d 875, 876 (N.J. Super 2001).
233. *Id.* at 882.
234. Nielson v. SwedishAmerican Hosp., 80 N.E.3d 706, 709, 712 (Ill. 2017).
235. *Id.* at 711–12.
236. *Id.* at 711.
237. *Id.* at 711.
238. *Id.* at 715.
239. *Id.*
240. *Id.*

> A document created 'in the ordinary course of the hospital's medical business, or for the purpose of rendering legal opinions or to weigh potential liability risk or for later corrective action by the hospital staff' is not privileged 'even though it later was used by a committee in the peer-review process.' . . . [T]he QCRs here. . . serve multiple purposes, including quality assurance (all medical-occurrence-QCRs), risk management (all QCRs), and, to a certain extent, billing (all QCRs).[241]

The court concluded that "[t]he fact that the QCRs do not commence an investigation, along with their dual purpose, compels a holding that the QCRs are effectively incident reports" and they are not privileged from discovery or use.[242]

In *Baptist Health Richmond, Inc. v. Clouse*,[243] the United States Department of Health and Human Services ("HHS") took the same position as in *Charles*, stating "the Patient Safety Act does not permit providers to use the privilege and confidentiality protections for [patient safety work product] to shield records required by external recordkeeping or reporting requirements."[244] HHS noted that hospitals used two approaches in misusing the Act by trying to shield from discovery documents that were discoverable.[245] One approach was to maintain the records in their patient safety evaluation system and refuse to disclose them as privileged and confidential.[246] A second approach was to send the original patient safety reports out of the system to meet other external obligations, place a duplicate copy in the patient safety evaluation system, and then destroy the original and refuse to disclose the copy as confidential and privileged.[247] The court held that the hospital had to meet state-mandated reporting requirements, reasoning that to the extent information collected in the provider's internal patient safety evaluation system is needed to comply with those state requirements, it is not privileged.[248]

The conclusion drawn from Michael Benson et al. is well stated: "The

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241. *Id.* at 715, 717.

242. *Id.* at 726.

243. Baptist Health Richmond, Inc. v. Clouse, 497 S.W.3d 759, 765 (Ky. 2016).

244. Dept. of Health and Human Services, 81 FR 32655-01 at 32657, Patient Safety and Quality Improvement Act of 2005—HSS Guidance Regarding Patient Safety Work Product and Providers' External Obligations (May 26, 2016).

245. Baptist Health, 497 S.W.3d at 765.

246. *Id.*

247. *Id.*

248. *Id.* at 766. (noting that "[t]he Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system." (citing Patient Safety and Quality Improvement, 73 FR 70732–01 at 70742 (emphasis added)).

well-intended immunity from civil liability for peer review established by the HCQIA, along with state immunity, privilege, and confidentiality, have [had the]. . . effect of shielding hospital quality improvement processes from outside scrutiny.[249] The forward momentum of data analytics, however, is likely to better ferret out adverse events of all kinds without running afoul of peer immunity restrictions on discovery and disclosure.[250]

In *Quimbey v. Community Health Systems Professional Services Corporation,*[251] a malpractice case, the court held that two of five documents produced by the hospital could be disclosed – the hospital's compilation of stroke data and its stroke data spreadsheets and compilations. Medication variance occurrence logs, incident and accident reports, and stroke committee minutes and agendas were however protected from disclosure.[252] The plaintiff contended that the hospital's failures in implementing the stroke program and in its hospital staffing and training caused Gloria Quimbey's death.[253] The court found that that such statistical information about hospital failures were potentially critical to the plaintiff's proof, thus more probative that any other evidence the plaintiff could obtain through discovery.[254]

Other courts have applied the more protective position of immunity statutes broadly, including protecting morbidity and mortality statistics, citing the usual justification for such statutes as ensuring that "employees are forthcoming with their concerns, issues, and criticisms."[255] But the trend is clear; more and more courts are comfortable distinguishing compilations and big data views from committee minutes.

IV. EFFECTS OF THE INCORPORATION OF DATA ANALYTIC TOOLS INTO HEALTH CARE DELIVERY.

A. Big Data and Legal Impacts.

Big data is slowly changing hospitals' relationship with both adverse events and substandard care. I predict new obligations for hospitals. First, automated detection programs will become the standard of care for all hospitals. By this I mean that corporate negligence will become a more robust claim for injured patients, as evidence becomes available as to hospital

249. Benson, et. al., *supra* note 72, at 20.

250. *Id.* (stating that "the resulting market forces can be expected to create a more credible and robust peer review process that will result in improved hospital quality and reporting.").

251. Quimbey v. Cmty. Health Sys. Prof. Service Corp., 222 F. Supp. 3d 1038, 1049–50 (D.N.M. 2016).

252. *Id.* at 1050.

253. *Id.* at 1048.

254. *Id.*

255. Willard v. State of Iowa, 893 N.W.2d 52, 64 (S.C. Ia. 2017).

measures not taken that could have reduced patient harm. As argued above, value-based purchasing and pay-for-performance models, driven by hunger for data about costs and value, will fuel the application of data analytics. Hospitals will be required to spot outliers of all kinds, due to physician deficiencies but also to design flaws in the hospital and system management flaws. The pressure for system improvement will grow as data mining brings past problems concealed by lack of awareness to light. The duty of hospitals will be to use "standard" data tools or tools that are being adopted by many hospitals.[256] The next level of negligence scrutiny is to ensure that the tools are being used properly, i.e. non-negligently.[257]

Second, staff privileging will also become more demanding as new forms of data become generally available. Privileging decisions may become better-grounded in real data about physician actions, leading to more trustworthy peer review. Critics, for example, talk about "sham" peer review—medical staff reviews used to drive out a physician for reasons unrelated to patient safety.[258] Data mining results are likely to reduce such "sham" reviews by failing to support claims made by fellow physicians in a hospital. Better understanding of multiple causes of adverse events, such as equipment failures or poor systems, will also ease the blame on physicians in many situations.

Third, more and more data will be needed as the Federal government relies more heavily on disclosure as a regulatory tool for purposes of reimbursement, and also for consumer shopping through websites such as *hospitalcompare.gov*. Reimbursement conditioned on the reduction of adverse events such as infections, and high cost factors such as hospital readmission, will continue the pressure.

B. Big Data Risks in the Healthcare Setting.

Data analytics presents long-term risks, as well as benefits. First, application of data analytics will be another source of financial pressure on disproportionate share hospitals and small rural hospitals, which will be motivated to join larger systems to absorb the high cost of both software and IT personnel. Effective health care data analytics officers will also be both hard to find and expensive to hire. Competition for data analytic experts with machine learning skills is high, with starting salaries beginning as

256. *See e.g.*, Washington v. Washington Hosp. Ctr., 579 A.2d 177 (D.C. App. 1990) (holding that standard of care at the relevant time *required* the presence of CO_2 monitors).

257. Price, *supra* note 140, at 420–21.

258. *See* Dinesh Vyas & Ahmed E. Hozain, *Clinical Peer Review in the United States: History, Legal Development and Subsequent Abuse,* 20 WORLD J GASTROENTEROLOGY 6357, 6359 (2014) (claiming significant abuse of the peer review system in hospitals); *see also* Benson et al., *supra* note 72.

$300,000.[259] Many hospitals will be unable to hire such talent unless they join larger systems that have more resources. They will have to face the reality that the role of the Data Analytics Officer is growing in importance for patient safety as medical staff policing changes.

Second, the power of data analytics reduces the protective capacity of peer immunity statutes, for better or for worse. Data mining means that patterns and variation lead to the discovery of more outliers in every aspect of hospital practice, beyond the obvious adverse events created by surgeons. As data analytics relies on algorithmic tools to drive searches, the limits of peer review will become apparent. By operating automatically and always dredging for poor outcomes, these tools, as courts have also begun to notice, are outside the usual peer immunity statutes.

Third, automated data analytics tools will be seen as better than human evaluators as some point, and probably well before the underlying assumptions have been completely vetted for accuracy in a range of cases.[260] Hospital enthusiasm for automated data mining may lead to overzealous hunting for "bad docs," doctors who appear to be below average. This could mean privilege restrictions or new training requirements.[261] Such a risk suggests the need for some sort of expert oversight before restrictions are imposed on physicians, requiring a different kind of peer review—of the data analytics programs as well as the physicians and other providers.

And for physicians who have chosen to be employees of hospitals rather than independent contractors on the medical staff, data mining use may lead to increased exposure, more frequent peer review, or termination, as the data points to physician outliers as the source of patient mortality, readmissions, or other negative outcomes for the hospital.[262] From a patient-plaintiff

259. Jeremy Kahn, *Sky-High Salaries Are the Weapons in the AI Talent War*, BLOOMBERG BUSINESSWEEK, (Feb. 13, 2018), https://www.bloomberg.com/news/articles/2018-02-13/in-the-war-for-ai-talent-sky-high-salaries-are-the-weapons; for an earlier prediction, *see* James Manyika et al., *Big data: The next frontier for innovation, competition, and productivity*, MCKENSEY GLOBAL INSTITUTE (2011), https://www.mckinsey.com/business-functions/digital-mckinsey/our-insights/big-data-the-next-frontier-for-innovation.

260. *See* criticisms of IBM's *Watson* software program, David H. Freedman, *A Reality Check for IBM's AI Ambitions*, MIT TECH. REV. (June 27, 2017) (accusing IBM of overhyping the program).

261. Frank Pasquale, *Professional Judgment in an Era of Artificial Intelligence and Machine Learning*, BOUNDARY 2 (2018) (forthcoming) (questioning the universality of computational thinking and the uncritical acceptance of the benefits of data analytics and algorithms).

262. A. Michael Froomkin, Ian Kerr & Joëlle Pineau, *When AIs Outperform Doctors: The Dangers of a Tort-Induced Over-Reliance on Machine Learning and What (Not) to Do About It*, UNIV. MIAMI RES., 1, 34 (Feb. 13, 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3114347 (contending that ". . .there may come a point where the reliability of the AI is so high that the human physician seems

perspective, more material moves into the discoverable category.[263] From the hospital physician's perspective, on the other hand, the role of peer review committees is reduced to a narrower role in evaluating peers who abuse substances, are abusive to staff, or suffer from personal failures not amenable to data mining of masses of hospital data.

Fourth, the reliance on data analytics to provide decision support means that the algorithms must be trustworthy and machine learning flawless.[264] Critics have noted however that a pure AI system may always need a human expert to check for biases and problems.[265] One could note however that human decision making in the complex health care setting is often flawed and dangerous. This is the negative side of the move toward the use of data analytics in any field, but perhaps health care is more vulnerable because of the potential for harm both to patients and to providers in the system.

CONCLUSION

Big data promises big changes to health care delivery. Patient safety will benefit as computer-driven introspection of hospital systems expand; the very concept of a systems approach to patient safety requires tools that are to the task of monitoring complex institutions with masses of disparate data pools.

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unnecessary or even – to the extent she may overrule valid diagnoses – unhelpful in that her inputs tend to reduce the probability of a successful outcome.").

263. *Id.*

264. I. Glenn Cohen & Harry S. Graver, *Cops, Docs, and Code: A Dialogue Between Big Data in Health Care and Predictive Policing*, 50 U.C.D. L. REV. 437, 460 (2017).

265. CATHY O'NEIL, WEAPONS OF MATH DESTRUCTION 87 (2016); FRANK PASQUALE, THE BLACK BOX SOCIETY (2015).