2022

Planning Patient Safety: Philosophical, Political, and Economic Changes Required for Preventable Death Abolition

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Planning Patient Safety

Philosophical, Political, and Economic Changes Required for Preventable Death Abolition

submitted to
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for
Senior Thesis
Spring 2022
April 25th, 2022

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Abstract

Preventable medical errors are an epidemic. Between 250,000 and 400,000 people die from preventable errors each year in the USA. This investigation questions mechanisms for quality care improvement to eliminate preventable fatalities. I evaluated current patient safety protocols, analyzed their shortcomings, and with additional research recommended actions for better results. Such actions to improve patient safety are explored from three different perspectives: philosophical, economical, and political aspects. Root problems within the health care system are addressed and such discoveries are used to construct effective solutions. In chapter one, improvements within hospitals are reviewed – namely cultural changes needed from both physicians and hospital leadership. Abolishing hierarchical systems which preclude healthy collaboration among medical teams, diverting focus to patient centered care, and regimenting shift hours so doctors' mental and physical strength are accounted for, cover some of the pivotal changes.

Next, chapter two discusses political approaches – enforced transparency and patient safety processes – only made possible through public policy implementation. Hospitals are public institutions and yet do not report all of their mistakes. However, as proven by the SEC's regulatory measures required for publicly traded companies, accurate reports foster greater accountability. What is measured improves; what is measured publicly improves faster. *Next,* aligned incentives promises compensation to hospitals for all procedures if such hospitals prove they followed every safety measure even when they hurt a patient. In converse, hospitals failing to meet the safety measures will not be paid for any procedures, both initial and follow-up for patients harmed by the hospital. I anticipate a steep mistake reduction with transparency and the aligning incentives strategy. It is a win-win for hospitals who will get paid more, patients who will receive better quality care, and taxpayers whose medical tax bills --nearly 20% of the national GDP – will reduce.

Chapter three's economic focus centers on GPOs' corrupt contracting tied to their payment structure and concludes with solutions to remedy their incentive for anti-competitive practices. GPOs are the middlemen contract negotiators between vendors and hospitals. Exclusionary GPO contracts preclude the entry of innovative medical products which may provide health benefits to patients. The supplier-based payments to GPOs have perverted the normal supply chain relationship and has resulted in lower quality products, product scarcity, and higher costs which have all led to sub-standard patient outcomes and even clinician harm. Their percentage-based payments from vendor revenue provide perverse incentives for GPOs to charge hospitals higher product prices since GPOs incur incremental benefits with each added dollar a hospital pays. However, while GPOs elevate, except for few GPO shareholder hospitals, most hospitals struggle. Thus, the federal government or hospitals must become responsible for financing GPO activity so this cycle of abuse will stop.

My findings illuminate an interdependency required among all three realms for effective improvements in patient safety.

Acknowledgements

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Mom, I would be half the woman I am without your example. You inspire me every day with the perseverance you show in your every pursuit, the generous compassion you emanate (even to those most undeserving), and your unrelenting commitment to family and education. These lessons are embedded within me. Whenever faced with conflict, you're my first call and the one I count on to steer me in a direction that makes me better. You are my mentor, confidant, and best friend.

Dad, words cannot encapsulate my gratitude for the life you've given me. At times I feel undeserving, for the wisdom, work ethic, and kindness you've modeled every day since my first steps remains the greatest gift I will ever know. I always sensed I'd follow in your footsteps one way or another, but to see through your life's work and carry out this noble mission you began, brings me indescribable honor. I promise to look up when challenges stump me but also look down in reflection at my highest point, and of course, to always live within a two-hour drive.

I love you both and owe everything I accomplish, whether it be today or fifty years from today, to your guidance. Thank you doesn't cut it.
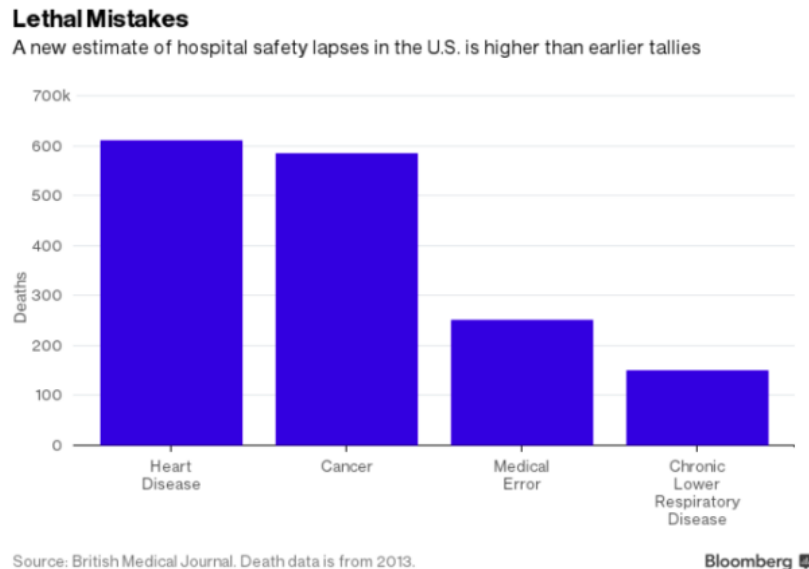
Introduction

The average person makes between five to seven mistakes per day. World-renown surgeon Peter Brennan asserted this reality as part of his effort to inspire preventative measures in healthcare to account for normal human circumstances. When a plane crashes, that is all anyone can talk about for weeks following the incident. It seems counterintuitive, then, for society to ignore preventable medical errors in the United States—a number equivalent to two plane crashes per day.

Where, then, is the discrepancy? Where is the radical change? Why is our country failing to protect people when there are ways it theoretically and tangibly could? Medical errors in hospitals are the third leading cause of death in the United States. In 1999, the Institute of Medicine published a report called "To Err is Human" that revealed this shocking fact.[1] Since then, doctors, nurses, hospitals, and state and federal governments have made significant reforms. Still, every single year, between 250,000 and 440,000 lives are lost due to medical errors in America.

Deaths caused by medical errors are more common than deaths caused by diabetes, car accidents, or pneumonia. Fortunately, some hospitals have taken it upon themselves to implement patient safety protocols to avoid such preventable deaths. Unfortunately, though, out of approximately 6,000 hospitals in the US, fewer than 100 adhere to the measures necessary to prevent physician errors from turning fatal. While to err is human, to purposely avoid putting simple processes in place that would prevent

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[1] Institute of Medicine (US) Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System. Edited by Linda T. Kohn et. al., National Academies Press (US), 2000. doi:10.17226/9728

human medical error is inhumane. The fact is most, if not all, preventable harm can be
avoided by putting evidence-based processes and practices in place in hospitals. If
implemented and followed with care, these are practices that can reduce human errors
and save countless lives every hour.

Lethal Mistakes
A new estimate of hospital safety lapses in the U.S. is higher than earlier tallies

Source: British Medical Journal. Death data is from 2013.

Bloomberg

There is proof of this promise at our fingertips, for the hospitals that *have* applied
patient safety practices have seen encouraging results. In fact, the Children's Hospital of
Orange County (CHOC) has achieved zero preventable deaths for nearly 60 months
now.[2] If one hospital can do this, so can others. When a human life is on the line, the
stakes are too high for mediocre measures and "A-minus" execution. If the ideas explored

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[2] Psqh. "Achieving Zero Preventable Deaths: One Hospital's Journey." *Patient Safety & Quality Healthcare*, 12 Jan. 2021, https://www.psqh.com/analysis/achieving-zero-preventable-deaths-one-hospitals-journey/.

below were widely implemented, CHOC's success can be a standard, not an aspiration. It is time for action.

Hospitals need improvement, and patients deserve reliable care. Those who are both capable and responsible for this are medical personnel and politicians. With patient care procedures mandated by law in Washington and doctors thoughtfully adherence to these practices, rather than fret over making it out alive, patients will have the luxury to focus on their health when they enter a hospital.

There are many reasons why so many hospitals are falling short compared to CHOC's success. Luckily, there are ways to encourage them to make these changes while providing medical providers the assistance they require to expedite patient safety and quality healthcare. This thesis will explore the philosophical, financial, and political changes necessary to revolutionize the American healthcare system. We will look at numerous suggestions—some as simple as fostering positive hospital culture and requiring full annual disclosures from medical institutions when reporting their mistakes.

However, before diving into proposals to eradicate preventable fatalities, common medical errors that often turn deadly and the reasons behind their frequency will be examined. It is imperative we recognize medical-mistake trends to decipher patterns that can help create efficient, wide-reaching solutions. Although physicians can make many different types of mistakes, a few fundamental issues are at the root of these errors.

Money Matters

FINANCIAL BURDENS. A conscious and unconscious factor that is proven to hinder the utmost quality care is a primary focus on financial incentives when caring for

patients. From discharging patients before they are perfectly healthy to prioritizing

money over people, such action or thought processes are culprits of hindered healthcare.

Hospitals pressured by monetary stressors are found to perform at a lower standard and

record adverse incidents at a higher rate than well-resourced medical institutions. In

2014, researchers investigated hospitals around the country to see if their financial state

correlated with care quality and discovered that financially stable hospitals had fewer

medical errors, fewer patient readmissions, and superior quality for both medical and

surgical patients.[3] The reason behind medical care disparities due to financial status is

that financially well-off hospitals can afford reliable systems and superior medical

technology and thus are predisposed to provide better care than struggling medical

institutions. The following are errors likely affected by hospital finance stability in

conjunction with rushed, overburdened medical staff.

Patient survey: 10 most common medical errors
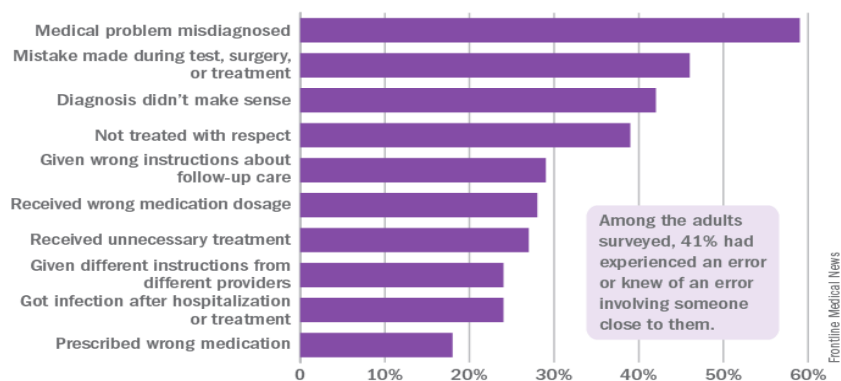
Note: Survey was conducted May 12, 2017, to June 26, 2017, and received 2,536 responses.
Source: NORC at the University of Chicago and IHI/NPSF Lucian Leape Institute

Careless Errors

[3] Akinleye, D. D., McNutt, L. A., Lazariu, V., & McLaughlin, C. C. (2019). Correlation between hospital finances and quality and safety of patient care. 14(8), e0219124. https://doi.org/10.1371/journal.pone.0219124

MISDIAGNOSIS. This is the most common type of medical error since receiving an accurate diagnosis is essential to treatment options.[4] A wrong diagnosis can delay treatment and cause the wrong medication to be prescribed, which both lead to preventable deaths. Not receiving a diagnosis is just as bad, if not worse at times, than receiving the wrong one. Patients told to rest assured of their health may suddenly incur worse symptoms and die prematurely.

GOING HOME. The cost of preventable readmissions is estimated at $17 billion.[5] One in five Medicare patients return to their hospital within thirty days following their discharge. Possible explanations include discharging patients before they are ready, misunderstanding patients' discharge information, miscommunication among hospital staff, allowing critical condition patients to fall through the cracks with no post-discharge follow-up, or due to medical care complications that require hospital re-admittance. Almost half of discharged patients have pending test results when allowed to leave, and, of these individuals, about 50% never have their discharge summaries reviewed. One study recorded that 12% of patients experienced preventable medical complications after being discharged, with medication errors comprising the leading mistake.[6]

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[4] E.S. Berner, M.L. Graber Overconfidence as a cause of diagnostic error in medicine Am. J. Med., 121 (2008), pp. S2-23, 10.1016/j.amjmed.2008.01.001

[5] Rau J. Medicare Fines 2,610 Hospitals In Third Round of Readmission Penalties. Kaiser Health News. 2014. http://kaiserhealthnews.org/news/medicare-readmissions-penalties-2015/. Accessed April 11, 2022.

[6] Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med. 2003;138:161-167.

IMPROPER SUPERVISION OF PATIENTS. Medical staff are stretched thin at many hospitals and neglectful in some, so, oftentimes, patients are left in their rooms for extensive periods before a nurse checks in to ensure their safety. A second issue related to improper supervision concerns relaxed follow-up visits. Too few visits can impede healing time and prevent detecting post-operative problems.

HEALTHCARE-ASSOCIATED INFECTIONS. Hospital-acquired infections (HAIs) affect 1.7 million people annually, according to the Centers for Disease Control and Prevention.[7] Patients are two times more at risk to die in a hospital if they acquire an infection, are five times more likely to be readmitted, and will certainly spend an average of seven extra days in a hospital bed. Common infections include pneumonia, surgical-site infections, urinary infections caused by catheters, and bloodstream infections that IVs are responsible for. The CDC estimates there are approximately 100,000 deaths due to infections each year, with those with weakened immune systems much more susceptible to lethal reactions.[8]

CLABSI. One example of fatal an HAI is CLABSI (central-line-associated bloodstream infection). CLABSI is one of the most common health-care-associated infections in the U.S. and occurs when germs (usually bacteria or viruses) enter the bloodstream through the central line. An estimated 250,000–500,000 CLABSIs occur in

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[7] Rodziewicz TL, Houseman B, Hipskind JE. Medical Error Reduction and Prevention. [Updated 2022 Jan 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499956/

[8] Reed, Deoine, and Sandra A Kemmerly. "Infection control and prevention: a review of hospital-acquired infections and the economic implications." The Ochsner journal vol. 9,1 (2009): 27-31.

U.S. hospitals each year.[9] The costs associated with CLABSIs include an estimated 28,000 deaths in the intensive care unit and up to $21.4 billion in avoidable costs annually.
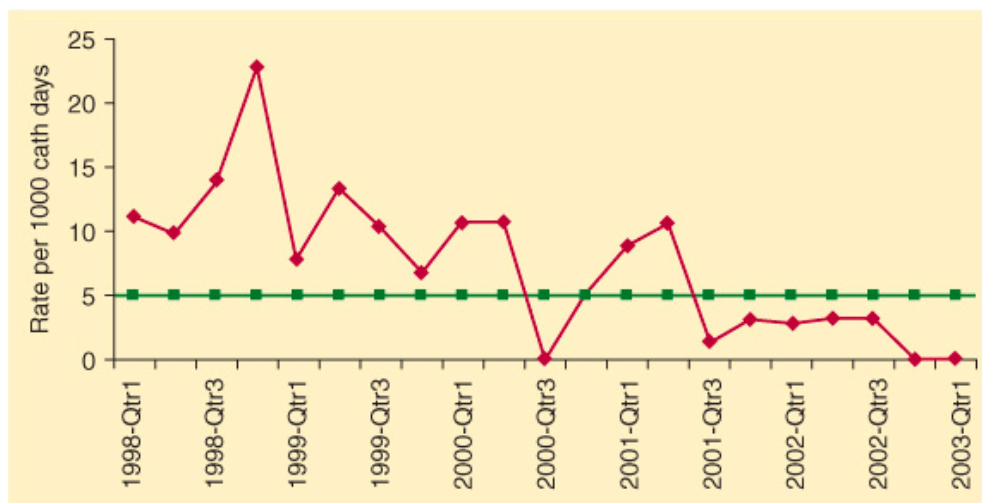
Marked decrease in catheter-related bloodstream infections after implementation of safety practices at Johns Hopkins Hospital.

SURGICAL SITE INFECTIONS. Surgical-site infections are among the most common adverse events in hospitalized patients, and they cause substantial increases in mortality, readmission rates, and costs. Approximately one in thirty "clean" surgeries will be complicated by a surgical-site infection. The rate is significantly higher for "dirty" procedures—those conducted following a patient trauma—emergency, or prolonged surgeries, and for patients with medical comorbidities.[10]

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[9] Perin, Daniele Cristina et al. "Evidence-based measures to prevent central line-associated bloodstream infections: a systematic review." Revista latino-americana de enfermagem, vol. 24 e2787. 1 Sep. 2016, doi:10.1590/1518-8345.1233.2787

[10] Reichman, David E, and James A Greenberg. "Reducing surgical site infections: a review." Reviews in obstetrics & gynecology vol. 2,4 (2009): 212-21.

VENTILATOR-ASSOCIATED PNEUMONIA. Of all HAIs, ventilator-associated pneumonia (VAP) is the leading cause of death, with far more fatal cases of VAP than of nosocomial urinary tract infections, CLABSI, or surgical site infections. About 15% of patients receiving mechanical ventilation, particularly for long periods, will develop VAP, which in turn results in prolonged mechanical ventilation and longer hospital stays.[11] Ventilated patients who develop VAP have a significantly higher mortality rate (46%) than those who do not (32%).

CATHETER-ASSOCIATED URINARY TRACT INFECTIONS. Urinary tract infections account for approximately 40% of HAIs in the U.S.[12] Most are associated with indwelling urinary catheters. However, although more common than VAP and CLABSI, urinary tract infections are less often fatal and thus have received less attention in the patient safety and infection control literature.

DEFECTIVE INFUSION PUMPS. Infusion pumps deliver nutrition and medication directly into a patient's body through a fluid-like substance. A patient's life may depend on the seamless transition of such fluids, so, when the machine fails or encounters a defect, consequences can become fatal. Between 2005 and 2009, the U.S.

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[11] Wu, Diling et al. "Risk Factors of Ventilator-Associated Pneumonia in Critically Ill Patients." Frontiers in pharmacology vol. 10 482. 9 May. 2019, doi:10.3389/fphar.2019.00482

[12] Ranji SR, Shetty K, Posley KA, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 6: Prevention of Healthcare–Associated Infections). Rockville (MD): Agency for Healthcare Research and Quality (US); 2007 Jan. Available from: https://www.ncbi.nlm.nih.gov/books/NBK43986/

Food and Drug Administration (FDA) received around 56,000 reports of adverse events attributed to defective infusion pumps.[13]

UNCOORDINATED CARE. Nearly half of hospital staff, from administrative assistants to physicians, believe patient information is lost regularly due to uncoordinated transfers between hospital units or resulting from caregiver shift changes according to an investigation by the Agency for Healthcare Research and Quality (AHRQ).[14] Doctors alternate looking after the same patients, thus inaccurate information handoffs are detrimental to patient safety—in some cases, patients are forced to repeat blood work, undergo identical MRIs, and, in more severe cases, take conflicting medications prescribed by separate physicians. The costs include time wasted, money lost, and poor patient care. Lack of coordination between doctors and nurses contributes to confusion, and medical errors are the inevitable aftermath. Safe care is contingent upon the quality of seamless delivery among medical staff working on a single patient.

MEDICATION MISTAKES. Prescribing and administering medication injures 1.5 million Americans every year and costs $3.5 billion, per a 2006 Institute of Medicine report.[15] Research indicates that over 60% of hospitalized patients miss their regular medication while in hospital care, with an average of 6.8 medications forgotten per patient. An astonishing 20% to 25% of all administered hospital medications contain an

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[13] FDA news release: FDA launches initiative to reduce infusion pump risks [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; Apr 23, 2010. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm209042.htm.

[14] Agency for Healthcare Research and Quality. (2015, November). Efforts to improve patient safety result in 1.3 million fewer patient harms (Publication 15-0011-EF). U.S. Department of Health and Human Services. https://www.ahrq.gov/hai/pfp/interimhacrate2013.html

[15] Reed, Deoine, and Sandra A Kemmerly. "Infection control and prevention: a review of hospital-acquired infections and the economic implications."

error—perhaps the wrong patient, the wrong time, the wrong medication, or the wrong dose. [16]Labeling errors wherein patients were mixed up have caused severe health problems due to side effects, and, with new drugs emerging on the market and countless available medications already, this is a frightening threat to patient safety.
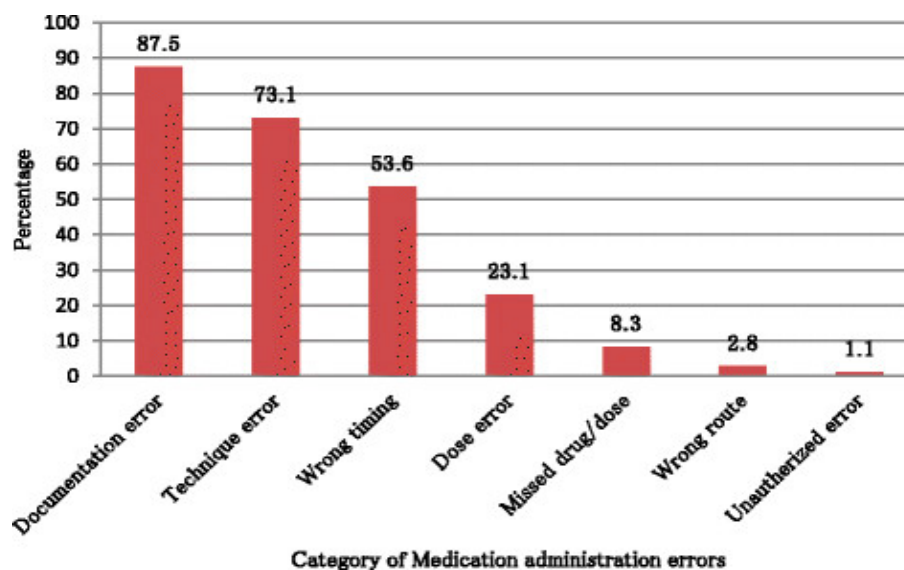
WRONG-SITE SURGERY. Wrong-site surgery occurs forty times a week in the U.S, according to a survey by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO). An X-ray film could be mislabeled, meaning a surgeon could amputate the incorrect leg. Wrong incisions, removing the incorrect organ, and unsanitary equipment can cause serious and potentially lethal complications. Marking the surgical site and talking through the procedure with the patient throughout the process and checking numerous times before operating have reduced such incidents.

[16] Tariq RA, Vashisht R, Sinha A, et al. Medication Dispensing Errors And Prevention. [Updated 2021 Nov 14]. In: Stat Pearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK519065/

Where the Problems Start

Mistakes signify system failure—not physician failure. For the most part, a hospital's structure, policies, and culture predetermine medical care quality and patient outcomes, independent of their employees' capabilities. Surgeons, nurses, and administrative workers enter the workforce with equal education per their specialties and thus share a similar foundational basis that, with the correct systems in place at their hospitals, should theoretically prepare them to care for patients in a safe way.

However, there are several main types of errors physicians make in healthcare systems, and the catalyst always circles back to system failure, for, with the right procedures implemented, the following examples can be avoided.

Knowledge-based errors take place when providers do not have the training or resources to prevent mistakes, such as prescribing medication for a patient without knowing the medication will negatively interact with other medications the patient is on. This error type is less common.

Rule-based errors come into play when a rule is applied incorrectly or not applied at all. Such mistakes could also be due to poorly formulated rules. When hospitals lack protocols for prevention, mistakes proliferate.

Action-based errors are straightforward. These occur when nurses or doctors mistakenly grab the wrong medication bottle from a drug shelf or accidentally push the wrong button on medical equipment.

Lastly*,* care providers may forget facts important to their patient's safety, such as allergies to treatment medication. Such an error is classified as a *memory-based error*.

To err is human, but errors are avoidable with systemic safeguards that, when followed, ensure safe healthcare. The single route to safety within medical institutions is creating standard systems that anticipate errors physicians can correct before people are hurt. Other high-risk industries adhere to such preventative strategies, but in what is arguably the highest-risk field, such an approach has been ignored until this past decade.
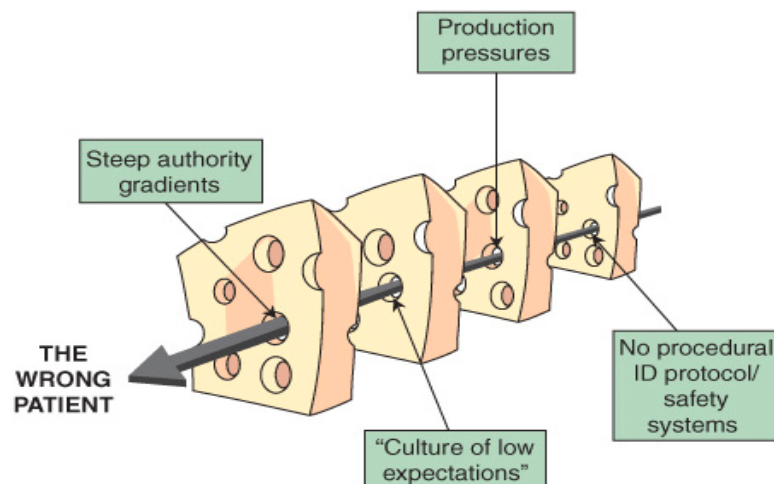
Swiss Cheese Model

British psychologist James Reason innovated the **"Swiss cheese model"** of organizational accidents. This mental model is key to understanding the necessity for system safety and highlights that imperfect human behavior is not the culprit for error. Reason described the model as follows:

> The model, drawn from innumerable accident investigations in fields such as commercial aviation and nuclear power, emphasizes that in complex organizations, a single "sharp-end" (the person in the control booth in the nuclear plant, the surgeon making the incision) error is rarely enough to cause harm. Instead, such errors must penetrate multiple incomplete layers of protection ("layers of Swiss cheese") to cause a devastating result.[17]

The idea behind the Swiss cheese model, when applied to medical errors, illuminates the flaws multiple layers within the healthcare system must have for medical errors to pass through the Swiss cheese "layers." Therefore, we should divert attention toward shrinking holes in defective Swiss cheese—systematic health care policies or lack

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[17] Reason, J., Hollnagel, E., & Paries, J. (2006). Revisiting the Swiss cheese model of accidents. Journal of Clinical Engineering, 27(4), 110-115.

thereof—and implement overlapping protective layers so we can mitigate any possibility for hole alignment, which results in fatal medical mistakes.

All underlying conditions responsible for errors are set for examination and refinement under the Swiss cheese model's motto. Health providers are encouraged to focus on root causes, for these holes piled on are responsible for the pinnacle catalyst of medical errors. If we develop a methodology that reveals the triggers for avoidable or unavoidable mistakes, problem solving to prevent root causes will save millions of lives. While exploring said medical errors, researchers review cases and categorize them based on the direct causes of each error, which, once identified, explicate the preventative measures that could have been taken to prevent each tragedy.

Some frequently documented causes are physician fatigue, lower-level physicians, and nurses afraid to speak up to their superiors, a physician forgetting a step in their

procedures, etc.[18] Readbacks, where the personnel being given an order read their order

back to their superior to ensure there was not a communication error, and checklists could

be simple solutions that create infallible individual physicians and foster an infallible care

system. For example, slips—which are mistakes made in carrying out regimented work

and are one of the leading causes of preventable medical errors—can be curtailed using

simple yet thorough checklists, readbacks, and other systematic safety methods.

Appropriate cross-checking and redundancy thwart the occurrence of the commonly

identified root causes of preventable medical errors by creating an environment where

these innocent slips with grave consequences will be caught and corrected before they

become actionable or consequential.

 The key to these safety methods' success does not lie solely in their simplicity but

also in their ability to be universally standardized. Trailblazing studies have discovered

that, city to city, hospital to hospital, there are "clinically indefensible variations" in

quality, procedures, and standards of care.[19] Even more concerning is that these same

variables are also dependent on patient income, race, and gender. Inconsistency in care

leads to an unreliable healthcare system. Maintaining such variations and disparities in

care are incongruent with the goal of eradicating preventable medical errors and engaging

in sound medical practice.

 More studies have examined the impacts of these inconsistencies on healthcare

organizations and physicians' abilities to provide healthcare according to four hundred

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[18] Wachter R.M.(Ed.), (2012). Understanding Patient Safety, 2e. McGraw Hill.
https://accessmedicine.mhmedical.com/content.aspx?bookid=396&sectionid=40414530
[19] Wachter R.M.(Ed.), Understanding Patient Safety

evidence-based quality markers. These studies revealed that, in practice, doctors and healthcare organizations follow these evidence-based measures of quality a meager 54% of the time, greatly varying from hospital to hospital and doctor to doctor, despite compliance with these procedures having shown effectiveness in ensuring quality and consistency of care.[20] The wide gap between what is accepted as best practice and what is observed as real practice has drawn attention to patients, providers, and policymakers to standardize adherence to these best practices, which can take the shape of checklists, readbacks, etc.

Mechanisms for Improvement

Whether the motivation comes from ethics, embarrassment, or finances, the next question is how to improve the quality of care. Approaches to improve patient safety will be explored in the following three chapters across three domains: philosophical, public policy, and economic reforms.

Philosophical improvements rely on hospital culture change. This means treating physicians with respect, encouraging small improvements on all levels, and abolishing the concept of hierarchy while maintaining leadership structures conducive to oriented goals. Doctors must not be frightened into improving—hospitals need employee engagement on all fronts wherein fear, shame, and finger pointing are removed from culture norms. Physicians' mentality needs development, too, for focusing on finances rather than human life is unlikely to render the best care.

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[20] Wachter R.M.(Ed.), Understanding Patient Safety

Greater efficiency removing financial pressures from hospitals will indirectly lead to less financial burdens and thus greater care for patients. The final philosophical alteration that will improve patient safety builds on doctor treatment, with regards to consideration for their work hours. Physicians are not robots and treating them in such inhumane ways—forcing 36-48 shifts for instance – is bound to end in tragedy for both doctors and their patients subject to their fatigued decision making.

The next chapter will analyze **economic improvement**s, paying attention to group purchasing organizations (GPOs) and their indirect harm to patient safety. Exclusionary GPO contracts preclude the entry of new innovative products, even if those products provide greater health benefits to patients. These GPO contracts sacrifice quality, are anticompetitive, and are potentially harmful to patients. Further, percentage-based payments provide perverse incentives to negotiate higher prices because this provides the GPO with a higher fee.

Some med-tech companies cut deals with GPOs to use their products and entirely ice out a superior company's products—such action culminates in subpar medical technology for patient use and thus a higher likelihood of preventable medical errors. A lack of transparency in GPOs' pricing structures makes it difficult to determine the impact of GPO contracting practices on hospitals, healthcare providers, and consumers. Thus, regulation of these organizations is vital to patients' wellbeing.

Political improvements will be explored in chapter three, with attention directed toward support for an "aligned incentives" bill and mandated hospital transparency. First, a bill for aligned incentives could guarantee that hospitals which adopt comprehensive patient safety measures would be rewarded with generous compensation and be off the

hook financially for any errors. Concurrently, if such measures were not in place and someone was hurt, the hospitals would not get paid for any of the care they provided. The bill would be a win-win for both patients—who would receive better care and pay fewer medical taxes—and hospitals—who would no longer be responsible for errors as long as they tried to prevent them.

By incentivizing hospitals to adopt evidence-based safety protocols by promising compensation for all procedures (both initial and follow-up surgeries for mistakes made) for those hospitals that comply, fatalities will be reduced exponentially, and it is very likely medical taxes will drop.

Now, here's my case for transparency. Hospitals are public institutions and do not report all mistakes made at the hands of physicians. Accurate reports will foster greater accountability. What is measured improves; what is measured publicly improves faster.

This list of potential approaches to improving safety will be discussed in greater detail later. Institutions quite naturally focus on the practices that are measured, publicly reported, and compensated. Because improving culture is both difficult and hard to measure, it risks being shuffled to the bottom of the deck, notwithstanding its importance to patient safety. This next chapter shows why.
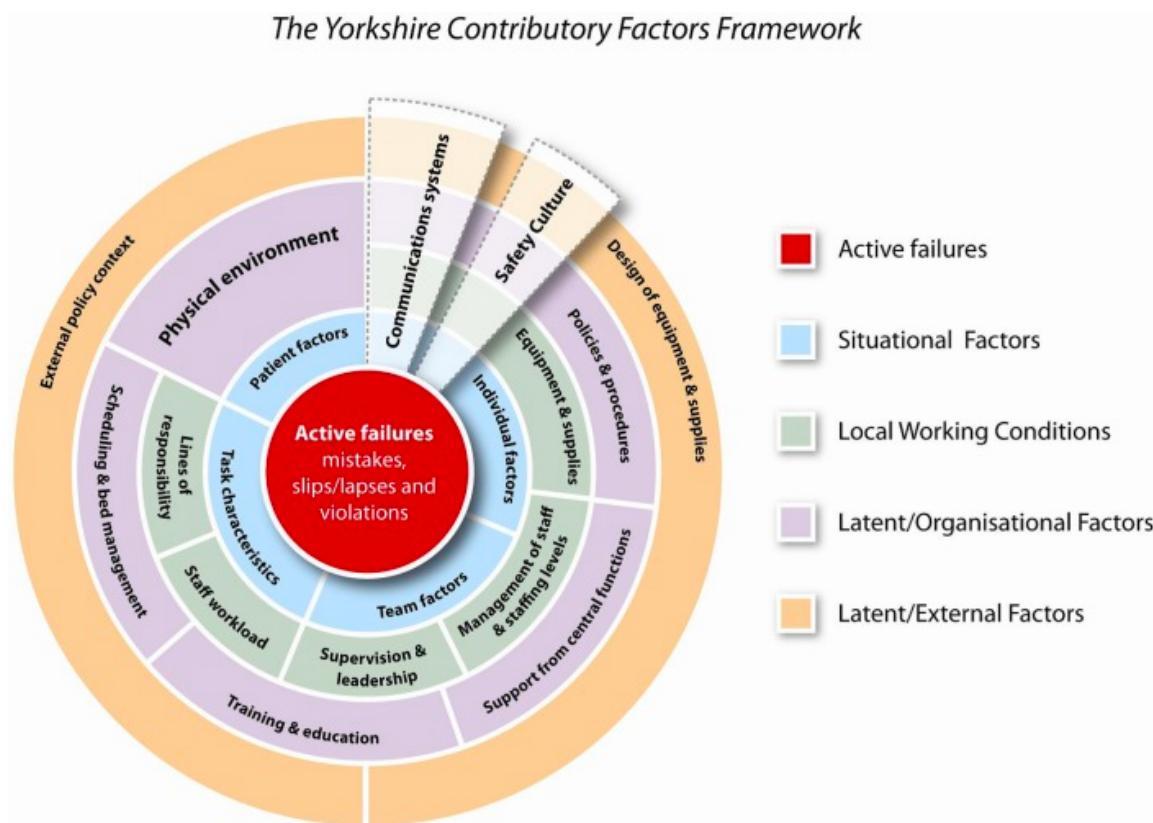
Chapter 1: Philosophical Improvements

Medical errors happen when doctors do not take every preventable measure to stop them from occurring. People are fragile specimens subject to invasive, rough medical treatments. If this medical treatment – whether it is an oral medication or a surgery – is not seamlessly delivered from start to finish, harm is inevitable. This analysis is not even about preventing all errors from taking place – asking for that outcome is unrealistic – but taking the right steps can prevent these errors from turning fatal; that is the focus here. Doctors are not superhumans, and we cannot expect flawless execution in all their actions. Everyone screws up from time to time at work, but since errors in the medical field can have fatal repercussions, doctors face exacerbated pressure. Pressuring someone into perfection is the wrong approach; it is time to foster a collaborative, encouraging culture in hospitals where mistakes are learning experiences rather than a threat to one's occupation.

According to *The Executive Guide to Healthcare Kaizen,* the four goals for improvement that should be fostered in our hospitals are safety and quality, customer satisfaction, people satisfaction, and financial stewardship.[21] Improvements in these areas can be made simultaneously, such as reducing patient waiting times while improving operating margins. Or, one improvement can lead to another, as indicated by research in healthcare improvement. Research published by the British NHS shows that organizations with higher staff engagement also "scored higher on measures of financial

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[21] Graban, M., & Swartz, J.E. (2014). The Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization (1st ed.). Productivity Press. https://doi.org/10.1201/b15381

Effectiveness, have higher patient satisfaction and have lower levels of patient

mortality."[22] Clearly, simple changes can have extraordinary outcomes. The question

now lies in execution and where to start.

The Yorkshire Contributory Factors Framework

Adjusting Cultural Practices: Eliminating Blame Shame and Developing Active

Leadership & Staff Engagement

Philosophical and cultural amendments to improving patient safety are feasible.

The improvements, while small, will have a cumulative significant impact on medical

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[22] Graban, M., & Swartz, J.E. (2014). The Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization (1st ed.). Productivity Press. https://doi.org/10.1201/b15381

error rates. An added plus is that these changes are low-cost, low-risk, and simple enough for every hospital in the country to make. However, each solution requires revamping organizational strategies and imposing a comprehensive management system within each medical institution. The primary areas for improvement concern administrative responses to medical errors, staff engagement, the abolition of hierarchical structures to allow for universal creative input, and our doctors' emotional and physical wellbeing.

We first need to adjust organizational culture, specifically with regards to unforced medical mistakes. The HHS encourages hospitals to "adopt a culture that eliminates the blame and shame associated with medical errors."[23] This cannot be emphasized enough, for if employees are far less likely to report blunders when they believe they will incur punishments by their administration for understandable human error. Reported data can help identify issues in the systems that are allowing mistakes to happen. Finger pointing and accusations only deter physicians from disclosing their mistakes or seeking help from their colleagues, which can increase danger for their patients. We must stop blaming and punishing the individuals.

There is unequivocal evidence from published medical and patient safety studies that preventable deaths are caused by systems problems.[24] It is very uncommon for a doctor to willfully commit a fatal medical mistake; thus, society needs to retain

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[23] Graban, M., & Swartz, J.E. (2014). The Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization (1st ed.). Productivity Press. https://doi.org/10.1201/b15381

[24] Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Washington (DC): National Academies Press (US); 2000. 2, Errors in Health Care: A Leading Cause of Death and Injury. Available from: https://www.ncbi.nlm.nih.gov/books/NBK225187/

respect for healthcare professionals based on the assumption they work hard at their jobs and act in good faith. In healthcare jobs, which are already complex and grueling, people cannot be scared into doing better. Cultural change is a crucial, indispensable ingredient in the equation for saving lives.

The second change focuses on leadership. Leaders at hospitals have a responsibility to:

- Actively engage the staff members they oversee

- Implement medical error safeguards and welcome suggestions from all members to instill collegiality and increase contribution-based satisfaction

- Make routine visits to clinical units to discuss safety issues and review recent errors with staff to uncover their root causes

- Spend time educating lower-level providers about common instigators that can lead to medical errors – if senior leaders forgo this step, they indirectly cripple medical staff who are unequipped to avoid errors

- Remind medical professionals of the reason they are where they are – to help people regardless of the monetary gains, despite the financial stress most hospitals are under

Financial strains extend to the workplace, where physicians are overwhelmed by the demands of their stressful jobs in addition to the financial stress that their administration places on them. It is unfair to ask so much of our doctors when they already have what is arguably the most emotionally and possibly physically taxing profession. When my surgeon has cut open my chest on the operating table, I want him to be focused on keeping me alive. That should be the single concern that the doctor has

during a procedure. Unfortunately, all levels of hospital staff endure consistent stress and frustration, mostly caused by process issues within the workplace, from mere disorganization to poor communication and understaffing.[25] These issues are fixable with the proper improvement methods.

It is inaccurate that we must obviously spend more money on people, resources, and facilities to see better quality patient care or increase hospital capacity. The Institute of Medicine (IOM) asserted the need for continuous learning and improvement in hospitals, highlighting how these strategies alone can spare hospitals significant financial costs and mitigating the processing issues to improve patient care and reduce medical errors.[26]

Continuous learning and improvement constitute "care continuity." This encapsulates learning, evolving care tactics, making mistakes, learning from those errors, and implementing innovative strategies to prevent them from recurring. Such methods go hand in hand with improved coordination and communication among medical staff, efficient patient care that will reduce waste while improving patient health, and comprehensive, in-tune leadership that can ensure that the system works as intended. As Dr. Paul Strange said, "The real goal is a cultural transformation of our organization to one which constantly seeks to improve the quality of medical outcomes, and make our processes safer. and to make our care more cost-effective. Transformation starts by

[25] Wachter R.M.(Ed.), Understanding Patient Safety
[26] Wachter R.M.(Ed.), Understanding Patient Safety

rethinking the way we see the world. Another way of thinking, not simply something that is done."[27]

Engaged Hospital Staff Make Fewer Mistakes, Yet Report Mistakes More Often

Engagement is an umbrella term covering three essential employee attributes: loyalty, commitment, and motivation. Improvement is all about engagement – indeed, engagement is the beginning, middle, and end of improvement. Engagement is essential for every level of improvement, from discovering issues that need fixing to coming up with solutions that can make a difference. Engaged employees work better, harder, and more efficiently. This goes without saying for practically any career, but when the stakes are high as they are in hospitals, engagement cannot be an afterthought. However, its importance has been severely downplayed in medical institutions.

According to research conducted globally regarding all professions, only one in three employees is engaged, and one in five is actively disengaged – essentially, they are disconnected from their organization's mission, lack aligned priorities, and report feeling underutilized.[28] This theoretically means that 20% of doctors are actively disengaged. We cannot stand for complacency when millions of people are affected; we cannot simply cross our fingers and hope for a miraculous change. It is the system's responsibility to adjust in order to promote and reward engagement. Luckily, the solution is quite simple: employees become more strongly engaged when they contribute to making an

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[27] Wachter R.M.(Ed.), Understanding Patient Safety
[28] Kular, S., Gatenby, M., Rees, C., Soane, E., & Truss, K. (2008). Employee engagement: A literature review.

organization better. This sounds like a win-win situation. All hospitals must do is give their doctors the freedom to improve their work, and the reinforcement from such improvements should feed into renewed engagement. It almost seems too easy – that's because it is. The cost to fix the system is not millions of dollars but rather appreciation and involvement. According to employees surveyed across the country, appreciation and involvement are the two things they want most.[29] Such findings were first reported in 1946, and recent investigations have since confirmed them.

The most effective improvers constantly seek out ways they can improve, compared with average workers. Thus, to inspire doctors to seek to improve patient care, we need to keep them engaged, which simply means appreciating their efforts and encouraging routine involvement in hospital affairs, separate from typical daily obligations. This cycle works beautifully – for once people start improving, they get swept up in wanting to make more improvements. This entails heightened attention and subsequent reporting of problems, which not only aids their mission for better patient care but improves their colleagues' performance too. One study suggests that high employee satisfaction correlates with better patient outcomes and lower rates of medical errors.[30] So, this is how it all ties together: employee engagement is a key predictor of patient satisfaction and patient safety – there is causation, not just correlation, between these factors.

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[29] Kular, S., Employee engagement: A literature review.
[30] Rathert, Cheryl, and Douglas R. May. "Health care work environments, employee satisfaction, and patient safety: Care provider perspectives." Health care management review 32.1 (2007): 2-11.

Management's job is to create an environment in which everybody can take joy in their work to reduce frustrations in their workplace. It is time we give hospital employees more power, control, and autonomy, which translates into improved employee satisfaction, heightened engagement, and, ultimately, the goal we seek – reliable patient safety. Cleanliness, order, and safety go together in creating a safe, effective workplace where problems are visible and readily addressed. In this culture, problems occur less often because people are continuously working to prevent problems through better systems and processes.

Where the Swiss Cheese Model Applies

Rather than focus on who is to blame, the focus should be on *what* is to blame. Most medical errors are caused by system failure, not because of a single individual human error.[31] Multiple errors must occur for a significant medical mistake to happen and take a life or cause irreparable damage. When a patient is given the wrong dose of medication, it might have been because the nurse ordered the incorrect amount. However, let us follow the path one must take for such a blunder to occur. Perhaps the nurse mistakenly input 100mg instead of 10mg. According to the Swiss cheese model, the system should have protocols that do not allow for even the possibility of such mistakes.

For example, the pharmacist could have noticed the dose was unusually high and quickly called to double-check its accuracy before dispensing the medication. This simple check could save a life. Let's pretend that the pharmacist did not catch the error. Still, the

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[31] Reason, J., Hollnagel, E., & Paries, J., Revisiting the Swiss cheese model of accidents.

second pair of hands that the medication fell into – the nurse – could prevent the fatality

by checking the medication's label. As a last resort, if family members are kept in the

loop regarding their loved one's medical care, as they should be, they too could prevent

the mistake. If they are informed that the patient is receiving 10mg but then hear that

100mg is being administered, they could identify the mistake before it causes harm. This

is just one simple example to show that systems can be put in place to stop human error

before it affects the patients.

Cost of Errors – How the Money Cloud Hinders Quality Care

Medical errors are a double-edged sword. In addition to tearing families apart,

their devastating impact cuts through the economy, raising healthcare insurance and taxes

even for those who are technically unaffected by the actual mistakes and preventable

deaths. There are numerous reasons behind this monetary situation: the Organization for

Economic Co-operation and Development (OECD) believes that 15% of hospital

expenditures and activity in OECD countries can be attributed to treating safety

failures.[32] Billions – maybe trillions – of dollars have been allocated toward patient safety

issues, with multiple studies estimating that medical errors cost the U.S. economy

between $9.3 to 9.58 billion.[33] To make matters worse, these studies were conducted over

ten years ago, and since medical outcome rates have not considerably improved, the

actual value could hit trillions of dollars in 2022.

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[32] Slawomirski, Luke, Ane Auraaen, and Nicolaas S. Klazinga. "The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level." (2017).

[33] Graban, M., & Swartz, J.E. (2014). The Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization (1st ed.). Productivity Press. https://doi.org/10.1201/b15381

These studies concluded that in 2009, the efficient delivery of health services should have only cost $130 billion; however, an additional $750 billion was spent. The excess funds came from preventable errors, fragmented care, and operational inefficiencies.[34] Our health system can control these absurd costs simply through improvements made within the hospital. Our hospitals are under increasing financial pressures tied to patient protection and the Affordable Care Act. Reimbursements to their health systems due to procedural payment structures place them in positions to lose substantial funds due to patient care penalties for preventable medical errors. There's good news and bad news. The bad news is that money clouds judgment and stirs up stress. The good news is that there are solutions to this problem. Simply by encouraging creativity and collaboration, innovative engagement can save funds.

For the cancer treatment centers of America, the objective is always to improve patient care. Of all the 450 treatment centers analyzed, only one spoke about financially driven care.[35] The manager of one of these centers said that one of the reasons they have been successful is that they don't have great expectations about big savings from ideas about improvement. Clearly, when finances are a primary issue, there is a tangible toll on doctors and patients. Shifting the focus to concern for patients alone will save lives. A monetary basis for work has negative impacts on patients, which only propagates future financial and emotional burdens.

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[34] Slawomirski, Luke, "The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level."

[35] Graban, M., & Swartz, J.E., Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization

If too much focus is placed on cost reduction, staff get discouraged because they also want to create a better workplace in order to improve medical care quality and keep patients safe. The bottom line is that savings and returns on investment are not the only things that matter; yes, they are an important part of the picture for healthcare organizations that are under significant financial pressure, but monetary driven care inevitably inhibits the progress of patient-oriented care.

Before discussing the solutions that will improve care delivery and patient outcomes, I will briefly provide an example of how treating finances as secondary to patients saves money. *Bright Ideas* was established in 1995 to engage all employees and improve innovation at Baptist Health Care Florida.[36] Since 2008, every employee has had the expectation of implementing three ideas per year to improve patient outcomes, save time, or improve safety. Over fifty thousand ideas have been implemented since 2000, and even though cost reduction was not the primary goal, there was an estimated savings of fifty million dollars.

Improving the Workplace to Save Lives

Cultural change is cheap. There is no need to spend money on new facilities or technology, which makes it the best option for quality care improvement when hospitals are financially strained. There can be important shifts from focusing on money to the time of staff at every level and their commitment to effort and discipline. There are many ways to engage medical staff to reduce medical errors: staff retention, mandated

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[36] Graban, M., & Swartz, J.E., Executive Guide to Healthcare Kaizen: Leadership for a Continuously Learning and Improving Organization

improvement workshops, accommodation of their hours, normalization of mistake discussion without consequences, and, of course, a structure in which senior leaders oversee the execution of the criteria. These changes will result in plentiful benefits for the monetary realm, which I discuss in detail below.

Staff Retention

Improving a workplace will reduce staff turnover and the costs associated with frequent employee changes. The estimated cost to replace the average hospital employee is $65,000, and the value is much higher when it comes to nurses and doctors.[37] Thus, the best way to reduce costs and save funds is to increase staff retention on all fronts. Cost reduction allows for more resources to be allocated to the treatment of patients, and when money is saved and doctors are not financially driven, using substandard products to save money, unforced fatal errors can be reduced. Shortcuts due to financial worries must be avoided, for they only result in worse financial predicaments because the problems caused by even a few inferior products can end up costing more, with patient lawsuits and treatments to compensate for the medical errors.

Improvement Workshops

The Virginia Mason Medical Center in Seattle, Washington is famed for its rapid process improvement workshops. The improvements that came from these workshops allowed providers to spend more time with patients, leading to better care, higher patient

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[37] Wachter R.M.(Ed.), Understanding Patient Safety

satisfaction, and improved staff satisfaction. Each year, 838 patients avoided a specific type of preventable harm compared to previous years, and these quality and safety improvements caused the hospital professional liability insurance rates to fall by almost 50% from 2004 to 2009.[38] This demonstrates the causation between better care outcomes and improved costs.

Freeing Staff Time

A collection of improvements that free up staff time can lead to reduced patient falls or infections, which not only have clear patient benefits but also reduce the amount of unreimbursed care provided by hospitals. Bill Douglas, Chief Financial Officer at Riverside Medical Center, asserted that patient safety improvements should not and do not start as "a cost-cutting initiative. But the end result is if you improve quality your cost will go down. If you focus on patient quality and safety you just can't go wrong. If you do the right thing with regard to quality, the costs will take care of themselves."[39]

Normalize Discussion to Learn from Mistakes

As mentioned before, to cultivate a safety culture, it is crucial to normalize discussions around physician errors and unintended poor outcomes. That is the single best way to learn from your own mistakes and the mistakes of others, ensuring that they are one-time incidents. There are many ways to go about this. One example is "morbidity and mortality (M&M) conferences" – these are common for healthcare systems that

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[38] Wachter R.M.(Ed.), Understanding Patient Safety
[39] Wachter R.M.(Ed.), Understanding Patient Safety

promote openness about their medical error rates.[40] The typical audience and speakers are predominantly physicians; however, there is a recent push to include nursing and hospital administration staff. Another strategy to soften mistake disclosure is for senior leaders to approach errors in an educative manner within their clinics and promote systems thinking and solutions in response to mistakes, instead of punishment. Safe organizations build in mechanisms to hear about errors from frontline staff, often via incident reporting systems or unit-based safety teams, which can help uncover the root causes of major errors.

Responsible Senior Leadership

Quality begins and ends in the boardroom. Senior leaders are tasked with overseeing their medical institutions. A culture that either fosters or hinders quality care and organizational improvement is contingent upon their leadership style – patient safety and improvement-oriented organizations see their efforts resulting in superior outcomes, while scattered, incohesive teams see poorer results. For a health organization to reach its optimal point, senior leaders must reiterate the guiding values and principles associated with holistic patient care; otherwise, continuous improvement remains a fantasy.

IU Health Goshen Hospital is a trailblazer in this domain. Each meeting at this hospital begins by reading the hospital's mission statement and reflecting on recent care quality to evaluate how aligned staff has been with the institutional values.[41] Reminding doctors, nurses, and staff that the reason they are in their profession can be integral in solving problems to keep patients safe. It starts with changing the focus from fiscal to

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[40] Epstein, Nancy E. "Morbidity and mortality conferences: their educational role and why we should be there." Surgical Neurology International 3.Suppl 5 (2012): S377.

[41] Wachter R.M.(Ed.), Understanding Patient Safety

patient responsibility. An evolved healthcare philosophy requires "everyday improvement, everybody improvement, and everywhere improvement." Continuous improvement seems to be more a goal than a reality in most hospitals and other healthcare organizations.

Senior leaders must ensure that improvement becomes a part of the organization's culture by first modeling and teaching these behaviors. This is called being a servant leader.[42] The manager's role is not to solve problems but to coach and mentor staff in problem solving. The Shingo model sets a solid example for how hospitals ought to operate and explains how the best managers link improvements to patient safety and quality care:

"This approach is neither top down nor bottom up. Strategies and goals flow generally, in a top-down direction, while ideas generally flow upward from front-line staff. Strategies are adjusted based on input from other levels and improvements ideas are refined based on input from leaders, thus engagement from all levels is necessary for productive improvements. The Healthcare organizations that practice this leadership style have chosen to because the methodology aligns with their strong sense of purpose and mission which is to serve patients and help the community."[43]

Make the PDSA Model Universal

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[42] Trastek, Victor F., Neil W. Hamilton, and Emily E. Niles. "Leadership models in health care—a case for servant leadership." Mayo Clinic Proceedings. Vol. 89. No. 3. Elsevier, 2014.

[43] Wachter R.M.(Ed.), Understanding Patient Safety

The PDSA model is a precedent all hospitals should follow. PDSA stands for: Plan, Do, Study, Act.[44] Passive work does nothing to improve patient safety and reduce preventable medical fatalities. So, when a physician sees something wrong with a current situation and identifies the root cause of the problem, they should first plan a change, with a hypothesis about the outcomes that the change will have. Then, they pilot the change and carry out small-scale tests. Afterward, they should study the changes and decide, based on those results, whether to adopt the innovation or amend it.

Each successive small improvement should be celebrated, rather than grousing about why the whole problem was not solved at once. Even if the proposed idea fails, people should be encouraged to try to make fixes. Otherwise, in a culture where people feel fear of being punished, people will be afraid to suggest changes or become incredibly cautious, only proposing those changes that are certain to work. Bringing teams together to examine their practices and participate in a PDSA cycle is the most likely path to success.

Supervisors and senior physicians must come to terms with the fact that they are not omniscient and thus do not have every answer. Rather than abuse their power and belittle lower-level staff, they can use their influence efficiently and help every employee meet their full potential to feasibly combat medical mistakes across the spectrum. Overmanaging by means of prescriptive rules is possibly less safe than tolerating a reasonable degree of flexibility and openness to suggestion when their subordinates have

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[44] Taylor, Michael J., et al. "Systematic review of the application of the plan–do–study–act method to improve quality in healthcare." BMJ quality & safety 23.4 (2014): 290-298.

recommendations. We want an environment where change and creativity are standard ways to practice medicine.

Examples Where PDSA Eliminated Preventable Deaths

For example, when a group of cardiac surgeons participated in an experiment where they each watched over their fellow physicians' care style and used these observations to formulate best practices, their critiques of each other led to improvement strategies. The result was a 24% reduction in cardiac surgery mortality.[45] With hundreds of thousands of lives lost due to inefficient practices or careless errors, even minimal changes are beacons of hope. A single life saved due to a doctor's creativity means that it is worth trying any and every new idea that a staff member has.

Here is a second example: when completing diagnostic upright radiographs in 2011, technologists were forced to wrap Velcro straps around patients' waists to place appropriate shielding devices on them.[46] This increased the risk of spreading infections from patient to patient. Russell Maloney innovated an IV pole that was modified to support a shield that could be raised and lowered according to height. The device did not require contact with the patient to be effective and was much faster than the traditional method; more importantly, it improved patient safety by reducing the possibility of infection.

Eheart was developed at Franciscan St Francis Health. With this protocol the average door-to-balloon time was reduced by 113 minutes. Patients receiving treatment

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[45] Wachter R.M.(Ed.), Understanding Patient Safety
[46] Wachter R.M.(Ed.), Understanding Patient Safety

within ninety minutes increased from 28% to 71%, the average heart attack size was reduced by 40%, and the average length of stay was reduced by two days.[47] Many of the improvements came from physician driven systemic changes to the process.

Being creative simply means generating new ideas, and most people underestimate or discount their own creativity. Imagine if even ten doctors at every hospital in the US came up with one idea per year tied to patient safety efforts that saves just one patient – already, that is 70,000 people saved, simply from making the workplace a safe space for doctors to voice solutions to practices they find to be inefficient.

How Aviation Is a Model for a Safe Healthcare Environment

The healthcare field is turning to aviation for guidance in its improvement endeavors.[48] Workers on planes and in operating rooms conduct their business as teams, so it only follows that they should follow similar protocols in their collaborative structures for successful outcomes. In aviation, a cohesive cockpit has hierarchical authority gradients with adequate flexibility to encourage input from crew members at every level. This well-orchestrated team dynamic follows a specific training model known as crew resource management (CRM), which champions communication and teamwork.[49] Commercial pilots attend mandated CRM courses alongside their crews to prepare for hypothetical emergencies. In these classes, they practice dealing with possible

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[47] Wachter R.M.(Ed.), Understanding Patient Safety

[48] Kapur, Narinder, et al. "Aviation and healthcare: a comparative review with implications for patient safety." JRSM open 7.1 (2015): 2054270415616548.

[49] Kapur, Narinder, "Aviation and healthcare: a comparative review with implications for patient safety."

issues using healthy dialogue, checklists from their experiences to apply if such disasters unfold in real life, follow-up conversations (debriefings), and various additional collaborative approaches.

CRM can and must be adapted to accommodate medical teams; already, studies have concluded that patient safety improvements are imminent if healthcare organizations require CRM courses for physicians and their operating room teams. Patient safety cannot happen in the absence of safety culture, and safety culture will not be established overnight. It is learned. Thus, achieving consistent patient safety requires promoting environments that foster teamwork, encourage creative solutions, and allow for organized communication and medical mistake disclosure – both within hospital walls and beyond them. Although these changes may appear to be straightforward, there are multiple aspects that hinder their execution.

In one study, physicians were questioned about their operating room dynamics and aviation crews were asked comparable questions about their aviation leadership style (crew culture, collaboration effectiveness). The study recorded the following observation: "While attending surgeons reported that teamwork in their operating rooms was strong, the rest of the team members disagreed, proving that one should ask the followers, not the leader, about the quality of teamwork." Moreover, "more germane to the patient safety question, while virtually all pilots would welcome being questioned by a coworker or subordinate, nearly 50% of surgeons would not" (see the figure below).[50]

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[50] Wachter R.M.(Ed.), Understanding Patient Safety

Believe that decisions of the "leader" should *not* be questioned
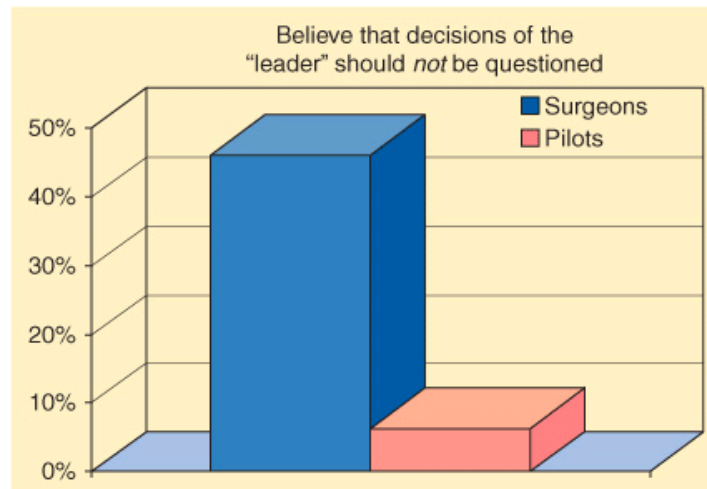
The Junior Nurse Impact: Speaking Up

It is those people working in the operating rooms day in and day out who need the courage to find their voice and challenge surgeons to save a life. Speaking up is important for patient safety; often, the healthcare professionals present in operating rooms are the most hesitant to voice their concerns. Speaking up can prevent human error and helps to fix technical and system deficiencies, which regularly contribute to preventable fatal medical mistakes. Speaking up is "defined as the raising of concerns by health care professionals for the benefit of patient safety and care quality upon recognizing or becoming aware of the risky or deficient actions of others within health care teams in a hospital environment"; these actions include "mistakes (e.g. missed diagnoses, poor clinical judgment), lapses, rule breaking, and failure to follow standardized protocols."[51]

A review evaluated twenty-six articles on factors that can help improve speaking-up behavior and team communication; it revealed that hesitancy to speak up can lead to

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[51] Okuyama, A., Wagner, C., & Bijnen, B. (2014). Speaking up for patient safety by hospital-based health care professionals: a literature review. BMC health services research, 14, 61. https://doi.org/10.1186/1472-6963-14-61

communication errors and thus to preventable deaths.[52] Learning effective communication and teamwork skills is crucial to improving patient safety for healthcare professionals. There are characteristics unique to frontline staff that make them ideal contenders for offering suggestions.

Medical residents and nurses are educated observers who, given their constant exposure to various procedures, can use their diverse viewpoints to notice early signs of unsafe conditions, which can contribute in a helpful way when doctors are stumped during surgery. If they do not feel comfortable mentioning their ideas, then the likelihood for medical errors and preventable fatalities increases. However, frontline workers are often deterred from speaking up because they are ignored when they do. They preemptively stop themselves from offering suggestions as a safe silence approach. The studies revealed that nurses seldom questioned their senior doctors' judgment, only speaking up in narrow circumstances such as when their input conformed to hospital policies. Most nurses claim that interjecting about a physician's practice is a high-risk and low-benefit action.

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[52] Okuyama, A et al., Speaking up for patient safety by hospital-based health care professionals: a literature review.
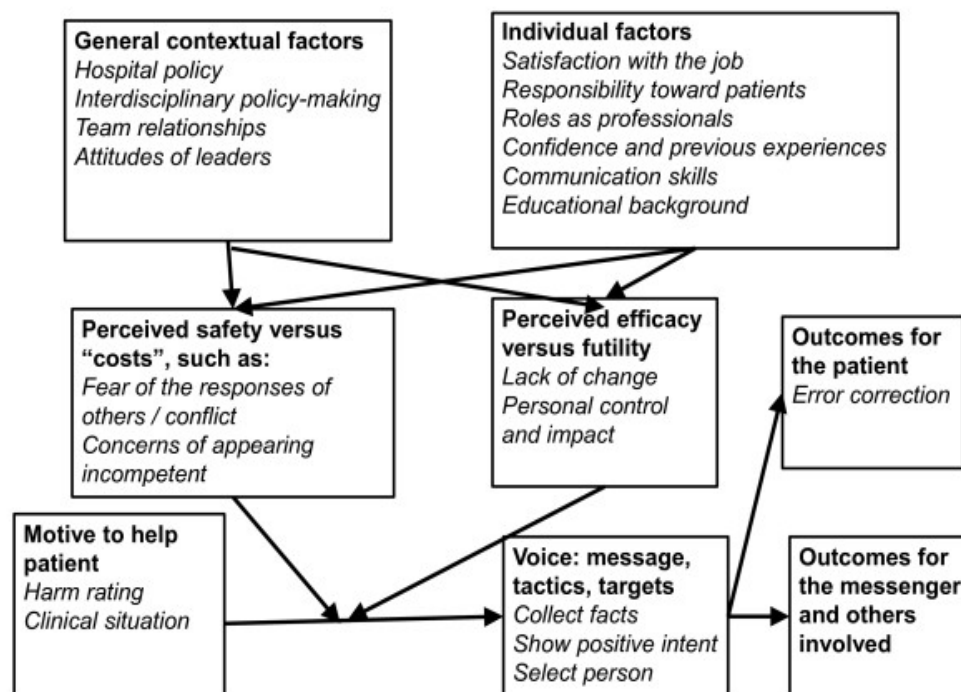
Model of healthcare professionals' speaking up. The bold text shows the framework of Morrison's model of employee voice. The italicized text shows identified factors for speaking up.[53]

A few studies reached telling conclusions about the interplay between speaking up and patient safety outcomes. Communication failure is a primary reason for medical errors, and trends noticed in these three studies indicated that when nurses and residents withheld suggestions, information did not always make its way efficiently or accurately to senior physicians. Thus, a lack of communication hinders patient safety and physician performance. Even worse, many junior staff admit to refraining from speaking up even when they were aware of patient safety risks. Finally, there is a motivating factor that should inspire collaboration among all medical levels within an operating room: 74–78%

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[53] Okuyama, Ayako et al. "Speaking up for patient safety by hospital-based health care professionals: a literature review."

of residents and attending physicians claimed to remember cases where residents voiced concerns that subsequently prevented a medical error, several of which could have turned deadly.

Caring For Hospital Employees Can Reduce Medical Mistakes

Looking after our doctors is the final fix needed within hospitals. It does not matter if a hospital is well staffed with well-trained physicians if these individuals are not well rested. Delivering safe care rests on an assumption that our doctors are healthy and rested when operating on their patients. This assumption is inaccurate, for evidence links low nurse-to-patient ratios, long resident work hours, and mental or physical exhaustion with poor patient outcomes due to preventable medical mistakes. If the end goal is the eradication of preventable medical errors that lead to fatalities, then it is crucial to account for the emotional and physical wellbeing of our physicians.

Mistakes Attributed to Fatigue Impairment

A pervasive problem plaguing both doctors and their patients is physician exhaustion and, of course, the fatal ramifications that fatigue has on patients. There is robust evidence that inadequate sleep has significant health and cognitive performance consequences: "Sleep related impairment disrupts connectivity and processing within and between the amygdala, anterior cingulate, and medial prefrontal cortex, resulting in emotional dysregulation. Further, insufficient sleep also results in reduced capacity to maintain attention including dose-dependent attention gaps proportional to increasing

hours awake – associated with reduced intraparietal sulcus and dorsolateral prefrontal cortex activity."[54]

These sleep impaired deficiencies cripple physicians' capacity to perform the critical cognitive tasks that they conduct routinely and, when well rested, with minimal difficulty. Such tasks may include patient diagnoses, follow-up treatment planning, and surgical procedures. A 2020 study assessed 11,395 physicians' sleep and wellness in relation to their burnout and self-reported clinically significant medical errors. The evidence illustrated clear associations between poor clinical performance and sleep-related impairment.[55] Emergency room doctors working night shifts took longer to intubate patients, displayed increased propensity for error as their shifts progressed, and exhibited a significant decline in cognitive performance after working five consecutive night shifts.

Sleep-impaired trainee physicians displayed deficiencies across a wide spectrum, from functional cognition complications, concentration problems, difficulty with working memory and visual memory, and issues related to operative dexterity, vigilance, and their ability to discern arrhythmias on electrocardiograms. Sleeplessness also resulted in impaired decision making, including reduced capacity for risk-benefit analysis and increased risk-taking behavior; when sleep-deprived residents were surveyed on how they

[54] Trockel MT, Menon NK, Rowe SG, et al. Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors. JAMA Netw Open. 2020;3(12):e2028111. doi:10.1001/jamanetworkopen.2020.28111

[55] Trockel MT, Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors.

would respond to a hypothetical case, the sleep-deprived doctors proposed riskier treatment options.

PROMIS is an eight-item scale used to measure tiredness, alertness, sleepiness, and functional deficits caused by sleep impairment. The study utilized PROMIS for each physician to assess their sleep-related impairment to see if their scores were associated with poor patient outcomes.[56] Each doctor was given a rating on a forty-point scale, with 16 to 19 considered to be high and 20 to 24 very high. The mean sleep-related impairment scale score was 16.9 overall, and it was 20.7 among training physicians. The study's hypothesis proved to be correct: a direct proportionality existed between sleep impairment and problems of interpersonal disengagement, work exhaustion, burnout, and professional fulfillment. Most troubling, to say the least, was the study's finding that linked self-reported clinically significant medical error to sleep-related impairment on a dose-response association level.

The same 7,538 physicians who provided a score for their sleep impairment also offered self-reports pertaining to medical mistakes they had made, revealing that, the greater one's sleep impairment, the more one is prone to make clinically significant medical errors. Moderate, high, and very high levels of sleep-related impairment increased physicians' likelihood of inflicting a significant medical error (66%, 141%, and 194% of the time, respectively).[57] In fact, with each additional point on the PROMIS scale, a doctor was 14% more likely to self-report a clinically significant medical error,
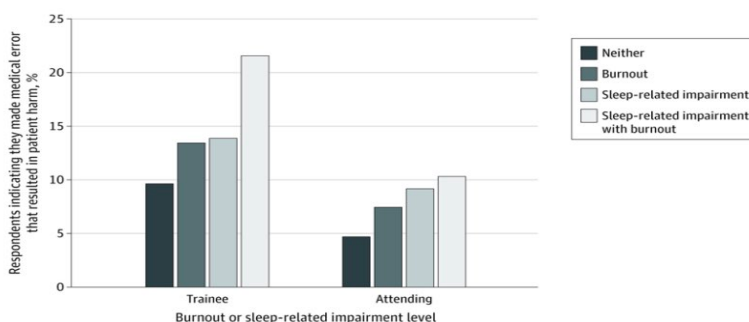
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[56] Trockel MT, Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors.

[57] Trockel MT, Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors.

with physician trainees having 118% greater odds of committing clinically significant medical errors compared with the attending physicians surveyed.

In line with these findings, physicians with better sleep scores (that is, less impairment) were less likely to self-report medical mistakes. The study notes: "The proportion of all physicians who made a clinically significant mistake was 7.5% of attending physicians and 16% of training physicians. Had these observed associations been due to sleep related impairment and burn out causing self-reported medical error, 37.7% of attending physicians and 39.9% of trainee physicians who reported making a self-reported medical error resulting in patient harm would have been able to avoid making these errors."[58]

Figure 2. Probability of Error That Resulted in Patient Harm, by Sleep-Related Impairment and Burnout Categories Among 7624 Physicians and Trainee Physicians

If the observed associations are explained by how sleep-related impairment and burnout cause errors, strategies to mitigate these factors can reduce medical errors. A reduced capacity for attention due to sleep deprivation contributes to a vicious cycle of

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[58] Trockel MT, Assessment of Physician Sleep and Wellness, Burnout, and Clinically Significant Medical Errors

making medical mistakes: sleep deprivation from excessive work hours decreases efficiency, which contributes to increased work hours. And conscious involvement in a medical error that resulted in patient harm contributes to the development of burnout, sleep-related impairment, or both.

*An Unfortunate Fatigue-Based Error Example*As an example, eighteen-year-old Libby Zion died twenty-seven years ago from a sleep-related medical mistake.[59] Zion was jerking uncontrollably and had a fever of 103 degrees when she was admitted to New York Hospital on March 4, 1984. After she was admitted, Zion was given Tylenol and evaluated by a resident and an intern. They prescribed Demerol, a sedative. But her thrashing continued, and the intern on duty – who was just eight months out of medical school – injected another sedative, Haldol, and restrained her to the bed. Shortly after 6 a.m., the teenager's fever shot up to 108 degrees and, despite efforts to cool her, she went into cardiac arrest. Seven hours after she was admitted, Libby Zion was declared dead. Her doctor had been on duty for almost 24 hours by then.[60]

We must act not only to reduce medical errors and save patients' lives; it is also because physicians deserve to be treated like human beings. They are not robots. There are multiple possible ways to improve this atrocious condition that harms hundreds of thousands of patients and hundreds of thousands of medical practitioners. The strategies to minimize medical errors related to sleep impairment are endless. They may include

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[59] Jones, Samuel V. "The moral plausibility of contract: Using the covenant of good faith to prevent resident physician fatigue-related medical errors." U. Louisville L. Rev. 48 (2009): 265.

[60] Jones, Samuel V. "The moral plausibility of contract: Using the covenant of good faith to prevent resident physician fatigue-related medical errors."

regulating shift length, reducing the number of successive night shifts one can take,

mandating periodic breaks over long shifts, or employing the "anchor sleep schedule."[61]

Of course, an effective mechanism for improvement could be legislation introduced at the

state and national levels to compel adherence to strict work hours for physicians.

Nonetheless, the key ingredient is transforming the cultural norms around sleep in

medicine.

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[61] Berger, Ann M., and Barbara B. Hobbs. "Impact of shift work on the health and safety of nurses and patients." Clinical journal of oncology nursing 10.4 (2006).

Chapter 2: Political Improvements

Transparency

What is measured improves. What is measured *publicly* improves faster. Transparency in healthcare is essential to reducing medical errors. When hospitals know they are held accountable for their mistakes, they are more incentivized to implement every precaution at their disposal to avoid the humiliation and financial repercussions that come with disclosing preventable mistakes—many of which turn fatal. This chapter will explore transparency in healthcare from its history and current applications to enforcement ideas targeted at patient safety improvement.

What is Healthcare Transparency?

This is how the Institute of Medicine (IOM) defines healthcare transparency: in both a truthful and comprehensible manner, hospitals must provide full disclosure regarding the public information about their system's quality, efficiency, and patient care experience, including analytic data pertaining to price and quality measures. Such measures are intended to influence the behavior of care providers and others to achieve better financial and quality outcomes. Two transparency types require published reports: price transparency and performance transparency.[62]

Price Transparency

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[62] Antos, Joseph, and Peter Cram. "Making hospital price transparency work for health care consumers." JAMA Health Forum. Vol. 2. No. 4. American Medical Association, 2021.

According to the IOM, price transparency is an essential component to overall hospital reporting. This includes "physicians, hospitals and other providers publicizing their usual charges for particular health care services, which may vary depending on their contracts and relationships with various payers, [i]nsurers making available to their subscribers the rates that they have negotiated with physicians and hospitals, and government agencies publicly reporting the average prices for common health care services."[63]

Performance Transparency

Performance transparency encapsulates all information that must be published related to hospital and individual physician performance across three realms: clinical quality, resource use, and experience of care.[64] Clinical quality measures the adequacy of offered services and if such services meet standard benchmark guidelines that should lead to positive outcomes. Clinical quality also considers resource use, which measures service intensity and/or service frequency.

Experience of care is arguably most pertinent to determining how a clinician or hospital measures up, for this component makes evaluations contingent on patient reviews. Patients are questioned—typically in survey form—about the care they received from a provider. Typical questions range from inquiries about appointment waiting times to poor communication or unresponsiveness.

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[63] Antos, Joseph, and Peter Cram. "Making hospital price transparency work for health care consumers."

[64] Antos, Joseph, and Peter Cram. "Making hospital price transparency work for health care consumers."

Why is Healthcare Transparency Important to Healthcare Professionals and Patients?

Simply put, transparency holds societal members and institutions accountable. Unfortunately, when someone knows they are not being watched, the likelihood of acting in an unethical way increases. It is inevitable that many people choose not to take the moral high ground if it means pouncing on an opportunity to salvage their reputation, increase finances, or conceal wrongdoing. This human problem extends to medical professionals and, even more so, the businessmen running hospital operations.

While, in any setting or workplace environment, acting in selfish and/or conniving ways is immoral, the stakes are astronomically higher when the culprit works in healthcare. The list of those affected is endless—patients, doctors, family members, employers, purchasers, health plans, healthcare professionals, and even policymakers. Transparency is important for numerous reasons, and, ultimately, all these reasons contribute to quality of care and often preventable medical mistakes and deaths.

Recent studies concluded that transparency is a precursor to informed decision making when it comes to selecting health insurance, the hospital or clinic someone goes to, the doctor one selects to perform an operation, or even a certain treatment course for a medical condition. [65] Moreover, informed decisions make for better outcomes. Without information, which only comes with reliable, honest, thorough transparency reports, patients and family members are blind to their options. Of course, some patients may not

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[65] Saghafian, Soroush, and Wallace J. Hopp. "The role of quality transparency in health care: Challenges and potential solutions." NAM perspectives 2019 (2019)

conduct a full background check on their physician or treatment, but many people do, and those people achieve better outcomes.

The truth of the matter is that transparency, while helpful to decision making on the patient end, is far more important in its safeguarding role that prevents unethical actions by hospitals and compels doctors to take patient care seriously. Fear of consequences is an effective deterrent. Also, research indicates that increased healthcare transparency strengthens relationships between physicians and healthcare systems by ensuring foundational trust.[66] Healthy competition is a final benefit incurred with medical affair disclosures, as competition leads to overall improvement in quality, safety, and efficiency.

Unfortunately, regulations and current oversight procedures are not regimented enough, and many hospitals intentionally slip through the cracks, failing to provide timely, dependable reports. It is hard to know if even those hospitals that do follow protocols are reporting every incident. There is practically no way to ensure doctors, other healthcare practitioners, and medical practices are honest unless each employee acts as an undercover officer—which, of course, is both unrealistic and, quite frankly, unsettling for fellow workers.

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[66] Saghafian, Soroush, and Wallace J. Hopp. "The role of quality transparency in health care: Challenges and potential solutions."

Nearly half of survey respondents who say they experienced a medical error say that it was reported to medical personnel, other health care facility staff, or to someone else.

No one reported the error
31%

The error was reported
45%

Unsure
24%
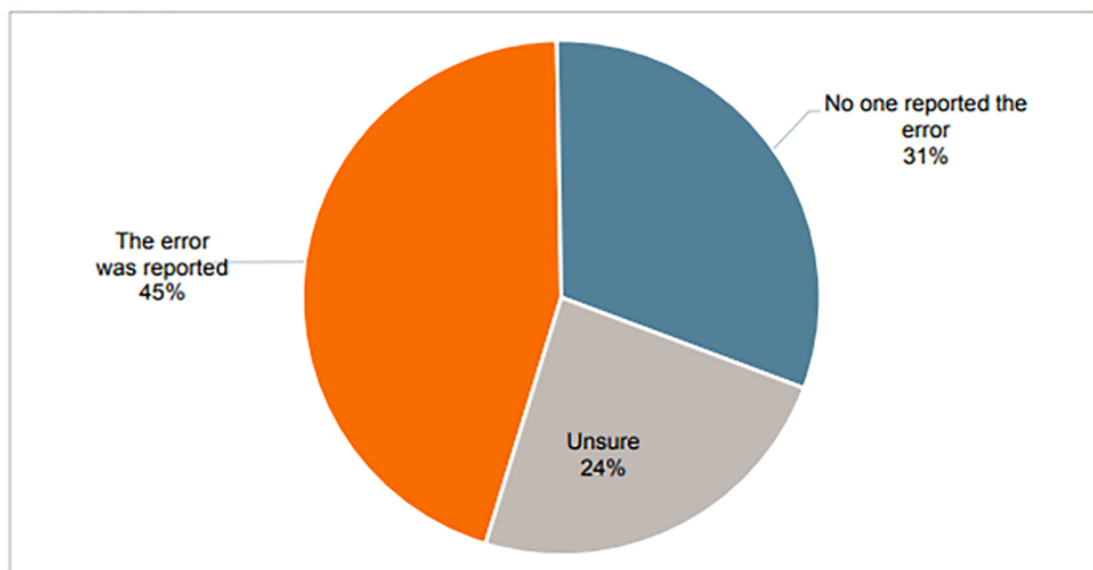
Question: Did [you/you or the person close to you] report the medical error, did someone else report it on [your/their] behalf, *or did no one report it?*

67

Current Practices—How Hospitals Report Errors:

Hospitals report medical errors in multiple ways, with some methods superior to others. The qualities composing best practices are timeliness and reliability. These two factors are relevant to each of the following report types. The most common disclosures manifest as self-reports by hospitals, patient safety indicators, hospital standardized mortality ratios, and direct reports looking at patient testimonials. Following a brief overview of the four transparency types, we will evaluate their effectiveness based on the mentioned desirable qualifications.

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[67] NORC at the University of Chicago and IHI/NPSF Lucian Leape Institute. Americans' Experiences with Medical Errors and Views on Patient Safety. Cambridge, MA: Institute for Healthcare Improvement and NORC at the University of Chicago; 2017.

Self-Reports

Most hospitals promise full transparency using self-reports.[68] Not only are self-reports the simplest way to document mistakes made within hospital walls, but when, done correctly, they also should be more accurate than any of the other methods. Mistakes are electronically tracked by providers and reported through a system called "incident reports."[69] While one may assume this tactic is relatively reliable and straightforward, incident reports prove problematic, as there are numerous issues concerning report frequency, namely ethical concerns.

While nurses are reliable reporters who utilize the incident reporting system, a great deal of doctors do not report their errors, or, if they do, they opt for informal reports, whether it be notifying a chief resident or keeping it under the radar by simply discussing the error with staff.[70] Therefore, the errors reported do not indicate the actual error rate at a hospital. Since reporting systems are informally enforced, report frequency is contingent on hospital standards and culture. For instance, if a medical practice highly encourages error reporting to promote safety culture or new leadership requires it, we are likely to see an increase in errors reported. Of course, this can be tricky, since an increase in errors reported may appear, which, on the surface, would seem to reflect an increase in errors as opposed to an increase in reporting.

Hospital Standardized Mortality Ratios (HSMR)

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[68] Wachter R.M.(Ed.), Understanding Patient Safety

[69] Mitchell, Imogen, et al. "Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human'." BMJ quality & safety 25.2 (2016): 92-99.

[70] Perez, Bianca, et al. "Understanding the barriers to physician error reporting and disclosure." Journal of patient safety 10.1 (2014): 45-51.

A second attempt at transparency pays credence to hospital standardized mortality ratios (HSMR), a method Professor Brian Jarman of Imperial College London pioneered. An HSMR value stems from the ratio of observed deaths to predicted deaths. To predict deaths, the HSMR considers patient age, sex, diagnosis, length of stay, comorbidities, and initial admission status.[71] For example, imagine we expect two hundred deaths in a hospital, but the resulting count is three hundred. The hospital's SMR equates to 300/200 (or 150%).

If HSMRs worked predictably, they could distinguish well-functioning hospitals from poorly run institutions, but this is very unlikely, as HSMRs are susceptible to subjective uncertainties, especially when deciding if a patient is prone to death notwithstanding physician blunders. Case in point, a 2010 investigation compared HSMRs and comprehensive hospital care quality and concluded that the HSMRs were nowhere near indicative of the hospital's outcomes.[72] Methodological problems include poor signal-to-noise ratio, unreliability, and uncertain case-mix adjustment. These issues are here to stay because we cannot merely tell people to change their predictive abilities.

Patient Safety Indicators

A third transparency method used to monitor hospital safety is through patient safety indicators (PSIs). PSIs are created by compiling vast arrays of administrative datasets and are intended to provide feedback to hospitals on incidents that were possibly

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[71] Scott, Ian A., et al. "Using hospital standardized mortality ratios to assess quality of care—proceed with extreme caution." Med J Aust 194.12 (2011): 645-648.
[72] Wachter R.M.(Ed.), Understanding Patient Safety

avoidable to pinpoint places for improvement in care delivery.[73] Thus, their main coverage follows surgical, procedural, and childbirth complications. By studying error frequency within their hospitals, staff can find mistake patterns that make fixing such targeted problems more efficient.

The Agency for Healthcare Research and Quality champions PSIs and formed a chart metric consisting of twenty-five outcomes or processes linked to patient safety. Harvard medical practice encourages consistent chart review; they argue this practice is the optimal way doctors can circumvent common preventable errors that cause preventable fatalities.[74] Conceptually, this technique sounds simple enough to execute, but, unfortunately, making charts and following up with tracking their contents entails intensive labor and additional funding overstretched hospitals cannot afford. Of course, the largest concern with each transparency mechanism follows here as well: doctors may leave out true error values, meaning chart patterns present inaccurate depictions of mistake trends.

Another human tendency distorting reliable error charting is hindsight bias. Research indicates hindsight bias in healthcare drives physicians to exaggerate (to a lesser or greater extent) their ability to have predicted past events.[75] Medical decision making at the time of decisions cannot then be fairly judged, for a doctor's overconfidence diminishes their self-accountability for committing medical malpractice.

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[73] McDonald, Kathryn M., et al. "Measures of patient safety based on hospital administrative data-the patient safety indicators." (2010).

[74] Wachter R.M.(Ed.), Understanding Patient Safety

[75] Arkes, Hal R. "The consequences of the hindsight bias in medical decision making." Current Directions in Psychological Science 22.5 (2013): 356-360

The Institute for Healthcare Improvement has since introduced the "global trigger tool" as a developed way to track adverse medical incidents.[76] Trigger tools are essentially clues that uncover the reason for medical mistakes. Per the Patient Safety network, trigger tools are used to "retrospectively analyze medical records in order to identify errors and adverse events, measure the frequency with which such events occur, and track the progress of safety initiatives over time." Initially, they seem awfully like PSIs, but the IHI notes that the main difference between the two is efficiency, since complete medical record reviews to locate adverse medical events are time consuming and expensive. According to the IHI, triggers are a great alternative because they fast-track the investigative process, screening medical records for patterns that led to harm and identifying cases that share characteristics with those who reported errors to see if they merit another look.

If we only paid attention to voluntary reports offered by hospitals, drawing deductions from error trends would be useless. Researchers found that between 10% to 20% of errors are reported, and, of the ones reported, 90% to 95% were listed as "no harm done."[77] Self-reports are biased, and, without honest, helpful data, making effective changes in healthcare delivery is hopeless. The best solution for accurately identifying adverse events and measuring the rate of these incidents over long periods is then, for the time being, trigger tools.

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[76] Classen, David C., et al. "'Global trigger tool'shows that adverse events in hospitals may be ten times greater than previously measured." Health affairs 30.4 (2011): 581-589.

[77] Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement (2009)

Though the tools are not perfectly specific, studies determined they have "good inter-rater reliability and often identify cases of medical errors that considered reporting or administrative database systems miss."[78] One of these studies tracked patient safety progress using global trigger tools at nine North Carolina Hospitals.[79] The findings found no real improvement in error rates from 2003 to 2008, despite the hospitals' claim to have implemented a wholehearted effort to reduce preventable errors.

Patient Testimonials

The last and most recent trend involves seeking answers directly from patients regarding errors made or harm done over their treatment courses. Patients are their own best representatives, as they do not have an incentive to fabricate a medical error, unlike physicians who have an incentive to conceal them. Thus, asking a patient if they endured discomfort during treatment due to an error is a better course of action than seeking these answers from medical staff.

One study demonstrated that patients are better able to identify errors missed by other assessment tools, such as hospital standardized mortality ratios or trigger tool assessments.[80] Of course, the drawback of this method is that it may weaken the trust

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[78] Moore, Carlton et al. "Medical errors related to discontinuity of care from an inpatient to an outpatient setting." Journal of general internal medicine vol. 18,8 (2003): 646-51. doi:10.1046/j.1525-1497.2003.20722.x

[79] Kirkendall, Eric S., et al. "Measuring adverse events and levels of harm in pediatric inpatients with the Global Trigger Tool." Pediatrics 130.5 (2012): e1206-e1214

[80] Wolf ZR, Hughes RG. Error Reporting and Disclosure. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 35.

between caregivers and patients, although this has not been explored enough to make a definitive claim to cease postoperative patient reports.

Two Options for Improvement

Combining Transparency Methods

As demonstrated, hospitals attempt to attain transparency in multiple ways. Each method comes with its flaws, and not even one promises fully accurate measurements. For the time being, efficiently gathered and effective data can be garnered if hospitals explore more than one transparency route. Combining PSIS, trigger tools, and patient testimonials is a safer approach compared to a single disclosure choice method, and better data equates to better performance. The steppingstone to better performance, therefore, is meaningful feedback, something made possible with effective evaluation methodologies. If hospitals must provide patient reviews alongside their independent PSIs, they will be more inclined to bestow the truth. If a hospital presents itself contradictorily to how patients experience it, the deception will unravel, and this will smear the institution's reputation and hopefully lead to meaningful reform.

It all comes down to accountability. Solution one passes the power to patients since hospitals are forced to align their reports with their clients'. Nevertheless, experience shows that current methods have barely improved provider performance, possibly because of how information is gathered and subsequently translated. Quality comparison furthermore demands unbiased, truthful recounts from patient testimonials. Those individuals seeking reviews must have no affiliation or stake in the patient's hospital if we are to accept their feedback as factual. If the interrogator has something

against the hospital—which is less likely than the reverse but by no means impossible—

or will suffer consequences if the patient narrates a negative experience due to medical

mishaps, the report may be distorted.

Once the information is acquired, assuming its contents are legitimate, the next

step entails thorough review. The reviewers must hold an authoritative, influential

position to change the course of hospital funding and other affairs contingent on their

satisfaction with provider performance, and this is best realized by looking at patient

outcomes. Key stakeholders and the federal government are concerned with hospital

quality, so perhaps these people are best suited for the job.[81] Representatives from each

district could analyze hospital success on a biannual basis and determine if changes in

healthcare are needed.

A New System: Mandated Quarterly Reports

The leading alternative is a new system compelling care reports from each

hospital on a consistent basis. I propose a transparency model analogous to the Securities

and Exchange Commission's (SEC) governing rule over publicly traded companies. The

SEC requires publicly traded companies to provide earrings reports relevant to the

public's wellbeing.[82] The reports illuminate problems the company may have

experienced, and their shortcomings are shown to company investors and potential

investors. Proceeding the review, investors and investment analysts offer solutions for

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[81] Fottler, Myron D., et al. "Assessing key stakeholders: who matters to hospitals and why." Hospital & health services administration 34.4 (1989): 525-546.
[82] Alberg, Tom A. "SEC Disclosure Requirements for Corporations." Bus. Law. 26 (1970): 1223.

improvement the company is encouraged to take if it wishes for its primary funding sources to continue with their support.

When companies release their quarterly earnings, the stock price is almost instantly affected. If you miss your numbers, the stock goes down. However, if you meet or beat your numbers, the stock increases. Every quarter, after releasing revenue and earnings for the last quarter, public companies also list the major events that have happened with their business and disclose all the risks with the company they can think of, and this, when buying the company's stock, shareholders not only know a company's performance, but they also can assess the amount of risk that they are taking by being an investor in that company.

What makes this system work is that any employee can turn into a whistle-blower.[83] If a company is lying about any of the information, then any of the employees can sue that company and recover a third of the money that the government or anybody else collects as a whistleblower. This generally keeps companies honest. Also, if the financials have been misstated, the executive team must return back to the company any additional compensation they could have gained due to the exaggerated financials, which represents another huge disincentive regarding any false information.

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[83] Press Release, SEC Surpasses $1 Billion in Awards to Whistleblowers with Two Awards Totaling $114 Million, No. 2021-117 (Sept. 15, 2021)

(This illustration depicts the ideal "corporate governance framework." The principles highlighted in this diagram align with hospital priorities. Optimal care delivery is only attainable if the above criteria are met.)[84]

Societies measure what they deem important. If it is important enough to report quarterly and annually the financial health and all the risks of a company so public investors can make informed decisions about their investments, we should do the same for something far more important than money: life. Hospitals are arguably public companies as well given that more than half of their revenue comes from taxpayers through either Medicare or Medicaid.[85]

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[84] "Corporate Governance Principles." Corporate Governance Principles - Annual Report ASM International, https://asmi-corporatereporting.com/2017/annualreport/governance/corporate-governance-principles.

[85] Himmelstein, David U, and Steffie Woolhandler. "The Current and Projected Taxpayer Shares of US Health Costs." American journal of public health vol. 106,3 (2016): 449-52. doi:10.2105/AJPH.2015.302997

Therefore, the same transparency that has permitted a robust stock market could create robust, healthy, safe hospital systems around the country by offering similar information on a quarterly basis in a system such as this. Perhaps a "Medical Exchange Commission" akin to the SEC could be created through which each hospital quarterly and annually reports their patient outcomes data as well as their medical errors. This would give patients the ability to choose the safest hospitals near them or even across the country for the care they need.

Further, it would promote competition among hospitals, which is truly a win-win situation for both patients and practitioners. The data will make every hospital work to show better outcomes with the fewest medical errors and thus achieve the best patient safety records. If our country values the health of our citizens, then clearly this is something we need to begin measuring. Like how earnings make or break a company's stock price, hospitals that are not performing well would suffer or go out of business if the public knew their track record and abstained from using their care providers. As such, hospital announcements would be carefully watched and meet quick reinforcement, be it positive or negative. All that matters at the end of the day is that there is something credible to respond to.

Takeaway

To a certain extent, the motive propelling these transparency solutions is for providers to feel pressure. Public dissemination pointing out deficiencies in care quality will surely force hospitals to double proof their work. However, this is a healthy pressure and remains within the bounds of our overarching theme—to improve performance for

the sake of improving lives, not out of fear. There are no conclusive studies that patients would even search for hospital data prior to admitting themselves to a hospital, but the benefits are evident regardless—many studies have already demonstrated considerable improvements in patient care and patient outcomes at hospitals that publicly report errors. The possibility for patients to use data to make medical choices should be at their disposal.

Transparency methods, as they stand, are not good enough. They are inaccurate and untimely and thus are no help to care providers looking to improve their practices or patients who are seeking out the best facilities for their care. Unless drastic measures are taken, such as the above-mentioned solutions, reducing medical errors and preventable deaths in hospitals is not a feasible goal. Combining current practices (solution 1) is intended as a stand-in for the ultimate change that needs to be made, which is (solution 2) the mandated quarterly reports. Quarterly report systems will better equip hospitals to acknowledge the mistakes they have made and implement reforms in response to error trends.

Consistently reviewing recent mistakes keeps doctors in touch with their own performance in addition to their colleagues'. Perhaps there is a secondary silver lining involved as well—collaboration amongst medical staff can inspire innovative solutions to prevent medical errors and foster healthy relationships in an improvement-oriented rather than consequence-driven work environment. Here we see the connection between philosophical and public policy reforms. They are interwoven, and one cannot reach its full potential without the other's cooperation.

The cost of healthcare is rising each year, which only heightens the necessity for transparency among America's hospitals.[86] With greater accountability will come fewer medical errors, and less errors plaguing hospitals is essential to reduce financial stress in the healthcare arena. For example, when hospitals must correct physician mistakes with follow0up procedures or reinstate patients they sent home prematurely, the avoidable costs add up, and consumers end up paying for it through medical insurance. Hospital culture is visibly on edge since care providers are now working hastily to not only provide quality care but quality care at the lowest cost.

Unfortunately, this often entails cutting corners to conserve institutional finances. This only leads to future monetary and emotional consequences which outweigh whatever burden the physician tried to avoid in the first place. I want to reiterate that healthcare providers and organizations are not guilty. Requiring performance data is simply one fix the system desperately needs. The next public policy amendment I will advance builds upon the financial aspect tied to performance.

Aligning Incentives

Financial Impact of Medical Errors

Every single year, about 250,000 people die in the United States because of medical errors in hospitals. These tragedies cost the nation's healthcare industry approximately $20 billion annually. If we included "non-preventable" adverse events or

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[86] Branning, Gary, and Martha Vater. "Healthcare Spending: Plenty of Blame to Go Around." American health & drug benefits vol. 9,8 (2016): 445-447

those taking place in ambulances, nursing homes, or assisted living facilities, the figure

would more than double. The losses pour out through many channels:

1.   **Value-based payment programs:** Commercial or government payers pay

hospitals according to care quality, which they decide on contingent upon outcomes.

Performance goes hand in hand with reimbursement rates, so poor performance equates

with losses.[87]

2.   **Capitated payment arrangements:** Errors can increase the total cost of care.

This can add up and exceed fixed payments hospitals are set to receive. Errors resulting

from hospital-acquired conditions are the main culprits for augmenting care costs

unnecessarily.[88]

3.   **Noncompliance with accreditors:** This represents a common reason for

monetary penalties and fines.[89]

4.   **Patient-filed lawsuits:** Often, patients or loved ones file lawsuits for hefty sums.

Some reasons include negligent credentialing, wrong-site surgery, diagnostic failure,

discharging prematurely, overmedicating, or leaving objects in the body. The legal costs

for dealing with the lawsuit process in addition to money won by the petitioners reaches

into the billions.

5.   **Physician mental health, employee turnover, treating providers:** The second

victim when a patient endures a medical mistake is the treating physician who caused it.

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[87] Akinleye, Dean D et al. "Correlation between hospital finances and quality and safety of patient care." PloS one vol. 14,8 e0219124. 16 Aug. 2019, doi:10.1371/journal.pone.0219124
[88] Akinleye, Dean D et al. "Correlation between hospital finances and quality and safety of patient care."
[89] Rosenstein, Alan H. "The quality and economic impact of disruptive behaviors on clinical outcomes of patient care." American Journal of Medical Quality 26.5 (2011): 372-379.

Cutting it close or committing a fatal error often causes severe, debilitating psychological

effects. Physicians report extreme sadness, anxiety, anger, guilt, and inadequacy, and

many take their own lives. The solution entails high-priced mental health support

hospitals pay for and bringing on new staff.[90]

6.   **Reputational harm and patient leakage:** Transparency can directly affect

patient volume, which then affects hospital revenue levels. Publicly reported quality

ratings and outcomes data may influence how patients select care providers, so

reputational damage following public patient safety errors can seriously cost hospitals.

Pay for Performance

In October 2008, Medicare set into effect a "no pay for errors" rule which applies

to every American acute-care hospital.[91] The intentions behind such a policy were

morally appropriate—to improve the care Medicare patients receive by giving hospitals

an incentive to prevent medical errors. The deal declared that any hospital responsible for

causing a preventable error would not receive Medicare reimbursements. "Pay-for-

performance" structures, as these came to be known, are making inroads, as seen in

Medicare's "value-based purchasing" and "no pay for errors" initiatives. These strategies

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[90] Chiu, Maria et al. "The direct healthcare costs associated with psychological distress and major depression: A population-based cohort study in Ontario, Canada." PloS one vol. 12,9 e0184268. 5 Sep. 2017, doi:10.1371/journal.pone.0184268

[91] Hartmann, Christine W et al. "The Medicare policy of payment adjustment for health care-associated infections: perspectives on potential unintended consequences." Medical care research and review : MCRR vol. 69,1 (2012): 45-61. doi:10.1177/107755871141360

assert that "anything but perfect performance leads to reimbursement cuts rather than additional payments for top performers."[92]

Evidence indicates that pay for performance may produce only a slightly better outcome than that generated by transparency alone. This is one example indicating the interdependence among the solutions for medical errors. No individual fix alone is sufficient to make effective changes in the lives lost annually. Thus, we must take it upon ourselves to adopt multiple solutions. As such, the line missing on this graph is performance by a hospital that both publicized their medical outcomes and had financial incentives driving their error-safeguard implementation.
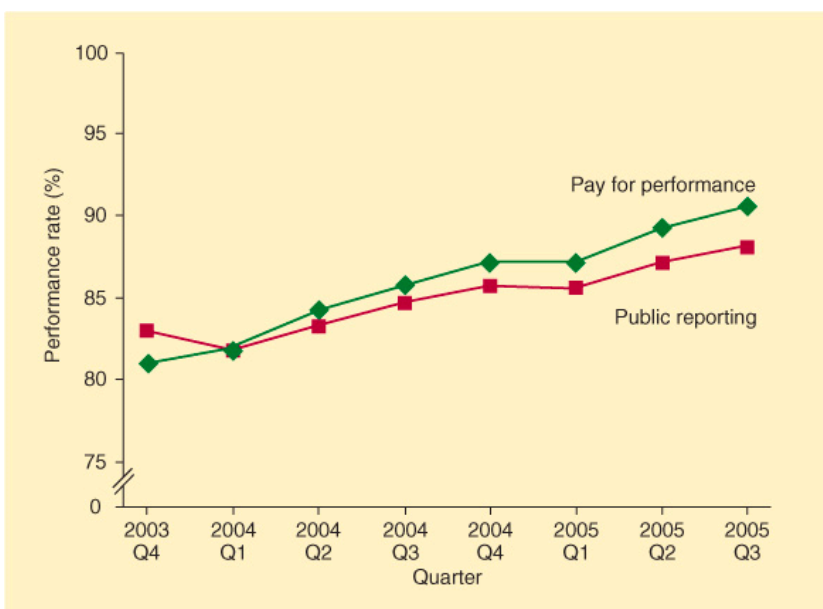
Despite positive results, I disagree with the threatening character such programs instill within healthcare institutions. The idea encapsulates everything that is wrong with our system. Fear will not stop preventable errors; in fact, the more likely outcome is

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[92] Wachter R.M.(Ed.), Understanding Patient Safety

doctors and nurses will hide their mistakes to avoid financial repercussions, simply

reinforcing a vicious cycle of concealment and less accountability which contributes to

more preventable deaths. A 2010 study explored and subsequently reinforced this

prophecy. The experiment studied internal medicine residents to see how awareness

about the Medicare "no pay for errors" rule would affect procedural decision making.[93]

The informed residents were "less likely to choose the most appropriate clinical

practice choices in response to clinical vignettes." The study's results explained that,

while real-life behaviors were not included in the experiment, "if these clinical practice

choices were to be implemented in practice, they could result in patient harm through

unnecessary tests, procedures, and other interventions." The reason for the disparity

pertained to misunderstanding the scope and content of the new rule which, illuminated

an even larger issue concerning resident competency specific to systems-based practices.

(The below graph proves "pay for performance" does not work: the control hospital and pay-for-performance hospital showed little difference in medical care outcomes, despite the looming financial threat hovering over the pay-for-performance institution.)

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[93] Mookherjee, Somnath et al. "Potential unintended consequences due to Medicare's "no pay for errors" rule? A randomized controlled trial of an educational intervention with internal medicine residents." *Journal of general internal medicine* vol. 25,10 (2010): 1097-101. doi:10.1007/s11606-010-1395-9

EXHIBIT 2

Average Overall Performance in Pay-for-Performance and Control Hospitals, Fiscal Years 2004–08
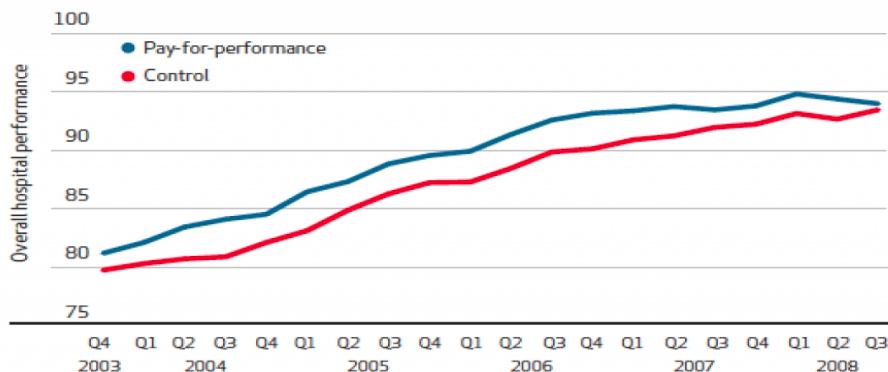
SOURCE Rachel M. Werner, Jonathan T. Kolstad, Elizabeth A. Stuart, and Daniel Polsky, "The Effect of Pay-for-Performance in Hospitals: Lessons for Quality Improvement," *Health Affairs* 30, no. 4 (2011): 690–8. Data from Hospital Compare: survey of patients' hospital experiences [internet], Department of Health and Human Services. NOTES Performance is averaged across the three conditions: acute myocardial infarction, heart failure, and pneumonia. The values shown are average composite performance scores.

Medicare's financial incentives and disincentives altered treatment decisions by placing undue pressure on physicians. In the face of adversity, our doctors must not abandon their purpose of putting patient safety first irrespective of any financial hindrance. The study exemplified how physicians respond to monetary-driven expectations. If merely telling residents about the Medicare rule influenced their ability to make evidence-based and patient-centered clinical decisions, the rule demands reform.

However, monetary-driven decisions are not all bad, as sometimes doctors pay better attention to details and monitor their patients more often than they otherwise would. Thus, the underlying message physicians must register when told about alterations to "care outcome payment policies" necessitates emphasis. Patient safety is the mission. Saving lives *always* comes before saving dollars. Financial stress cannot compromise quality of care.

Pay for Performance: Sources of National Health Care Funding, 2016
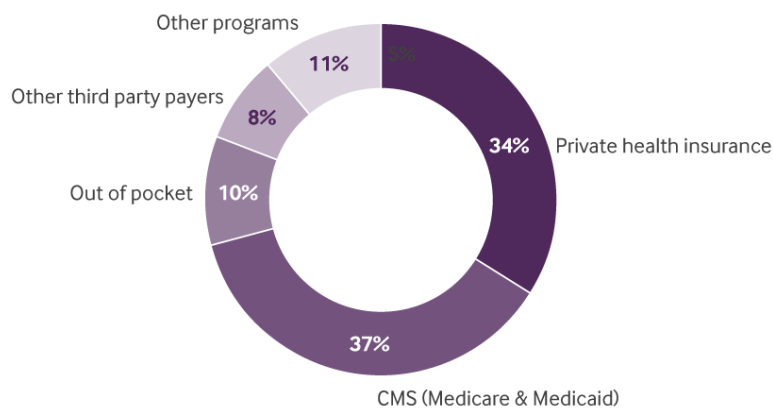
Source: CMS.gov, National Health Expenditures by Source of Funds and Type of Expenditure, 2016 data
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This is our fundamental issue: most hospitals do not have financial incentives to implement safety protocols that have been proven to reduce medical errors. Other hospitals that do adhere to Medicare's reimbursement rule and have financial incentives to perform superbly are threatened by the prospect of financial penalties for putting protocols in place but failing regardless. Both options have shortcomings. One is permissive, the other authoritarian. It is about time we meet in the middle and welcome the authoritative parent: aligned incentives.

This is my idea for the aligned incentives bill. The meaning of the phrase means "aligned incentives" is simple: responsibility for both finances and patients need to complement each other to prevent financial hindrances that deter doctors from making optimal health decisions for their patients. We need to tell hospitals that, if they put all the right safety protocols in place, ones that have been proven to reduce medical errors, mistakes they make will be compensated. Under the current financial penalties, practitioners are deterred from disclosing their mistakes. However, by aligning

incentives, we tell hospitals that we are not *forcing* them into implementing safety procedures out of fear, but we are *encouraging* them with financial benefits.

Although research shows $20 billion is lost each year because of the 250,000 preventable deaths the United States incurs, the actual estimate, including errors that do not turn fatal, is far worse. A 2019 estimate based on inflation since "The Social Cost of Adverse Medical Events" was published had the following to say on the issue:

> A large percentage of every dollar in healthcare is spent addressing medical errors, making this an estimated $1.44 trillion issue. In the United States, millions of Medicare patients will suffer harm or die from a condition acquired during their time in a hospital. Estimates put the cost to the Centers for Medicare and Medicaid Services (CMS) for these preventable medical deaths and permanent harm events at tens of billions of dollars. The annual marginal cost of preventable medical errors in hospitals is approximately $17.1 billion, mainly attributable to post-surgical complications, healthcare-associated infections, and pressure ulcers.[94]

Indiana Senator Todd Young proposed this bipartisan bill for aligned incentives wherein the hospitals that adopted comprehensive patient safety measures would be rewarded with generous compensation and be off the hook financially for any errors, but, if the measures were not in place and someone was hurt, the hospitals would not get paid for any of the care they provided. The bill was a win-win for both patients—who would

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receive better care and pay fewer medical taxes—and hospitals—who would no longer be responsible for errors as long as they reasonably tried to prevent them. The bill was shot down by lobbyists with self-interested motivations. These lobbyists work for, believe it or not, hospital and medical associations.

Doctors do not like being told what to do or how to do their jobs by politicians. Their pride prevents them from taking action that is not only good for their patients, but which actually benefits them as well. The American College of Obstetricians and Gynecologists (ACOG), the American Hospital Association (AHA), and 3M forcibly lobbied against Young's bill, so the aligned incentives bill died before it was born. One group of doctors did not want to be told how to practice, hospitals were afraid of falling short of meeting all the measures, and 3M was coming out with a new product that would no longer be useful or profitable should the bill pass.

Faced with all this lobbying, Senator Young dropped the bill, as he did not want to risk losing re-election. A *Newsweek* op-ed sums up the problem succinctly:

> Hospitals are the biggest employers in every community, from a rural town in Ohio to New York City. And it's understandable that most, if not everyone, is afraid of change. However, we need to put our fears aside and let the lawmakers do this. There's no real reason to push back. In fact, if hospitals instituted proper aligned incentives and transparency, they would save money. One study showed that implementing patient safety reforms could reduce the cost of our entire health care system by 20% to 45%.[95]

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[95] Kiani, Joe. "Aligned Incentives and Transparency Are What Our Hospitals Need, That's Engineer's Order." Newsweek, Newsweek, 9 Apr. 2021,

To navigate around putting simple processes in place, proven to prevent human

medical error, is unethical. It is overdue our country rectifies this mendable absurdity.

https://www.newsweek.com/aligned-incentives-transparency-are-what-our-hospitals-need-thats-engineers-order-1582039.

Chapter 3: Economic Improvements

What are GPOs?

Group purchasing organizations, commonly referred to as GPOs, are purchasing intermediaries between healthcare-related suppliers and hospitals in need of the medical devices and services these suppliers provide. They negotiate contracts between the care providers (hospitals primarily) and vendors, such as distributors and manufacturers of medical devices, commodities, branded drugs, generic drugs, and services from food packaging to laundry.[96]

A GPO is effectively a middleman. They were created with the intention to relieve hospitals of negotiating purchasing contracts with vendors and to save hospitals money by cutting deals with vendors using purchase-pooling strategies. According to the Healthcare Supply Chain Association (HSCA)—a trade association which represents fourteen healthcare GPOs—of the 98% of hospitals that rely on GPO services, approximately two to four GPOs are enlisted per each U.S. hospital to carry out these specific functions.[97]

Around the U.S., over 600 GPOs operate in various markets. However, a very small fraction of them controls the healthcare market. These GPOs range in **size (**dictating services for between 10,000–400,000 hospital beds), **scale** (some operate nationally while others engage with strictly regional vendors), **ownership type** (some are owned by hospitals), **target customers** (serving not-for-profit hospitals, for-profit

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[96] Hu, Qiaohai, and Leroy B. Schwarz. "Controversial role of GPOs in healthcare-product supply chains." Production and Operations Management 20.1 (2011): 1-15.

[97] Bruhn, William E., Elizabeth A. Fracica, and Martin A. Makary. "Group purchasing organizations, health care costs, and drug shortages." JAMA 320.18 (2018): 1859-1860.

hospitals, or both), **service options** (some offer broad portfolios of products and services, but others only offer specific product categories and certain types of health care, like long-term care), and **contracting services** that make some more attractive than others (this is ultimately responsible for which GPOs are selected by hospitals to cut their deals with supply vendors).[98]

Since its inception, the market for GPOs has progressively consolidated with large mergers between those GPOs that were already powerful and dominating the market. In 2012, the five largest American GPOs grossed $130.7 billion. From household medical supplies like cotton balls and bandages and heavy-duty devices such as pacemakers and stents to both branded and generic drugs, these GPOs all reported similar contracting for a wide array of products.

The point is they have everything covered. Imagine the impact a union among such dominating contenders has on both the vendors seeking purchasing contracts and smaller GPOs searching for companies to supply their hospitals. It essentially wipes out any chance for competition among these weaker groups and compels vendors to cut enticing deals with the powerful GPOs simply as a security mechanism to ensure their products will have a place to go so that their companies will stay afloat.

By consolidating hospital contracts, GPOs operate in anticompetitive ways. And, as if it already was not bad enough that GPO mergers hinder the outflow of products from existing healthcare companies, possibly putting them out of business and eliminating the drive to produce exceptional products given binding promises to buy from certain

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[98] Bruhn, William E., Elizabeth A. Fracica, and Martin A. Makary. "Group purchasing organizations, health care costs, and drug shortages."

companies for years on end even worse is the adverse effect they have on creativity. Up and coming startups with innovations that could revolutionize medical care in hospitals and at home are deterred from investing in their admirable pursuits because, without GPOs to link their devices to hospitals, their creations will sit idle in a warehouse.

The Bigger Problem with GPOs

There is a misconception that the worst thing a GPO can do is cut deals with supply vendors, bundling products for cheaper prices, potentially ignoring those companies with superior technology. This scenario seems plausible, for it could be perceived as a strategy to cut costs for financially overburdened hospitals looking for places to budget. However, this is not the common problem GPOs have posed. The reality is far worse. The underlying issue—companies with mediocre products getting into business with GPOs—persists, but the reason for it has nothing to do with helping hospitals attain lower prices. It is purely selfish. The basis behind this tactic has everything to do with how GPOs are compensated.

Despite their purpose—to make seamless connections between hospitals and vendors—GPOS are paid by vendors, not hospitals or government agencies.[99] Thus, GPOs hunt out medical suppliers who charge the *highest* prices to our hospitals because, with greater revenue for vendors, comes greater cuts of that revenue, which are then allocated for GPOs. So, not only are hospitals paying higher prices, but they are paying

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[99] United States Government Accountability Office, Report To Congressional Requesters. *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs.* Kristi Peterson, October 2014

these prices for medical technology that may not even be the most reliable in the market. It is a lose-lose predicament for care providers but a win for vendors and a win for GPOs. Serious problems arise when big business interferes with patient care. As discussed in a prior chapter, these nuisances already plague hierarchical structures inside hospitals, where doctors are incentivized by paychecks rather than saving lives.

This disease now infects hospitals from the outside. The ways in which medical supplies and life-saving technological machines are delivered to hospitals operate according to financial gains for third parties with little to no concern for those the products are meant for: patients. This demands rectification. Shockingly, this unethical operation is not illegal, so this problem cannot currently be fixed with federal oversight. Devising new laws to change how GPOs are financed can solve this problem. This will end the price "fixing" GPOs and eager vendors conduct regularly. A smarter tactic is to have the government pay GPOs for their services or put a cap on how much a GPO can profit from hospital-vendor contracts. In essence, changing the hand a GPO feeds from levels the playing field.

How GPOs are Paid

GPOs rake in billions each year by means of contract administrative fees their client vendors pay them for helping create attractive contracts.[100] They are a small percentage of the sum paid to vendors by their hospitals for various medical products. These fees, although they appear miniscule compared to what vendors make from the

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[100] United States Government Accountability Office, *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs*. Kristi Peterson

deals, are GPOs' main source of operating revenue, and thus GPOs clearly have a stake

in the number a given vendor proffers. The issue with this payment structure is it

dissuades GPOs from acting impartially to the medical device companies—the contracts

are not an accurate reflection of device quality or reliability, but a reflection of which

company has a GPO in their corner.
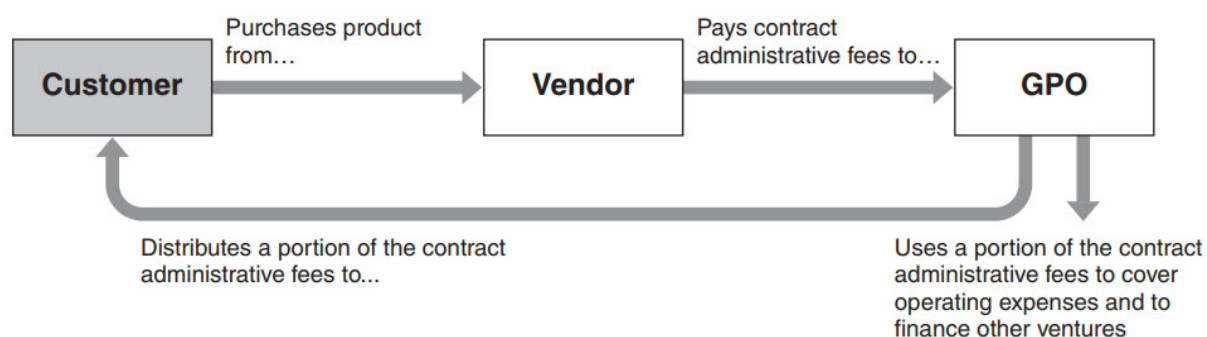
Source: GAO.

101

GPOs "Self-Regulate"

The Healthcare Group Purchasing Industry Initiative (HGPII) permits GPOs to

self-regulate. [102]This privilege is contingent upon guidelines, such as following business

conduct standards and a principle of ethics. These guidelines, while in theory could

prevent corrupt business operations, are realistically far too soft to make a real difference

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[101] United States Government Accountability Office, *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs*. Kristi Peterson
[102] United States Government Accountability Office, *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs*. Kristi Peterson

in how GPOs go about their typical practices. GPOs need more than a simple demand asking for "higher" accountability to society.

Current methodologies meant to monitor adherence to ethical principles are annual public accountability questionnaires in addition to sharing best practices through annual forums. The questionnaire is over a hundred questions long and asks for member GPOs to describe their "codes of conduct and conflict of interest policies, policies on contracting practices such as sole-source and bundled product contracts, contract administrative fees, including the reporting of fees to GPOs' customers, their supplier grievance process, and activities to ensure compliance with their policies."

Put bluntly, these requirements are comical. Asking an organization raking in billions each year to prove truthfulness by means of a questionnaire and "promise" to be ethical is absurd. It more so resembles the instructions a second-grade teacher gives to his or her class prior to a spelling exam; such rules are not fitting for titan middlemen controlling billion-dollar industries that are singlehandedly responsible for supplying all of America's hospitals with life-saving equipment. While the association can revoke a GPO's membership from the HGPII if the GPO violates the group's standard, this provision has yet to be used, which is unsurprising.

If we asked a president to self-report his performance in the White House, I would expect for the president and almost everyone working in his administration to commend his job well done and avoid pointing out criticism where it is not already visible in the public eye. If we handed President Trump an accountability questionnaire requiring him to report information on his moral political principles, policy-making decisions, and business practices, all of which are questionable and have now been investigated, it is

extremely unlikely he would willingly admit to faults. If we cannot expect the leader of the free world to follow the rules, there is not one reason to place such a lofty responsibility on GPOs.

Holes in Self-Regulation Processes

Questionnaires

The self-regulation process commences with a review of the public interest questionnaire wherein one designated HGPII representative simply confirms the GPO satisfactorily completed the questions.[103] Following this checkmark, each GPO's answers are uploaded to a GPO-members-only website where other head organizers are allowed to critique or comment on the given responses. This step precedes compiling the GPO annual report, which, again, is made available on the GPO-members-only site. GPOs are expected to present their codes of conduct and conflict of interest policy in written terms. In addition, all GPOs are said to have a repertoire, binding them with an unofficial verbal agreement to have sole-source contracts and to make their deals competitively.

Forums

The forum aspect proves even softer than a GPO's word of honor. Such forums are conducted annually and facilitate discussions relevant to ethical business conduct. GPOs send representatives to meet with other GPOs' members, and supposedly they devise ways to include weaker, diverse vendors while simultaneously analyzing

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[103] United States Government Accountability Office, Report to the Ranking Member, Committee on Finance, U.S. Senate. *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson, August 2010.

healthcare policy—although legislative issues are out of scope for these businessmen—

and the representatives discuss overall ethics specific to their business operations.

Somehow, these strategies are expected to prevent corruption.

In a final bid to prove their wholehearted efforts to comply with ethical standards,

GPOs started a vendor grievance process in 2010 wherein, if a vendor believes a GPO's

decision was unfair, they can issue complaints to third parties provided by the American

Arbitration Association.[104] The association reviews vendor complaints and makes a final

decision through which it either accepts the GPO's conduct or appeals its denial of a

contract to the complainant vendor. If the latter verdict is reached, the member GPO is

forced into one of three options:

1. They can bid or rebid the vendor's product.

2. GPOs can go back on their decision and award a new contract with the

    vendor.

3. They can reevaluate their decision.

There is really no point in offering options one and two when the obvious choice

GPOs will consider is option three. Without stringency, GPOs are shown to ignore the

promises they make with other competitor GPOs pledging to include and respect smaller

vendors, respect competitive contracting, and respect American healthcare.[105] An

objective, better way to monitor these organizations is ensuring these reports make it to

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[104] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.
[105] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

the DOJ desk where a third-party reviewer impartial to GPO success lays eyes on the yearly acquisitions to pinpoint unusual financial gains.

GPO Regulation Oversight

Technically, there exist certain provisions GPOs must meet to collect these contract administrative fees. Such provisions fall under a broad "security check" better known as the Social Security Act and more specifically the Social Security Act's supposed rottweiler "anti-kickback statute."[106] The statute broadly forbids knowing or willful acceptance of special payments in exchange for rewards to purchase items and services, given these items and services were paid for under federal healthcare programs.

Under the statute's technicalities, a company is held liable for fraud if it is found to offer doctors or other healthcare providers any financial incentive to use a company's products or services. These include both Medicare and Medicaid payments. Normally, the kickbacks are discovered as free travel, gifts, free services, sometimes monetary payments, and essentially any item of monetary value. A hospital's attempts to mask kickbacks may present themselves as doctors compensated for speaking opportunities or paying unreasonably higher prices for office spaces. Those found to violate the anti-kickback statute could be subject to criminal or civil penalties.

Primary Overseers

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[106] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

Current oversight mechanisms include promises by GPOs to self-regulate through

HGPII initiatives and compliance with oversight provided by federal agencies. These

three departments are the Department of Health & Human Services (HHS), which is

responsible for overseeing the adherence to anti-kickback statute provisions; the Federal

Trade Commission (FTC), which is tasked with enforcing federal antitrust laws; and the

Department of Justice (DOJ), which is ultimately responsible for enforcing both the anti-

kickback statute and federal antitrust laws. [107]

At the HHS, the Inspector General's role includes a responsibility to enforce the

anti-kickback statute. The Office of the Inspector General verbalized the salient reason

for forming and protecting adherence to the anti-kickback statute: to shield patients and

federal healthcare programs from abuse through preventative measures which block

financial corruption from entering the room when healthcare decisions are at stake. The

"safe harbor" provision of the anti-kickback statute followed a decade later when

Congress enacted a plausible exception to this law.

This exception, however, doubles as a loophole, for it allows fees paid by vendors

to GPOs. Of course, for the safe harbor to appear legitimate, a few years passed, and the

Inspector General's office developed qualifications GPOs are required to satisfy if they

want safe-harbor protection.[108] It applies in the following capacity:

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[107] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.
    [108] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

1. A GPO needs a written agreement for each individual vendor it works with to supply hospitals with their products.

2. The contract must lay out the way a GPO will be paid for their services, which can follow one of two avenues. (a) The vendor can declare a commitment to pay the GPO up to 3% of the purchase price of the goods or services provided by that vendor. (b) If the GPO's payment is not fixed at a maximum of 3% of the purchase price, the agreement must specify the amount a GPO will be paid— either a fixed sum or fixed percentage of the purchase value acquired by the vendor.

3. Annually, GPOs are obliged to publicize, in writing and at the request of the Secretary of Health, the monetary value they made off each vendor. This provision was created for the oversight of healthcare-providing services.

On paper, this law seems effective, but how does it prevent corruption from GPOs? Nothing in this arrangement states a GPO is forbidden from colluding with vendors to construct high prices to elevate their cut from the vendor's purchase price revenue. Since the HGPII formed in 2005 to promote best practices and public accountability among member GPOs, the government has kept one eye open on certain activities, but solving the injustice requires more.

In fact, the GPO safe harbor statutory provision and additive regulations allow for GPOs to operate as they please without routine check-ins with the HHS to ensure compliance with contractual agreements between GPOs and their vendor clients. Instead, the HHS simply informs GPOs of their office's authority to intervene at any time for an

investigation if they believe a GPO is working corruptly.[109] This nebulous blanket statement fails to provide explicit details laying out what constitutes corruption. If GPOs know they are not mandated to report on their activity unless a whistleblower gives the HHS a reason to investigate, one can guess at the likelihood of anti-kickback statute violations.

Another failed attempt to appear formidable in hopes of deterring corruption is the HHS's threat to punish GPOs with civil money penalties or exclusion from federal healthcare programs. Additionally, the HHS holds the power to involve the DOJ if they suspect severe anti-kickback statute noncompliance. Once in the hands of the DOJ, repercussions take a turn for the worse with criminal and civil actions. Both the DOJ and FTC enforce federal antitrust laws for GPOs to follow. Typically, for the DOJ to pursue a GPO for misconduct, allegations are a necessary prerequisite and take the form of agency-filed written complaints, complaints pertaining to merger notifications, or from the agency itself following an investigation on its own volition.[110]

As mentioned earlier, the DOJ is authorized to take criminal action if the anti-kickback statute is violated. In 1996, the DOJ and FTC formulated a guide—Statement 7 of the Statements of Antitrust Enforcement Policy in Health Care—that could be referred to when deciding if a GPO's activity seems concerning. Statement 7 says GPOs are likely to raise antitrust concerns if and only if:

[109] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.
[110] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

(1) the arrangement accounts for so large a portion of the purchases of a product

or service that it can effectively exercise market power in the purchase of the

product or service, or (2) the products or services being purchased jointly account

for so large a proportion of the total cost of the services being sold by the

participants that the joint purchasing arrangement may facilitate price fixing or

otherwise reduce competition. If neither factor is present, the joint purchasing

arrangement will not present competitive concerns.[111]

Pursuing a plausible antitrust concern is contingent on satisfying these rules,

otherwise GPOs are under an "antitrust safety zone," which renders them untouchable by

federal agencies.[112] Once again, the problem lies in the statute's concept, for, with the

safe-harbor provision, all the DOJ issues are empty threats. It is almost as if the rules

were meant to be broken. The government certainly has the wherewithal to create strict

policies, so why in the case of GPOs are both the rules and tactics for enforcing them

made broad enough to evade punishment, let alone an investigation?

The answer is shocking. A select, small number of hospitals are shareholders in

GPOs, and these hospitals profit from the corruption.[113] Each time ideas for new

legislation are discussed, aiming to redefine GPO oversight or eliminate some loopholes

which make it easy for GPOs to act corruptly, lobbyists hired by these select hospitals

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[111] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

[112] Sethi, S. Prakash. "Government Created Protections of the GPO Industry: Financial Burden of GPO Activities on the US Healthcare Industry." Group Purchasing Organizations. Palgrave Macmillan, New York, 2009. 35-43.

[113] Becker, Cinda. "Above-Board?" Modern Healthcare, 10 Oct. 2005, https://www.modernhealthcare.com/article/20051010/NEWS/510100313/above-board.

intervene and frighten politicians into backing down. The cycle of abuse will remain eternal until tangible action—enforced policies—are enacted and enforced. Otherwise, the culture of corruption will persist indefinitely. This messy ordeal will be discussed in detail toward the end of this chapter, followed with ideas for how to reshape GPO payment structures linked to necessary, novel oversight policies.

Ineffective Evaluation

Despite claiming an active effort to prevent corruption by GPOs, since 2004, the Office of the Inspector General at HHS has done little to prove this. The HHS has turned and continues to turn a blind eye to how contract administrative fees are allocated, thus creating a safe environment for anti-competitive practices to flourish.[114] Aside from ethical responsibilities, there is practically no incentive for GPOs to operate fairly if the HHS does not review contract disclosures and oversee annual activity. Unfortunately, it seems as if every single rule made to prevent corruption was made with an intention for violation.

For example, although the Inspector General's office is supposed to impose the anti-kickback statute, the law provides a method to bypass responsibility. Current regulations include yet another loophole stating the HHS is not technically required to keep up with GPO financial disclosures or contractual agreements made with client vendors and that, even if the HHS did routinely inspect these documents, it still would

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[114] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

not be enough to instigate any investigation.[115] In essence, the anti-kickback statute is not a concern for GPOs because the rules are all on their side.

In cases where extreme violations compel investigation, there have still been no repercussions. Since 2004, the HHS, in conjunction with the DOJ, has investigated a total of two GPOs for alleged misconduct.[116] The GPOs were reported for breaching the anti-kickback statute provisions given their operations conformed to the safe harbor without adequately meeting the two simple requirements required for safe-harbor qualification. Imagine the unethical severity of actions these GPOs must have taken to avoid every loophole possible. Despite this, and despite acknowledgment by the departments of such wrongdoing, neither the HHS nor DOJ imposed administrative punishments.

How GPOs Hurt Patient Outcomes

Financial Hindrance

In 2014, the U.S. Government Accountability Office studied five dominating GPOs to evaluate the effect, if any, their contracting prices and funding structure have on healthcare fees—those fees relating both to healthcare providers and eventually the trickle-down effect these impacts have on patients, our healthcare consumers. The five GPOs analyzed in the study follow typical funding practices, with administrative fees

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[115] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

[116] United States Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices.* Kristi Peterson.

being their primary revenue source. These fees totaled almost $2.3 billion. Of this value, approximately 70% of the sum was passed onto GPO customers and owners.

The report said the following:

The views of experts varied widely on the effects of this funding structure. Some suggested it creates misaligned incentives for GPOs to negotiate higher prices for medical products to increase the amount of vendor fees that they receive. Others suggested that competition between GPOs incentivizes them to negotiate the lowest possible prices and mitigates these concerns. There is little empirical evidence available to either support or refute these concerns.[117]

Without additional research, yes, the study alone technically could not reach a conclusion. However, from the extensive reviews conducted prior to this analysis, there is indisputable evidence GPOs are motivated to make anti-competitive contracts that include exorbitant prices for personal gain.

Following reviews from the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services, which sets Medicare rates, the study confirmed their hypothesis that GPO funding adversely affects Medicare payment rates. Hospital payment statistics showed a gradual upward trend in payments positively correlated with the prices GPOs set for hospitals. One may ask how these hospitals manage the extra burden. The answer is us. Hospitals offload additional charges onto patients. The "pay-to-play" toxic culture GPOs run on hurts the American public, and

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[117] United States Government Accountability Office, *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs.* Kristi Peterson.

practically no one affected knows about it. Remember that hospitals are not to blame; GPOs are.

A few major GPOs dominate the market, roping in powerful vendors and thus impeding competitive product output to care providers. High fees close the gap between well-capitalized, better-known players and lesser-known, small manufacturers who cannot get up to speed with the giants in their industry. With market domination so severe that only one or two vendors control product delivery to given regions, production problems can destroy a hospital's ability to care for patients. This unfortunate scenario unfolded in Puerto Rico after Hurricane Maria hit when GPO fees led to an intravenous saline bag shortage in Puerto Rico and all over the U.S.

A key maker of fluid bags was crippled by the hurricane, and medical centers were scrambling to pay a 600% markup just to get their hands on the indispensable product, while some hospitals simply could not afford it. Erin Fox, director of the University of Utah's drug information service, said at the time "hospitals don't have the money to pay that kind of markup. The University of Utah's hospital usually goes through about 800–1,000 "mini-bags" of IV fluids every day. Since the shortages began, we are struggling to get by with less than half that It affects every single medication that we are giving in our hospital."[118]

This means affluent areas with hospitals who can pay these astronomical prices can do their job as practitioners—not optimally, but they would still be getting done. However, those hospitals that cannot rally their assets to buy essential items are left high

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[118] "Hospitals Face Critical Shortage of IV Bags Due to Puerto Rico Hurricane." The Guardian, Guardian News and Media, 10 Jan. 2018, https://www.theguardian.com/us-news/2018/jan/10/hurricane-maria-puerto-rico-iv-bag-shortage-hospitals.

and dry with nowhere to source from. This is disheartening, for medical care already has

latent biases against economically disadvantaged people, so GPOs are yet another

obstacle weakening the weak.[119]

LIFE SCIENCES IN PUERTO RICO
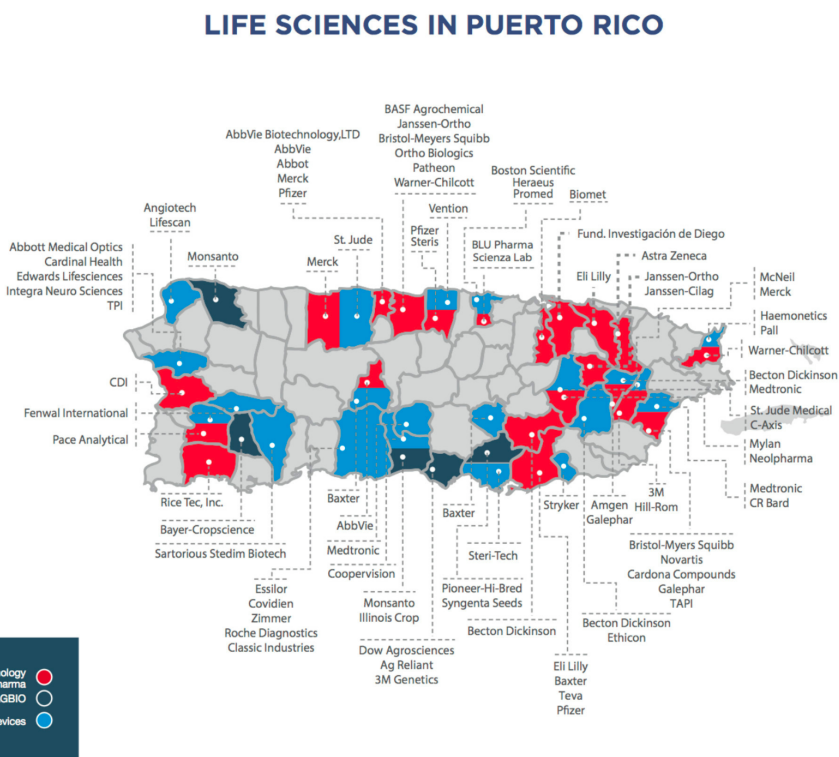
With one sole supplier setting high fees for GPOs to mooch off, this pushes out

other healthcare companies who can prevent supply shortages. Had there been numerous

outlets for the IV fluid bags, it is likely hundreds of people who died in Puerto Rico

would not have. Tragedies like this one inspired some health networks to make their own

GPOs or produce their own products to avoid future shortages. It is ironic how the

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[119] Stepanikova, Irena, and Karen S Cook. "Effects of poverty and lack of insurance on perceptions of racial and ethnic bias in health care." Health services research vol. 43,3 (2008): 915-30. doi:10.1111/j.1475-6773.2007.00816.x

starting point for GPOs was to make life easier for hospitals, but now many of these

hospitals are going out of their way to avoid GPOs hurting their employees and patients,

both financially and physically.

A more sensical approach is for hospitals to advocate a GPO structural revamp

rather than produce supplies themselves. But, of course, this is not possible with modern

power dynamics that perpetuate constant corruption among these middlemen. Today, our

pharmaceutical infrastructure is not prepared for less than flawless execution from

vendors due to GPOs. If medical suppliers, healthcare providers, and GPOs worked

together with a united mission to ameliorate healthcare delivery systems, manufacturers

could make their product supplies redundant, ensuring each region sources from multiple

companies. Not only would this method follow competitive practices, but also it would

double as a safeguard so, in case another natural disaster like Hurricane Maria occurred,

sole suppliers shut down unexpectedly, or a vendor merged with a different organization,

other vendors supplying the hospitals could compensate for the shock shortage.

GPOs' "pay-to-play" perverse incentives dictate price inflation, and people at the

top of the food chain are the reason nothing changes. For example, take Todd Ebert, CEO

of the industry trade group Healthcare Supply Chain Association. He stated the U.S. Food

and Drug Administration (FDA) consistently experiences "quality control problems,

manufacturing issues and barriers to getting new suppliers in line" but that "GPOs are on

the front lines of the drug shortage fight working vigorously with healthcare providers,

manufacturers and distributors to help prevent and mitigate drug shortages and ensure a safe and reliable supply of products."[120]

Paying More

A pilot study by the General Accounting Office shows that hospitals buying two common items, safety needles and pacemakers, often paid more when using group purchasing organizations — which are supposed to be saving them money — than did hospitals purchasing the items on their own.

AMOUNT HOSPITALS PAID WHEN THEY USED BUYING GROUPS Compared with what they paid when ordering on their own

+40 percent MORE

+30

+20

+10

+ 5

0

−10

−20

−30 percent LESS

PACEMAKERS On three-fifths of the models, hospitals paid up to 39 percent more than if they had ordered on their own. They saved as much as 25 percent on the rest.

SAFETY NEEDLES Hospitals paid from 1 to 5 percent more.

Source: General Accounting Office
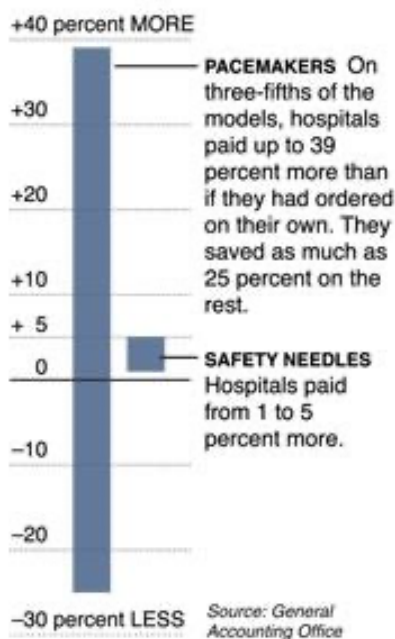
A second way price inflation stems from GPOs comes from anticompetitive sole-source contracting practices. When only one company in an industry makes supplies every single hospital needs, these medical facilities are willing to do whatever it takes—paying more than necessary or more than they are comfortable with—for the products. GPOs and their client vendors are well aware of their position. Thus, it follows that these companies inflate product values, putting many hospitals in a bind.

One study found that using GPOs was no guarantee of better price options. On the contrary, these price options often cost hospitals more money than if the hospitals directly negotiated with vendors—"at least 25 percent higher" in some cases, according to the U.S. Government Accountability Office (G.A.O.). The office declared:

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[120] Bannow, Tara. "Professors Argue Gpos' 'Pay to Play' Fees Drive up Healthcare Costs." Modern Healthcare, 1 Nov. 2018, https://www.modernhealthcare.com/article/20181019/TRANSFORMATION02/181019863/professors-argue-gpos-pay-to-play-fees-drive-up-healthcare-costs.

At issue are hundreds of millions, if not billions, of dollars in annual health care costs, much of it paid indirectly by taxpayers through programs like Medicare and Medicaid and by private insurers.[121]

In the case of pacemakers, it found that, while some hospitals using buying-group contracts got better prices on some models, they got much worse prices on others.

The two largest, domineering GPOs, Premier and Novation, failed to deliver affordable, realistic prices for products they endorsed compared to smaller purchasing groups who struck helpful deals for the hospitals they supplied.[122] The issue here is that most hospitals worked with Premier and Novation, so essentially most hospitals were scammed.

In sum, moral accountability is lacking. Putting stress on our practitioners and institutions with monetary nuisances is unwise. These very people hold ours and our loved ones' lives in their hands. The stakes are too high in the medical industry to allow for big-business money grubbers to supersede the ability for a physician to do his or her job. Conditions for surgery and post op require perfection to avoid medical errors. Leaving a doctor with no option but to improvise in the case of equipment shortages is unacceptable. An operating room is a failure if it is less than 100% prepared, and failure, in these circumstances, means death.

Stifling Innovation

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[121] United States Government Accountability Office, *Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs.* Kristi Peterson.
[122] Bogdanich, Walt. "Medicine's Middlemen." PNHP, 4 March (2002) https://pnhp.org/news/medicines-middlemen/.

Although GPOs impact medical supply costs for hospitals and thus health insurance costs for consumers, the salient purpose of this paper is to uncover the harmful implications GPOs have on patient care outcomes and how they are tied to preventable deaths in hospitals. A clandestine cause for preventable fatalities is how impossible GPOs have made it for new companies to break into the medical supply/device market.[123] Many innovative medical devices, having already proved their superiority to older vendors' market supply, are iced out.

GPOs prefer sole source contracting with vendors they have reliably worked with; since these vendors are indebted to GPOs for keeping their companies in business, they relinquish lofty percentages of their profits that smaller, new players cannot match. It always comes down to what manufacturers are willing to pay GPOs, not what they are able to provide hospitals.

For example, in 2002, newborn Joshua Diaz lay lifeless, his life ending before it began.[124] His physician, Dr. Mitchell R. Goldstein, was not prepared to let the little boy go and did everything he could to save him even if that meant using "experimental" technology.

For half an hour, doctors could not detect Joshua's pulse or read his oxygen levels to know if oxygen in his blood was transferring to vital organs. At their disposal was a commonly used, yet unreliable, pulse oximeter. The monitor failed at the exact moment its function was vital to saving this boy. Dr. Goldstein turned to his nurses and, as a last resort, requested an experimental, noninvasive pulse oximeter made by Masimo

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[123] Bogdanich, Walt. "Medicine's Middlemen."
[124] Bogdanich, Walt. "Medicine's Middlemen."

Corporation. It took mere seconds for the foreign device to read the baby's oxygen levels.

Seven years later, when asked about Joshua's miraculous survival, Dr. Goldstein replied

that, were it not for the second monitor, "We probably would have given up."[125] After all

that time, Masimo still could not break into the pulse oximeter market.

The ramifications are inconceivable. Between the day Masimo's monitor saved

the boy's life and seven years later, imagine how many people died who could have

lived. *The New York Times* investigated this case and interviewed Joe Kiani, Masimo's

CEO. Mr. Kiani confirmed what was behind any person's understandable confusion as to

why the life-saving device was locked out and labeled "experimental" for years on end:

GPOs.[126] Once again, corrupt, financially driven GPOs have blood on their hands.

Masimo's enormous competitor had secured "exclusive contracts to sell its device to

thousands of hospitals, in part by paying fees to two national purchasing groups that

largely determine[d] which products many hospitals buy. These two private groups act as

middlemen for about half the nation's nonprofit hospitals, negotiating contracts last year

for some $34 billion in supplies, from pharmaceuticals to pacemakers, bandages to beds."

To make matters worse, Masimo's competitor—Mallinckrodt—helped finance the

GPO's private venture-capital fund and generously donated another $1 million to the

GPO's private research service.[127] These were not gifts; they were bribes. And they

worked. This is why nothing changes and why GPOs are detrimental to American

healthcare. It did not matter that in private conversations the GPO admitted Masimo

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[125] Bogdanich, Walt. "Medicine's Middlemen."
[126] Bogdanich, Walt. "Medicine's Middlemen."
[127] Bogdanich, Walt. "Medicine's Middlemen."

made the better pulse oximeter. It did not matter that scientific evaluations from medical professionals determined Masimo's device could save millions of babies' eyesight while Mallinckrodt's could not. *All* that mattered was the profit the GPO knew it would rake in if it contracted with the worse-off company. It took years, but Masimo successfully won an antitrust lawsuit, enabling it to sell its product through GPOs.

The following anecdote encapsulates GPO corruption. A GPO approached Masimo and encouraged the CEO to inflate his prices by 50%. Only then would they cut a deal. When Mr. Kiani said he knew his product was not worth that price and increasing it by that much would overstretch hospitals he wanted to help, the GPO left the negotiating table. Buying groups do not choose the products best for patients, insurers, hospitals, or taxpayers unless the deal is most attractive amongst a cohort of average vendors offering the GPOs unbelievable rates. Following a three-year investigation, *New York Times* journalists shed light on this conflict of interest:

> Premier and Novation, which say their contracting decisions are untainted by supplier payments, release no public accounting of how much each supplier pays them, or the terms of individual contracts. "Billions of dollars are being controlled by two companies, and nobody knows who they are," said Larry R. Holden, president of the Medical Device Manufacturers Association, a Washington-based group of mostly small companies. "Nobody looks at their books. Nobody knows what companies they are investing in." The big buying groups "are like a form of government," said Peter Vincer of the Technology Management Group, an

equipment maintenance company in Oak Creek, Wis. "They say who can play and what it costs to play."[128]

Innovation Improves Patient Safety

There is more to the story than meets the eye—not only for the general public but for contenders at the negotiating table too. After Masimo met with Premier, the GPO responsible for contracting with their competitor, a Masimo official emerged from the discussion absolutely sure his company had struck a deal. The positive impression he believed he made on the GPO was not misguided, for internal documents from Premier explicitly stated, "Clinical trials conducted and published by well-respected physicians in the U.S. indicate that Masimo SET has significant clinical advantages to neonates and some highly critical adult patients. We can conservatively say Masimo technology will remain superior to Nellcor through the remainder of 1999."[129]

One might think such praise insinuated an eagerness to contract with Masimo and drop Nellcor, a unit within Mallinckrodt, the oximeter manufacturers with unreliable readings. However, this assumption would be incorrect, and Masimo was unaware these statements were made until years later. Premier returned with a shock response: the GPO told Masimo's CEO they needed to further evaluate their device before reaching a decision. This evaluation lasted over two years. At that point, Masimo's competitor had emerged with their own improved technology. Nevertheless, after surveying the Nellcor

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[128] Bogdanich, Walt. "Medicine's Middlemen."
[129] Bogdanich, Walt. "Medicine's Middlemen."

and Masimo oximeters, fifteen of twenty hospitals said Masimo's was more accurate than

any other pulse oximetry devices. Premier still shot Masimo's offer down.

Two years passed before hospitals could say with certainty that the measurements

they took were accurate. In those two years, people died at the hands of medical errors,

many of which can be attributed to faulty machines, as in Joshua Diaz's case. When

doctors are uninformed, they are helpless, and that is not their burden to carry. Even so,

when a surgeon loses a patient, they blame themselves, and the trauma such loss inflicts

may contribute to a vicious circle of depression and anxiety and thus more preventable

mistakes, as discussed in Chapter 1's "Philosophy Improvements."

Envision the following scenario. While a surgeon operates on a little girl's heart, a

businessman from a company shown to produce malfunctioning monitors golfs with a

GPO representative. They lunch and laugh and relish in their contractual profits. The

surgeon sees oxygen is not reaching her blood. He gives up. The child dies. The oximeter

was wrong. The child could have made it. The GPO supplied the hospital with the device.

The parents grieve their late daughter and sue the hospital for malpractice. Her surgeon

believes he screwed up, that he caused her death. Little do they know that two men at a

country club premeditated the error.

While Masimo was certainly an anticompetitive contracting victim, the real

victims are the patients. Dr. Sola, a well-respected Argentinian practitioner, when asked

his thoughts pertaining to GPO practices, wisely remarked, "In a country with freedom of

choice, this was the hardest thing for me to understand. If the baby was choosing

consciously, we know what the baby would choose."[130] He was right; if prior to every operation patients were presented with an array of supplies and devices to use on their bodies, without a doubt each person would select the product proven more reliable, irrespective of the vendor's name brand.

Unfortunately, our reality neglects patient preference. GPOs make the decision for us, and, adhering to their unprincipled track record, they really do not care if we live or die. Changing the dynamic between GPOs and vendors is long overdue. In the final section, I will briefly sum up the main points and offer a solution to current financing methods.

Solution and Alternatives

Before proposing solutions to GPO corruption and how these alternatives will ameliorate patient care, product quality, and hospital finances, consider the following argument.

Four Premises:
1. Reduced competition inflates prices by giving one company all the market's business and wiping out competitors.
2. Reduced competition stifles innovation by giving one company all the market's business and wiping out competitors.
3. GPO sole-source contracting reduces competition, wiping out competitors and leading to the above consequences.
4. Due to the current payment structure wherein vendors pay GPOs they contract with, GPOs are motivated to make sole-source contracts.

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[130] Bogdanich, Walt. "Medicine's Middlemen."

Conclusion: Purchasing agents should not be paid by the companies buying their products.

Below, I present the one and only solution. Transparency is not enough to prevent kickback contracting, and, if we are to abolish GPOs entirely, hospitals will be overburdened with having to cut deals with vendors. To create an environment conducive to competitive practices—where all hospitals and vendors are equally accounted for—GPOs must be paid through government funding or directly by the hospitals they supply. Regardless of whichever option is preferred, the first step is removing the safe-harbor provision which provides incentives for GPOs to negotiate higher prices for products and services given that their compensation increases as prices increase. Once the safe harbor is repealed, either funding option can feasibly work.

Solution (1): Hospital Membership Fees

The following is a recommendation inspired by economist Hal J. Singer, president and managing partner of Empiris, LLC, an economic consulting firm. He has authored a book and dozens of academic publications pertinent to GPO practices in addition to testifying in courts and regulatory agencies on litigation matters involving GPO contracting corruption. Mr. Singer's extensive GPO research, in conjunction with years of expertise, has equipped him with enough informed knowledge to devise a solution for a safe transition from GPO practices under safe harbor to functioning after safe-harbor abolition.

Hospitals must take responsibility for financing GPOs via a membership fee program.[131] Of course, while this paper's primary argument condemns GPOs for their corrupt contracting, if GPOs carried out their duties as initially intended, they could seriously benefit the hospitals they work for—and, as a result, their patients. GPOs create a distribution channel for the procurement of hospital medical supplies. This allows medical practices to focus on medical issues and avoid the intricacies of a supply-chain conundrum, namely the hefty contracting and administrative costs incurred from direct-vendor purchasing. Even with the safe-harbor repeal, GPO efficiencies should remain intact, as they are irrelevant to the financing GPOs require to perform their activities.

A financial benefit imminent with the safe-harbor repeal is improved federal fund savings. Three independent changes that will follow with improved GPO practices cumulatively will save hospitals and thus the government billions per year. These changes are outlined below.

(1) Rebate Allocation:

Once GPOs are paid by member hospitals, when medical suppliers refund hospitals for contractual changes, these rebates will no longer go through GPOs first. Eliminating this step will ensure hospitals receive the total rebate value. Currently, when vendors rebate hospitals, hospitals are skimmed. In essence, GPOs wrongfully keep

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[131] Hal J. Singer, The Budgetary Impact of Eliminating the GPOs' Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act, Prepared for the Medical Device Manufacturers' Association (2006).

between 21% to 31% of the rebate.[132] Thus, hospitals pay more than they technically have to for the items supplied to them.

(2) Side-Payment Abolition:

The obvious alteration removing safe-harbor promises is the end to side payments from vendors to GPOs. As discussed earlier, side payments inflate product prices for hospitals, so, by limiting this side hustle, GPOs will no longer have an incentive to cut deals with companies contingent on the inflated prices the vendor sets for their product(s). According to Singer, "the large settlements that resulted from recent antitrust litigation involving GPO exclusionary practices—a byproduct of significant agency costs—suggest that the size of the inflation associated with exclusionary behavior facilitated by GPOs is economically significant."[133] Side payments are kickbacks. Without safe harbor, kickbacks are illegal. In the absence of kickbacks, GPOs will engage in fair contracting.

(3) Medicare-Cost Misrepresentation:

The third federal finance benefit incurred after the safe harbor no longer applies concerns incorrect Medicare reporting. Wrong reports stem from the issues discussed in change #1—indirect rebate payments to hospitals through GPOs confuse hospitals and

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[132] Barlas, Stephen. "GAO Report Questions Rebates to Hospitals: An Accurate Accounting of Those GPO Rebates Is at Issue." P & T : a peer-reviewed journal for formulary management vol. 40,2 (2015): 83-114

[133] Hal J. Singer, The Budgetary Impact of Eliminating the GPOs' Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act.

distort their written reports. When GPOs pay hospitals a fraction of the rebates they are owed, they do it using net-revenue distributions.[134]

The issue is not only the resulting lessened price paid, but the transfer causes a lag, so it makes deciphering which rebates are associated with which vendors and the specific products they are refunding quite arduous. Thus, hospitals struggle when reporting these accurately to Medicare, often leading to flawed reports. Medicare then over-charges. Without the middlemen interfering, hospitals can receive rebates firsthand and have a grip on the transfer timing and the products each rebate is linked to. This reduces Medicare over-charging and ultimately saves the federal government large sums.

The federal savings associated with the safe-harbor repeal is estimated at $4 billion annually.[135] Hal Singer made the following table which summarizes the budgetary impact from eliminating the GPOs' safe-harbor exemption from the anti-kickback statute.

SUMMARY OF ANNUAL BUDGETARY IMPACT (IN MILLIONS OF DOLLARS)

<u>Elimination of skimming</u>

Captured Net Revenues	824.3
Less Competitive Return on GPOs' Expenses	298.5
Incremental Savings to GPO Member Hospitals	525.7
Incremental Savings to Federal Government*	241.8

<u>Elimination of distortion</u>

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[134] Barlas, Stephen. "GAO Report Questions Rebates to Hospitals: An Accurate Accounting of Those GPO Rebates Is at Issue."

[135] Hal J. Singer, The Budgetary Impact of Eliminating the GPOs' Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act.

Incremental Savings to GPO Member Hospitals	7,816.5
Incremental Savings to Federal Government*	3,595.6
<u>Accurate reporting</u>	
Unrecognized Rebates	296.1
Incremental Savings to Federal Government*	136.2
Total Savings to Federal Government	**3,973.6**
Total Savings to GPO Member Hospitals**	**8,206.0**

Solution (2): Government Funding

The second approach to eliminating the safe-harbor provision is more straightforward: GPOs make much more than required for their operations to continue comfortably. The federal and state governments can take responsibility for funding GPOs and guarantee their efficiency persists with greater federal oversight. According to a 2005 OIG report that audited the three largest GPOs, during the audit's course, the GPOs collected $1.8 billion in administrative fees and incurred operating costs of 500 million. They are clearly overcompensated, for, of the remaining $1.3 billion, the three GPOs held onto $415 million for venture capital investment and miscellaneous business ventures and paid their members $898 million.[136]

The government can easily pay GPOs for their work, especially since, once their operations are monitored via the anti-kickback statute, federal savings will increase by a

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[136] Hal J. Singer, The Budgetary Impact of Eliminating the GPOs' Safe Harbor Exemption from the Anti-Kickback Statute of the Social Security Act.

projected $4 billion annually. Therefore, the transition from vendor to government

financing of GPOs proves financially seamless and superior.

Conclusion

Interdependency among the three domains—philosophical, economic, and political changes—is essential for effective improvements in patient safety. No solution works without the others' unification. For example, a hospital noticed uncanny patient deaths following surgical procedures. Surgeons had no explanation for the unexpected deaths, and despite attempts to find the culprit, they hit a wall with each investigation. As a final attempt to uncover the reason behind the fatalities, one surgeon took his gloves and placed them underneath a water faucet. He allowed the glove to fill up and then squeezed the glove and watched as tiny water droplets emerged. The glove brand had made defective gloves which his team used during surgical procedures; they were porous.[137]

Thus, in surgery, patients were acquiring lethal bacterial infections that medical staff were completely unaware of and incapable of preventing since the holes were microscopic. How are we supposed to tell our doctors to triple-check every safety protocol so they avoid inflicting infections if such errors are completely out of their control? In this case, the porous gloves were attributed to corrupt contracting practices by group purchasing organizations (GPOs). GPOs had provided a hospital supply contract to a vendor with subpar medical equipment at an anticompetitive price that not only cost the hospital additional funds but cost patients' lives.

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[137] JAMA and Archives Journals. "Perforated Surgical Gloves Associated With Surgical Site Infection Risk." ScienceDaily. ScienceDaily, 22 June 2009. <www.sciencedaily.com/releases/2009/06/090615161705.htm>.

This one case illuminates the necessity for alignment among the three improvement sectors because without the economic side fixed, medical error safeguards cannot work effectively even if physicians follow them. Adhering to this same example, let us see how public policy weaves into the narrative. Without legislation forcing hospitals to implement safety processes and public report transparency to incentivize thorough compliance with such processes, hospitals simply will not. At least, they have not so far. Therefore, we cannot hope for change. We must plan it.

Chapter One Summary

In chapter one, we reviewed philosophical improvements. The first tactic involves adjustments to organizational culture. Hospitals must "adopt a culture that eliminates the blame and shame associated with medical errors." If employees realize they are unlikely to be punished by the administration for an understandable human error, then they are more likely to report medical errors which help identify the issues in systems that allow mistakes in the first place. Finger-pointing and accusations only deter physicians from disclosing their mistakes The second method focuses on leadership. *Improvement is about engagement.* Leaders at hospitals need to actively engage staff and put the proper procedures in place to implement safety initiatives. Leaders must be receptive to creative solutions from lower-level staff because their diverse input can save lives. Senior staff are not infallible, and it is about time they come to terms with this.

Engagement extends to respect—leaders must treat colleagues with consideration. We need to abolish the concept of hospital hierarchy while maintaining leadership structures conducive to oriented goals. The third change concerns motivation for health

care. Right now, the people-over-profit motto is muffled by financial noise. However, greater efficiency in removing financial pressures from hospitals will indirectly lead to fewer errors and thus lessened financial burdens. The final philosophical alteration imperative for successful patient care lies on well-rested doctors, mainly considering their work hours. Physicians are not robots and treating them in inhumane ways—forcing 36–48 hour shifts for instance—is bound for destruction. Both doctors and their patients are subject to fatigued decision-making, and with seven thousand deaths attributed to sloppy penmanship per year, adjusting shift length cannot wait.

Chapter Two Summary

Political improvements are explored in chapter two, with attention directed toward support for an "Aligned Incentives" bill and mandated hospital transparency. Hospitals are public institutions and do not report all the mistakes made at the hands of physicians. Accurate reports will foster greater accountability, and transparency holds societal members and institutions accountable. The essential takeaway remains: "What is measured improves; what is measured publicly improves faster." Unfortunately, regulations and current oversight procedures are not regimented, for only 10%–12% of errors are reported by hospitals. Many hospitals intentionally slip through the cracks, failing to provide timely, dependable reports. It is hard to know if even those hospitals that do follow protocols are reporting every incident.

I propose a transparency model analogous to the Securities and Exchange Commission's governing rule over publicly traded companies, which requires them to provide earnings reports relevant to the public's well-being since hospitals are arguably

public companies, given more than half of their revenue comes from taxpayers through either Medicare or Medicaid. Therefore, the same transparency that has allowed a robust stock market could create robust, healthy, and safe hospital systems around the country by offering similar information on a quarterly basis in a system such as this.

The second public policy initiative championed is aligned incentives. Medical mistakes cost the nation's healthcare industry approximately $20 billion per year. Payment structures are flawed, for most hospitals are paid for performance or service. The first method threatens and encourages concealment, while the latter provides no incentive for methodical, double-proofed care. Aligning incentives says hospitals that adopt comprehensive patient safety measures will receive generous compensation and be off the hook financially for all medical errors made, simply under the condition they can prove all safety protocols were followed. On the other hand, if measures were not in place and someone incurred preventative harm, the guilty hospital would not receive payment for any care provided. The bill is a win-win for patients and hospitals.

Chapter Three Summary

The final area of study, economic improvements, focused specifically on GPOs and their indirect harm on patient safety. GPOs, the middlemen contract negotiators between vendors and client hospitals, are anticompetitive in their practices, but how they are financed explains the incentive for corruption. Vendors, not hospitals, pay GPOs for their services, so a percentage of whatever a vendor makes from their product supply revenue goes to the GPO that helped construct the contract. Thus, GPOs have it in their best interest to work with medical supply companies they can profit from, even if such

companies manufacture subpar products for inflated prices. Of course, if the Anti-kickback Statute's Safe Harbor provision had not been repealed in the Reagan era, vendors could not dangle monetary carrots in front of GPOs to convince them into contracting with their companies.

The salient problems with current GPO financing are as follows: Companies hike their prices up at rates uncomfortable for hospitals and create deterrence for creative inventions because of sole-source contracts that make it near impossible for new players to enter the market, existing companies with superior products are iced out unless willing to comply with GPO directives, and sole-source contracts make hospitals vulnerable to medical supply shortages if an unseen event impacts vendor production. Regulating GPOs is vital to patient well-being. The only viable solution for immediate, efficient progress is removing the safe harbor and changing how GPOs are paid. Financing must be sourced from hospitals directly or the federal government. Federal savings from repealing the safe harbor are estimated at $4 billion annually, which is more than enough to keep GPOs on their feet.

Ongoing Efforts and Their Implications for the Future

In the last three decades, there have been some incredible milestone moments in the journey on patient safety. The first was the "to err is human" report by the Institute of Medicine (IOM), which publicized for the first time the gravity of the problem where hundreds of thousands of people were reported to have died from medical errors each year in the United States. The second was the work of Dr. Peter Pronovost who showed

that one can create actionable patient safety solutions from simple checklists and, if not

eliminate, at least reduce medical errors stemming from human error.[138]

The third was the Clinton Global Initiative's work, which showed how

commitment-based movements work. The price to enter the conference was not a simple

payment. The first time, that was all it took; however, to return a second time, a

commitment to make a difference was the added entry price. Secretary Jeremy Hunt,

former secretary of state for health and social care in the UK, spearheaded transparency

as a policy for all NHS hospitals and created the Ministerial Summit on Patient Safety.[139]

Then the American Patient Safety Movement Foundation extended the momentum,

bringing everyone together to solve this problem and un-siloed the healthcare ecosystem

looping in nurses, doctors, and hospital CEOs, along with engineers, medical tech

executives, government officials, and most importantly, patient advocates.

If we take system-based approaches, such as the Pronovost checklist, and build on

them to account for all error types, we can grow closer to eliminating medical errors.

Such checklists have been deployed now in about a hundred hospitals. Each hospital has

almost hit zero preventable fatalities, proving such protocols are effective if enforced. So

this is the good news—knowing we can do something about the error epidemic. The

Children's Hospital of Orange County sets a model example: For over five years now,

their annual record continuously hits the magic zero. Employee bonuses are tied to their

impressive zero deaths, consistent with aligning incentives, and transparency is standard.

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[138] Pronovost, Peter J., and Eric Vohr. Safe patients, smart hospitals: how one doctor's checklist can help us change health care from the inside out. New York: Plume, 2011

[139] Iacobucci, Gareth. "Performance data on all surgeons in England will be published within two years." BMJ: British Medical Journal (Online) 345 (2012).

They transitioned from hoping for zero deaths to planning for zero. Their commendable enforcement of such effective processes remains elusive for few hospitals, but there are ways to scale the progress—have government agencies demand transparency from hospitals and enforce the aligned incentives bill. The government is responsible for putting national processes in place, and in health care, they certainly have the wherewithal since a considerable portion of healthcare costs are spent by the government. Thus, our leaders have the right and ability to demand these life-saving changes.

As a final touch, love for patients can influence life or death outcomes. We cannot expect people to love strangers. A lesson we learned during the pandemic is the importance families have on patient outcomes. When COVID prevented loved ones from entering hospitals to oversee patient care, more people died from medical errors than ever before.[140] Families are invaluable as they help the stressed and strained clinicians, nurses, and doctors to love their patients and be advocates for their patients so that optimal care is provided. After all, Plato said a good doctor must have the experience of having an unsound body, and family members of the sick know how to care for them. I am hopeful for the future, but it takes the will and voice of people to push their government to say enough is enough.

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[140] Kakemam, Edris, et al. "Burnout and its relationship to self-reported quality of patient care and adverse events during COVID-19: A cross-sectional online survey among nurses." Journal of nursing management 29.7 (2021): 1974-1982.

Unfortunately, in the last few years, there has been some slowdown, most recently the criminalization of a nurse for making a human error[141]. While that nurse made a mistake, the system failed her, for had the correct processes been in place, her human error would have not become fatal. To criminalize her actions despite her owning the mistake will have a chilling impact on the journey to patient safety because who will come forward and report mistakes now? Without reporting about mistakes, we cannot learn from them to improve for the future.

One country by law criminalizes medical errors: Japan. In Japan, if a doctor makes a medical error, the police show up, and medical staff are incarcerated.[142] One can imagine the impact such a policy has inflicted on their patient safety progress—by some miracle, every single Japanese hospital reaches an astonishing zero preventable deaths per year. So while it appears they do not have a medical error problem, they really do. People die, but the mistakes are buried along with the deceased. They are never reported. The system perpetuates a blind medical practice since learning from mistakes is out of the question when even acknowledging their occurrence is forbidden. Patient safety is not a spur-of-the-moment movement but a continuous effort, and a continuous effort relies on fostering a safety culture which comes from an openness to learn.

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[141] Kelman, Brett. "Former Nurse Found Guilty in Accidental Injection Death of 75-Year-Old Patient." NPR, NPR, 25 Mar. 2022, https://www.npr.org/sections/health-shots/2022/03/25/1088902487/former-nurse-found-guilty-in-accidental-injection-death-of-75-year-old-patient.

[142] Nagamatsu, Soichiro, Masahiro Kami, and Yoshinori Nakata. "Healthcare safety committee in Japan: mandatory accountability reporting system and punishment." Current Opinion in Anesthesiology 22.2 (2009): 199-206.

Ignorance cripples us. It is time for change on all fronts. Transparency, aligning incentives, reforms to cultural norms within hospitals, and restructured GPO financing are vital and necessitate compulsory implementation. Ultimately, my findings indicate that saving 250,000 lives per year is within reach. I wholeheartedly believe it can be done, and I hope my research has shown you why.

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