CHALLENGES AND OPPORTUNITIES FOR THE IMPROVEMENT OF HEALTH SYSTEMS

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fidhs

Foundation for the Innovation & Development of Health Safety

Purpose

The Foundation for the Innovation and Development of Health Safety (FIDHS) is dedicated to the advancing the overall quality and output of medical treatments, where quality, safety, innovation and sustainability play a central role.

To support that effort, the FIDHS has identified several specific objectives:

- ✓ To contribute to the implementation of personalized medicine, targeting the best possible / most efficient results for each individual;
- ✓ To contribute to initiatives aiming to heighten the safety for patients and healthcare providers;
- ✓ Facilitate the streamlined adoption of new systems & technologies enabling a better control and administration of treatments;
- ✓ To promote the creation and implementation of joint efforts between institutions aiming to maximize the sharing of knowledge and practices;
- ✓ To foster collaboration between authorities & regulatory bodies to expedite the adoption of state-of-the-art protocols and treatments.

FIDHS plans to develop initiatives directed to the sharing of information between the health care community and the general population. It also aims to support the publication of research on ongoing efforts within its areas of interest, and to facilitate the discussion on strategies to reduce medical errors and to monitor the effectiveness of interventions.

As it is commonly known, there are numerous ways to drive these initiatives, including addressing healthcare through the lens of cost, regulation, managing data, research, security and safety. This present document focuses specifically on the issue of safety. In that, it is intended to describe the landscape of weaknesses in health care delivery that endanger patients, and intends to help in the proposal of solutions to correct the limitations of the systems in place.

Overview

The prevalence of medical errors worldwide is difficult to quantify. The first major literature to address the issue *To Err is Human: Building a Safer Health System* in 2000, included estimates of 98,000 deaths per year in the US from medical errors. This amounted to roughly twice the number of automobile deaths in the same year causing resounding alarm. Estimates from then on vary widely, but a study from John's Hopkins in 2016 claimed that medical error was the third leading cause of death in the US[1]. Although these shockingly large estimates are controversial, the article brings to light the impact of these mistakes globally and issues in the collection of data and research priorities surrounding medical mistakes. These key articles sparked hospital initiatives to improve quality of care in the US, but little visibility into the problems at-scale, globally makes it difficult to recognize improvement. Difficulties in identifying the current state of mistakes arise from things such as not including medical error as an option for death codes on certificates in parts of the US. In order to work around lack of data continuous efforts are being made to investigate these issues using creative data sources and systematic reviews of specific cases. Many of the articles to be discussed in this paper make such interpretations and/or inferences by combining several sources of data.

In spite of imperfect data, rough estimates from global systematic reviews show that in primary and ambulatory care, one of the most common forms of patient care with over 8 billion encounters yearly in OECD countries alone, nearly 20-25% of patients in this care are harmed in developed and developing countries[2]. The economic and humanitarian impact of these errors cannot be overstated. Between 5.7 and 8.4 million deaths occur each year in low- and middle- income countries as a result of

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[1] Makary, Martin A, and Michael Daniel. "Medical Error—the Third Leading Cause of Death in the US." BMJ, 3 May 2016, www.bmj.com/content/353/bmj.i2139, 10.1136/bmj.i2139.

[2] Auraaen, A., L. Slawomirski and N. Klazinga (2018), "The economics of patient safety in primary and ambulatory care: Flying blind", OECD Health Working Papers, No. 106, OECD Publishing, Paris, https://doi.org/10.1787/baf425ad-en.

poor quality of care. When including these figures in assessing the cost of medical errors, the burden in

lost productivity alone amounts to somewhere between 1.4 to 1.6 trillion dollars a year[3].

In order to explore the causes of these errors and identify solutions it is easier to group the

errors into major categories. In a systematic review of adverse effects of medical treatment (AEMT),

researchers from the University of Washington categorized causes of harm into six groups[4]:

1) adverse drug events

2) surgical and perioperative adverse events

3) misadventure (incorrect dose, accidental laceration, etc.)

4) adverse events associated with medical management

5) adverse events from medical or surgical devices

6) other

This article will focus on three of the most common incidences of medical error. According to a meta-

analysis of journal articles on medical error (1) drug management incidents made up on average 25%, the

highest proportion of preventable patient harm followed by (2) incidents related to surgical procedures

and healthcare infections, and finally (3) diagnosis[5]. These three categories will guide further discussion

throughout the paper as they outline the groups of error most prevalent in medical care today and

coincide with the framework of other articles addressing medical errors.

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[3] National Academies of Science, Engineering, and Math. "Crossing the Global Quality Chasm: Improving Health Care Worldwide : Health and Medicine Division." Nationalacademies.Org, 28 Aug. 2018, nationalacademies.org/hmd/Reports/2018/crossing-global-quality-chasm-improving-health-care-worldwide.aspx.

[4] Sunshine, J. E., Meo, N., Kassebaum, N. J., Collison, M. L., Mokdad, A. H., & Naghavi, M. (2019). Association of Adverse Effects of Medical Treatment With Mortality in the United States. JAMA Network Open, 2(1), e187041. https://doi.org/10.1001/jamanetworkopen.2018.7041

[5] Panagioti, Maria, et al. "Prevalence, Severity, and Nature of Preventable Patient Harm across Medical Care Settings: Systematic Review and Meta-Analysis." BMJ, 17 July 2019, p. l4185, 10.1136/bmj.l4185. Accessed 22 Sept. 2019.

The quantification and ranking of the magnitude of these errors overtime can be seen in the figure below, with surgical and perioperative events consistently ranking with the most fatalities in the US. These, however, are declining over time with the number of adverse drug effects increasing.
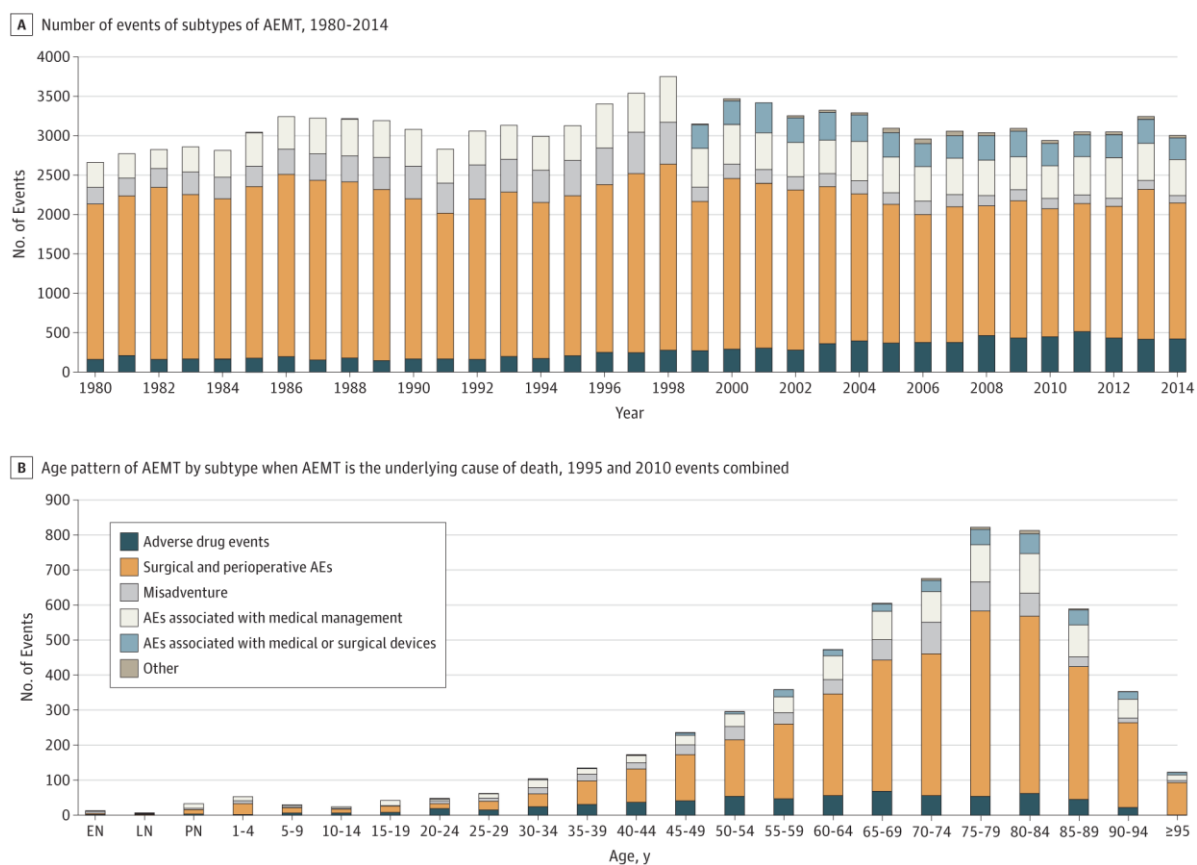

Figure 1: Sunshine, Jacob E., et al. "Association of Adverse Effects of Medical Treatment With Mortality in the United States." JAMA Network Open, vol. 2, no. 1, 18 Jan. 2019, 10.1001/jamanetworkopen.2018.7041. Accessed 15 Nov. 2019.

It is important to note that the above graphic only counts errors resulting in death and is not representative of the medical errors that occur most frequently. For example, although adverse drug events are not identified as the highest medical error induced cause of death in the US, medication error

ranks among the most common medical mistakes globally. Also, the above figures are limited by available data, and thus are biased to include inpatient harm more than outpatient. So, medication error, a leading cause of error, as well as things like delayed diagnosis is less prominent in the above figure due to the limitations of the data. However, this graphic still expresses the age distribution of grave errors as well as shows their trend over time.

Other common errors to be addressed in further detail include misdiagnoses, surgical mistakes, and incorrect health records. Errors outside the explicitly detailed errors in this paper exist, including nursing mistakes with IV pumps, but errors like these are not easily recorded and quantified. These do, however have significant impacts on patient safety, and should therefore be a consideration for the foundation. Increased monitoring and collecting of new data points from suspected forms of medical errors, are necessary to identify and evaluate the prevalence of some of these errors and are a logical first step in improving patient safety at scale.

Medication Error – Adverse Drug Events

Use of prescription and over the counter drugs has become widespread. In the U.S., for example, nearly 1/3 of adults use 5 or more medications. In large national survey, 81% of Americans said they had taken medication in the previous week[6]. This new reliance on medication comes with an increased potential for harm. Adverse drug effects are responsible for nearly 700,000 emergency room visits each year with over 100,000 hospitalizations in the U.S. alone. Globally, medication error was identified as a leading cause of avoidable harm in the healthcare industry with an estimated $42 billion

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[6] Wittich, Christopher M., et al. "Medication Errors: An Overview for Clinicians." Mayo Clinic Proceedings, vol. 89, no. 8, Aug. 2014, pp. 1116–1125, 10.1016/j.mayocp.2014.05.007.

in global costs arising from medication errors. The WHO ascribes these errors to a multitude of causes including weak medication systems, human factors including fatigue, poor environmental conditions, and staff shortages[7]. These factors result in mistakes in prescribing, transcribing, dispensing, administration and monitoring practices of drugs, that cause adverse drug events such as patient harm, and sometimes death. The American Society of Health-System Pharmacists categorized medication errors on the basis of the categories that follow: prescribing, omission (ordered drug not administered), timing, use of an unauthorized drug (not authorized by a legitimate prescriber), improper dosing, wrong dosage form, wrong drug preparation, wrong administration technique, expired drugs, failure to use laboratory data to monitor toxicity or effect, compliance, and other errors[8]. The transition from inpatient to outpatient care is one of the key points of medication error with one study showing 49% of patients experience at least one medication error in this transition of care[9].

The American Society of Health-System Pharmacists identified issues such as drug product nomenclature, illegible handwriting, labeling errors, excessive workload (among physicians, nurses, or pharmacists), and medication availability (manufacturer shortages of medications) as the most common causes of the most prevalent medication errors[10].

Further risk factors for patients include the use of several drugs (both necessary and unnecessary) for treatments, limited health literacy, weak numeracy in self-administering drugs, as well as age specific risks like lower doses for children. Certain drugs are high-risk for patients and a list of

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[7] World Health Organization. The Third WHO Global Patient Safety Challenge: Medication Without Harm. 10 Sept. 2019, www.who.int/patientsafety/medication-safety/en/, /entity/patientsafety/medication-safety/en/index.html.
[8] "ASHP Guidelines on Preventing Medication Errors in Hospitals." American Journal of Hospital Pharmacy, vol. 50, no. 2, 1993, www.ncbi.nlm.nih.gov/pubmed/8480790?dopt=Abstract. Accessed 24 Dec. 2019.
[9] 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, no. 8, 2003, pp. 646–51, www.ncbi.nlm.nih.gov/pubmed/12911647?dopt=Abstract, 10.1046/j.1525-1497.2003.20722.x. Accessed 24 Dec. 2019.
[10] "ASHP Guidelines on Preventing Medication Errors in Hospitals." American Journal of Hospital Pharmacy, vol. 50, no. 2, 1993, www.ncbi.nlm.nih.gov/pubmed/8480790?dopt=Abstract. Accessed 24 Dec. 2019.

high-risk drugs is maintained. A higher level of attention is necessary for prescribing these drugs. These drugs include medications like antidiabetic agents, oral anticoagulants, antiplatelet agents, and opioid pain medications. High-risk drugs account for over 50% of emergency room visits for adverse drug effects[11].

The US Department of Health and Human Services broke down the medication process into the stages of ordering, transcribing, dispensing and administration. Electronic health record systems serve as a useful tool in preventing errors in the ordering and transcribing phases. The most frequent errors occur in the administration step for both inpatient and outpatient administration of drugs according to studies. A detailed strategy for preventing errors at each step is outlined in an article from the Patient Safety Network is the following:

Table. Strategies to Prevent Adverse Drug Events

Stage	Safety Strategy
Prescribing	• Avoid unnecessary medications by adhering to conservative prescribing principles • Computerized provider order entry, especially when paired with clinical decision support systems • Medication reconciliation at times of transitions in care
Transcribing	• Computerized provider order entry to eliminate handwriting errors
Dispensing	• Clinical pharmacists to oversee medication dispensing process • Use of "tall man" lettering and other strategies to minimize confusion between look-alike, sound-alike medications • Automated dispensing cabinets for high-risk medications.

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[11] Agency for Healthcare Research and Quality. "Medication Use Leading to Emergency Department Visits for Adverse Drug Events in Older Adults." Ahrq.Gov, 19 Dec. 2007, psnet.ahrq.gov/issue/medication-use-leading-emergency-department-visits-adverse-drug-events-older-adults. Accessed 24 Dec. 2019.

- Adherence to the "Five Rights" of medication safety (administering the Right Medication, in the Right Dose, at the Right Time, by the Right Route, to the Right Patient)

- Barcode medication administration to ensure medications are given to the correct patient

Administration
- Minimize interruptions to allow nurses to administer medications safely

- Smart infusion pumps for intravenous infusions

- Multicompartment medication devices for patients taking multiple medications in ambulatory or long-term care settings

- Patient education and revised medication labels to improve patient comprehension of administration instructions

The article further states the importance of well implemented information technology solutions in improving medication safety overall. Even with computerized provider order entry, errors still occur and the development and use of more sophisticated computing techniques such as an outlier detection system are necessary to further improve technological processes[12].

Specifically, computerized physician order entry systems significantly cut down on sources of medication error. These systems eliminate the illegibility of handwriting and ambiguity of medical abbreviations. Other features of these systems include incorporating drug databases to identify drug interactions and bar code-assisted medication administration which resulted in a 56% reduction in the error rate of an adult ICU by lowering wrong administration time occurrences[13]. Overall, the computerized order entry systems have been shown to reduce medication errors by almost half in studies at major hospitals[14].

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[12] Agency for Healthcare Research and Quality. "Medication Errors and Adverse Drug Events | PSNet." Ahrq.Gov, 7 Sept. 2019, psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events.
[13] DeYoung, Jaculin L, et al. "Effect of Bar-Code-Assisted Medication Administration on Medication Error Rates in an Adult Medical Intensive Care Unit." American Journal of Health-System Pharmacy : AJHP : Official Journal of the American Society of Health-System Pharmacists, vol. 66, no. 12, 2009, pp. 1110–5, www.ncbi.nlm.nih.gov/pubmed/19498127, 10.2146/ajhp080355. Accessed 26 Oct. 2019.
[14] Bates, D W, et al. "The Impact of Computerized Physician Order Entry on Medication Error Prevention." Journal of the American Medical Informatics Association : JAMIA, vol. 6, no. 4, 1999, pp. 313–21, www.ncbi.nlm.nih.gov/pubmed/10428004?dopt=Abstract, 10.1136/jamia.1999.00660313. Accessed 24 Dec. 2019.

In an article detailing medical error prevention in the US, they've identified the major actions to decrease errors as the following:

- ✓ Automating dispensing devices.

- ✓ Barcoding.

- ✓ Computerizing the medication administration record.

- ✓ Computerizing order entry and decision support.

- ✓ Intercepting error messages at the time medications are ordered.

- ✓ Prompt warnings for drug interaction, allergy, or overdose.

- ✓ Providing drug-specific information.

- ✓ Filling prescriptions using robotics.

- ✓ Providing up-to-date information on new drugs.

Incorporating these features in health systems was identified as a major area for growth as these technology systems are not yet universal in hospital systems. Other organizations for the advancement of healthcare like the Network for Excellence in Health Innovation, cite articles showing the cost saving potential of proven solutions. E-prescribing reduced medication errors by 85% in an ambulatory care setting and generated a net cost savings of $403,000. Similarly, a Bar Code Electronic Medication Administration system that identified correct dosage led to a 51% decrease in medication errors and an annual saving of $2.2 million in a large academic hospital. Although figures range, the cost of preventable medication errors is often estimated to be in the tens of billions of dollars annually in the US alone.[15,16]

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[15] NEHI. Preventing Medication Errors: A $21 Billion Opportunity.
https://www.nehi.net/bendthecurve/sup/documents/Medication_Errors_%20Brief.pdf.
[16] Wittich, Christopher M., et al. "Medication Errors: An Overview for Clinicians." Mayo Clinic Proceedings, vol. 89, no. 8, Aug. 2014, pp. 1116–1125, 10.1016/j.mayocp.2014.05.007.

Surgical Error – Surgical and Perioperative Events

Surgical errors make up a significant portion of medical errors worldwide and have some of the gravest impacts on patients. Examples of the most commonly occurring errors include leaving foreign objects in a patient's body, anesthesia mistakes, nerve damage, and wrong-site, wrong-procedure, wrong-patient surgery with anesthesia errors being the most frequent deadly error. Although a relatively rare error with estimates of occurring in 1/112,000 surgeries, wrong-site, wrong-procedure, wrong-patient surgery, are entirely preventable mistakes.

These errors have largely been combatted by building redundant systems, or a series of administrative and operational checks that repeatedly reaffirm the site, procedure and patient. This includes standards for site marking, and a surgical timeout- a pause before the beginning of the procedure to review the critical details of the procedure[17]. These specific examples are aspects of the Universal protocol, a solution proposed by the [Joint Commission for Transforming Healthcare](), a non-profit health accrediting agency in the U.S. Also, important to note, wrong-site wrong-procedure surgeries can be very costly to hospitals. These mistakes are considered events that should never occur and health insurance agencies such as the Centers for Medicare and Medicaid Services, do not reimburse hospitals for the costs associated with these errors.

The most common adverse event associated with surgery was hospital-acquired infection, however preventable injuries like sores and urinary retention are also common and costly. These preventable injuries unnecessarily raise costs by elongating hospital stays. It is estimated that each hospital-acquired surgery related infection and severe pressure ulcer costs approximately $30,000 in

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[17] Agency for Healthcare Research and Quality. "Wrong-Site, Wrong-Procedure, and Wrong-Patient Surgery | PSNet." Ahrq.Gov, 7 Sept. 2019, psnet.ahrq.gov/primer/wrong-site-wrong-procedure-and-wrong-patient-surgery.

additional hospital stays making these errors among the costliest for hospitals[18]. The average length of stay for adverse events in surgery in a study of Swedish hospitals was shown to be much greater than the average patient stay (see figure)[19].
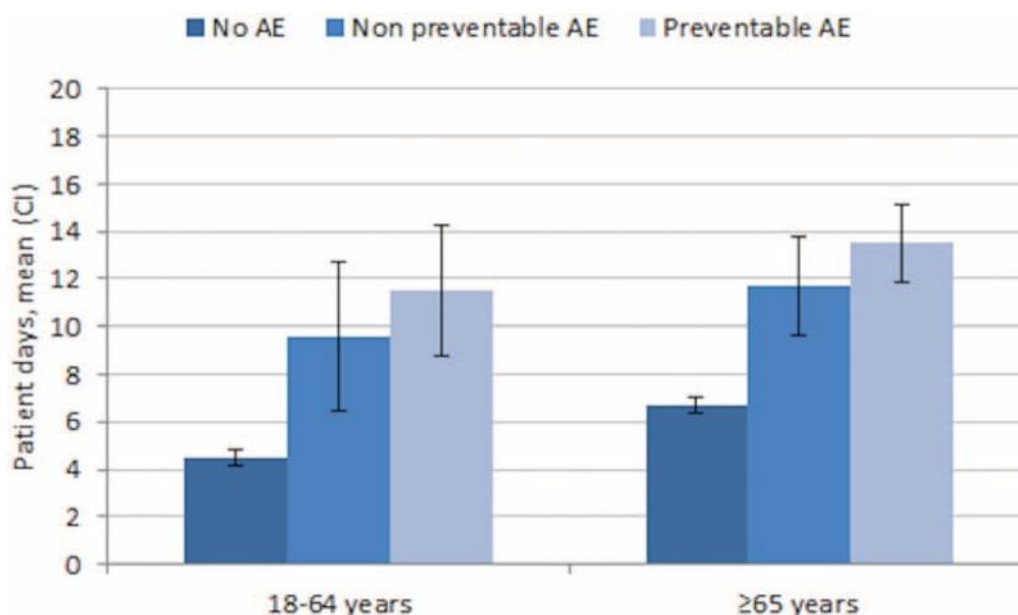
With all the hospital admissions identified in the study as many as 15% ended up with an adverse surgery event. These errors are an opportunity to prevent patient harm and save on the cost of hospitalization by implementing a combination of human and IT checks to create a system of repeated validation of procedure in order. The collection of data on the outcome of surgeries and corresponding adverse events will also be essential moving forward to monitor the progress and continuously improve the surgical system at the hospital level and beyond.

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[18] Anand, Priyanka, et al. "Estimating the Hospital Costs of Inpatient Harms." Health Services Research, vol. 54, no. 1, 11 Oct. 2018, pp. 86–96, 10.1111/1475-6773.13066. Accessed 24 Dec. 2019.

[19] Nilsson, Lena, et al. "Preventable Adverse Events in Surgical Care in Sweden." Medicine, vol. 95, no. 11, Mar. 2016, p. e3047, 10.1097/md.0000000000003047. Accessed 3 Nov. 2019.

Misdiagnosis – Misidentified illness and Mistreatment

A majority of diagnoses are made efficiently and effectively by doctors with extensive medical training. Misdiagnosis, however, can have grave and expensive consequences. In studies done in Colorado, Canada, Australia, New Zealand, and a panel study from Harvard, misdiagnoses amount to a significant portion of adverse events ranging from 10-20% of adverse events[20].

Often when diagnosed correctly, physicians differ in their approach to treatment. Although physicians can and should exercise their best judgement in treatment for their patient whether it adheres to national standards or not, the deviation occurs at rates suggesting the lack of consideration for widely accepted standards. For instance, "although 95% of physicians were aware of lipid treatment guidelines from a recent study, they followed these guidelines only 18% of the time."[18]. Decision support tools in the form of IT solutions are being developed and used to mitigate the problem. Although work is needed to be done to encourage the use of these tools and their incorporation into the health system, these tools have the potential to improve patient outcomes by offering diagnostic suggestions and supplementing a doctor's own abilities. A direct connection to other health systems like the electronic health record system and the treatment process has the potential to utilize patient data across the board in a more organized and wholistic way. Creating a feedback system to the doctors may also mitigate the misdiagnosis problem as doctors can become more aware and learn from mistakes made in diagnosis.

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[20] Berner, Eta S., and Mark L. Graber. "Overconfidence as a Cause of Diagnostic Error in Medicine." The American Journal of Medicine, vol. 121, no. 5, May 2008, pp. S2–S23, 10.1016/j.amjmed.2008.01.001. Accessed 17 Sept. 2019.

Other Errors – Infection, Bad Medical Devices, Etc.

One of the leading causes of further harm to patients are nosocomial infections. Though one of the leading sources of nosocomial infection falls under the surgical error umbrella, urinary tract infections, respiratory tract infections, and bloodstream infections originating from the hospital are significant, and frequent enough to remain an issue. According to an article on patient safety in the EU from the WHO, "Infections associated with health care affect an estimated 1 in 20 hospital patients on average every year (estimated at 4.1 million patients)". The UK National Audit Office estimates costs upwards of £1 billion per year stemming from infections[21]. Countries like the US are putting measures in place such as protocols and guidelines to address this safety issue[22].

Yet another source of patient harm includes medical device error. In the US, the FDA sought to monitor and address this issue and found that medical devices have caused over 80,000 deaths in the US since 2008. Medical devices are part of a multi-billion-dollar industry and have been touted as a cure-all for certain conditions, yet these devices have the potential to harm patients as well. For example, take the spinal cord stimulator to prevent pain disorders. The associated press found evidence of the dangers of this wonder tool uncovering patients that had been shocked, burned, or sustained spinal cord damage[23]. Although the FDA is a global gold-standard for monitoring medical devices, it's abbreviated approval process for devices has resulted in negative consequences for patients.

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[21] Dr. Tello, Juan. "Data and Statistics." Who.Int, 21 Apr. 2019, www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics, http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics.

[22] CDC. "Preventing Healthcare-Associated Infections." CDC.Gov, 2019, www.cdc.gov/hai/prevent/prevention.html.

[23] Associated Press. "Medical Devices for Pain, Other Conditions Have Caused More than 80,000 Deaths since 2008." STAT, STAT, 25 Nov. 2018, www.statnews.com/2018/11/25/medical-devices-pain-other-conditions-more-than-80000-deaths-since-2008/.

Other medical errors include injuries from falls and immobility, obstetrics complications,

pressure ulcers, blood clots, and ventilator associated pneumonia[24]. Of the most common errors, these

rank alongside previously discussed errors, however, these are largely preventable through bureaucratic

means, such as protocols or trainings for those providing care.

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[24] Brennan, Troyen A., et al. "Incidence of Adverse Events and Negligence in Hospitalized Patients." New England Journal of Medicine, vol. 324, no. 6, 7 Feb. 1991, pp. 370–376, 10.1056/nejm199102073240604. Accessed 15 Oct. 2019.

Conclusion

Although it is difficult to identify the number of medical errors in primary care as data for hospitalization is much more readily available, consistent errors in use of medication, like failure to review necessity of medication after several refills, are compounded by the large quantity of prescriptions from primary care. For hospitalizations, there is a wealth of data suggesting the prevalence of medical errors globally. Data from European hospitals show that medical errors and health care related adverse events occur at a rate of 8-12% of hospitalizations. In England alone, the UK department of health estimated that over 850,000 adverse events occur each year in hospitalization settings. Over 23% of EU citizens claim to have been affected by an adverse event with 18% claiming to have experienced a serious medical error. The EU data reveals the urgency of reducing these errors as statistics show the potential for the prevention of over 750,000 harm-inducing medical errors per year. This would achieve tremendous financial and humanitarian benefits with 3.2 million fewer hospital days, 260,000 fewer incidents of permanent disability, and 95,000 fewer deaths per year in the EU[25].

In an article by the Milken Institute School of Public Health at George Washington University, costs associated with medical error amounted to as much as $19.8 billion in the US when considering economic impact, with indirect economic impacts totaling more than a trillion. The majority of the $19.8 billion figure is made up of additional medical expenses followed by lost economic productivity[26]. These

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[25] Dr. Tello, Juan. "Data and Statistics." Who.Int, 21 Apr. 2019, www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics, http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics.

[26] Sophia, Bernazzani. "Tallying the High Cost of Preventable Harm - Costs of Care." Costs of Care, 5 Oct. 2015, costsofcare.org/tallying-the-high-cost-of-preventable-harm/.

errors constitute huge expenses with large potential cost-savings when addressing the main causes of medical error, (1) medication error, (2) surgical error, and (3) error in diagnosis.

Legislative, administrative, and health IT solutions can make significant progress in cutting down errors. The proven success of health systems such as computerized physician order entry systems, electronic health record systems, and bar code electronic medication administration systems shows a promising avenue for cost savings and patient safety. Each of these systems have all had proven success cases which cut down errors by over 50% when implemented. The area of healthcare IT has not only room, but the need to grow in its potential savings due to:

✓ The potential to further develop systems to prevent errors, by incorporating features such as computerized dispensing mechanisms for patients at high risk of medication non-compliance or drug-drug interaction databases preventing negative drug interactions.

✓ The possibility to interconnect systems, in a timesaving and safety increasing process.

The focus of the paper largely lies in the medication error space, as preventable adverse events in surgery and diagnoses have serious and costly implications that need to be addressed https://www.centerfortransforminghealthcare.org/. Software solutions to the medication errors have demonstrated higher effectiveness in addressing these issues rather than the implementation of human processes. Potential for diagnosis suggestion engines or mobile apps to create checks on wrong-site, wrong-person, wrong-side procedures could save on additional medical expenses and improve patient safety.

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