A Tale of Two Cases: Preventing Errors in Oncology and Medicine

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Abstract: Betsy Lehman, a knowledgeable health reporter for the Boston Globe, died due to an overdose of the chemotherapy that was supposed to treat her breast cancer [1]. Willie King, a diabetic patient in Florida, already concerned about having to live with one leg, woke up to discover that the surgical team amputated the wrong limb [2]. Ben Kolb, a 7-year-old boy from St. Lucie, Florida, died after the surgeon who was operating his ear injected epinephrine instead of the local anesthetic lidocaine [3]. The common thread: medical errors.

“It was the best of times; it was the worst of times…
...It was the age of wisdom; it was the age of foolishness
It was the epoch of belief; it was the epoch of disbelief
It was the season of light; it was the season of darkness
It was the spring of hope; it was the winter of despair…
In short, the period was so far like the present period”

Charles Dickens, A Tale of Two Cities, 1859 [4]

“As to diseases, make a habit of 2 things:

To help, or at least do no harm”

Hippocrates, Epidemics, 400 B.C.E. [5]

INTRODUCTION: A TIME OF PARADOXES

As in the story by Charles Dickens, we live in a time of paradoxes. Scientific advances have improved the prevention, diagnosis and treatment of most maladies. Fewer people die of infectious diseases today than in any previous era. Cardiovascular mortality has fallen significantly [6]; and even cancer deaths are finally trending down [7].

Medical errors, however, are real and prevalent [8].

Despite the warning from Hippocrates, our fragmented and dysfunctional health care systems often fail to perform that which is their purpose – to improve patients’ well being – and often act to worsen it.

This article presents background information on the prevalence and significance of medical errors, as well as on ongoing initiatives that tackle the issue.
It then describes 2 representative cases which will serve as background for a discussion of the 2 most important causes of mistakes in healthcare: systems failure (a problem of execution) and biased medical judgment (a problem of planning).

DEFINITIONS AND METHODS

The Institute of Medicine (IOM), established by the United States National Academy of Sciences in 1970, advises the federal government on issues related to medical care, research and education [9].

Borrowing from research on human errors in general [10], the IOM defines medical errors as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”.

A semi-structured review of the available medical, administrative and legal literature was undertaken by searching available databases and search engines (EMBASE, PUBMED, Google Scholar, EBSCO Host, CINAHL and the Johns Hopkins University Medical, Legal and Management electronic libraries) using a series of terms related to medical errors.

Specific data on the recent history of research and public policy on medical errors – mostly for the United States of the America, as well as on medical error typology, causes and prevention were specifically sought after. Representative articles were identified and their references searched for a more thorough review.

A North-American perspective was chosen because of the wealth of data available for U.S. healthcare.

BACKGROUND: A BRIEF HISTORY AND “THE INSTITUTE OF MEDICINE” REPORT

Before 1995, medical errors were seen by the medical community and society at large as rare, individual mistakes, committed by imprudent, poorly trained or negligent practitioners.

In the mid-to-late nineties, however, a series of high-profile cases brought the issue to the fore, while 2 studies and a 1999 report by the United States Institute of Medicine shed light into the subject’s prevalence and on its human toll and economic costs [8].

The 2 studies, conducted in Colorado and Utah [11] and New York [12], found that over half of the adverse events seen in hospital admissions were preventable and therefore classifiable as medical errors [13]. Considering that adverse events were seen in 2.9 to 3.7% of these admissions, the Institute of Medicine extrapolated that 44,000 to 98,000 Americans died each year due to medical errors [14]. This is more than the yearly death toll for motor vehicle accidents, breast cancer or AIDS [15].

Patients victimized by medical errors stay longer in the hospital at a higher cost [16, 17]. The estimated economic burden from preventable adverse events – including health care and societal costs – range between US$ 17 billion and 29 billion [18].

While these data have been criticized for their retrospective nature and alarmist tone [19, 20] they provided the basis for the Institute of Medicine Report: “To Err is Human: Building a Safer Health System”. This report estimated the severity of the issue and made recommendations on how to approach it, generating much media and public interest. This culminated in action by congress and President Bill Clinton. Aiming at reducing healthcare mistakes, The Patient Safety and Quality Improvement Act was finally signed in 2005 [21], creating a framework for the independent and confidential collection and analysis of data on medical errors [22].

The Institute of Medicine recognized that much can be learned from the collection and analysis of errors. Moreover, the IOM also appreciated that building safety into systems of care is a more effective way to reduce them than individual punishment [23, 24]. As such, it recommended a series of steps to approach the problem:

1. Establishment of a Centre for Patient Safety within the Agency for Healthcare Research and Quality, which should gather and analyze data on medical errors as well as set standards for safety.
2. Establishment of a Mandatory Reporting System for Adverse Events that result in death or harm.
3. Encouragement of the development of voluntary reporting efforts for medical errors.
4. Protection of these voluntary data so they could not be used in malpractice suits.
5. Greater focus of performance standards for healthcare organizations and professionals on patient safety.
6. Continuous improvement.

FIRST CASE: WHEN SYSTEMS FAIL

Failure of execution is one of the most common causes of medical errors – one for which a framework of improvement has been extensively studied and implemented.

\footnote{An important aspect of the management of medical errors is out of the scope of this article: their aftermath. Patients should be informed that a mistake has happened and the health care team should apologize for it. Medical and financial assistance should be provided to help the patient and family cope with their loss. Finally, the patient should also be informed of the efforts taken to prevent the same mistake from happening again.

The second set of victims is the health care team. They also need help. While most physicians are non-critical of colleagues who are involved in errors, we are not trained to and do not provide systematic support to peers when mistakes happen. Policies should be created to support practitioners involved in medical errors.

For good discussions on these subjects please see references [37-40]. Another topic worth mentioning is the implications the United States legal system has on medical errors. For a discussion on the subject see reference [41].

One journalist likened the situation to that of an airliner going down daily for a year. These estimates might actually be conservative as an Australian study suggested an 8.8% prevalence of medical errors during hospital admissions [42] and no studies actually included patients seen in clinics [20]. Moreover, in one of the only prospective studies conducted to date, investigators from Israel [43] reported that the doctors they observed made 554 errors over 4 months – a whopping 1.7 mistakes per patient per day.}

\footnote{In the above cited reports approximately half of the errors resulted from execution mistakes during surgery. Other significant causes were drug treatment, therapeutic mishaps and diagnostic mistakes [13].}
The Case: Chemotherapy Overdose

Mr. N., a 61-year-old man, came for a regular follow-up visit in the Medical Oncology clinic. He had been seen for a little longer than a year due to a lung adeno-carcinoma (the most common type of lung cancer). At diagnosis, the disease had already spread to his liver, adrenal gland and bones. He had initially received chemotherapy with 2 agents (Carbo-platin and Gemcitabine) aiming at prolonging his life and relieving his symptoms of cough, pain and difficulty breathing. After an initially successful treatment (the size of his cancerous lesions shrunk and he felt better), his disease progressed.

He started treatment with second-line chemotherapy, with a new agent called Pemetrexed. At this visit the...
consultant oncologist, after speaking with the patient and reviewing his chemotherapy orders, realized that he received an overdose. Pemetrexed, also known by its brand name, Alimta, is usually given once every 3 weeks, at a dose of 500 mg/m². Mr. N. had actually received it once weekly for 3 weeks.

Thankfully, the therapeutic index – the ratio between a drug’s effective and toxic doses – of Pemetrexed is wide [25], and he did not suffer any adverse events. He had no symptoms of nausea, vomiting or diarrhoea, common side effects of the drug. His complete blood count was also normal.

Because of the incident, the Department of Medical Oncology started an investigation. The case-specific chemotherapy form (Exhibit 1) was reviewed and a series of mishaps were identified. (Exhibit 1 was modified to protect patient and medical centre confidentiality).

First, despite a standing order that the chemotherapy is to be given every 3 weeks, the medical officer (a licensed physician who is undergoing postgraduate training) wrote weekly dates in the available slots. Second, the consultant physician (a medical oncologist who supervises the medical officer) reviewed the orders and signed only the first date. Third, despite this single signature, the order was processed by the pharmacist and chemotherapy nurses and the patient received it once weekly instead of once every 3 weeks.

The error was disclosed to the patient and the corresponding medical authority⁴. As no harm resulted and the mistake stemmed from a system failure rather than gross negligence in the use of a relatively new agent, all practitioners involved were briefed and the chemotherapy ordering, preparation and administration process was reviewed by a multi-disciplinary team.

This team consisted of all of the department’s 5 medical oncologists, its 2 general practitioners, one of its pharmacists and its 3 chemotherapy nurses and nurse manager.

The Action: Reviewing Chemotherapy Ordering, Preparation and Administration

Ordering, preparing and administering chemotherapy is a highly specialized endeavor. Briefly, it involves a myriad of steps (Exhibit 2). It is a highly customized process that serves as a perfect example of a complex professional service in operational management terms.

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⁴ For discussions on disclosure of errors, please see references [37, 44].
First, there is an initial patient-physician encounter, when the medical history, laboratory and pathology tests and radiographic exams are reviewed. Once the physician makes a decision that chemotherapy is appropriate for a determined patient, he chooses a specific regimen – usually a combination of multiple drugs and pre-medications. At the institution in this case, pre-printed chemotherapy orders are used for 80-90% of prescriptions. If a pre-printed order is not available for a specific regimen, the physician uses a blank order sheet. The oncologist calculates the dose of the medications according to each patient’s body surface area\(^1\). The order is reviewed by a clerk who then schedules the chemotherapy appointment and forwards the form to the pharmacy department.

The pharmacist re-checks the patient’s body weight and height and independently re-calculates the BSA and chemotherapy doses. He or she then prepares the medication on the day of administration. This process involves withdrawing the drug from its vials and diluting it in a solvent for administration (usually normal saline, a solution of sodium chloride in water at 0.9%).

At this point the medication is transported to the administration room where 2 chemotherapy-trained nurses re-check the medication identification labels against the patient’s and make sure that the physician has checked the patient’s blood counts. If all is right, venous access is established (or it might have been established at the time of blood drawn) and the patient receives the pre-medication (to prevent nausea, vomiting, allergic reactions and other adverse events) followed by the chemotherapy infusion.

The nurses monitor the patient’s vital signs before, during and after the infusion. If no reactions are seen the patient is then discharged home with a scheduled follow-up visit to see the medical oncologist, as well as with instructions to go to the emergency department if any unexpected event – especially fever – occurs.

When the chemotherapy form in this specific case was reviewed, a major potential source of errors was found: the availability of slots to write chemotherapy in more than one date. Second, it was not clear to the nurses if one signature meant that all doses were approved or if only one of them was – and which (Exhibit 1).

The form was re-written making it unlikely for a physician to write more than one dose per each 3-week cycle (Exhibit 3). A recommendation was also made to evaluate the use of a computer entry system for chemotherapy orders similar to one already in use at the hospital for regular medications.

The Evidence: A Systems Approach to Prevent Execution Errors in Medicine

While the public and the legal profession have tended to see medical errors as letdowns by individuals, it is now clear that only by recognizing that humans are fallible and make mistakes one can act and develop systems to identify, analyze and prevent errors [26].

As such, most hospitals and cancer centres have developed chemotherapy safety programs as part of their wider patient safety programs [27].

An often cited example is that of the Children’s Hospital of Philadelphia [28].

A series of initiatives, starting with the development of a non-punitive reporting system and with the use of the rapid cycle change method, led to an increase in the recognition of near misses while decreasing actual errors.

The experience at the Children’s Hospital of Philadelphia and other centers allowed the most important actions to improve medical systems and patient safety to be identified as follows:

1. Driving fear out of the process – an open and non-punitive environment leads professionals to understand that personal blame is not the goal of the process, improving the system is.
2. Collecting data on errors and analyzing them – provides evidence of why mistakes happen and allow individuals to come up with solutions to correct them.
3. Focusing on Output rather than Input – often, what seems to be clearly stated to one member of the health care team is not so for another. Ambiguity should be driven out of the system.
4. Simplifying and Standardizing – complexity increase the probability of mishaps.
5. Using Constraints and Forcing functions – these are features of a system that force people to do the right thing.
6. Reducing “hand-offs” – the more professionals involved in a task, the more likely errors will occur.
7. Paying attention to Human Factors – every attempt should be made at achieving a safe work environment, keeping distractions and interruptions at a minimum.

SECOND CASE: WHEN JUDGMENT FAILS

While failure of execution is an important reason for medical errors, of equal or greater importance is failure of planning [29].

The Case: A Bias in Judgment Leads to a Fatal Delay in Diagnosis

A 60 year old man with multiple myeloma, a cancer of plasmacytes, the cells responsible for making antibodies, went to a community hospital emergency room because of light-headedness. His physical examination was unremarkable, except for mild tachycardia. Electrocardiogram and chest x-ray were normal, as was a computed tomography of the brain. Laboratory tests were unrevealing.

He was discharged home only to return 36 hours later, now with difficulty breathing and a low blood pressure. Initial measures were successful and a computed tomography with angiogram diagnosed a pulmonary embolism [clots in the arteries that take blood to the lungs]. Patient

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\(^1\) Body Surface Area (BSA) is the square root of the product of patient’s height in cm x his or her weight in Kg divided by 3600.
suddenly became more short of breath and collapsed. Resuscitation attempts were unsuccessful.

The cause of death was deemed to be pulmonary embolism – a lethal, but often preventable, complication of the treatment he was receiving for his cancer.

The Action: A Lawsuit is Settled

A lawsuit was settled by the hospital for an undisclosed sum.

The Evidence: Biases in Medical Judgment

Had the emergency room contacted the patient’s oncologist he or she would likely have learned (or remembered) that light-headedness is an unusual presenting symptom of a common treatment-related complication – and maybe the adverse event could have been prevented.

While this case also exemplifies a failure of communication, more importantly it exemplifies a failure of planning. Most physicians who make such mistakes are not “rogue” or
“bad apples” [30]. They are average (and even superior) practitioners who happen to be human, and, as such, they are susceptible to biases in judgment [31].

Several biases have been well described in the mental processes of making a diagnosis and deciding on a treatment plan. Human minds tend to selectively gather and interpret data that are available or that confirm or refute one’s pre-conceived mental models. Moreover, prior events distort one’s ability to rationally assess probabilities, interfering with decision making. In treatment, physicians tend to feel more regret if errors are due to actions taken versus inaction. The way questions are framed also interferes in the process as aversion to negative outcomes lead people to make different decisions if outcomes are presented in a positive (survival) or negative (mortality) term.

SYNTHESIS: IMPROVING CLINICAL JUDGMENT WITH DECISION SUPPORT SYSTEMS

As physicians often err because of biases in judgment, significant effort has been put into developing systems that can minimize mistakes in the decision-making process [32]. Initially, these took the shape of algorithms and print-based care forms, which guided the physician over a few critical steps of decision making in diagnosis (e.g., how to work-up chest pain) or treatment (how to manage it).

Currently, however, most of the research and practice efforts rely on computer based decision support systems [33]. These systems work by making the most up-to-date information (the knowledge base founded on guideline-, medical literature- and outcomes-based data) easily available to practitioners while also integrating it with patient-specific data thereby supporting the clinical decision process.

Evidence shows that these support systems improve prescribing practices [34], reduce serious medication errors [35] and improve adherence to established practice standards [36].

A systematic review, however, suggested that only 66% of these improve practice and a recent study identified features of a system, which predict its efficacy [33]. As such much research still needs to be done in the field.

CONCLUSION: TO ERR IS HUMAN... BUT ERRORS CAN – AND SHOULD - BE PREVENTED

Medical practice is a human activity and – as such – it is prone to biases and errors. Healthcare provider organizations have to bear that in mind and create operational systems that minimize situations in which mistakes occur. This is best done in a guilt-free, non-punitive environment, stimulating professionals to report errors and near misses so that an open discussion can optimize operational methods, improving the quality and safety of patient care.

Moreover, human decision-making process is biased, and failure of planning is a common cause of medical errors. Decision support with computer and other guiding systems prevent mistakes and should be implemented in an attempt to increase healthcare safety.

Medical errors can and should be prevented.

EPILOGUE: THE FUTURE

Starting with a late 20th century movement to improve healthcare quality and safety, Information Technology is now ubiquitous. All of a patient’s medical data are recorded and stored in safe, internet-supported, databases from where access can be obtained instantaneously (and from any location) by any member of the healthcare team. The team includes not only physicians but a myriad of professionals that cater to all of a patient’s needs.

Medical Centers are organized around symptoms and diseases rather then by specialist departments. Costs and waiting times are reduced as a consequence of value-based competition.

Decision-support tools are now used at every patient visit, saving further time and resources in the diagnostic process and allowing patients to have increased interaction with their physician - who can now work as a true patient advocate helping them navigate through the several possible treatment options with an adequate estimate of probable outcomes.

Medical errors are measured in 6 sigma fashion with fewer than 3.4 errors per million provider encounters.

Hippocrates and Charles Dickens rest in peace.

(Hopefully, I am still alive and working).

REFERENCES

[3] Reeder J. St. Lucie boy’s death ruled bad reaction to epinephrine. The Palm Beach Post. December 16, 1995; local:1B.

It is however more common for trainees to err than for more experienced practitioners [45]. Moreover, mistakes are also more common when a new procedure or test is first introduced into practice [13].

Research on decisions in situations of uncertainty and its biases owes much to the pioneering works of Kahneman [46, 47] and Tverski [48-50].

8 For a discussion of “Silos” in management see reference [51].
9 For a discussion on value-based competition in healthcare see reference [52].


