

Understanding and Responding to 'Iatrogenesis'

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In the usual circumstances, medical treatment helps the patient recover from the illness. However, on occasions, medical intervention does harm rather than good. This review is an attempt to analyze the factors leading to medical harm to the patients.

Key Words: intervention, medical errors, review

At the present time health care is a profitable industry. It needs to recognize and use the ideas, models, and methods from the safety science that have already been developed and applied to other industries.³⁸ Public and State agencies have given more priority to the iatrogenic situation and patient safety since the Institute of Medicine (IOM) report of 1999²⁰ estimated 44,000-98,000 hospital deaths annually due to medical errors in the United States. Major failures in health care are a product of a distinctive culture of the health care system. Secrecy, deference to authority, defensiveness and protectionism are endemic across all hospitals and biomedical clinics in most countries. The ever present rhetoric about primacy of patient's interest is always subordinated to the needs and interests of health care organizations and professionals.⁴⁰ Our medical community must accept the fact that it has paid far less attention to error and safety than in other comparable industries.¹⁰ This must change with:

- Growing public demand for accountability;
- Continuing advancement in measuring and reporting health care quality and patient outcome data;
- Health care organizations becoming more principled in terms of clinical and managerial leaders.

Understanding 'Iatrogenesis'

Scope of the Problem

Many studies have been undertaken on 'iatrogenesis' in the last 30 years (**Table 1**).^{5,9,25,33,36} Measuring and identifying 'iatrogenesis' can be very demanding. The terms used to identify 'iatrogenesis' have been potentially compensable event (PCE) in the California study²⁵ and adverse event study in Utah and Colorado.³⁷ Defining medical error has

also proved elusive as it carries with it implications of blame, failure etc. A reasonable definition by consensus^{17,22,24,29} would be "An error is an act or omission leading to an unanticipated, undesirable outcome or to a substantial potential for such an outcome." When a research is designed to identify and measure 'iatrogenesis', it entails a huge amount of chart reviews. Variable agreement among physician reviewers is a stumbling block. This was highlighted by the Harvard Medical Practice Study.⁹ Here the physician reviewers were in significant agreement as regards the presence of an adverse event ($k=0.61$), but only in fair agreement as to identifying negligent care ($k=0.24$). This is further made obvious by Hayward and Hoefer¹⁵ who found out that if a reviewer rated an event as definitely or probably preventable, then the chances that the next reviewer rating it as definitely not preventable (18%) was higher than the chances that he would agree (16%). This disagreement will not prevent the identification of an adverse event, but will affect judgments of errors and preventability. As shown in **Table 1** it would be reasonable to assume that about 2% of hospitalized patients will experience a major permanent injury or death solely because of medical care. It is very humbling to note that, with the exception of anesthesia mortality, exposure to health care is associated with more adverse events than mortality from firearms, motor vehicles and other hazardous exposures.³⁵

How Errors Happen and Why should We Change?

Hospital care has been the center of quality improvement since the days of Florence Nightingale¹⁸ and Codman.¹⁹ Medical errors will occur in the course of accomplishing hundreds of tasks that go towards patient care. Reason,²⁹ a proponent of cognitive psychology has divided task-oriented behavior into schematic and attentional patterns.

S. No /Ref. No	Result
1/33	20% had a complication of medical care unrelated to their medical illness. 1.6% had a complication causing or contributing to death.
2/25	4.6% involved potentially compensable event (PCE). 0.6% involved a PCE producing death or permanent major disability.
3/36	36% patients had at least one iatrogenic illness. 2% suffered Iatrogenesis contributing to death.
4/9	3.7% resulted in an adverse event. 1% was a negligent adverse event. 0.6% fatal or permanently disabling adverse event.
5/5	6.5% adverse drug event (ADE). 0.06% had fatal ADE. 5.5% potential ADE.
6/11	6.5% ADE. 0.2% fatal ADE.
7/1	45.8% adverse event of medical care. 17.7% at least temporary injury.
8/37	2.9% adverse event. 0.2% fatal adverse event. 30% adverse events were negligent.
9/15	6% deaths were definitely or probably preventable. 50% of patient would still have died during this admission. Optimal care for 10,000 patients would mean one more patient living at least 3 more months in good cognitive health.

Table 1: Major epidemiologic studies of adverse events in US hospitals.

Errors could also be classified similarly (Table 2). Table 2 suggests that a person is very unlikely to repeat a slip but very likely to keep repeating a mistake.^{17,29} A widely quoted definition of health care quality is “The degree to which health services for individuals and population increases the likelihood of desired health outcomes and are consistent with current professional knowledge”.²³ Here a clear distinction has been made between outcomes of care (desired health outcomes) and process of care (consistent with current professional knowledge). Langley’s PDCA (plan, do, check, act) cycle is a very robust method.^{8,21} This system has four major key points:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What can we do to make a change an improvement?
- Check your idea (PDCA).

Choosing an improvement aim is always daunting because the vast number of possible areas of focus will invite chaos. Medical professionals will be less threatened and more comfortable with familiar and often less effective idea changes.⁷ More promising change ideas will come from examining the process of care from outside, allowing one to see where interactions between tasks offer opportunities to change the way in which work occurs.²¹ Leadership in improvement efforts consists of an explicit specific and shared sense of purpose.³¹ Multidisciplinary teams will identify more interactions where changes would be useful and avoid overemphasis on isolated tasks within the process.¹² This will greatly enhance the likelihood of success in the implementation of the quality improvement process.

Some High Profile Examples of Health Failure

The patient safety movement in any country usually takes off after a high profile instance of major health care failure.²⁰ Single instances of failure do get huge attention from the media time and time again.³²

- The Boston Globe reporter who suffered a fatal medication error at the Dana-Farber Cancer Institute.
- The blood-type mismatched heart lung transplant at the Duke University Medical Center.³²

Usually a major high profile failure will do substantial harm to many patients over a long period of time. The best cited one would be the failure in the pediatric cardiac surgery at the Royal Bristol Infirmary, England. Here cardiac surgeons continued and were allowed to continue operating on newborn patients in spite of repeated warnings about the poor outcomes. This was only stopped when the Department of Health, UK intervened. The subsequent inquiry concluded that 35 deaths were avoidable.³⁹

Common Patterns in Major Health System Failures

Single instance errors do not usually have any pattern. Major health system failures have a distinct pattern as put up by Walsh and Shortell.⁴⁰

They are Longstanding Problems

Usually years pass before the system acknowledges something is wrong. Here are a few examples:

1. Doctors at the national Women’s Hospital in New Zealand left women with cervical cancer untreated for 20 years, to follow the progress of the disease despite, at minimum, spreading discomfort with what they were doing;²⁷
2. Dr. Harold Shipman murdered more than 200 persons in 23 years of general practice in England. This in spite of the fact that people, including the police, were concerned about the patterns and number of deaths;³⁴
3. Dr. Robert Brewer was practicing in Virginia for more than a decade, even though gross errors and glaring instances of failure were known by all the hospitals he worked in.²

Behavior type	Features	Associated error type	Error inducing conditions	Examples
Attentional	Needs analysis, planning oversight. Generates mental effort, intellectual satisfaction. Quite error prone.	MISTAKE Wrong rule applied. Pattern recognition failure. Knowledge based mistakes, wrong judgment.	Inadequate training and experience. Key information presented in ambiguous or inconsistent ways.	Misinterpreting signs of pulmonary embolus for pulmonary edema. Prescribing antibiotic that fails to meet the bacterial flora.
Schematic	Automated, repetitive, monotonous, unrewarding. Needs oversight for best performance.	SLIPS Inappropriate persistence or lapse in automaticity. Unconscious fumbles.	Stress, fatigue, distraction, inadequate oversight.	Telemetry observer fails to notice premature ventricular contractions. Nurse receiving numerous pages gives wrong drug to patient.

Table 2. Cognitive psychology categorization of human behavior and error types.

Situations are Known but not Handled Well

Usually key people and stakeholders knew something was wrong but did nothing about it. Some examples are given below:

1. In the Bristol Royal Infirmary case the poor outcomes were known to referring consultants, general practitioners, professional leaders of the Royal College of Surgeons and civil servants;³⁹
2. A similar situation was seen in the Pediatric cardiac surgery unit of Winnipeg Manitoba.³ The public and professional view of these events focused on one easily dramatized factor: the inexperience of a surgeon whose credentials were impressive but untried. The deaths were not due solely to a single individual. Errors occurred at all levels of the cardiac surgery program — in its hiring procedures, lack of monitoring, lack of a complaints procedure, and even in the administrative decision to develop a pediatric cardiac surgery program at a center with a caseload too low to sustain excellence;
3. Serious problems at the King Edward Memorial Hospital, Perth, Australia. Here we find a long history of dissent, concern, repeated complaints and litigations stretching back to several years;¹³
4. The famous Redding Medical Center lawsuit where more than 50% of the cardiac surgeries were deemed unnecessary.³⁰

Lack of Distinct Management

Major failures center around individual professionals and small teams and not from failure of the system as a whole.²⁸ However, there is a distinct lack of response from the management. Such organizations did not have the fundamental system for quality review, incident reporting and performance management. Usually the staff are disempowered, vulnerable and poorly placed to raise concerns.¹⁶ Furthermore, the health care organizations have

been downright complacent in the face of outright evidence that patients were being harmed. They were slow to suspect wrongdoings and distinctly slow to address the problem.¹⁴

Responding to 'Iatrogenesis'

We are bound to assume that in the larger context slips and mistakes are made by diligent people working in a flawed system. Slips and errors will occur from time to time. The aim should be to anticipate the settings in which they occur and to develop strategies to reduce their occurrence in the future. They should be used as markers for system improvement and not for finger pointing. The final aim is to achieve a positive culture for identifying and presenting errors.

Reporting

The logistics involved to detect errors by active surveillance makes it virtually unfeasible but for rare instances. Thus reporting an incident (passive surveillance) is the only way out. Mandatory incident reporting has potential for punishment and risks alienating health care providers and inhibiting reports. Voluntary confidential incident reporting will have more chance to stimulate documentation of errors, as it promotes a positive culture. Non-medical industries have established reporting systems which have the following characteristics that should be useful to the medical industry also:⁴

- Focus on near misses;
- Incentives for voluntary reporting;
- Emphasis on system approaches to error analysis;
- Organizational culture supportive of quality improvement.

Among all these, health systems should focus on near misses. They are no-harm events and occur 8-300 times more often than adverse events.⁶ They should be actively reported. They are less likely to invoke guilt or other psychological

barriers to reporting.⁴ They also do not involve medico-legal risks. Their analysis is not likely to be affected by hindsight bias, in judging health care as inappropriate when harm has already occurred.²² Under reporting is a key fear factor in the voluntary reporting systems. Only 1.5% of adverse events and 6% of adverse drug events will be identified through traditional incident reporting.²⁶ Organizations should strive for a culture conducive to reporting rather than haggle about a mandatory/voluntary reporting system.

Analyzing Errors

This means systematically examining systems and processes and not habitual blaming and biases. RCA (Root cause analysis) is the model error analysis tool and is the one championed for health care systems by many experts.²¹ The Joint Committee for Accreditation of Health Care Organizations (JCAHO) has mandated the use of RCA in its accredited hospitals since 1997.²⁹ RCA has 2 stages. In the first stage “Active Errors” are sought. This is a simple matter of obtaining a rigid chronology of events to find where/who made the error. It is the second part of detecting “Latent Errors,” which are accidents waiting to happen, that all must concentrate on. To site an example, an active failure is incorrectly programming an infusion pump. If the hospital uses different types of infusion pumps, this is a latent error as it makes incorrect calibration of infusion pumps more likely to happen. Hindsight bias is a major drawback of RCA. The Agency for Health Care Research and Quality (AHRQ), has commissioned production of evidence-based review on practices for improving patient safety. This is based on their reports that important guidelines like deep vein thrombosis (DVT) prophylaxis and use of beta blockers in the preoperative period to prevent cardiac events in non-cardiac surgeries have come up. Their full text report is available free online at <http://www.ahrq.gov/clinic/ptsafety/>

Conclusions

Doctors must be actively involved and contribute a visible leadership in the promotion of a culture of patient safety. This is the only way the known barriers to disclosure (reporting), investigation (analysis) and recommendation (changes) will be overcome. Only when changes happen will improvement have a chance to occur.

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