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CURRENT TOPICS

Healthcare Safety & Accountability

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HEALTHCARE SAFETY & ACCOUNTABILITY

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FOREWORD

The Association for Healthcare Safety and Accountability operates within areas that are crucial for the human agenda and that have increasingly acquired a relevance and inevitability for all health care professionals (physicians, nurses, researchers, technology experts, administrators) whose work includes the mission to achieve optimal performance in their own field while aiming at excellence in what they do.

The experience gained in the last few years by various constituent bodies of the University of Milan, the Healthcare Accountability Laboratory among them, has been conspicuous for its particular importance and for the quality of its initiatives and partnerships, aiming as it does to develop and expand a network of international co-operation which makes possible the implementation of shared and shareable results.

The Association for Healthcare Safety and Accountability is a further shining example of the far-reaching and strategic view which the Healthcare Accountability Laboratory can display in the projects it shares with the University of Milan to generate synergism as well as sustainable and competitive partnerships on the international scene.

The academic world fosters, spurs, and contributes to these important projects which create the conditions for comparing experiences and knowledge integration, the underpinning of progress in healthcare and a pledge for an ever greater protection of patient's rights.

Prof. Gianluca Vago
Rector
Università degli Studi di Milano, Italy

"The history of science, like the history of all human ideas, is a history of irresponsible dreams, of obstinacy, and of error.
But science is one of the very few human activities - perhaps the only one - in which errors are systematically criticized and fairly often, in time, corrected.
This is why we can say that, in science, we often learn from our mistakes, and why we can speak clearly and sensibly about making progress there".

Karl R. Popper
Conjectures and Refutations: The Growth of Scientific Knowledge (1963)

"Responsibility assumes that we know the alternatives, that we know how to choose from among them, and that we use this knowledge to push them aside through cowardice, opportunism, or ideological fervor".

Paul K. Feyerabend
Killing Time: The Autobiography of Paul Feyerabend (1999)

about

HEALTHCARE SAFETY AND ACCOUNTABILITY

Healthcare Safety and Accountability (HealthCSA) is a key reference organization for the study and the development of mechanisms and processes that are involved in the interpretation, evaluation and improvement of the professional healthcare responsibility and accountability, healthcare safety, healthcare reliable organization, systems of quality in which professional of excellent clinical competence manage the intrinsic risk of their profession caring for the patients.

The medical and scientific knowledge and experience, together with the medical-legal skills for the interpretation and evaluation need to be actively integrated in order to determine an efficient proactive and responsible healthcare management.

HealthCSA has strong interdisciplinary skills in the fields, avail the collaboration of the best experts in the fields of healthcare, management, forensic, legal and insurance sectors.

Relevant activities are carried out in the training and professional development, consulting services that enhance the scientific and organizational skills.

HealthCSA is associated with the Healthcare Accountability Lab, Forensic Medicine and Insurance Section, Department of Biomedical Sciences for Health, University of Milan, Italy.

HealthCSA is working with the University of Milan to organize the University Master's Degree of 2nd Level in "Healthcare Accountability Management". The Master is based on interdisciplinary education open to all professionals who interface with healthcare responsibility. The Master provides effective tools and methods for interfacing with the ranges of interpretation and evaluation of healthcare responsibility/liability/accountability, through an interdisciplinary curriculum that allows the participants to develop strategies to assess risks, liability and damages in the organizational, forensic and insurance activities through lectures, training and application of case studies.

Seminars, practical exercises, laboratory workshop and internships will be held both at the Departmental Section of Legal Medicine and the Healthcare Accountability Lab of the University of Milan, both in Hospitals and Healthcare Institutes, Insurance Companies and well-known Brokerage and Law Firms with recognized activities in the professional healthcare accountability.

HealthCSA is active in the fields and disciplines of specialization like Professional healthcare Responsibility/Liability/Accountability; Forensic Medicine and Insurance; Risk management; Clinical management of healthcare facilities; Safety in Healthcare; Privacy,

informed consent; Quality healthcare system; High Reliable Organization; Professional healthcare education and training; Development of human competence for professionals; Development of technical skills for healthcare professionals; Regulations and laws.
Our activities are aimed at specialist doctors, healthcare professionals, researchers and all those involved in medicine and health, clinical and translational research, healthcare administration and legislation.
It is our goal to establish and share a common ground for healthcare professionals, researchers and scientists from multidisciplinary background to establish international collaboration and partnership with Universities, Medical Research Institutes, Hospitals, Scientific Societies, School of Law.
Collaborative initiatives intend to create synergies and develop a new sustainable paradigm in healthcare, creating high reliability organization, in which competent healthcare professionals operate aiming towards high quality excellence, sharing a culture of safety and responsibility.
We invite everyone to collaborate and to send feedback, comments and contributions to info@healthcsa.org, the Society is always willing to consider partnership and collaborations.

NEW PERSPECTIVES FOR THE HEALTHCARE SYSTEMS

1.1 INTRODUCTION

It is the nature of Medicine as a science and art to improve itself.
In the global context, science and knowledge in medicine accumulate too quickly to be absorbed, understood and implemented, and often contain contradictions and disputes.
The changing organization, financing, and priority of healthcare systems are creating new imperatives for an interdisciplinary approach, attentive to the problems emerging within abroad conception of medicine, which acts as a stimulus to formulate reasoned interpretations, facilitating the updating of medical professionals through the diffusion of innovations and best practices.
Has clearly become imperative to understand that the improvement and development of healthcare service require a systemic approach to the problems, and respond to the educational and training needs of the healthcare professional.
Professional responsibility and safety in healthcare are constantly evolving, so as to require detailed knowledge of the requirements and responsibilities associated with activities of individual operators.
Thus, the need to apply a new perspective and paradigm to understand the constant changes of healthcare systems.
We have to integrate a wide range of new perspectives to our analytical approach to understand and learn from different array of healthcare situations.
Extensive scientific literature has been published about healthcare systems that unintentionally and systemically generate various circumstances in which significant harm is experienced by the persons receiving care. The evidence that the magnitude of patient harm was unsustainable and unreasonable lead to the conditions to evaluate new approaches to provide solutions to unintentional patient harm.
Patient safety and responsibility are fundamental principles of healthcare.
Evidence has shown that to maintain and increase the health status of their populations, countries must strengthen their health systems in terms of addressing patient safety and quality of care.
Expectations of health system performance are mounting, challenging its readiness to change and adjust to technological development and emerging health threats.
Safety and accountability are part of the quality agenda and therefore a dimension of the quality culture, requiring broad commitment from both the organization and the community.
The contemporary culture every day demands more reliability, more competence, more transparency, more safety and more public

accountability from every aspect of life.
It is time to reflect on the progress we have made and on the road ahead in patient safety, accountability and on areas that have not received the attention they deserve.

1.2 SAFETY

Primum non nocere is a Latin phrase that means *First do no harm*. It is a fundamental principle for medical services all around the world. The physicians and the other healthcare providers must always consider the possible harm that any clinical intervention might do.
The concept of patient Safety implies the prevention of errors and of adverse events associated with the healthcare.
Every point in the process of care-giving contains a certain degree of inherent unsafety. Slight mistakes accumulate and grow to gross errors if unchecked.
Adverse events may result from problems in practice, products, procedures or systems.
Patient Safety improvements demand a complex system-wide effort, involving a wide range of actions for performance improvement, environmental safety and risk management (infection control, safe use of medicines, equipment safety, safe clinical practice, safe environment of care, adoption of guidelines, protocols, procedures, best practice).
While healthcare has become more effective, it has also become more complex with greater use of new technologies, medicines and treatments. Health services treat sick patients who often present with significant co-morbidities requiring even more difficult decisions as to healthcare priorities. Increasing economic pressure on health systems often leads to overloaded healthcare environments.
Unexpected and unwanted events can take place in any setting where healthcare is produced and delivered (lab and research center, primary-secondary-tertiary care centers, community care, social and private care, acute and chronic care).
It has been estimated that every 10th patient experiences preventable harm or adverse events inside the hospital, causing suffering and loss for the patient, the family and the healthcare providers and also taking a high financial toll on healthcare systems.
Reported rates of medical errors -possibly overinflated by the media- are shocking. It has been estimated that approximately 225,000 deaths per year are caused directly by the medical care itself (medication errors and unnecessary healthcare treatment). This makes the medical errors the third leading cause of death in the United States, after heart

diseases and cancer.
Given the current social and judicial climate about the clinical malpractice phenomenon, defensive medicine is increasingly practiced by healthcare professionals. The fear of litigation, more than the fear of reprimand, stops actions to prevent future errors and also damages the doctor-patient relationship.
Poor communication often prompts patients to files lawsuits in the first place. I'm sorry laws, which hold expressions of apology, fault or sympathy to be inadmissible as evidence of an admission of liability, are an important step in the right direction toward achieving a balance that encourage transparency between physicians and patients and pave the way for better care over all.
Healthcare must achieve Safety successes already seen in other high-risk industries such as aviation and we must learn to balance Safety, Quality and Accountability.
For caregivers who knowingly and recklessly violate safe practice, discipline is the right course.
But most errors that lead to patient harm occur because of bad systems or bad processes, not because of bad people.

1.3 RESPONSIBILITY AND ACCOUNTABILITY

Responsibility is a form of trustworthiness: it is the trait of being answerable to someone for something. The relevance of this meaning is clear, either in social and political context. In the healthcare systems the significance of Accountability became even more complex, considering the dynamic concept in which meanings and contents are layered in relation to the public need for information. Information that is essential in order to improve the quality of the healthcare systems and the sustainability of their insurance protection.
Accountability in the healthcare system demands the development of valid and reliable measures of quality.
Among these measures, we can identify:

- the recognition of the need for a wide systemic change
- the need to establish a clear policy for responsibility for functions related to Safety and improvement
- the ability to master and apply modern methods for quality planning, control and improvement
- the ability to establish a High Reliability Organization
- the imperative of working with multidisciplinary teams to achieve excellent healthcare goals
- the acknowledgement of professional excellence as a key factor to impact on evidence-based risk management
- the need to involve patients and their relatives in the whole

healthcare process, empowering and educating the patients and their immediate Social Network as partners in the process of care
- the approach to trust the goodwill and the good intentions of the staff and to be cautious about using blame
- the need to provide appropriate training and continuous medical education programs
- the aptitude to learn from failure and to be pro-active in the risk assessment.

Iatrogenic and unwanted medical errors evoke strong opinions and raise issues of fairness, Quality, Competence, Responsibility and Accountability.

The tendency to assign blame when mistakes occur is inimical to an environment in which we hope that learning and improvement will take place. But at the same time there is some unerasable need to hold people accountable for egregious errors.

Systemic problems in procedures are very often beyond the single case.

If we want to establish an environment that promotes disclosure of errors and near-misses, the fastest way to drive reporting underground is to punish someone who has made a mistake.

People in the medical field are well intentioned and feel great distress when they harm patients.

Medical negligence is almost always committed by the well-intentioned, because medicine is a risky business that someone must manage.

It is growing factor that the healthcare community takes errors very seriously, and there are many fail-safe mechanisms in place at most if not all hospitals and healthcare centers.

It has been demonstrated that while punitive actions may reduce deliberate reckless behaviour, it is not effective in reducing the occurrence of most types of human errors. We also know this from our day-to-day lives, where inadvertent errors are quite common. For example, even though the consequences to refuel with petrol instead of diesel are potentially severe, many people have made this error, some more than once (modern vehicle design and refueling system has made it virtually impossible to refuel the car using the wrong fuel).

Errors must be used to reinforce a learning environment in which we are fixed on the problems rather than inflexible on the people.

Whoever commit an error must show concern for the patient who suffered. We need to change the culture regarding the disclosure of medical errors. As clinicians we cannot learn from what we do not know and what we do not know can seriously harm our patients.

Any detected error must be reported before it develops the potential

to cause harm. Like realizing that a wrong dose of medication could be administered to a patient or that a patient has been wrongfully listed to get a procedure due to an error in the electronic system. And the institutions must also work on discovering how the errors occurs to prevent similar ones. It is not an easy task to change the current culture and to establish a new paradigm, but we must start.

The current healthcare focus on personal blame has been tried for decades and it is not making us safer. Instead, we need to turn our cultural approach and to recognize that bright, well-educated, skilled and well-intentioned professional will make errors.

To become safer, we need to allow discussion of these errors, to understand them, to learn from them and to redesign our systems to reduce their likelihood and to mitigate their consequences. We can‘t do this unless doctors and nurses feel safe enough to be transparent about their errors.

Should we continue with the same ineffective approach to the healthcare Safety that we have used so far? Or do we follow the lead of other safety-critical high-reliable industries and service providers?

Physicians have a powerful incentive to apologize when they make a mistake: doing so may decrease the likelihood that they will be sued.

In 2010 a paper has been published in the journal Annals of Internal Medicine showing that the average monthly rate of malpractice lawsuits fell by more than half after the physicians routinely apologized for their errors and offered fair compensation to the patients and their families.

Healthcare professionals are human and are involved in that most human activity of art and science: medicine. The trouble with medical errors is that too much energy is focused on punishing those who make errors and not enough in using those errors as opportunities to improve the delivery of care for everyone.

Healthcare, as an industry, has often failed to police itself, letting incompetent operate in a very critical environment. This issue will not be solved by lawyers or by regulators alone. It will be resolved practitioner by practitioner, patient by patient and system by system, through a dedication to admitting errors when they occur, forgiving the error, removing the incompetent and all working together toward better reporting, better outcomes and Accountability across the board.

Any patient who is harmed deserves a full disclosure, a sincere apology, an appropriate compensation and an explanation of how the event will be studied to improve care in the hospital.

Sharing of information, development of knowledge and research, consistent education and training followed by continuing medical

education program are an important part of a learning culture.
When an error or a near-miss can be identified as something that It could have happened to anybody is a relevant sign that reflect a systemic, rather than a personal, problem.

1.4 THE QUALITY-SAFETY-EXCELLENCE-ACCOUNTABILITY (QSEA) MODEL

The new perspective for the Healthcare management is that the Healthcare system must be regarded as a High Reliability Organization (HRO). Daily dealing with people health and people life, a hospital setting should be in fact the typical example of a HRO.
High Reliability Organizations are complex systems usually operating in a high-stress environment, aiming at giving their clients specific and preordained results (the final goal), collaterally managing goods of great values from the clients themselves (the intermediate trust) and always accepting the philosophical concept that mistakes did happen, do happen and will happen.
A complementary definition of HROs can describe them as autarchic systems that are able to answer all the possible inconveniences in real time, that is systems able to answer all the incoming problems using preexisting and pre-validated behavioural frames.
Some HROs seem also to share the crucial feature of managing people lives just to offer them very sophisticated goals as very common or basic goods: therefore HROs cannot but be High Performance Organizations. HROs must always tend to the excellence which is the virtuous and prospective combination of Quality (Technical Q + nonTechnical Q) and Safety (Technical S + nonTechnical S). Both the Quality (a dimension primarily about the performance result) and the Safety (a dimension primarily about the single client) depend either on human and structural variables. The certified performance Excellence is in turn the basis for the whole system Accountability (a dimension primarily about the community). The deep essence of the system Accountability is the official, clear and uptodate communication to all the potential stakeholders about the performance level granted by the system itself. The Accountability model is a clear step towards a world of informed and responsible choices from all the potential stakeholders and of virtuous competition among similar systems. The QSEA model is then a linear model starting from intrinsic and separated systemic features and getting to a dimension of public and unitary communication and certification.
Regarded as a HRO, a Healthcare system must always work for reaching the excellence as opposite to the mean standard. The best clinical outcome for every patient is the everyday mission for every Healthcare system.

An easy example of a HRO is the airplane: it is a close system that routinely manages passengers lives (the intermediate trust) to make them fly big distances all around the world (the final goal nowadays perceived as a normal result) and that can trust only in the trained cabin crew capabilities to solve all the inflight problems (the autarchic connotation).
A quite different HRO model can be imagined for the Healthcare system, where the final goal and the intermediate trust are about the same good (people health), where the intermediate trust is about a deficient health and where the final goal is about the restoration of a perfect health. Opposite to the linear HRO model from the airplane set, such a circular HRO model brings a different rule to describe the Negative Outcome Risk (NOR) of the whole model, being the NOR the most important public label for a HRO. For linear HRO models: NOR ≡ SNOR, where SNOR is the System Negative Outcome Risk that is the intrinsic NOR for a certain HRO. For circular healthcare HRO models: NOR = SNOR + PNOR, where PNOR is the inerasable Patient-linked NOR (the natural risk for a certain disease to get worse despite of correct medical intervention).
In HROs the structural complexity itself entails the existence of systemic risks of failure (SNOR). In other terms, a zero NOR HRO does not exist. A HRO is by definition not an infallible system (infallible human systems do not exist), it is otherwise a fallible system where Basic Risk Management projects and Crisis Management projects do exist and do successfully work. The combination of the Basic Risk Management and the Crisis Management can be defined as the System Vulnerability Management. In such perspective, small NORs are the first result of virtuous System Vulnerability Management processes. Every human rule is the preventive response to a perceived systemic vulnerability.
An effective Clinical Risk Management project is able to reduce the frequency of the clinical mistakes and of the clinical crises and also to reduce the measure of the patient damage consequent to a clinical mistake. An effective Clinical Crisis Management project helps the medical team to answer a clinical crisis the best and the fastest way. Under a certain point of view, the effective Clinical Crisis Management provides the plug for some of the holes in the Reason‘s cheese slices of an imperfect Clinical Risk Management. However, not all the clinical crises come from Risk Management failures.
The crisis is a negative stressing circumstance requiring the use of extraordinary energies to restore the homeostatic balance of the whole system. A crisis must always be managed and it can be solved, attenuated or simply communicated to the stakeholders. The detection

time of a mounting crisis is a crucial variable for its management: the sooner the detection, the greater the chance for solving or attenuating its negative effects. In the clinical setting, every crisis increases the SNOR and can produce either a real Negative Outcome or a terminal Medical Malpractice Claim. According to the crisis detection time, we can identify crises simply determining an increase of the SNOR (I class crises) and crises already determining a NO (II class crises) or a MMC (III class crises). As the worst example, IV class crises are crises recognized and managed after two or more similar crisis experiences.

	Resolution	Attenuation	Communication
I class crisis	+	++	+++
II class crisis	+/-	+/-	+/+
III class crisis	-	-	+/-
IV class crisis (for the previous episodes)	-	-	-

Crucial tools for both the Risk Management and the Crisis Management are the Incident Reporting Systems (IRS), the Root Cause Analysis (RCA) and the Failure Mode and Effects Analysis (FMEA). Like in a virtuous circle, all the previous mistakes must learn something (IRS, RCA) and the analysis about the happened mistake must identify and erase the systemic permitting basis for it (FMEA). The Incident Reporting should be about Averse Events, no-Harm Events and Near Misses and it should be a no-blame activity. Differentiating the risk pathway potentially leading to a negative outcome from the negative outcome itself:

	Risk Pathway	Negative Outcome
Adverse Event	Completed	Happened
No-Harm Event	Completed	Not Happened
Near Misses	Not Completed	Not Happened

Resting on the human professional competence of the whole resident clinical and non-clinical team (HumPC = Hum Clinical Competence + Hum nonClinical Competence) and on the value of both the hospital environment (E) and the resident technical equipments (TE), an effective System Vulnerability Management (SVM) guarantees the patients to receive the best hospital care (BHC). In very basic mathematical terms: BHC = HumPC + TE + E + SVM, a formula

very similar to the general SHEL paradigm by Edwards (Software + Hardware + Environment + Lifeware, where S ≈ SVM, H ≈ TE, E ≡ E and L ≈ PC) used for describing and analyzing the performance status of every human system.

One or more failing addends in this sum clearly determine the performance level in a certain medical setting to separate from the optimal one, thus creating a relevant medicolegal issue. Every single hospital placing distant from the HRO paradigm (a quite common circumstance in the Authors professional experience) is a relevant medicolegal issue.

All the hospital workers must be specifically trained for the crises recognition and the crises reporting.

A special attention must be paid to the Clinical Competence. The CC is a professional competence further to get after academic degrees. It is a complex and dynamic combination of singular talent, everyday experience, personal ongoing training and never-ending professional updating. The so-called pyramid of the CC has the theory (the academic contribution) as the first and the widest floor, the performance capability (the capability of using the right theoretic basis inside a real case) as the second and intermediate floor and the action (the good everyday practice) as the third and the smallest floor. The pyramid apex is represented by the faculty of teaching. The smaller the floor of a certain pyramid level, the smaller the amount of practitioners able to reach it and to stay there: the CC can be also a tool to make professional selection towards excellence. The CCs from different practitioners can synergically act towards the excellent performance status of a Healthcare system (a shift from the SHEL model to the SHELL model by Hawkins).

The combination of E and TE can be seen as the measure of the basic Hospital Competence (HospC). The SVM rules the meeting between the HumPC and the HospC.

The Clinical Risk Management aims at reducing the SNOR and at preventing the Clinical Crises: it is obviously an anticipatory management and it is about an epidemiological dimension. The Clinical Crisis Management aims at erasing or reducing the negative outcome for a definite single patient (NO) and also the connected damage for the hospital, from the perspective that every private NO is the basis for a hospital loss. The Clinical Crisis Management can be therefore considered as the individual dimension of the Clinical Risk Management (NO versus NOR).

Every small clinical crisis can detonate in the public opinion thus growing much bigger and much more painful for the hospital. Macroscopic clinical crises must be managed by professional Crises

Managers and by trained Crisis Teams according to the general theory of the non-clinical Crisis Management. Every hospital should have its own Crisis Consultants and Crisis Managers for managing all the macroscopic crises. For a hospital, even the simple or temporary loss of reputation is a cancer.

The Clinical Crisis Management (a specific version of the Crisis Resource Management already developed for the airplane crews and for many other professional fields) interested first of all the anesthesiologists as the specialists of the emergency medicine, but nowadays it should widen its influence on all the hospital crews. In fact the crisis response cannot but be an organized team response. Generally considered as acute and not prevented problems needing a very fast solution to avoid very negative outcomes, the clinical crises may be very heterogeneous coming for example from an intra moenia cardiac arrest (a very typical kind of a pure clinical crisis) to the management of an exanguinating patient refusing blood transfusions for a religious purpose (a kind of medico-legal crisis quite common in Italy).

A new branch of the forensic medicine deals nowadays with global Healthcare systems organization and can exploit its traditional background about ex-post judicial analyses on clinical malpractice cases to optimize the Healthcare systems evolution, to lead the SVM and to prevent future clinical mistakes. To do this, the forensic medicine must intensively cooperate with other clinical and non-clinical branches. The contribution from this kind of forensic medicine can help to establish real evidence-based SVM projects. Programming and executing failures about the Risk and the Crisis Management are in fact autonomous sources for clinical malpractice and for clinical malpractice claims. As written above, also a clinical malpractice claim is a crisis to be managed at best (III class clinical crisis). A simple theoretical model to describe the Malpractice Claim Risk in individual cases assumes the MCR as a function of the Negative Outcome measure: MCR = k x NO, where

1. NO = Expected Clinical Outcome (ECO) - Reached Clinical Outcome (RCO)
2. k is a patient-linked variable = Social Network Effect (SNE) + Experience-linked Anger (EA)
3. ECO is influenced by the patient Personal Technical Knowledge (PTK)
4. PTK = 1 = Good PTK + Bad PTK
5. Bad PTK directly correlates with ECO and with MCR
6. Good PTK inversely correlates with ECO and with MCR.

According to this model, after the NO production the MCR can be

still partially managed working on the patient-linked k variable and above all working on the EA. Professional psychologists can manage such crises at best and therefore they must be always present inside a virtuous Healthcare system. Professional psychologists may also run at best all the precious Alternative Dispute Resolutions pathways. On the contrary, specialized lawyers will manage at best all the judicial disputes about medical malpractice. Specialized forensic pathologists will be in turn useful for the ADR attempts and necessary for the judicial proceedings.

Shifting from a singular perspective to an epidemiological one, the cumulative MRC per year is another main label for a HRO and it will influence the concrete chances for a certain hospital to find and to maintain a good insurance coverage. Specialized insurance brokers are always needed to tailor the best insurance coverage for Healthcare systems.

For a certain hospital, the cumulative MCR directly correlates with the gap between the Best Hospital Care (BHC = 10/10 HPC + 10/10 TE + 10/10 E + 10/10 SVM) and the Current Hospital Care (CHC = x/10 HPC + x/10 TE + x/10 E + x/10 SVM). An excellent Healthcare system shows a Hospital Care gap very close to zero, while an accountable Healthcare system (made up by Accountable Care Organizations) is an excellent system that can publicly certify all its performance virtues.

"If a great man makes a mistake, he realizes it.
Having realized it, he admits it.
Having admitted it, he corrects it.
He considers those who point out his faults
as his most benevolent teachers".

Lao Tzu (c.604 - 531 B.C.)

SELECTED ABSTRACTS

The selected abstract presented in this publication aims to stimulate and create awareness among the healthcare professionals for a better and sustainable medical practice. Also because doctors often rationalize and may even ignore their own symptoms, because of their personal knowledge and fear of what might be the underlying cause of their illness.
And the doctors themselves can be the patient.

Literature search method

Systematic literature searches of health and biomedical bibliographic databases and web database (Medline, Highwire, Science Direct, Ovid, Medscape, Google Scholar) were conducted.

Keywords: safety, responsibility, accountability, medical malpractice, risk management, medical error, sentinel events, high reliability organization, clinical competence, medical education.

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WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI: ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

World Medical Association.

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Abstract
PREAMBLE, GENERAL PRINCIPLES, RISKS, BURDENS AND BENEFITS, VULNERABLE GROUPS AND INDIVIDUALS, SCIENTIFIC REQUIREMENTS AND RESEARCH PROTOCOLS RESEARCH ETHICS COMMITTEES, PRIVACY AND CONFIDENTIALITY | INFORMED CONSENT, USE OF PLACEBO, POST-TRIAL PROVISIONS, RESEARCH REGISTRATION AND PUBLICATION AND DISSEMINATION OF RESULTS, UNPROVEN INTERVENTIONS IN CLINICAL PRACTICE, ARTICLE INFORMATION

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.
2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who

are involved in medical research involving human subjects to adopt these principles.

GENERAL PRINCIPLES

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care".

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers

requires the supervision of a competent and appropriately qualified physician or other health care professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.
15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

NewYork Times. Sunday Review. The opinion pages. 2013 October 20
http://www.nytimes.com/2013/10/20/opinion/sunday/sunday-dialogue-handling-medical-errors.html?_r=0

SUNDAY DIALOGUE: HANDLING MEDICAL ERRORS

Readers discuss apologies, disciplinary actions and lawsuits.

To the Editor:
The tendency to assign blame when mistakes occur is inimical to an environment in which we hope learning and improvement will take place. But there is some need to hold people accountable for egregious errors. Where‘s the balance?
Here‘s an example. Several years ago a patient woke up from orthopedic surgery at my former hospital and asked her surgeon, "Why is the bandage on my left ankle instead of my right ankle?" It was at that moment that her doctor realized he had operated on the wrong leg. He immediately reported the error to the proper people in the hospital. A thorough apology was also offered to the patient.
We realized that there were systemic problems in our preoperative procedures that went beyond this case. Our clinical leaders spent several weeks strengthening our care delivery system to minimize the chance of a similar error in the future.
Upon hearing of this case, one of our trustees asked me what I, as chief executive of the hospital, intended to do to punish the doctor. I replied: "Nothing. He already feels terrible about this mistake. Further punishment does not act as a deterrent in these kind of inadvertent errors". A senior physician added that if we want to establish an environment that promotes disclosure of errors and near misses, the fastest way to drive reporting underground is to punish someone who

has made a mistake.
The trustee replied: "Well, maybe. But in my field, we would certainly punish anyone who violated rules or procedures in this manner, even if by accident".
His field? Investment banking. I laughed, thinking of how rarely people in that field seem to get punished when they break the rules.
People in the medical field are well intentioned and feel great distress when they harm patients. Let‘s reserve punishment for clear cases of negligence. Other errors should be used to reinforce a learning environment in which we are hard on the problems rather than hard on the people.
PAUL LEVY
Newton, Mass., Oct. 14, 2013
The writer is the former chief executive of Beth Israel Deaconess Medical Center and the author of "Goal Play! Leadership Lessons From the Soccer Field".
Readers React…

Health Serv Res. 2013 Oct 1. doi: 10.1111/1475-6773.12102.
[Epub ahead of print]

ACCOUNTABLE CARE ORGANIZATIONS IN THE UNITED STATES: MARKET AND DEMOGRAPHIC FACTORS ASSOCIATED WITH FORMATION

Lewis VA, Colla CH, Carluzzo KL, Kler SE, Fisher ES.

Abstract
BACKGROUND: The Accountable Care Organization (ACO) model is rapidly being implemented by Medicare, private payers, and states, but little is known about the scope of ACO implementation.
OBJECTIVE: To determine the number of accountable care organizations in the United States, where they are located, and characteristics associated with ACO formation.
STUDY DESIGN, METHODS, AND DATA: Cross-sectional study of all ACOs in the United States as of August 2012. We identified ACOs from multiple sources; documented service locations (practices, clinics, hospitals); and linked service locations to local areas, defined as Dartmouth Atlas hospital service areas. We used multivariate analysis to assess what characteristics were associated with local ACO presence. We examined demographic characteristics (2010 American Community Survey) and health care system characteristics (2010 Medicare fee-for-service claims data).
PRINCIPAL FINDINGS: We identified 227 ACOs located in 27 percent

of local areas. Fifty-five percent of the US population resides in these areas. HSA-level characteristics associated with ACO presence include higher performance on quality, higher Medicare per capita spending, fewer primary care physician groups, greater managed care penetration, lower poverty rates, and urban location.
CONCLUSIONS: Much of the US population resides in areas where ACOs have been established. ACO formation has taken place where it may be easier to meet quality and cost targets. Wider adoption of the ACO model may require tailoring to local context.
PMID: 24117222

Health Aff (Millwood). 2013 Oct;32(10):1781-1788.

ACCOUNTABLE CARE ORGANIZATION FORMATION IS ASSOCIATED WITH INTEGRATED SYSTEMS BUT NOT HIGH MEDICAL SPENDING

Auerbach DI, Liu H, Hussey PS, Lau C, Mehrotra A.

Abstract
Medicare's approximately 250 accountable care organizations (ACOs) care for a growing portion of all fee-for-service beneficiaries across the United States. We examined where ACOs have formed and what regional factors are predictive of ACO formation. Understanding these factors could help policy makers foster growth in areas with limited ACO development. We found wide variation in ACO formation, with large areas, such as the Northwest, essentially empty of ACOs, and others, such as the Northeast and Midwest, dense with the organizations. Key regional factors associated with ACO formation include a greater fraction of hospital risk sharing (capitation), larger integrated hospital systems, and primary care physicians practicing in large groups. Area income, Medicare per capita spending, Medicare Advantage enrollment rates, and physician density were not associated with ACO formation. Together, these results imply that underlying provider integration in a region may help drive the formation of ACOs.
PMID: 24101069

BMJ. 2013 Aug 9;347:f5038. doi: 10.1136/bmj.f5038.

IMPROVING THE SAFETY OF PATIENTS IN ENGLAND

McKee M.

Extract

Berwick's report should be required reading for everyone

The health service in England has been subjected to unprecedented scrutiny in recent years, with the Francis Report, Keogh Review, and now a report from a panel chaired by the American patient safety guru, Don Berwick. Although all deal with the same problem, the reports are quite different. Whereas Francis, a lawyer, produced a document stretching to more than 1700 pages, with 290 recommendations, Keogh and Berwick, both doctors, wrote concise analyses, with Berwick's amounting to only 46 pages and 10 recommendations. For those unwilling to read even that, Berwick adds three letters, to senior government officials, to NHS staff, and to the people of England. Each emphasises four fundamental principles, that quality and safety must be placed above all else, that patients and carers must be empowered and heard, that staff should be developed and supported, and that there should be thorough and unequivocal transparency.

PMID: 23935089

https://www.gov.uk/government/publications/berwick-review-into-patient-safety. Last Modified: 08/19/2013

A PROMISE TO LEARN – A COMMITMENT TO ACT: IMPROVING THE SAFETY OF PATIENTS IN ENGLAND

The National Advisory Group on the Safety of Patients in England; 2013.

An independent group of experts in quality improvement, patient safety, and organizational and systems theories was chartered to review issues that compromise patient safety in England's National Health Service (NHS), following events that led to serious lapses in patient care at Mid Staffordshire Hospitals. The group's report includes ten recommendations for the NHS to address underlying causes of unsafe care at Mid Staffordshire and other patient safety issues that could lead to harm elsewhere in the NHS. These recommendations to improve systems, safety, and culture in the NHS are broadly applicable to other health care institutions and settings.

N Engl J Med. 2013 Aug 22;369(8):694-5. doi: 10.1056/NEJMp1307084.

TAKING OUR MEDICINE--IMPROVING ADHERENCE IN THE ACCOUNTABILITY ERA

Rosenbaum L, Shrank WH.

Extract

A new patient with an abnormal electrocardiogram comes to your office. He is 53, smokes, and has hypertension and hyperlipidemia. Though he comes for preoperative risk evaluation, he needs more than "medical clearance" — he needs a primary doctor. Given his risk factors and hesitance to change his lifestyle, you recommend aspirin, a statin, and an antihypertensive. When he doesn't show up for his stress test, you call him, and he says he doesn't understand what the fuss is all about — he feels fine. "Why don't you wait until something is wrong with me to give me these medications?" he asks, launching into a litany of justifications for not taking them: cost, nuisance, potential side effects, not wanting to put anything "unnatural" in his body, and lack of perceived benefit. You attempt to educate him about his risk, but he says, "No disrespect to you, Doctor, but I've just never been a pill person. But," he adds, "if something were to happen, you would still take care of me, right?"

Of course you would. Our willingness to care for patients has never depended on their willingness to do what we say. But an estimated one third to one half of U.S. patients do not adhere to prescribed medication regimens. Because nonadherence leads to increased complications and hospitalizations, it costs the United States an estimated $100 billion to $290 billion annually.2 In a health care delivery system where physician payment will increasingly be tied to patient outcomes, nonadherence poses both new challenges and opportunities.

Recognizing that such behavior costs money and lives, researchers have begun testing interventions to improve adherence. Although the multifactorial nature of nonadherence means there will never be a one-size-fits-all solution, interventions ranging from education to elimination of selected copayments to telephone-based counseling have achieved modest improvements in clinical trials. But even if we had more robust interventions, we'd lack simple, cost-effective ways of targeting the right intervention to the right patient.

PMID: 23964931

Int J Legal Med. 2013 May;127(3):541-3.
doi: 10.1007/s00414-013-0839-2.

MEDICAL MALPRACTICE AND LEGAL MEDICINE

Ferrara SD.

Extract
Legal Medicine and the European Medicolegal Academic Community have commenced the virtuous course of action and the difficult task of contending with Malpractice or Bad Healthcare, which have long passed the stage and the connotation of mere epidemic.
Developed in the early 1980s in North America as a result of a series of significant cultural, social, structural, and economic factors relating to post-modern Western society, the phenomenon of malpractice has definitively assumed the dimensions and the severity of a pandemic, whose transversal invasiveness does not spare nations, structures, politico-institutional regimes, social classes, professional contexts, or cultural and ideological orientations. All are united and nourished by the propellant of the claim for compensation of damage, allegedly unjust, insofar as endured for the more or less serious subjective and/or objective fault-based liability of physicians, institutions, or health professionals. This concerns the fulfillment of the centuries-old path of emancipation that sees the decline of the trust of the "patient–child" in relation to the "doctor–father," once the exclusive protagonist of acts as a matter of priority driven by the principle of "first do no harm." It therefore concerns the definitive affirmation of the "patient/sick-man," the new and unique protagonist of the "confrontation–conflict" with the "physician and the institution." Both of these are technocrats, called upon to guarantee not only the means but also the results of the healthcare process: technocrats who provide healing, even at the advanced stages of illness, for virtually all diseases, and technocrats who dispense constant physical and mental well-being, guaranteeable by reason of the pluripotency of science that has become, in the social imaginary, a media-constructed myth of the infallibility as well as the supremacy of man over nature and the dominion of reason over the mystery of life. In truth, in the current and most advanced post-genomic era of "systems biology," science is only the cognition and vehicle of probability (rather than certainty) and, often, of the limited possibility of healing or partial therapy. The specialistic multi-fragmentation of knowledge and the know-how of each discipline are exhausted in the endless comparison between two kinds of truth (i.e., "reason and fact"), which belong to the current global society of risk, both environmental and behavioral, in which clinical and therapeutic medicine are an "art of scientific mimesis," which is still "art," although with a scientific foundation and increasingly technological content.
PMID: 23455848

Int J Legal Med. 2013 May;127(3):545-57. doi: 10.1007/s00414-013-0836-5. Epub 2013 Apr 6.

MALPRACTICE AND MEDICAL LIABILITY. EUROPEAN GUIDELINES ON METHODS OF ASCERTAINMENT AND CRITERIA OF EVALUATION

Ferrara SD, Baccino E, Bajanowski T, Boscolo-Berto R, Castellano M, De Angel R, Pauliukevi□ius A, Ricci P, Vanezis P, Vieira DN, Viel G, Villanueva E; EALM Working Group on Medical Malpractice.

Abstract
The manuscript presents the European Guidelines on medico-legal Methods of Ascertainment and Criteria of Evaluation in cases of suspected subjective "Medical Responsibility and/or Liability" developed by an international working group under the patronage of the European Academy of Legal Medicine. It includes a step-by-step illustrated explanation of approved Flow Charts, articulated in 18 sequential steps and comprehensive of both Methods of Ascertainment and Evaluation Criteria.
PMID: 23564275

Int J Prev Med. 2013 May;4(5):592-8.

CLINICAL RISK ASSESSMENT IN INTENSIVE CARE UNIT

Asefzadeh S, Yarmohammadian MH, Nikpey A, Atighechian G.

Abstract
BACKGROUND:Clinical risk management focuses on improving the quality and safety of health care services by identifying the circumstances and opportunities that put patients at risk of harm and acting to prevent or control those risks. The goal of this study is to identify and assess the failure modes in the ICU of Qazvin's Social Security Hospital (Razi Hospital) through Failure Mode and Effect Analysis (FMEA).
METHODS:This was a qualitative-quantitative research by Focus Discussion Group (FDG) performed in Qazvin Province, Iran during 2011. The study population included all individuals and owners who are familiar with the process in ICU. Sampling method was purposeful and the FDG group members were selected by the researcher. The research instrument was standard worksheet that has been used by several researchers. Data was analyzed by FMEA technique.
RESULTS:Forty eight clinical errors and failure modes identified,

results showed that the highest risk probability number (RPN) was in respiratory care "Ventilator's alarm malfunction (no alarm)" with the score 288, and the lowest was in gastrointestinal "not washing the NG-Tube" with the score 8.
CONCLUSIONS:Many of the identified errors can be prevented by group members. Clinical risk assessment and management is the key to delivery of effective health care.
PMID: 23930171

Chest. 2013 Apr;143(4):1127-35. doi: 10.1378/chest.12-1908.

LIMITATIONS OF MEDICAL RESEARCH AND EVIDENCE AT THE PATIENT-CLINICIAN ENCOUNTER SCALE

Morris AH, Ioannidis JP.

Abstract
We explore some philosophical and scientific underpinnings of clinical research and evidence at the patient-clinician encounter scale. Insufficient evidence and a common failure to use replicable and sound research methods limit us. Both patients and health care may be, in part, complex nonlinear chaotic systems, and predicting their outcomes is a challenge. When trustworthy (credible) evidence is lacking, making correct clinical choices is often a low-probability exercise. Thus, human (clinician) error and consequent injury to patients appear inevitable. Individual clinician decision-makers operate under the philosophical influence of Adam Smith's "invisible hand" with resulting optimism that they will eventually make the right choices and cause health benefits. The presumption of an effective "invisible hand" operating in health-care delivery has supported a model in which individual clinicians struggle to practice medicine, as they see fit based on their own intuitions and preferences (and biases) despite the obvious complexity, errors, noise, and lack of evidence pervading the system. Not surprisingly, the "invisible hand" does not appear to produce the desired community health benefits. Obtaining a benefit at the patient-clinician encounter scale requires human (clinician) behavior modification. We believe that serious rethinking and restructuring of the clinical research and care delivery systems is necessary to assure the profession and the public that we continue to do more good than harm. We need to evaluate whether, and how, detailed decision-support tools may enable reproducible clinician behavior and beneficial use of evidence.
PMID: 23546485

Perm J. 2013 Spring;17(2):73-9. doi: 10.7812/TPP/12-106.

DISCLOSING MEDICAL MISTAKES: A COMMUNICATION MANAGEMENT PLAN FOR PHYSICIANS

Petronio S, Torke A, Bosslet G, Isenberg S, Wocial L, Helft PR.

Abstract

INTRODUCTION: There is a growing consensus that disclosure of medical mistakes is ethically and legally appropriate, but such disclosures are made difficult by medical traditions of concern about medical malpractice suits and by physicians' own emotional reactions. Because the physician may have compelling reasons both to keep the information private and to disclose it to the patient or family, these situations can be conceptualized as privacy dilemmas. These dilemmas may create barriers to effectively addressing the mistake and its consequences. Although a number of interventions exist to address privacy dilemmas that physicians face, current evidence suggests that physicians tend to be slow to adopt the practice of disclosing medical mistakes.

METHODS: This discussion proposes a theoretically based, streamlined, two-step plan that physicians can use as an initial guide for conversations with patients about medical mistakes. The mistake disclosure management plan uses the communication privacy management theory.

RESULTS: The steps are 1) physician preparation, such as talking about the physician's emotions and seeking information about the mistake, and 2) use of mistake disclosure strategies that protect the physician-patient relationship. These include the optimal timing, context of disclosure delivery, content of mistake messages, sequencing, and apology. A case study highlighted the disclosure process.

CONCLUSION: This Mistake Disclosure Management Plan may help physicians in the early stages after mistake discovery to prepare for the initial disclosure of a medical mistakes. The next step is testing implementation of the procedures suggested.

PMID: 23704848

Chest. 2013 Jan;143(1):222-7. doi: 10.1378/chest.12-1916.

FIVE MYTHS OF MEDICAL MALPRACTICE

Hyman DA, Silver C.

Abstract

We identify five myths of medical malpractice that have wide currency in medical circles. The myths are as follows: (1) Malpractice crises are caused by spikes in medical malpractice litigation (ie, sudden rises in payouts and claim frequency), (2) the tort system delivers "jackpot justice," (3) physicians are one malpractice verdict away from bankruptcy, (4) physicians move to states that adopt damages caps, and (5) tort reform will lower health-care spending dramatically. We test each assertion against the available empirical evidence on the subject and conclude by identifying various nonmythical problems with the medical malpractice system.

PMID: 23276845

Comment in: *Ethics of the malpractice system. [Chest. 2013]*

The Commonwealth Fund Issue Brief; September 2013.

HOSPITAL READMISSIONS: MEASURING FOR IMPROVEMENT, ACCOUNTABILITY, AND PATIENTS

Marks C, Loehrer S, McCarthy D.

Abstract

The Commonwealth Fund and the Institute for Healthcare Improvement convened 15 experts in May 2013 to help address the controversy over the measurement of hospital readmissions. Experts agreed that Medicare should, through payment and other means, be encouraging greater coordination of care, improvement in care transitions, and mitigation of risks that leave patients vulnerable to readmission. While the current readmissions metric is undoubtedly an imperfect proxy for broader health system failures, it also provides a valuable foundation on which to build a better policy — one that is useful for improvement, fair for accountability, and above all, relevant to patients.

Evidence Report/Technology Assessment, no. 211 (Rockville, MD: Agency for Healthcare Research and Quality, Mar. 2013)

MAKING HEALTH CARE SAFER II AN UPDATED CRITICAL ANALYSIS OF THE EVIDENCE FOR PATIENT SAFETY PRACTICES: EXECUTIVE SUMMARY

Paul G. Shekelle, Robert M. Wachter, Peter J. Pronovost, Scott Lucas, Meredith Noble, James T. Reston, Karen Schoelles, Nancy Sullivan, Fang Sun, Kelley Tipton, Jonathan R. Treadwell, Amy Tsou, Sallie J. Weaver, Bradford D. Winters, Elizabeth Pfoh, Renee Wilson, Kathryn Martinez, Sydney Dy, Zack Berger, Breanne Johnsen, Jody Larkin, Aneesa Motala, Roberta M. Shanman, Kathryn M. McDonald, Sumant R. Ranji, Stephanie Rennke, Eric Schmidt, Kaveh G. Shojania, Sydne Newberry, Mary E. Vaiana.

OBJECTIVES: To review important patient safety practices for evidence of effectiveness, implementation, and adoption.
DATA SOURCES: Searches of multiple computerized databases, gray literature, and the judgments of a 20-member panel of patient safety stakeholders.
REVIEW METHODS: The judgments of the stakeholders were used to prioritize patient safety practices for review, and to select which practices received in-depth reviews and which received brief reviews. In-depth reviews consisted of a formal literature search, usually of multiple databases, and included gray literature, where applicable. In-depth reviews assessed practices on the following domains:

- How important is the problem?
- What is the patient safety practice?
- Why should this practice work?
- What are the beneficial effects of the practice?
- What are the harms of the practice?
- How has the practice been implemented, and in what contexts?
- Are there any data about costs?
- Are there data about the effect of context on effectiveness?

We assessed individual studies for risk of bias using tools appropriate to specific study designs. We assessed the strength of evidence of effectiveness using a system developed for this project. Brief reviews had focused literature searches for focused questions. All practices were then summarized on the following domains: scope of the problem, strength of evidence for effectiveness, evidence on potential for harmful unintended consequences, estimate of costs, how much is known about implementation and how difficult the practice is to

implement. Stakeholder judgment was then used to identify practices that were "strongly encouraged" for adoption, and those practices that were "encouraged" for adoption.
RESULTS: From an initial list of over 100 patient safety practices, the stakeholders identified 41 practices as a priority for this review: 18 in-depth reviews and 23 brief reviews. Of these, 20 practices had their strength of evidence of effectiveness rated as at least "moderate," and 25 practices had at least "moderate" evidence of how to implement them. Ten practices were classified by the stakeholders as having sufficient evidence of effectiveness and implementation and should be "strongly encouraged" for adoption, and an additional 12 practices were classified as those that should be "encouraged" for adoption.
CONCLUSIONS: The evidence supporting the effectiveness of many patient safety practices has improved substantially over the past decade. Evidence about implementation and context has also improved, but continues to lag behind evidence of effectiveness. Twenty-two patient safety practices are sufficiently well understood, and health care providers can consider adopting them now.

JAMA Intern Med. 2013;173(6):425-426.
doi:10.1001/jamainternmed.2013.225.

MEASURING DIAGNOSTIC ERRORS IN PRIMARY CARE: THE FIRST STEP ON A PATH FORWARD. COMMENT ON “TYPES AND ORIGINS OF DIAGNOSTIC ERRORS IN PRIMARY CARE SETTINGS”

Newman-Toker DE, Makary MA.

Abstract
Diagnostic errors are increasingly recognized as an important source of preventable harm in many health care settings.1 Missed, wrong, and delayed diagnoses have been underappreciated by internal peer review, autopsy reports, and examination of malpractice claims. All of these methodological approaches have limitations. Internal peer review is often challenging because of local hospital politics, physician-vested interest, and sampling error. Autopsy studies may overestimate diagnostic performance when necropsy rates are low,2 and they often miss nonlethal diagnostic errors. Malpractice claims may capture nonlethal errors; however, they are most often associated with permanent disability or death.3 Only about 1% of adverse events due to medical negligence result in a claim.4 Thus, malpractice-based rates of diagnostic errors substantially underrepresent the true impact

of these events and are biased toward cases with a clear paper trail (eg, missed cancers evident on radiographic images), in which the burden of legal proof can be met more easily. None of these approaches is well suited to real-time surveillance for errors that might be rectified before harm occurs.
PMID: 23440273

Minn Med. 2012 Nov;95(11):37-9.

ACHIEVING ACCOUNTABILITY FOR HEALTH AND HEALTH CARE

Magnan S, Fisher E, Kindig D, Isham G, Wood D, Eustis M, Backstrom C, Leitz S.

Abstract
There is no well-established mechanism at the local level to discuss or manage the balance of investments in health care and the other social determinants of health. We propose the development of voluntary regional organizations and/or use of current organizations to work with stakeholders of the health system to 1) review local data on health, experience and quality of care, and costs of care (Triple Aim); 2) create shared goals, actions and investments to meet the Triple Aim; and 3) involve citizens in local delivery system reform and stewardship of financial resources. These accountable health communities (AHCos) would contribute to co-creating a sustainable health system.
PMID: 23243752

Educ Health (Abingdon). 2012 Sep-Dec;25(3):180-94.
doi: 10.4103/1357-6283.109785.

THE SOCIAL ACCOUNTABILITY OF MEDICAL SCHOOLS AND ITS INDICATORS

Boelen C, Dharamsi S, Gibbs T.

Abstract
CONTEXT:There is growing interest worldwide in social accountability for medical and other health professional schools. Attempts have been made to apply the concept primarily to educational reform initiatives with limited concern towards transforming an entire institution to commit and assess its education, research and service delivery missions to better meet priority health needs in society for an efficient, equitable an sustainable health system.
METHODS:In this paper, we clarify the concept of social accountability

in relation to responsibility and responsiveness by providing practical examples of its application; and we expand on a previously described conceptual model of social accountability (the CPU model), by further delineating the parameters composing the model and providing examples on how to translate them into meaningful indicators.
DISCUSSION:The clarification of concepts of social responsibility, responsiveness and accountability and the examples provided in designing indicators may help medical schools and other health professional schools in crafting their own benchmarks to assess progress towards social accountability within the context of their particular environment.
PMID: 23823638

Clin J Am Soc Nephrol. 2012 Sep;7(9):1535-43. Epub 2012 May 24.

COMPARING MANDATED HEALTH CARE REFORMS: THE AFFORDABLE CARE ACT, ACCOUNTABLE CARE ORGANIZATIONS, AND THE MEDICARE ESRD PROGRAM

Watnick S, Weiner DE, Shaffer R, Inrig J, Moe S, Mehrotra R; Dialysis Advisory Group of the American Society of Nephrology.

Abstract
In addition to extending health insurance coverage, the Affordable Care Act of 2010 aims to improve quality of care and contain costs. To this end, the act allowed introduction of bundled payments for a range of services, proposed the creation of accountable care organizations (ACOs), and established the Centers for Medicare and Medicaid Innovation to test new care delivery and payment models. The ACO program began April 1, 2012, along with demonstration projects for bundled payments for episodes of care in Medicaid. Yet even before many components of the Affordable Care Act are fully in place, the Medicare ESRD Program has instituted legislatively mandated changes for dialysis services that resemble many of these care delivery reform proposals. The ESRD program now operates under a fully bundled, case-mix adjusted prospective payment system and has implemented Medicare's first-ever mandatory pay-for-performance program: the ESRD Quality Incentive Program. As ACOs are developed, they may benefit from the nephrology community's experience with these relatively novel models of health care payment and delivery reform. Nephrologists are in a position to assure that the ACO development will benefit from the ESRD experience. This article reviews the new ESRD payment system and the Quality Incentive Program, comparing

and contrasting them with ACOs. Better understanding of similarities and differences between the ESRD program and the ACO program will allow the nephrology community to have a more influential voice in shaping the future of health care delivery in the United States.
PMID: 22626961

Eur J Hum Genet. 2012 Aug;20(8):837-43. doi: 10.1038/ejhg.2012.24. Epub 2012 Feb 15.

ONE THING LEADS TO ANOTHER: THE CASCADE OF OBLIGATIONS WHEN RESEARCHERS REPORT GENETIC RESEARCH RESULTS TO STUDY PARTICIPANTS

Miller FA, Hayeems RZ, Li L, Bytautas JP.

Abstract
Even as debate continues about the putative obligation to proactively report genetic research results to study participants, there is an increasing need to attend to the obligations that might cascade from any initial report. We conducted an international, quasi-experimental survey of researchers involved in autism spectrum disorders (ASD) and cystic fibrosis (CF) genetics to explore perceived obligations to ensure updated information or relevant clinical care subsequent to any initial communication of research results, and factors influencing these attitudes. 5-point Likert scales of dis/agreement were analyzed using descriptive and multivariate statistics. Of the 343 respondents (44% response rate), large majorities agreed that in general and in a variety of hypothetical research contexts, research teams that report results should ensure that participants gain subsequent access to updated information (74-83%) and implicated clinical services (79-87%). At the same time, researchers perceived barriers restricting access to relevant clinical care, though this was significantly more pronounced ($P<0.001$) for ASD (64%) than CF (34%). In the multivariate model, endorsement of cascading obligations was positively associated with researcher characteristics (eg, clinical role/training) and attitudes (eg, perceived initial reporting obligation), and negatively associated with the initial report of less scientifically robust hypothetical results, but unaffected by perceived or hypothetical barriers to care. These results suggest that researchers strongly endorse information and care-based obligations that cascade from the initial report of research results to study participants. In addition, they raise challenging questions about how any cascading obligations are to be met, especially where access challenges are already prevalent.
PMID: 22333903

Series: The Culture and Politics of Health Care Work
ILR Press, Cornell University Press, May 2012
FIRST DO LESS HARM: CONFRONTING THE INCONVENIENT PROBLEMS OF PATIENT SAFETY
Koppel R, Gordon S (Editors)

Abstract
Each year, hospital-acquired infections, prescribing and treatment errors, lost documents and test reports, communication failures, and other problems have caused thousands of deaths in the United States, added millions of days to patients‘ hospital stays, and cost Americans tens of billions of dollars. Despite (and sometimes because of) new medical information technology and numerous well-intentioned initiatives to address these problems, threats to patient safety remain, and in some areas are on the rise. In First, Do Less Harm, twelve health care professionals and researchers plus two former patients look at patient safety from a variety of perspectives, finding many of the proposed solutions to be inadequate or impractical. Several contributors to this book attribute the failure to confront patient safety concerns to the influence of the "market model" on medicine and emphasize the need for hospital-wide teamwork and greater involvement from frontline workers (from janitors and aides to nurses and physicians) in planning, implementing, and evaluating effective safety initiatives. Several chapters in First, Do Less Harm focus on the critical role of interprofessional and occupational practice in patient safety. Rather than focusing on the usual suspects-physicians, safety champions, or high level management-these chapters expand the list of "stakeholders" and patient safety advocates to include nurses, patient care assistants, and other staff, as well as the health care unions that may represent them. First, Do Less Harm also highlights workplace issues that negatively affect safety: including sleeplessness, excessive workloads, outsourcing of hospital cleaning, and lack of teamwork between physicians and other health care staff. In two chapters, experts explain why the promise of health care information technology to fix safety problems remains unrealized, with examples that are at once humorous and frightening. A book that will be required reading for physicians, nurses, hospital administrators, public health officers, quality and risk managers, healthcare educators, economists, and policymakers, First, Do Less Harm concludes with a list of twenty-seven paradoxes and challenges facing everyone interested in making care safe for both patients and those who care for them.

BMJ Qual Saf. 2012 Jan;21(1):70-7.
doi: 10.1136/bmjqs-2011-000114. Epub 2011 Sep 22.

HOW EVENT REPORTING BY US HOSPITALS HAS CHANGED FROM 2005 TO 2009

Farley DO, Haviland A, Haas A, Pham C, Munier WB, Battles JB.

Abstract
CONTEXT: Information is needed on the performance of hospitals' adverse-event reporting systems and the effects of national patient-safety initiatives, including the Patient Safety and Quality Improvement Act (PSQIA) of 2005. Results are presented of a 2009 survey of a sample of non-federal US hospitals and changes between 2005 and 2009 are examined.
METHODS: The Adverse Event Reporting System survey was fielded in 2005 and 2009 using a mixed-mode design with stratified random samples of non-federal US hospitals; risk managers were respondents. Response rates were 81% in 2005 and 79% in 2009.
RESULTS: Virtually all hospitals reported they had centralised adverse-event-reporting systems. However, scores on four performance indexes suggested that hospitals have not effectively implemented key components of reporting systems. Average index scores improved somewhat between 2005 and 2009 for supportive environment (0.7 increase; $p<0.05$) and types of staff reporting (0.08 increase; $p<0.001$). Average scores did not change for timely distribution of event reports or discussion with key departments and committees. Some within-hospital inconsistencies in responses between 2005 and 2009 were found. These self-reported responses may be optimistic assessments of hospital performance.
CONCLUSIONS: The 2009 survey confirmed improvement needs identified by the 2005 survey for hospitals' event reporting processes, while finding signs of progress. Optimising the use of surveys to assess the effects of national patient-safety initiatives such as PSQIA will require decreasing within-hospital variations in reporting rates.
PMID: 21949437

Am J Perinatol. 2012 Jan;29(1):65-70.
doi: 10.1055/s-0031-1285825. Epub 2011 Aug 10.

WHEN BAD THINGS HAPPEN: ADVERSE EVENT REPORTING AND DISCLOSURE AS PATIENT SAFETY AND RISK MANAGEMENT TOOLS IN THE NEONATAL INTENSIVE CARE UNIT

Donn SM, McDonnell WM.

Abstract
The Institute of Medicine has recommended a change in culture from "name and blame" to patient safety. This will require system redesign to identify and address errors, establish performance standards, and set safety expectations. This approach, however, is at odds with the present medical malpractice (tort) system. The current system is outcomes-based, meaning that health care providers and institutions are often sued despite providing appropriate care. Nevertheless, the focus should remain to provide the safest patient care. Effective peer review may be hindered by the present tort system. Reporting of medical errors is a key piece of peer review and education, and both anonymous reporting and confidential reporting of errors have potential disadvantages. Diagnostic and treatment errors continue to be the leading sources of allegations of malpractice in pediatrics, and the neonatal intensive care unit is uniquely vulnerable. Most errors result from systems failures rather than human error. Risk management can be an effective process to identify, evaluate, and address problems that may injure patients, lead to malpractice claims, and result in financial losses. Risk management identifies risk or potential risk, calculates the probability of an adverse event arising from a risk, estimates the impact of the adverse event, and attempts to control the risk. Implementation of a successful risk management program requires a positive attitude, sufficient knowledge base, and a commitment to improvement. Transparency in the disclosure of medical errors and a strategy of prospective risk management in dealing with medical errors may result in a substantial reduction in medical malpractice lawsuits, lower litigation costs, and a more safety-conscious environment.

PMID: 21833897

Chest. 2011 Aug;140(2):519-26. doi: 10.1378/chest.10-2533.

ACCOUNTABILITY FOR MEDICAL ERROR: MOVING BEYOND BLAME TO ADVOCACY

Bell SK, Delbanco T, Anderson-Shaw L, McDonald TB, Gallagher TH.

Abstract

Accountability in medicine, once assigned primarily to individual doctors, is today increasingly shared by groups of health-care providers. Because patient safety experts emphasize that most errors are caused not by individual providers, but rather by system breakdowns in complex health-care teams, individual doctors are left to wonder where their accountability lies. Increasingly, teams deliver care. But patients and doctors alike still think of accountability in individual terms, and the law often measures it that way. Drawing on an example of delayed lung cancer diagnosis, we describe the mismatch between how we view errors (systems) and how we apportion blame (individuals). We discuss "collective accountability," suggesting that this construct may offer a way to balance a "just culture" and a doctor's specific responsibilities within the framework of team delivery of care. The concept of collective accountability requires doctors to adopt transparent behaviors, learn new skills for improving team performance, and participate in institutional safety initiatives to evaluate errors and implement plans for preventing recurrences. It also means that institutions need to prioritize team training, develop robust, nonpunitive reporting systems, support clinicians after adverse events and medical error, and develop ways to compensate patients who are harmed by errors. A conceptual leap to collective accountability may help overcome longstanding professional and societal norms that not only reinforce individual blame and impede patient safety but may also leave the patient and family without a true advocate.

PMID: 21813531

Issue Brief (Commonw Fund). 2011 Jul;14:1-18.

ADMINISTRATIVE COMPENSATION FOR MEDICAL INJURIES: LESSONS FROM THREE FOREIGN SYSTEMS

Mello MM, Kachalia A, Studdert DM.

Abstract

The United States requires patients injured by medical negligence to seek compensation through lawsuits, an approach that has drawbacks related to fairness, cost, and impact on medical care. Several countries, including New Zealand, Sweden, and Denmark, have replaced litigation with administrative compensation systems for patients who experience an avoidable medical injury. Sometimes called "no-fault" systems, such schemes enable patients to file claims for compensation without using an attorney. A governmental or private adjudicating organization uses neutral medical experts to evaluate claims of injury and does not require patients to prove that health care providers were negligent in order to receive compensation. Information from claims is used to analyze opportunities for patient safety improvement. The systems have successfully limited liability costs while improving injured patients' access to compensation. American policymakers may find many of the elements of these countries' systems to be transferable to demonstration projects in the U.S.

PMID: 21770079

PLoS Med. 2011 Apr;8(4):e1000431.
doi: 10.1371/journal.pmed.1000431. Epub 2011 Apr 5.

STRATEGIES AND PRACTICES IN OFF-LABEL MARKETING OF PHARMACEUTICALS: A RETROSPECTIVE ANALYSIS OF WHISTLEBLOWER COMPLAINTS

Kesselheim AS, Mello MM, Studdert DM.

Abstract

BACKGROUND: Despite regulatory restrictions, off-label marketing of pharmaceutical products has been common in the US. However, the scope of off-label marketing remains poorly characterized. We developed a typology for the strategies and practices that constitute off-label marketing.

METHODS AND FINDINGS: We obtained unsealed whistleblower complaints against pharmaceutical companies filed in US federal

fraud cases that contained allegations of off-label marketing (January 1996-October 2010) and conducted structured reviews of them. We coded and analyzed the strategic goals of each off-label marketing scheme and the practices used to achieve those goals, as reported by the whistleblowers. We identified 41 complaints arising from 18 unique cases for our analytic sample (leading to US$7.9 billion in recoveries). The off-label marketing schemes described in the complaints had three non-mutually exclusive goals: expansions to unapproved diseases (35/41, 85%), unapproved disease subtypes (22/41, 54%), and unapproved drug doses (14/41, 34%). Manufacturers were alleged to have pursued these goals using four non-mutually exclusive types of marketing practices: prescriber-related (41/41, 100%), business-related (37/41, 90%), payer-related (23/41, 56%), and consumer-related (18/41, 44%). Prescriber-related practices, the centerpiece of company strategies, included self-serving presentations of the literature (31/41, 76%), free samples (8/41, 20%), direct financial incentives to physicians (35/41, 85%), and teaching (22/41, 54%) and research activities (8/41, 20%).
CONCLUSIONS: Off-label marketing practices appear to extend to many areas of the health care system. Unfortunately, the most common alleged off-label marketing practices also appear to be the most difficult to control through external regulatory approaches.
PMID: 21483716

J Econ Perspect. 2011 Spring;25(2):93-110.

EVALUATING THE MEDICAL MALPRACTICE SYSTEM AND OPTIONS FOR REFORM

Kessler DP.

Abstract
The U.S. medical malpractice liability system has two principal objectives: to compensate patients who are injured through the negligence of healthcare providers and to deter providers from practicing negligently. In practice, however, the system is slow and costly to administer. It both fails to compensate patients who have suffered from bad medical care and compensates those who haven't. According to opinion surveys of physicians, the system creates incentives to undertake cost-ineffective treatments based on fear of legal liability--to practice "defensive medicine." The failures of the liability system and the high cost of health care in the United States have led to an important debate over tort policy. How well does malpractice law achieve its intended goals? How large of a problem

is defensive medicine and can reforms to malpractice law reduce its impact on healthcare spending? The flaws of the existing system have led a number of states to change their laws in a way that would reduce malpractice liability--to adopt "tort reforms." Evidence from several studies suggests that wisely chosen reforms have the potential to reduce healthcare spending significantly with no adverse impact on patient health outcomes.
PMID: 21595327

N Engl J Med. 2011 Mar 31;364(13):1243-50.
doi: 10.1056/NEJMsa1009336.

RELATIONSHIP BETWEEN QUALITY OF CARE AND NEGLIGENCE LITIGATION IN NURSING HOMES

Studdert DM, Spittal MJ, Mello MM, O'Malley AJ, Stevenson DG.

Abstract
BACKGROUND: It is unclear whether high-quality health care institutions are less likely to be sued for negligence than their low-performing counterparts.
METHODS: We linked information on tort claims brought against 1465 nursing homes between 1998 and 2006 to 10 indicators of nursing home quality drawn from two U.S. national data sets: the Online Survey, Certification, and Reporting system and the Minimum Data Set Quality Measure/Indicator Report. We tested for associations between the incidence of claims and the quality measures at the facility calendar-quarter level, correcting for facility clustering and adjusting for case mix, ownership, occupancy, year, and state. Odds ratios were calculated for the effect of a change of 1 SD in each quality measure on the odds of one or more claims in each facility calendar-quarter.
RESULTS: Nursing homes with more deficiencies (odds ratio, 1.09; 95% confidence interval [CI], 1.05 to 1.13) and those with more serious deficiencies (odds ratio, 1.04; 95% CI, 1.00 to 1.08) had higher odds of being sued; this was also true for nursing homes that had more residents with weight loss (odds ratio, 1.05; 95% CI, 1.01 to 1.10) and with pressure ulcers (odds ratio, 1.09; 95% CI, 1.05 to 1.14). The odds of being sued were lower in nursing homes with more nurse's aide-hours per resident-day (odds ratio, 0.95; 95% CI, 0.91 to 0.99). However, all these effects were relatively small. For example, nursing homes with the best deficiency records (10th percentile) had a 40% annual risk of being sued, as compared with a 47% risk among

nursing homes with the worst deficiency records (90th percentile).
CONCLUSIONS: The best-performing nursing homes are sued only marginally less than the worst-performing ones. Such weak discrimination may subvert the capacity of litigation to provide incentives to deliver safer care.
PMID: 21449787
Comment in: *Quality of care and negligence litigation in nursing homes. [N Engl J Med. 2011]*

BMC Med Ethics. 2010 Oct 18;11:17. doi: 10.1186/1472-6939-11-17.

WHICH MEDICAL ERROR TO DISCLOSE TO PATIENTS AND BY WHOM? PUBLIC PREFERENCE AND PERCEPTIONS OF NORM AND CURRENT PRACTICE

Hammami MM, Attalah S, Al Qadire M.

Abstract
BACKGROUND: Disclosure of near miss medical error (ME) and who should disclose ME to patients continue to be controversial. Further, available recommendations on disclosure of ME have emerged largely in Western culture; their suitability to Islamic/Arabic culture is not known.
METHODS: We surveyed 902 individuals attending the outpatient's clinics of a tertiary care hospital in Saudi Arabia. Personal preference and perceptions of norm and current practice regarding which ME to be disclosed (5 options: don't disclose; disclose if associated with major, moderate, or minor harm; disclose near miss) and by whom (6 options: any employee, any physician, at-fault-physician, manager of at-fault-physician, medical director, or chief executive director) were explored.
RESULTS: Mean (SD) age of respondents was 33.9 (10) year, 47% were males, 90% Saudis, 37% patients, 49% employed, and 61% with college or higher education. The percentage (95% confidence interval) of respondents who preferred to be informed of harmful ME, of near miss ME, or by at-fault physician were 60.0% (56.8 to 63.2), 35.5% (32.4 to 38.6), and 59.7% (56.5 to 63.0), respectively. Respectively, 68.2% (65.2 to 71.2) and 17.3% (14.7 to 19.8) believed that as currently practiced, harmful ME and near miss ME are disclosed, and 34.0% (30.7 to 37.4) that ME are disclosed by at-fault-physician. Distributions of perception of norm and preference were similar but significantly different from the distribution of perception of current practice ($P < 0.001$). In a forward stepwise regression analysis, older age, female

gender, and being healthy predicted preference of disclosure of near miss ME, while younger age and male gender predicted preference of no-disclosure of ME. Female gender also predicted preferring disclosure by the at-fault-physician.
CONCLUSIONS: We conclude that: 1) there is a considerable diversity in preferences and perceptions of norm and current practice among respondents regarding which ME to be disclosed and by whom, 2) Distributions of preference and perception of norm were similar but significantly different from the distribution of perception of current practice, 3) most respondents preferred to be informed of ME and by at-fault physician, and 4) one third of respondents preferred to be informed of near-miss ME, with a higher percentage among females, older, and healthy individuals.
PMID: 20955579

Health Aff (Millwood). 2010 Sep;29(9):1569-77.
doi: 10.1377/hlthaff.2009.0807.

NATIONAL COSTS OF THE MEDICAL LIABILITY SYSTEM

Mello MM, Chandra A, Gawande AA, Studdert DM.

Abstract
Concerns about reducing the rate of growth of health expenditures have reignited interest in medical liability reforms and their potential to save money by reducing the practice of defensive medicine. It is not easy to estimate the costs of the medical liability system, however. This article identifies the various components of liability system costs, generates national estimates for each component, and discusses the level of evidence available to support the estimates. Overall annual medical liability system costs, including defensive medicine, are estimated to be $55.6 billion in 2008 dollars, or 2.4 percent of total health care spending.
PMID: 20820010
Comment in: *The medical malpractice muddle. [Health Aff (Millwood). 2010] The cost of lawsuit risks when treating the uninsured. [Health Aff (Millwood). 2010]*

Ann Intern Med. 2010 Aug 17;153(4):213-21. doi: 10.7326/0003-4819-153-4-201008170-00002.

LIABILITY CLAIMS AND COSTS BEFORE AND AFTER IMPLEMENTATION OF A MEDICAL ERROR DISCLOSURE PROGRAM

Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, Rogers MA.

Abstract

BACKGROUND: Since 2001, the University of Michigan Health System (UMHS) has fully disclosed and offered compensation to patients for medical errors.

OBJECTIVE: To compare liability claims and costs before and after implementation of the UMHS disclosure-with-offer program.

DESIGN: Retrospective before-after analysis from 1995 to 2007.

SETTING: Public academic medical center and health system.

PATIENTS: Inpatients and outpatients involved in claims made to UMHS.

MEASUREMENTS: Number of new claims for compensation, number of claims compensated, time to claim resolution, and claims-related costs.

RESULTS: After full implementation of a disclosure-with-offer program, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters (rate ratio [RR], 0.64 [95% CI, 0.44 to 0.95]). The average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters (RR, 0.35 [CI, 0.22 to 0.58]). Median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Average monthly cost rates decreased for total liability (RR, 0.41 [CI, 0.26 to 0.66]), patient compensation (RR, 0.41 [CI, 0.26 to 0.67]), and non-compensation-related legal costs (RR, 0.39 [CI, 0.22 to 0.67]).

LIMITATIONS: The study design cannot establish causality. Malpractice claims generally declined in Michigan during the latter part of the study period. The findings might not apply to other health systems, given that UMHS has a closed staff model covered by a captive insurance company and often assumes legal responsibility.

CONCLUSION: The UMHS implemented a program of full disclosure of medical errors with offers of compensation without increasing its total claims and liability costs.

PRIMARY FUNDING SOURCE: Blue Cross Blue Shield of Michigan Foundation.

PMID: 20713789

Comment in: *Patient compensation without litigation: a promising development. [Ann Intern Med. 2010]*

Ann Intern Med. 2010 Aug 17;153(4):266-7.
doi: 10.7326/0003-4819-153-4-201008170-00010.

PATIENT COMPENSATION WITHOUT LITIGATION: A PROMISING DEVELOPMENT

Localio AR.

Abstract

In 1977, Bernzweig eloquently outlined the severe dysfunction in the United States' fault and no-fault injury compensation systems. Although recent legislation seeks to promote patient safety through confidential error reporting , the dysfunction persists, and initiatives to compensate injured patients are lacking. Advocates of "reform" focus on laws to limit medical liability insurance premiums and costs of the practice of defensive medicine. Common statutory changes, which neglect the predicament of injured patients, are caps on payments for pain and suffering. These caps range about 6-fold across the 50 states, and California's cap, fixed at $250 000 in 1975, has never been adjusted for inflation. One must question the equity of such wide-ranging limits. Meaningful reform must recognize 4 underlying issues. First, many patients (and at times their family members) are injured; however, as few as 1 in 50 patients injured by medical negligence ever files a claim and fewer receive compensation. Second, expert disagreement about the cause of adverse medical events is pervasive, a reality that will challenge any form of adjudication model, judicial or administrative. Third, litigation, liability insurance, and reporting systems (such as the National Practitioner Data Bank) create disincentives for providers of care to admit error. Fourth, litigation, and even no-fault injury compensation programs, can be expensive, unpleasant, and fraught with ill will and delays.

In this issue, Kachalia and colleagues add to our understanding of new modes for compensating patient injured by medical error. The University of Michigan Health System (UMHS) identifies errors, discloses them to the injured patients, and offers financial compensation,all without the involvement of the legislature, Congress, courts, or administrative agency and with greatly reduce expenses for attorneys. Model for routine, voluntary disclosure of medical adverse events are not new. Three decades ago, Jeffrey O'Connell, the well-known author of automobile accident compensation reform, proposed a plan to prompt physicians and hospitals to identify errors and approach the injured patient with an unsolicited early offer of compensation. More than 10 years ago in Annals, the Department of Veteran Affairs described its disclosure policy. What is new, however, is a private-sector plan, adopted without legislative imprimatur, to accept responsibility and offer compensation.

PMID: 20713794

Comment on *Liability claims and costs before and after implementation of a medical error disclosure program. [Ann Intern Med. 2010]*

Br J Anaesth. 2010 Jul;105(1):3-6. doi: 10.1093/bja/aeq124.

CRISIS RESOURCE MANAGEMENT AND TEAMWORK TRAINING IN ANAESTHESIA

Gaba DM.

Abstract

Over 20 yr ago, my research group was the first of what would become many who would recognize that there were sufficient parallels in the cognitive profile of the work of anaesthetists to that of airline pilots to justify examining, adapting, and adopting the paradigm of Crew (originally "Cockpit') Resource Management (CRM), then fairly recently begun in aviation training. The CRM paradigm can be summarized as the articulation of principles of individual and crew behaviour in ordinary and crisis situations that focuses on skills of dynamic decision-making, interpersonal behaviour, and team management. Just as these were found to be of equal or greater importance to ensuring safety of flight of airliners, so too were they found to be relevant for patient safety in anaesthesia.

Over the years, the theoretical focus and implementation methods for CRM training in aviation evolved as various theories and techniques came in and out of vogue. Nonetheless, the overall focus on what are widely known as "non-technical skills' of individuals and teams has remained at the core.

That the adaptations of CRM to healthcare started in anaesthesiology is no coincidence. As I have articulated elsewhere, anaesthesiologists have a special need to emphasize patient safety. We share with pilots a cognitive profile of "hours of boredom and moments of terror', and an analogous work process that combines technical skill and decision-making in a complex and diverse interpersonal environment (indeed, that of healthcare is probably more challenging than that of aviation). The general applicability of CRM to healthcare has now spread far beyond anaesthetics, first to analogous specialities such as critical care, emergency medicine, neonatology, multidisciplinary operating theatre care, and more recently to a number of less acute settings of care (e.g. medical wards). Thus, as for much of the patient safety movement, anaesthesiology has been the pioneer, providing a gift of experience in CRM to the rest of medical practice.

PMID: 20551023

BMC Health Serv Res. 2010 Jun 2;10:150.
doi: 10.1186/1472-6963-10-150.

HEALTH AND LIFE INSURANCE AS AN ALTERNATIVE TO MALPRACTICE TORT LAW

Sumner W 2nd.

Abstract
BACKGROUND: Tort law has legitimate social purposes of deterrence, punishment and compensation, but medical tort law does none of these well. Tort law could be counterproductive in medicine, encouraging costly defensive practices that harm some patients, restricting access to care in some settings and discouraging innovation.
DISCUSSION: Patients might be better served by purchasing combined health and life insurance policies and waiving their right to pursue malpractice claims. The combined policy should encourage the insurer to profit by inexpensively delaying policyholders' deaths. A health and life insurer would attempt to minimize mortal risks to policyholders from any cause, including medical mistakes and could therefore pursue systematic quality improvement efforts. If policyholders trust the insurer to seek, develop and reward genuinely effective care; identify, deter and remediate poor care; and compensate survivors through the no-fault process of paying life insurance benefits, then tort law is largely redundant and the right to sue may be waived. If expensive defensive medicine can be avoided, that savings alone could pay for fairly large life insurance policies.
SUMMARY: Insurers are maligned largely because of their logical response to incentives that are misaligned with the interests of patients and physicians in the United States. Patient, provider and insurer incentives could be realigned by combining health and life insurance, allowing the insurer to use its considerable information access and analytic power to improve patient care. This arrangement would address the social goals of malpractice torts, so that policyholders could rationally waive their right to sue.
PMID: 20525190

Crit Care. 2010;14(2):217. doi: 10.1186/cc8858. Epub 2010 Mar 9.

PATIENT SAFETY AND ACUTE CARE MEDICINE: LESSONS FOR THE FUTURE, INSIGHTS FROM THE PAST

Brindley PG.

Abstarct

It is estimated that approximately 40,000-100,000 Americans die annually from medical errors. Thousands more suffer harm from medical errors. Still others are exposed to errors, but are lucky enough to suffer no obvious harm. In fact, medical errors are now the eighth leading cause of death in the USA; data are no less alarming from other nations. Regardless of the exact figures, it seems that patient safety is far from adequate.

Crudely put, if medicine were a patient, we physicians would say it is time to admit there is a problem. We would expect urgent action, and we would welcome any ideas, rather than tolerate further delays. This chapter hopes to provide a call-to-arms, but most importantly a range of ideas, both new and old, to achieve the sort of care that our patients deserve.

PMID: 20236461

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www.dh.gov.uk/publications

RESPONSIBILITY AND ACCOUNTABILITY MOVING ON FOR NEW WAYS OF WORKING TO A CREATIVE, CAPABLE WORKFORCEBEST PRACTICE GUIDANCE

Department of Health, UK

Abstract

This document brings together the existing guidance and practice recommended by different professional bodies. It is intended to help multi-disciplinary teams in their discussions and decision making about patient care, by clarifying their formal professional accountability and responsibility. It highlights where inaccurate assumptions may be made about other professions and therefore aims to enhance decision making. This is a source document to help clarify what can be complex issues.

J Patient Saf. 2009 Dec;5(4):205-9.
doi: 10.1097/PTS.0b013e3181be2a88.

THE CHALLENGES TO TRANSPARENCY IN REPORTING MEDICAL ERRORS

Paterick ZR, Paterick BB, Waterhouse BE, Paterick TE.

Abstract
In an ideal health care environment, physicians and health care organizations would acknowledge and factually report all medical errors and "near misses" in an effort to improve future patient safety by better identifying systemic safety lapses. Truth must permeate the health care system to achieve the goal of transparency. The Institute of Medicine has estimated that 44,000 to 98,000 patients die each year as a result of medical errors. Improving the reporting of medical errors and near misses is essential for better prevention of medical errors and thus increasing patient safety. Higher rates of reporting can permit identification of the root causes of errors and create improved processes that can significantly reduce errors in future patient care. Multiple barriers exist with respect to reporting medical errors, despite the ethical and various professional, regulatory, and legislative expectations and requirements generating this obligation. As long as physicians perceive that they are at risk for sanctions, malpractice claims, and unpredictable compensation of injured patients as determined by the United States' tort law system, legislative or regulative reform is unlikely to affect the underreporting of medical errors, and patient safety cannot benefit from the lessons derived from past medical errors and near misses. A new infrastructure for creating patient safety systems, as identified in the Patient Safety and Quality Improvement Act of 2005 is needed. A patient compensation system guided by an administrative health court that includes some form of no-fault insurance must be studied to identify benefits and risks. Most urgent is the development of a reporting system for medical errors and near misses that is transparent and effectively recognizes the legitimate concerns of physicians and health care providers and improves patient safety.
PMID: 22130212

Health Care Manage Rev. 2009 Oct-Dec;34(4):312-22.
doi: 10.1097/HMR.0b013e3181a3b709.

FROM A BLAME CULTURE TO A JUST CULTURE IN HEALTH CARE

Khatri N, Brown GD, Hicks LL.

Abstract
BACKGROUND: A prevailing blame culture in health care has been suggested as a major source of an unacceptably high number of medical errors. A just culture has emerged as an imperative for improving the quality and safety of patient care. However, health care organizations are finding it hard to move from a culture of blame to a just culture.
PURPOSE: We argue that moving from a blame culture to a just culture requires a comprehensive understanding of organizational attributes or antecedents that cause blame or just cultures. Health care organizations need to build organizational capacity in the form of human resource (HR) management capabilities to achieve a just culture.
METHODOLOGY: This is a conceptual article. Health care management literature was reviewed with twin objectives: (a) to ascertain if a consistent pattern existed in organizational attributes that lead to either blame or just cultures and (2) to find out ways to reform a blame culture.
CONCLUSIONS: On the basis of the review of related literature, we conclude that (a) a blame culture is more likely to occur in health care organizations that rely predominantly on hierarchical, compliance-based functional management systems; (b) a just or learning culture is more likely to occur in health organizations that elicit greater employee involvement in decision making; and (c) human resource management capabilities play an important role in moving from a blame culture to a just culture.
PRACTICE IMPLICATIONS: Organizational culture or human resource management practices play a critical role in the health care delivery process. Health care organizations need to develop a culture that harnesses the ideas and ingenuity of health care professional by employing a commitment-based management philosophy rather than strangling them by overregulating their behaviors using a control-based philosophy. They cannot simply wish away the deeply entrenched culture of blame nor can they outsource their way out of it. Health care organizations need to build internal human resource management capabilities to bring about the necessary changes in their culture and management systems and to become learning organizations.
PMID: 19858916

Arch Intern Med. 2009 Nov 9;169(20):1888-94.
doi: 10.1001/archinternmed.2009.387.

DISCLOSURE OF HOSPITAL ADVERSE EVENTS AND ITS ASSOCIATION WITH PATIENTS' RATINGS OF THE QUALITY OF CARE

López L, Weissman JS, Schneider EC, Weingart SN, Cohen AP, Epstein AM.

Abstract
BACKGROUND: Little is known about how the characteristics of adverse events (AEs) affect the likelihood of disclosure or how the disclosure of an AE relates to patients' perception of quality of care.
METHODS: The study included a random sample of medical and surgical acute care adult patients in Massachusetts hospitals between April 1 and October 1, 2003. The unit of analysis was the AE, and multivariable regression analyses accounted for clustering at the patient level.
RESULTS: Overall, 603 patients reported 845 AEs, and 40% of AEs were disclosed. The AEs that required additional treatment (odds ratio [OR], 1.64; 95% confidence interval [CI], 1.16-2.32) or affected patients who reported good health (OR, 2.04; 95% CI, 1.29-3.24) were more likely to be disclosed. Disclosure was less likely if the events were preventable (OR, 0.58; 95% CI, 0.41-0.83) or if the patients were still affected by the AE at the time of survey (OR, 0.49; 95% CI, 0.31-0.78). Higher-quality ratings were associated with disclosure (OR, 2.04; 95% CI, 1.39-2.99) of preventable and nonpreventable events and with patients who felt that they were able to protect themselves from AEs (OR, 1.98; 95% CI, 1.21-3.24). Lower-quality ratings were associated with events that were preventable (OR, 0.55; 95% CI, 0.40-0.76), with events that caused increased discomfort (OR, 0.62; 95% CI, 0.46-0.86), or with events that still adversely affected the patient at the time of the survey (OR, 0.68; 95% CI, 0.46-0.98).
CONCLUSIONS: Rates of disclosure of AEs by medical personnel remain low in hospitalized patients. Disclosure of some of these events is associated with higher ratings of quality by patients.
PMID: 19901141

Arch Intern Med. 2009 Nov 9;169(20):1894-6.
doi: 10.1001/archinternmed.2009.351.

ENTERING THE SECOND DECADE OF THE PATIENT SAFETY MOVEMENT: THE FIELD MATURES: COMMENT ON "DISCLOSURE OF HOSPITAL ADVERSE EVENTS AND ITS ASSOCIATION WITH PATIENTS' RATINGS OF THE QUALITY OF CARE"

Wachter RM.

Abstract
December 1, 2009, marks the 10-year anniversary of the Institute of Medicine report on medical mistakes, To Err is Human, the blockbuster that launched the modern patient safety movement.1,2 The occasion of this anniversary gives us an opportunity to reflect on the progress we have made in patient safety and on areas that have not received the attention they deserve.
PMID: 19901142

J Am Coll Cardiol. 2009 Sep 8;54(11):985-8.
doi: 10.1016/j.jacc.2009.07.014.

HEALTH CARE DELIVERY SYSTEM REFORM: ACCOUNTABLE CARE ORGANIZATIONS

Dove JT, Weaver WD, Lewin J.

Abstract
Health care reform is moving forward at a frantic pace. There have been 3 documents released from the Senate Finance Committee and proposed legislation from the Senate HELP Committee and the House of Representatives Tri-Committee on Health Reform. The push for legislative action has not been sidetracked by the economic conditions. Integrated health care delivery is the current favored approach to aligning resource use and cost. Accountable care organizations (ACOs), a concept included in health care reform legislation before both the House and Senate, propose to translate the efficiencies and lessons learned from large integrated systems and apply them to nonintegrated practices. The ACO design could be real or virtual integration of local delivery providers. This new structure is complicated, and clinicians, patients, and payers should have input regarding the design and function of it. Because most of health care is delivered in the ambulatory setting, it remains to be determined

whether the ACOs are best developed in parallel among physician practices and hospitals or as partnerships between hospitals and physicians. Many are concerned that hospital-led ACOs will force physician employment by hospitals with possible unintended negative consequences for physicians, hospitals, and patients. Patients, physicians, other providers, and payers are in a better position to guide the redesign of the health care delivery system than government agencies, policy organizations, or elected officials, no matter how well intended. We strongly believe-and ACC has proclaimed-that change in health care delivery must be accomplished with patients and physicians at the table.
PMID: 19729113

Forensic Sci Int. 2009 Sep 10;190(1-3):67-73.
doi: 10.1016/j.forsciint.2009.05.014. Epub 2009 Jun 26.

MEDICAL NEGLIGENCE IN DRUG ASSOCIATED DEATHS

Madea B, Musshoff F, Preuss J.

Abstract
According to epidemiological studies adverse drug events are one of the most frequently encountered complications during medical treatment, a leading cause of hospitalisation and frequent cause of death. However, medical malpractice claims due to medication errors seem to be relatively rare. Based on a retrospective multicentre study on medical malpractice cases with lethal outcome (n=4450), drug related cases (n=575) were further evaluated. In 50% of cases a causal connection between drug therapy and death could be ruled out already after autopsy. In 232 cases a causal connection between drug therapy and death could be approved (drug allergies, relative overdose, wrong application, mix-up of drugs and sepsis after injection abscess). However, within the legal context only in 70 cases a medication error was approved which was in 42 cases causal for death, in 28 not. Administration of contraindicated drugs, incorrect application and relative overdose in renal insufficiency are the prevalent mistakes. Concerning the frequency of ADE in epidemiological studies medication errors are underreported in all data sources on medical malpractice; this seems to be due to the fact that even doctors and attending physicians rarely recognize an ADE; furthermore approving the connection between drug effect and death is extremely difficult for the expert witness.
PMID: 19560295

Curr Opin Anaesthesiol. 2009 Apr;22(2):199-206.
doi: 10.1097/ACO.0b013e328323f7aa.

HEALTHCARE SAFETY COMMITTEE IN JAPAN: MANDATORY ACCOUNTABILITY REPORTING SYSTEM AND PUNISHMENT

Nagamatsu S, Kami M, Nakata Y.

Abstract
PURPOSE OF REVIEW: The publication of To Err is Human by the Institute of Medicine highlighted the increased international concern about patient safety. Each country has developed its own medical adverse event reporting system. In 2007, the Japanese government attempted to establish a new accountability system in medicine, after an obstetrician was arrested for manslaughter. This paper reviews how this accountability system affected Japanese physicians' behavior, and describes different types of medical adverse event reporting systems.
RECENT FINDINGS: In general, reporting of adverse event systems can be either mandatory or voluntary, with the purpose being either for learning or for accountability. The goal of a newly proposed mandatory accountability system from the Japanese government was to investigate the cause of death in medical cases in order to clarify liability. Reports generated by this system could potentially be cited in civil law suits, administrative sanctions, and criminal prosecutions. After announcement of this new system, Japanese physicians began to act defensively, fearing criminal prosecution. Refusing to see high-risk patients and 'bouncing' (sometimes referred to as 'turfing' or 'dumping') to other hospitals became national phenomena. In addition, medical school graduates began avoiding highly legally vulnerable specialties. Even though this new system is not yet legalized in Japan, at least 153 obstetrics hospitals and 3320 clinics have closed.
SUMMARY: The new system of investigating medical adverse events in Japan allows for incident reports to be utilized in court. This has led to widespread fear of prosecution and defensive medicine. The lessons from Japan should be considered when other countries implement nationwide accountability systems.
PMID: 19390246

MedCare.2009Feb;47(2):234-42.doi:10.1097/MLR.0b013e31818475de.

RELATIONSHIP BETWEEN MALPRACTICE LITIGATION PRESSURE AND RATES OF CESAREAN SECTION AND VAGINAL BIRTH AFTER CESAREAN SECTION

Yang YT, Mello MM, Subramanian SV, Studdert DM.

Abstract
BACKGROUND: Since the 1990s, nationwide rates of vaginal birth after cesarean section (VBAC) have decreased sharply and rates of cesarean section have increased sharply. Both trends are consistent with clinical behavior aimed at reducing obstetricians' exposure to malpractice litigation.
OBJECTIVE: To estimate the effects of malpractice pressure on rates of VBAC and cesarean section. RESEARCH DESIGN, SUBJECTS, MEASURES: We used state-level longitudinal mixed-effects regression models to examine data from the Natality Detail File on births in the United States (1991-2003). Malpractice pressure was measured by liability insurance premiums and tort reforms. Outcome measures were rates of VBAC, cesarean section, and primary cesarean section.
RESULTS: Malpractice premiums were positively associated with rates of cesarean section (beta = 0.15, P = 0.02) and primary cesarean section (beta = 0.16, P = 0.009), and negatively associated with VBAC rates (beta = -0.35, P = 0.01). These estimates imply that a $10,000 decrease in premiums for obstetrician-gynecologists would be associated with an increase of 0.35 percentage points (1.45%) in the VBAC rate and decreases of 0.15 and 0.16 percentage points (0.7% and 1.18%) in the rates of cesarean section and primary cesarean section, respectively; this would correspond to approximately 1600 more VBACs, 6000 fewer cesarean sections, and 3600 fewer primary cesarean sections nationwide in 2003. Two types of tort reform-caps on noneconomic damages and pretrial screening panels-were associated with lower rates of cesarean section and higher rates of VBAC.
CONCLUSIONS: The liability environment influences choice of delivery method in obstetrics. The effects are not large, but reduced litigation pressure would likely lead to decreases in the total number cesarean sections and total delivery costs.
PMID: 19169125

Qual Saf Health Care. 2008 Dec;17(6):416-23.
doi: 10.1136/qshc.2007.024638.

ADVERSE-EVENT-REPORTING PRACTICES BY US HOSPITALS: RESULTS OF A NATIONAL SURVEY

Farley DO, Haviland A, Champagne S, Jain AK, Battles JB, Munier WB, Loeb JM.

Abstract
CONTEXT: Little is known about hospitals' adverse-event-reporting systems, or how they use reported data to improve practices. This information is needed to assess effects of national patient-safety initiatives, including implementation of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This survey generated baseline information on the characteristics of hospital adverse-event-reporting systems and processes, for use in assessing progress in improvements to reporting.
METHODS: The Adverse Event Reporting Survey, developed by Westat, was administered in September 2005 through January 2006, using a mixed-mode (mail/telephone) survey with a stratified random sample of 2050 non-federal US hospitals. Risk managers were the respondents. An 81% response rate was obtained, for a sample of 1652 completed surveys.
RESULTS: Virtually all hospitals reported they have centralised adverse-event-reporting systems, although characteristics varied. Scores on four performance indexes suggest that only 32% of hospitals have established environments that support reporting, only 13% have broad staff involvement in reporting adverse events, and 20-21% fully distribute and consider summary reports on identified events. Because survey responses are self-reported by risk managers, these may be optimistic assessments of hospital performance.
CONCLUSIONS: Survey findings document the current status of hospital adverse-event-reporting systems and point to needed improvements in reporting processes. PSQIA liability protections for hospitals reporting data to patient-safety organisations should also help stimulate improvements in hospitals' internal reporting processes. Other mechanisms that encourage hospitals to strengthen their reporting systems, for example, strong patient-safety programmes, also would be useful.
Comment in: *The frustrating case of incident-reporting systems. [Qual Saf Health Care. 2008]*
PMID: 19064656

Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment). Henriksen K, Battles JB, Keyes MA, et al., editors. Rockville (MD): Agency for Healthcare Research and Quality; 2008 Aug

USING AN ANONYMOUS WEB-BASED INCIDENT REPORTING TOOL TO EMBED THE PRINCIPLES OF A HIGH-RELIABILITY ORGANIZATION

Paul Conlon, PharmD, JD; Rebecca Havlisch, RN, JD; Narendra Kini, MD, MSHA; Christine Porter, MHSA.

Abstract

High-reliability organizations (HROs) are complex and have the potential for catastrophic failures yet operate with few such defects. Examples include; nuclear aircraft carriers, nuclear power plants, and air traffic control. Health care is also a highly complex industry with many catastrophic defects that would benefit from employing the principles of HROs. HRO reliability results from a capability to discover, manage, and reduce unexpected events. Paper-based reporting systems impede reporting of both actual and near-miss events. In April 2001, Trinity Health designed and implemented an anonymous Web-based reporting tool known as PEERs (Potential Error and Event Reporting System) that was based on the Aviation Safety Reporting System. The goal was to increase the reporting of actual events and near misses, facilitate the management of events, and identify potential safety problems before patients were harmed. Thirty-six Trinity Health hospitals and affiliates are currently using the PEERs system, and over 200,000 reports have been generated. Approximately 80 percent of these reports would have been overlooked in the paper system. The reports are standardized and are immediately available for use by the PEERs coordinator/safety officer. Significant care practice changes have resulted from PEERs reporting. In 2006, 59 root cause analyses were performed as a result of PEERs reports, 16 policies and 123 processes were changed, and an additional 50 policies are undergoing revision. A systemwide council of PEERs Coordinators meets regularly to share lessons learned and best practices related to patient safety. This information is routinely shared with management. The PEERs system nurtures a blame-free environment where reporting is encouraged. It has increased the reporting of events in a manner that allows for timely, efficient, and thorough analysis. PEERs facilitates the discovery, management, and eventual reduction of adverse events.

Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment).
Henriksen K, Battles JB, Keyes MA, et al., editors.
Rockville (MD): Agency for Healthcare Research and Quality; 2008 Aug

IMPROVING THE VALUE OF PATIENT SAFETY REPORTING SYSTEMS

Peter J Pronovost, MD, PhD, Laura L Morlock, PhD, J Bryan Sexton, PhD, Marlene R Miller, MD, MSc, Christine G Holzmueller, BLA, David A Thompson, DNSc, MS, Lisa H Lubomski, PhD, and Albert W Wu, MD, MPH.

Abstract
Use of patient safety reporting systems (PSRS) to identify and mitigate risks to patients who are harmed by medical care has been a national priority for nearly a decade. Yet, most reporting systems are still new and focus on reporting events. To improve the value of PSRS, we must use the data to identify safety hazards, prioritize where to focus resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm. We developed and implemented a Web-based PSRS and discuss in this paper the benefits, limitations, and challenges we encountered. First, we discuss the benefits of PSRS as part of a patient safety learning community. The remainder of the paper focuses on the challenges we faced that still need to be resolved to improve the value of reporting systems. We address these challenges as follows: what to report, how to minimize reporting burden and costs, how to conduct expert reviews and prioritize safety efforts, how to place incidents into taxonomies, how to know that the reporting system actually improved patient safety, and who should be responsible for attempting risk mitigation.

J Health Polit Policy Law. 2008 Aug;33(4):725-60.
doi: 10.1215/03616878-2008-014.

ADMINISTRATIVE COMPENSATION OF MEDICAL INJURIES: A HARDY PERENNIAL BLOOMS AGAIN

Barringer PJ, Studdert DM, Kachalia AB, Mello MM.

Abstract
Periods in which the costs of personal injury litigation and liability insurance have risen dramatically have often provoked calls for reform of the tort system, and medical malpractice is no exception. One proposal for fundamental reform made during several of these volatile periods has been to relocate personal injury disputes from the

tort system to an alternative, administrative forum. In the medical injury realm, a leading incarnation of such proposals in recent years has been the idea of establishing specialized administrative "health courts." Despite considerable stakeholder and policy-maker interest, administrative compensation proposals have tended to struggle for broad political acceptance. In this article, we consider the historical experience of administrative medical injury compensation proposals, particularly in light of comparative examples in the context of workplace injuries, automobile injuries, and vaccine injuries. We conclude by examining conditions that may facilitate or impede progress toward establishing demonstration projects of health courts.
PMID: 18617673

Soc Sci Med. 2008 Jan;66(2):387-402. Epub 2007 Oct 10.

BEYOND NEGLIGENCE: AVOIDABILITY AND MEDICAL INJURY COMPENSATION

Kachalia AB, Mello MM, Brennan TA, Studdert DM.

Abstract

Disenchantment with the tort system and negligence standard in the United States is fueling interest in alternate compensation systems for medical injury. One possibility is experimentation with administrative "health courts," through which specialized adjudicators would utilize neutral experts to render compensability determinations. Compensation would be based not on negligence, but rather on a broader avoidable medical injury (avoidability) standard. Although considerable interest in health courts exists, stakeholders frequently express uncertainty about the meaning and operation of an avoidability standard. Three nations-Sweden, Denmark, and New Zealand-have long operated administrative schemes. We conducted interviews with administrators and stakeholders in these systems. Our goal was to garner lessons on how to operate a health court, and specifically, how to develop and apply alternate compensation criteria such as avoidability. This article reports our findings on the origins and operations of the systems, the evolution of their compensation criteria, and how these criteria are actually applied. We found that all three systems had their primary genesis in ensuring compensation for the injured, as opposed to sanctioning providers. All have abandoned the negligence standard. The Nordic systems use an avoidability standard, principally defined as injury that would not occur in the hands of the best practitioner. Their experience demonstrates that this definition is feasible to apply. New Zealand's recent move to a

no-fault system sheds light on the benefits and drawbacks of a variety of compensation standards. Key lessons for successfully applying an alternate standard, such as avoidability, include a strict adherence to national precedent, the use of neutral and experienced experts, and a block on routine transfer of information from compensation investigations to disciplinary authorities. Importantly, all three nations are harnessing their systems' power to improve patient safety, and the avoidability standard appears to be well suited for this task.
PMID: 17931762

RAND Corporation, 2008. http://www.rand.org/pubs/technical_reports/TR596

IMPROVING PATIENT SAFETY IN THE EU: ASSESSING THE EXPECTED EFFECTS OF THREE POLICY AREAS FOR FUTURE ACTION

Conklin, Annalijn, Anna-Marie Vilamovska, Han de Vries and Evi Hatziandreu.

Abstract
This report, written and published in English in 2008, was prepared for the Health and Consumer Protection Commission (DG SANCO) in support of their Impact Assessment of the Patient Safety and Quality Legislative proposal for 2008. It presents our findings of a study in which we assess the expected effects of three policy areas for future action towards improving patient safety in the EU-27. Our study was informed by a mixture of methods, including the existing European and international studies and evaluations on patient safety and related initiatives, as well as primary qualitative data based on 32 key informant interviews with identified experts. The report will allow patient safety experts, DG SANCO, and other interested stakeholders to understand the extent to which it is possible to provide a clear and compelling account of the expected impacts of (1) establishing effective reporting and learning systems, (2) redress mechanisms, and (3) developing and using knowledge and evidence at the EU level.

Health Aff (Millwood). 2007 May-Jun;26(3):w425-35.
Epub 2007 Apr 24.

CHANGES IN PHYSICIAN SUPPLY AND SCOPE OF PRACTICE DURING A MALPRACTICE CRISIS: EVIDENCE FROM PENNSYLVANIA

Mello MM, Studdert DM, Schumi J, Brennan TA, Sage WM.

Abstract
The extent to which liability costs cause physicians to restrict their scope of practice or cease practicing is controversial in policy debates over malpractice "crises." We used insurance department administrative data to analyze specialist physician scope-of-practice changes and exits in Pennsylvania in 1993-2002. In most specialties the proportions of high-risk specialists restricting their scope of practice did not increase during the crisis; however, the supply of obstetrician-gynecologists decreased by 8 percent in the three years following premium increases in 1999. We discuss methodological issues that could explain the disparate findings regarding physician supply effects in studies using administrative data sets and survey data.
PMID: 17456502

Health Aff (Millwood). 2007 Jan-Feb;26(1):215-26.

DISCLOSURE OF MEDICAL INJURY TO PATIENTS: AN IMPROBABLE RISK MANAGEMENT STRATEGY

Studdert DM, Mello MM, Gawande AA, Brennan TA, Wang YC.

Abstract
Pressure mounts on physicians and hospitals to disclose adverse outcomes of care to patients. Although such transparency diverges from traditional risk management strategy, recent commentary has suggested that disclosure will actually reduce providers' liability exposure. We tested this theory by modeling the litigation consequences of disclosure. We found that forecasts of reduced litigation volume or cost do not withstand close scrutiny. A policy question more pressing than whether moving toward routine disclosure will expand litigation is the question of how large such an expansion might be.
PMID: 17211031
Comment in: *Bad modeling? [Health Aff (Millwood). 2007]*
Open disclosure: details matter. [Health Aff (Millwood). 2007]

IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2007. Available on www.IHI.org

ENGAGING PHYSICIANS IN A SHARED QUALITY AGENDA

Reinertsen JL, Gosfield AG, Rupp W, Whittington JW.

Abstract

The unique relationship between physicians and the American hospitals in which they practice arose historically when lay board members recognized their need to draw on the expertise of physicians to fulfill the board‘s fiduciary responsibility for quality. But the context for this traditional relationship has radically changed in the last few years.

Hospitals and their physicians are increasingly in competition with each other. For example, many hospitals have begun to employ various types of physicians whom independent medical staff members fear will steal their business, while the independent physicians themselves build and develop rival surgi-centers, imaging facilities, and even whole hospitals. In some communities, "organized medical staffs" often have trouble generating much enthusiasm from their membership, who are challenged by the demands of their daily professional and business lives, including onerous administrative burdens, lowered reimbursement, escalating malpractice premiums, and overall decreased satisfaction with their roles as physicians.

As a result, the medical staff organization is seen by many as an obsolete and moribund structure, incapable of fulfilling its purposes of overseeing quality, at precisely the time that hospitals and physicians are coming under intense pressure to produce measured quality and safety results. Some hospitals are making dramatic improvements in quality, despite the difficulties they face with the organized medical staff, even while many others struggle to implement evidence-based protocols and rigorous safety practices. Yet even in the most advanced hospitals, one of the most common questions raised is, "How can we do an even better job of engaging our physicians in the quality and safety agenda?" Given the deep-seated nature of these realities, and the importance of physician engagement to achieving quality results, it is surprising that so few hospitals have actually articulated a plan to improve the engagement of their physicians.

This white paper presents a framework on which hospital leaders might build a written plan for physician engagement in quality and safety. The paper includes tools to help hospital leaders assess organizational factors that will inform the degree of difficulty in engaging physicians, as well as to identify and prioritize initiatives for

which physician engagement is essential. While the principal focus of the paper is on American hospitals and their organized medical staffs, the framework might also be applied to many other types of health care systems and in settings outside the United States.

World Hosp Health Serv. 2006;42(2):14-6.

PHYSICIAN ACCOUNTABILITY, PATIENT SAFETY AND PATIENT COMPENSATION

Gray JE.

Abstract

In Canada, the response to adverse medical events follows one or more of three main paths: patient safety, physician accountability and patient compensation. While their goals differ, each of these responses serves a valuable function. There are however competing imperatives inherent in each response, particularly in terms of information disclosure: Effective patient safety depends on the full and protected disclosure of all information relevant to an adverse event and requires a "no blame" environment. While natural justice demands that a physician be held accountable for his actions, the doctor should be accorded the right of due process and be judged against an established standard of care. This is necessarily a fault-finding activity. Patient compensation meets both accountability demands and the social justice imperatives of supporting a patient injured through physician negligence. The most effective approach is one that achieves balance between competing imperatives. With clear information disclosure rules, patient safety, physician accountability and patient compensation can operate synergistically.

PMID: 16900793

Med J Malaysia. 2006 Dec;61(5):577-85.

CRITICAL INCIDENT MONITORING IN ANAESTHESIA

Choy YC.

Abstract

Critical incident monitoring in anaesthesia is an important tool for quality improvement and maintenance of high safety standards in anaesthetic services. It is now widely accepted as a useful quality improvement technique for reducing morbidity and mortality in anaesthesia and has become part of the many quality assurance

programmes of many general hospitals under the Ministry of Health. Despite wide-spread reservations about its value, critical incident monitoring is a classical qualitative research technique which is particularly useful where problems are complex, contextual and influenced by the interaction of physical, psychological and social factors. Thus, it is well suited to be used in probing the complex factors behind human error and system failure. Human error has significant contributions to morbidities and mortalities in anaesthesia. Understanding the relationships between, errors, incidents and accidents is important for prevention and risk management to reduce harm to patients. Cardiac arrests in the operating theatre (OT) and prolonged stay in recovery, constituted the bulk of reported incidents. Cardiac arrests in OT resulted in significant mortality and involved mostly de-compensated patients and those with unstable cardiovascular functions, presenting for emergency operations. Prolonged-stay in the recovery extended period of observation for ill patients. Prolonged stay in recovery was justifiable in some cases, as these patients needed a longer period of post-operative observation until they were stable enough to return to the ward. The advantages of the relatively low cost, and the ability to provide a comprehensive body of detailed qualitative information, which can be used to develop strategies to prevent and manage existing problems and to plan further initiatives for patient safety makes critical incident monitoring a valuable tool in ensuring patient safety. The contribution of critical incident reporting to the issue of patient safety is far from clear and very difficult to study. Efforts to do so have tended to rely on incident reporting, the only practical approach when funding is limited. The heterogeneity of critically ill patients as a group means that huge study populations would be required if other research techniques were to be used. In the era of evidence-based medicine, anaesthetists are looking for alternative evidence-based solutions to problems that we have accepted traditionally when we cannot quantify for good practical reasons. In the quest for patient safety, investment should be made in reliable audit, detection and reporting systems. The growing recognition that human error usually result from a failure of a system rather than an individual should be fostered to allow more lessons to be learnt, an approach that has been successful in other, safety-critical industries. New technology has a great deal to offer and investment is warranted in novel fail-safe drug administration systems. Last but not the least the importance of simple and sensible changes and better education should be remembered.

PMID: 17623959

AORN J. 2006 Sep;84(3):406-8, 411-4, 417-20; quiz 421-4.

USING MEDICAL-ERROR REPORTING TO DRIVE PATIENT SAFETY EFFORTS.

Stow J.

Abstract

IMPROVING PATIENT SAFETY has become one of the driving forces in health care delivery. Honest, accurate disclosure of medical errors and close calls is crucial to gain a better grasp of problems, make effective changes, and evaluate progress. ALTHOUGH FEAR OF MALPRACTICE litigation remains a major deterrent to medical-error reporting, disclosure allows organizations to benefit from one another's experiences. Accountability necessitates mandatory reporting to external organizations, but a wide variety of reporting systems exist, each with its own advantages and shortcomings. National standardized reporting is a major objective for the patient safety movement. STAFF MEMBER INVESTMENT is a key factor in the safety process and needs to extend beyond the reporting procedure.

PMID: 17004665

Milbank Q. 2006;84(3):459-92.

"HEALTH COURTS" AND ACCOUNTABILITY FOR PATIENT SAFETY

Mello MM, Studdert DM, Kachalia AB, Brennan TA.

Abstract

Proposals that medical malpractice claims be removed from the tort system and processed in an alternative system, known as administrative compensation or "health courts," attract considerable policy interest during malpractice "crises," including the current one. This article describes current proposals for the design of a health court system and the system's advantages for improving patient safety. Among these advantages are the cultivation of a culture of transparency regarding medical errors and the creation of mechanisms to gather and analyze data on medical injuries. The article discusses the experiences of foreign countries with administrative compensation systems for medical injury, including their use of claims data for research on patient safety; choices regarding the compensation system's relationship to physician disciplinary processes; and the proposed system's possible limitations.

PMID: 16953807

Arch Surg. 2006;141:931-939

WRONG-SIDE/WRONG-SITE, WRONG-PROCEDURE, AND WRONG-PATIENT ADVERSE EVENTS. ARE THEY PREVENTABLE?

Samuel C. Seiden, MD; Paul Barach, MD, MPH

Hypothesis: Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events (WSPEs) are devastating, unacceptable, and often result in litigation, but their frequency and root causes are unknown. Wrong-side/wrong-site, wrong-procedure, and wrong-patient events are likely more common than realized, with little evidence that current prevention practice is adequate.

Design: Analysis of several databases demonstrates that WSPEs occur across all specialties, with high numbersnoted in orthopedic and dental surgery. Databases analyzed included: (1) the National Practitioner Data Bank (NPDB), (2) the Florida Code 15 mandatory reporting system, (3) the American Society of Anesthesiologists (ASA) Closed Claims Project database, and (4) a novel Web-based system for collecting WSPE cases (http://www .wrong-side.org).

Results: TheNPDBrecorded 5940WSPEs(2217 wrongside surgical proceduresand3723wrong-treatment/wrongprocedure errors) in13years. FloridaCode15occurrences ofWSPEsnumber 494 since 1991, averaging 75 events per yearsince2000. TheASAClosedClaimsProjecth asrecorded 54cases ofWSPEs.Analysis ofWSPEcases,includingWSPE cases submitted to http://www.wrong-side.org, suggest several common causes of WSPEs and recurrent systemic failures.

Based on these findings, we estimate that there are 1300 to 2700 WSPEs annually in the United States. Despite a significant number of cases, reporting of WSPEs is virtually nonexistent, with reports in the lay press far more common than reports in the medical literature. Our research suggests clear factors that contribute to the occurrence of WSPEs, as well as ways to reduce them.

Conclusions: Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events, although rare, are more common than health care providers and patients appreciate.

Prevention ofWSPEsrequiresnewandinnovative technologies, reporting of case occurrence, and learning from successful safety initiatives (such as in transfusion medicine and other high-risk nonmedical industries), while reducing the shame associated with these events.

PMID: 16983037

Ann Surg. 2005 Nov;242(5):621-8.

EFFECTS OF A MALPRACTICE CRISIS ON SPECIALIST SUPPLY AND PATIENT ACCESS TO CARE

Mello MM, Studdert DM, DesRoches CM, Peugh J, Zapert K, Brennan TA, Sage WM.

Abstract
OBJECTIVE: To investigate specialist physicians' practice decisions in response to liability concerns and their perceptions of the impact of the malpractice environment on patient access to care.
SUMMARY BACKGROUND DATA: A perennial concern during "malpractice crises" is that liability costs will drive physicians in high-risk specialties out of practice, creating specialist shortages and access-to-care problems.
METHODS: Mail survey of 824 Pennsylvania physicians in general surgery, neurosurgery, orthopedic surgery, obstetrics/gynecology, emergency medicine, and radiology eliciting information on practice decisions made in response to rising liability costs.
RESULTS: Strong majorities of specialists reported increases over the last 3 years in patients' driving distances (58%) and waiting times (83%) for specialist care or surgery, waiting times for emergency department care (82%), and the number of patients forced to switch physicians (89%). Professional liability costs and managed care were both considered important contributing factors. Small proportions of specialists reported that they would definitely retire (7%) or relocate their practice out of state (4%) within the next 2 years; another third (32% and 29%, respectively) said they would likely do so. Forty-two percent of specialists have reduced or eliminated high-risk aspects of their practice, and 50% are likely to do so over the next 2 years.
CONCLUSIONS: Our data suggest that claims of a "physician exodus" from Pennsylvania due to rising liability costs are overstated, but the malpractice situation is having demonstrable effects on the supply of specialist physicians in affected areas and their scope of practice, which likely impinges upon patients' access to care.
PMID: 16244532
Comment in: *Annals of surgery. [Ann Surg. 2005]*

Account Res. 2005 Jul-Sep;12(3):163-91.

RESEARCHERS' VIEWS OF THE ACCEPTABILITY OF RESTRICTIVE PROVISIONS IN CLINICAL TRIAL AGREEMENTS WITH INDUSTRY SPONSORS

Mello MM, Clarridge BR, Studdert DM.

Abstract

We conducted a mail survey of 884 U.S. medical school faculty active in clinical research to elicit their views about the acceptability of provisions in contracts for industry-sponsored clinical trials that would restrict investigators' academic freedom and control over trials. We compared their responses to results from a similar survey of research administrators at 107 medical schools. There was substantial variation among clinical researchers in their acceptability judgments, with a relatively large proportion of clinical trial investigators willing to accept provisions that give industry sponsors considerable control over the dissemination of research results. There were significant differences in the perceptions of clinical trial investigators versus other recently published clinical researchers; investigators with a high versus low percentage of research support from industry; junior versus senior faculty; and investigators at institutions with high versus low National Institute of Health (NIH) funding ranks. There was also a significant divergence of views in a number of areas between clinical trialists and research administrators who negotiate clinical trial contracts on their behalf. Medical school faculty could benefit from additional guidance about what their institution views as acceptable parameters for industry-sponsored clinical trial agreements.

PMID: 16634168

JAMA. 2005 Jun 1;293(21):2609-17.

DEFENSIVE MEDICINE AMONG HIGH-RISK SPECIALIST PHYSICIANS IN A VOLATILE MALPRACTICE ENVIRONMENT

Studdert DM, Mello MM, Sage WM, DesRoches CM, Peugh J, Zapert K, Brennan TA.

Abstract

CONTEXT: How often physicians alter their clinical behavior because of the threat of malpractice liability, termed defensive medicine, and the consequences of those changes, are central questions in the ongoing medical malpractice reform debate.

OBJECTIVE: To study the prevalence and characteristics of defensive

medicine among physicians practicing in high-liability specialties during a period of substantial instability in the malpractice environment.

DESIGN, SETTING, AND PARTICIPANTS: Mail survey of physicians in 6 specialties at high risk of litigation (emergency medicine, general surgery, orthopedic surgery, neurosurgery, obstetrics/gynecology, and radiology) in Pennsylvania in May 2003.

MAIN OUTCOME MEASURES: Number of physicians in each specialty reporting defensive medicine or changes in scope of practice and characteristics of defensive medicine (assurance and avoidance behavior).

RESULTS: A total of 824 physicians (65%) completed the survey. Nearly all (93%) reported practicing defensive medicine. "Assurance behavior" such as ordering tests, performing diagnostic procedures, and referring patients for consultation, was very common (92%). Among practitioners of defensive medicine who detailed their most recent defensive act, 43% reported using imaging technology in clinically unnecessary circumstances. Avoidance of procedures and patients that were perceived to elevate the probability of litigation was also widespread. Forty-two percent of respondents reported that they had taken steps to restrict their practice in the previous 3 years, including eliminating procedures prone to complications, such as trauma surgery, and avoiding patients who had complex medical problems or were perceived as litigious. Defensive practice correlated strongly with respondents' lack of confidence in their liability insurance and perceived burden of insurance premiums.

CONCLUSION: Defensive medicine is highly prevalent among physicians in Pennsylvania who pay the most for liability insurance, with potentially serious implications for cost, access, and both technical and interpersonal quality of care.

PMID: 15928282

Comment in *Tort reform and the patient safety movement: seeking common ground. [JAMA. 2005]*

JAMA. 2005 Jun 1;293(21):2618-25.

IMPACT OF MALPRACTICE REFORMS ON THE SUPPLY OF PHYSICIAN SERVICES

Kessler DP, Sage WM, Becker DJ.

Abstract

CONTEXT: Proponents of restrictions on malpractice lawsuits claim that tort reform will improve access to medical care.

OBJECTIVE: To estimate the effects of changes in state malpractice law on the supply of physicians.

DESIGN: Differences-in-differences regression analysis that matched data on the number of physicians in each state between 1985 and 2001 from the American Medical Association's Physician Masterfile with data on state tort laws and state demographic, political, population, and health care market characteristics.

MAIN OUTCOME MEASURE: Effect on physician supply of "direct" malpractice reforms that reduce the size of awards (eg, caps on damages).

RESULTS: The adoption of "direct" malpractice reforms led to greater growth in the overall supply of physicians. Three years after adoption, direct reforms increased physician supply by 3.3%, controlling for fixed differences across states, population, states' health care market and political characteristics, and other differences in malpractice law. Direct reforms had a larger effect on the supply of nongroup vs group physicians, on the supply of most (but not all) specialties with high malpractice insurance premiums, on states with high levels of managed care, and on supply through retirements and entries than through the propensity of physicians to move between states. Direct reforms had similar effects on less experienced and more experienced physicians.

CONCLUSION: Tort reform increased physician supply. Further research is needed to determine whether reform-induced increases in physician supply benefited patients.

PMID: 15928283

Comment in *Tort reform and the patient safety movement: seeking common ground. [JAMA. 2005]*

JAMA. 2005 Jun 1;293(21):2660-2.

TORT REFORM AND THE PATIENT SAFETY MOVEMENT: SEEKING COMMON GROUND

Budetti PP.

Extract

According to Sage, "doctors hate malpractice suits . . . passionately and continuously. . . . Eliminating malpractice suits takes precedence over every other political objective. . . . No contradictory belief, however well-reasoned, empirically based, or sincerely held, succeeds in crowding out antipathy toward malpractice from physicians' minds. Not the large number of patients who die unnecessarily each year from medical errors; not the desirability of allowing patients to sue [health maintenance organizations] HMOs for improper care."

Sage's vivid depiction of the profession's bilious antagonism toward medical malpractice provides important context for drawing lessons from 2 articles in this issue of JAMA that explore the behavior of physicians in specialists that pay the highest malpractice insurance premiums and have the greatest risk of being sued. The study by Studdert et al. reveals the extraordinary extent to which physicians report going against their own clinical judgment in the hope of minimizing their malpractice exposure. The study by Kessler et al. finds evidence that certain tort reforms enhance the likehood of high-risk physicians practicing in states enacting those reforms. Each study provides insight into attitudes towards malpractice and even towards practicing medicine, and underscores the need for new approaches to both tort reform and the patient safety movement.

PMID: 15928290

Comment on *Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. [JAMA. 2005] - Impact of malpractice reforms on the supply of physician services. [JAMA. 2005]*

Cornell Law Review. 2005; 90:893-994

IN THE U.S.: IS MALPRACTICE LIABILITY PART OF THE PROBLEM OR PART OF THE SOLUTION?

Hymant DA, Silvertt C

Abstract

The conventional wisdom among patient safety advocates and legal scholars is that medical malpractice lawsuits impede efforts to improve health care quality bry encouraging providers to hide mistakes. This belief provides the normative basis for ongoing state and federal

efforts to curtail medical malpractice exposure. Groups pressing for tort reform, including the American Medical Association, contend that when doctors and other providers are insulated from liability, patients will be better protected from harm. This Article canvasses the evidence bearing on the connections between malpractice exposure, error reporting, and health care quality, and concludes that the conventional wisdom is wrong. Some evidence, such as the Harvard Medical Practice Study and the history of anesthesia safety, shows that the quality of health care improves as the risk of being sued rises. No evidence shows that malpractice lawsuits cause the quality of health care to decline. Nor does any rigorous evidence show that fear of malpractice lawsuits discourages error reporting-to the contrary, the historical record suggests that liability risk has encouraged providers to discuss treatment risks with patients. Generally, the frequencies with which providers report errors after they occur and discuss errors with patients correlate poorly with liability risk. Thus, there is no foundation for the widely held belief that fear of malpractice liability impedes efforts to improve the reliability of health care delivery systems. Health care error rates are higher than they should be not because providers fear malpractice liability, but because providers have defective incentives and norms. Since providers often lose money when quality improves, there is no "business case for quality." Moreover, providers' norms and attitudes, which are often highly punitive, impede efforts to improve quality by discouraging the creation of work environments in which error-reporting and other predicates for quality improvement can flourish. The tort system's major deficiency lies in its failure to subject providers to sufficient economic pressure to overcome these defective incentives and norms. The main cause of this shortcoming is the rarity with which injured patients assert their claims.

Limiting malpractice liability will not protect patients from harm, and may well have the opposite effect. In fact, contrary to the conventional wisdom, malpractice liability itself has the potential to kick-start quality improvement.

This Article concludes with a series of recommendations for improving the tort system's potential to encourage quality improvement. The recommendations include new arrangements for error reporting, rewards for making error reports, immunity for providers that follow treatment guidelines, and allowing insurance premiums to rise. In combination, these recommendations create both carrots and sticks encouraging providers to protect patients from harm.

Miller's Anesthesia, 6th ed. Philadelphia: Elsevier Churchill Livingstone, 2005, pp 3021-3072

HUMAN PERFORMANCE AND PATIENT SAFETY

Rall M & Gaba D. In Miller R (ed.),

Extract

Key Points

1. Clinical excellence is not achieved only by the use of sound medical knowledge. Human factors and the interaction of team members, as well as organizational conditions in the system of care, also play a major role. Therefore, the study of human performance and related organizational matters is very important.
2. The health care system in general and clinical institutions in particular must provide appropriate organizational characteristics to allow and foster safe patient care practices (e.g., improve safety culture, integrate effective incident reporting and analysis systems).
3. High-reliability organization theory describes the key features of systems that conduct complex and hazardous work with very low failure rates. Errors do occur in such organizations, but their systems make them more impervious to errors and their sequelae (resilience).
4. In dynamic domains such as anesthesia, continuous decision-making, as described in the cognitive process model, is critical to achieving safe patient care.
5. Several error mechanisms have been demonstrated through human factors research. Understanding these psychological "traps" (for example, "fixation errors") can help anesthetists avoid or mitigate them.
6. The introduction and spread of crisis resource management training, including the application of realistic simulation exercises, is likely to improve patient safety in anesthesia and other acute care domains.
7. Like all human beings, the performance of individual anesthetists can be adversely influenced by "performance-shaping factors,"including noise, illness, aging, and especially sleep deprivation and fatigue.
8. A particular technique of human factors research called "task analysis" has been useful in understanding the work of anesthetists.
9. Observation of anesthetists during routine operations or in the handling of adverse events (using realistic patient simulators) has improved our knowledge of critical decision-making and team interactions.
10. Future progress on patient safety in anesthesia will require interdisciplinary research and training, improvements in systems safety and organizational learning, and the involvement of all levels of the health care industry.

J Health Econ. 2004 Sep;23(5):935-49.

TO ERR ON HUMANS IS NOT BENIGN. INCENTIVES FOR ADOPTION OF MEDICAL ERROR-REPORTING SYSTEMS

Zivin JG, Pfaff AS.

Abstract

Concerns about frequent and harmful medical errors have led policy makers to advocate the creation of a system for medical error reporting. Health providers, fearing that reported information about errors would be used against them under the current medical malpractice system, have been reluctant to participate in such reporting systems. We propose a re-design of the malpractice system -- one in which penalties are a function of the health provider's reporting efforts -- to overcome this incentive problem. We also consider some alternatives to this mechanism that address two important ways in which reporting effort may not be observable: hospitals may have interests distinct from individual physicians and may not be able to observe their reporting efforts, and a regulatory agency or a court may not be able to adequately observe reporting efforts by a provider.

PMID: 15353187

Arch Intern Med. 2004 Aug 9-23;164(15):1690-7.

COMMUNICATING WITH PATIENTS ABOUT MEDICAL ERRORS: A REVIEW OF THE LITERATURE

Mazor KM, Simon SR, Gurwitz JH.

Abstract

BACKGROUND: Ethical and professional guidelines recommend disclosure of medical errors to patients. The objective of this study was to review the empirical literature on disclosure of medical errors with respect to (1) the decision to disclose, (2) the process of informing the patient and family, and (3) the consequences of disclosure or nondisclosure.

METHODS: We searched 4 electronic databases (MEDLINE, CINAHL, PsycINFO, and Social Sciences Citations Index) and the reference lists of relevant articles for English-language studies on disclosure of medical errors. From more than 800 titles reviewed, we identified 17 articles reporting original empirical data on disclosure of medical errors to patients and families. We examined methods and results of the articles and extracted study designs, data collection procedures,

populations sampled, response rates, and definitions of error.
RESULTS: Available research findings suggest that patients and the public support disclosure. Physicians also indicate support for disclosure, but often do not disclose. We found insufficient empirical evidence to support conclusions about the disclosure process or its consequences.
CONCLUSIONS: Empirical research on disclosure of medical errors to patients and families has been limited, and studies have focused primarily on the decision stage of disclosure. Fewer have considered the disclosure process, the consequences of disclosure, or the relationship between the two. Additional research is needed to understand how disclosure decisions are made, to provide guidance to physicians on the process, and to help all involved anticipate the consequences of disclosure.
PMID: 15302641

Int J Qual Health Care. 2004 Aug;16(4):317-26.

WHAT MAKES AN ERROR UNACCEPTABLE? A FACTORIAL SURVEY ON THE DISCLOSURE OF MEDICAL ERRORS

Schwappach DL, Koeck CM.

Abstract
BACKGROUND: Although the importance of disclosing medical errors to patients has been argued, little is known about the relative effect of different attributes of error handling and communication on patients' judgments about errors.
OBJECTIVES: This study investigates how different characteristics of medical errors and of physicians' subsequent handling of errors contribute to patients' evaluations of the incident and their attitudes towards potential consequences and sanctions for the physician.
MATERIALS AND METHODS: A factorial survey using the vignette technique presented hypothetical scenarios involving medical errors to members of the general public in an Internet-based study. Members of a German Internet survey panel participated (n = 1017). Multiple ordered logistic regression models were estimated to explain citizens' judgments of error severity and their attitudes towards reporting of errors, wishing for referral to another physician, and supporting sanctions against the health professional involved as a response to characteristics of the presented errors.
RESULTS: While the severity of the outcomes of errors remains the most important single factor in the choice of actions to be taken, the

professional's approach to the error is regarded as essential in the overall evaluation of errors and the consideration of consequences. In errors with a severe outcome, an honest, empathic, and accountable approach to the error decreases the probability of participants' support for strong sanctions against the physician involved by 59%. Judgments were only marginally affected by respondents' characteristics.
CONCLUSIONS: The handling of errors strongly contributes to citizens' choice of actions to be taken, and they are sensitive to failures to name the incident as an 'error'. For the success of de-individualized, systems-oriented approaches to errors, communication of clear accountability to patients will be crucial.
PMID: 15252006

Arch Intern Med. 2004 Aug 9-23;164(15):1690-7.

COMMUNICATING WITH PATIENTS ABOUT MEDICAL ERRORS: A REVIEW OF THE LITERATURE

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PMID: 15302641

Am J Manag Care. 2004 Apr;10(4):281-4.

MALPRACTICE PREVENTION, PATIENT SAFETY, AND QUALITY OF CARE: A CRITICAL LINKAGE

Pawlson LG, O'Kane ME.

Abstract
There is growing evidence of a negative effect of the current American preoccupation with malpractice on efforts to reduce error, enhance safety, and improve other domains of quality. The use by some insurers of systems assessment and risk analysis programs, linked to rewards for performance--which, taken together, we term proactive risk management--offers an opportunity to enhance our focus on systems and to bring patient safety and malpractice risk reduction into close congruence with other quality improvement efforts. Given the increasing burden of malpractice, as well as the emerging concerns about patient safety, managed care organizations and their providers need to work together with malpractice insurers and quality improvement experts to refocus their efforts on creating systems improvement; driving measurement, analysis, and feedback; and developing incentives for performance that will align quality and risk management efforts and drive breakthroughs in quality, including patient safety.
PMID: 15124505

Health Aff (Millwood). 2003 Nov-Dec;22(6):207-16.

THE MCLAWSUIT: THE FAST-FOOD INDUSTRY AND LEGAL ACCOUNTABILITY FOR OBESITY

Mello MM, Rimm EB, Studdert DM.

Abstract
Recent litigation brought by a group of overweight children against the McDonald's Corporation that seeks compensation for obesity-related health problems has provoked an intense public response. Many have derided this lawsuit as representing the worst excesses

of the tort liability system, while others have drawn parallels to tobacco litigation. Fast-food litigation raises the question of where accountability for the economic and public health consequences of obesity properly rests. In this paper we consider the reasonableness of the claims against fast-food companies and discuss several social effects that the litigation may have irrespective of its outcome in court.
PMID: 14649448

Crit Care Med. 2003 Aug;31(8):2107-17.

RESULTS OF A CLINICAL TRIAL ON CARE IMPROVEMENT FOR THE CRITICALLY ILL

Burns JP, Mello MM, Studdert DM, Puopolo AL, Truog RD, Brennan TA.

Abstract
OBJECTIVE: To develop, deploy, and evaluate an intervention designed to identify and mitigate conflict in decision making in the intensive care unit.
DESIGN: Nonrandomized, controlled trial.
SETTING: Seven intensive care units at four Boston teaching hospitals.
PATIENTS: A total of 1,752 critically ill patients, including 873 study cases analyzed here.
INTERVENTION: Social workers interviewed families of patients deemed at high risk for decisional conflict and provided feedback to the clinical team, who then implemented measures to address the problems identified.
MEASUREMENTS AND MAIN RESULTS: Patient or surrogate satisfaction with intensive care unit care and the probability of choosing a specific plan for treatment in the intensive care unit was studied. Inclusion criteria identified 873 patients at risk for decisional conflict. Thirty-nine percent of the patients in the intervention phase of the study (172 patients) received the intervention. In multivariate analyses, receiving the intervention significantly increased the likelihood of deciding to forgo resuscitation (odds ratio [OR] = 1.81, p =.017), the likelihood of choosing a treatment plan for comfort-care only (OR = 1.94, p =.018), and the likelihood of choosing an aggressive-care treatment plan (OR = 2.30, p =.002). Receiving the intervention did not significantly affect overall satisfaction with the care provided (OR = 0.68, p =.14), satisfaction with the amount of information provided (OR = 0.86, p =.44), or satisfaction with the degree of involvement in

decision making (OR = 0.84, p =.54).
CONCLUSIONS: Although there was no impact on patient or surrogate satisfaction with care provided in the intensive care unit, the intervention did facilitate deliberative decision making in cases deemed at high risk for conflict. The lessons learned from the experience with this intervention should be helpful in ongoing efforts to improve care and to achieve outcomes desired by critically ill patients, their families, and critical care clinicians.
PMID: 12973167

Pediatrics. 2003 Sep;112(3 Pt 1):553-8.

NATURE OF CONFLICT IN THE CARE OF PEDIATRIC INTENSIVE CARE PATIENTS WITH PROLONGED STAY

Studdert DM, Burns JP, Mello MM, Puopolo AL, Truog RD, Brennan TA.

Abstract
OBJECTIVE: To determine the frequency, types, sources, and predictors of conflict surrounding the care of pediatric intensive care unit (PICU) patients with prolonged stay.
SETTING: A tertiary care, university-affiliated PICU in Boston.
PARTICIPANTS: All patients admitted over an 11-month period whose stay exceeded 8 days (the 85th percentile length of stay for the PICU under study), and intensive care physicians and nurses who were responsible for their care.
METHODS: We prospectively identified conflicts by interviewing the treating physicians and nurses at 2 stages during the patients' PICU stay. All conflicts detected were classified by type (team-family, intrateam, or intrafamily) and source. Using a case-control design, we then identified predictors of conflict through bivariate and multivariate analyses.
RESULTS: We enrolled 110 patients based on the length-of-stay criterion. Clinicians identified 55 conflicts involving 51 patients in this group. Hence, nearly one half of all patients followed had a conflict associated with their care. Thirty-three of the conflicts (60%) were team-family, 21 (38%) were intrateam, and the remaining 1 was intrafamily. The most commonly cited sources of team-family conflict were poor communication (48%), unavailability of parents (39%), and disagreements over the care plan (39%). Medicaid insurance status was independently associated with the occurrence of conflict generally (odds ratio = 4.97) and team-family conflict specifically (odds ratio = 7.83).

CONCLUSIONS: Efforts to reduce and manage conflicts that arise in the care of critically ill children should be sensitive to the distinctive features of these conflicts.
Knowledge of risk factors for conflict may also help to target such interventions at the patients and families who need them most.
PMID: 12949283

Intensive Care Med. 2003 Sep;29(9):1489-97. Epub 2003 Jul 19.

CONFLICT IN THE CARE OF PATIENTS WITH PROLONGED STAY IN THE ICU: TYPES, SOURCES, AND PREDICTORS

Studdert DM, Mello MM, Burns JP, Puopolo AL, Galper BZ, Truog RD, Brennan TA.

Abstract
OBJECTIVE: To determine types, sources, and predictors of conflicts among patients with prolonged stay in the ICU.
DESIGN: We prospectively identified conflicts by interviewing treating physicians and nurses at two stages during the patients' stays. We then classified conflicts by type and source and used a case-control design to identify predictors of team-family conflicts.
SETTING: Seven medical and surgical ICUs at four teaching hospitals in Boston, USA.
PATIENTS: All patients admitted to the participating ICUs over an 11-month period whose stay exceeded the 85th percentile length of stay for their respective unit (n=656).
MEASUREMENTS AND RESULTS: Clinicians identified 248 conflicts involving 209 patients; hence, nearly one-third of patients had conflict associated with their care: 142 conflicts (57%) were team-family disputes, 76 (31%) were intrateam disputes, and 30 (12%) occurred among family members. Disagreements over life-sustaining treatment led to 63 team-family conflicts (44%). Other leading sources were poor communication (44%), the unavailability of family decision makers (15%), and the surrogates' (perceived) inability to make decisions (16%). Nurses detected all types of conflict more frequently than physicians, especially intrateam conflicts. The presence of a spouse reduced the probability of team-family conflict generally (odds ratio 0.64) and team-family disputes over life-sustaining treatment specifically (odds ratio 0.49).
CONCLUSIONS: Conflict is common in the care of patients with prolonged stays in the ICU. However, efforts to improve the quality of care for critically ill patients that focus on team-family disagreements over life-sustaining treatment miss significant discord in a variety of other areas.
PMID: 12879243

Ann Intern Med. 2003 Jul 1;139(1):40-5.

THE RISE OF LITIGATION IN HUMAN SUBJECTS RESEARCH

Mello MM, Studdert DM, Brennan TA.

Abstract

Owing to widespread public concern about the adequacy of protections for human research subjects and recent instances of serious injury to subjects at several major research institutions, lawsuits against investigators, institutional review boards, and academic institutions are becoming increasingly common. Several claim-promoting conditions are ripe to promote the further growth of this litigation and raise the stakes for research institutions. While this litigation may serve a valuable compensation function for injured subjects, it will also have profound effects on institutional review boards, leading to a more legalistic, mechanistic approach to ethical review that does not further the interests of human subjects or scientific progress.

PMID: 12834317

Comment in: *Minimizing risk in clinical research. [Ann Intern Med. 2003] - The rise of litigation in human subjects research. [Ann Intern Med. 2004]*

Health Aff (Millwood). 2003 Jul-Aug;22(4):26-36.

MEDICAL LIABILITY AND PATIENT SAFETY

Sage WM.

Abstract

Political debate over medical malpractice reform seldom takes meaningful account of its policy context, including the emerging science of patient safety. Instead, stakeholders on both sides use the rhetoric of patient safety to support entrenched positions on hardened proposals such as capping damages and limiting access to information about errors. Despite its déjà vu quality, the current malpractice crisis can only be understood and addressed as the product of changes in the health care system since the last crisis nearly twenty years ago--changes that also informed the patient safety movement. Patient safety may therefore serve as a bridge between medical liability and health policy.

PMID: 12889746

Comment in: *Creating a safe environment. [Health Aff (Millwood). 2003] - The medical liability crisis of 2003: must we squander the chance to put patients first? [Health Aff (Millwood). 2003]*

Br J Anaesth. 2003 May;90(5):580-8.

ANAESTHETISTS' NON-TECHNICAL SKILLS (ANTS): EVALUATION OF A BEHAVIOURAL MARKER SYSTEM

Fletcher G, Flin R, McGeorge P, Glavin R, Maran N, Patey R.

Abstract

BACKGROUND: Non-technical skills are critical for good anaesthetic practice but are not addressed explicitly in normal training. Realization of the need to train and assess these skills is growing, but these activities must be based on properly developed skills frameworks and validated measurement tools. A prototype behavioural marker system was developed using human factors research techniques. The aim of this study was to conduct an experimental evaluation to establish its basic psychometric properties and usability.

METHOD: The Anaesthetists' Non-Technical Skills (ANTS) system prototype comprises four skill categories (task management, team working, situation awareness, and decision making) divided into 15 elements, each with example behaviours. To investigate its experimental validity, reliably and usability, 50 consultant anaesthetists were trained to use the ANTS system. They were asked to rate the behaviour of a target anaesthetist using the prototype system in eight videos of simulated anaesthetic scenarios. Data were collected from the ratings forms and an evaluation questionnaire.

RESULTS: The results showed that the system is complete, and that the skills are observable and can be rated with acceptable levels of agreement and accuracy. The internal consistency of the system appeared sound, and responses regarding usability were very positive.

CONCLUSIONS: The findings of the evaluation indicated that the ANTS system has a satisfactory level of validity, reliability and usability in an experimental setting, provided users receive adequate training. It is now ready to be tested in real training environments, so that full guidelines can be developed for its integration into the anaesthetic curriculum.

PMID: 12697584

Obstet Gynecol. 2003 Apr;101(4):751-5.

REDUCED MEDICOLEGAL RISK BY COMPLIANCE WITH OBSTETRIC CLINICAL PATHWAYS: A CASE--CONTROL STUDY

Ransom SB, Studdert DM, Dombrowski MP, Mello MM, Brennan TA.

Abstract

OBJECTIVE: To estimate whether guideline compliance affected medicolegal risk in obstetrics and whether malpractice claims data can provide useful information on guideline noncompliance by focusing on the claims experience of a large health system delivering approximately 12000 infants annually.

METHODS: We retrospectively identified 290 delivery-related (diagnosis-related groups 370-374) malpractice claims and 262 control deliveries at the health system during the period from 1988 to 1998. Clinical pathways for vaginal and cesarean delivery implemented in 1998 were used as a "standard of care." We compared rates of noncompliance with the pathways in the claims and control groups, calculated an odds ratio for increased risk of being sued given departure from the guideline standards, and calculated the elevated risk of litigation introduced by noncompliance. We also compared the frequencies of different types of departures across claims and control groups.

RESULTS: Claims closely resembled controls on several descriptive measures (mother's age, location of delivery, type of delivery, and complication rates), but noncompliance with the clinical pathway was significantly more common among claims than controls (43.2% versus 11.7%, P <.001; odds ratio = 5.76, 95% confidence interval 3.59, 9.2). In 81 (79.4%) of the claims involving noncompliance with the pathway, the main allegation in the claim related directly to the departure from the pathway. The excess malpractice risk attributable to noncompliance explained approximately one third (104 of 290) of the claims filed (attributable risk = 82.6%). There were no significant differences in the types of deviation from the guidelines across claims and control groups.

CONCLUSION: In addition to reducing clinical variation and improving clinical quality of care, adherence to clinical pathways might protect clinicians and institutions against malpractice litigation. Malpractice data might also be a useful resource in understanding breakdowns in processes of care.

PMID: 12681881

JAMA. 2003 Feb 19;289(7):889-94.

MEDICAL MONITORING FOR PHARMACEUTICAL INJURIES: TORT LAW FOR THE PUBLIC'S HEALTH?

Studdert DM, Mello MM, Brennan TA.

Abstract
A remarkable development in personal injury litigation in recent years involves attempts to expand legal claims beyond existing injuries to anticipated future harms. Attorneys have begun to sue on behalf of individuals exposed to defective pharmaceutical products who have no current injury, but who may be at risk for developing one after a latency period. This strategy seeks to make drug manufacturers pay for medical monitoring, a court-ordered program that provides diagnostic tests to exposed individuals to facilitate early detection of adverse health effects. Because medical monitoring does not depend on the existence of an actual injury and large populations may be exposed, some commentators have warned that it has the potential to spiral out of control. We examine medical monitoring in the context of 2 major cases involving diet drugs and an oral hypoglycemic drug. We conclude that this expansion of tort law should be applied sparingly, but that the performance of courts to date in these cases gives cause for optimism. Judges appear to be paying close attention to sophisticated epidemiological, clinical, and cost-effectiveness considerations. Medical monitoring arms the courts with a new mechanism for addressing harms proactively rather than reactively, which could yield new victories for public health.
PMID: 12588274

Online J Issues Nurs. 2003;8(3):2.

HEALTH SYSTEMS' ACCOUNTABILITY FOR PATIENT SAFETY

Keepnews D, Mitchell PH.

Abstract
Patient safety experts, including the Institute of Medicine Committee on Quality of Health Care in America, have emphasized the need to focus on systems failure as the source of most error in health care. This requires an emphasis on prevention and on health systems' accountability for error. This article discusses traditional and evolving approaches to systems' accountability for error. While there are some significant recent developments, such as the JCAHO new Patient

Safety Goals, many issues remain about how to determine and enforce systems' accountability for error. These include identifying what systems will be held accountable for and how accountability will be enforced. While reporting of errors is one route toward accountability, many questions remain regarding the most effective approach toward error reporting. Research on and evaluation of reporting systems and other approaches toward systems' accountability will be important in moving forward in this area.
PMID: 14656192

Unfallchirurg. 2002 Nov;105(11):1033-42.

INNOVATIVE TRAINING FOR ENHANCING PATIENT SAFETY. SAFETY CULTURE AND INTEGRATED CONCEPTS

[Article in German]

Rall M, Schaedle B, Zieger J, Naef W, Weinlich M.

Abstract
INTRODUCTION: Patient safety is determined by the performance safety of the medical team. Errors in medicine are amongst the leading causes of death of hospitalized patients. These numbers call for action. Backgrounds, methods and new forms of training are introduced in this article.
METHOD: Concepts from safety research are transformed to the field of emergency medical treatment. Strategies from realistic patient simulator training sessions and innovative training concepts are discussed.
RESULTS: The reasons for the high numbers of errors in medicine are not due to a lack of medical knowledge, but due to human factors and organisational circumstances. A first step towards an improved patient safety is to accept this. We always need to be prepared that errors will occur. A next step would be to separate "error" from guilt (culture of blame) allowing for a real analysis of accidents and establishment of meaningful incident reporting systems. Concepts with a good success record from aviation like "crew resource management" (CRM) training have been adapted my medicine and are ready to use. These concepts require theoretical education as well as practical training. Innovative team training sessions using realistic patient simulator systems with video taping (for self reflexion) and interactive debriefing following the sessions are very promising.
CONCLUSION: As the need to reduce error rates in medicine is very high and the reasons, methods and training concepts are known, we are urged to implement these new training concepts widely and consequently. To err is human - not to counteract it is not.
PMID: 12402130

Acad Emerg Med. 2002 Nov;9(11):1156-61.

MEDICAL ERRORS-WHAT AND WHEN: WHAT DO PATIENTS WANT TO KNOW?

Hobgood C, Peck CR, Gilbert B, Chappell K, Zou B.

Abstract

OBJECTIVES: 1) To determine how and when emergency department (ED) patients and their families wish to learn of health care errors. 2) To assess the error threshold this population believes should trigger reporting to government agencies, state medical boards, and hospital patient safety committees. 3) To evaluate the role patients and families believe medical educators should play in this process.

METHODS: A 12-item survey was administered to a convenience sample of ED patients and families during evaluation in a tertiary care academic ED. Results were tabulated and data were reported as percentages. Statistical significance was analyzed using the chi-square test.

RESULTS: 258 surveys were returned (80%). A majority of respondents wished to be informed immediately of any medical error (76%) and to have full disclosure of the error's extent (88%). An overwhelming majority of respondents endorse reporting of errors to government agencies (92%), state medical boards (97%), and hospital committees (99%). Most respondents believe medical educators should focus on teaching students to be honest and compassionate (38%) or on how to tell patients about mistakes (25%). The frequency of hospital admission or physician visits per year had no impact on any response pattern (ns with chi(2) test).

CONCLUSIONS: Regardless of health care utilization, a majority of respondents want full disclosure of medical error and wish to be informed of error immediately upon its detection. Respondents support reporting of errors to government agencies, the state medical board, and hospital committees focused on patient safety. Teaching physicians error disclosure techniques, honesty, and compassion were endorsed as a priority for educators who teach error management.

PMID: 12414464

Qual Saf Health Care. 2002 Sep;11(3):266-9.

LESSONS LEARNED FROM NON-MEDICAL INDUSTRIES: ROOT CAUSE ANALYSIS AS CULTURE CHANGE AT A CHEMICAL PLANT

Carroll JS, Rudolph JW, Hatakenaka S.

Abstract
Root cause analysis was introduced to a chemical plant as a way of enhancing performance and safety, exemplified by the investigation of an explosion. The cultural legacy of the root cause learning intervention was embodied in managers' increased openness to new ideas, individuals' questioning attitude and disciplined thinking, and a root cause analysis process that provided continual opportunities to learn and improve. Lessons for health care are discussed, taking account of differences between the chemical and healthcare industries.
PMID: 12486993

J Crit Care. 2002 Jun;17(2):86-94.

ICU INCIDENT REPORTING SYSTEMS

Wu AW, Pronovost P, Morlock L.

Abstract
Intensive care is one of the largest and most expensive components of American health care. Studies suggest that errors and resulting adverse events are common in intensive care units (ICUs). The incidence may be as high as 2 errors per patient per day; 1 in 5 ICU patients may sustain a serious adverse event, and virtually all are exposed to serious risk for harm. Theories of error developed in aviation and other high-risk industries suggest that errors are likely to occur in all complex systems. Reporting of incidents, including both adverse events and near misses, is an essential component for improving safety. Voluntary, confidential reporting is likely to be more important than mandatory reporting. There have been a few efforts to apply such systems in medicine. In intensive care, the Australian Incident Monitoring System (AIMS)-ICU has been the most prominent. We have designed a Web-based ICU Safety Reporting System (ICUSRS). The goal is to identify high-risk situations and working conditions, to help change systems, and reduce the risk for error. The analysis and feedback of reports will inform the design of interventions to improve patient safety. The effort is aided substantially by collaboration with the 30 participating ICUs and important stakeholders including the Society of Critical Care Medicine, the American Society for Health-

care Risk Management, the Food and Drug Administration Center for Devices and Radiological Health, the Foundation for Accountability, and the Leapfrog Group. A demonstration and evaluation of the system is underway, funded by the Agency for Healthcare Re-search and Quality.
PMID: 12096371

Nihon Geka Gakkai Zasshi. 2002 Mar;103(3):309-13.

STATE OF THE ART AND PROBLEMS IN MEDICAL SAFETY MANAGEMENT

[Article in Japanese]

Furukawa T, Kitajima M.

Abstract

The principle of medical safety management is to build a safe medical system that is equipped to prevent patient injuries due to medical errors occurring in it and not to attribute them only to individual responsibility. Methodologically, this means identifying and reducing the potential risk of medical errors by systematic reporting and tracking of errors and near misses. According to some major clinical studies on medical malpractice in the USA, the incidence of medical accidents is reported to be 3-5%, 30% of which were due to negligence, and 7-14% resulted in patients' deaths. It is also reported that 66% of the medical accidents occurred in surgical specialties and 45% were related to surgeries, which were shown to have the highest risk of medical accidents. On the other hand, according to a nationwide survey on reported errors and near misses in Japan, 50% were related to drugs, especially injections. Other major causes reported in the study were manipulation and management of medical instruments, downfalls of patients, and aspiration. These safety problems listed above were shown to compose 95% of all of medical errors and near misses. To establish a rational safety management system, it is necessary to develop research methods appropriate for the study of medical errors, which facilitate clinical research, and can be expected to yield sufficient scientific data. A generalized guideline for voluntary reporting of patients' deaths and injuries due to medical errors, in relation to Article 21 of the Doctors' Law should be established. However, for essential improvement of transparency and accountability in medicine, it is necessary to set up a new specialized institute to accept reports on medical errors, give hospitals advice for a safer medical system, and disclose information on medical errors. Moreover, such an institute should continue to study medical safety by

analyzing nationwide reports of medical errors and near misses. For the latter purpose, legal protection of the disclosure of information must be assured.
PMID: 11968763

Health Technol Assess. 2001;5(22):1-194.

THE MEASUREMENT AND MONITORING OF SURGICAL ADVERSE EVENTS

Bruce J, Russell EM, Mollison J, Krukowski ZH.

Abstract
BACKGROUND: Surgical adverse events contribute significantly to postoperative morbidity, yet the measurement and monitoring of events is often imprecise and of uncertain validity. Given the trend of decreasing length of hospital stay and the increase in use of innovative surgical techniques--particularly minimally invasive and endoscopic procedures--accurate measurement and monitoring of adverse events is crucial.
OBJECTIVES: The aim of this methodological review was to identify a selection of common and potentially avoidable surgical adverse events and to assess whether they could be reliably and validly measured, to review methods for monitoring their occurrence and to identify examples of effective monitoring systems for selected events. This review is a comprehensive attempt to examine the quality of the definition, measurement, reporting and monitoring of selected events that are known to cause significant postoperative morbidity and mortality. METHODS - SELECTION OF SURGICAL ADVERSE EVENTS: Four adverse events were selected on the basis of their frequency of occurrence and likelihood of evidence of measurement and monitoring: (1) surgical wound infection; (2) anastomotic leak; (3) deep vein thrombosis (DVT); (4) surgical mortality. Surgical wound infection and DVT are common events that cause significant postoperative morbidity. Anastomotic leak is a less common event, but risk of fatality is associated with delay in recognition, detection and investigation. Surgical mortality was selected because of the effort known to have been invested in developing systems for monitoring surgical death, both in the UK and internationally. Systems for monitoring surgical wound infection were also included in the review. METHODS - LITERATURE SEARCH: Thirty separate, systematic literature searches of core health and biomedical bibliographic databases (MEDLINE, EMBASE, CINAHL, HealthSTAR and the Cochrane Library) were conducted. The reference lists of retrieved

articles were reviewed to locate additional articles. A matrix was developed whereby different literature and study designs were reviewed for each of the surgical adverse events. Each article eligible for inclusion was independently reviewed by two assessors. METHODS - CRITICAL APPRAISAL: Studies were appraised according to predetermined assessment criteria. Definitions and grading scales were assessed for: content, criterion and construct validity; repeatability; reproducibility; and practicality (surgical wound infection and anastomotic leak). Monitoring systems for surgical wound infection and surgical mortality were assessed on the following criteria: (1) coverage of the system; (2) whether or not denominator data were collected; (3) whether standard and agreed definitions were used; (4) inclusion of risk adjustment; (5) issues related to data collection; (6) postdischarge surveillance; (7) output in terms of feedback and wider dissemination. RESULTS - SURGICAL WOUND INFECTION: A total of 41 different definitions and 13 grading scales of surgical wound infection were identified from 82 studies. Definitions of surgical wound infection varied from presence of pus to complex definitions such as those proposed by the Centres for Disease Control in the USA. A small body of literature has been published on the content, criterion and construct validity of different definitions, and comparisons have been made against wound assessment scales and multidimensional indices. There are examples of comprehensive hospital-based monitoring systems of surgical wound infection, mainly under the auspices of nosocomial surveillance. To date, however, there is little evidence of systematic measurement and monitoring of surgical wound infection after hospital discharge. RESULTS - ANASTOMOTIC LEAK: Over 40 definitions of anastomotic leak were extracted from 107 studies of upper gastrointestinal, hepatopancreaticobiliary and lower gastrointestinal surgery. No formal evaluations were found that assessed the validity or reliability of definitions or severity scales of anastomotic leak. One definition was proposed during a national consensus workshop, but no evidence of its use was found in the surgical literature. The lack of a single definition or gold standard hampers comparison of postoperative anastomotic leak rates between studies and institutions. RESULTS - DEEP VEIN THROMBOSIS: Although a critical review of the DVT literature could not be completed within the realms of this review, it was evident that a number of new techniques for the detection and diagnosis of DVT have emerged in the last 20 years. The group recommends a separate review be undertaken of the different diagnostic tests to detect DVT. RESULTS - SURGICAL MORTALITY MONITORING SYSTEMS: The definition of surgical mortality is relatively consistent between monitoring systems, but duration of

follow-up of death postdischarge varies considerably. The majority of systems report in-hospital mortality rates; only some have the potential to link deaths to national death registers. Risk assessment is an important factor and there should be a distinction between recording pre-intervention factors and postoperative complications. A variety of risk scoring systems was identified in the review. Factors associated with accurate and complete data collection include the employment of local, dedicated personnel, simple and structured prompts to ensure that clinical input is complete, and accurate and automated data capture and transfer.
CONCLUSIONS: The use of standardised, valid and reliable definitions is fundamental to the accurate measurement and monitoring of surgical adverse events. This review found inconsistency in the quality of reporting of postoperative adverse events, limiting accurate comparison of rates over time and between institutions. The duration of follow-up for individual events will vary according to their natural history and epidemiology. Although risk-adjusted aggregated rates can act as screening or warning systems for adverse events, attribution of whether events are avoidable or preventable will invariably require further investigation at the level of the individual, unit or department.
CONCLUSIONS - RECOMMENDATIONS FOR RESEARCH: (1) A single, standard definition of surgical wound infection is needed so that comparisons over time and between departments and institutions are valid, accurate and useful. Surgeons and other healthcare professionals should consider adopting the 1992 Centers for Disease Control (CDC) definition for superficial incisional, deep incisional and organ/space surgical site infection for hospital monitoring programmes and surgical audits. There is a need for further methodological research into the performance of the CDC definition in the UK setting. (2) There is a need to formally assess the reliability of self-diagnosis of surgical wound infection by patients. (3) There is a need to assess formally the reliability of case ascertainment by infection control staff. (4) Work is needed to create and agree a standard, valid and reliable definition of anastomotic leak which is acceptable to surgeons. (5) A systematic review is needed of the different diagnostic tests for the diagnosis of DVT. (6) The following variables should be considered in any future DVT review: anatomical region (lower limb, upper limb, pelvis); patient presentation (symptomatic, asymptomatic); outcome of diagnostic test (successfully completed, inconclusive, technically inadequate, negative); length of follow-up; cost of test; whether or not serial screening was conducted; and recording of laboratory cut-off values for fibrinogen equivalent units. (7) A critical review is needed of the surgical risk scoring used in monitoring systems. (8) In the

absence of automated linkage there is a need to explore the benefits and costs of monitoring in primary care. (9) The growing potential for automated linkage of data from different sources (including primary care, the private sector and death registers) needs to be explored as a means of improving the ascertainment of surgical complications, including death. This linkage needs to be within the terms of data protection, privacy and human rights legislation. (10) A review is needed of the extent of the use and efficiency of routine hospital data versus special collections or voluntary reporting.
PMID: 11532239

Committee on Quality of Health Care in America, Institute of Medicine. National Academies Press; Washington, DC: 1999. ISBN: 9780309068376.

TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM

Kohn L, Corrigan J, Donaldson M, eds.

One measure of the impact of this report, the first in the series of reports by the Institute of Medicine (IOM) on the quality of health care in the United States, is that one can still refer to ☒The IOM Report☒ and everyone will recognize the reference to To Err is Human (despite the fact that, as of this writing, the IOM has released approximately 250 reports since To Err). In fact, many argue that the modern field of patient safety began with this report‘s publication. Although the report has been criticized for its strong focus on medication errors and computerized order entry (to the exclusion of other safety concerns) and the relatively limited discussion of the impact of the malpractice system, there is no mistaking its impact. Perhaps its most famous contribution was the extrapolation of the Harvard Medical Practice Study data and the Utah and Colorado Medical Practice Study data, which led to the famous estimate of 44,000 to 98,000 deaths per year from medical errors (the equivalent of a jumbo jet a day). Whether one believes these numbers or not, it is clear that the IOM report was essential in placing the issue of medical mistakes on the public and professional agenda.

Med Device Technol. 1999 Mar;10(2):88-92.

FORESIGHT BEGINS WITH FMEA. DELIVERING ACCURATE RISK ASSESSMENTS

Passey RD.

Abstract

If sufficient factors are taken into account and two- or three-stage analysis is employed, failure mode and effect analysis represents an excellent technique for delivering accurate risk assessments for products and processes, and for relating them to legal liability. This article describes a format that facilitates easy interpretation.

PMID: 10387618

Wien Klin Wochenschr. 1998 Apr 10;110(7):266-71.

RISK AND PROCEDURE EDUCATION IN ANESTHESIOLOGY. OVERVIEW OF AUSTRIAN AND GERMAN LEGAL REGULATIONS

[Article in German]

Muhm M, Berzlanovich A, Hellwagner K, Hiesmayr M,Bauer G.

Abstract

Informed consent is currently an ethical, medical and legal requirement. An increase in public discussion of real or supposed malpractice has led to critical attitude in patients and increased demands on informed consent by the courts. Unfortunately, the legal requirements of informed consent have developed from atypical situations involving dissatisfied and injured patients rather than from the more usual occurrences of physicians helping patients with subsequent patient satisfaction. In addition, laws have not set forth clear guidelines for physicians to follow. We review the elements of informed consent based on current Austrian and German jurisdiction in the particular field of anesthesiology and summarize the legal and medical realities in order to point out specific criteria for decision making.

PMID: 9611343

Health Commun 1998;10(2):175-97.
DOI: http://dx.doi.org/10.1207/s15327027hc1002_4

BEARING THE BURDEN OR BARING THE SOUL: PHYSICIANS' SELF-DISCLOSURE AND BOUNDARY MANAGEMENT REGARDING MEDICAL MISTAKES

Allman J.

Abstract
Within a boundary management framework, this study explored how physicians manage self-disclosure regarding medical mistakes amidst boundary constraints imposed by risk management, legal mandate, and the medical culture. Descriptive statistics from questionnaires and exemplars from accompanying narratives showed that the 39 internists and family physicians in this study chose to control their own boundaries by revealing errors most often to other physicians to facilitate learning. Although risk management and the medical culture do not appear to deter physicians from disclosing errors at a superficial level, physicians maintain tight personal boundaries at the emotional level. Perhaps if physicians could disclose errors at the emotional level, their mental energies could be more positively channeled to patients' needs, resulting in improved patient care.

Lancet. 1997 Feb 1;349(9048):309-13.

AN ALTERNATIVE STRATEGY FOR STUDYING ADVERSE EVENTS IN MEDICAL CARE

Andrews LB, Stocking C, Krizek T, Gottlieb L, Krizek C, Vargish T, Siegler M.

Abstract
BACKGROUND: Data about the frequency of adverse events related to inappropriate care in hospitals come from studies of medical records as if they represented a true record of adverse events. In a prospective, observational design we analysed discussion of adverse events during the care of all patients admitted to three units of a large, urban teaching hospital affiliated to a university medical school. Discussion took place during routine clinical meetings. We undertook the study to enhance understanding of the incidence and scope of adverse events as a basis for preventing them.
METHODS: Ethnographers trained in qualitative observational research attended day-shift, weekday, regularly scheduled attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings in three study units as

well as various departmental and section meetings. They recorded all adverse events during patient care discussed at these meetings and developed a classification scheme to code the data. Data were collected about health-care providers' own assessments about the appropriateness of the care that patients received to assess the nature and impact of adverse events and how health-care providers and patients responded to the adverse events.
FINDINGS: Of the 1047 patients in the study, 185 (17.7%) were said to have had at least one serious adverse event; having an initial event was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more adverse events than those with short stays. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay, 37.8% of adverse events were caused by an individual, 15.6% had interactive causes, and 9.8% were due to administrative decisions. Although 17.7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1.2% (13) of the 1047 patients made claims for compensation.
INTERPRETATION: This study shows that there is a wide range of potential causes of adverse events that should be considered, and that careful attention must be paid to errors with interactive or administrative causes. Healthcare providers' own discussions of adverse events can be a good source of data for proactive error prevention.
PMID: 9024373
Comment in: *Estimation of adverse events in medical care. [Lancet. 1997]*
Medical errors: reporting and punishment. [Lancet. 2000]

Clin Perform Qual Health Care. 1996 Jul-Sep;4(3):137-47.

COMPLICATIONS, ADVERSE EVENTS, AND IATROGENESIS: CLASSIFICATIONS AND QUALITY OF CARE MEASUREMENT ISSUES

Fleming ST.

Abstract
Accountability in the healthcare system demands the development of valid and reliable measures of quality, particularly outcome measures that have been risk-adjusted for factors that increase the probability of a poor outcome. Although the literature documents the existence of complications, adverse events, and iatrogenic illness, these concepts have not been compared and discussed thoroughly. This article ponders complications as a measure of quality of care by proposing

a three-level classification scheme and by examining the incidence, consequence, and determinants of these events.
PMID: 10159302

Ann Intern Med. 1996 Jan 15;124(2):229-39.

WHAT IS ACCOUNTABILITY IN HEALTH CARE

Emanuel EJ, Emanuel LL.

Abstract
Accountability has become a major issue in health care. Accountability entails the procedures and processes by which one party justifies and takes responsibility for its activities. The concept of accountability contains three essential components: 1) the loci of accountability--health care consists of at least 11 different parties that can be held accountable or hold others accountable; 2) the domains of accountability--in health care, parties can be held accountable for as many as six activities: professional competence, legal and ethical conduct, financial performance, adequacy of access, public health promotion, and community benefit; and 3) the procedures of accountability, including formal and informal procedures for evaluating compliance with domains and for disseminating the evaluation and responses by the accountable parties. Different models of accountability stress different domains, evaluative criteria, loci, and procedures. We characterize and compare three dominant models of accountability: 1) the professional model, in which the individual physician and patient participate in shared decision making and physicians are held accountable to professional colleagues and to patients; 2) the economic model, in which the market is brought to bear in health care and accountability is mediated through consumer choice of providers; and 3) the political model, in which physicians and patients interact as citizen-members within a community and in which physicians are accountable to a governing board elected from the members of the community, such as the board of a managed care plan. We argue that no single model of accountability is appropriate to health care. Instead, we advocate a stratified model of accountability in which the professional model guides the physician-patient relationship, the political model operates within managed care plans and other integrated health delivery networks, and the economic and political models operate in the relations between managed care plans and other groups such as employers, government, and professional associations.
PMID: 8533999

Aviat Space Environ Med. 1992 Sep;63(9):763-70.

ANESTHESIA CRISIS RESOURCE MANAGEMENT TRAINING: TEACHING ANESTHESIOLOGISTS TO HANDLE CRITICAL INCIDENTS

Howard SK, Gaba DM, Fish KJ, Yang G, Sarnquist FH.

Abstract

The authors have developed a course in Anesthesia Crisis Resource Management (ACRM) analogous to courses in Crew (Cock-pit) Resource Management (CRM) conducted in commercial and military aviation. Anesthesiologists do not typically receive formal training in crisis management although they are called upon to manage life-threatening crises at a moment's notice. Two model demonstration courses in ACRM were conducted using a realistic anesthesia simulation system to test the feasibility and acceptance of this kind of training. Anesthesiologists received didactic instruction in dynamic decision-making, human performance issues in anesthesia, and in the principles of anesthesia crisis resource management. After familiarization with the host institution's operating rooms and with the simulation environment, they underwent a 2-h simulation session followed by a debriefing session which used a videotape of their simulator performance. Participants rated the course as intense, helpful to their practice of anesthesiology, and highly enjoyable. Several aspects of the course were highly rated, including: videotapes of actual anesthetic mishaps, simulation sessions, and debriefing sessions. Scores on written tests of knowledge about anesthesia crisis management showed a significant improvement following the first course (residents) but not the second course (experienced anesthesiologists). Although the ultimate utility of this training for anesthesiologists cannot easily be determined, the course appeared to be a useful method for addressing important issues of anesthesiologist performance which have previously been dealt with haphazardly. The authors believe that ACRM training should become a regular part of the initial and continuing education of anesthesiologists.

PMID: 1524531

N Engl J Med. 1991 Feb 7;324(6):377-84.

THE NATURE OF ADVERSE EVENTS IN HOSPITALIZED PATIENTS. RESULTS OF THE HARVARD MEDICAL PRACTICE STUDY II

Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H.

Abstract

BACKGROUND: In a sample of 30,195 randomly selected hospital records, we identified 1133 patients (3.7 percent) with disabling injuries caused by medical treatment. We report here an analysis of these adverse events and their relation to error, negligence, and disability.

METHODS: Two physician-reviewers independently identified the adverse events and evaluated them with respect to negligence, errors in management, and extent of disability. One of the authors classified each event according to type of injury. We tested the significance of differences in rates of negligence and disability among categories with at least 30 adverse events.

RESULTS: Drug complications were the most common type of adverse event (19 percent), followed by wound infections (14 percent) and technical complications (13 percent). Nearly half the adverse events (48 percent) were associated with an operation. Adverse events during surgery were less likely to be caused by negligence (17 percent) than nonsurgical ones (37 percent). The proportion of adverse events due to negligence was highest for diagnostic mishaps (75 percent), noninvasive therapeutic mishaps ("errors of omission") (77 percent), and events occurring in the emergency room (70 percent). Errors in management were identified for 58 percent of the adverse events, among which nearly half were attributed to negligence.

CONCLUSIONS: Although the prevention of many adverse events must await improvements in medical knowledge, the high proportion that are due to management errors suggests that many others are potentially preventable now. Reducing the incidence of these events will require identifying their causes and developing methods to prevent error or reduce its effects.

PMID: 1824793

N Engl J Med. 1991 Feb 7;324(6):370-6.

INCIDENCE OF ADVERSE EVENTS AND NEGLIGENCE IN HOSPITALIZED PATIENTS. RESULTS OF THE HARVARD MEDICAL PRACTICE STUDY I

Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH.

Abstract

BACKGROUND: As part of an interdisciplinary study of medical injury and malpractice litigation, we estimated the incidence of adverse events, defined as injuries caused by medical management, and of the subgroup of such injuries that resulted from negligent or substandard care.

METHODS: We reviewed 30,121 randomly selected records from 51 randomly selected acute care, nonpsychiatric hospitals in New York State in 1984. We then developed population estimates of injuries and computed rates according to the age and sex of the patients as well as the specialties of the physicians.

RESULTS: Adverse events occurred in 3.7 percent of the hospitalizations (95 percent confidence interval, 3.2 to 4.2), and 27.6 percent of the adverse events were due to negligence (95 percent confidence interval, 22.5 to 32.6). Although 70.5 percent of the adverse events gave rise to disability lasting less than six months, 2.6 percent caused permanently disabling injuries and 13.6 percent led to death. The percentage of adverse events attributable to negligence increased in the categories of more severe injuries (Wald test chi 2 = 21.04, P less than 0.0001). Using weighted totals, we estimated that among the 2,671,863 patients discharged from New York hospitals in 1984 there were 98,609 adverse events and 27,179 adverse events involving negligence. Rates of adverse events rose with age (P less than 0.0001). The percentage of adverse events due to negligence was markedly higher among the elderly (P less than 0.01). There were significant differences in rates of adverse events among categories of clinical specialties (P less than 0.0001), but no differences in the percentage due to negligence.

CONCLUSIONS: There is a substantial amount of injury to patients from medical management, and many injuries are the result of substandard care.

PMID: 1987460

Comment in: *Incidence of adverse events and negligence in hospitalized patients. [N Engl J Med. 1991]*

West J Med. 2000 June; 172(6): 393–396.

HUMAN ERROR MODELS AND MANAGEMENT

Reason J

Extract

The problem of human error can be viewed in 2 ways: the person approach and the system approach. Each has its model of error causation, and each model gives rise to different philosophies of error management. Understanding these differences has important practical implications for coping with the ever-present risk of mishaps in clinical practice.

PERSON APPROACH

The long-standing and widespread tradition of the person approach focuses on the unsafe acts—errors and procedural violations—of people on the front line: nurses, physicians, surgeons, anesthetists, pharmacists, and the like. It views these unsafe acts as arising primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness. The associated countermeasures are directed mainly at reducing unwanted variability in human behavior.

These methods include poster campaigns that appeal to people's fear, writing another procedure (or adding to existing ones), disciplinary measures, threat of litigation, retraining, naming, blaming, and shaming. Followers of these approaches tend to treat errors as moral issues, assuming that bad things happen to bad people—what psychologists have called the "just-world hypothesis."

SYSTEM APPROACH

The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organizations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in "upstream" systemic factors. These include recurrent error traps in the workplace and the organizational processes that give rise to them.

Countermeasures are based on the assumption that although we cannot change the human condition, we can change the conditions under which humans work. A central idea is that of system defenses. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defenses failed.

CONCLUSIONS

High-reliability organizations are the prime examples of the system approach. They anticipate the worst and equip themselves to deal with it at all levels of the organization. It is hard, even unnatural, for

individuals to remain uneasy over the long term, so their organizational culture takes on a profound importance. Individuals may forget to be afraid, but the culture of a high-reliability organization provides them with both the reminders and the tools to help them remember. For these organizations, the pursuit of safety is not so much about preventing isolated failures, either human or technical, as about making the system as robust as is practicable in the face of its human and operational hazards. High-reliability organizations are not immune to adverse events, but they have learned the knack of converting these occasional setbacks into enhanced resilience of the system.

SUMMARY POINTS

- The problem of human fallibility has 2 approaches: the person and the system
- The person approach focuses on the errors of individuals: forgetfulness, inattention, or moral weakness
- The system approach concentrates on the conditions under which people work and tries to build defenses to avert errors or mitigate their effects
- High-reliability organizations, which have fewer accidents, recognize that human variability is the approach to averting errors, but they work hard to focus that variability and are preoccupied with the possibility of failure

PMCID: PMC1070929

RELATED WEB RESOURCES

http://www.who.int/topics/patient_safety/en/
World Health Organization - Patient safety

http://www.euro.who.int/en/health-topics/Health-systems/patient-safety
WHO - Regional Office for Europe - Patient safety

http://www.cdc.gov/nhsn/
National Healthcare Safety Network

http://www.ahrq.gov/
Agency for Healthcare Research and Quality

http://psnet.ahrq.gov/default.aspx
Patient Safety Network

http://www.hssa.ca/
Healthcare System Safety and Accountability

http://www.ihi.org/
Institute for Healthcare Improvement

http://ec.europa.eu/health/patient_safety/
European Commission - Patient safety Policy

http://www.ema.europa.eu/ema/
European Medicines Agency - Safety monitoring of medicines

http://healthsocialaccountability.org/
Global Consensus for Social Accountability of Medical Schools

http://www.healthcsa.org
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- Translate knowledge about the quality, safety and responsibility of care into effective action
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