Medical Event Reporting System for Transfusion Medicine

Patient Safety and the "Just Culture": A Primer for Health Care Executives

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I. Executive Summary

As part of the ongoing effort to improve transfusion safety, MERS-TM provides a standardized means of organized data collection and analysis of transfusion errors, adverse events, and near misses. Its effectiveness depends on the willingness of individuals to report such information. This report is designed as an aid for health care executives, labor attorneys, labor leaders, and human resource specialists who must struggle with what to do, in the disciplinary context, with an erring health care professional. It is a guide for more thoroughly understanding the problems posed by current disciplinary approaches, and to possible changes in your current disciplinary policies as you contemplate implementation of a new reporting and investigation system.

Today, most corporate disciplinary systems literally prohibit human error. That is, mere human error, when coupled with harm to a patient, will raise the specter of social condemnation and disciplinary action. Advances in patient safety, especially when involving the management of human error, depend upon our collective ability to learn from our mistakes – whether they are near misses or mistakes resulting in actual harm to a patient. To promote a culture in which we learn from our mistakes, organizations must re-evaluate just how their disciplinary system fits into the equation. Disciplining employees in response to honest mistakes does little to improve overall system safety. Yet, mishaps accompanied by intoxication or malicious behavior presents an obvious and valid objection to today's call for blame-free error reporting systems.

It is through the lessons of our everyday errors that we can design our work environment to be less error prone and more error tolerant. Few people are willing to come forward and admit to an error when they face the full force of their corporate disciplinary policy, a regulatory enforcement scheme, or our onerous tort liability system. To collect productive investigative data, we must promote a culture in which employees are willing to come forward in the interests of system safety. Yet, no one can afford to offer a "blame-free" system in which any conduct can be reported with impunity – as society rightly requires that some actions warrant disciplinary or enforcement action. It is the balancing of the need to learn from our mistakes and the need to take disciplinary action that this report addresses. Ultimately, it will help you answer the question: "Where do you draw the disciplinary line?"

II. The Problem Statement

On October 12, 1999, Dr. Lucian Leape, a professor at the Harvard School of Public Health, gained the attention of a US Congressional subcommittee when he briefed them on the state of human error management in the US medical industry.[1] The numbers are staggering: an estimated one million people injured by errors in treatment at hospitals each year in the US, with an estimated 120,000 deaths arising from those errors.[2] A number three times greater than those who die in automobile accidents and 1000 times greater than those who die in commercial aircraft accidents, these errors are accompanied by an estimated $33 billion price tag.

As a result of a punitive work environment and because hospital personnel (as well as most of the public) tend to regard health care provider errors as evidence of personal carelessness, most hospitals are unaware of the extent of their errors and injuries. Dr. Leape reported that only 2 to 3% of major errors are reported through hospital incident reporting systems. Health care workers often report only what they cannot conceal.

Dr. Leape went on to tell Congress that health care organizations must make error prevention a major strategic objective, and that hospitals should eliminate punitive error reporting systems so that reporting can be made "safe" for employees. Systems should be established to track error and the effectiveness of corrective measures. Regulators must become a force for error reduction rather than a force for error concealment. We must all be educated regarding the central roles of system design and corporate responsibility in managing human error.

Ultimately, Dr. Leape said, the single greatest impediment to error prevention is that

"we punish people for making mistakes."

It is this very bold statement that this primer addresses. Just what is the role of punitive sanction in the safety of our health care system? Does the threat and/or application of punitive sanction as a remedy for human error help or hurt our system safety efforts?

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[1] Testimony, United States Congress, House Committee on Veterans' Affairs, Dr. Lucian L. Leape, MD, October 12, 1997.

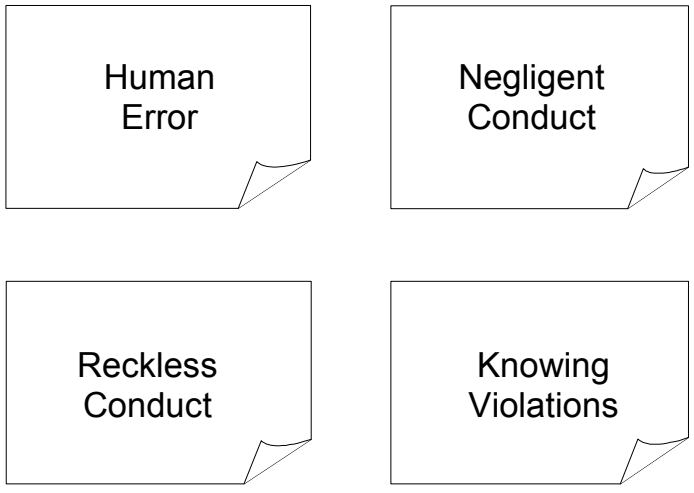
[2] The later released IOM report put the number of deaths at between 44,000 and 98,000 deaths in the US each year.

III. An Introduction to Disciplinary System Theory

Determining when a health care professional warrants disciplinary sanction requires that we first attempt to define, or at least better describe, what we mean by disciplinary action. In our context, we will think of disciplinary action as harm dispensed by an authority to deter future undesirable conduct. Quite simply – punishment. Punishment that harms directly through its sanction (fine or license action) or, perhaps even worse, the often-resulting public condemnation of the individual involved.

A. The Four Evils

Four behavioral concepts are important to an understanding of the inter-relationship between discipline and patient safety: human error, negligence, intentional rule violations, and reckless conduct. These behavioral categories are presented here because they are the principal labels we use socially, and legally, to describe blameworthy conduct. One or more of these behavioral categories will be applied in most mishap investigations, and the label often determines when disciplinary sanction is appropriate. The question we will specifically address is whether all or only some of these labels warrant disciplinary sanction in the post-mishap setting.



As you will see in the examples that follow, the "four evils" are not mutually exclusive; they overlap each other in definition - and they can all occur in the same mishap. Following is a short description of each.

1. Human Error

Human Error is a social label. It may be characterized as follows:

> When there is general agreement that the individual should have done other than what they did, and in the course of that conduct inadvertently causes or could cause an undesirable outcome, the individual is labeled as having committed an error.

Human error is a term that we use to describe our everyday behavior – missing a turnoff on the freeway, or picking up strawberry ice cream instead of chocolate. The threshold for labeling behavior "human error" is very low – we make errors every day with generally minimal consequences. In the health care profession, we make similar types of errors – perhaps not at the frequency of those in our off-work hours, but often with much more potential for dire consequences. We use terms like mistake, slip, and lapse to basically tell the same story – that someone did other than what they should have done, and inadvertently caused an undesirable outcome. When a physician prescribes the wrong dosage, we will likely label her actions a human error. We understand that the physician did not intend her error or its undesirable outcome even though the consequences are potentially life threatening.

2. Negligent Conduct

Negligence, at least in our social dialogue, is conduct subjectively more culpable than human error. Negligence, as a legal term, arises from both the civil (tort) and criminal liability systems. Negligence is the term generally used when an individual has been harmed by the healthcare system. A basic tenant of common law is that he who is negligent must pay for the resulting damages. In most states, negligence is defined as failure to exercise the skill, care, and learning expected of a reasonably prudent health care provider.[3] Criminal negligence, as defined by the Model Penal Code, involves an

[3] See Washington Pattern Jury Instruction WPI 105.01 Negligence – General Health Care Provider.

objective determination that a person *should have been aware* that they were taking a substantial and unjustifiable risk toward causing an undesirable outcome.[4]

3. Reckless Conduct

Reckless conduct, alternatively referred to as gross negligence, involves a higher degree of culpability than negligence. Reckless conduct in both the civil liability and criminal systems involves conscious disregard of risk.[5] Reckless conduct differs from negligent conduct in intent; negligence is the *failure to recognize* a risk that should have been recognized, while recklessness is a *conscious disregard* of a visible, significant risk. Consider the term "reckless driving." For most of us, it connotes a much higher degree of culpability than mere human error.

4. Intentional Rule Violations

Most rules, procedures, and duties will require or prohibit a specific behavior. The intentional rule violation occurs when an individual chooses to knowingly violate a rule while he is performing a task. This concept is not necessarily related to risk taking, but merely shows that an individual knew of or intended to violate a rule, procedure, or duty in the course of performing a task.

B. Application to Transfusion Scenarios

Consider now the application of these four labels to three transfusion scenarios. Pay attention to the labels as the conduct in each scenario gets progressively more culpable.

1. Scenario 1- The Memory Error

> A medical technologist receives a sample for type and crossmatch. As she brings up the patient record on the computer, the computer flashes a warning that the patient has autologous units on hold.
>
> She goes to the refrigerator to retrieve the autologous units. Before she can get the units, someone asks her a question about an antibody identification problem. She takes a few minutes to help the other technologist. When finished, she remembers she was going to the refrigerator for two A Pos units, but gets two

[4] See Model Penal Code (1962) Section 2.02. General Requirements of Culpability.

[5] See Model Penal Code (1962) Section 2.02. General Requirements of Culpability.

> homologous units rather than the two autologous units. The two homologous units are crossmatched and labeled for the patient.
>
> The issuing technologist looks at the pick-up slip and goes to get the two units off the shelf. During the computer crossmatch, a computer warning indicates that the patient has autologous units available. The issue technologist notices that she has two homologous units. The issue is delayed until the autologous units are made available.

This event involves a simple memory error. The system is robust and catches the error; however, a technologist has made an error and has to rely on system defenses to catch it. What should happen to this technologist? Clearly, from a system safety perspective, she should be part of the process of learning how the system can be improved. Does the system safety perspective also require that she be disciplined?

With respect to the "four evils," into which category has our nurse fallen? The answer is illustrated in the table below:

Scenario 1 - Analysis of the Four Evils

The Evil	Definition	Apply to this event?	Rationale
Human Error	Should have done other than what they did.	Yes	Technologist pulls homologous blood rather than what she should have pulled – the autologous blood.
Negligence	Failure to exercise expected care. Should have been aware of substantial and unjustifiable risk.	Yes	Technologist pulls homologous blood rather than what she should have pulled – the autologous blood. Expectation is that technologist will pull correct blood.
Recklessness	Conscious disregard of substantial and unjustifiable risk.	No	Technologist was not aware of risk she was taking – either in pulling wrong blood, or in being distracted by interruption to work flow.
Intentional Rule Violation	Knowingly violates a rule or procedure.	No	No intentional violations present.

In this first scenario, the technologist made a simple error in not remembering the exact blood specification she was to pull. The system worked in that the issue technologist caught the error before the blood made it to the patient. In any high-risk system, it is

wise to design the system so that single human errors (single point failures) cannot directly lead to a catastrophic result. From a learning perspective, it is helpful to understand the types of distractions that can arise, and how employees react to the interruptions. In this case, the system could be altered to re-confirm the computer order before continuing after any interruption. Many aircraft pilots rely on this process – repeating the pre-flight checklist when any interruptions occur.

2. Scenario 2 – The Misplaced Tube

> A new transfusion service phlebotomist is on the early morning shift drawing samples on the hospital floor. She checks Ms. Jones' requisition and armband before she draws her samples.
>
> Ms. Jones is really annoyed about the bright lights the phlebotomist has turned on, and the phlebotomist is trying to placate Ms. Jones by turning them off quickly. She knows that there is a strict procedure to label tubes at the bedside, but as she has already positively identified the patient, and this is the only set of tubes she has, she decides to label the tubes at the nurse's station.
>
> She lays the tubes down at the nurse's station and begins labeling. However, a nurse comes to the nurse's station with an unlabeled tube of blood and lays it down nearby. Not noticing this, the phlebotomist mistakenly thinks one of her tubes has rolled away. She picks up the nurse's tube and also labels it with Ms. Jones's information.
>
> Ms. Jones is a new patient and her blood type is unknown. The mislabeled tube is used to type and cross units for her. Ms. Jones has a moderately severe transfusion reaction when the first unit is being transfused.

This event adds one element not present in the first scenario – the knowing violation of procedure. Here, just as in the first scenario, the phlebotomist is trying her best to serve the needs of her patient. She wants to handle the blood safely, but she wants to comfort her patient by turning off the light as soon as she can. Mislabeling the blood is a negligent error, and she has knowingly violated hospital procedure by labeling the blood at the nursing station. From a system safety perspective, what should be the outcome of this event? This particular phlebotomist learned the risks associated with labeling blood at the nursing station. Others could learn the same lesson. From a system perspective, are there changes that can be made to improve the tolerance of the system to this type of error? Could labels be automatically generated at the bedside? This is one event – but the precursors to the error in this mishap are the same precursors that might someday result in a fatality. To improve system safety, this event should be analyzed, among other events in the organization, to determine where these particular contributors to error fit into the risk assessment of the blood handling system.

Scenario 2- Analysis of the Four Evils			
The Evil	**Definition**	**Apply to this event?**	**Rationale**
Human Error	Should have done other than what they did.	Yes	Phlebotomist mis-labels blood.
Negligence	Failure to exercise expected care. Should have been aware of substantial and unjustifiable risk.	Yes	Phlebotomist mis-labels blood. Expectation is that phlebotomist will label blood correctly.
Recklessness	Conscious disregard of substantial and unjustifiable risk.	No	Mislabeling the blood was an unjustifiable risk – however the mislabeling was inadvertent. Violation of the procedure was conscious; however, nurse did not perceive a significant and unjustifiable risk in labeling blood at nursing station.
Intentional Rule Violation	Knowingly violates a rule or procedure.	Yes	Policy requires that blood be labeled at bedside. Phlebotomist knows of policy and chooses to deviate to placate disturbed patient.

From a disciplinary perspective, this event poses a difficult dilemma. Should disciplinary action be taken against the phlebotomist in this case? Does the presence of an intentional rule violation influence the decision? Would other phlebotomists or nurses have done the same to ease the disturbance to the patient? Could a supervisor counsel the phlebotomist without taking formal disciplinary action? From a learning perspective, would the phlebotomist have told a different story had she known that an intentional violation of procedure would have subjected her to possible disciplinary sanction? Would the event description instead have been a story of adherence to procedure – and no idea on the part of the employee how the blood could have been mislabeled?

3. Scenario 3 – The Reckless Technologist

> The evening shift of the transfusion service had three technologists on duty, two bench technologists and one supervisor.
>
> One of the bench technologists issued a unit of blood. The procedure called for two technologists to manually review the patient and unit information before issue. The other bench technologist was on her dinner break, leaving the supervisor as the second checker. The issuing technologist had a personality conflict with the supervisor and avoided speaking to her.
>
> The issuing technologist chose not to ask the supervisor to review the unit. She falsified the other technologist's initials in the box indicating the review had been performed and issued the unit.
>
> The correct unit was issued, and there was no patient harm. However, the other bench technologist noticed that her initials had been falsified and reported it to the supervisor.

This event demonstrates the most culpable conduct of the three scenarios. In this case, you probably had both an analytical reaction and an emotional reaction to the technologist's conduct. The difference in this case is the introduction of the employee's reckless conduct.

What is it that really separates this technologist from the technologist and phlebotomist in the previous scenarios? Specifically, is it the reckless conduct *per se* or is it the intentional violation of procedure? In the second scenario, the technologist knowingly violated the procedure to label blood tubes at bedside, but the technologist's behavior in this event is, for most people, far less culpable than the technologist's behavior in the third scenario. Disciplinary system research shows that we react more strongly to the risk-taking behavior of others, than to their *per se* adherence to policies or rules.[6] Consider your view of the driver you see weaving in and out of lanes ahead of you. Are you reacting to the violation of traffic rules, or to the risk that you know (or at least assume) the driver is taking? Do you have the same reaction to those around you who are knowingly exceeding the speed limit? Probably not. If you are like most people, culpability is based upon our perceptions of risk-taking behavior, not on our perception of whether the individual knew they were violating policy.

[6] Marx, David. The Link Between Employee Mishap Culpability and Commercial Aviation Safety, Seattle University School of Law, January 30, 1998.

Scenario 3 - Analysis of the Four Evils			
The Evil	**Definition**	**Apply to this event?**	**Rationale**
Human Error	Should have done other than what they did.	Possibly	Possibly. The term human error is generally used for far less culpable conduct.
Negligence	Failure to exercise expected care. Should have been aware of substantial and unjustifiable risk.	Yes	In the criminal version of negligence the technologist not only *should have been aware*, but *was aware* of the risk. Meets and exceeds the threshold for criminally negligent conduct. In the civil liability system, although the technologist did not exercise due care, there are no damages – technically, the technologist is not negligent.
Recklessness	Conscious disregard of substantial and unjustifiable risk.	Yes	Technologist knew of risk of skipping second set of eyes review – but due to personality conflict with supervisor decided to forego the review. The risk of her conduct was significant and unjustifiable, and it could likely be shown that she knew of the risk she was taking.
Intentional Rule Violation	Knowingly violates a rule or procedure.	Yes	It was a knowing violation to forgo the review and sign on behalf of a person who did not do the review as required.

So what do you do with the technologist in this case? How do you balance the competing needs of system safety objectives and discipline for this event? What, if anything, can you learn from the event to prevent similar events in the future? Are there system features that could be changed to reduce the likelihood of similar events?

Anyone who is old enough to read this report has likely already formed a good sense of his or her own justice system. Compare it to the "four evils" defined earlier. You know what conduct bothers you, you know when you are willing to say "to err is human," and you know when you would take disciplinary action against an individual in a mishap. With your own sense of justice better articulated through your understanding of the "four evils," consider the following disciplinary policies of organizations and regulatory agencies having oversight of high-risk industries.

C. Disciplinary Decision-Making Strategies

We will now review three types of disciplinary policies: those predominantly considering outcome, those considering adherence to procedures, and to those considering risk.

1. Outcome-Based Disciplinary Decision-Making

While it may seem strange to some, much of our disciplinary decision-making hinges upon outcome. If a nurse makes an error that causes no harm, we consider the nurse to be lucky. Yet, if another nurse makes the same error resulting in injury to a patient, we consider the nurse to be blameworthy, and disciplinary action may follow. The social sciences call this a severity bias - the more severe the outcome, the more blameworthy the actor.[7]

Until recently at one hospital in Texas, any nurse who made a medication error was given a score based upon the circumstances of the event.[8] Error scores ranged from 1 point (wrong time) to 5 points (incorrect medication). Method errors ranged from 2 points (topical) to 6 points (epidural). The class of drug used added from 1 point (antacids) to 6 points (blood solutions). According to the disciplinary policy, accumulating 1 to 18 points warranted coaching, 19-36 warranted a written warning, 37-54 points required mandatory attendance at an individualized remedial medication review, and finally, more than 55 points left the nurse open to termination for gross negligence. Now consider the point values associated with the *outcome* of the medication error: 5 points for no harm, 15 points for moderate injury, 25 points for severe injury, and 70 points for death.

A disciplinary scheme where outcome plays such a dominant role is questionable. Theoretically, an intoxicated nurse who causes no harm through her error could be in the 10-20 point range, where a well-meaning nurse who kills his patient would be in the 80's or 90's. In this system, it is the outcome that drives the disciplinary decision-making. If system safety is the goal of disciplinary action, how is this supported by a system that allows the intoxicated - but fortunate - nurse to remain, and the well-meaning nurse to be terminated? This is a fundamentally flawed system, based upon the notion that we can totally control our outcomes. In managing human error, we can only control our *intended* behaviors to reduce our likelihood of making a mistake, but we cannot truly control when and where a human error will strike.

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[7] See Fiske, S. and Taylor, S. Social Cognition, New York; McGraw-Hill, 1991.

[8] Parkland Hospital, Dallas Texas.

At times, basing disciplinary decision-making on outcome is necessary. In our criminal system, drunk drivers suffer far greater consequences for killing someone than for merely damaging property. The driver's intent, to drink and drive, is the same, yet the outcome is very different. As a society, we have shaped our legal system around not only intent, but around the notion that the punishment should fit the severity of the crime. Where an individual has made a decision to cause harm, the greater the intentional harm, the greater the evil and hence the greater the punishment required.

What is troublesome about outcome-based disciplinary decision-making is that the reckless individual who does not injure another sometimes receives less punitive sanction than the merely erring individual who has caused injury. Yet, whether disciplinary sanction will be effective is dependent on the intent of the erring individual. Punishment deters those who consciously choose to disregard risk or intend to harm others, but has little to no impact on the individual who does not intend to make a mistake.

2. Rule-Based Disciplinary Decision-Making

Rule-based disciplinary decision-making is the easiest to understand. Most high-risk industries have rules, policies, and procedures intended to prevent mishaps from occurring. Some are based upon the outcome; some control behavior. Most outcome-based rules merely state that certain outcomes, such as injury to a patient, are prohibited. A behavioral rule might be a requirement to check an armband or a work hour limitation. In either case, there are two questions that need to be asked: did an individual violate a rule, and did the individual intentionally violate a rule. In many organizations today, disciplinary action is possible for any rule violation – intended or not. Those who have revised their policies to encourage learning from mishaps have raised the disciplinary threshold to intentional rule violations.

The Federal Aviation Administration has developed a system for pilot self-reports that provides an enforcement-related incentive for errors reported through the Aviation Safety Reporting System (ASRS).[9] The FAA will forego certificate action against the airman who reports a violation as long as the violation of Federal Aviation Regulations was "inadvertent and not deliberate," among other considerations. In other words, when the violation is intentional, the FAA believes the need to discipline outweighs the potential

[9] U.S. Department of Transportation Federal Aviation Administration, Aviation Safety Reporting Program, Advisory Circular No. 00-46C, February 4, 1985.

benefits of learning from an event. Many corporations have similar provisions – allowing an employee to report her error as long as there were no intentional violations associated with the event. It is a rational scheme – discipline for those who choose to violate, the opportunity to learn from those who violate inadvertently.

There are, however, some difficulties associated with the rule-based approach to disciplinary action. First, not all intentional violations are bad. Particularly in heavily rule-based professions, such as medicine and aviation, there will always be circumstances where the vast overlap of rules does not fit the circumstances facing the professional performing his job. If a health care provider felt it was necessary to violate a policy to save a patient, and the facts supported that conclusion, should the health care provider simply follow procedure and injure his patient? What also of malicious compliance – where a disgruntled employee knowingly follows a flawed procedure merely to cause damage to the organization? The bottom line is that we do not judge humans solely based upon whether they knowingly violated policy – but rather on whether they knew the risks they were taking increased the potential for harm (discussed in the next section).

Another problem is that intentional violations of rules and procedures occur everyday, even in high-risk industries such as health care and aviation. In commercial aviation, there is tremendous evidence of normative violations of procedure. In aircraft maintenance, one US air carrier found that over 50% of its mishaps involved a knowing violation of company policy.[10] Most of these violations were the result of norms that had developed over time – without the workforce's knowledge that the norms were significantly increasing risk of a mishap. Likewise, at least one US air carrier has found that over 50% of its pilot errors involved knowing violation of policy.[11]

The important point is that violations in themselves are critical learning opportunities for improving safety. Much can be learned through an understanding of why certain violations become the norm. Unfortunately, in a disciplinary model that takes action against every intentional deviation from policy, there will be little learning about violations. Employees will report that they were conscientiously following procedure when the error occurs – when the facts are possibly quite different.

[10] Johnson, William. Installation Error in Airline Maintenance, Galaxy Scientific Corporation, January 2001.

[11] Personal communication, de-identified US air carrier.

3. Risk-Based Disciplinary Decision-Making

Another method used to determine whether discipline is warranted, and the basis of our civil liability system, considers the intent of an employee with regard to an undesirable outcome. Negligence, gross negligence, and recklessness are all concepts related to risk creation.

Recklessness is a "high crime"- demonstrating greater intent than mere negligent conduct. If an individual intends to take a significant and unjustifiable risk, disciplinary action should be taken. Many organizations adopting a reporting culture in their efforts to learn from mistakes have raised the threshold for possible disciplinary action to reckless conduct, using discipline only to deter intentionally or knowing unsafe acts. If the act were inadvertent, such as in the case of negligence, then the employee would be safe to report in these systems. I am aware of no organization in the world, even those professing a "blame-free" disciplinary system that will not discipline an individual who has been reckless toward the safety of others.

But what to do with the negligent employee? If the employee knew and consciously disregarded the risk they were taking, the usefulness of disciplinary action – as a deterrent to both the employee in question and to other employees - cannot be ignored. If an employee had no reason to know he was creating a risk, there should be no discipline. Negligence, however, sits squarely in the middle of these two circumstances, where an employee should have known, but was unaware, of the risk they were taking. Most corporate disciplinary systems have set their threshold at negligence – that is, allowing disciplinary action where an employee should have been aware of the risk they were creating. This would be the case of the physician who writes a prescription for 100 mg of a drug rather than the intended 10 mg of the drug. Was he aware of what he had done? No. Should he have been aware? Yes.

Our civil liability system does not allow punitive sanction for negligent conduct because there is no intent to cause harm involved in negligence. Historically, negligence has been only a compensatory concept – intended to compensate the victim, not punish the negligent actor. Clearly, in medicine, negligence is the threshold for compensating victims of harm caused through the medical system. To that end, it is important to distinguish negligence and human error from reckless conduct. Negligence and human error are both terms for conduct that is generally viewed as inadvertent – the individual does not intend to engage in his error or negligence. In general, states allow for punitive damages only when the individual involved was reckless – that is, acting in conscious disregard of substantial and unjustifiable risk.

What to do with negligent employees often sits squarely in the middle of disciplinary decision-making. Consider the following two excerpts:

Against punishing the negligent actor…

> A person acts "recklessly" with respect to a result if he consciously disregards a substantial risk and acts only "negligently" if he is unaware of a substantial risk he should have perceived. The narrow distinction lies in the actor's awareness of risk. The distinction, one of the most critical to criminal law, between negligence and all three higher levels of culpability, reflects that a defendant acting purposely, knowingly, or recklessly is aware of the harmful consequences that may result and is therefore both blameworthy and deterrable, but a defendant acting negligently is unaware of harmful consequences and therefore is arguably neither blameworthy nor deterrable.[12]

For punishing the negligent actor…

> No one has doubted that purpose, knowledge, and recklessness are properly the basis for criminal liability, but some critics have opposed any penal consequences for negligent behavior. Since the actor is inadvertent by hypothesis, it has been argued that the "threat of punishment for negligence must pass him by, because he does not realize that it is addressed to him." So too, it has been urged that education or corrective treatment, not punishment, is the proper social method of dealing with persons with inadequate awareness, since what is implied is not a moral defect. This analysis, however, oversimplifies the issue. When people have knowledge that conviction and sentence, not to speak of punishment, may follow conduct that inadvertently creates improper risk, they are supplied with an additional motive to take care before acting, to use their faculties and draw on their experience in gauging the potentialities of contemplated conduct. To some extent, at least, this motive may promote awareness and thus be effective as a measure of control.[13]

From a system safety perspective, our concern is whether it is more beneficial to punish the negligent health care provider in hopes that she pays better attention to avoid future punitive sanction, or whether it is more beneficial to allow the negligent provider to come forward so that the system may learn from the erring individual? The data to answer this question has been mounting for years within high-risk industries outside of medicine. In the aviation industry and in industrial injury prevention programs there have been tremendous reductions in adverse events by creating a culture of positive reinforcement

[12] Robinson & Grall, "Element Analysis in Defining Criminal Liability: The Model Penal Code and Beyond," 35 Stan. L. Rev. 681, 1983, pp. 695-96.

[13] American Law Institute Model Penal Code, Article 2. General Principles of Liability, Explanatory note § 2.02 (1962).

of safe behaviors, and by creating disciplinary systems that allow erring employees to come forward and report their mistakes.

D. Distinguishing Compensatory and Punitive Goals

As you consider the role of discipline in your corporate setting, it is important to recognize that in practice, punishments can have both a compensatory and a punitive component. Punishment can deter an individual from inflicting future harm, and if it comes in an economic form, it can compensate a victim for his loss. Consider the basic malpractice claim. A physician makes a mistake that injures a patient. There are two broad questions to be answered. First, should the victim be compensated and who will compensate him for his loss? Second, what should be done with the erring physician? Will punitive action deter future undesirable conduct by this or other physicians?

Punitive objectives differ from compensatory objectives in that they are not tied to a victim's actual damages, but are calculated to deter future wrongdoers through financial pain. The more money an individual or organization has, the more the jury believes is required to deter them from engaging in similarly improper future conduct. In the United States, our tort liability system is quite simply a form of social insurance where those who err must pay the damages of those who have been injured. If the damages to the victim are $5000, the wrongdoer pays $5000 to the injured party. In contrast, one can look to New Zealand where the social insurance for medical mistakes comes directly from the government, much like Worker's Compensation claims in the United States. In New Zealand, the criminal system deals with the reckless health care provider (the punitive objective), while the compensation comes from the Accident Compensation laws (the compensatory objective).[14]

While in the tort system compensatory and punitive actions are highly inter-related, these two objectives should be bifurcated in corporate disciplinary action. There are many social systems available for compensating victims: a disciplinary system need not be one of those systems. In the civil liability system where both compensation and punishment are the objectives, recklessness is generally the threshold for punitive damages, whereas negligence is purely a compensatory concept – strictly compensating victims for an injury they have received.

[14] New Zealand Accident Compensation Act 1982.

IV. Where We Stand Today

Earlier, we looked at a medication errors policy that made disciplinary action dependent on the fate of the injured patient. Consider the following additional examples from both the regulatory and corporate environments.

A. The Regulatory Perspective

Consider the excerpt of the Washington State statutes governing state disciplinary action against individual health care providers. The statute provides, in part, that "the following conduct, acts, or conditions, constitute unprofessional conduct…

> (1) The commission of any act involving moral turpitude, dishonesty, or corruption…
> (2) Misrepresentation or concealment of a material fact in obtaining a license…
> (3) All advertising which is false, fraudulent, or misleading;
> (4) Incompetence, *negligence*, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed…
> (6) The possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes…[15]

Health care providers who violate this statute are subject to disciplinary action by the state. Interestingly, the Washington State Legislature has given equal weight to human error (negligence) and acts of moral turpitude, misrepresentation, and fraud. All of the acts defined by the legislature as unprofessional conduct involve intent or knowledge of the wrongdoing – except for the one provision involving human error (negligence) that can or does lead to patient harm. Clearly we can have no expectation that acts of fraud or misrepresentation would be reported in the interests of safety – these are crimes in our society. However, is it any more reasonable to expect that an erring physician would report an error in the interests of safety and in the face of a statute that labels human error as unprofessional conduct – held in the same disrepute as fraud, drug dealing, and acts of moral turpitude?

[15] RCW 18.130.180

Compare the Washington State statute with a regulatory authority example from the United Kingdom – where in aviation they are a world leader in event reporting. The Civil Aviation Administration (CAA) requires that air carriers in the UK report human error events that can be used to improve flight safety. To that end, the CAA states:

> "The Authority gives an assurance that its primary concern is to secure free and uninhibited reporting and that it will not be its policy to institute legal proceedings in respect of unpremeditated or inadvertent breaches of the law which come to its attention only because they have been reported under the scheme, except in cases involving dereliction of duty amounting to gross negligence [recklessness]."

In contrast to the Washington State provision that deems human errors themselves to be "unprofessional conduct," the CAA requires that human error events be reported to the Authority for safety analysis. Further, and unique to the CAA approach to managing human error, is the following provision:

> "Where a reported occurrence indicated an unpremeditated or inadvertent lapse by an employee, the Authority would expect the employer to act responsibly and to share its view that free and full reporting is the primary aim, and that every effort should be made to avoid action that may inhibit reporting. The Authority will accordingly make it known to employers that, except to the extent that action is needed in order to ensure safety, and except in such flagrant circumstances as are described [above], it expects them to refrain from disciplinary or punitive action which might inhibit their staff from duly reporting incidents of which they may have knowledge."[16]

Recognizing the need to learn from the mistakes of airmen, the CAA has taken a step yet unseen in the United States. That is, it has advised air carriers in the UK that they must alter their disciplinary standards to support system safety.

B. The Corporate Perspective

Following is a typical boilerplate corporate disciplinary policy used today by a large US corporation. The substantive sections are italicized for ease of reading.

> This policy of progressive discipline is mandatory for all employees responsible for causing a mishap. The purpose of this policy is to provide a consistent corporate disciplinary policy. In order to ensure consistent discipline, any deviation from this policy must be discussed with Employee Relations and the Vice President of Safety prior to taking action.

[16] CAP 382, Civil Aviation Administration of England, 1993

1. Employee(s) involved in, or witness to, a mishap (regardless of the severity), who fail to report the incident are subject to termination.
2. Employee(s) tested positive for drugs or alcohol who are involved in a mishap will be terminated immediately.
3. Mishaps which are the result of a violation of established Corporate Policy and Procedures will result in five days suspension of the employee involved without pay, for the first offense and termination of employment for the second offense in an eighteen month period.
4. Any employee acting with purposeful actions and conduct motivated by a malicious or discriminatory purpose (harassment, horseplay) will be terminated.
5. *Any employee involved in any mishap resulting from a judgment error but who notifies management in a timely fashion (within 10 minutes of the mishap) will be disciplined as follows:*

a) *For the first offense in an eighteen-month period, a letter of discipline will be retained in the employee's personnel file for eighteen months, AND the employee will receive five days off without pay.*

b) *Any employee involved in two mishaps will be terminated.*

6. Any employee involved in a mishap in the past eighteen months is not eligible for a promotion or temporary upgrade.
7. Anyone who knowingly assigns an employee to a position for which he/she is not adequately trained, or exposes him/her to an obvious risk, or intentionally conceals, obscures, or misrepresents information associated with a mishap will be terminated.
8. Prior to the employee's return to work, the most senior management person in the station/department will meet with the employee and discuss the mishap and their return to work. Documentation of the counseling session, along with a signed statement from the management employee, will be retained in the employee's personnel file for eighteen months. A copy will be sent to the Safety Department for review.
9. *Mishaps which are the result of negligence will not be tolerated; any employee that negligently performs their duties and causes a mishap will be terminated."*[17]

Consider the relationship between this disciplinary policy and an organization's effort to promote open communication following errors. Provision 5 provides a "two strikes and you're out" philosophy – dependent solely upon the existence of an undesirable outcome, and a human error. Provision 9 provides termination for one event involving negligence – with no distinction made between negligent and reckless conduct.

In contrast, consider the following mishap-specific disciplinary policy now used by an international air carrier.

[17] De-identified U.S. Airline Disciplinary Policy, 1996.

Event Reporting Policy – ABC Air Carrier

ABC Airlines operates in a complex and dynamic industry in which there are many competing pressures on the business and its people. Within this environment, there needs to be a safety and security culture which embraces the highest corporate and industry standards. Such standards are at the core of ABC's commercial reputation.

Maintaining and enhancing a positive Group safety and security culture requires a willingness to address and remedy all operational shortcomings as soon as they become evident. This in turn relies on comprehensive reporting of all incidents and risk exposures, whether large or small, which may pose hazards to the Group's customers, staff or operations. Those who observe, discover, are involved in, or are even responsible for such incidents and risk exposures have no discretion as to whether or not they report the circumstances. As a matter of Group policy, all safety issues without exception must be reported – immediately – through appropriate channels.

As a matter of policy, the Group is committed to the greatest possible openness and frankness in reporting. Subject to specific limited qualifications set out below, no blame will be apportioned to individuals following their reporting of mishaps, operational incidents or other risk exposures, including those where they themselves may have committed breaches of standard operating procedures.

The only exceptions to this general policy of no blame apportionment relate to the following serious failures of staff members to act responsibly, thereby creating or worsening risk exposures:

- Premeditated or intentional acts of violence against people or damage to equipment/property;
- Actions or decisions involving a reckless disregard toward the safety of our customers, our fellow employees, or significant economic harm to the company; or
- Failure to report safety incidents or risk exposures as required by standard operating procedures and/or this policy.

Staff members who act irresponsibly in one of these ways remain exposed to disciplinary action. A staff member's compliance with reporting requirements will be a factor to be weighed in the company's decision-making in such circumstances.

Outside these specific and rarely invoked exceptions, staff members who make honest mistakes or misjudgments will not incur blame – provided that they report such incidents in a proper fashion.

This second disciplinary policy is dramatically different from the first. It reasonably balances the benefits of a learning culture with the need to retain personal accountability and discipline.

C. A Note on Repetitive Errors

In nearly every discussion regarding disciplinary system design, the question will be raised about what to do with the repeat offender. That is, can the health care system afford someone who makes repeated errors while on the job? The answer to this question is difficult as the causes of repeat errors have two different sources. On the one hand, an individual may be in a job, or performing a specific task, that is very prone to error. Just as we can design systems to minimize human error through human factors, we can design systems that directly result in a pronounced rate of error. Consider, for example, if automobile makers were suddenly allowed to vary the location of accelerator, brake, and clutch peddles. Perhaps the accelerator in some cars is on the left of the brake, the clutch in the middle and the brake on the right. In each vehicle, you could easily learn which of the two or three peddles below did what particular function. Your life experience and strong habits regarding the positioning of brake, clutch, and accelerator, however, would produce a very pronounced rise in automobile accidents. Drivers in stressful situations would most likely resort to their strong habits associated with the more traditional layout of these controls. The healthcare system is no different – drug labels and equipment layouts lacking standardization and good design will lead providers to make repetitive errors. If errors are occurring repeatedly, it is critical for the system designers to be aware of the rate of error.

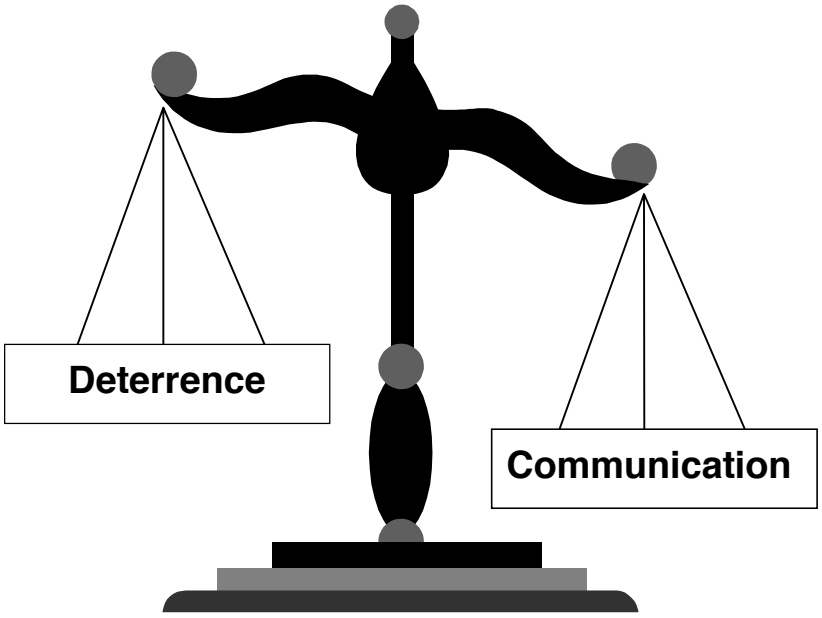
On the other hand, a source of the repeated errors may be with the individual. Recent traumatic events in one's life or a significant distraction in life can cause some individuals to lose focus on the details of their work – possibly leading to an increased rate of error. While we like to think that the individual who recently made the error will be the last to make that same error again, what we know of post-traumatic stress tells us that the erring individual may now be at a higher risk of error. In these cases, it may be an appropriate remedy to remove the individual from his current task or to supplement the task to aid in controlling the abnormal rate of error. This action, however, should not be considered a punitive measure as we have discussed throughout this document. Provisions can be made to deal with repetitive errors without invoking the stigma of disciplinary action and social condemnation. A change to a more suitable job function, retraining, or help with posttraumatic stress are all non-punitive tools that must be available to organizations.

D. A Note on Qualification

One additional issue that nearly always arises in a review of disciplinary strategy is that of lack of qualification. That is, can an unqualified provider cross the threshold of recklessness if he does not recognize himself as unqualified or as taking a substantial risk in continuing to care for his patients? As with repetitive errors, lack of qualification should not immediately result in punitive disciplinary action. Lack of qualification may only mean that the system failed in its duty to ensure the individual provider was fully trained in the task. In rare cases where providers intentionally sneak into the system knowing themselves to be unqualified, they are reckless with every patient they see and should be dealt with accordingly.

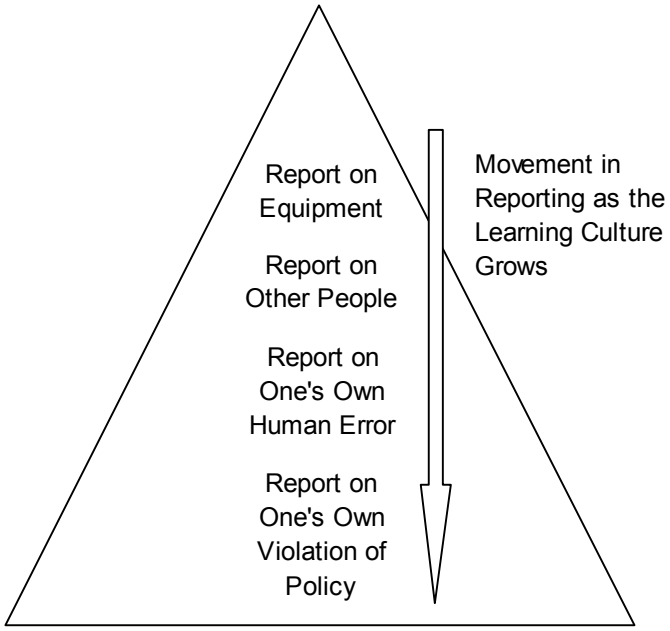
V. Your Task as a Health Care Executive

To implement a system such as MERS-TM, you should be re-evaluating the role of your disciplinary system as it relates to system safety. Is your current disciplinary policy supportive of or detrimental to your system safety efforts? Your job requires that you balance the interests of communication with those of deterrence.



In the context of event investigation, the important question is whether human factors learning from events outweigh the deterrent effect of punishment against negligent employees. If the threat of discipline increases one's awareness of risk or at least increases one's interest in assessing the risks, does this heightened awareness outweigh the learning from thorough error investigations? As you review your disciplinary system, think about how it really treats human error. If an employee makes a mistake, can he safely come forward so that your organization can learn from the event?

To evaluate your own system, consider the evolution of reporting that naturally occurs in most safety reporting and investigative systems, as shown on the illustration that follows. First, employees will report on equipment that has failed. There can be no backlash by the equipment so there is little to lose by the reporting employee. Second, employees will begin to report on each other even though reporting employees risk being ostracized by peers, especially when they report errors others may not have reported.



Third, employees will begin to report their own errors. The employee knows he may be acting against his own self-interests - but also believes that because his action was inadvertent, he has a low risk of discipline action. Lastly, employees will report their own intentional violations in cases where those violations occurred with an error on the part of the employee. In a culture where employees know that divulging their violation will educate others of the risk and that the data will be used to prevent future events, you will begin to see self-reporting of violations. It is at this point you may truly have a reporting culture. As stated earlier, one US air carrier found that over 50% of its technician errors involved normative violation of procedures – a fact that was crucial to the air carrier's error reduction efforts.

VI. Conclusion

Simply put, every one of the IOM's estimated 98,000 deaths caused by healthcare provider error is an opportunity to learn how the system may be modified, and how at-risk behaviors can be managed to significantly reduce the rate of harm.[18] Our system has been too focused on blaming the individual provider, with too little emphasis on how we could have learned from the errors of the past. There need be no loss of accountability because of disciplinary system changes. It is instead a different type of accountability – one that requires an employee raise her hand in the interests of safety. Not reporting your error, preventing the system and others from learning – this is the greatest evil of all. Yes, there are obstacles within the tort system, within the criminal system, and within the regulatory environment that make re-design of your disciplinary system a tough job. Those who step up to this challenge, however, will serve the future safety of the health care system. In the final analysis, we must all be held accountable for our efforts to make the system safer.

[18] Institute of Medicine. To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press, 1999.

About the Author

David Marx is a human error management consultant to hospitals, air carriers, and regulators. He received the 2000 Whittle Award for Outstanding Contribution to Flight Safety from the International Federation of Airworthiness for his work in developing human error investigation systems now used at air carriers throughout the world. David has been an investigation process researcher for the Federal Aviation Administration, and has just recently completed a yearlong review of NASA Space Shuttle processing quality. Combining his technical capability with a Juris Doctor in Law, David has spent considerable time helping air carriers, hospitals, and regulatory authorities develop safety-supportive enforcement and disciplinary systems.