Smith Seminars
MEDICAL ERRORS
AARC-Approved for 2 CRCE

Objectives

1. List the definitions, theories, models, and classifications of errors
2. Identify the terminology used in medical errors
3. Factors involved in documentation of medical errors
4. Identify solutions and remedies of medical errors
5. List the types of technical failure causing errors
6. Factors involving litigation of medical errors

Human error in medicine, and the adverse events that may follow, are problems of psychology and engineering, not of medicine. The following brief description of a serious problem stemming from a simple, well-established and very low-tech medical device shows that even in such technology there is much room for improvement. The case also reveals that there is even more room for improvement in the philosophy and general outlook of the people who design, manufacture, and market such devices – they need to know some psychology. They need to know about human behavior, ergonomics, and statistics.

To cure medical error, one must know something about the disease. What is an error? Why do errors occur? Why do medical errors occur? The causal mechanisms of medical errors, if there are any, must be the same as those of errors in nuclear power plants or aircraft, or in the kitchen. Although most people use the term medical errors, what they talk about are medical accidents. What is the difference between error and accident?

Definitions, Theories, Models, and Classifications

What is an error? From the viewpoint of an external observer, an error is a failure to perform an intended action that was correct given the circumstances. An error can occur only if there was or should have been an appropriate intention to act on the basis of a perceived or a remembered state of events. Then, if the action finally taken was not the one that was or should have been intended, there has been an error.

An error must not be defined by an adverse or serious outcome. An adverse outcome or accident may happen with no antecedent error. This may occur if the intention was the proper one, the action was properly executed, and the outcome was not certain. Examples are playing a game, deciding whether to carry an umbrella, administering a medication, or performing an operation known to be risky.

What Is an Accident?

An accident is an unplanned, unexpected, and undesired event, usually with an adverse consequence. An adverse outcome after an error, by this definition, must be construed to be an accident. No one plans, expects, or desires an accident. An error is a psychological event with psychological causes, if errors are caused at all (there is always the possibility that causes of all or some errors cannot be identified). An error may have any of a number of causes. A defined causal mechanism can give rise to a classification of errors.

As for almost anything, there are an almost unlimited number of classifications of error. Errors can be classified according to a hypothetical internal causative process.

Input Error or Misperception

The input data are incorrectly perceived, and then an incorrect intention is formed based on that misperception, and the wrong action is performed predicated on the incorrect intention. Thus an action was committed other than that which would have been intended had the input been correctly perceived. For example, a person may be confronted by the phrase "1000 mg" and see it as "100.0 mg." The person decides that it should be administered as a bolus into a Y-port and successfully does so, fatal overdose results.

Intention Error or Mistake

The input data are correctly perceived, an incorrect intention is formed, and the wrong action is performed predicated on the incorrect intention. Thus an action was committed other than that which should have been intended given that the input was correctly perceived. For example, a person may be confronted by the phrase "1000 mg" and see it as "1000 mg." That person incorrectly decides that it should be administered as a bolus into a Y-port and successfully does so, fatal overdose results.

Execution Error or Slip

The input data are correctly perceived, the correct intention is formed, and the wrong action is performed. Thus an action was committed other than that which was intended. For example, a person may be confronted by the phrase "1000 mg" and see it as "1000 mg." The person correctly decides that it should be administered as a drip after dilution in a drip bag. That person becomes distracted while approaching the patient and, from habit, injects the contents as a bolus into a Y-port, fatal overdose results.

One can classify errors according to the assumed locus of the causal process.

Endogenous Error

This is an error that arises from processes inside the actor. The elimination or reduction of such errors must involve psychology, physiology, or neurology. The error resulting from distraction cited previously is endogenous. It probably results from the capture of the lower probability process of injection into a bag by the higher probability process of injection into a Y-port. It should be noted that about four times as many of the bolus doses as the concentrates are sold and the two task sequences have common elements of action. Such a situation is an opportunity for a capture error.

Exogenous Error

This is an error that arises from processes outside the actor. The elimination or reduction of such errors involves design of objects and work environments and correction of policies, protocols, and procedures. For example, the inconsistent use of an extraneous ".0" in the quantity "100" induces the false interpretation of "1000" as "100.0" and could lead to an overdose accident. The unnecessary custom of keeping both bolus and dilution syringes in the same area permits the substitution error.

Errors can be classified according to the observable nature of the error. If an error actually results in an action, then there is a phenomenon that can be observed. The particular appearance of the

error may be called its mode. An example of a phenomenological classification of error (by modes) follows.

Error of Omission

This is an error characterized by the leaving out of an appropriate step in a process.

Error of Insertion

This is an error characterized by the adding of an inappropriate step to a process.

Error of Repetition

This is an error characterized by the inappropriate adding of a normally appropriate step to a process.

Error of Substitution

This is an error characterized by an inappropriate object, action, place, or time instead of the appropriate object, action, place, or time.

Why Are There So Many Classifications?

The various classifications serve different purposes. The internal cause classification may provide a theoretical basis for a program of behavioral or neurological research. The locus of causal process classification divides the universe of error into those that can be analyzed and cured by engineering, design, societal, and procedural changes, and those that can be analyzed and cured through psychological intervention and modification. The observable nature of the error classification provides a basis for the analysis of the consequences that will follow on the expression of the error in a particular working environment (an operating room or a nursing station, for example).

It is obvious that the various classifications are sometimes in conflict with regard to the ways in which errors may be differentiated. The classification organized in terms of hypothetical internal causal mechanisms conflicts with the classification organized in terms of the phenomena. For example, the three differently classified examples of input error, intention error, and execution error constructed for the internal causal process classification all lead to a single class of substitution error in terms of the observable nature of the error. The conflicts serve to emphasize that for the most part each classification serves a special purpose. The conflicts arise because of the differences of the goals.

How to Talk About Errors

Much of the discourse about errors is confusing because of the differences in terminology used. One person's error may be another's accident. One person's slip may be another's mistake. A generally accepted, standard terminology has yet to be established.

The mode of an error will result in some kind of expression, that is, something wrong will be done in the particular environment in which the action occurs. The expression must depend on what is available to be done in the environment. In a medical setting, an error of substitution (its mode) may result in a nurse's picking up a 2-g pre-filled Lidocaine syringe (its expression) instead of a 100-mg syringe. A wrong act has been substituted for the right act.

Finally, the expression may lead to a negative consequence, that is, something adverse will happen as a result of what was erroneously done; that is an accident caused by an error. For

example, the syringe substitution error can result in a massive overdose of Lidocaine. Attention is usually directed to the negative consequence because that is usually reported. Attention is also directed to the identifiable error that led to the consequence because it usually identifies the person who can be assigned responsibility.

What Is a Medical Error?

It is common to discuss errors in medical settings in terms of their expressions, that is, what was done wrong. It is common to report errors in medical settings only in terms of their adverse consequences, that is, what happened to the patient. This habit has serious shortcomings. Only those consequences that result in injury or death are noted. The number of incidents involving Lidocaine overdose, for example, is an interesting statistic, but it does not indicate much about the number of errors or why they occurred.

In reality, what are reported are not medical errors but medical accidents consequent on errors for which someone might be held responsible. What is not seen are those errors that occurred and were caught before they were completed. There is no good estimate of the probability of substitution errors on the night shift, or by physicians, or by pharmacists.
It would be of great importance to know the modes of the errors that were not harmful. The information could, for example, help in estimating the risk of the introduction of a new drug, a new package, or a new device into a health-care setting. Some kind of better data collection process is needed.

A medical error is an error that happens in a medical setting and is made by someone who is engaged in a medical activity. Some small fraction of medical errors leads to accidents that usually happen to a patient, the very person the medical establishment is dedicated to protecting and helping. It is usually the case that if there is no adverse outcome, no accident. The error is not reported and does not become part of the experience base of the practice of medicine.
It is clear that to understand what accidents are likely to happen to patients, information must be accumulated about all errors: those that injure or kill, and the near misses or those that have not yet done so. Then appropriate protective measures can be in place to wait for the error and interdict the accident rather than to be put into place after the accident.

Why Is a Medical Error Different from Any Other Error?

The high level of sophistication of modern medicines and medical devices makes the effect of misadministration more likely to be harmful than would be the case, for example, if the medicines were pharmaceutically inert (homeopathic remedies, perhaps).
Because of the very personal nature of medicine, the myth and mystique that surrounds it, and the image of the doctor in today's society, error in medicine is always seen as a special case of medicine rather than as a special case of error. Because of the frequency of litigation against hospitals and physicians in consequence of real or imagined medical error, the other class of persons studying errors are, risk managers, insurance specialists, and legal counsel. The consequence is that medical errors are usually analyzed exclusively by persons qualified in medicine, risk analysis, or law rather than by persons qualified to study error. The unfortunate result has been the isolating of medical errors from much, though not all, of the body of theory, analysis, and application that has been developed to deal with error in other fields such as aviation and nuclear power. Because of the intensely personal nature of medicine and because of

the ostensibly curative, helping, and ameliorative nature of the medical process, the consequences of medical error are viewed with more alarm than those in many other enterprises. That all of us, sooner or later, will receive the benefits, and be exposed to the risks, of modern medicine exacerbates the sense of alarm. The adverse outcomes are directly opposed to the ostensive nature of the whole enterprise.

It is difficult to convince politicians and administrators, patients and physicians, judges and lawyers, and juries, that one need not necessarily know anything particularly deep about medicine to be able to identify, analyze, and rectify the mechanisms that led to a medical error. The problems that arise and remain unsolved because of this difficulty have led to repeated injuries and deaths to patients and to subsequent expensive litigation. The solution lies in the application of non-medical knowledge to the cure.

Much as human behavior in a medical setting is still behavior and not medicine, human error in a medical setting is still error and not medicine. Medical error must be considered to be the result of the expression of error in a situation in which there is medically significant things to be done and done wrong. If an error that was expressed in a medical setting instead happened to occur in a nuclear power plant, the only differences would be in the words used.

The Biases in the Data

A major problem for the collector of medical error data is that so little is reported. Reporting biases stem from hospitals' fear of litigation and from the fact that the interest of administrators and regulators is directed to the adverse outcomes rather than to the mechanisms that led to the outcomes. Under doses rarely kill or injure and therefore do not get reported. Yet an under dose is the same error as an overdose but with the opposite sign. Pharmaceuticals are frequently inherently dangerous. Anesthetics, in particular, can be considered as designed to bring patients to a state between life and death. As a consequence, the potential for catastrophic outcome of minor overdose errors is very much increased. In general, that which is beneficial in small amounts may be of no avail in lesser amounts and malign in greater amounts. The result is that overdoses are more frequently reported than under doses, so that the statistics are distorted. There is no generally accepted error reporting system designed to reveal all those errors that occur but have not (on that occasion at any rate) led to adverse consequences. Such a universal reporting system is necessary because there are so many identifiable errors that are benign except under special circumstances. If they were identified and appropriate actions taken they might still occur but would effectively be disarmed through design changes.

Fear of litigation is one of the major reasons for the underreporting of inconsequential errors. The argument appears to be that error reports might be used to prove at some later date that a hospital knew that its staff made errors of a particular kind. Then, the logic seems to go, if at some later time the same kind of error resulted in an accident to a patient, negligence could be alleged. The negligence could have been in not disciplining or discharging personnel, in not increasing training or motivation, or in not changing something (no matter what).

The Mental Act of God

Should people, the actors, be blamed for their errors? Should they be held responsible? Blame implies a theory that incipient errors can be perceived by the actor before they are executed and voluntarily controlled to prevent their execution. Responsibility implies a theory that adverse consequences arise because of flaws in behavior.

An act of God is defined thus: "In law; a direct, sudden, and irresistible action of natural forces, such as could not humanly have been foreseen or prevented" (The American College Dictionary), and is also defined thus: "Operation of uncontrollable natural forces" (Concise Oxford Dictionary).

Errors, to the extent that we have data, are random; the moment when an error will occur cannot be predicted. There is no aura that signals to an actor that an error is about to occur even though people can be trained to be aware of a heightened probability of error. From the point of view of the actors, the errors that they commit are Mental Acts of God . The actors are the victims of the error. The patient is the victim of the expression of the error in a badly designed medical setting that permits the error to be completed and to produce an injury. Blaming people for making errors is like blaming them for breathing. They will do both willy-nilly. Preventing medical injury will require attention to the systemic causes and consequences of errors, an effort that goes well beyond identifying culpable persons.

Why Do Accidents Happen?

An accident can be the result of an error that is made, that is not detected and interrupted by anyone, and that can be completed in an action that injures or kills a patient. It is my belief that with the best of personnel selection and training, the highest of dedication, and the greatest of motivation, errors will still be made. An error-free environment is an illusory goal or, worse, a deliberate abdication of responsibility on the part of those who should do something about the consequences of error but prefer the easier route of blaming the people for Mental Acts of God.

What Is The Solution?

An error can occur, and can be self-detected and sometimes corrected, at many points in the sequence of mental and physical events encompassing perception, decision, and the initiation of action. An error can occur, and can be self-detected and sometimes corrected at many points between the beginning and the end of an action.

Such detection can be of the mode of an error, of its expression, or of its consequence. For example, a nurse may start to reach for a 2-g Lidocaine syringe and change the motion toward its correct goal, the 100-mg syringe. This correction might be a conscious act or not; little has been done on the analysis of such barely expressed errors. For example, a nurse may actually pick up the wrong syringe and immediately return it to be replaced with the correct one. There has been an error, but the detection and correction occurred in the same moment as the action. There are many opportunities for self-detection. Experience indicates that the probability and frequency of such self-corrected errors will be high. Errors are much more likely than might be thought on the basis of data from present reporting systems.

What Are the Remedies?

To reduce the probability of error, one can work on people, on procedures, or on the work environment. A reduction of error probability may be achieved by application of personnel factors aimed at improving human performance such as more powerful motivation, improved and mo re frequently renewed training, and the use of scientifically designed work-rest schedules.

Error may also be reduced and the probability of self-detection increased through the use of standard vocabularies and symbol sets, by standardized labeling and packaging, and by standardized design of the controls, displays, and interfaces of devices. Medical materials and devices should always be stored in a standard way and in standard locations in any medical environment. It is an unfortunate fact that the process of the administration of pharmaceuticals, from the writing of a prescription to the preparation of the dose to the administration of the medication, is full of problems. Some of these stem from appalling handwriting and ambiguous abbreviations, poorly designed packaging, and nonstandard labeling.

To improve self-detection of errors, there must be two kinds of remedies. Some must be psychological, for example, suggested the possibility of training in the use of tactics leading to improved probability of self-detection of error. Other remedies must depend on the redesign both of the elements of the system and of the system as a whole. In an ideal world, a prescription would say in clear and unambiguous words what medication was to be given to which patient, when, how, how much, and so on. A medication container would tell the person holding it what its name is, what the appropriate dose is, how it should be used, and what the consequences will be if it is used in any of a variety of improper ways. It would say all this in multiple ways, clearly and unambiguously, as if on the assumption that the person holding it was blind, stupid, and ignorant. Medical things should announce their identities to the user through many independent and redundant perceptual routes.

The probability of error detection can be increased through the use of variation of shape, texture, color, mass, and size, all of which actively engage human perception and memory. This would provide parallel channels of information feedback about the identity of what has been grasped, whether a container of pharmaceutical or a control on a medical device. Detection can also be improved by providing more active feedback to the user. The use of a bar-code reader and voice synthesizer on the cabinet in which medicines are stored would allow immediate confirmation by a watchful chip of what was picked up. Such equipment is in widespread industrial use, and costs are low. A cabinet so equipped that announced to nurses what they had just picked up would be an inexpensive and powerful collaborator against error.

Finally, to interdict the completion of the error in action, such as the bolus injection into an IV Y-port of a preloaded syringe of concentrated Lidocaine, the syringe should be designed so as not to fit where the contents should not be injected. What is needed is a design aimed either at physical interdiction of consummation of an error, in the manner of a lock-and-key pair, or at slowing or interfering with the consummation of the error. For example, the requirement of additional preparatory acts to be performed in order to use the syringe containing the concentrate would have offered renewed opportunity to detect the error in syringe selection. Ideally the

device used not in accord with its intended use should simply not work at all, and should complain loudly about it.

Preventive Analysis

It is always possible to find a reason for an accident and equally impossible to find a cause. The argument rests on the fact that, virtually without exception, accidents can be traced back to reasons masquerading as apparent causes, but prediction of the accident on the basis of knowledge of those same causes never occurs. There are an enormous number of chains of events antecedent to an accident. It can be said of each event that without that event, the accident would not have happened. These must be considered as reasons for the accident. They are the result of rationalization after the fact. Knowledge of the putatively causal events would not have led a rational observer to predict the accident. Nor would such knowledge have led even a sophisticated observer/analyst to alter the estimated probability of the accident. It must therefore be accepted that errors will inevitably occur and that the times of accidents cannot be predicted. The best approach is not to try exclusively only to prevent errors but also to reduce the probability of making errors and to increase the probability of self-detection and interruption of errors. In addition, failure mode analysis and fail-safe design must be used to interrupt or interdict the consummation of those errors that are executed, thereby minimizing the consequences even if the error occurs and is not detected.

Failure Mode Analysis

It must be accepted that errors will inevitably occur and that the times of accidents cannot be predicted. However, it is possible to predict the forms that errors will take. This makes preventive design possible. The remedy is to prevent the translation of the error into an accident. The manufacturers and the FDA must stop expecting health care providers to use things correctly every time. Each medication package and each medical device must be subjected to failure mode analysis. In brief, the designer of anything to be used in the medical arena must ask: What incorrect actions can people do? What adverse result can arise from these incorrect actions? How can those actions be prevented from being completed?

The application of failure mode analysis means that the possible ways in which each package or device can be misused should be exhaustively tabulated. Then the outcomes of each misuse are identified and evaluated, and those that are unacceptable must be designed out. That is, if a possibility is undesirable, then the possibility must be eliminated unless there is overwhelming reason to waive the requirement. This is like locking the barn door before the horses gallop out; the more usual approach has been to use a running horse detector to shut the door. For example, the IV system with tubing, bags, Y-ports, and the like can be designed so that a prefilled syringe that is supposed to be injected into a drip bag and used as a drip in dilute form must be incapable of being injected into the arm of a Y-port. This requires, of course, meticulous analysis of even such simple systems as a prefilled syringe or the IV set. It also requires the enforcing of standards industry wide to provide assurance of incompatibility where it is necessary. Because the greater concentration of technical knowledge rests in the manufacturing establishment, it should be the responsibility of the manufacturers to perform the analysis and present the results for evaluation by the FDA.

Problems with the use of medical equipment or devices can be broadly divided into two types. One type is when the equipment malfunctions as a result of a technical problem that is not caused by the user. This type of malfunction may be a result of an inherent defect in the design or manufacturing of the device (e.g., software error or inadequate mechanical assembly), or it may be a result of a random failure of a component. It may occur without warning to the user, and it can be relatively innocuous or can result in direct harm to the patient.

The second type of problem is when the user causes or initiates a malfunction. This type of malfunction can be one in which a technical failure occurs secondarily to the user's actions, or it may be one in which the medical objective of the device is compromised although the condition of the equipment remains unchanged. This can present a classic human-factors question in the evaluation of user error. Is the design adequate because it does allow proper use of the equipment, or is it inadequate in that it creates situations in which a user error is predictable? The types of medical equipment that are associated with user problems range from the relatively simple, such as catheters and syringes, to the most technologically complex, such as computer-controlled diagnostic equipment. Inclusively, they are covered under the definition of a medical device that is used by the U.S. Food and Drug Administration (FDA). Under this definition, a medical device is: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to effect the structure or any function of the body, and which does not achieve its primary function through chemical action or by being metabolized.

User problems in the use of medical equipment are of concern because of their effect on the quality and cost of health care. Preventing user error is a design, user-training, and risk-management issue. In this regard, users of interest include physicians, nurses, other health-care providers, support personnel, and patients, and other lay users. User error is also an issue for the FDA in its role in regulating the marketing of medical devices. In the aftermath of patient injuries, it is also an issue for the courts as attempts are made to assign blame for the injury. From any of these perspectives, a prerequisite to understanding causation and prevention is an understanding of the nature of user error and design principles for error control.

Technical Failure Versus User Error

The distinction between technical failure of medical equipment and user-initiated failure or malfunction of the equipment is an important one with respect to prevention of related patient injuries. User-initiated malfunctions can be generally characterized as ones in which the user had the opportunity to operate the device without incident but, for any of a variety of reasons, failed to do so. The user may be a physician, nurse, therapist, or other direct patient-care professional. In addition, relevant users of the equipment can include installers, clinical engineers and maintenance personnel, housekeeping staff, and other hospital employees who work with or around the equipment.

The hospital itself is a user of medical equipment through its corporate responsibility to select and maintain the equipment, assure the training of hospital personnel, and establish appropriate policies and procedures concerning staffing and equipment-use issues. It has recently been

suggested in this regard that the term user should include the entire spectrum of responsible individuals, and those with hands-on responsibility should be termed operators. Under this classification, operators become a subset of users. It is not yet known if this attempt to clarify terminology will find universal acceptance.

Operator-initiated problems have been identified as the most frequent cause of medical equipment incidents. In anesthesia, for example, operator-caused equipment problems have been cited in the past as very significant, including a high percentage that occur during the set-up of the equipment. It is operator problems that are the focus of human factors, including attention to the user (e.g., training, policies and procedures, working conditions, etc.) and to the design of the equipment (e.g., types and locations of switches and displays, durability, operating requirements, etc.). This range of the human factors perspective is of particular interest in that one of the principles of human-factors engineering, as it relates to the design of safe systems, is that reliance on the operator is the last choice of hazard-prevention methods. This choice is always to be preceded by elimination of the hazard, providing guards to protect against the hazard, or providing automated warnings of hazardous operating conditions.
Operator-initiated problems have often been characterized with the term user error or operator error with the implication that the problem was totally caused by, and can therefore be blamed on, the operator. In using this term, it must be remembered that the human-factors perspective often rejects this assessment of cause through the concept that bad design can cause users to make mistakes, that such mistakes may be predictable and preventable, and that therefore the result can be blamed on the design. In this perspective, bad designs have been considered "accidents waiting to happen" or "traps" for the user. Thus the term user error, although perhaps correctly identifying what occurred, should not be interpreted as necessarily attributing any or all of the blame to the user. The importance of understanding the causes of human error in the use of medical devices is, therefore, to reduce patient and other injuries and the burdens on medical personnel that may impair their effectiveness. Risk management efforts are thereby enhanced and the waste of materials and money reduced.

Impact of User Error

It is fortunate that many equipment problems in the medical setting do not cause significant, if any, harm to the patient. In some of these cases, it may be that the malfunction is easily detected and corrected or the equipment replaced without incident. In other cases, the equipment may not have been doing anything particularly important at the time of the malfunction, or the malfunction may be compensated for by other equipment. Also, the event that the equipment was meant to deal with may not have occurred. Thus, a miss set monitor alarm is not of direct consequence unless the event being monitored occurs and is missed as a result of the lack of alarm function.

The frequency of relatively harmless events is hard to determine because they generally go unnoticed or unreported. This does not mean that they are unimportant. An improperly functioning or otherwise misused device that is innocuous sometimes may cause injury at other times. Physically harmless device use problems can also have other consequences, such as increased cost as a disposable must be discarded or a diagnostic procedure repeated. Whereas many instances of device malfunction may be without serious consequence, some equipment mishaps, whether caused by technical malfunction or the user, can be of catastrophic

consequence to the patient. This can occur when the equipment or procedure is highly invasive, otherwise life threatening, or life supporting. There can also be serious consequences if an important diagnostic result is erroneous or misleading as a result of user error or malfunction. In addition, equipment problems associated with one patient can have adverse effects on other patients. For example, attention and effort can be diverted toward the equipment problem and away from the patients.

Finally, it should be noted that the patient is not the only one at risk with respect to user-related equipment problems. Others in the hospital such as staff and visitors can also be at risk from medical equipment. Risks to various hospital staff include the danger of accidental needle sticks. Improved collection containers have been marketed, and point of use signage is now common. However, according to a medical device industry newsletter, relatively little has been seen in the form of new products that will automatically protect the user. Thus, the effort to date emphasizes improvement in the behavior of the user rather than the improvement in the equipment. However, the latter is always preferred from the human factors and safety engineering perspectives because it provides reduced risk in a way that is independent of the training of the user.

User Error: Litigation

Medical mishaps may result in civil litigation in which patients or their families seek monetary compensation for their injuries and financial losses. A case of this kind can include physicians, nurses, other health-care providers, the hospital, and the manufacturers of medical devices as defendants. In general, it would be alleged that the medical personnel and hospital were negligent in the provision of care and that this negligence was the direct cause of the patient's injuries.

With respect to the medical device manufacturer, it would generally be alleged that the manufacturer was negligent in the design, manufacturing, or the adequacy of the instructions associated with the medical device. Alternatively, under the theory of strict liability, it can be alleged that the medical device was in a defective, unreasonably dangerous condition regardless of the care taken by the manufacturer in designing, producing, and marketing the product. On one hand, the various defendants may be allies in resisting the claims of the patient; on the other hand, they may seek to distribute or redis tribute blame among themselves.

In a typical user error mishap, there will be no precipitating technical failure of the equipment and in fact, the equipment will be in normal operating condition after the mishap. In this type of case there are issues for the user, the manufacturer, and the hospital. For the user, the question is the degree to which they should be directly blamed for the error. With respect to the manufacturer, the question is the degree to which the manufacturer should be blamed for designing equipment that is prone to error or failing to provide adequate instructions and warnings. For the hospital, the question is the degree to which the hospital is responsible for selecting and controlling the use of equipment that may be prone to error.

These issues must always be considered in the context of the real environment of use, which may include fatigue, aggressive personalities, and the stress of medical emergencies. The resolution

of these issues is dependent on the recognition of the role of user issues and device design in controlling errors in the use of equipment.

The purpose of understanding user error in the use of medical equipment is to prevent injury and improve the effectiveness and efficiency of medical care. The reason for focusing on this aspect of medical care is that user error has been identified as a significant factor in medical device-related incidents, and many instances of user error appear, at least in retrospect, to have been preventable. More importantly, the analysis of past user error and accomplishments in some areas of medicine and in other industries have demonstrated that user error can be substantially prevented if proper attention is paid to dealing realistically with the user, the environment, and the design of the equipment. User issues are related to underlying intellectual and physical ability, general education, specific task and device training, and work scheduling. These issues also address stereotypical characterizations of human ability and performance and the understanding of human variability as it relates to these and other factors. Environmental issues address general working conditions, including shift schedules, lighting, noise, temperature, distractions, and workload.

The design perspective addresses the need and obligation to incorporate features in a medical device that will facilitate its use and prevent foreseeable errors and misuse under common user and environmental conditions. User and environmental conditions can always be improved, and in many areas they need to be. However, the first principle of designing for safety must be that these conditions are a given that must be the basis for design decisions. Thus, the hierarchy of hazard elimination, provision of protective measures, provision of automated warnings, and lastly, training the user should be the basis of product design.

Conclusion

There are many errors that occur in medical settings. Those that are not prevented from running their courses can lead to accidents. These are the ones that come to our attention; the others are lost in the course of time. The lost errors are those that have not or have not yet injured or killed a patient. The lost information could have been used to predict what errors are likely to injure or kill a patient in the future.

There must be a system for voluntary and anonymous reporting of all errors that occur in the medical system. The reports must be collected into a single database that will permit search and collation of data by multiple attributes. Such a system is needed to predict the kinds of incorrect things people are likely to do in the future.

Many errors stem from the absence of a controlled vocabulary for use in the medical setting. Such errors could be eliminated by appropriate design as well as promulgation and enforcement of the use of a controlled vocabulary. All communication of medical orders and all names of medical preparations and devices should conform to the standards of the controlled vocabulary. This is especially true of prescriptions that are an erroneous link between the medical system and the patient. Other errors stem from poor handwriting and the use of improper abbreviations, especially in the writing of prescriptions. Improvements in training and work schedules will be effective in reducing, but will not eliminate, errors of medical personnel.

Because not all errors can be eliminated, it is necessary to increase the probability of self-detection of errors before they are expressed in action through training, through design of devices and containers, and through consideration of the error-inducing aspects of the social and physical environment in which errors occur.

Finally, because not all errors will be self-detected, it is necessary to eliminate or diminish the consequences of error in the medical setting through design. Human failure mode analysis is the necessary tool.

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