THE ERROR MANUAL

Supplemental Information
on
Engineering Errors
Managerial Errors
and
Medical Errors

for use with

Human Error: Causes and Control

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Preface

This is a supplement to the book on Human Error: Causes and Control. It serves to augment and helps to clarify the concepts, theories, techniques, and methods described in that book. It is important that this Error Manual be used in conjunction with the more definitive Human Error book which contains explanatory text, reference material, and “how to do it” information.

This Error Manual presents supplemental ideas and examples from which selections can be made to fit the needs of a particular situation. The authors cannot ensure proper application and usefulness of this information to a particular situation, because of the variety of skills among the readers of the book, their varied perceptions about human error, and their differences in the ability to apply effective countermeasures.

The use of examples has been favored in the Manual to enable the use of the Socratic Method, which involves a series of questions leading to answers that at first may not be obvious or problem responsive. This is analogous to the root cause methods, used in human error evaluations, where there is a search for true causes and more pin-pointed relevant remedies. This approach to learning is also a help where caveats or rules are memorized, then repeated or explained to assure meaning and basic understanding, and finally creatively applied to a set of facts or assumptions to demonstrate comprehension and the usefulness of the caveats or rules. Case examples help in self-learning, self-test, and application by analogy.

Human error problems are widespread. Older methods for prevention and correction have been proven insufficient and the toll continues. The Human Error book and this Error Manual may stimulate a more effective resolution of a serious social and industrial problem.
A. Introduction

This Error Manual provides additional information concerning the detection and prevention of human error. The Preface of the book “Human Error: Causes and Control” suggested that the selections of information, the use of case examples, and the specific interpretations that could be made to fit the needs of a particular group or situation are quite varied. The reader may have a particular personal interest or focus, such as on the prevention of medical error. This subject is covered in a generic fashion in the Human Error book, but some added detail should be instructive and helpful. Readers or students may have different interests, different levels of familiarity with the background or context of various case examples, different levels of comprehension of technical words or the vocabulary utilized in various subject areas, and different understandings of the corrective and preventive actions that are economically and technically feasible in various activities. Similarly, there are variations in the attitudes and motivations of those who could enact, help enable, perhaps accept, possibly modify, or even reject the recommendations of the human error specialist. Such differences may be unfortunate. They suggest the need for a diverse selection of material, concepts, techniques, and preventive applications pertaining to human error. The differences also suggest the need for something beyond mere passive learning, so there is in this Manual an attempt to require some interaction, rational reasoning, logical deductions, and critical evaluations. The format of the case examples in this Manual varies to reflect possible needs. Hopefully, this Manual will provoke thought and discussion that will serve to encourage attempts to reduce human error and its consequences.
B. Medical Error - Clinical Practice

1. Cultural Factors

There are distinct cultural differences between medical error and error in other occupations. In an industrial situation, attempts at process control serve to reduce product or output variability or unwanted error. The product is uniform and machine tools are adjusted to assure that all products turn out to be the same. However, in a medical setting the product or output is the patient and each patient is markedly different, has different diseases, is treated differently, has different needs, and has different levels of recovery. The process control is far different when there are highly independent diagnosticians, surgeons, anesthesiologists, nurses, and technicians. Even the diagnostic and treatment options generally involve highly subjective professional decisions. Such differences suggest that generic human error control, while quite valuable, is not sufficient to adequately treat medical error.

2. Teamwork

Because of the differences in medical specialists as individuals and the differences in what medical facilities are utilized in their role as independent contractors, medical teams are formed that may be just a loose bunch of strangers, a friendly group of some professional acquaintances, or a closely knit
team experienced in working with each other. Members of an experienced team may anticipate the actions and needs of other team members, so there is a faster, more harmonious, and well-organized relationship. It may be expected that the patients involved in a team effort will do better, but the results can be dramatically different. The death rates from heart surgery can vary four or fivefold between hospitals and surgical groups. Good teamwork has been advocated, encouraged, and has become something of a buzzword for many years. What is now being emphasized by the management of some medical institutions is a far more intensive teamwork. A team in which greater equality among all team members is achieved by good leadership and clearly established goals. It is assumed that proper teamwork is essential to reduce medical error. Quere: Should there be greater study of behavioral group dynamics and cohesion to determine those factors that actually promote teamwork in different medical settings?

3. Transparency

There are those who suggest that medical errors be considered private, proprietary, and covert matters. This assumes that a hospital can obtain better information, to determine remedial measures, if the transgressors do not fear repercussions from patients, lawyers, government agencies, internal review boards, external boards, and the public media. There that been legislative or code protection attempts which tend to suppress public knowledge of facts and encourage corrective action within the confines and secrecy of the discipline. There are those who have advocated an error data transmission system to provide overall data to some national agency, in a fashion used in aviation safety where no assigned pilot fault serves to reveal safety errors for corrective purposes. In medical error, secrecy has not helped, there is no satisfactory place to send the information, and there may be ethical violations.

For example, the rights of hospitalized patients were described, in January 1973, by the American Hospital Association (Nursing Outlook 24:29) as follows: “the patient has a right to obtain from his physician complete current information concerning his diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand”. Also see informed consent and other ethical constraints in Chapter 12 of the Human Error book, Professional Responsibility (Ethics). The more appropriate choice is transparency of medical errors if there is to be sufficient correction and prevention in terms of the public good.
4. **Consistency**

A patient received a new container of pills and looked at the package insert (the patient counseling information sheet) furnished by the dispensing pharmacist. The insert said “drink plenty of fluids while taking the medication”. The patient looked at the pill container and saw a yellow flag saying “this medication should be taken with PLENTY of WATER”. The graphic of a running faucet and a glass being filled emphasized its importance. So the patient asked the prescribing physician just how much is “plenty”? Is it a half glass of water, a full glass, or more? Is it while actually taking the pill or just in general while on the medication? The response was “just enough to help swallow the pill”. The matter seemed unimportant to the physician, but was indicated as important on the yellow container flag and in among a page full of fine print describing side effects, precautions, and interactions. This episode may seem rather minor, but it demonstrates inconsistencies on exactly what the patient should do. The impression of the patient is what is important.

Minor differences and inconsistencies could suggest to the patient that a generally accepted protocol or procedure was not being followed. Someone was correct, and someone was in error. It might be important to one doctor, but not the other. Much of the elimination of medical error involves consistently and precisely following a prescribed order or procedure so that everyone is aware of what was most likely done.

5. **Medical Interviews**

The time spent with each patient, by the medical specialist, has been drastically shortened by the economics of organized or managed health care plans. Gone are the days of home visits by family physicians where they got to know a great deal about individual patients, their family members, the immediate circumstances surrounding disease and pathology, and possible treatment options. Today, a relatively short office visit presents a rather limited opportunity to obtain a broad spectrum understanding of the background, cultural, ethnic, racial, and personality characteristics that might make a difference in diagnosis. Some patients may have difficulty explaining the real reasons for seeking help, their deeply hidden concerns, their possibly embarrassing symptoms, their fears, and their primary problems or trouble sources. This imperfect communication, with a few probing questions from the
doctor, must be compressed into a rather limited available diagnostic time. There can be misunderstandings, misinterpretations, insufficient verification of facts, and resultant errors in diagnosis and treatment. Mistakes can be lessened if the diagnostician can quickly cut to the point without disturbing the necessary trust and rapport with the patient. The patient’s beliefs, goals, and requests are very important and should be heard and heeded. Demonstration of empathy non-verbally is critically important. The diagnosis, tests, and treatment must be explained. There is much to do and just too little time. The burden has been placed on the medical specialist to limit general exploration that is not relevant to the patient’s stated concerns, to properly prioritize the symptoms and issues, and to verbally penetrate the non-essential language being used even if it is interesting. In one instance, emergency room treatment was based on the statement of a police officer who accompanied the unconscious patient to the hospital. Unfortunately, the police officer was reporting what he heard from bystanders, which was incorrect, so the diagnosis was wrong and the treatment fatal. Important information should be verified with others or rechecked for accuracy with the patient. The use of plain English, joint decision-making regarding treatment options, and refined interview techniques all aid in the medical error control. Special training may be necessary to help a medical specialist to properly allocate time (save time) and to quickly derive valid and error-free conclusions from the patient communications.
C. Medical Error - Medical Devices

1. Portable Medical Devices

In many portable medical devices the tethered or plug-in power system has been replaced by a battery-based system for mobile or field use. Reliability and safety are very important for such life-saving devices. There may be significant differences between a device’s published performance data in a specification sheet (the user expectations) and the device’s real world reliability (its actual performance). Battery packs may have sealed lead acid cells, nickel cadmium cells, or nickel-metal hydride cells that may generate explosive hydrogen gas during charging. Lithium-ion cells also have some potential safety problems. Future lithium-ion batteries may have much higher voltage outputs and extended service life. Counterfeit batteries are becoming a problem. Inadvertent overstressing of the batteries is a common human error. Safety considerations include fuses and battery packs with cells of the same chemistry and capacity. Preferably, a smart battery system is used that monitors battery operation, predicts remaining run time, has a cycle counter (the number of charge and discharge cycles), and a communication advice to indicate its status to the host device. A safety circuit may be used to protect the battery pack from overcharging, overdischarging, exposure to excessive temperatures, short circuits, or other
human misuses. **Quere:** Should portable medical devices have built-in design countermeasures for conditions of misuse or should the countermeasures be offered as options or cost deletions for knowledgeable users?

2. **Patient Restraints**

   To reduce falls or other injuries to patients, physical or drug restraints have been commonly used. For at-risk patients suffering cognitive impairment, unpredictable behavior, seizures, or spasms a padded bed was developed that was covered with a zip-in nylon netting, canopy, or enclosure. In 2005, the U. S. Food and Drug Administration issued a Public Health Notice indicating they were aware of 30 entanglements with 8 deaths when patients became trapped between the mattress and the canopy or side rail. If the head became entrapped, there could be asphyxiation and severe neurological damage. Patient restraints are frequently used if a nurse has a suspicion that the patient may be attempting to alter or remove an endotrachial, oropharyngeal, or nasopharyngeal intubation tube intended to prevent airway obstruction, for example, by the patient’s tongue for those having general anesthesia or who are semi conscious. **Quere:** an overworked nurse may quickly decide on the simplest approach requiring the least future attention, is by the use of arm restraints, without determining what the patient’s real problem might be. What might be the most serious error, quick restraints without real knowledge or leaving the possible risk of intubation tube dislocation?

3. **Medication Errors**

   At a hospital in California, an error-reduction program included a mistake-proofing rule to check the identification of each patient before administering medications or performing medical procedures. Each patient had a bar coded wrist band with the patient’s name printed in English. Some nurses would ask the patient, “Who are you?” (to which the patient might think, “You don’t know me even though you have been treating me”) or “Are you John Doe? (to which the patient might think “Have you or will you confuse me with someone else?”). In other words, some nurses routinely read the wrist band identification system and others did not. Some physicians neither asked or looked at the wrist band. The rule should not have common exceptions, if it is to become an automatic habit.
Medical health providers often “buck the system” as revealed by in vitro fertilization (IVF) procedures where more than the recommended number of embryos are implanted in the womb. In a number of European countries there is a ban on implanting more than 3 embryos, but in the United States there are only voluntary guidelines. In 2002, there were 35% multiple births and 4% triplets (or higher) following IVF in the United States as contrasted with 10% multiple births and 0% for triplets in Sweden. The health risks of multiple births are suffered by the patients, whereas the fertility clinic may enjoy the publicity from a high success rate.

A study sponsored by the European Commission, conducted in Italy in 2004, attempted to reduce medical errors and costs at the hospital unit-dose level. Hospital patients were required to wear bar code bracelets (wrist bands) that could be read by smart medicine carts (trolleys) so that the patients received only the prescribed medications in the correct dosage. In the hospital ward, the patient wristbands digitally indicated to the cart which medications were needed. An incorrect patient-medication match resulted in a warning sound. The risk of improper intravenous, intramuscular, intradermal, and subcutaneous drug administrations were reduced by 71%. **Quere:** If there is an expression of personal independence and feelings of superior competency by ignoring the rules or guidelines, are the future error reduction efforts forced toward smart computer controlled medicine carts and sophisticated patient radio identification systems that encode all vital information concerning a patient? That is, medical staff independence (rule breaking) may require automatic circumventing of opportunities for human error.
D. **Augmentation of Key Chapters**

1. **Introduction**

   This Supplement to the Human Error: Causes and Control book serves to augment the information contained in each chapter of the Human Error book.

   The purpose of Chapter 1 in the Human Error book is to illustrate, with examples, that human error abounds in every aspect of modern life. That book may be used for self-education and as a personal reference. But, it may be also used for instructional purposes in company training courses, seminars at professional conferences, or in university courses. Under those circumstances, students may be asked to discuss their personal experiences and knowledge concerning human error. The examples in Chapter 1 of the Human Error book include remedies that suggest that error reduction is a realistic goal. In essence, errors can be predicted and prevented in a reasonable manner. The use of Discussion Questions (from Chapter 13) should be Socratic or open ended: For novice students or trainees start with Questions 3 and 4 (The Unguarded Saw and The Stairway). These questions should be easily understood and are relevant to everyday life experiences. Then, use Questions 1 and 2 (Smart Robots and Flexible Workers) as an instruction on errors in manufacturing and the effect of management decisions on human error.
Pigging

A device called a pig is used in pipelines to clean them, inspect them, and gather intelligence about the pipeline. The pig is a circular object, that can be made to expand to the diameter of the pipe, then pulled through the length of the pipe to assure that the full flow of fluid is unimpeded. Large diameter gas lines use robotic pigging to remove ferrous debris by magnets, brush the walls to remove fine powders, check for damage and wear, determine cracking and ruptures by ultrasonic inspection, and clean the gas pipes of sediments, residues, paraffin waxes, scales, sand, and metal scraps. Computer analysis of the data may assist in pipeline integrity management, including assessment of dents, flat spots, buckles, ovalities, and corrosion growth.

Pigs are also used to block the flow by pneumatically inflating a rubber ring, bladder, or balloon to cause it to stay in-place and seal the pipeline. In Ohio, a sewer line was plugged with an inflatable pig. A worker was sent into the large sewer pipe to make repairs. Suddenly, the inflatable pig came loose, the sewerage engulfed the worker, he suffocated, and was killed.

Was this an error of the worker to enter the plugged sewer line? Was it an error of the company that used the pig to hold back a large volume of sewerage? Was the pig defective because of a design error?

Answers: Absent expert knowledge, the worker had to enter the sewer line to make a repair or otherwise he could lose his job. In this case, the company that used the inflatable pig was doing what was advertised as the pig’s capability. There may have been a design defect, but a thorough design analysis was not completed nor was the pig available for detailed inspection after the accident. This interesting case suggests that assignment of possible human error may be different or impossible under actual accident circumstances with personnel who are not sophisticated in human error evaluation.

Food Safety

There is a widely known dictum to eat wisely and exercise a little. It is suggested that this can reduce severe coronary heart disease, reduce overweight, and improve mobility. Other people suggest that this is an unpleasant lifestyle change, some sort of coercive behavior modification, or an unwanted control that reduces personal choice and individual freedom. If an overweight individual who
has health problems decides not to undergo nutritional changes recommended by a medical specialist, could this be considered a human error? Among healthy individuals, is eating too much and failing to exercise enough some sort of human error? Is it error on the part of the food industry not to provide convenient, tasty, and healthy foods? Are bad food habits the result of hereditary factors that cannot be controlled? Are “food police” a viable option in terms of public health? Should error specialists become involved in food safety matters?

2. Data Collection

The purpose of this chapter is to suggest sources where human error data could be found. It describes how data might be clarified, classified, and utilized for error prevention purposes. The examples serve to illustrate the desirable and undesirable characteristics of human error from the perspective of prevention. The remedies suggest that the general context, immediate setting, and overall surrounds play an important role in determining effective error countermeasures. Socratic Discussion Questions (from Chapter 13): Questions 5 and 6 (Acceptable Defects and Instinct) suggest that defect rates and errors are considered during the manufacturing process and that remedies are often not very sophisticated. Questions 7 and 8 (Anger and Fear) suggest that human reactions and personality factors play a role in creating human error in job assignments where risk is involved.

Ignorance

The failure to gather error data, perform appropriate analyses, and institute effective remedies may be termed an intentional ignorance of the facts. It is a matter of not knowing what is not known. It might be a matter of thinking “we know” when we don’t. Ignorance based opinions, pat answers, or groping in the dark for some elemental knowledge can set the stage for catastrophic events, since pure luck goes only so far.

There is also a dis-confirmation bias, where people quickly accept information that supports their existing viewpoint and reject or ignore information that is inconsistent with their beliefs, however speculative they may be. People are quick to judge and then close their minds. Stereotypes, personal attitudes, mental shortcuts, and prior experiences tend to prevail over balanced and independent decision-making. Should human error specialists evaluate such biases by asking open ended questions? Is objective data always necessary? Can
objective data serve to quell speculative opinions that may be misleading?

Answers: Open ended questions permit answers that seem true and correct from the perspective of the person who answers. Without the inherent guidance of a content framed hypothetical question that suggests an answer, the person who answers may not know how to answer other than to rely upon his own biased speculative beliefs or frame-of-mind. That is, the question should not suggest an answer. Objective data may not be available and reliance may have to be placed on good logic as dictated by peer-accepted methodology. Data is not always necessary. Objective data may defuse speculation because “the facts reveal” argument suggest what is apparently true.

Nurses’ Errors

Many nurses believe they have imperfect memories and that they might forget some critical treatment information. They may worry about completing every medical procedure without mistakes. In the field of healthcare just one error, of low probability or frequency, may have significant health consequences. The highly motivated nurse may search for a means to reduce such error. Cognitive functions such as memory, experience retention, and learning reside in the neocortex of the brain. Understanding the function and plasticity of the relevant neural circuits may be of help. The highly dynamic cortical circuits undergo changes in shape, function, and interconnection in response to stimulation. This is the physical basis for behavioral flexibility and adaptability. It may effect personality and broader cognitive functions. In the past, memory might have been assigned to one or more areas of the brain in the form of a brain map. More recent neuroscience research has revealed the overall system function of the brain and the presence of many multiple sites (parcellation) for even closely related functions. These microcircuits suggest that there are multiple access pathways to brain locations that could have error reduction potential. Plasticity, in general, occurs in response to training and periodic retraining (rehearsals of correct procedures to form automatic habits). There is vigorous current neuroscience research that could produce results (activity dependent rules) that might help the conscientious nurse avoid human error when working within the hospital culture.

3. Risk Assessment

The purpose of this chapter in the Human Error book is to indicate that human error analysis can have a methodology that can be generally accepted and be capable of replication (the hallmark of scientific endeavors). It also suggests
that this methodology be compatible with other allied disciplines. The text and examples describe various risk assessment techniques and the meaning of frequency, severity, risk acceptance, and other commonly used terminology. The caveats, in this and other chapters, are derivative principles of good practice. Socratic Discussion Questions (from Chapter 13): Questions 9 and 10 (Decision Support and Problem Employees) suggest that significant error rates and problem employees are tolerated. Questions 11 and 12 (Aircraft Control and The Zoo) suggest that human errors may be frequent and easily rationalized. These examples suggest the need for formal risk assessment, including better analytic inquiry and the application of basic principles of human risk engineering.

**The Falling Shower Stalls**

A truck driver for a freight company delivered a pallet of shower stalls in 10 boxes to a plumbing company. A forklift driver employed by the plumbing company raised the pallet, weighing 11,000 pounds, and started to turn the forklift. The boxes slipped off the forks of the forklift and fell on the truck driver, hitting his back, knocking him down, and causing a shoulder injury that permanently limited his right arm motion.

Was it an error for the forklift driver to have turned too fast? Was it an error not to have lowered the load before turning? Did the injured truck driver stand too close to the forklift? Was it an error for the truck driver to turn his back on the operation? **Answers:** The forklift driver should have lowered the load and, then, turned slowly. But, forklift drivers are often jockeys that want to demonstrate their skill by quick maneuvers. There has been a high frequency of forklift driver errors and, as a consequence, a steady improvement in features that improve driver visibility, handling, overhead protection, and warnings to other workers. The truck driver should have been at a safe distance, attentive, and facing the operation to observe what was happening to the load he had delivered. There had been no risk assessment of the operation. In essence, there may be multiple sources and types of human errors to be included in a predictive risk assessment for one operation.

**Radical Thinking**

A radical change in thinking, particularly if it diverges from traditional approaches to problem solving, is difficult for most humans. Risk assessment in general, has been one of those radical changes in thinking that prompts evasion
and avoidance. Darwin’s theory of evolution, as an adaptation to an ever changing world, is illustrative of what occurs to radical thinking over a long period of time. Behavioral genetics may account for more than half of the variance in cognitive abilities, temperament traits, personality attributes, and mental disorders. But some consider gene expression networks and the emphasis on specific brain activities to be radical thinking that omits the overall complexities of human thought and emotion. They consider a linear relationship between brain functions and behavior or the relationship between gene expression and behavior as too illusory.

Is the control of human error a form of radical thinking that is illusionary? Is the location of specific brain functions, by imaging techniques, just a hope of radical thinkers? Answers: It may be wise to proceed carefully, reasonably, prudently, and diligently in well developed areas of inquiry. If problems persist, some reasonable attempt to resolve the problems should be made even if it may be considered somewhat radical or too innovative by others. However, activities such as risk assessment are not so much radical as they are advanced and sophisticated problem-solving activities. There may be changes and improvements in human error detection and countermeasures, but that cannot occur until there is careful, attentive, and persevering efforts to achieve better methodology. In essence, act now to achieve some benefit and then review the lessons learned.

4. **Alternative Analytic Methods**

The purpose of this chapter is to demonstrate that the detailed methods of risk assessment illustrated in Chapter 3 may not be necessary. Simpler or discrete studies may be used.

**Roadway Visibility**

Some vehicle drivers may have difficulty staying within the correct roadway lane when it is dark or raining and the road edges are somewhat obscured. There are roadways that use white cement concrete, rather than conventional gray cement concrete, for median barriers, curbs, bridge rails, nosings, and some other structures. The premise is that in nighttime conditions or rainy weather, the white concrete is 2 to 3 times more reflective than the gray concrete. This provides a better visual guide or pathway for drivers, particularly for seniors who may have visual problems. This would be in addition to road
edge markings, such as a white line on the edge of the road, and raised pavement markers between lanes (green or red depending on the approach path). Quere: Is this overkill to prevent just a few human errors? Since roadways without the reflectant concrete, edge markers, and lane dividers have been in use for many years, and vehicle drivers have accommodated or adjusted to those conventional roadway conditions, should roadway improvements be limited to just those sections of roads with known visibility and error problems? How much of an analysis should be performed? What data should be used? Is a detailed analysis as shown in Chapter 3 justified?

Work Zone Fatalities

There may be widely held a priori conclusions that something should be done about a safety problem that includes some human error causation. An example would be work zone fatalities at roadway construction sites. There have been claims of driver inattention, carelessness, poor vision, and failure to slow down in marked traffic lanes. Construction planning strategies have included doing the construction work at night when there is a reduced volume of road users or diverting traffic to other roadways. Research efforts have included improved methods of alerting drivers about the work zones by using portable changeable message boards, flashing lights, and arrow panels to encourage motorists to move out of upcoming closed lanes. There has been a replacement of old incandescent bulbs with longer lasting and stronger light-emitting diodes (LED lights). Exposed workers may use electrolumination (neon vests) to illuminate themselves while working in the dark. Quere: should the signs be tested on-site to be sure that they are visible to on-coming motorists? Do they actually serve some needed traffic control system purpose? What should be done about pedestrians that must traverse the work zone? Are longitudinal channelizing or delineating barricades useful during the day and the night? Are work zone walkways appropriate? Are cones, drums, and crash cushions useful to reduce driver error? How are visual disabilities considered? Can the night visibility of traffic signs and pavement markings be tested? Should vehicle drivers depend only on their headlights to illuminate signs that can reflect back the light (retroreflectively) when the signs may be at ground level, street sign level, or overhead. Each of the remedies developed by transportation agencies and manufacturers are based on premises that may not have evolved from systematic analytic procedures, but are believed to have a good effect.
**Blinded Motorists**

The ability of an automobile driver to see the roadway and properly navigate can be hampered at night on unlighted roadways, impeded by the glare from the headlamps of approaching vehicles, and challenged by the “black hole” effect of entering a dark tunnel. The human eye (vision system) must quickly adjust to gross changes in illumination that can cause a temporary “blindness”. If the driver cannot see the lane markings, pedestrians, bicyclists, and inanimate objects in the vehicle pathway, judgment errors can occur. The vehicle may not maintain its speed (an error) and help sustain the traffic flow (an error). Preventive measures include improved tunnel lighting, particularly at the transition zones where vehicles enter and exit the tunnel. The ultimate criterion is whether or not the motorist’s eye can quickly adjust to the variations in light level in his visual field. Night-vision systems have been installed on some vehicles. These included the use of thermal cameras, sensitive to the long-wave infrared portion of the electromagnetic spectrum, with a display projected on the windshield. Another night-vision system used near-infrared illuminators (to avoid blinding approaching traffic) with a virtual image of the road scene projected on the windshield or plastic display. A diode laser has been used for the near-infrared light source. Superluminescent LEDs are very powerful and can be used for vehicle navigation systems (fiber optic gyroscopic systems) and other purposes such as optical coherence tomography (in biomedicine) and in engineering testing (measurement). This illustrates the fact that new technology may seem to correct one problem, but can create new problems such as blindness, reliability, and practical adaptability to a defined need. Some human error problems take considerable research and development time.

Additional comments on automobile and highway safety may be found in Chapter 13: Discussion Question 16 Averaging the Errors, Question 31 Close Call, and Question 50 Attitude Matters.
5. **Behavioral Vectors**

The purpose of this chapter is to stress the differences among people and how such individual differences could contribute to unwanted human error. In addition, it is important to understand how such attributes and variables are evaluated. In this section, there are examples of human characteristics, skills, personality traits, symptoms, and test evaluations. In terms of differential diagnosis, there are questions as to what is normal or impaired in various populations. Socratic Discussion Questions (from Chapter 13) include: Question 17 (Building Evacuation) describes the effect of mental confusion during emergency building egress. Question 18 (Social Information) describes choice behavior and learning-by-example in relation to personality traits. Question 19 (Pollution) describes intentional conduct disorders. Question 20 (Sea Spray) suggests undesirable personality characteristics under adverse environmental conditions. In general, behavior varies but is generally predictable.

**Neuroticism**

Recent reports from clinical psychologists indicate that persons with high psychometric test scores on neuroticism may cope poorly when there is emotional stress. One study (J. Pers. Soc Psych., 89, 107, 2005) suggested they may suffer from unreliable or inefficient low-level cognitive processing. This may occur even with good motivation and conscientiousness. This further suggests some propensity for human error. Does this mean that neurotics should be removed from important work tasks? **Answer:** There are considerable individual differences that may outweigh such a clinical diagnosis. Remember that the general principles, that describe how information is processed by neuronal circuits and its resultant behavior, is still in its rudimentary stage. Descriptive models are improving with current imaging technology and better computational methods of image analysis.

**Mental Alertness**

There are drugs that enhance mental alertness and such stimulants may be used by students, work shift personnel, aircraft pilots, and others to combat sleepiness. One such drug is an ampakine that amplifies the glutamate
(neurotransmitter) signals involved in learning and memory. Other similar drugs effect other brain systems such as sleep system regulation.

Since such drugs affect important behavioral vectors, should they be selectively utilized to improve mental functioning and prevent the effects of sleep deprivation? **Answer:** The use of such drugs has occurred many times, with great promise, and a belief that any adverse side effects would be minor, temporary, or controllable. Historical experience does not favor their use. Addiction is a frequent complication. The use of any drug should raise a caution flag. They introduce uncertainty in human error analysis and control.

6. **Countermeasures**

The purpose of this chapter in the Human Error: Causes and Control book is to provide detailed information on error prevention, correction, and control. Once an error has been identified with particularity and a risk assessment has been conducted, it should be the time to determine the effective remedies. The remedies should be very specific and well targeted. The Human Error book describes the 12 basic principles of error countermeasures, the 25 specific generic countermeasures, and the 7 fundamental caveats relating to countermeasures.

**The Rule of Two** (Item 2 under Specific Countermeasures)

A rotary control knob is located near the edge of an equipment panel. The panel is at waist height and slanted lightly upward from the horizontal. Despite instructions, both operators and visitors tend to lean over and put a hand on the panel. Sometimes they balance themselves by leaning on or sitting on the edge of the panel. This could cause inadvertent movement of the control knob and an unwanted error in machine operation.

The Rule of Two requires two independent human errors or actions before a change in machine operation. Should the control knob require both a push-down and a turn, a pull-up and a turn, a detent (ball-in-groove) requiring extra force before a turn of the knob, or a cover that must be lifted before the knob can be turned? **Answers:** The push and turn might result from one downward force (such as sitting on the edge of the panel). The pull-up and turn requires two
independent actions. The detent results in discrete (step by step) adjustments, not continuously variable adjustments. A cover is typically used for highly critical switches. This analysis suggest that the pull-up and turn is the better choice for these circumstances.

**Worker Replacement**

An assembly line for consumer products included a series of large metalworking stamping presses. The stamped metal parts were transferred from one press to another by a worker. This was called manual unloading and loading of a press. This work was monotonous, each worker walked miles going back and forth between the machines each day, they got physically tired, then took a break, but would begin to mishandle and inadvertently misload parts (a production error). There were inherent safety problems with work being performed so close to the operating presses. The safety problems were reduced by restricted access which required installing an 8 foot high perimeter safety fence and operator access gates tied to shut-off safety switches on the press. The press feeding (manual loading and unloading or parts transfer) problem was resolved by installing mechanical robots to handle the parts between the presses. This automatic press tending system nearly doubled production, with fewer workers, and achieved much higher quality (fewer errors). The robotic transfer system was amortized (it paid for itself) in less than two years and, thereafter, was a significant profit item. Robots can replace workers who cannot perform to what is required, but this may induce labor disputes, adversely effect worker morale, have high initial robotization costs, and involve possible equipment control reliability problems. Robots as an error countermeasure should be evaluated in terms of their general acceptability in a specific situation, industrial culture, and competitive need.

**The Missing Cleaner**

An employee of a food processing plant was told to clean a large meat mixer-grinder at the end of the first shift workday. Everything had to be cleaned and washed down for sanitary purposes. He stood on a work platform that was in front of the large meat mixer-grinder. The top cover had been removed, so he could easily reach in from the top of the mixer-grinder. As he leaned forward and reached inside the tub of the food mixer, he lost his balance and tumbled inside. Before he could climb outside, another worker pressed the “on” button to start the rotation of the cutting blades of the meat mixer-grinder. This machine start-
up was part of the cleaning operation, it cleaned the blades of meat and the cleaning water in the tub. The first employee was found to be missing at the end of his work shift, but the ground meat weighed an extra 200 pounds, the same weight as the missing employee. It was found that the second employee had turned the electric power switch on, pushed the machine start button on, had not seen or heard the co-employee working in an adjacent room, was doing a routine task, and was unaware of any accident. **Quere:** Did either employee commit a human error? Did the employer commit an error in terms of worker procedures, machine guarding, lock-out, or work supervision? What would be the effective countermeasures to protect employees working on structures and equipment that were slippery because of the abundant use of cleaning water and steam? Should the controls have been located in a room separate from the machine?

**Drug Caps and Talking Labels**

Mistakes in the use of drugs have been common because of the consumer packaging utilized. At one time, unattended children could easily open a pill container, consume much of the contents, and suffer a medication overdose. The countermeasure to this unwanted behavior was child-resistant caps. The cap had to be pushed down and turned (rotated) at the same time. For adult consumers, there have been a number of common problems including improper dosage level, dose scheduling or timing, product mix-up, incorrect medication, and counterfeited drugs. The countermeasures include unit packaging (single dose pouches) usually in blister packs. Dose timing information (such as day of week) on the drug package serves as a reminder of whether or not the drug was taken when it should have been. Color coded plastic rings on pill bottles serve to identify a particular person’s medication in multi-member households or residences.

The use of talking labels has been made possible by the use of radio frequency identification devices that are inserted between seal layers on the cap of a pill bottle or in a tag at the top of a pill vial. It is also a product identification feature that helps to thwart counterfeiting, product diversion, and ingredient substitution. Taggants (small particles) may be added to the ingredients for tracking, tracing, identification, or product signature (authentication) purposes. Small chips in the label or tags may have an individual serial number to track-and-trace a product all along the supply chain to protect against counterfeits, lost inventory, and adulteration. Tamper resistant and tamper evident packaging is now commonplace and should become a redundant system (such as container packaging plus colored pill coatings).
Drug usage information has gradually become less difficult to read, understand, and to rely upon to base personal drug taking behavior. The printed label has become a sophisticated information and countermeasure device. There is still much that can be done to reduce drug errors by healthcare specialists and the end user or consumer.

7. Human Factors Design Guidelines

The scope of human factors is somewhat ambiguous and there is a significant overlap with human error activities. This chapter in the Human Error book describes human factors, includes its 10 most commonly used methods and techniques, provides 25 illustrative human factors design guidelines, 9 caveats, and 6 self-governance principles. This is an important chapter for those who may need to understand this scientific discipline.

Drug Labels

The design of drug labels should comply with applicable Human Factors Design Guidelines to prevent errors in the dispensing or in the consumption of the drugs. The first step would be to collect all applicable data; such as, prior customer complaints on product identification and use, adverse-event reports that include errors and injuries, interview data that indicates possible confusion in product identification, recommended dosage, perceived efficacy, the manifestation of undesirable side effects, precautions, drug interactions, overdoses, mix-ups with other products including those of competitors, the clarity of the directions or instructions, and any patient counseling information (package inserts). Based on the accumulated information, specific human factors tests may be performed to determine visual fixations, eye scan paths, readability, information comprehension, time required response accuracy, and a positive acceptance of the information including pictorals (graphics).

The next step would be to organize and layout the information in the available space of the label. The key questions are what items of information should be communicated, what are the relative priorities, how can it be effectively communicated, and where should it be located. The information that identifies the drug, and discriminates it from all others, should be on the front panel in a size denoting its importance. It should not look-like or sound-like other products. The text should be aligned, oriented, and grouped to enhance readability and comprehension. Less important information, that may be
perceived as clutter, should be relegated to fold-out or expandable labels (outserts and inserts) or separate leaflets and pamphlets.

The final step is to consider the tamper-evident packaging, pill protection barriers, anti-microbial procedures, child resistant features, and counterfeiting-roadblocks such as micropatterns holograms, and color shifting inks. Is protective packaging necessary? Are bar codes or radio frequency identification tags necessary? Is single-dose packaging essential to reduce patient errors? What are the costs of the packaging, shipping, desiccation, monitoring, and dispensing systems? Is brand protection and recognition a major consideration? What future actions can be expected from the prescribing physician and dispensing pharmacist?

**Scope of Inquiry**

This listing of Drug Label issues suggests a current controversy that exists among human factors specialists. Should the specialist restrict his efforts to narrowly defined human factors issues and present only limited information for others to consider or should all factors influencing the human factors issues be considered and weighed as to their possible effect? The limited view is easy and defensible among peers. The expanded view is more difficult, but usually is better received by those who might rely upon the results.

8. **Testing and Functional Validation**

Appropriate testing may be critical, but is often minimized or overlooked. It can be a valuable source of useful information if properly planned, can help identify and remove uncertainty, and need not be costly. This chapter in the Human Error book describes the general principles of error testing, the 9 types of relevant testing, the cautions, and 5 caveats relating to functional validation.

**Evacuation Dynamics**

The functional validation (real life test) of the occupant evacuation (exit) dynamics of the World Trade Center in New York City occurred on 11 September 2001. Between the first and second aircraft strikes and the collapse of both buildings, 2000 people failed to escape. Some of the reasons for the evacuation problems seems to have been some human errors. Individuals may
manifest an unexpected time lag in their exit during emergencies. At the WTC, some 23% delayed exiting the WTC buildings by more than an hour. Groups may exhibit a herd mentality, where people look to each other for support, cues, information, and navigation. This crowd or cluster behavior could result in people passing by exits that could be clearly seen and heeded. Two or more herds may merge and the crowd crush (high people density) could result in injury as people try to exit a crowded room faster than a narrow exit may permit. A crowded exit is slower than an orderly exit and people may get stuck on gridlocked exit or stairs. Full evacuation of tall skyscraper buildings has not been a design requirement because of assumptions that there would be only localized fires (confined to a few floors) or localized damage from other means.

Studies to better understand the behavior of crowds is being conducted by computer simulation, survivor interviews, and by full scale evacuations of buildings. Studies are being conducted on external pole systems (slide down safety), fabric (tumble down inside) tubes, better stairways, fire drills, and elevators that can be used during emergencies (they do not open on burning floors). People react differently during uneventful situations, as contrasted with emergency conditions, panic motivations, and fear reactions. The type and magnitude of human errors will vary accordingly. It is important that the study of human error should include individual and group behavior in both normal and high stress situations.

Testability

All complex products should be designed for testability so that, in theory, all potential faults are testable and identifiable. This assumes that certain faults, such as operator error, are predicted and test modes have been provided. Testability permits real-time testing and real-life assessment of the functionality of the product. But, the question is what errors, and under what specific conditions, combinations, and sequences?

Testability includes fault detection during research and development, pre-delivery (after manufacture of prototypes and production items), diagnosing and fault verification in the field (during customer use), and after repairs or product improvement has been accomplished. Not all faults are detectable, there are test limitations, but most common faults are diagnosable and testable.

Note: See the following Discussion Questions from Chapter 13 in the Human Error book: Question 4 The Stairway, and Question 17 Building Evacuation.
9. Managerial Errors

In addition to human-machine interactive errors, there may be human-person interaction errors that may be a source of significant damage. In the past, considerable attention has been given to the interaction of humans with equipment, systems, and related environmental conditions. This may be a technical or engineering approach to improving human performance and reducing human error. However, managerial errors usually involve people interaction (person-to-person); such as, a manager's control of subordinates or a manager's decision-making within an organization that effects company performance by altering human behavior. A management error effects the objective of human performance and the context in which it occurs. This chapter in the Human Error book describes error vector analysis to determine root causation, the IMED method, 15 conduct clusters, 5 overlays, and the 7 caveats to consider in evaluating managerial error.

Indecision

As has previously been discussed (where compulsive disorders exist), the manager who is a nondecider makes all subordinates hesitant and inefficient, because they do not know what is really wanted. The indecisive and uncertain boss may want to be involved in every decision, but can make very few actual decisions. The manager usually fails to tell the subordinates exactly what was wanted, when, where, and how. Indecisions may be rewarded, in some organizations, more frequently than decisions which could be feared, unwanted, or inappropriate. There are few decision-free environments in industrial enterprises so the problem can become acute. There may be decision avoidance behavior (delays) in the form of unending questions, meetings without action items, continual requests for additional data, and letting someone else make the decisions. Of course, the manager receives more information from more diffuse sources than the subordinate, so there is more to digest and also more information barriers that can be erected. Quere: If an indecisive manager is an impediment to the smooth flow of business, what should be done to correct the situation? Could excessive decision delays produce human error?

Medical Management

The overall management of a hospital is often split between clinical practice, research efforts, teaching facilities, those obtaining grants and
donations, those in a building or facility planning group, those involved in administrative and financial affairs, and perhaps several other semi-independent groups. The clinical practice, for example, includes resident staff and independent contractors, stars and residents, interns and nurses, medical device technicians, and many unique specialists. In other words, it is a heterogeneous assemblage rather than a traditional command and control structure where people receive orders from above and are assigned the details of a job. Medical management is far more complex and may encounter many participants resistant to change, command, or control. There is usually a shortage of nurses, sometimes too few pharmacists, and many residents, interns, and others receiving instruction, training, or experience. Rigid protocols and error-reducing procedures may be hard to install and nearly impossible to enforce.

**Medical Equipment**

There are over 75 million products from over 12,000 suppliers that could be used in a hospital. Compatibility between equipment is safety essential. Something new is coming on the market every hour of every day. There is a constant need to calibrate and monitor equipment. The results of better pharmaceutical process control is needed. Error-free documentation without calculation mistakes is a goal. There are sponge counts, charting corrections, and calls for a higher level of care. Quere: How can this wealth of information be processed by medical management without excessive error? How can continuous improvement be controlled? Should the medical manager attempt to control only what matters to reduce error variability and obvious quality attributes? Is it important that both patients and health care workers feel confident and proud about management decisions?

10. **Organizational Errors**

Some human decisions may be categorized as resulting in organizational or institutional errors. Such errors may have devastating effects on the companies and trade groups. This chapter of the Human Error book discusses leadership errors and 7 other contributing error causes, principles, the effects of organizational culture, ERP teams, causations, and presents 7 caveats to consider in evaluating organizational error.

**Charismatic Leadership**
The simple line and staff form of organization is the most familiar method of structuring or arranging groups or collections of workers to achieve particular functions or objectives. Each worker reports to some one person of higher authority in the organization and receives from that person their marching orders, guidance, directions, or job instructions. The incentive to perform the assigned job is usually a monetary payment for the services rendered. It is expected that all employees will exert their full diligent effort to accomplish their tasks for the ultimate benefit of the organization. Unfortunately, if the leadership of the organization is faulty, some groups of workers may be left without something to do. Large government agencies may have small groups isolated, forgotten, or overlooked with cosmetic justification or superficial purpose. They may indicate that “no one bothers us”. One major airline had a departmental west coast representative who just made one telephone call a week, rarely did anything else, but used the time to moonlight as a legal secretary and attend law school. The comments were that there was poor management and the organization fostered this inactivity. Poor management may result in close attention to some organizational elements, a general awareness of other organizational elements, and an ignorance of the existence of other organizational elements.

A study, by the authors of this book, compared two large hospitals in the same geographical area. One had a chief-of-staff who was very intelligent, knowledgeable, informal, and conversant with all the specialties represented in the conventionally organized general hospital. He enjoyed learning, was creative, and very sociable. He did not rule by organizational authority, yet was very efficient and tended to uplift all activities in a complex organization with extensive facilities. He was friendly, aware of what was going on professionally throughout the hospital, and actively assured the good reputation and success of the hospital. In essence, he manifested a charismatic form of leadership. In contrast, another large general hospital was tightly organized in a rigidly bureaucratic fashion. It had fairly remote management, highly independent cells and departments, and there was little gentle guidance or encouragement toward true professional conduct. Some of the “top brass” were involved in external activities that were questionable in terms of professional ethics. The hospital did not have good leadership and, subsequently, developed a bad reputation as an organization and experienced a steady crop of troubles. In essence, good management is a required prerequisite before any organization can work effectively, efficiently, and with minimum error.

**Adaptability**
The internal records of some of the major automobile assemblers provide interesting information on their organizational structure and function over several decades. One company routinely rejected or ignored the results of almost all of their one and two year independent (but internal) research efforts, apparently because something new was not really needed to market their vehicles. Sales meant more than research findings. The present market produced the profits, not some future market. The company policy was that low cost was the primary concern because this enabled competitive pricing (sales). Also that each vehicle model needed only one identifiable feature to distinguish it for sales promotion (marketing). This did not reduce promotion of future exotic vehicles to help establish an image of advanced research and development. Real leadership in the industry was illusory and the status quo was most defensible. The actual products being sold gradually aged, fell out of favor, and market share was relinquished to other companies that aggressively adapted to the marketplace. The organization, as a whole, tolerated mediocrity and had a high tolerance for avoidable errors. The decline of the company was foreseen two decades earlier based on its own records.

A second major automobile company became known for serious engineering design problems that continued for ten to twenty years despite seemingly strong delegated efforts to correct the problems. Little was actually done if the problem was not immediately apparent to the customer, if excuses were palatable, or if denials were accepted. Some errors were fairly simple and should have been caught at the first design review. Others were debatable, but should have been corrected based on customer dissatisfaction. The eventual costs were many multiples of the potential costs of correction and prevention, plus loss of customer good will (future sales). There was an organizational failure to adapt to the marketplace in terms of error-free products. Subsequently, the market share declined, many of the company’s top managers resigned or retired, and other companies began to raid the critical talent, particularly the most creative designers. Restructuring of the organization also resulted in the loss of valuable experience at all levels of the company. Turnover, personnel shortages, and extended work weeks also took a toll. In essence, adaptability to a demanding market must be built over time, it is not the result of a sudden impulse, desire, or decision.

11. Management Challenges
In the Human Error book, this chapter emphasizes the current need for top managers to quickly resolve certain important substantive policy issues. Among the needed management controls are track-and-trace systems for incoming and outgoing components and products that will provide immediate current status or life history information that can help eliminate traceability errors and human error sources. It is also a management challenge to prevent depersonalization and its intentional human errors. It indicates that management policy should encourage incisive restoration of trouble sources and provide for quality commandos. There is a discussion of outsourcing and error, predictive knowledge or corporate intelligence, error R&D, contagion, cognivitis, rising stars, robotization, and error detectives.

Reason for Change

The 1999 report of the Institute of Medicine (USA) indicated that between 44,000 and 98,000 people die each year from medical errors. Another report in 2005, by the National Academy of Engineering and the Institute of Medicine (USA), indicated that the healthcare industry has neglected engineering strategies and technologies, and that this inattention has contributed to 100,000 preventable deaths each year. Such reports have had great impact on the healthcare industry, allied disciplines, regulators, and the public. They provide a good reason to attempt change and strive for improvement. The status quo may be difficult to change in a hospital with a medical staff of 700, processing 400,000 patients a year, employing nearly 2000 people, with many inpatient departments (such as surgical, anesthesiology, cardiology, pulmonology, orthopedics, radiology, intensive care, etc.), outpatient services (such as emergency, oncology, diagnostic, etc.), and community programs (such as health education and disease prevention). The change program should have a sense of controlled urgency, a known meaningful policy direction with a predicted outcome or goal, credibility rather than an exhibition of gamesmanship, an absence of irritating posturing, and an apparent self-interest and incentives for those involved in the attempted beneficial change. Such fundamental change must be initiated, controlled, monitored, and evaluated by top management whether the “change” is being made in the healthcare industry, government agencies, engineering firms, or manufacturing enterprises.

As part of a change action plan intended to foster real change in an organization, the lessons learned (past experiences) constitute valuable intellectual property that should not be ignored nor forgotten. These lessons help to prevent repetition of mistakes and a loss of momentum in the change process.
Top management should view a commitment to beneficial change as a form of social responsibility and good corporate citizenship.

Verification of improvement is an active ongoing process or internal audit procedure, that reveals redirection in mortality and morbidity, elimination of waste in terms of costs, improvement of core values by measurement of appropriate benchmarks, and the continuous reduction of all forms of medical errors. This is a primary management challenge to be resolved appropriately.

**Standard Practices**

Human errors are frequently blamed on someone not following the custom and practice that was anticipated and expected by others. An engineer newly assigned to a design group may not be aware of all of the group’s existing standard work practices. He may remain oblivious if no one informs him of some routine detail procedure that is already familiar to others. There may not be a design guide or group design manual for him to learn the results of past experiences or to consult as a reference. Whether or not there is a significant turnover of personnel in a given organizational function, when human errors occur the proposed remedy is often in the form of documentation (records) including standard practices (manuals). Some companies use group design manuals to document the results of costly research efforts that need not be repeated on new projects or to present derivative equations, graphs, numerical charts, nomograph checks, or sets of design recommendations. This should be the place to record the types of human errors that have been experienced in the past and how they can be avoided.

The management challenge is how to balance the need for establishing uniform or standard work practices that are documented, the desirability of having a good experience retention system without proprietary information leakage, and the desire to create an effective error reduction information bank. There should be a keen awareness that standards-making bodies, such as the ISO, have promulgated requirements, intended to cure quality and environmental program deficits, that have required extensive and costly documentation. The ISO 9000 and 14000 series have had worldwide application with varied results. Advocates encouraged that each manufacturing station have documented work practices sufficient that a new worker could quickly assume that function. In human error control efforts, the suggested remedy may be for a somewhat familiar call for documentation of standard work practices. Top management has to consider the costs of a wide variety of possible programs to
improve a particular function, remain competitive or compliant, and determine what has and what will work in a particular situation.

**Decision-Making by Specialists**

Many employees, occupying responsible decision-making positions, develop a habit of shifting that ultimate responsibility to others. They may do some work, then present their facts, opinions, and beliefs to their immediate supervisors, some project engineers, or to peers in other disciplines. They want someone else to make closure on the information, support decisions, or make the final decisions. They want to avoid possible future blame for making a decision that might be wrong or inappropriate. Subsequently, they characteristically fault management for failure to understand, fully support, and adequately fund their activities. The management challenge is both to clearly delegate responsibility and to convey what is actually wanted in the decision-making process. *Quere:* Do personality factors effect the evasion, delegation, blame, and forms of decision-making? In what way does human error serve as an excuse in the decision-making process?

**Clinical and Pre-Market Testing**

At one time, if a new product seemed to function properly it was rushed into production and put out into the marketplace to work its intended benefits or wonders. Unfortunately, the product may not have worked as intended in the real world and harm resulted. Regulations, standards, liability, and ever higher proof of performance and safety ensued. More and more pre-market testing was instituted for pharmaceutical drugs, medical devices, industrial machines, and consumer products. The management challenge was how much testing of what attributes and variables would be appropriate or necessary in a world marketplace? Testing costs money, time, and the effort of specialists. How much reliance could be placed on more economical simulations and analogies to products already proven to be safe, effective, and free from combinatorial effects?

There have been widely publicized reports of harm from drugs that have passed all tests, been marketed for a few years, then a forced recall occurs, and sometimes a total withdrawal from the market. The drug may not have been tested long enough. The product may have been subject to accelerated testing using only a few of the factors or conditions that might be experienced during the product’s service life. The direct and indirect cost of recalls has escalated.
Sponsors of clinical trials now must negotiate detailed agreements including risk allocation, financial consideration, indemnification, and many other factors. Phase I, II, and III clinical trials have rapidly expanded in complexity, size, cost, and now operate almost as a separate discipline with regulatory counterparts. Does the panel include “extreme users” (those of high error probability) and medical specialists (not stand-ins) for medical devices? Are there appropriate tests for predictable errors by all humans who may come into contact with the product? Are there tests to determine the biocompatibility and biodurability of implants and grafts composed of alloys, ceramics, and polymers? Do fluropolymers have the strength, lubricity, and durability for orthopedic implants? Every material will elicit some biological response, what is it? If the material will be in close proximity to the spinal fluid, is there an effect? Do the usability tests include predictable human error?

There have been cases in which medical devices, approved by the FDA, have subsequently manifested human error as well as manufacturing problems. Stents, inserted into 1.5 million people in 2005 in the USA, are the metal scaffolds used to keep open clogged arteries (to prevent restenosis). They are inserted by installation wires, threaded through the arteries, and the stent is expanded in place by a small removable inflatable balloon. Some balloons became stuck and attempts to withdraw or remove them caused tears in the artery lining. The stent manufacturer sent staff people to “retrain” the doctors at the hospitals (to prevent errors). The FDA had received reports of stent balloon withdrawal problems in 485 patients that included 79 serious injuries during 2003 to 2005. In 2004, the same manufacturer recalled 99,200 stents because the balloons did not inflate. Manufacturing changes corrected the problem. The FDA had approved the stent, based on a clinical trial of 1,000 patients that indicated its safety and effectiveness. How much testing was needed to avoid post-marketing problems?

Combination products are those that combine a drug or biologic agent with a medical device, such as a drug-eluting stent (a drug-device product). The active ingredient of this stent’s drug coating was paclitaxel which had been approved earlier to treat cancer. Combination drugs may be regulated by three different federal agencies in the USA; as a medical device (CDRH), as a drug (CDER), and as a biologic (CBER). The approval process may include evaluation of reports of early animal studies, pharmacokinetic testing where live animals receive doses and time-release profiles are developed from human trials, toxicity testing, biocompatibility testing, and clinical trials with control groups.
There is a significant management challenge in attempting to balance the expensive and time consuming clinical and pre-marketing testing with what is needed to avoid design, manufacture, test, or human error problems. Is the mandated regulatory approval sufficient from the perspective of past experience and proposed future regulations worldwide? The management imperative is to take sufficient action today to avoid tomorrow’s adverse financial and human consequences. Is there merit in trials and tests that take longer, use more subjects, have more diverse test populations, and include reasonably foreseeable combination effects?
E. Current Viewpoints

There has been a long history of attributing accidents, near-accidents, and undesirable incidents to human error. It has been relatively easy to blame the proximate human operator or bystander as the perpetrator or guilty party. This occurs if a quick conclusionary opinion has to be expressed, if there is a reluctance to fault other persons who might react aggressively to accusations, if there are contributory factors that seem defensible or excludable, or if an analysis yields insufficient proof to convince others of any other substantial cause, blame, fault, or guilt. There is usually a heavy burden on those injured or blamed to prove innocence or freedom from any fault, since they generally lack the resources to gather pertinent information and may be excluded in all respects from the fault-finding process.

In 1919, there was an article on Safeguarding the Punch Press by A.L. Kaems and R.T. Solensten (in Live Articles on Accident Prevention, Number 7, New York: The Underwriter Printing and Publishing Co., pages 5 to 23). It stated that “the human being is not infallible” and there was a need for the “education of the ignorant workers” so they would “do their work in a safe manner”. It indicated that if “the operator’s attention” was “momentarily distracted” there could be “unintentional movement” by hand or foot. A “false motion” could cause injury and did account for 78% of all power press accidents in 1916. In some accidents, there was a failure “to shut off power” or an “error in the sequence” of motions. The article emphasized that “accidents are bound to occur” where there is “a motion of the foot independently of any action of the
operator’s hand.” The article also described mechanical safeguards that were not universally adopted for nearly a half-century for various reasons, including the premise that human error was correctable by the person who committed the error.

In the same 1919 publication, another author stated that an “inanimate machine” could “hardly be blamed for accidents caused by the ignorance of or improper application of such a machine by the user” (page 137). It concluded that safety calls for “the education of the user”. Still another author (at page 139) discussed misssteps, thoughtlessness, incautiousness, and workers doing stunts. The focus was on human mistake or errors.

The Human Error book describes “old human error principles” reported by Peters in 1963 (at pages 142 and 143).

The early analyses and reports on human error tended to be conclusionary and simplistic. They rarely provided useful preventive information. Some were too narrow in focus, others were so complicated that application was excessively costly, time delayed, and ineffective in terms of possible symbiosis with other disciplines or design functions. The outcome was that human error was disregarded in most system safety, reliability, quality, and other functions. In a practical sense, human error analysis was considered negatively in terms of usability and beneficial results. Despite the essential negativity, there have been efforts to categorize human error. For example, was a human error related to skills, rules, or knowledge? Was it related to mistakes, violations, mismatches, or slips and lapses? Was it safety-critical, serious, an inconvenience, or having no-effect? There are conflicts and disagreements that should be understood. Thus, a short discussion of current perspectives or viewpoints might be informative in dealing with human error problems.

1. Quality

In 1998, Kenneth A. Kern, a clinical professor of surgery at the University of Connecticut, discussed human error in an article entitled “The National Patient Safety Foundation”, published in the Bulletin of the American College of Surgeons, Vol. 83, No. 11, November 1998. He reported a “wide range of surgical errors”, but they involved less than 4% of hospital admissions. Examples included a hernia operation on the wrong side, a retained sponge after abdominal surgery, and the incorrect use of a surgical stapler resulting in the severance of the cervical esophagus. He indicated that the American College of
Surgeons had “long advocated” programs to reduce preventable patient risks, citing their 1985 Patient Safety Manual (2d Ed.). He concluded that “this type of risk reduction program falls under the general category of total quality improvement (TQI) or continuous quality improvement (CQI).”

There was a list of “tools used to analyze adverse events and errors” that included the critical incident technique, sentinel event investigations (root cause), the human factors process, error management strategy, and crew resource management. This list reflected the need to utilize tools from all disciplines. The actions of Kenneth Kern have stimulated quality specialists to attempt to apply or extend their techniques to the reduction of human error in healthcare activities.

In 2003, David C. Hsia, a physician at the Agency for Healthcare Research and Quality at the U.S. Department of Health and Human Services, wrote an Editorial for the Journal of the American Medical Association, 15 January 2003, entitled “Medicare Quality Improvement, Bad Apples or Bad Systems?” It stated that the “critical issue was whether these errors represent failures of humans or systems” referring to the 2000 Institute of Medicine’s report on medical errors. The “quality improvement organizations” (QIO), using 24 quality indicators, reported a 70 to 73% improvement in appropriate care for Medicare patients between 1999 and 2001. This illustrates the continued use of quality concepts in the reduction of human error.

2. Systems

In 2000, James Reason, a psychologist at the University of Manchester, discussed human error in an article published in the British Medical Journal, 320, 18 March 2000, pages 768-770. The article was entitled: “Human error: models and management” and it stated that human error “can be viewed in two ways: the person approach and the systems approach.” The person approach focuses on unsafe acts, “blaming them for forgetfulness, inattention, or moral weakness.” The system approach focuses on the “conditions under which individuals work” including “recurrent error traps”. He concluded that “we cannot change the human condition, but we can change the conditions under which humans work”, we “know more about what causes adverse events than how they can best be avoided”, and “high reliability organizations are the prime examples of the systems approach”. In essence, these are human factors engineering (ergonomics) concepts which have been widely adopted where there are human performance problems in a systems context. The arguments of James Reason have stimulated a broader systems approach to error reduction.
In 2004, the Texas Nurses Association adopted a “Resolution on systems for distinguishing human errors from system errors” (24 April 2004). It resolved that “cultures of safety need to be created within all health care organizations” and this “requires that employees be able to trust that they can fully report errors, particularly human errors, without fear of being wrongfully blamed”. It mentioned the “chilling effect on nurses reporting errors and particularly near misses, thereby reducing identification of system errors”. This suggests that errors may be perceived as human (individual) or system (group). There are continuing questions as to the exact meaning of “systems” in different occupations.

3. Medication Errors

In 1999, the Board of Trustees of the American Hospital Association (AHA) targeted medication safety as the first objective in a patient safety initiative (November 1999). In 2001, the AHA met with President Clinton at the White House and announced an “initiative to improve medication safety, because medication errors are one of the most common sources of overall medical errors.” Dosing errors and adverse drug events became the subject of many articles in the medical literature.

In 2005, Mary E. Foley, a registered nurse, discussed medication errors in an article published in Nursing, November 2005, entitled “Infused, not Ingested”. It reported on a case where a CT scan required a contrast agent to be administered orally (via a nasogastric tube), but the nurse infused it intravenously. The nurse failed to disclose the error until the next day and the patient developed an acute renal failure that fortunately was resolved. This article reported a study in which “medication errors occurred in 1 out of every 5 cases in the typical hospital or skilled nursing facility”, but that “nurses also prevent many medication errors”. The causes included nursing overload, fatigue, and staffing problems such as floating to areas of need despite the competencies required.

4. Blame

There are varying viewpoints as to whether the occurrences of human error should be openly reported, for purposes of transparency in investigating all possible causes and remedial actions. Each effected person may have good reasons to want full, partial, or even non-disclosure of the facts. A more
traditional approach is to reveal errors only to a restricted peer group, one that is capable and willing to institute immediate beneficial changes without incurring adverse publicity. There are also those who firmly believe that minimum personal and group harm results from total non-disclosure, particularly for near-misses and trivial damage. Thus, there are strongly held arguments as to how much should be revealed or disclosed, to whom, and for what purpose.

There are also arguments that much is to be gained from non-confrontational actions and the avoidance of personal blame, shame, stigma, and possible loss of job functions. Others believe that firm action is necessary to encourage those who are reluctant or who refuse to acknowledge their part in an error situation. There may be state statutory provisions as to how medical error is to be handled, perhaps by a closed-door professional committee or panel. There may be much to consider when making reports to state licensing boards, meeting other statutory requirements, and dealing with the possibility of common law liability. Many employees fear that accurate disclosure may bring some punishment, so excuses may prevail. A work supervisor may quickly conclude that a worker is to blame for his error and ignore any facts to the contrary. The difficult-to-resolve issues of disclosure and personal blame are still of major concern. This is only one reason why the Human Error: Causes and Control book was needed.