Defining Failure: The Language, Meaning and Ethics of Medical Error[1]

Christiane Schubert, PhD
School of Science and Technology, Loma Linda University
1898 Business CenterDr., San Bernardino, CA-92408, USA

Gerald Winslow, PhD
Loma Linda University Medical Center
Loma Linda, CA-92350, USA.

Susanne Montgomery, PhD
School of Science and Technology, Loma Linda University
1898 Business CenterDr., San Bernardino, CA-92408, USA.

AhlamJadalla, PhD, RN
School of Nursing, California State University Long Beach
1250 Bellflower Blvd. Long Beach, CA-90840, USA.

Abstract

Despite the technical sophistication of modern medicine errors cannot be avoided. As errors are situated in the complexity and dynamicity that characterize healthcare environments they are difficult to define. A conceptual framework of medical error needs to account for the reality of medical work and the nature of error as a language-mediated social and legal construct. We identify four aspects that serve as a distinct framework: the notion of intent, the etiology of medical error and its multi-factorial flow, peer-reviewed contexts, and outcomes that may or may not result in harm to patients. The former assume moral quality and become concerns of justice. Specifically, a restorative justice approach supports the disclosure of errors to patients and addresses their physical, mental, spiritual, and social effects. The result of this contextually grounded, outcome-oriented model and accompanying definition of medical error provides practical guidance for hospital policies on dealing with medical error issues.

Keywords: Medical error, ethics, restorative justice, conceptual model, healthcare, wholeness.

1. Introduction

Twelve years ago, the Institute of Medicine (IOM) unleashed an unprecedented response to the problem of medical error. In its well-known report *To Err is Human* (Kohn, Corrigan, & Donaldson, 1999), the Institute revealed that the number of deaths related to medical errors in the United States may range from 44,000 to 98,000 each year (p. 1). Following the publication of the report, healthcare organizations, research institutions, and policymakers worldwide began to develop research agendas and patient safety programs that aim to prevent medical errors and increase patient safety (Dietz, Borasio, Schneider, &Jox, 2010). However, where modern medicine allows for highly sophisticated diagnostic technology and treatment, some errors are difficult to prevent because of the complexity of medical knowledge, the uncertainty of clinical predictions, time pressure, communication and other factors (see Mazor, *et al*, 2004; Liang, 2004; Paget, 1988).

Eventually, every physician, medical student, nurse, or hospital administrator arrives at the question of what exactly is a medical error.

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Articles that discuss medical errors often begin with a discussion of the variety of definitions and the difficulty finding workable concepts (for example, Bosk, 1986; Smith & Forster, 2000; Kalra, 2004; Crigger, 2004; Grober&Bohnen, 2005; Rosenthal, Cornett, Sutcliffe, &Lewton, 2005). A possible explanation for this difficulty is that there might not be enough common ground to agree on a "universal definition," one that is clear about whether or not to include near-misses, nicked nerves and other accidents of high risk procedures, late-night decisions made in overcrowded emergency departments, or mistakes that become evident only as time goes by. Indeed, it is not the wrong-side surgery that unleashes conceptual trouble, but the subtle nuances of decisions, communications, and procedures as they are situated in the complex environments in which modern medical practice takes place.

Certainly more than a "semantic quibble" the determination of that which "lies between the two extremes of blame-free accident and deliberate harm" profoundly affects medical care (Quick, 2006, p. 24-25). In fact, what counts in the decision-making arena as medical error by virtue of definition or classification determines important aspects of how medical errors are handled. These include disclosure to patients, reporting of errors to hospital management, claims investigation, patient compensation, and improvements in patient safety. In other words, the degree of inclusiveness of a definition potentially affects *all* of medical care and conceptual clarity is of utmost concern. Although a few works in the literature respond to the unease by offering universal definitions (for example, Grober&Bohnen, 2005; Banja, 2005), medical error models (e.g. McNutt and Abrahms, 2002) or discipline-specific definitions (e.g. Dietz, et al., 2010), in the real world of health practitioners, a practical definition remains difficult to find.

In this paper we present a conceptual framework of medical error that is anchored in the complex environment of medical care delivery. It is in this context that we highlight the notion of error as a contested concept that is socially and legally constructed. Sharpening the conceptual lens, we discuss philosophical notions of intent and intentional action, the language and meaning of medical error, and its etiology and context. The development of an outcome-oriented conception of error sets the stage for healing their effects by restoring human "wholeness" (see Tillich, 1967; Cowling, 2000; Rice, 2006; Schubert, 2008 on a healing perspective of wholeness). In this light, restorative justice[2] as a conception of justice that restores the physical, mental, spiritual and social-relational aspects of human wellbeing elevates the problem into moral dimensions. The result of this deep engagement presents a comprehensive, outcome-oriented model from which we derive a distinctive definition.

2. Characteristics of Medical Care

Healthcare is a multidisciplinary environment in which decisions are made not only by individuals but by teams of physicians, nurses, respiratory therapists and other medical professionals. Prior to developing a conceptual framework for medical error, we address four characteristics of medical care that provide the context in which the discussion will take place. These include (1) uncertainty in medicine, (2) the increasing complexity of medical care systems, (3) the confusion and fusion of concepts and contexts, and (4) linking medical errors with blame.

2. 1. Uncertainty in Medicine

Medical practice is sophisticated yet characterized by uncertainty. Paget (1988) argues that medicine is essentially an "error-ridden-activity"; it is "a process of discovery and response, of risked action and error" (p. 7). Between diagnosis and cure often lies an array of decision-making processes, of success and disappointment; moments of despair, patience and hope. In this shared emotional space, professional experience and patient expectations meet to embark on a mutual path forward. Gorovitz and MacIntyre (1976) eloquently describe that medicine, just as science, is to some degree experimental and that patients and the public have to learn to acknowledge the "necessary fallibility" (p. 64) of individual physicians. This suggests that therapeutic interventions, just as medical research and science, aim at progress while risking failures.

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[2] Established originally in the field of criminal justice (e.g. Braithwaite, 2002; Zehr, 1990), restorative justice has many roots: for instance, Yazzie and Zion (1996) offer a Navajo perspective on peacemaking. Hadley (2001) explores the notion of restorative justice in the major religious traditions and Wolterstorff (1999), Marshall (2001) and others worked out a biblical perspective. Its principles have recently found application in other fields.

Medicine is risky. It is also creative as it has been recognized in the healthcare professions of many cultures. Rather than attributing to medicine scientific characteristics, the German expression for medical work and its associated errors captures its artistic nature.

The German terminology for medical error is 'aertzlicherKunstfehler.' The practice of medicine, or more specifically the work of a physician, is described metaphorically as 'physicians' art.' It follows that medical errors are mistakes in the doctor's art. Similarly, the Arabic labelling of a physician is 'hakeem' which means 'wise man.' Human skill guided by wisdom and emotional sensitivity with reverence to the context in which care takes place is as important if not more important in medical decision making than technical sophistication. In other words, 'hakeem' highlights the historical richness of human inter-subjective experience.

Both the artistic analogy of medical work and the scientific one as alluded to by Gorowitz and McIntrye (1976) signal purposeful progression under uncertainty, yet the measuring stick for art is creativity, whereas for science it is rules or laws. Medicine is even more complex as it is characterized by both creativity and rules that govern processes aimed at improving a patient's condition and maximize her wellbeing. As improved technology promises greater precision in diagnosis and treatment, patients enter the medical arena with an expectation of perfection. As a result, physicians feel obligated to live up to this perfect image. Yet, they rarely succeed. Hilfiker (1988) addresses the uncertainty of medical diagnosis by noting that errors are always possible in the "midst of the humdrum routine of daily care. . . . Was that baby with diarrhoea more dehydrated than he looked, and should we have hospitalized him? Will that nine-year-old with stomach cramps whose mother I just lectured about psychosomatic illness end up on the operating room table tomorrow with a ruptured appendix?" (p. 63). These and other questions prompt Hilfiker to question his competence as a physician. But as he considers his outstanding credentials from medical school, his over-average exams scores noted on the diploma of the National Board of Medical Examiners, and his reputation as a good physician indicated by "townspeople" and colleagues, he realizes that it is not competence that is the problem. Accepting the inherent uncertainty of medical predictions, the author simply concludes that, "I have to learn to live with my mistakes" (p. 63).

Errors exist. Many of them become apparent over a period of time. Indeed, it is often only in retrospect that something can be identified as an error. Medications are given in increasing or decreasing increments until the condition of a patient is stabilized or the problem has been solved. In many cases it is extremely difficult to find the point in time at which something has "become" an error. We must remember that a human being is multidimensional and complex. As such, physical, emotional, spiritual, and social factors may interact in shaping a person's course of illness and intersect in the patient's response to treatment modalities. How far can actions be pushed in order to achieve perfection? Can we consider something an error when a physician orders a medication at 9 A.M., but is administered by a nurse 60 minutes later? In addition to accounting for system-related factors that often prevail in health care systems a definition of medical error needs to be able to deal with inconsistent timing in treatment plans, patients' varying physiology, and the effect of minute anatomic differences on the preciseness of invasive procedures. Additionally, standards that aid the determination of whether an error had in fact occurred, or if the unexpected outcome may fall in the realm of predictable risk within the complex environments of healthcare, have to be chosen wisely.

The attempts to determine medical error objectively, particularly with the application of standards outside of the medical profession have been criticized by the medical profession (e.g., Marjoribanks, Good, Lawthers, & Peterson, 1996; Dekker, 2007). Standards are socially, legally and even geographically constructed. Dekker (2007) argues that an error becomes visible only because a group of experts have agreed on a definition and associated use of language, which wrongly suggest that an objective "truth" can be discovered. Medical practice is too complex to trust in knowledge gained through locally or legally constructed snapshots of reality. Errors often "unfold in time" as Paget (1988) notes, and they occur in the intersecting social realities of a diverse set of people: patients, families, doctors, nurses, hospital administrators, and the legal community. Hilfiker (1988) describes the decision-intensive requirements of seriously ill, hospitalized patients and notes that, "although in most cases no single mistake is obvious, there always seem to be things that could have been done differently or better: administering more of this medication, starting that treatment a little sooner" (p. 61). Arguably, the only certainty is guaranteed by the autopsy—that is, if physicians and the public are prepared to accept the shocking revelation that approximately 40% of autopsies show that a major misdiagnosis lead to patients' deaths (Gawande, 2002).

2.2. The Increasing Complexity of Medical Care Systems

A second challenge to defining medical error is the fact that medicine is complex and multidisciplinary in nature. Its practice is carried out through a network of highly specialized medical professionals and changing front line actors.

Sutcliffe, Lewton, and Rosenthal (2004) describe this complex environment, pointing out that acutely sick patients have shorter stays in hospitals today than they used to. Moreover, the organizational structure of clinical medicine involves multiple handoffs with several intersections where critical information is communicated between individuals who are situated in the "horizontal differentiation of labor" and "vertical divisions of hierarchy and power" (p. 187). In their study of how communication failures contribute to medical "mishaps," the authors discovered that communication-related problems are not merely the function of faulty transmission or information exchange. Instead, they are deeply rooted in hierarchical differences between communicators. Professional distance is particularly pronounced in communication patterns between residents and attending physicians, medicine residents and other specialties, and between residents and nurses.

Highlighting the significant role that interprofessional conflict plays in patient safety, Baldwin and Daughtery (2008) found in their national multi-disciplinary survey of hospital residents that those residents who experienced conflict with professional colleagues had a higher rate of error and adverse patient outcomes than those residents who did not find themselves in conflict. Additionally, due to the structure of many teaching hospitals attending physicians see their patients through the eyes of their residents who "present" patients to them. As a result, disease narrative may unfold in a double hermeneutic. In those hospitals that have residents, organizationally shaped communication patterns between residents and attending physicians need to be considered as possible sources for medical error. On a community, Sutcliffe et al. (2004) indicate that it is also important to be aware of their finding that communication failures emerge in situations of "role conflict and ambiguity" mostly between hospital and community physicians.

The realities of the modern medical care environment make it extremely difficult to detect, to record and to measure medical errors. Specifically, challenges emerge when errors cause direct harm to patients as conversations are carried out between patients, healthcare staff, and hospital representatives that require utmost conceptual clarity. In many medical settings, the threat of legal repercussions makes conversations difficult when things go wrong and magnify the challenge of extracting concepts from contexts.

2.3. The Confusion and Fusion of Concepts and Contexts

The third complicating factor when developing a definition of medical error is the variety of concepts that attempt to capture the essence of medical error (Hofer, Kerr, & Hayward, 2000; Quick, 2006). The literature is filled with terms such as the following: adverse events (Veterans Hospital Administration, 2003), negligent adverse events (Veterans Hospital Administration, 2003), preventable adverse events (Kohn, Corrigan, & Donaldson, 1999), inadvertent occurrences (Liang, 2004), unintended events (Liang 2004), unintended acts (Leape, 1994), mistakes (Liang, 2004), medical mishaps (Rosenthal et al., 2005), possible mistakes (Howe, 1997), and unwarranted failures (Banja, 2005). Reason (1990), whose work on human error offers the most defined notion of failure, distinguishes two basic categories of error: 'mistakes' and 'slips' and 'lapses.' Mistakes, according to Reason, are planning failures. Slips and lapses are failures in the execution of an act, or intentional acts that fail to proceed as planned. One of the dangers of this diverse menu is that its terms might be used interchangeably regardless of their differences as to cause, process, and outcome.

One way to understand the specific choice of words in language—one might call it *medical errorism*—is to consider Wittgenstein's discourse on the structure and meaning of language. In *The Blue and Brown Books* (1958) and *Philosophical Investigations* (1967), Wittgenstein develops a complex analysis of how the words and concepts that make up language are used to create meaning. Wittgenstein argues that the meaning of words in sentences that constitute a language system is much more complex than pointing to and naming objects. In *Investigations* he notes that there are more "kinds of word" (p 2, §1) than nouns and names given to objects or people. Words have different functions as they are employed in language and can be interpreted in various ways. To illustrate the diverse functions of words, Wittgenstein often employs analogies such as "tools in a tool box" (p. 6, §11) and "[language] is like looking into a cabin of a locomotive" with similar looking handles that perform very distinct functions (p. 7. §12).

Our language and its concepts are "instruments" (p. 152, §569). The similarity between toolboxes, locomotive cabins, and instruments is that they are categories of items from which specific words are chosen to fit particular purposes, just as the words *mistake* and *error* are chosen to accommodate definitions for medical errors. Taking a word from the toolbox and putting it into a sentence and into a context gives the word meaning.

It follows that the meaning of a word is not an object in itself but emerges from "its use in the language" (Wittgenstein, 1958, p. 20, §43.) The dynamic process that determines how words are used in a language system is the result of participation in what Wittgenstein refers to as "language-games."

The participation in language-games is a social process, one in which members who relate to each other with a common understanding of their worlds create stories and texts. Perhaps similar to Blumer's (1969) notion of the social nature of objects that are created by interacting individuals, Wittgenstein argues that "speaking of language is part of an activity, or a form of life" (Wittgenstein, 1967, p. 11, §23). Thus, when we engage in everyday life, we do this by participating in language-games in which words create meaning that is familiar to those who are familiar with the language-game. Confusion emerges when concepts are used that don't fit into a particular language-game or when individuals are unfamiliar with the setting. Consequently, caution is warranted when specialized medical error language is used to fit research agendas or provides the foundation of a policy. However, if one investigates a particular language-game, one can obtain an insight into how society in general, or groups or professions in particular, understand and dialog about certain issues such as medical errors.

Where the literature places great emphasis on the search for conceptual clarity, practitioners in the health care field tend to articulate medical errors with concepts that are intertwined with their professional experience, rather than choosing more abstract categories. For instance, Emergency Department physicians draw on shared experiences of their fast-paced environment while hesitantly responding to the notion of "definition" (Schubert, 2008). The rapid turn-over of patients, the short period of time that physicians spend with patients, unknown medical histories, the evaluation of information as seen through the eyes of their residents, and the lack of beds for referrals to the units and patients waiting in the lobby for many hours make their work difficult, thus running the risk of errors. As a result, medical errors, if defined as such, can easily become a function of the environment.

Indeed, medical errors can hardly be separated from their environmental circumstances. More often than not they are embedded in a myriad of factors giving rise to social and economic issues that reach far beyond the immediate case. A definition needs to hold up when conditions are far less than optimal in places where different concerns and expectations shape everyday medical decisions. As we encounter over-crowded and under-funded hospitals in locations in which healthcare is among the lowest priorities the availability of resources and access to them also determines success or failure. In a resource-depleted neighborhood one can raise the question of whether an error has been made when a physician orders a test or treatment that a patient without health insurance under the age of 65 cannot afford.

Another perspective of medical error that calls for the inclusion of environmental factors in a definition emerges when the boundaries between concept and context become even more blurred. Consider the failure of providing an environment that contributes to the healing of patients a medical error. Even if medical judgement and diagnosis are correct and specific medical procedures are carried out without failure the atmosphere of the hospital room may be counterproductive to recovery and improvement. Impediments of this context may include noise, unnecessary traffic in patient areas, disrespectful and loud conversations, transgression of visitation rules, and neglect of patients' need to rest. Any of these conditions may lead to the failure to provide a setting in which the sick can heal. We recently encountered a sign at Kaiser Permanente that advises visitors and healthcare staff to walk and talk quietly because "patients are healing."

2.4. Linking Medical Errors with Blame

Where it is often difficult to pinpoint a single source or find a specific person who is to blame in the environmental contexts just described, the notion of fault is more attractive in settings in which the error pathway is narrower. In those conditions, blame is an easily unleashed co-notation of error even if blaming someone does little in regards to preventing future errors or healing their effects. In fact, blame and the medical error discourse are intimately connected. Paget (1988) points out the important difference between "what a mistake denotes and what a mistake connotes."

Where a mistake *denotes* that something has gone wrong, it *connotes* "being blameworthy or at fault" (p. 6). Grober and Bohnen (2005) note that the term *error* is "excessively negative and antagonistic," eliciting feelings of guilt, anger, inadequacy, and depression. These factors, the authors argue, "perpetuate the culture of blame" (p. 42). It comes to no surprise then that some healthcare providers have difficulty separating error from questions of fault or blame.

For instance, a physician may blame the nursing staff providing a definition of a medical error as "something that has been done to a patient that has not been done the way it has been ordered" (Schubert, 2008).Acutely aware of the negative effects that are associated with connecting errors and blame, the National Ethics Committee of the Veterans Hospital Administration (VHA) (2003) made a particular effort in their policy recommendation to distinguish the term *medical errors* from *adverse events*. The committee points out that the term *error* indicates that "something was done wrong, that somebody made a mistake in the provision of care" (p. 2). In contrast, an *adverse event* implies that "something bad had happened, not that anybody did anything wrong" (p. 2). The VHA then chose the term *adverse events* for their medical error policy.

Results of studies or policy implications are strongly dependent on how broadly or how narrowly medical error is defined. Should a definition include or exclude potential errors that reach the patient but which either do not cause any negative effects or, by good luck, cause positive effects? Should near-misses, which are those acts or events that almost reach the patient but do not, be included in definitions of medical error? And by what standard should errors be judged to fall into the category of unfortunate "things that just happen?" Many attempts have been made constructing sensible definitions for medical error, including the definition proposed by the IOM[3]. Conceptual frameworks and practical definitions, such as the IOM, are process-oriented, vague, lack a measuring stick, and are separated from organizational, environmental and social contexts. We conclude that a contextualized framework of medical error is needed that (1) clarifies notions of intent; (2) describes the etiology of medical error as a multi-factorial flow; (3) allows for context specificity; and (4) that is outcome-oriented thus acknowledging the multi-dimensional effects of medical error.

3. A Medical Error Framework

Two premises underlie the proposed framework: First, medical errors cannot be eradicated completely; they occur even when great care is taken and the most sophisticated technologies are employed. Second, even though many errors are deeply rooted in system complexities, such as organizational factors and work environment (Kalra, 2004), somebody is making a decision at some point and is taking responsibility, but not necessarily blame, when things have gone wrong. Even if an error is not the result of any particular person's mistake, someone is filling the gap between systems and patient, between technological precision and suffering and hope. And it is this person or persons who negotiate between their own notion of just resolution, the patients' needs and perspectives, and the ethics and policies of the organization. It follows that a clear definitional framework is as crucial to systems improvement as it is to the delicate relationship between hospitals and patients, and between doctors and patients and their families. Drawing on the four considerations discussed in earlier sections, which are the inherent uncertainty of medicine, the increasing complexity of medical care systems, the confusion and fusion of concepts and contexts, as well as the linking of medical errors with blame, four elements are the signposts that will guide dialog and policy development. These are: *Intent*, *etiology*, *context*, and *outcome* (see Fig. 1).

3.1. Intent

A common characteristic of medical errors of all kinds is that they are not made on purpose, unless, of course, we venture into the criminal realm. However, the fact that something has not been done on purpose does not suffice for its selection as a definitional term. Any appraisal of medical error needs to start with a specific analysis of the state of mind of the person who makes the mistake or is responsible for it. At least as far back as Aristotle's *Ethics*, philosophers have argued that an understanding of things gone wrong depends on the mindset of those who are responsible. According to Aristotle (1976), when an injury occurs contrary to reasonable expectation, it is a "misadventure." If it occurs consistent with reasonable expectation but without malice, it is a "mistake" as long as the agent him or herself is the one carrying responsibility for it.

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[3] A medical error is "the failure of a planned action or the use f a wrong plan to achieve an aim" (Kohn Corrigan, & Donaldson, 1999, p. 28).

However, if the mistake is not the person's responsibility, it remains to be a "misadventure." When an agent acts knowingly but without pre-meditation the result would be an "injury." Relating error to justice, Aristotle notes that all of these acts do not make the man unjust or wicked because they were not done with malice. Moreover, he finds "pardonable" those mistakes that happen *in* ignorance or *as the result of* ignorance (pp. 192-194). When discussing medical errors in the context of justice, it is indeed important to understand the state of mind of the person erring.

The notion of intention and other related yet different concepts such as foresight, prediction, intentional action and moral responsibility ought to be given due consideration. The idea that someone does something intentionally or that it is someone's expressed intention to do doing something is a challenging philosophical problem with tremendous practical consequences. Anscombe (2000) has written extensively on the subject. In her major work *Intention*, she explores three related notions of intention: the "expression of intention," "an action as intentional," and "with what intention the thing was done" (p. 1, §1). She notes that in order to understand intention, the differences between the three concepts and their relationships to each other warrants careful consideration. In this light, it is important to distinguish the expression of an intention to do something from the notion of prediction (p. 1-5, §2).

A key criterion that Anscombe carries into her discussion of intentional action is the kind of justification one provides for an action towards an event in the future. The justification for the expression of intention is grounded in an actor's reasoning why something in the future might be "useful" or "attractive" (p. 6, §3). She later points out that intention, particularly the more explanatory intentions in acting, are similar to "forward-looking motives" (p. 21, §13). Prediction, on the other hand, is based on observational evidence, not reason. The role of reason in justification is fundamental to her explanation of intentional action, the most important of the three concepts and a consideration that makes up the major part of her book.

According to Anscombe (2000), an action is intentional when it is the result of an inner process, it is voluntary[4] (either in terms of bodily movements or from inner reflection), and when the question "why?" can be applied to it (see pp. 9-11, §5). But not all answers to the question "why" classify an action as intentional, which is the case if an answer states observational evidence or causality. This kind of knowledge, which stems from the assessment of a present reality, is not rooted in intention. To this effect, Anscombe points out that,

> Certainly in modern philosophy we have an incorrigibly contemplative conception of knowledge. Knowledge must be something that is judged as such by being in accordance with the facts. The facts, reality, are prior, and dictate what is to be said, if it is knowledge. And this is the explanation of the utter darkness in which we found ourselves. (p. 57, §32)

Instead, reasons for acting need to be based on "non-observational" knowledge. For instance, the mention of a history of moral considerations play a role, the interpretation of actions, or pointing to "something in the future;" are all valid answers to the requisite question "Why?" (see p. 24, §16 for summary). But what does Anscombe mean by "non-observational" knowledge?

Anscombe (2000) explains non-observational knowledge as "practical knowledge." This form of knowledge is rooted in the sort of calculated reasoning as the ancient Greeks once described (p. 57, §33 et seq.). Drawing on Aquinas, she distinguishes practical knowledge from speculative knowledge and describes that "practical knowledge is 'the cause of what it understands,' unlike 'speculative' knowledge, which 'is derived from the objects shown'" (p. 87, §48). Since practical knowledge does not emerge from a preconceived reality or from facts that are known to us, we chose concepts that guide our investigations and interests (p. 84, §46). The analogy of a project director whose task is to supervise the erection of a building without being present at the building site represents Anscombe's concept of practical knowledge. Rather than relying on speculation, this person "must settle everything in *a* right order" (p. 82, §45).

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[4] Anscombe (2000) notes that intentional actions can also be described as involuntary when an actor does not want to something but does it nevertheless. However, since the act is being performed, we would argue that the act is voluntary and thus intentional despite the perhaps involuntary antecedent event. On the other hand, voluntary actions that are not intentional can be actions that constitute side effects of actions that are intentional. This is best captured by the concept of the "double effect."

The knowledge with which the director operates to erect the building is guided by concepts known to him or her; it is practical knowledge that provides the foundation for his intentional actions. Thus, Anscombe concludes that "'Intentional action' always presupposes what might be called 'knowing one's way about' the matters described in the description under which an action can be called intentional, and this knowledge is exercised in the action and is practical knowledge" (p. 89, §49). The argument that she makes in regards to this kind of practical knowledge underlying the notion of intent rather than observational knowledge or other kinds of evidential knowledge distinguishes her work from others.

The requirement of intent in criminal prosecution is perhaps the most common application of the term; the fine nuances that emerge when looking at intent in medical error cases are less explored. Shaw (2006) claims that in ethics, intent is often discussed in reference to the principle of "double effect." In the *Medallist's Address*, Anscombe (2001) rejects the usefulness of the double effect as a decision tool. However, the distinction of what is intended and what can be foreseen or predicted as possible results of an intended action is important and consistent with her work in *Intention* (2000), particularly in her discussion of voluntary action (see footnote #1). The double effect entails that "an agent may cause something or allow something bad as long as, first no evil is intended as an end or a means and second, that the foreseen bad is not out of proportion with the anticipated good" (p. 187). Interestingly, this statement has both deontological constraints, which categorically rule out intended means and ends that are "evil" or which we would call "harms-in-themselves," and utilitarian criteria, that is, choosing an action based on the consideration of the relative weight of the anticipated good. In other words, actions or decisions that cause harm are acceptable, but only if they do not also intend harm for its own sake, and only if the foreseen good consequences outweigh the bad.

The principle of the double effect is also helpful for illustrating the importance of intent as element in a definition of medical error. It clarifies that there are three kinds of harms but only one corresponds to error. The overall intention is to improve the patient's condition with a certain medical approach or technology. Possible side effects are considered and trade-offs are evaluated. The "intentional action" that results is based on "practical knowledge" grounded in calculated reason, as Anscombe (2000) describes. If harm results because of the procedures, it is unintended even though it might have been foreseen by a hunch or even predicted by observational evidence. For instance, a physician may try a very risky procedure knowing that the odds of causing death are high. Yet without performing the procedure death is certain. If the surgeon proceeds while foreseeing the likelihood of her patient dying from the procedures, the patient's death may still be fully unintended. If death results it need not be the consequence of a medical error.

In contrast, if harm is inflicted for its own sake, it is caused intentionally. In this case, the overall notion of intent has shifted from the good to the bad. The Hippocratic tradition's well known maxim "First, do no harm" could perhaps be re-phrased to read, "first, do no intentional harm for the sake of harm itself and don't risk any harm unless there is a proportional greater good reasonably expected." Both situations in which harm is caused exclude a notion of a physician having "erred." If the overall intent is to improve the patient's condition, what properties of the principle of the double effect have to change so that a decision or an action becomes an error? Either the process of "causing or allowing" something to happen must be flawed or there is a failure to foresee or predict that the bad consequences outweigh the good. Or perhaps foresight and skills are lacking altogether. What is important to reiterate is what both Anscombe (2000) and Shaw (2006) state quite clearly, though not in reference to a discussion about medical errors: *intent* is not the same as *intentional action* (causing or allowing something to happen), and does not equate to foresight or prediction.

Closely related to the notion of intent is the relationship between moral responsibility and failure. It is clear that intentional harms caused to patients incur moral responsibility; however, such acts fall outside this discussion of medical error and are rarely found in everyday medical practice. As the previous paragraphs explain, harms are not intended when things go wrong in medicine whether they fall into the categories of acceptable risk or foreseeable consequences or fit the notion of errors leading to failures. Where the former instance does not incur moral responsibility, the latter raises specific moral questions from which concerns about justice and fairness arise. Moral responsibility, at least as what concerns consequentialist theories in ethics, is not dependent on motive but is linked to the very consequences of an act and the obligation of an actor to respond. In order to allow a healing morality to unfold, it is imperative that hospitals create an environment that encourages such responsive actions and that promote restorative dialog.

3.2. Etiology

Failures may result in undesired outcomes, yet not all are due to error. In order to identify specific causal factors in which errors are embedded and which can be incorporated in a definition of medical error, this paper expands on McNutt and Abrams' (2002) model of medical error to clarify and distil the possibilities. Taking both systems and human factors into consideration the authors developed a model of error that defines error "only at the deepest reaches of the medical care system" (p. 24). As such, the model represents the etiology of error on three levels that are analogous to the dynamics of the disease process.

In a model of disease, a patient presents with certain symptoms that "come to our attention via disease" (p. 23). Going further back, "diseases come to our attentions via myriad causes" (p. 23). Causal factors include genetic and environmental factors.

According to McNutt and Abram (2002), this same flow can be used for analysing and researching adverse events. Similar to the disease process "adverse events present via failure; and failure via errors" (p. 24). Helpful for this present conceptual investigation is the clarification of the antecedent processes of adverse events and the necessary separation of the terms *error*, *failure*, and *outcomes*. As the authors emphasize, failures are not synonymous with errors, and errors are not the same as adverse events. Specifically, we adopt the authors' proposition that errors are embedded in human, organizational, and technical factors which, acting alone or in concert, are the causes of failure. In addition to the three categories of errors, we add a fourth category involving "environmental factors." These primarily include but are not limited to the socio-economic geography of the setting. Environmental factors may also include spatial concerns within the hospital frequently associated with elevated noise-levels, dense traffic in patient care areas and other barriers to a patient's healing process.

The multi-factorial model described above highlights the reality that errors can be linked to the decisions or actions of individuals as they participate in a complex system that is shaped by organizational culture and policy, technical design complexities and environmental constraints. Considered as such, a multi-factorial model allows for more comprehensive and integrative approaches to healing the effects of medical errors than blaming and punishing individuals.

3. 3. Context

An important issue that comes to light specifically in the study of post-medical error procedures and policies, and one that speaks against universality, is the choice of contextual reference points. One consideration of context has already been incorporated into the definition of medical error: the presence and consideration of multiple factors contributing to failure. Another, more crucial bridge between context and concept is the standard against which medical errors are measured. Considering that many medical errors are nearly inseparable from their contexts, a definition should include a standard that is highly sensitive to the specific medical environment in which a patient is treated. This includes the consideration of place, the healthcare team and its treatment approach, the current state of technology, hospital policy, and resources. As physicians often describe errors in light of their working conditions and the kinds of information they rely on when treating patients, a definition of error needs to include a measure that detects these particulars rather than relying on legally constructed categories of place, hierarchy, and expertise.

Smith and Foster (2000) suggest that reviewing medical errors by "skilled and knowledgeable peers" would respond to the particular context in which they occurred. A responsive standard of this kind is preferable to exclusive reliance on the current legal standard of care criterion, which is abstract. In this same vein, an assessment of acceptable "risk" of a treatment or procedure along with a patient's written informed consent as to his or her understanding of such risk is imperative. For instance, a surgeon performs a highly invasive procedure in which he nicks a nerve nearby the operating site. As a result, the patient suffers from prolonged leg pain. Let's say for the sake of argument that a nicked nerve in this location is well within the acceptable risk of the procedure. Has the surgeon committed an error? Under definitions that do not include an explicit, context-dependent standard, nicking the nerve would indeed be an error. Thus, a peer review criterion is beneficial for illuminating the subtle nuances that emerge in situations in which error is the prime suspect.

3. 4. Outcome

Today, few definitions of medical error focus specifically on patient outcomes (e.g., Veterans Hospital Administration, 2003; Grober&Bohnen, 2005). For instance, Grober and Bohnen (2005) offer a definition in which outcome matters but is not the distinguishing factor. According to the authors, a medical error is "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result" (p. 42). The authors intend their definition to be "inclusive" and "explicit," referencing the "key domains of error causation" as well as the failed act that caused or could have caused an unintended outcome. The nature of the outcome—whether it is harmful or potentially harmful—is left open; it is simply unintended. Moreover, the failed act is contributory and not solely responsible for the possible outcome.

The challenges of accepting a definition such as the one offered by Grober and Bohnen (2005) are twofold. First, error is assessed at the level of the failed action or planning process, not at the root cause level. Second, as many other definitions also hold, the range of possible outcomes is nearly infinite as the only requirement is for the result to be unintended. These problems are magnified in the absence of a standard. As a result, the definition captures nearly all error-based failures. Those definitions that include a classification of outcomes, such as actual versus potential harm, and definitions which have other build-in standards are more discriminatory. As such, they eliminate these cases. Having no potential for serious harm, such as giving Tylenol sixty minutes late is within the range of acceptable risk inherent in any medical treatment and does not present a deviation from any standard of care.

The use of outcome calls for a distinction between errors that are exclusively a matter of patient safety and those circumstances that evoke notions of fairness when things have gone wrong. In the former category we find near-misses, which are those instances in which error could have caused harm but reconsideration or safeguards re-directed practical actions or cognitive processes before missing the mark. An important commonality of both kinds of errors, near misses and those that reach the patient but have no noticeable effect, is that they have the *potential* to cause harm to a patient. The focus on potential harm reflects the important distinction that Hofer et al. (2000) make when defining medical error in terms of "failed processes that have been rigorously demonstrated to cause adverse outcomes" (p. 13). Without this potential, errors of these categories might be less relevant for corrective action or policy considerations.

While acknowledging that errors occur without impacting patients or their care, it is this latter category that is of interest to us; the category includes those errors that cause actual, recognizable harm to a patient. These are the errors that Hofer et al. (2000) describe as the "very small subset of errors that demand attention because its existence undermines both the public's and the profession's confidence in the whole system" (p. 11). In order to provide clarity about the kinds of harm that ought to be addressed with patients and their families, the National Quality Forum (NQF) (2007) suggests time and severity indicators, which require physicians and hospitals to be open about serious harms such as death, long-lasting disability or events that require the patient to receive substantial additional care. Broadening the spectrum of harm, we defend a view of human life that is based on the understanding that humans are multidimensional beings. A perspective that focuses on human 'wholeness' highlights the notion that medical errors impact more than the physical wellbeing of patients; consequently, harm represents a range of interdependent and interacting factors that comprise a healthful human existence. These include physical, mental, spiritual, and social aspects. Although our framework does not rank harm on a severity or time scale, it does regard harm as having a "recognizable effect" on one or more of these aspects resulting in the reduction of patients' personal and relational experience of wholeness. It presupposes that a competent team of healthcare providers, by which we mean physicians, nurses, psychologists, chaplains and other professionals, who are knowledgeable in the field of the patient's disease process and committed to healing in the framework of whole person care can render judgment about the effects of mistakes on a patient's wholeness.

In his theology of healing, Rice (2006) conceptualizes healing as counteracting illness or reducing its effects with the aim to restore the wholeness of human beings. If our goal is to return to a state of wholeness by counteracting illness, then a response to harm caused by medical errors should take place within the same framework. A conception of outcomes as suggested places high demands on justice and it is with this particular understanding that the disclosure of medical errors to patients and the restoration of patients, healthcare providers and hospitals should be discussed.

4. A Conceptual model and definition of medical error

A conceptual model that explains concepts of intent, etiology, context, and outcome is deeply rooted in the four considerations discussed at the beginning of this chapter: The uncertainty in medicine, the complexity of modern medical care systems, the fusion of concepts and contexts, and the link of medical errors with blame. Figure 1 represents the multi-factorial model we propose, which includes both of the two categories: errors that are a matter of patient safety and errors that find additional consideration in theories of justice. Specifically, we promote the notion of restorative justice as we conceptualize justice as those decision and actions that have the potential to restore the physical, mental, spiritual and social dimensions of human wellbeing. The model generates the following definition:

> "An error occurs when organizational, human, technical, or environmental factors lead to an unintentional failure of an intended practical action or cognitive process, which results in recognizable physical, spiritual, mental, or social harm to a patient. The standard that determines whether harm is due to error is the consensus of a competent, multidisciplinary group of healthcare providers whose practice is concerned with treating a condition similar to the patient's and who, if they had the same information at the time the error unfolded, also think that it would have come about but should not have."

Based on an in-depth understanding of the characteristics of medical care in today's world the proposed model and accompanying definition provide a foundation for the development of hospital policies that aim healing the multi-dimensional effects of medical errors. Our conception implies the investigation of errors as embedded in dynamic systems. Through its restorative justice approach, it aims to address the needs of patients who are harmed (e.g. Gallagher, Studdert, & Levinson, 2007) and of healthcare providers who cause harm unintentionally (e.g. Devencenzi, & O'Keefe, 2006) in a framework that promotes patient safety.

5. Conclusion

Any definition of medical error should be accepted with caution. Meanings are embedded in concepts and language. As social products they are deeply intertwined with the contexts in which they are situated. Converging on the treatment of a single patient is a large network of human interactions that evolve around the use of highly sophisticated technology. When developing a definition of error for hospital policies, organizations struggle with addressing the complexities of the modern medical care environment, as the boundaries between what constitutes a medical error and "things that just happen" might not always be conveniently clear.

Yet medical errors need to be discussed in the healthcare community and with patients. In order to develop post-medical error policies, both for quality improvement and restorative justice, we should release the subject from its semantic imprisonment and embrace medicine's complexity to bring into the forefront its human side. Medical practice is as much a relational and ethical matter as it is a technical concern. Our proposed model improves the clarity of terms and eliminates the confusing semantics that are common to modern medical discourses. As an outcome-oriented approach, the model treats medical errors from an ethics perspective by taking their multi-dimensional effects on human wellbeing into consideration.

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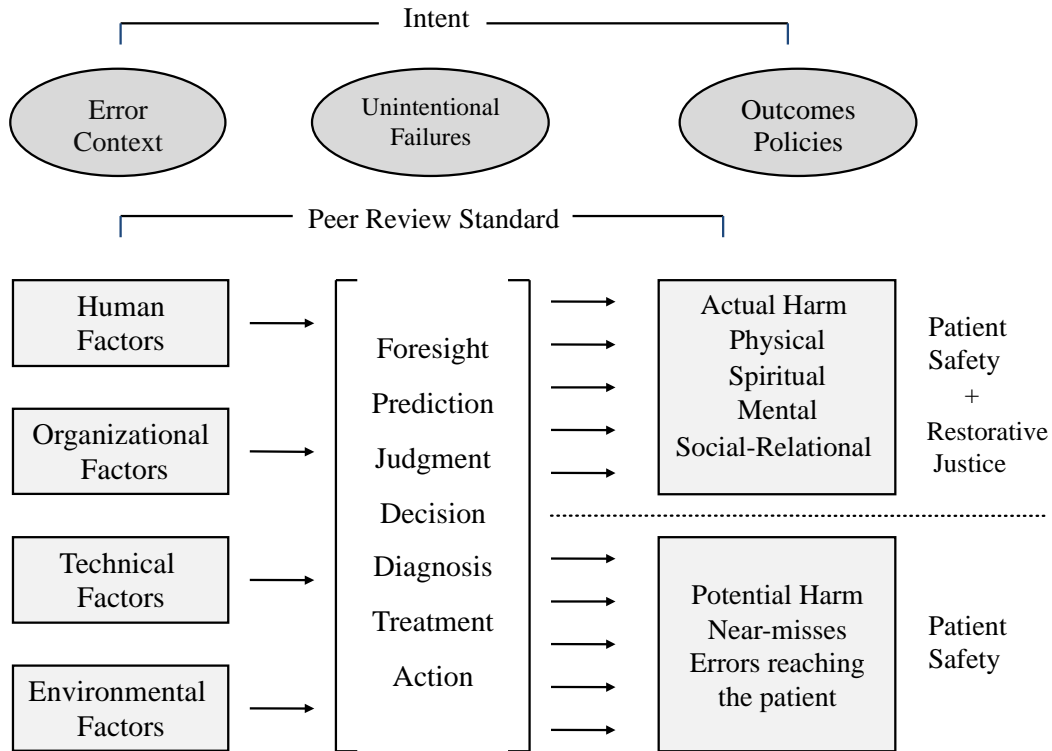Zehr, H. (1990). *Changing lenses: A new focus for crime and justice*. Scottsdale, PA: Herald Press.

Figure 1. Conceptualmodelofmedicalerror.