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Acceptance of Uncertainty: uncertainty as a heuristic tool applied to the issue of medical errors

Angelika Potempa
The University of Texas Rio Grande Valley

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medical errors.

Abstract: This is an exploration of uncertain certainties and certain uncertainties with

reference to, mainly, systemic approaches to medical errors.

1. Background

In a universe that is perceived as ordered, unexpected issues inevitably spring up,

which have put humans on a tightrope walk; they can embrace uncertainty and move

towards a relativist stance or make efforts to develop tools for the control of the

conditions of actions and, with it, their effects. The semantic field to which

uncertainty (being of indeterminate time or occurrence) belongs reflects this situation.

Words such as *dubious, obscure, hesitant to suspend, interrupt, err, mistake, peril,*

chance, stake, unsafe and *safe* as well as *empiric, adventure, danger, dominion* and

variability are related to the feeling of insecurity and the desire for the right

knowledge in order to do what is right (etymonline). *Certainty*, the antonym, promises

safety, and control and, with it, appears to be preferable. What induces insecurity and

fear then needs to be overcome or eliminated. Organization, government and legal

rules, science and technology are some of the means to this end, however

unreachable.

The discourse on the ethics of errors in the medical field has taken place in

this context and has necessarily been shaped by the desire to avoid any unnecessary

risks and to not harm but benefit patients. Guided by the idea that, when human lives

are concerned, there should be no room for error, the focus has mainly been on

outcome control and causal analysis of errors. Central to these efforts have been

improved standards of care, technical equipment, expertise, and management of the

medical caregiver-patient relationship in order to increase trust in and reputation of

the health care system as well as to lower the costs for healthcare providers, patients,

and society as a whole. More recently, in addition to retroactive "damage control,"

models of prospective continuous quality improvement (CQI) and no-fault liability

have been developed, that is, a more process-oriented approach, particularly with

regard to disclosure measures and the development of a higher level of responsiveness

and accountability both on individual and health care system levels (Sharpe, 2015;

Leape, 2001; Rubin & Zoloth, 2000). Moreover, the need has been articulated to not

only focus on risk prevention and management but also on overcoming "white-coat

silence" (Gawande, 2002, pp. 70-74, 94-106; Groopman, 2008, pp. 1-25, 272-279).

The professional culture in the medical field needs to change from one of self-

regulation and blame or silence with regards to mistakes to a culture of self- and

external regulation, disclosure, and support (Sharpe, 2004, 2015; Rosner, Berger,

Karg et al., 2000; Rubin & Zoloth, 2000; Runciman, Merry &Walton, 2007; Wu,

McCay, Levinson et al., 2014; Leape, 2001). This has gone hand in hand with

reacknowledging that medicine is an "uncertain art" (Nuland, 2008) in the pursuit of

which the health care professional needs to weigh probabilities and develop a

tolerance toward the inevitability of uncertainty. In this context, practitioners, such as

C. Wellbery (2009, 2010), J. Groopman (2008), S. B. Nuland (2008), B. Lown (1999)

and A. Gawande (2002, 2015) articulated that uncertainty should not be reduced to a

necessary evil but welcomed as an opportunity to deepen the relationship to the

patient and consider alternative possibilities. Furthermore, both medical personnel and

patients are coping with angsts and uncertainties, which factor into the dynamics of

their relationship. Sharpe, Leape, Bosk, Scofield, and Chambers went even further

and broadened MacIntyre's and Gorowitz's idea of a theory of medical fallibility

(1975) in order to express a general need for society to alter its discourse on

uncertainty and errors in health care – that uncertainty and errors cannot be

eliminated; they are an imminent part of what we consider scientific and

technological progress, although reducible and manageable. Others again, such as the

physicians M. and Ch. Witte, focused specifically on the limits of our knowledge, the

unknown that exists within the known and linked to it. They built on the results of

Ignorance Studies (theories of non-knowledge) and Nepistemologies, that is, theories

of how new knowledge come into being (Root-Bernstein, 2003).

By focusing on the morphology of change under the condition of the

interrelatedness of properties of objects, co-existence and co-evolution of

environments and their organisms, New Materialist and Object-Oriented Ontology

perspectives are also accentuating the need for a non-dichotomizing, "normalizing"

approach to knowledge and technology- related uncertainty. They recognize that we

have "only" the certain certainties of best scientific evidence, which are tied to and

accompanied by uncertainties. Furthermore, if nothing is fully itself, a particular

ethical perspective needs to be taken, as Timothy Morton, for instance, articulated. He

tied interconnectedness not just to the need to learn "to live in the shadow of

wrongness" but also to an ethical impetus, the need to care about far away and

seemingly strange and foreign organisms (Morton, 2010, p. 13). Approaches, which

reduce uncertainty to a solely epistemological problem (Djugolbecovic in Adams,

Tomori, & Bennett, 2001), oversimplify the issue. Already in the 1970s the ethicist

Hans Jonas had suggested to apply a *Precautionary Principle* in case of the absence

of scientific consensus on whether development and implementation of a new

technology could cause severe or irreversible harm to the environment or the public.

This approach adds the *First Do No Harm* principle to the principles of risk assessment for situations in which potentially strong hazards might occur for which the scientific community lacks in certain information. As implicated above, these risks are grounded in the fact that, because of the interconnectedness of things, all our models of whatever part of reality are necessarily reductionist as their complexity and interactions with their environments are concerned and, with it, uncertain (imprecise). This reductionism is coupled with the system developers' and, also, politicians', economists', and financiers' value choices and the infusion of guiding principles into the system and the criteria for the evaluation of its "proper" functioning. Consequently, determination and management of hazards should be done in an interdisciplinary manner and not just by specialists in the respective field and include the perspectives of the layperson who might be exposed to the effects. This again warrants transparency of decision-making and non-sensationalist, accurate, and non-abstruse publication of the findings. WHO discussions of environmental issues as public health issues (Martuzzi & Tickner, 2004), for instance, exemplify the latter approach.

The following discussion of medical errors will have to be seen within this context of efforts to change the discourses on uncertainty and science. The notion of uncertainty will be utilized as a heuristic for making educated guesses about phenomena that deserve further research with regards to medical errors. This approach expands on Witte's (1995) understanding of ignorance, which concerns:

- what we do not know (a known unknown that can be researched or an unknown known, that is, existing knowledge one is not aware of);

- what we think we know but don't;

- what we take for granted but don't really know;

- what we don't want to know. There is also what we just ignore (because of the

particular focus of a study);

- what the scientific community cannot agree upon and that requires further research;

- what we are used to seeing and portraying in the particular ways that are typical of a

cultural or scientific community (Daston & Gallison, 2003, pp. 22-27, 43-48) or a

subculture;

- what we denote by using particular concepts whose meaning changes with different

contextual configurations and in relation to other concepts and/or ideological frames

(Freeden, 1996, pp. 44-55, 68-77, 86-90; Rubin & Zoloth, pp. 18-20) and

- what we cannot know, that is, the unknown unknown, the research questions of the

future, a fundamental uncertainty.

The following analysis of medical errors will, consequently, start with the known

knowns and proceed to uncertainties that are related to them, that what is not or

insufficiently looked at, ignored, not really known, or one-sidedly portrayed. For this

purpose, the analytical approach will necessarily have to step out of the health care

system and look at its interactions with its environments.

2. From Known Knowns to Relative Certainties or Uncertainties

2.1. General Knowns

(1) What catches the public eye are the so-called "never events," that is, events that

should never happen (e.g., surgery on the wrong site, body part, or patient or use of

the wrong drug, or retention of foreign objects in a patient after surgery) as well as the

perceived great danger of medical malpractice lawsuits. More recently, patient safety

organizations have paid growing attention to apologies for medical mistakes and

patient checklists that are to help the prevention of mistakes. The message, though,

that medical mistakes or *adverse events*, and, since 2011 *serious reportable events*,

are not rare, does not seem to have made it yet to the broader public. Since the 1990s,

we know that they are not just a problem of some "bad apples" who lack in

knowledge or skills; they are endemic and an "industry" or health care system

problem, although to a high degree preventable (Harvard Medical Study, 1991; To Err

is Human, 1999). Despite a huge number of quality enhancement programs that

incorporate a "margin of safety," many of them coupled with financial incentives for

error prevention, as in the case of the programs of the Centers for Medicare and

Medicaid Services and Obamacare, the high numbers have subsisted. Because of

medical care in hospitals that has gone awry an estimated 250,000 deaths per year

occur, which would make it the third leading cause of death in the U.S. (Makary in

McMains, 2016) This figure equals roughly 3 crashed Boing 787-200 per day. Even if

it were "only" 98,000 deaths as To Err is Human approximated (Allen, 2013), the rate

is rather high for a sector that is expected to heal or help patients manage their

symptoms but not kill them…

(2) We also know that there is no unified national data collection and management

system; transparency laws that regulate reporting differ from state to state. There is

evidence that the rate of underreporting of medical errors is high; providers are

reluctant to admit mistakes for fear of repercussions (Kagan & Barnoy, 2013;

Levinson, 2012; Ruggieri, 2012, pp. 87-90). Based on the possibility to gain data and

to manage and interfere, the majority of data refers to hospital populations, although,

nursing home populations and other institutions are sometimes also taken into

consideration. The majority of medical care happens outside of hospitals, though.

Also, the figures we have are based on approximations and extrapolations: how can

deaths be measured that are due to treatments that should have been provided but

were not and based on medical records that are not always accurate. More so, under

"cause of death," there is no column for medical mistakes (Makary).

(3) That there is no universally or US-wide accepted definition or taxonomy of

medical errors and of harm complicates the situation further. (Clarke, 2015, pp. 158-

159; Rubin & Zoloth, pp. 4-112; Runciman, Merry & Walton, pp. 30-51; Berlinger,

2005). Differences in the understanding of medical errors and harms influence the

choice of methods to prevent and mitigate errors. And, vice versa, different systems

models and reporting methodologies shape the understanding of what errors are, what

is noteworthy to be reported and/or prevented and what is tolerable (e.g., outcome-

oriented reporting, equal utilization of "best practices," and utilization of disease

oriented evidence, such as, surrogate markers like blood levels, test results, image

findings, as well as prescription of particular drugs).

(4) A bio-medical understanding of errors dominates the discourse, due to its being

embedded in a repair approach to medicine ("the doc will fix it"), efforts to avoid

medical malpractice suits and to make health care "businesses" provide service for

"pay" (Leape; Rubin & Zolot). On an individual level, medical errors are widely seen

as dependent upon knowledge, skills, and competency (Runciman, Merry & Walton,

pp. 10, 112-123). They are generally understood as a pursuit of the wrong plan of

treatment based on the right, wrong or an incomplete diagnosis, or the wrong

execution of the right plan. In other terms, errors are deviations from or violations of

reasonable treatment and best practices that lead to adverse effects that can be

immediate, delayed, cumulative, or long-term (James, 2013), although there is no

agreement on the time frame.

On a systemic level, medical errors are often considered "accidents," that is, the

malfunctioning of a system that can either be unforeseeable and, consequently,

unpreventable (an uncertain uncertainty related to the complexity of the system and

its interactions that can "happen") or, in the case of a higher probability of

occurrence, preventable through safety measures (certain uncertainties with a

relatively high chance of occurrence). Because these known uncertainties can be

prevented, their occurrence can ultimately be reduced.

(5) The persistence of high numbers of adverse events has been linked to a variety of

factors, such as flaws in the thinking of medical professionals and resulting practices,

e.g., "defensive medicine" (Lown, 1999, pp. 140-157; Ofri, 2013, pp. 185-193). Other

important influences are the complex dynamic of a more partnership-oriented

relationship between patient and medical care provider, difficulties to change

behaviors, the fracturedness of both the insurance and the health care systems with

their mesh of private and public sectors and different administrative layers and

responsibilities, the need to replace outdated information technologies through

electronic record keeping, the fast-paced implementation of new techniques,

technologies, and medications, unalike safety standards of different industries,

proneness to political influences, and dependence on different funding sources

(Sharpe & Faden, 1998; Sharpe, 2004, 2014).

(6) As mentioned above, the focus has shifted from outcomes to remedying flaws in

the process of providing quality care, thereby accepting a moral obligation of both

individual and "system" to act preemptively to avoid or minimize potential harm to

patients. One way is to tackle the problem by implementing top-to-bottom measures,

rules, and regulations and combining these with changes in the cultures of medical

professionals and management, with full knowledge, though, that both health care and

insurance systems are fractured. If "system" is a misnomer (Leape, p. 78), the efforts should focus on improvement of care not on system change.

Those who opted for system change, adopted "industrial efficiency" approaches that have been used by other industries, such as aviation and car production, industries, which have systematic quality improvement programs and high safety rates. In this context, business/service provider/industry – consumer/customer/patient models based on complexity, systems analysis and change theories as well as utilitarian cost-benefit calculations have been applied. For this purpose, experts defined the health care "industry" as a complex, open, interconnected and self-adjusting large-scale socio-technical or socio-technical-system (Reid, Compton, Grossman & Fanjiang, 2005; Ravitz, Sapirstein, Pham & Doyle, 2013) or, even a politico-technical system (Eveland, 2016). The goal is to transform an underperforming, turbulent system (Bar-Yam, 2006) via incremental measures into a system that shows as a zero-mistake system on the individual level and is cost efficient as a whole. This purpose requires to address both the large scale of the different tasks that the system has to address as well as its high complexity and to translate the apparent quality problems of the health care system into system management and change problems. Considering this, a "one-size-fits-all" approach won't do, as the experiences with aviation and engineering models show (Stolzer & Goglia, 20015; Ravitz, Sapirstein, Pham, & Doyle). "Fixing the system" by applying the right scientific model, more comprehensive data collections, and implementing the right management tools (Bar-Yam, pp. 464-465), will undoubtedly lead to improvements but not to the "fix" that people normally expect from the application of science and technology (Hochschild, Crabill & Sen, 2012; Kennedy & Overholzer, 2010). Why not? – Because of all the uncertainties that systems have to (and therefore do) eliminate; after all they are, to use Feyerabendian

terminology, manufactured to make things manageable (1988, 209-210). And the

creators can neither think nor act in value neutral ways; they are politico-socio-

culturally embedded and part of power games.

The following will therefore elucidate this in more detail.

2. 2. Uncertainties, that is, unknowns linked to the knowns

(1) System level

 To the many variables that determine systems outcomes belong: what is defined as

system/subsystem level efficiency, well-functioning, health, care, and health care

quality? What is included in or omitted from the understanding of "industry" or

"health care system?" Is healing or health maintenance the target or both? – If so,

value-orientations and treatment goals and expectations are different for chronically

ill, disabled, or dying people in comparison to other patients; what is considered an

error, will differ, too.

        To continue with this line of questions: How are the structure of the system, its

subsystems, and elements defined? What is understood by medical error or mistake

and how and when are they targeted (Clarke, pp. 160-163, 168)? How is the in-system

dynamic described and included into systemic models (from interactions between

members of different professions who are differently positioned in hierarchies to

patient-care giver partnerships)? If the medical caregiver-patient relationship has

process character, how it that integrated? Furthermore, assessment of possible risks as

well as mistakes that have been made depends on the position of the participant in the

system and, therefore will differ (Dickensen, 2003, p. 147). That is, whether one is a

patient, the patient's family, a resident or a more experienced doctor, a nurse, a

technician, an insurance agent or a company, a hospital/clinic, or a politician who

votes for bills or distribution of funds, or someone who represents cases, programs, or

the industry in the media, makes a difference. Even the distinction between

"customer" and "patient" can change things. If right treatment includes safe treatment,

the guideline would be to not deviate from or violate what is defined as reasonable

treatment that is provided with average skills and follows "best practices."

This, however, can only function with a "generic customer" included in a model that

overlooks cultural, genetic, sex, age, and other differences as well as political

influences that determine how best practices are defined. Current controversies over

efficiency and necessity of mammograms, breast and colon cancer tests, over

radiation exposure through computer tomography, or over beta blocker efficiency for

post-myocardial infarction and, in general, new medications testify to how political

influences, changing denotations, and new scientific evidence impact or change not

only the understanding of best practices but also call for more differentiating and

individualizing approaches (Prasad et al., 2013; Freedman, 2010; Ricci, Cox, &

MacDonald, 2006; McKinnon, Cheng, Garside, Masuda, & Miller, 2015).

What adds to it is that if one of the system goals is to further a more partnership-like

relationship between medical caretaker and patient or patient advocate, the

understanding of errors would change, too. What patients (disabled or very young or

old or facing the end of their lives) see as errors and what they consider proper and

timely treatment may differ from recommended best practices (Wellberry; Torrey,

2016).

Other questions to consider are: What is the greatest or intolerable or

negligible harm and who has the power to decide what that is and what harm to

avoid? (Stolzer & Goglia, 2015, pp. 150-153)? Is avoidance of the worst possible

outcome in the course of action (Max/Min) desirable and why? How would that be

negotiated? How can social justice and fair treatment be served under the influence of

different markets, competition, differing legal rules and regulations, and limited

resources? – The decision-procedures are not value-neutral either; they are influenced

by value judgments and power structures. Who needs to know what and when in order

to make what decision? What are the costs for eliminating or limiting hazard factors?

What information is considered crucial and, therefore, needs to be passed on to

whom? Moreover, if there is no evidence of harm that does not mean that we can

automatically consider a substance or process as harmless. This becomes especially

important when considering the interactions of whatever is designated as "system,"

with its environments, i.e., that which seems to lie outside of medical or health care.

More generally speaking, another bundle of indeterminacies concerning safe and

quality treatment results from the manifoldness of interactions of the health care

sector with others.

(2) Systems and environments

J. James's typology of medical errors, although developed to measure in-hospital

adverse events (2013, pp. 122-124), is quite comprehensive and allows for pointing

out a variety of uncertainties connected to the working of the system as well as its

functioning in different environments. James distinguished between five different

types of errors that may lead to a patient's immediate or delayed (months or years)

experience of harm: 1. errors of commission (wrong action or improper performance

of the right action), 2. errors of omission (a particular action was not performed that is

necessary to treat or heal a patient according to institutional protocol or professional

standard), 3. errors of communication (between health care service providers or

between provider and patient), 4. contextual errors (disregarding unique and possibly

constraining circumstances or conditions of the patient, such as developmental

disabilities, finances, religious or cultural beliefs) and 5. diagnostic errors, which can

also lead to (1) or (2). More so, one needs to take into consideration that much

depends on providing the right tests, diagnoses, and treatments in a timely manner.

Hospitals and medical institutions and their "customers" are geographically

situated, though. That means, traffic and road conditions, income levels, availability

of transportation, previous experiences with medical facilities and care providers,

cultural beliefs concerning when and what kind of care to seek and, even, a family's

immigration status matter for whether and when help is sought as well as for when

and what kinds of actions are taken on the side of the health caregiver. The racial,

ethnic, age, income, and educational make-up of the community, shared beliefs and

experiences need to also be taken into consideration as influences for errors. The

same is true for what types of medical facilities are available within what time frame

because this determines test and treatment options, risks because of experience level,

and opportunities for follow-ups. There is sufficient evidence showing that people in

rural, poor or medically underserved areas or being African American or Hispanic

have a higher likelihood of being exposed to non-standard treatment and errors. (2014

National Healthcare Quality and Disparities Report; Anderson Mattox, 2010; Kirby,

Taliaferro, & Zuvekas, 2006; Molina, Silva, & Rauscher, 2015)

And, to stay with the geographical aspect, food availability, air, water and soil

pollutants belong to the factors that influence people's health status as well. If

prevention of avoidable health risks or timely and sufficient response to existing

dangers are included in the error definition, then omission of such would count as an

error. Acting on such cases, however, as the example of water pollution in Flint, MI,

shows, is dependent on the collaboration of and with other governmental agencies, in

this case the Michigan Department of Environmental Quality and local, state, and

federal politicians. More so, our limits of what kinds of chemical substances can be

found – where and what and in what mixture with what as well as what kinds of

effects and the nature of such effects (immediate, cumulative, long-term) –is quite

limited. Patient symptoms can be influenced by such factors, which can easily stay

unrecognized. But the doctor or practitioner cannot be expected to play environmental

detective to the degree of the famous TV character, Dr. House.

Since dealing with errors and possible adverse events requires dealing with

responsibilities and accountability, a whole other slew of queries raises with reference

to the moral and legal distribution of responsibilities, culpability, and restitution (from

apologies and forgiveness to remedying the situation and financial reparation). Even

if the "originator" or "polluter pays" principle is applied, how does this work in cases

of collective/compound agents? – Such cases require that responsibilities be

negotiated, and the negotiation process itself is neither value- nor power-neutral. Is

there anything like a "weighted" or "collective responsibility" and/or guilt and if so,

what would that be? – In this case medical ethicists are faced with similar problems as

military or engineering ethicists who are dealing with the utilization of robots, drones,

and nanotechnology. Implementation and utilization of technologies in the medical

sector, including IT (Intelligent Technologies), do not only have the potential to make

procedures safer but to also create new sources of errors, some of them related to the

functioning of the technologies themselves, others to the human factor and to how

possible disturbances in man-technology collaboration can be prevented: If robots are

used, can these be considered "responsible moral or legal agents?" Technology can

malfunction (technical, electricity supply, weather or other reasons) or be ill

calibrated (depending on software or human influence). Software can have glitches or

get hacked and, with it, certainly be the cause of adverse events. The same is true for new safety measures, such as electronic health records (EHR). Outsourced patient record transcription (to people whose understanding of medical English might be limited or who are hard to reach in order to double check) adds another failure cause (McCann, 2014; Allan, 2015). Even if EHR allows for a more complete picture of how certain ailments in particular populations evolve and, with it, the development of new algorithms that can help to discover the early onset of these ailments, consideration of individual circumstances will still be necessary. Moreover, doctors will still have to rely on the information that patients provide or not provide (don't want the doctor to know, don't consider relevant, or err about).

Another factor is that choices with regard to technologies, software, or new technical components are taking the offers of a great number of suppliers into consideration, which bring not only different industry standards but also different levels of user-friendliness and fitness to be integrated into the picture. The influences of special interests or of financial restrictions play a role, too. In these cases, it is hard to determine when and where a mistake happened as well as where what course of action to take so as to avoid future mistakes. If the originator principle would be given up, mistakes would become part of the functioning of "the system" and individual wrongdoing ameliorated. This, however, would veil decision-making processes and hinder transparency and organizational learning (Clarke, p. 162), although it would protect the reputation of different professions and industries. Using the traditional approach of pointing to the human factor and stressing that it is people who implement, supervise, and maintain technologies and who train to learn new technologies, is also too simplistic. We know that decisions are not made by abstract agents but by real life persons with real life interactions that are shaped by mutual

perceptions, power games, knowledge, skills and momentary circumstances.

However, these people function within systems with rules and regulations with

different organizational climates, goals, professional hierarchies and decision-making

chains, all of which can collide. Moreover, what it means that a decision is optimal or

"good-enough under the circumstances" or plain "wrong," and what kinds of short-

and long-term affects they might have, will have to be negotiated and, as already

stressed, this process is rule- and value-guided. How open decision-making processes

should be and how and to what degree hierarchies need to be broken down that

impede self-critical and open decision-making processes, will also have to be further

analyzed.

The field gets even muddier with view to newly-emerging technologies. Traditionally,

technologies and technical devices have been seen as artificial neutral tools that apply

scientific knowledge in accordance with human purposes. Nanotechnology, new

forms of prenatal genetic testing, germline and genome editing (CRISPR), genetic

pharmacology and their applications (molecular-level individualized "repair" that can

eradicate disease and "abnormalities" vectors, growing of human-animal chimeras for

organ transplants, etc.) are challenging this perspective. For complex open systems,

because of their interactions with environments, irreversibility is impossible, that is,

the system cannot be restored to its original status before the new technologies.

However, we might think we control certain processes based on risk extrapolation,

but what kind of evidence do we have? Our technological abilities might be ahead of

our scientific insights and the availability of evidence for decision-making. What

about minor abnormalities in unexpressed genes of somatic cells and the possibility of

spontaneous mutations? What if the experts cannot agree on what certain data mean?

Can we really foresee what will be "positive" outcomes from "negative" ones? What

criteria to apply when determining this? Do we really know what is morally

permissible or relevant and what should not be permitted? Even on the cellular level,

we cannot foresee all possible interactions. Which tests and practices should become

standard and "best practice" and recommended for whom and what conditions? What

if, despite average skill level and "best practices," things go wrong? – Is the intent to

repair decisive or the "unsuccessful" outcome for the evaluation of the case?

Admission of errors and apologies will have another dimension, too. – Who to and by

whom? What about restitution? And, generally speaking, what norm is applied to

distinguish normal from abnormal species-function? The common definition of

disability, for instance, refers to something that is required or expected to perform in

society (looks, skills and abilities). That makes this definition relational. (Medical

Dictionary) If what is seen as aberration/not-normal depends on the understanding of

"the" normal human being and of "life quality," is "restoring" of the "normal" a right

and not to do that a failure or a crime? What kinds of conditions will the physician

have to anticipate and test for so that he or she cannot get accused of negligence?

Does what is extraordinary, normal or mandatory need to be negotiated? Or is the

medical profession simply correcting the individual's genetic "bad luck," when

testing for and repairing particular aberrations from the "healthy norm" (physical

deformity, disability, illness, or non-normal mental functions)? What to do with all

the knowledge about genetic lineages and possible "aberrations" that is acquired?

Considering the complexity of this knowledge, which is challenging even for the

expert, how can the layperson understand what it means? Who should know what? –

Only the patient or the whole family? What to do if someone does not want to know

or is under-age? (Dickensen, 2003, pp. 172-174) Wouldn't we need best

communication practices or protocols, too, and a qualified genetic counseling service?

What is to be considered misuse of testing and knowledge and how can it be

prevented?

In case of prenatal tests and changes, how can the autonomy principle of bio-ethics be

applied? – We won't be able to ask future generations for permission. On what should

the research and healing concentrate, rare conditions or spectacular illnesses or

common ones? – We have limited funds. Moreover, with each of the new

developments, new expectations are raised (and provided to the public) concerning

what can become "standard treatment." And age, ethnicity, genetic lineage, and

gender could factor in, as do costs and resource distribution. This, in turn, raises

issues of discrimination, social justice and fairness as well as the question of social-

political and individual culpabilities. (Denson, 2007, pp. 148-149; Cochran, & Kenny,

2014; Yeo, 2009; Day, 2014) The new chances then come with choices that won't be

"innocent."

Before pointing out some conclusions, let me mention four more lines of questions

that should be asked because of their links to the issue of mistakes.

The first concerns the influence of the media on the perception of mistakes (as

in the cases of the Ebola scare in Dallas and of debates in online forums) as well as

the impact of advertisement (for new technologies and medicinal products and

medications). If, in a patient-centered approach, the patient's perception matters, the

media would also be indirectly part of the patient's evaluation of what counts as

"good service," error, and apology (Kennedy, & Overholzer, 2010; Halpern, J., 2001;

Torrey, 2015; Irwin, 2015; Forde, & Wu, 2015).

The second involves food. It is not "just" food availability that we should be

concerned about but also what we eat, since the chemicals that we take in with and as

food do not only influence symptomatically but, also, treatment options (e.g., the

efficacy of antibiotics; Combating Antibiotic Resistance, 2016).

The third relates to the standards that apply in the vast array of alternatives to

"school medicine" (from self help and the sale of brain stimulation devices to online

Telemedicine) and in the beauty and cosmetics industries (from Botox injections,

cosmetic fillers, intense Pulse Light and thermal wrinkle treatments to chemical peels

and weight-loss programs) as well as in ancillary services of the health care industry

(e.g., ambulance drivers, 911- operators) (Carter, & Forte, 2016).

The fourth is linked to globalization effects and the possibility of exposure to

new, formerly unknown or "irrelevant" or neglected illnesses (e.g., Zika, Yellow

Fever, and Ebola; Gostin, 2015). There are no books or safety checklists to follow.

Conclusions

1. It seems necessary to accept that the term medical error will always stay elusive to

a degree. Focusing on more precise taxonomies, and based on it, the development and

implementation of more rules and regulations, although helpful to improve systemic

and individual behaviors, won't solve the problem of their occurrence either. What is

needed is a more realistic approach to uncertainty. Steps towards such would require

to change the socio-political discourses on errors and uncertainties with regards our

expectations towards science and technology in medical education and the health care

professions and in society in general, without strengthening the dichotomic position

that many people display who oscillate between blind trust and a "fix it" attitude or

deep-seated distrust. (Valdesolo, 2014; Trust in, 2002) This discourse needs to focus

on the understanding of the "no harm principle," of care, vulnerability, collective

responsibility, accountability, quality of life and a "good" life, good/normal/average

health, illness, and disability. Moreover, people need to understand that measurability

does not guarantee objectivity and that tests, data collection and technology

development are based on previous value decisions and, therefore, come with a

particular focus. From the beginning, they have an ethical component, which concerns

what is developed by whom for whom and what is not pursued. How are private and

tax money spent? What other problems are not tackled and why? Furthermore,

scientific knowledge, including medical, and medical standards have a high turnover

rate (Freedman, 2010; Elvin, Edwards, Kinnersley, & Grol, 2000).

2. If we want an accountable and responsive system, the issue of errors needs to be

dealt with prospectively, interdisciplinary, with public input and transparent

procedures and by considering long and short-term influences from what is not the

"healthcare industry." Since we are dealing with an open system, shifting the focus to

local/regional "systems" and communities and their ability to become "islands of

excellence" might be a promising way to tackle the problem (Bar-Yam, 2016,

Gladwell, pp. 182-191, Sharpe, 2003, pp. 8-15; Forde, & Wu, 2015). This means,

high-reliability organizations with an atmosphere of "collective mindfulness"

(Manheimer, 2015, p. 139) and a higher level of decentralized decision-making and

transparency that orients towards patient in-care and quality of life. The ideal would

be a harm-free, low-cost care over a prolonged period of time, maximal a lifetime.

References

Adams, J. R., Tomori, C., & Bennett, C. L. (2001, Nov. 1). Uncertainty in Medicine:

A talk with Dr. Djulbegovic. *Physicians Practice.* Retrieved from

http://www.physicianspractice.com

Allen, A. (2015, May 4). Electronic records errors growing issue in lawsuits.

Politico. Retrieved from http://www.politico.com/story/2015/05/electronic-

record-errors-growing-issue-in-lawsuits-117591

Allen, M. (2013, Sept. 20). How Many Die From Medical Mistakes In U.S.

Hospitals? *ProPublica.* Retrieved from

https://www.propublica.org/article/how-many-die-from-medical-mistakes-in-

us-hospitals

As brain stimulation finds non-medical uses, now is the time to consider its

Implications (Editorial). (2016, March 02) *Nature* 531, 8.

doi:10.1038/531008a

Bar-Yam, Y. (2006). Improving the Effectiveness of Health Care and Public Health:

A Multiscale Complex Systems Analysis. *American Journal of Public

Health96 (3),* 459-466. Retrieved from

http://www.necsi.edu/projects/health/ajph/Bar-Yam.pdf

Berlinger, N. (2005). *After Harm. Medical Errors and the Ethics of Forgiveness.*

Baltimore: Johns Hopkins University Press.

Carter, O., & Forte, J. (2016). Medical risks: Regulate devices for brain stimulation.

Nature, 533 (179), pp. 283-284. Retrieved from doi:10.1038/533179d

Charles C., Gafni, A., & Whelan, T. (1997, March). Shared decision-making in the

medical encounter: what does it mean? (or it takes at least two to tango).

Social Science & Medicine. 44 (5), pp. 681–92.

Clarke, J. N. (2015). Medical error and patient advocacy. In Surbone, A. & Rowe, M.

(Eds.), *Clinical oncology and error reduction* (pp. 158-171). Chichester, UK,

Hoboken, NJ: Wiley Blackwell.

Cochran, J., & Kenny, C. C. (2014). *The Doctor Crisis: How Physicians Can and

Must Lead the Way to Better Health Care*. New York, NY: Public

Affairs.

Combating Antibiotic Resistance. (2016). *FDA*. [Weblog]. Retrieved from

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm092810.htm

Darr, K. (1991). *Ethics in Health Services Management.* Baltimore, MD: Health

Professions Press.

Daston, L. J. & Gallison, P. (2003). *Objectivity.* London, UK, Cambridge, MA:

MIT Press.

Day, T. (2014) About Medical Care for the Elderly. *NCPC*. Retrieved from

https://www.longtermcarelink.net/eldercare/medical_care_issues.htm

Dickensen, D. (2003). *Risk and Luck in Medical Ethics.* Cambridge, UK, Oxford, UK,

and Malden, MA: Polity.

Disability. (n.d.) In *Medical Dictionary*. Retrieved from http://medical-

dictionary.thefreedictionary.com/disability

Elwyn, G., Edwards, A., Kinnersley P., & Grol, R. (2000, November). Shared

Decision making and the concept of equipoise: the competences of involving

patients in healthcare choices. *The British Journal of General Practice. NCBI

Resources.* 50 (460), 892–9.

Err (n. d.). In Etymonline. Retrieved from

http://etymonline.com/index.php?term=err

Feyerabend, P. (1988). *Against Method.* London, UK, New York, NY: Verso.

Forde, P., & Wu, A. W. (2015). Professional and ethical responsibilities in

adverse events and medical errors: discussions when things go wrong. In

A. Surbone & M. Rowe (Eds.), Clinical Oncology and

error reduction (pp. 145-157). Hoboken, NJ: Wiley Blackwell.

Freeden, M. (1996). *Ideologies and Political Theory: A Conceptual Approach.*

Oxford, UK, New York, NY: Oxford University Press.

Freedman, D. H. (2010), Oct. 22). Lies, Damned Lies, and Medical Science. *The

Atlantic*. Retrieved from

http://www.sott.net/article/216757-Lies-and-Medical-Science

Gawande, A. (2002). *Complications: A surgeon's notes on an imperfect science.*

New York, NY: Picador. Henry Holt and Company.

Gawande, A. (2015). *Being Mortal. Illness, Medicine and What Matters in the End.*

New York, NY & London, UK: Metropolitan Books and Wellcome

Collection.

Gorovitz, S. & MacIntyre, A. (1975). Toward a theory of medical fallibility.

Hastings Center Report, 5 (3), 13-23. Retrieved from doi: 10.2307/3560992

Gostin, L. (2015, May 27). JAMA Forum: Critical Choices for the WHO After the

Ebola Epidemic. *News @ JAMA.* Retrieved from

https://newsatjama.jama.com/2015/05/27/jama-forum-critical-choices-for-the-

who-after-the-ebola-epidemic/

Groopman, J. (2008). *How doctors think*. Boston, MA, New York, NY: A Mariner

Book, Houghton Mifflin Company.

Halpern, J. (2001) *From Detached Concern to Empathy. Humanizing Medical*

Practice. New York, NY: Oxford University Press.

Hochschild, J., Crabill, A., & Sen, Maya. (2012, Dec.,) Technology Optimism or

Pessimism: How Trust in Science Shapes Attitudes toward Genomic Science.

Executive Summary. *Issues in Technology Innovation at Brookings* 21.

Retrieved from:

http://www.brookings.edu/~/media/Research/Files/Papers/2012/12/genomic-

science/genomic-science.pdf?la=en

Irwin, K. (2015). Impact of Shared Decision-Making on Doctor/Patient Relationship

I*ndustryView*. Retrieved from

http://www.softwareadvice.com/medical/industryview/sdm-report-2015/

Kathlyn Irwin.

James, J. T. (2013). A new, evidence-based estimate of patient harms associated with

hospital care. *Journal of Patient Safety, 9 (3),* 122 – 128.

doi: 10.1097/PTS.0b013e3182948a69

JD Eveland. (2016, April 6) J. D. Politico-technical systems. [Blog]. Retrieved from

h[ttps://medium.com/socio-techtonic-change/politico-technical-systems-](https://medium.com/socio-techtonic-change/politico-technical-systems-)

[8](https://medium.com/socio-techtonic-change/politico-technical-systems-8)ffa91465824#.5m3z9brd7

Kennedy, D., & Overholzer, G. (Eds.). (2010). *Science and the Media.* American

Academy of Arts & Sciences. PDF document. Retrieved from

http://www.amacad.org/pdfs/scienceMedia.pdf

Leape, (2001). Crossing the Quality Chasm. A New Health System for the 21st

Century. Executive Summary. *National Academies.* PDF. Retrieved from

http://www.nationalacademies.org/hmd/Reports/2001/Crossing-the-Quality-

Chasm-A-New-Health-System-for-the-21st-Century.aspx

Levinson, D. R. (January 2012). Department of Health and Human Services,

Inspector General. *Hospital incident reporting systems do not capture most

patient harm.* Retrieved from:

Lin, W. K., & Gostin, L. O. (2016, Jan. 18). Evidence-Based vs. Politically Mandated

Care. *JAMA.* 315 (10), pp. 977-978. Retrieved from doi:

10.1001/jama.2016.0322

Lown, B. (1999). *The Lost Art of Healing.* New York, NY: Ballentine Books.

Manheimer, E. (2015). Prevention of errors and patient safety: institutional

perspectives. In A. Surbone & M. Rowe (Eds.), Clinical Oncology and

error reduction (pp. 127-144). Hoboken, NJ: Wiley Blackwell.

Martuzzi, M. & Tickner, J. A. (Eds.). (2004). The precautionary principle: protecting

public health, the environment and the future of our children. World Health

Organization. (PDF Document). Retrieved from

http://www.euro.who.int/__data/assets/pdf_file/0003/91173/E83079.pdf

http://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf

McCann, E. (2014, July 18). Deaths by medical mistakes hit records. The way IT is

Designed remains part of the problem. *Healthcare IT News.* Retrieved from

http://www.healthcareitnews.com/news/deaths-by-medical-mistakes-hit-
records

McKinnon, M. C., Cheng, S., Garside, R., Masuda, Y. J., & Miller, D. C. (2015).

Sustainability: Map the evidence. Comment. *Nature,* 528 (7581). Retrieved

from http://www.nature.com/news/sustainability-map-the-evidence-1.18962

McMains, V. (2016, May 5). Johns Hopkins study suggests medical errors are

Third-leading cause of death in U.S. Physicians advocate for changes in how

deaths are reported. *HUB.* [Web log]. Retrieved from

http://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death

Morton, T. (2010). *The Ecological Thought*. Cambridge, MA & London,

England: Harvard University Press.

Mercola, J. (2014, June 11) . 1 in 5 Elderly U.S. Patients Injured by Medical Care.

Mercola.com [Weblog]. Retrieved from

http://articles.mercola.com/sites/articles/archive/2014/06/11/medical-care-

injuries.aspx

Munson, Ronald. (2012). *Intervention and Reflection. Basic Issues in Bioethics*.

Boston, MA: Wadsworth.

Nuland, S. B. (2008). *The uncertain art: Thoughts on a life in medicine.* New York,

NY: Random House.

Ofri, D. (2013). *What Doctors Feel. How Emotions Affect the Practice of Medicine.*

Boston, MA: Beacon Press.

Prasad, V., Vandross, A., Toomey, C., Cheung, M., Rho, J., Quinn, S., Chacko, S. J.,

… Cifu, A. (2013). A Decade of Reversal: An analysis of 146 contradicted

medical practices. *Mayo Clinic Proceedings* 88 *(8), 790-798*. Retrieved from

http://dx.doi.org/10.1016/j.mayocp.2013.05.012

Ravitz, A.D., Sapirstein, A., Pham, J. C. & Doyle, P. A. (2013) Systems Approach

and Systems Engineering Applied to Health Care: Improving Patient Safety

and Healthcare Delivery. Johns Hopkins Applied Technical Digest 31 (4), pp.

354-365. Retrieved from http://techdigest.jhuapl.edu/TD/td3104/31_04-

Ravitz.pdf

Reid, P.P., Compton, W. D., Grossman, J. H., & Fanjiang, G. (2005). *Building a

Better Delivery System: A New Engineering/Health Care Partnership.*

National Academy of Engineering (US) and Institute of Medicine (US)

Committee on Engineering and the Health Care System. Washington, DC:

National Academies Press.

Ricci, P.F., Cox, L. A., & MacDonald, T. R. (2006). Science-policy in environmental

and health risk assessment: if we cannot do without, can we do better? *Human*

& Experimental Toxicology, 25 (1), pp. 29-43. Retrieved from

doi:10.1191/0960327106ht582oa

Ricci-Cabello, I., Gonçalves D. C., Rojas-García, A. & Valderas, J. M. (2015).

Measuring experiences and outcomes of patient safety in primary care: a

systematic review of available instruments. *Family Practice*. 32, pp. 106-119.

Retrieved from https://psnet.ahrq.gov/resources/resource/28327

Rosner F., Berger J. T, Kark P., Potash, J., Bennett, A. J. for the Committee on

Bioethical Issues of the Medical Society of the State of New York. (2000).

Disclosure and prevention of medical errors. *Arch Intern Med*; 160 (14), 2089-

2092. doi:10.1001/archinte.160.14.2089

Root-Bernstein, R. (2003). Problem Generation and Innovation. *International*

Handbook on Innovation. Atlanta, GA: Elsevier Science Ltd., pp. 170-179.

Retrieved from http://nepistemology.com/sites/default/files/root-bernstein.pdf

Rubin, S. B., & Zoloth, L. (Eds.). (2000). *Margin of Error. The Ethics of Mistake in*

the Practice of Medicine. Hagerstown, MD: University Publishing Group.

Ruggieri, P.A. (2012). *Confessions of a Surgeon. The good, the bad, and the*

Complicated… Life behind the O. R. doors. New York, NY: Berkeley Books.

Runciman, B., Merry, A. II. & Walton, M. III. (2007). *Safety and ethics in*

healthcare: a guide to getting it right. Hampshire, UK, Burlington, VT:

Ashgate Publishing Company.

Shane, D. (2007). Frankenstein, Bioethics, and Technological Irreversability. In

Schreier, B. (Ed.), *Studies in Irreversibility. Texts and Contexts.* (pp. 134-

166). Newcastle, UK: Cambridge Scholars Publishing.

Sharpe, V. A., & Faden, A. I. (1998). *Medical Harm: Historical, Conceptual, and

Ethical Dimensions of Iatrogenic Illness*. Cambridge, UK, New York, NY:

Cambridge University Press.

Sharpe, V. (2003). Ethical Values and Issues at Stake in Proposed Patient Safety

Reforms. *The Hastings Center,* pp. 3-19. Retrieved from

http://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/

patient_safety.pdf

Sharpe, V. A. (2015). Mistakes, Medical. *Encyclopedia of Global Bioethics.* Springer

Science+Business Media Dordrecht, 1-8.

doi: 10.1007/978-3-319-05544-2_296-1.

Stolzer, A. J., & Goglia, J. J. (2015). Safety Management Systems in Aviation.

Burlington, VT: Ashgate Publishing.

Surbone, A., & Rowe, M. (Eds.). (2015). *Clinical oncology and error reduction.*

Chichester, UK, Hoboken, NJ: Wiley Blackwell.

Tickner, J.A., & Martuzzi, M. (Eds.). (2004). The precautionary principle protecting

public health, the environment and the future of our children. *World Health*

Organization. Retrieved from

http://www.euro.who.int/__data/assets/pdf_file/0003/91173/E83079.pdf

Torrey, T. (2016, Apr. 6). Serious Reportable and Adverse Events in Patient Safety.

Hospital Safety Means Reducing Medical Errors. *Very Well.* [Web log].

Retrieved from https://www.verywell.com/serious-reportable-adverse-or-

never-events-2615072

Trust in science and technology: Science and Technology: Public Attitudes and Public

Understanding. *Science And Engineering Indicators.* (2002). Retrieved from

http://www.nsf.gov/statistics/seind02/c7/c7s2.htm

Valdesolo, P. (2014, Sept. 23). Trust in Science Reduces Concerns about Climate

Change. Surprising psychology poses an obstacle on thoughts about global

warming. *Scientific American.* Retrieved from

http://www.scientificamerican.com/article/trust-in-science-reduces-concerns-

about-climate-change/

Weirich, P. (2015) *Models of Decision-Making: Simplifying Choice.* Cambridge, UK:

Cambridge University Press.

Wellberry, C. (2009, Aug. 31). Is Medical Uncertainty Necessary? Commentary.

[Weblog].Retrieved from http://medhum.med.nyu.edu/blog/?p=199

Wellberry, C. (2010, May 15). A Case of Medical Uncertainty. Curbside

Consultation. *The Lancet.* 375. Retrieved from

**http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(10)60719-
2.pdf**

Witte, M. H. (1995). *Medical Ignorance, Failure, and Chaos: Shifting Paradigms for*

the 21ˢᵗ Century. Retrieved from

http://kathydettwyler.weebly.com/terrains-of-ignorance----a-lecture-by-dr-

marlys-witte-1995.html

Wu, A.W., Levinson, W., Iedema, R., McDonald, T. B., Bismark, M. M., Kraman, S.

S., & Gallagher, T. H. (2014). Disclosing Adverse Events to Patients:

International Norms and trends. *Journal of Patient Safety,* 10 (3), pp. 121-124.

Retrieved from

http://journals.lww.com/journalpatientsafety/pages/viewallmostpopulararticles

.aspx

Yeo, G. (2009). How Will the U.S. Healthcare System Meet the Challenge of the

Ethnogeriatric Imperative? *Journal of the American Geriatrics Society.* 57 (7),

pp. 1278-85. Retrieved from DOI: 10.1111/j.1532-5415.2009.02319.x