Medical Error and Harm

Understanding, Prevention, and Control



Milos Jenicek



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This book is not dedicated to all those who (think they) do not make errors; it is dedicated to the rest of us.

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Author's Very Short Introduction: Minimizing Errors in Medicine

Thoughts to Think About

Cusjuvis hominis est errare, nullius nis insipientis in errore perseverare [To err is human, but to persevere in error is only the act of a fool].

-Marcus Tullius Cicero, 106-43 BC

Errare humanum est [To err is human].

—(Probably) Plutarch, 46–120 AD (Morals, cca 100 AD)

To err is human; to forgive, divine.

-Alexander Pope in 1711, 1688-1744

To err is human; to forgive is not company policy.

—Sign on a company bulletin board in Grand Rapids (undated)

It is human to err; and the only final and deadly error, among all errors, is denying that we have ever erred.

—G. K. Chesterton, 1874–1936

To err is human—but it feels divine.

—Mae West, 1893–1980 (attributed)

To err is human, but to really foul things up requires a computer.

—Farmer's Almanac, 1978

To err is human, but when the eraser wears out ahead of the pencil, you're overdoing it.

—J. Jenkins, 1843-1911

To err is human, to forgive is divine. While this may apply in general, forgiving, forgetting or ignoring errors in medicine isn't acceptable, since consequences could be disastrous.

Errors in everyday life lead to traffic accidents and their victims. Errors in industry injure workers and harm communities. Both situations are fertile grounds for errors that health professionals can make when caring for patients. Errors in medicine, then, are evidence that something has gone wrong in patient and community healthcare and that something has caused harm and should be prevented and corrected. This book is about such evidence and what physicians can and should do about it.

Examples of medical errors abound, such as unjustified exploratory and diagnostic procedures; foreseeable but unanticipated adverse effects of medical interventions or drugs; undesirable or incorrect surgical decisions and their outcomes; treatment unsupported by evidence of its effectiveness, efficiency, and efficacy.

All types of errors and their consequences, whether medical or otherwise, have multiple implications, such as their correction and prevention, legal pursuits, quests for repair and compensation, finding and implementing improvements, or evaluations of these initiatives and activities. Economic, social, physical, and mental health consequences are important for those committing errors and their victims. Modern life does not always simplify or eliminate error problems and challenges. It may, in fact, make them more frequent and sophisticated and more challenging to control.

At the social level, medical errors are matters taken to courts as topics of various litigations that should lead to corrections requested by plaintiffs and made by health professionals, their institutions, and working environments for the material and other compensation of victims by their perceived perpetrators.

Any medical error is a product of various "external" circumstances, including the environment, working conditions, and pressures; rapidly evolving technology; and managerial, administrative, or system functioning. These external factors only contribute to the essence (the internal factors) behind the medical error, namely, the physician's own faulty reasoning, logic, critical thinking, and decision making. "Internal factors" are about what happens "in our cranium,"

"in the craniums" of those with whom we are working, and "in the craniums" of those who created the working environment and tools of the healthcare situation at hand. They include our physiological and pathological attributes, attitudes, motor and sensory skills, as well as our responses to external factors. External factors are about what happens "outside the cranium."

Dealing with medical error is a learned experience like anything else. Is harm also caused by not teaching, learning, and understanding medical errors as faults in critical thinking? Understanding, preventing, and correcting such faults are the primary responsibility of every health professional.

Our message reflects the following essential theses:

- Medical error and harm, however interconnected, are not identical either on a theoretical level or on a practical level.
- The methodology of the study and management of medical error and harm is split between unique cases and multiple cases and events.
- Human (individual) and system error, however interconnected, are not identical; their understanding and control are methodologically complementary and more useful if handled separately.
- Uses of evidence regarding medical error and harm in dealing with them by way of argumentation, critical thinking, and informal logic is as important as producing the best evidence itself; both are necessarily interconnected.
- Medical error and harm are mass phenomena like disease and health; therefore, they must also be studied and controlled by epidemiological methods.
- However uneasy it may make some humanists, clinical care of individual patients and series of patients, health protection, and health promotion at both the individual and community levels also means "manufacturing health" (within the framework of stringent ethics and laws); medicine benefits from and must use experience with error and harm from "outside" sources such as industry, new technology development, transportation, business, economics, administration and management, finances, in addition to psychology, ergonomics, kinesiology, sociology, and biostatistics to humanely and effectively "produce" the best possible health of individuals and groups of individuals.

In this spirit, the book presents these elements, although not necessarily in the exact order indicated:

■ A short history, concepts, methodologies of study and management, applications, and other experiences with error in general, across various domains of human activity, initiative, and endeavor.

- A semantic (definitions) and taxonomic (classification) overview and challenges in the medical error and harm domains.
- A methodology and experience overview in medicine and other health sciences.
- How studies, understanding, and decisions regarding errors should be carried out at various stages of clinical practice such as risk assessment in the patient, diagnosis, treatment, or prognosis.
- How to understand and deal with errors in the broader framework of medical care.
- How to understand and deal with errors in community medicine and public health.
- A discussion on whether dealing with errors is a learned experience and on why, where, and how we should implement and practice this kind of learning.
- The most important strategies and what we should do in the future pertaining to error in medicine.

A short executive summary in each chapter, expanding the customary conclusions of most current written messages in medicine, takes into account existing recommendations from business writing¹⁻³ and introduces each chapter, allowing the reader not only to better understand the message as a whole but also to decide if the chapter is applicable given his or her knowledge and experience. Conclusions in most of the chapters complete the executive summary and outline the following chapter. To make the message even more reader friendly, nominal and qualitatively assembled sets of items are bulleted where important.

This book is about errors in medicine such as those arising from various causes due to faulty information, thinking, reasoning, and communication leading to potentially serious mistakes in our understanding, decision making, and management of health problems. In fact, errors in reasoning, communication, and decision making underlie most of the other aforementioned reasons. Correct reasoning is, however, only one of many ways to avoid errors in what we do. Comments on harm that errors in reasoning and decision making often produce follow.

We also examine here the underlying problems of cognition of and critical thinking about health problems as a "person approach." Equally important is the "system approach," relevant in particular for surgical specialties and emergency medicine.

In human pathology, we learn about common underlying mechanisms and then individually about important health disorders and diseases and how to treat each one. Similarly, in dealing with errors attributed to critical thinking in medicine, we learn about paradigms, elements, and rules of critical thinking itself, and then we familiarize ourselves with their "pathology" (i.e., critical thinking disorders, flaws, and fallacies as diseases of reasoning) that ultimately produce medical error and its consequences. How can we understand, prevent, minimize, and otherwise control them?

Some first-time readers may ask where they should start and what they should read before tackling the human error problem to better understand the philosophy, objectives, and content of this book. Some notions and topics are repeated in various forms from one chapter to another. These repetitions are intentional to help experienced readers (who may choose to read selectively just one particular chapter) avoid a more laborious search for particular information elsewhere in the text. What might be the most useful for the overall domain?

We currently benefit from many first steps and initiatives in the development of methodologies, applications, and strategies and in the implementation and evaluation of the general and medical error and harm domain as seen in contributions from prominent and highly competent authors from around the world including in the United States, United Kingdom, Denmark, Italy, Australia, and Canada. It is now easier to move forward in this area.

The following "essential" references are only a few turning points and a partial list of background and complementary readings that have inspired this book. Read in chronological order, they appropriately reflect how our understanding of medical error is developing and maturing over time:

For human error in general: Jastrow,⁴ Reason,⁵ Cacciabue,⁶ and Peters and Peters⁷ with their numerous contributors summarize the human error problem over the past three generations.

For error in medicine: In general medicine, Fagerhaugh et al.,⁸ Bogner et al.,⁹ Kohn et al.,¹⁰ and Vincent et al.,¹¹ have defined the error problem in the research and practice of medicine. In medical specialties, emergency medicine benefits the most so far from Croskerry et al.'s¹² coverage of patient safety and its determinants. In a similar spirit, Sharpe and Faden¹³ offer a historical review of the transition from our vision and understanding of iatrogenesis and iatrogenic illness to our present grasp of the medical error and harm problem. Their monograph also illustrates well the still often confusing concepts and dimensions of error, harm, and iatrogenesis. It also suggests that the main problems lie in the fields of surgery, clinical pharmacology, hospital (nosocomial), and other infections and perhaps mental care.

For the review of strategies to manage error: *Medical Error*, edited by Rosenthal and Sutcliffe, ¹⁴ provides a 2002 update of the medical error situation as seen through past experience, by patients, healthcare providers (including evidence-based medicine), and system or human paradigms

of medical error and harm. Its list of medical error and harm-related Web sites to know and use is also helpful. In addition, *Medical Mishaps*¹⁵ compares **medical error experience in various parts of the world**.

For logic, epidemiology, and critical thinking-related methodological in medicine and health sciences: To set the medical error problem in the even broader context and longer tradition of more general principles, techniques, and methods, it is worthwhile to consult the current edition of the *Dictionary of Epidemiology*. ¹⁶ See Jenicek's *Foundations of* Evidence-Based Medicine¹⁷ for general epidemiological topics, and Jenicek and Hitchcock's¹⁸ Evidence-Based Practice: Logic and Critical Thinking in Medicine for fundamentals of modern logic and critical thinking in medicine. Or see some of Jenicek's other references for additional teaching and learning tools and handling of fallacies in medicine and as introductory readings to modern logic and critical thinking in our understanding and decision making in medical care. 19,20 They may prove useful as complementary reading. Thus, we are answering here the call for fundamental and clinical epidemiology and evidence-based medicine to complete and expand basic contributions of psychology, operational research, or computer sciences in the general human and medical error domains. Realizing that not all readers will be familiar with epidemiology, we have inserted some reminders of its principles and tools within related messages.

The domain of error in medicine and other health sciences is still in a state of flux, subject to multiple paradigms and not always convergent semantics, definitions, terminology, taxonomy, research methodologies, descriptions, search for causes, interventions, and their evaluations. It is not only relatively recent but also stems from many crucial and valuable contributions well beyond the health sciences, such as psychology, philosophy (logic/argumentation and critical thinking), ergonomics, operational research, health administration and evaluation, engineering, and computer sciences. These contributions cannot be omitted just for the sake of promoting the "purity" of medicine, but should be organically integrated as part of our "mainstream understanding" of the medical error challenge. Let us reflect on this diversity in the text with references to our preferred perspectives, as summarized again in the glossary at the end. This book stands side by side with longer-rooted concepts, terms, and approaches in clinical and fundamental epidemiology (risk, hazard, others), clinical pharmacology (adverse effects), and elsewhere across the entire medical field (e.g., outcome research, evidence-based strategies, knowledge translation).

An introductory example of iatrogenesis, error, and harm can illustrate this point. **Iatrogenesis** and **iatrogenic artefact** mean "adverse effects or

complications caused by or resulting from medical treatment or advice" by any health professional in mainstream, alternative, or complementary medicines, ²¹ clinical and community care, and public physical, mental, or social health. Those effects are also termed iatrogenic illness (personal or individual perception: "I feel that I have a problem with my health"), iatrogenic disease (objective dimension: "Yes, this is a medical problem"), or sickness (perception by others: "He or she does not look well; he or she looks sick!"),^{22,23} resulting from medical care. In this situation many questions arise immediately, namely:

- Is everything related to healthcare viewed as "iatrogenic?"
- Is everything avoidable, or is something inherent to what we are doing with patients (e.g., adverse effects of chemotherapy for cancer)?
- What exactly does "harm" mean?
- Do any erroneous understanding and action lead to harm?
- Are "error" and "harm" interchangeable notions? Are they different but complementary, yielding together even more powerful information for improvement in patient and community care?
- What does all this mean for our consideration of prevention, control, understanding, or other desire to do something useful to achieve the ideal of a most effective and harmless care?

Implications are important: economically, politically, legally, and professionally. For example, concerns about error and harm lead to the disproportionate practice of "defensive medicine" (nothing must be omitted), overmedication, overcare, number and extent of surgeries, their cost, legal implications, and social burdens. In many such instances, we and our patients expect less.

The chapters that follow will cover some additional elements and points to ponder in our quest to develop, advance, and practice the best medicine possible.

Our ultimate goal is to provide the highest level of quality of care and patient safety. Within this context, there are two crucial virtues and qualities to understand and adopt:

- 1. If we consider today **quality of care** as a level of performance and achievement assessed both by subjective value judgments and by more objective views of its structure, process, or impact, ¹⁴ then minimizing medical error and its impact is one of the cornerstones of quality-of-care assurance and management.
- 2. We currently view **patient safety** as the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of the best practices, shown to lead to optimal patient outcomes.¹²

Freedom from medical error, its prevention, and control of medical error itself and its consequences are at the core of patient safety concepts and strategies to deal with them. Effective prevention, care, and cures benefit both their recipients and their providers in competent and compassionate environments, both inside and outside hospitals and medical offices.

Before we examine this more closely, we want to acknowledge the assistance of key contributors to this project. The author remains grateful to several colleagues, friends, and experts whose invaluable insights helped make this book possible:

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Chapter 1

Putting Medical Error in Context: Minimizing Errors in Medicine—Beyond the "Oops!" Factor

Executive Summary

Making errors, understanding their causes and occurrences, and preventing them will always be an integral part of medicine, however regrettable this may be. In fact, error consequences may be disastrous for patients, healthcare workers, and entire communities. This chapter provides physicians and other healthcare providers with ways to address the medical error problem by offering a range of concepts, methods, techniques, and strategies grouped under the term *lathology*.

The medical error domain has many stakeholders including patients, physicians, other health professionals, legal specialists involved in litigation, health economists, sociologists, psychologists, ergonomists, and social workers. Patient safety as a whole may be considered synonymous with the absence of medical and other healthcare error in the practice and research not only of medicine but also of any health-related domain.

Current dealings with error in manufacturing, in new technology development and its uses, and in transportation benefit from major contributions and developments brought about by many specialists working mainly in nonmedical fields. Health professionals are currently adding a new dimension to the increasingly integrated world of medical lathology.

Medical errors not only occur sporadically but may also be epidemic, endemic, and even pandemic in nature. Logically, clinical and field epidemiology are gradually focusing more on the search for medical error causes, investigation of their occurrence, and effectiveness of corrective programs and interventions. Their involvement in lathology is growing, as are the modern critical thinking argumentation and informal logic underlying medical reasoning, decision making, and epidemiological contributions to them.

A wide array of medical error causes such as inadequate training; failures of traditional and new medical technologies in their development and uses; physiological, psychological, and environmental influences; data and information management; execution deficiencies; health system functioning failures; communication breakdowns; rule-based errors; and errors in reasoning and decision making will be examined to varying degrees in subsequent chapters.

The notion of medical error is separate from medical harm. Medical error does not always lead to harm. Having said this, medical error and medical harm have specific causes that are sometimes synonymous and sometimes different. The study of both is crucial to improve patient safety.

Thoughts to Think About

Medical statesmanship cannot thrive only on scientific knowledge, because exact science cannot encompass human factors involved in health and disease. Knowledge and power may arise from dreams as well as from facts and logic.

—René J. Dubos, Mirage of Health (ch 6), 1959

Most men die of their remedies, not of their diseases.

-- Molière, 1622-1673

Mistake, error, is the discipline through which we advance.

-William Ellery Channing, 1830 (1780-1842)

In medicine, there are many Popes, but none faultless.

-Karl H. Bauer, 1890-1978

If you shut the door to all errors, Truth will be shut out.

—Rabindranath Tagore, 1928

We have our faults and our virtues; we meet with failures and achieve success. many of our faults are entirely unavoidable, and arise from the fact that medicine is not an exact science ... some things are quite impossible, and our work is carried out upon a jar, a chemical mixture in a retort, or a wooden Indian from the front of a cigar store.

—J. Chalmers Da Costa, 1863–1933

Every hospital should have a plaque in the physicians' and students' entrances: "there are some patients who we cannot help; there are none who we cannot harm."

-Arthur L. Bloomfield, 1888-1962

The pilot is by circumstances allowed only one serious mistake, while the surgeon may commit many and not even recognize his own errors as such.

—John S. Lockwood, 1907–1950

Don't make the wrong mistakes!

—Lawrence ("Yogi") Berra (1925–)

Not making errors in the practice of medicine is an essential attribute of patient safety, quality of clinical care, and community well-being. In health research, it is not only a prerequisite for academic and institutional (organization) promotion and honor, but it also carries the risk that erroneous research results will be perpetuated and magnified by the decisions of even the best-intended users, ending up eventually at courts of law. Errors in practice and research in medicine cannot be completely eliminated and avoided. Understanding their nature and nurture helps minimize them as much as possible. Despite the harm they cause, they are important lessons on how to improve what we know and do.

Introductory Comments: Errors as Part of Advances in Medicine

Medicine in clinical and community domains advances in many ways, including the following:

- Spectacular results in fundamental areas like stem cell research, medical genetics, or molecular explorations.
- Production, evaluation, and uses of the best evidence in basic and clinical pharmacology, surgical disciplines, and other clinical care covering all age groups.
- Continuous improvement of research, reasoning, critical thinking, and decision-making methodologies in all domains.
- Ever improving and refocusing medical education.
- Expanding structure, process, and impact of medical care evaluation including knowledge translation.
- Development of new technologies including their ethical context.
- Better focus, attention, and actions to understand, prevent, and control human and system errors in clinical care, community medicine, and public health within all the aforementioned domains as well as in the expanding experience resulting from their correction.

We often forget that learning from our own errors and correcting them is an extremely powerful educational and learning tool (if done right) and that our patients benefit immensely from otherwise unfortunate errors committed in the past. This is perhaps the greatest advantage of increasing the attention we give to the medical error domain.

Errors in medicine, so dreaded both by physicians and their patients, are undoubtedly more than warning evidence that something is wrong, causes harm, and should be prevented and corrected. This book is about such evidence and what physicians can and should do about it.

How to View Medical Errors Today

Medical errors happen in like risk assessment, diagnosis, treatment, prognosis, and related decisions. They occur also, sometimes endemically, in research and the practice of clinical, family, and community medicine or public health. Sometimes rare or not, expected or not, explained or not, they are an important part of the general error problem across various human endeavors. While most of the effort in medicine is focused on good evidence of beneficial actions and their results, uses,

and effects, it should be noted that "bad" events such as medical errors, good evidence about them, as well as their control require equal attention, understanding, control, and prevention. The opposite would be contrary to medical ethics.

Medical errors also play an infrequently mentioned double role from the point of view of cause—effect relationships. On one hand, medical errors are caused by something. Methodologically speaking, they are dependent variables, consequences of something. We need to know their causes, to prevent and correct them. On the other hand, medical errors cause harm such as death or injury; errors here are the causes of harm and serve as independent variables in the association with their consequences. Harm itself may lead to a cascade of other consequences. Both cases and directions are relevant in our quest to provide quality care.

Medical errors belong to a larger family of errors across various domains such as errors in the development and use of new technologies, ergonomics, administration, management, politics, and economics. Experience in all these fields, acquired over the past three generations, is already partially applied in medicine. However, the specifics of medicine require additional attention to human and other factors affecting both care providers and their patients or health communities in the setting and context of their practice. Errors occur not only in fundamental, clinical, and community health research and evaluation but also in directly disturbing situations in daily practice and care. They also take place in knowledge translation (i.e., on the way from evidence producers to evidence users) and in beneficial or noxious consequences of evidence uses or nonuses.

Any medical error is then a product of various circumstances including the environment; working conditions and pressures; rapidly evolving technology, managerial, administrative, or system functioning; and other "external" factors. These external factors contribute only to the essence (i.e., the "internal factors") behind the medical error, namely, the physician's own faulty reasoning, logic, critical thinking, decision making, and his or her sensory-motor performance. This book mainly focuses on external factors where experience is still not as rich as it is for error in general. It also highlights internal factor circumstances where faulty reasoning and decisions occur. An interface between the former and the latter is the reality of our day-to-day life.

In human pathology, we learn about common underlying mechanisms and then about each individual important health disorder and disease and how to treat them. Similarly, in dealing with errors attributed to critical thinking in medicine, we learn about paradigms, elements, and rules of critical thinking itself, and then we familiarize ourselves with their "pathology" (i.e., their own disorders, flaws, and fallacies) as "diseases of reasoning" that ultimately lead to and produce medical error and its consequences. Without such learning and experience, how can we prevent and otherwise minimize medical errors?

Dealing with medical error is a learnt experience like anything else. Is harm also caused by not teaching, learning, and understanding medical errors as faults in critical thinking?

What Is Covered in This Book

As already mentioned in our short introduction to this book and the study of human error in general, we intend to expand this experience into the health sciences, clinical practice, and research and community medicine. Various steps of the medical cognitive process, argumentation, and decision making common to almost all activities will then be applied to all stages of clinical work such as assessing risk in the patient, making diagnosis, prescribing a treatment plan, making prognosis, and evaluating what was achieved and what was not or went wrong in this ever repetitive process. We will also review possible preventive measures against error and ways to control the error problem. Because errors in reasoning, communication, and decision making may occur—and they really do—in any of the aforementioned steps and activities, they are more than worthy of discussion in the chapters that follow.

Understanding and doing something about medical error also requires some basic knowledge of "shoe-leather-," research-, and clinical epidemiologies, modern informal logic, and critical thinking as outlined in some other writings. Readers are encouraged to search for any additional information beyond this book that they might need.

Just as our previous book was about fallacy-free reasoning in medicine,¹ this book is about errors and harm in medicine such as those arising for various reasons and causes from faulty information, thinking, reasoning, and communication in conjunction with other related error causes leading to potentially serious mistakes in our understanding, decision making, and management of health problems.

Considering the Medical Error Problem in Light of Recent Experience

From our recent discussion of the error problem in the fallacy domain of medicine,¹ let us now attempt to link the error problem to flawless reasoning and decision making.

Medical errors occurred too often in the past, occur today, and will unfortunately occur in the future. We must learn to live with them and do the best we can given the evolving circumstances of medical practice and research.

Several major medical periodicals²⁻⁵ stress the urgency and magnitude of the problem in medicine²⁻⁸ and surgery as well.⁹⁻¹² Some leading newspapers and magazines¹³⁻¹⁶ and monographs¹⁷ try to explain the challenge (especially diagnosis)¹⁷ to a more general readership. The *American Iatrogenic Association*¹⁸⁻²⁰ as well as the *Level1Diet* initiative (709 references on care error so far)²¹ offer a selection of major reports and articles dealing with the problem of medical errors. The University of Toronto's *Medicalerror* Web site,²² and its numerous quality improvement links and lists, extends and updates reference readings. Leading national and international institutions initiate and further develop directions and strategies to handle the problem of errors in medicine and surgery.²³⁻²⁷ The entire "medical error prevention and control" movement is gaining clearer objectives and focus and is becoming better structured and organized.

In a broader perspective of errors in medicine, we face the general problem of medical errors as the difference between actual behavior or measurement and the norms of expectations for the behavior or measurement.²⁸ More specifically for medicine, we face the problem of failures in planned action to be completed as indicated (error of execution) or use of an incorrect plan to achieve an aim (error of planning); the accumulation of errors results in accidents.²³ An error may then be an act of commission or an act of omission.²⁹ For example, in surgery, an error is more than tying a bad knot, a poorly executed suture. Many medical errors are, in a broader sense, clinical errors that can be made by other health professionals or when working together.

In more general terms, Bruce Bagley, past president of the American Association of Family Physicians, is perhaps correct in saying that "…a medical error is anything that happened in my office that shouldn't have happened and that I absolutely do not want to happen again."²⁴

Errors in medicine are imputable to several reasons:

- Inadequate training (knowledge, attitudes, skills).
- Failure of medical technologies ("the machine is poorly designed or broken").
- Inappropriate uses of medical technologies ("the tool is used where, when, and in whom it should not be").
- Physiological and psychological factors such as the physician's, other health professional's, or patient's condition and disposition like fatigue or stress.
- Data and information recording, processing, and retrieval caused by information technology and its uses (information technology inadequacy and failure).
- Deficient skills in execution (motion or sensory activities as based on past experience).
- Taxonomical errors due to causes of errors (classification of faulty activities due to poorly explained or used etiology).

- System (health services functioning) failures ("triage and subsequent emergency care does not work as it should").
- Communication errors and breakdowns.
- Rule-based errors (guidelines, user guides not followed).
- Errors in reasoning and decisions about health problems.

The chapters that follow are mainly about the last item in the list. In fact, errors in reasoning, communication, and decision making underlie most of all the other previously mentioned reasons. Fallacy-free reasoning is, however, just one of many ways to avoid errors in what we do.

Making a medical mistake is not necessarily malpractice with all its legal and financial consequences, but it may be so.³⁰ It may also cause (or not) some kind of harm. This book is about errors in reasoning and decisions in medicine beyond the malpractice problem.

Across the literature, medical errors are studied and evaluated in two ways that are not always clearly specified. One approach is to investigate causes of medical errors (i.e., errors are consequences or dependent variables). In the other approach, medical errors are linked as causes to harm (i.e., errors are causes or independent variables). Current taxonomies of medical errors do not always specify this possible double role of errors.

Medical errors are not limited to diagnosis or treatment decisions. They may occur at any stage of medical work: assessing the risk of disease, understanding its causes, and effectiveness of intervention to prevent or cure or otherwise control a health problem or its prognosis at an individual or community level.

Medical errors may also be studied through quantitative methods such as biostatistics or computer science, through methods adopted from other domains such as aviation,³¹ or through qualitative methods.³² With the recognized place of humanities in medicine,³³ the door opens to informal logic and critical thinking³⁴ (a natural companion to evidence-based medicine and clinical epidemiology³⁵) as guardians against medical errors.

In this book, one of many trying to contribute to the minimization of medical errors, we are strongly interested (compared with others) in the underlying problems of cognition of and critical thinking about health problems^{2,34,36,37} as a *person approach*. An equally important approach is the *system approach*, relevant in particular for surgical specialties and emergency medicine. Medical informatics and computer science not only contribute to a better understanding and management of medical errors through detection and surveillance systems or understanding of systems themselves³⁸; they also enrich the current taxonomy of medical errors.³⁹⁻⁴¹ Communication breakdowns and errors are in focus too.⁴² Interpretation and evaluation slips and mistakes, ambiguous information, or heuristic situations are categories used by informaticians^{40,41} reflecting, under

different names, errors in reasoning, argumentation, and decision making as outlined and illustrated in the chapters that follow.

Links between evidence-based medicine and critical thinking are being established, ^{34,35,43} and cognitive psychology is even being proposed as one more basic science for medicine. ⁴⁴

Medical Error and Patient Safety

Croskerry et al. 45 defined *patient safety* as "the reduction and mitigation of unsafe acts within the healthcare system, as well as through the use of best practices, shown to lead to optimal patient outcomes." The World Health Organization (WHO) Alliance for Patient Safety sees it as "freedom from unnecessary harm or potential harm associated with healthcare;" *harm* implies "impairment of structure or function of the body and/or any deleterious effect arising therefrom." 46

Hence, patient safety is compromised by harm. Harm itself is often due to error. Error in this context is a failure to carry out a planned action (elements in healthcare in our case) as intended or the application of an incorrect plan and may manifest itself by doing the wrong thing (an error of commission) or by failing to do the right thing (an error of omission), at either the planning or execution phase. Avoiding medical error is one of the cornerstones of patient safety.

National and international institutions, healthcare professionals, professional associations, governments, healthcare, and the legal system are paying, each in its own way and for its own purposes, bringing increasing attention to patient safety and consequently to medical errors.

Glossaries, taxonomies, original research, and data and information gathering through various surveillance and other systems are growing in numbers. The original methodology from the error problem in society and its components is being adapted and expanded for healthcare and all health professions involved.

Recognizing the need for teaching and learning to ensure patient safety in the aforementioned spirit and dimension, WHO now offers a patient safety curriculum for medical schools including some teaching summaries and audiovisual tools for the undergraduate level.⁴⁷

Besides the political and strategic support and direction of international bodies like the WHO World Alliance for Patient Safety or the Linnaeus-PC Collaboration, several national agencies were created to coordinate initiatives in the medical error and patient safety domains, to standardize and expand research methodology, and to offer harmonized strategies, including the Canadian Patient Safety Institute, the Institute for Safe Medication Practices Canada, the National Patient Safety Agency (UK), the U.S. Agency for Healthcare Research and Quality (AHRQ), the Joint Commission (formerly the Joint Commission on

Accreditation of Healthcare Organizations, JCAHO), the Institute of Medicine's Committee on Quality of Healthcare in America, and the U.S. Department of Veteran Affairs' National Center for Patient Safety.

Based on the history of the worldwide expansion of attention to medical error and patient safety, Hofoss and Delikas⁴⁸ propose directions for performing patient safety research:

- Specific investigation of adverse event cases.
- Delivery system reviews.
- Study of organizational culture.
- Patient safety culture.

In addition to such directions, let us add refinements in medical error study methodology an enhancement of its tools beyond the crucial contributions of psychology, operational research, information technology applications, uses, and advancement. Epidemiology and medical specialties themselves represent some still underused approaches in the core of the medical problem challenge.

We are entering a domain with its own specific identity that we may call **lathology**, the domain of study and control of medical error and harm. This will be discussed in greater detail in Chapter 2.

Subsequent chapters should then be, we hope, on the right track.

How This Book Might Contribute to the Present State of Human Error Experience and Patient Safety

The chapters that follow will not provide answers to all questions about how to make the best decisions in medicine and performing clinical and extraclinical acts well. However, they should at least support your own justifications for finding answers to your questions. It's all about making sense. Fallacy-free reasoning and decision making is as important for limiting the frequency and severity of medical errors as a safe, effective, and properly used new medical technology. The critical thinking approach is only one among many helping us understand and better solve the problem of medical errors. Nevertheless, it is important.

Errors result not only from an individual person's failures but also and more often from failures of systems, various elements of physical and human environments, and their interconnections. ^{49,50} Extensive research on this topic must still be done. ⁵¹

Both medical error and harm are entities that should be examined separately and connections between them should be sought. In an extreme view, patients do not care if some medical error was committed, but if some harm to their health does occur, they want to know if such harm is related to medical error and how it should be explained, corrected, prevented, and compensated.

In human pathology, we learn about common underlying mechanisms and then about each individual important health disorder and disease and how to treat them. Similarly, let us stress again that, in dealing with errors attributed to critical thinking in medicine, we learn about paradigms, elements, and rules of critical thinking itself, and then we familiarize ourselves with their own "pathology" (i.e., "critical thinking disorders, flaws, and fallacies as diseases of reasoning"). The long journey described and explained in the following pages is worth taking and perhaps necessary to reach our *primum non nocere* ideal.

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