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978-0-521-63490-8 - Medical Harm: Historical, Conceptual, and Ethical Dimensions of Iatrogenic Illness

Virginia A. Sharpe and Alan I. Faden

Excerpt

[More information](#)

Introduction

'Tis impossible to separate the chance of good from the risk of ill.

David Hume

The phrase 'medical harm' seems paradoxical. It defies our expectations about medicine; our expectations that medicine will benefit, rather than harm us and that individual and institutional providers will improve rather than diminish our health. But iatrogenic illness – literally, illness that is 'induced by the physician' – has come to be recognized as a significant source of patient risk. In the United States, it has been estimated that during hospitalization, as many as a third of patients suffer from complications related to their medical or nursing care.¹ Between 5% and 13% of hospital admissions result from the adverse effects of diagnosis or treatment.² The 1991 Harvard Medical Practice Study concluded that almost 70% of iatrogenic complications are preventable and affect more than 1.3 million hospitalized patients annually.³ During the fee for service era, patients were believed to be at considerable risk for *unnecessary* treatments.⁴ Today, there is growing concern regarding the risks associated with economically-motivated denials of *necessary* care.⁵

In the last half of the twentieth century, attention to the problem of medically induced illness in the United States has come from a number of sources including the medical and legal professions, federal agencies and consumer advocacy groups.

It was in the 1950s and 1960s, after the enormous post-war expansion in pharmacological therapies, that the occurrence of iatrogenic complications – particularly adverse drug reactions – began to receive attention in the medical literature. From the professional point of view at this time, iatrogenic adverse effects were regarded as the inevitable price of medical progress; 'the price we must pay for the modern management of disease,'⁶ and were

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Excerpt

[More information](#)

defined as the sequelae of *sound and sanctioned* medical practice. The earliest studies based on this narrow definition found that roughly one out of every 20 patients suffered from a major toxic reaction while receiving hospital care.⁷

Iatrogenic illness has been viewed quite differently from the perspective of medical malpractice law. In the 1950s the average number of claims per physician per year in the United States was 1 in 100. In the 1970s that number had grown ten-fold to 10 in 100. Since then, the total number of claims has roughly doubled.⁸ The story told in malpractice verdicts against providers is one not of the inevitable downsides of conscientious care but, rather, of the most egregious harms following from a violation of professional standards. From the point of view of tort law, it is the blameworthiness of negligent injury or illness that stands out as the most significant dimension of medical harm.

Since the late 1960s, iatrogenic illness has also been the focus of governmental agencies. The late 1960s and early 1970s saw the establishment of the Hospital Infections Branch of the Center for Disease Control (CDC)⁹ and the Task Force on Prescription Drugs under the US Department of Health Education and Welfare (HEW).¹⁰ The establishment of these two bodies was prompted by two disquieting episodes in the recent history of medical harms. The CDC investigation and surveillance of nosocomial infection (infection contracted in the hospital) was prompted by a pandemic of staphylococcal infections sweeping hospitals in the United States. Statistics at the time revealed that over half of the infected patients became infected after admission to the hospital.¹¹ Subsequent data demonstrated that in 1970 only about 10% of hospitals in the United States had any sort of infection control program.¹² By the 1980s, nosocomial infection was identified as the fifth leading cause of hospital death and infection control had become an integral part of hospital quality management.

The HEW Task Force on Prescription Drugs was, in part, a response to the thalidomide disaster in which infants exposed to the drug *in utero* were born with deformed or missing limbs. The thalidomide experience triggered the establishment of national and international post-marketing drug surveillance systems. In recent years, the Food and Drug Administration (FDA) in the United States has introduced the MEDWatch program to facilitate the reporting of serious adverse drug and device events by health providers and manufacturers.¹³ While these regulatory strategies have addressed the public health implications of drug-induced illness, governmental attention to another type of iatrogenic harm – unnecessary surgery – has had a slightly different focus.

Cambridge University Press

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Excerpt

[More information](#)*Introduction*

3

In 1967, a British study on surgical rate variation determined that surgeons in the United States performed twice as many operations per capita as their British counterparts.¹⁴ These data were followed in 1974 by a presurgical screening study of American union members. This study found that in almost one-quarter of cases, a second opinion failed to support a recommendation for surgery.¹⁵ On the basis of these data the US House of Representatives convened a subcommittee on unnecessary surgery. Extrapolating from the presurgical screening study data, the subcommittee, in 1974, concluded that 2.4 million or 17.6% of surgical interventions in the United States were unnecessary, resulting in costs of 3.9 billion dollars.¹⁶ With the prospect of fewer unnecessary surgeries and enormous anticipated savings, the Department of Health, Education, and Welfare and many private insurers and employers promptly instituted second opinion programs. Thus, in the case of unnecessary surgery, the focus has tended since the 1970s to be on the direct aggregate economic costs of the phenomenon rather than on its human costs in morbidity, mortality, pain, suffering, or loss of livelihood to individuals. In other words, unnecessary surgery has typically been understood in terms of unnecessary expenditures rather than in terms of iatrogenic harm.

It is the consumer advocacy literature that has emphasized the patient's perspective on iatrogenic harm. Reports of the dangers associated with drugs and devices, including thalidomide, the Dalkon Shield, Diethylstilbestrol (DES), coupled with a growing distrust of institutions and traditional forms of authority in the 1960s and 1970s gave rise to a host of books intended not only to galvanize health consumers but also to educate them about particular health care risks.¹⁷

One of the most influential books of this period was Ivan Illich's *Medical Nemesis*.¹⁸ In this and other works, Illich harshly criticized social institutions for augmenting the problems that they were originally intended to solve. In classical Greek mythology, Nemesis was divine retribution against mortal hubris that presumed the ability to acquire the attributes of the gods.¹⁹ For example, because of their attempt to transform their mortal natures, Prometheus and Sisyphus were condemned by Nemesis to a self-defeating existence of progress turned in on itself. Likewise, argues Illich, the medical industry and those of us who naïvely subject ourselves to its machinations have created a self-reinforcing iatrogenic loop where the supposed remedies have themselves become pathogenic. In its most general sense, Illich's term *iatrogenesis* meant the paradoxical counterproductivity in human societies that paralyzes autonomous action. *Clinical iatrogenesis*, the by-product of modern bureaucratized medicine, comprises 'all clinical conditions for

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Excerpt

[More information](#)

which remedies, physicians or hospitals are the pathogens,' or 'sickening agents.'²⁰ In the book, Illich enumerated the general and specific dangers of clinical care and the medicalization of life and death. Above all, he encouraged patients and people generally to become more independent and self-reliant in the task of health.

During this period of increased, and sometimes highly charged, attention to patient harms, the definition of iatrogenic illness in the medical literature became more inclusive of harms associated with contraindicated and substandard care as well as physician and nursing error. The subtitle of Moser's *Diseases of Medical Progress*²¹ reveals the transformation that was occurring in the professional literature during this period. In its first edition in 1959, the book's subtitle was *A Survey of Diseases and Syndromes Unintentionally Induced as a Result of Properly Indicated, Widely Accepted Therapeutic Procedures*. By its third edition, 10 years later, the subtitle reflects a broader and more circumspect view of the problem: *A Contemporary Analysis of Illness Produced by Drugs and other Therapeutic Procedures*.

Studies during the 1960s and 1970s also began to distinguish iatrogenic complications according to severity, including not only serious but also moderate and minor adverse effects in their definitions. One study, for example, defined an iatrogenic adverse effect as any 'complication resulting from reactions to medication or procedures, physical injury or accident, psychological decompensation, nosocomial infections, and medical or nursing errors – including errors of omission.'²² In this study, a 38% complication rate was reported in hospitalized patients, twice that reported in studies limited to adverse effects of *sound* medical care and eight times as high as studies that reported only 'major toxic events.'

In recent years, the preventability of iatrogenic adverse events has emerged as one of the most pressing questions in the study and improvement of health care quality. In the Harvard Medical Practice Study (HMPS) of acute care, nonpsychiatric hospitals in New York State, over 30,000 patients' charts were reviewed for the occurrence of iatrogenic adverse events.²³ Based on the study findings, it has been estimated that almost 4% of hospitalized patients each year suffer from a hospital-related injury and that more than two-thirds of these events are preventable.

Because adverse drug events (ADEs) constituted the largest percentage of iatrogenic complications in their study (19%), authors of the HMPS have recently done two further investigations of preventable ADEs in 4031 hospitalized medical and surgical adult patients.²⁴ Of the life-threatening and serious ADEs, 42% were judged to be the result of preventable error. What is striking about these most recent studies is their identification of

Cambridge University Press

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Virginia A. Sharpe and Alan I. Faden

Excerpt

[More information](#)*Introduction*

5

system failures as major factors contributing to preventable error. The most common systems failures were in drug knowledge dissemination, drug dose and identity checking, and patient information availability. The lesson of these studies of ADEs is that their occurrence is more directly related to defects or breakdowns in the complex processes that comprise tertiary care than to individual incompetence. This is also the lesson from recent studies on the prevention and control of nosocomial infection. Data from the multi-site Study on the Efficacy of Nosocomial Infection Control (SENIC)²⁵ has revealed that over 30% of the three million annual hospital infections in the United States are preventable through programs that emphasize active surveillance of processes in medical, surgical, and nursing care. The most successful prevention measures are not those that target individual providers but those that discern the complex relationships between the agent, source, and route of transmission, the environment, and the host of infection. With the implementation of organized surveillance and control activities, SENIC found that a hospital's infection rates could be reduced by one-third.

Recently reported events highlight the significance of system failures in the occurrence of iatrogenic harm. In the case of Betsy Lehman, a Boston woman, who died from an overdose of chemotherapeutic agents, the four-fold error in drug dosage went unnoticed by at least a dozen nurses, doctors, and pharmacists at Dana Farber Cancer Institute. This happened despite the fact that a similar error had resulted in a life-threatening complication for a different patient two days earlier.²⁶ Subsequent investigation of Dana Farber's quality assurance procedures revealed that in 5% of cases, one patient's records were found in another patient's file; nurses who administered high doses of chemotherapy to 27 patients did not have access to detailed instructions; and reports of medication errors were collected but not reviewed.

In the case of Willie King, a Florida man who had the wrong leg amputated, the misidentification of the patient's leg began with an entry error in the hospital's computer system, and was repeated on the operating room schedule and blackboard. When the surgeon entered the operating suite, the incorrect leg was already draped and sterilized.²⁷ It was not until the surgery was well underway that a surgical nurse realized the error.

In both cases, the patient's outcome was directly attributable to breakdowns in communication and in the processes of care.

Attention from all of these different quarters has raised awareness about the occurrence of iatrogenic illness. It also has raised fundamental questions about how we do, and how we should, reflect on the problem of medical

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Excerpt

[More information](#)

harm. These questions cannot be strictly practical, for the fact of harm to individuals, and especially within a context such as medicine where the presumptive obligation is one of benefit, carries with it enormous ethical significance. How, for example, are we to understand iatrogenic harm in light of the practitioner's ancient obligation to 'do no harm'? How, in light of the evidence that most preventable harms are the result of system failures, are we to understand accountability? The ethical dimensions of medical harm are linked, moreover, to important conceptual questions. What and whose values should inform the definition of medical harm? If, as is increasingly the case, assessments of harm (and benefit) are understood in terms of the 'appropriateness' of care, what and whose values should inform the definition of appropriateness? Further, as third-party payers increasingly influence clinical decision making, what and whose values will determine what constitutes an acceptable risk? These fundamentally normative issues are inescapably embedded in the practical and policy questions surrounding medical harm, its prevention, and compensation. We believe that explicit attention to these normative questions should be central to practical and policy deliberations. In this book, a framework is provided for reflecting on these normative questions. We do so, by situating these normative concerns within an historical context that illuminates the forces that have shaped the twentieth century perception of medical harm. In the remainder of this introduction we look particularly at nineteenth century America to provide the historical context from which the themes of this book are drawn.

Although the term 'iatrogenic illness' was not coined until the early twentieth century, medical harm is in no sense a modern notion. The seventeenth century BC Code of Hammurapi describes penalties for harmful physician error depending upon the social status of the patient.²⁸ The Hippocratic corpus also contains references to the subject, the most notable of which are the injunction 'to help or at least to do no harm,'²⁹ and the physician's pledge to use his treatments 'to help the sick, but never with a view to injury and wrongdoing.'³⁰ In the first century AD, Pliny the Elder cautions his compatriots against physicians because, he says, they not only learn their skills at the expense of their patients' lives, they also cast blame on the patient for the harms that befell him during his treatment.³¹ The theme of the physician-poisoner was commonplace in classical Roman literature and the paradox of the murderous healer was the subject matter of a great many rhetorical exercises.³² In this same vein, Al-Ruhawi, an Islamic physician of the Middle Ages makes use of the ambiguous Greek term

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Excerpt

[More information](#)*Introduction*

7

pharmakon, which had the double meaning: remedy/poison. As he explains, the virtuous and skillful physician is like a nourishing remedy while the ignorant or unskilled practitioner is ‘like poison’ to the patient.³³ In the seventeenth century, the philosopher Leibniz referred to hospitals as *Seminaria mortis* – places where the seeds of death are sown.³⁴ Throughout the eighteenth century, the German city of Halle was apparently a center for the study of iatrogenic illness.³⁵ One work originating from this region was the 1728 treatise on ‘Doctors as the Cause of Illness,’ which presents case histories that demonstrate the harmful effects of bloodletting.³⁶ Other texts throughout the seventeenth and eighteenth centuries detailed the harms associated with the uses and misuses of medications such as mercury, phosphorus, arsenic, opium, and digitalis.³⁷ One layperson’s response to the use of calomel (mercurous chloride) as a ‘cure-all’ in febrile illness showed some awareness of the serious harm of mercury poisoning:

Since calomel’s become their boast,
How many patients have they lost,
How many thousands they make ill,
Of poison with their calomel.³⁸

These historical references not only bear witness to the phenomenon of medical harm but also reflect its normative character within a particular cultural context. In the Code of Hammurapi, for example, the blameworthiness of such a harm or the degree of censure was relative to the status of the victim. If a free citizen died while in the physician’s care, the physician’s hand or fingers were to be cut off. If the patient were a slave, the physician was required to pay recompense to the owner.³⁹ The Hippocratic injunction ‘to help the sick, but never with a view to injury and wrongdoing,’ is reflective of Pythagorean teleology that interpreted the technical and moral demands of the craftsman according to the proper end of the craft – in this case, patient benefit. The signal importance of this orientation to the proper end of medicine transcended even the social dichotomy between freemen and slaves. The Oath goes on to specify that the physician should abstain from mischief, injustice, and sexual relations with free and slave alike. It has also been argued that the Hippocratic injunction to ‘do no harm’ reflected the physician’s status as a craftsman whose livelihood was dependent on the good will of his customers.⁴⁰ The precarious economic position of the doctor, in other words, added to his incentive to avoid harm to patients.

In nineteenth century America, the notion of medical harm was textured by cultural attitudes towards Providence, by debates on the relative power

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Excerpt

[More information](#)

of the medical ‘Art’ vs. ‘Nature’ as a healing force, and by corresponding beliefs regarding the proper goal of therapy and the moral responsibility of the physician. The notion of medical harm was also shaped by political forces: substantial rhetoric regarding ‘brutal’ and ‘murderous’ practices and medical ‘quackery’ was deployed by competing therapeutic schools vying for professional prominence.

In the early nineteenth century, therapeutics in the United States was characterized by a debate between those who championed Benjamin Rush’s ‘heroic’ application of the art of medicine and those such as Jacob Bigelow who defended the healing powers of nature. Heroic medicine was based more or less explicitly on the theory of counter-irritation: because the body was believed to house only one affliction at a time, the proper therapy for routing out a serious disease was a remedy of even greater potency. Thus, the more virulent the remedy, the better its chances of counteracting disease. This reasoning provided the justification for toxic doses of calomel (mercurous chloride), serial bloodletting, and violent blistering – all of which had been, for example, administered to George Washington upon his death bed in 1799.⁴¹ Natural healing, by contrast, was based on the belief that most diseases would, if left alone, resolve themselves. By letting nature take its course, Bigelow asserted, ‘the amount of death and disaster in the world would be less.’⁴² This conflict in medical epistemology translated into a moral conflict as well. In keeping with the epistemological distinction between ‘Art’ and ‘Nature’, a moral distinction was made between harms of omission and harms of commission. According to the heroic healers, the harms associated with therapeutic intervention were necessary and thus justified. Harms of omission were, however, reprehensible. This sentiment is captured in one Ohio physician’s declaration in 1849 that the doctor’s duty is not ‘to stand by and do nothing . . . [but] to study every disease and interfere.’⁴³ The failure to administer calomel in desperate cases was regarded as abandonment of the patient.⁴⁴

Natural healers, or ‘nature-trusters’, by contrast, saw medical intervention as an inherently harmful affront to the natural order. Restraint was laudable, intervention was culpable. J. Marion Sims, one of the nineteenth-century’s most famous gynecological surgeons said that at the time of his graduation from medical school in 1835 medical practice was heroic and murderous.

I knew nothing about medicine, but I had sense enough to see that doctors were killing their patients, that medicine was not an exact science, that it was wholly empirical and that it would be better to entrust entirely to Nature than to the hazardous skill of the doctors.⁴⁵

Cambridge University Press

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Virginia A. Sharpe and Alan I. Faden

Excerpt

[More information](#)*Introduction*

9

We find this same sentiment expressed by Thomas Jefferson in a letter to one of Rush's contemporaries:

[T]o an unknown disease, there cannot be a known remedy. Here then, the judicious, the moral, the humane physician should stop. Having been so often a witness to the salutary efforts which nature makes to re-establish the disordered functions, he should rather trust to their action, than hazard the interruption of that, and a greater derangement of the system by conjectural experiments on a machine so complicated and so unknown as the human body, and a subject so sacred as a human life⁴⁶

In a less diplomatic frame of mind, Jefferson observed about heroic healers that this 'inexperienced and presumptuous band of medical tyros let loose upon the world, destroys more of human life in one year, than all the Robinhoods, Cartouches & Macheaths do in a century.'⁴⁷

Notwithstanding these different theories of disease and therapeutics, practitioners on both sides of the debate sought to defend their actions with reference to the principles of Christian and gentlemanly rectitude. The Christian gentleman was guided in his actions by virtuous intentions. Thus, in the Christian practitioner, bad outcomes could not logically be the result of bad faith. The force of this appeal often became the tool of one's detractors. By casting aspersions on someone's moral character, one could effectively undermine faith in his therapeutic competence.

In the mid to late nineteenth century, therapeutic breakthroughs such as the acceptance of anesthesia, the germ theory of disease, and surgical antisepsis and asepsis, revolutionized medical practice. Humoral theories of disease and constitutional approaches to therapy were largely supplanted in the late nineteenth and early twentieth centuries by discrete explanatory systems based in pharmacological specificity, immunology, physiology, and laboratory science. The successes of medical science and technology, especially in the field of surgery, offered legitimacy to the emerging medical profession. Rigorous educational standards were adopted for medical training, licensure laws were reestablished and a unified profession institutionalized and safeguarded its authority through various forms of self-regulation. During this period, a fragmented mix of 'regular' and sectarian practitioners eager to incriminate one another, gave way to a consolidated profession of regulars under the aegis of the American Medical Association (AMA) and state medical societies. The AMA's 1847 Code of Ethics was essential in establishing and maintaining this new professional solidarity. It did so not only by prohibiting consultation with 'irregulars' but also by condemning in its members any public criticism of the work of a colleague.

With the rise of scientific medicine, empirical evidence began to displace

Cambridge University Press

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Excerpt

[More information](#)

theoretical dogma as the arbiter of therapeutic efficacy. In this same period, belief in direct Providence as the cause of ‘misfortune’ gave way to belief in human culpability and responsibility as earthly sources of harm and remediation. The growth of the insurance industry in the mid nineteenth century was one manifestation of this shift. Another was the rise in medical malpractice cases when patients looked to the courts for redress.⁴⁸ Rather than give themselves over to fate, or to an uncritical naturalism, Americans began to insure themselves against the risks of daily life and to seek accountability in the actions of others. As these cultural influences came together, both the benignity of natural processes and the ministrations of physicians were opened to question. The moral distinction between acts and omissions in medicine gave way to a conservative therapeutic middle course wherein the physician’s duty was to minimize total harm regardless of its source.⁴⁹

The period of professional consolidation and therapeutic triumph raised the expectations of both practitioners and the public regarding the benefits of medical care. Among the public, higher expectations led to intensified demands and dissatisfaction when treatments failed or patients experienced unfavorable results. Between 1830 and 1900, medical malpractice cases in the United States increased more than 2000%.⁵⁰ Among practitioners, inflated expectations about medicine’s potential inhibited the development of realistic standards of care. Finally, physicians – chilled by the upsurge in malpractice cases – looked to statistics for an accurate assessment of therapeutic efficacy. Frank Hamilton’s work on fracture treatment provided evidence – for use both in court and in practice – on what benefits might be reasonably expected from these interventions.⁵¹ This represented one of the first systematic efforts in what is today known as outcomes research.

The adoption of experimental and statistical techniques as a basis for therapeutic decision making and evaluation was not, however, immediate or wholehearted. Evidence of the instability surrounding the notion of scientific standards in medical practice is found in the tension between the growing acceptance of a philosophy of conservative medicine and surgery in the last half of the nineteenth century and the fact that during the same period, practitioners from vastly different therapeutic camps (sectarians and regulars) were allowed to provide expert testimony interchangeably at each other’s malpractice trials.⁵² Likewise, the theory of regional therapeutics – echoed in the locality rule in medical malpractice⁵³ – that medicine should be practiced and assessed according to *local* standards and to particularities of constitution and meteorology – suggested that, despite the growing application of scientific medicine and the calculation of relative harms and