

SECTION ONE

The Evolution of Patient Safety

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CHAPTER 1

Medical harm: a brief history

Over the last ten years there has been a deluge of statistics on medical error and harm to patients, a series of truly tragic cases of healthcare failure and a growing number of major government and professional reports on the need to make healthcare safer. There is now widespread acceptance and awareness of the problem of medical harm and a determination, in some quarters at least, to tackle it. It seems that we are only now waking up to the full scale of medical error and harm to patients. Yet, awareness of medical harm and efforts to reduce it are as old as medicine itself, dating back to Hippocrates classic dictum to 'abstain from harming or wronging any man'.

The cure can be worse than the disease

Medicine has always been an inherently risky enterprise, the hopes of benefit and cure always linked to the possibility of harm. The word 'pharmakos' means both remedy and poison; the words 'kill' and 'cure' were apparently closely linked in ancient Greece (Porter, 1999). Throughout medical history there are instances of cures that proved worse than the disease, of terrible suffering inflicted on hapless patients in the name of medicine, and of well intentioned though deeply misguided interventions that did more harm than good. Think, for example, of the application of mercury and arsenic as medicines, the heroic bleeding cures of Benjamin Rush, the widespread use of lobotomy in the 1940s and the thalidomide disasters of the 1960s (Sharpe and Faden, 1998). A history of medicine as harm, rather than benefit, could easily be written; a one-sided, incomplete history to be sure, but a feasible proposition nonetheless.

Looking back with all the smugness and wisdom of hindsight, many of these so-called cures now seem to be absurd, even cruel. In all probability though, the doctors who inflicted these cures on their patients were intelligent, altruistic, committed physicians whose intention was to relieve suffering. The possibility of harm is inherent to the practice of medicine, especially at the frontiers of knowledge and experience. We might think that the advances of modern medicine mean that medical harm is now of only historical interest. However, for all its genuine and wonderful achievements, modern medicine too has the

potential for considerable harm, perhaps even greater harm than in the past. As Chantler (1999) has observed, medicine used to be simple, ineffective and relatively safe; now it is complex, effective and potentially dangerous. New innovations bring new risks, greater power brings greater probability of harm and new technology offers new possibilities for unforeseen outcomes and lethal hazards. The hazards associated with the delivery of simple, well understood healthcare, of course remain. Consider, for example, the routine use of non-sterile injections in many developing countries. Before turning to the hazards of modern medicine however, we will briefly review some important antecedents of our current concern with the safety of healthcare.

Heroic medicine and natural healing

The phrase 'First do no harm', a later twist on the original Hippocratic wording, can be traced to an 1849 treatise 'Physician and patient' by Worthington Hooker, who in turn attributed it to an earlier source (Sharpe and Faden, 1998). The background to this injunction, and its use at that point in the development of Western medicine, lay in a reaction to the 'heroic medicine' of the early 19th century.

Heroic medicine was, in essence, the willingness to intervene at all costs and put the saving of life above the immediate suffering of the patient. As Sharpe and Faden (1998) have pointed out, when reviewing the history of iatrogenic harm in American medicine, it is this period that stands out for the violence of its remedies. Heroism was certainly required of the patient in the mid-19th century. For instance, in the treatment of cases of 'morbid excitement' such as yellow fever, Benjamin Rush, a leading exponent of heroic medicine, might drain over half the total blood volume from his patient. Yet Rush was heroic in his turn, staying in fever ridden Philadelphia to care for his sick patients. Rush explicitly condemned the Hippocratic belief in the healing power of nature, stating that the first duty of a doctor was 'heroic action, to fight disease'.

Physicians more trusting of natural healing on the other hand saw heroic medicine as dangerous, even murderous. Sharpe and Faden quote the assessment of J. Marion Sims, a famous gynaecological surgeon, writing in 1835 at the time of his graduation from medical school:

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 trust entirely to Nature than to the hazardous skill of the doctors.
(SHARPE AND FADEN, 1998: P. 8)

These extreme positions, of heroic intervention and natural healing, eventually gave way to a more conservative position, espoused by such leading physicians as Oliver Wendell Holmes, who attempted to objectively assess the balance of risk and benefit of any particular intervention. This recognizably modern approach puts patient outcome as the determining factor and explicitly

broadens the physician's responsibility to the avoidance of pain and suffering, however induced – whether from the disease or the treatment.

Judgements about what constitutes harm are not straightforward and are irretrievably bound up with the personal philosophies of both physician and patient. To the sincere, if misguided, heroic practitioners, loss of life was the one overriding harm to be avoided and any action was justified in that pursuit. This was moderated by the more conservative position in striking a balance between intervening to achieve benefit and avoiding unnecessary suffering. Such dilemmas are of course common today when, for instance, a surgeon must consider whether an operation to remove a cancer in a terminally ill patient, which might prolong life, is worth the additional pain, suffering and risk associated with the operation. The final decision nowadays may rest with the patient and family, but they will be strongly influenced by medical advice. The patient too must decide whether to 'first do no harm' or whether to risk harm in the pursuit of other benefits. From this we can already see that there is no absolute state of safety that we can aspire to, but that safety must always be seen in the context of other objectives. Safety can, however, be prioritized and become an explicit goal instead; in contrast, for much of medical history, safety was an objective but one not backed by analysis and systematic action.

Hospitalism and hospital acquired infection

Dangerous treatments were one form of harm. However, hospitals could also be secondary sources of harm, in which patients acquired new diseases simply from being in hospital. By the mid-19th century, anaesthesia had made surgery less traumatic and allowed surgeons time to operate in a careful and deliberate manner. However, infection was rife. Sepsis was so common, and gangrene so epidemic, that those entering hospital for surgery were 'exposed to more chance of death than the English soldier on the field of Waterloo' (Porter, 1999: p. 369). The term 'hospitalism' was coined to describe the disease promoting qualities of hospitals, and some doctors believed they needed to be periodically burnt down. As late as 1863, Florence Nightingale introduced her *Notes on Hospitals*, as follows:

It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm. It is quite necessary, nevertheless, to lay down such a principle, because the actual mortality in hospitals, especially in those of large crowded cities, is very much higher than any calculation founded on the mortality of the same class of diseases amongst patients treated out of hospital would lead us to expect.

(SHARPE AND FADEN, 1998: P. 157)

Puerperal fever, striking mothers after childbirth, was particularly lethal and widely known to be more common in hospitals than in home deliveries. A small number of doctors in both England and America suspected that this was caused by transfer of 'germs' and argued that doctors should wash between an autopsy

and a birth. These claims of the contagious nature of puerperal fever, and the apparently absurd possibility of it being transferred by doctors, were strongly rebutted by many, including the obstetrician Charles Meigs, who concluded his defence of his position with the marvellous assertion that 'a gentleman's hands are clean' (Sharpe and Faden, 1998: p. 154). Bacteria were apparently confined to the lower classes.

Dramatic evidence of the role of hygiene was provided by Ignaz Semmelweiss in Vienna in his study of two obstetric wards. In Ward One, mortality from infection hit a peak of 29% with 600–800 women dying every year, whereas in Ward Two mortality was 3%. Semmelweiss noted that the only difference between wards was that patients on Ward One were attended by medical students and those on Ward Two by midwifery students. When they changed places, mortality rates reversed. Following the rapid death of a colleague who cut his finger during an autopsy, Semmelweiss concluded that his colleague had died of the same disease as the women and that puerperal fever was caused by conveying putrid particles to the pregnant woman during examinations. He instituted a policy of hand disinfection with chlorinated lime, and mortality plummeted. Semmelweiss finally published his findings in 1857, after similar findings in other hospitals, but found it difficult to persuade his fellow clinicians and his beliefs were still largely ignored when he died in 1865 (Jarvis, 1994).

Lister faced similar battles to gain acceptance of the use of antiseptic techniques in surgery, partly from scepticism about the existence of micro-organisms capable of transmitting infection. However, by the end of the 19th century, with experimental support from the work of Pasteur and Koch, the principles of infection control and the new techniques of sterilization of instruments were fairly well established. Surgical gowns and masks, sterilization and rubber gloves were all in use and, most importantly, surgeons believed that safe surgery was both a possibility and a duty. However, one hundred years later, with transmission of infection well understood and taught in every nursing and medical school, we face an epidemic of hospital acquired infection. The causes of these infections are complex, with antibiotic resistant organisms, hospital overcrowding, shortage of time and lack of easily available washing facilities all playing a part. However, as in Semmelweiss's time, a major factor is difficulty of ensuring that staff, in the midst of all their other duties, do not forget to wash their hands between patients.

Surgical errors and surgical outcome

Ernest Codman, a Boston surgeon of the early 20th century, was a pioneer in the scientific assessment of surgical outcome and in making patient outcome the guiding principle and justification of surgical intervention. Codman was so disgusted with the lack of evaluation at Massachusetts General Hospital that he resigned to set up his own 'End-Result' hospital. This was based on the, for Codman, commonsense notion that 'every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been

successful, and then to enquire “if not, why not” with a view to preventing similar failures in the future’ (Sharpe and Faden, 1998: p. 29). Crucially Codman was prepared to consider, and more remarkably make public, the occurrence of errors in treatment and to analyse their causes (Box 1.1).

BOX 1.1 Codman’s categories for the assessment of unsuccessful treatment

Errors due to lack of technical knowledge or skill;
 Errors due to lack of surgical judgement;
 Errors due to lack of care or equipment;
 Errors due to lack of diagnostic skill;
 The patient’s unconquerable disease;
 The patient’s refusal of treatment;
 The calamities of surgery or those accidents and complications over which we have no known control.

(FROM SHARPE AND FADEN, 1998)

From 1911 to 1916, there were 337 patient discharged from Codman’s hospital, with 123 errors recorded. In addition to errors, he recorded ‘calamities of surgery’ over which he had no control, but which he believed should be acknowledged and made known to the public. He was unsparing of himself, noting, after ligating a patient’s hepatic duct which led to their death, that he ‘had made an error of skill of the most gross character and even during the operation had failed to recognize it’ (Neuhauser, 2002).

Codman challenged his colleagues to demonstrate the efficacy of their procedures, and not rely solely on the prestige of their profession to justify their actions. Unless the methods of science were applied to the evaluation of outcomes, Codman contended, there was nothing to distinguish a surgeon from a genial charlatan. His denunciations of humbuggery, by which he meant putting income ahead of outcome, culminated in his presentation of a large cartoon at a meeting of the local Surgical Society. In the picture, an ostrich is shown with its head beneath a pile of golden surgical eggs depicting the lucrative practices threatened by objective evaluation and publication of findings. This episode caused uproar but, anticipating this, Codman had already resigned his post at Massachusetts General Hospital.

Although Codman was ostracized and ridiculed by many, his proposals were nevertheless adopted by the American Surgical Society, but the eventual ‘minimum standards for hospitals’ instituted after the First World War omitted two of the most crucial components: the analysis of outcomes and the classification of error. The Minimum Standard ran until 1952, until it was overtaken by the formation of the organization that eventually became the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the largest accrediting body in the United States (Sharpe and Faden, 1998).

Iatrogenic disease

In the early decades of the 20th century, the scientific understanding of disease was well advanced, the excesses of heroic treatments had been curbed, but few effective treatments were available. Entering medical school in 1933, Lewis Thomas reflected that the purpose of the curriculum was:

... to teach the recognition of disease entities, their classification, signs, symptoms, and laboratory manifestations and how to make an accurate diagnosis. The treatment of disease was the most minor part of the curriculum, almost left out altogether ... nor do I remember much talk about treating disease at any time in the four years of medical school except by the surgeons, and most of their discussions dealt with the management of injuries, the drainage or removal of infected organs and tissues and, to a very limited extent, the excision of cancers.

(THOMAS, 1984: PP. 27–28)

When medicine could achieve relatively little, it was hardly surprising that medical harm was far from people's minds, though Thomas does describe some fairly hair-raising treatments for delirium tremens involving massive doses of paraldehyde.

In the 1920s, however, the potential harmful effects of medicine were explicitly recognized with the introduction of the term 'iatrogenic disease'. The term 'iatrogenic' comes from the Greek word for physician 'iatros' and 'genesis', meaning origin; iatrogenic disease is therefore an illness induced, in some way, by a physician. The first usage is credited to Bleuler's 1924 textbook of psychiatry and implied at that time a nervous problem induced as a result of a physician's diagnosis of a disease (Sharpe and Faden, 1998). Thus a diagnosis of heart disease, for instance, could make the patient extremely anxious and induce an iatrogenic neurosis. Clinicians were therefore extremely careful when discussing diagnoses to avoid distressing or depressing the patient unduly. This well intentioned paternalism is a far cry from today's insistence on disclosing risks of all kinds which of course, as Bleuler and others recognized, carries its own hazards.

With the advances of medical science in the mid-20th century, the term iatrogenic disease broadened in scope to include harm due to the medical intervention itself. The particular stimulus for this was the increasing use of penicillin and other antibiotics. In the post war years there was a massive expansion in the medicines available, the usage of drugs and the availability of hospital beds and hospital treatments. By the mid-1950s some doctors, notably David Barr and Robert Moser, were beginning to realize that there were potential hazards associated with the enormous increase in drug use and availability. Barr's paper 'The hazards of modern diagnosis and therapy' (Barr, 1956) set out some of the major risks, but largely in the spirit of pointing out that there was an inevitable price to pay for therapeutic advance. However, Moser (1959) went further in also considering the overuse of medical therapy,

coining the phrase ‘antibiotic abandon’ to describe the use of penicillin for anything and everything. Moser’s view of iatrogenic disease, at least by the time of his 1959 book, ‘Diseases of medical progress’, was subtly different from Barr’s in that he viewed these diseases of progress as those that would not have occurred if sound therapeutic practices had been employed. There is a suggestion at least, in this view, that harm is not entirely an unavoidable by-product of medical success, but may also be due to unsound practice, in which treatments are given without clear indications and without due regard for the balance of risk and benefit. At that time however, as Sharpe and Faden point out, questions of the balance of risk and benefit lay largely with the clinician, with little if any consideration of the patient’s perspective.

Systematic studies of the hazards of hospitalization

While iatrogenic harm had been noted, it was seldom systematically studied. One of the first explicit, systematic prospective studies of iatrogenic complications was carried out by Elihu Schimmel in 1960/61 at Yale University Medical School. In retrospect, although it had limited impact at the time, it can be seen as a landmark study of the quality and safety of medical care.

Schimmel, with the support of his departmental chairman, succeeded in mobilizing the junior doctors of three hospital wards to report and describe adverse episodes resulting from acceptable diagnostic or therapeutic measures deliberately instituted in the hospital. The use of an explicit definition of harmful episodes was remarkably progressive in outlook, but the study took care not to implicate the actions of clinical staff in any harm that might result from treatment; reactions due to error, and reactions from previous treatment, and situations that were only potentially harmful were excluded. Even when errors were omitted, the results were striking with 20% of patients experiencing one or more untoward episodes including 16 fatalities (Box 1.2 and

BOX 1.2 The hazards of hospitalization

The occurrence of hospital-induced complications in a university medical service was documented in the prospective investigation of over 1000 patients. The reported episodes were the untoward consequences of acceptable medical care in diagnosis and therapy. During the 8-month study, 240 episodes occurred in 198 patients. In 105 patients, hospitalization was either prolonged by an adverse episode or the manifestations were not resolved at the time of discharge. Thus, 20% of the patients admitted to the medical wards experienced one or more untoward episodes and 10% had a prolonged or unresolved episode. The severity of the 240 episodes was minor in 110, moderate in 82 and major in 48, of which 16 ended fatally.

Patients encountering noxious episodes had a mean total hospitalization of 28.7 days compared with 11.4 days in other patients. The risk of having such episodes seemed directly related to the time spent in the hospital. The number and variety of these reactions emphasizes the magnitude and scope of hazards to which the hospitalized patient is exposed. A judicious selection of diagnostic and therapeutic measures can be made only with knowledge of these potential hazards as well as the proposed benefits.

(ADAPTED FROM SCHIMMEL, 1964: P. 100)

Table 1.1). Schimmel’s summary bears a remarkable resemblance in both content and tone to the findings of the major record reviews of adverse events of the 1980s and 1990s. Schimmel remarked that the economic loss and emotional disturbance suffered by many patients were beyond the scope of the study, yet could not be considered insignificant complications of their medical care. Today we still have yet to assess the full economic consequences of harm to patients and have barely addressed the emotional trauma.

In his conclusion, Schimmel both defends the practice of medicine and yet argues for much greater attention to risks. The difficulty of balancing potential benefit and potential harm, and the need for constant review and monitoring of that balance, both during a patient’s treatment and as medicine evolves, is expressed with great clarity:

The classical charge to the physician has always been primum non nocere. Modern medicine, however, has introduced procedures that cannot always be used harmlessly. To seek absolute safety is to advocate therapeutic nihilism at a time when the scope of medical care has grown beyond previous imagination and power. The dangers of new measures

Table 1.1 Examples of fatal episodes

Agent or procedure	Manifestation of the episode	Age (years)	Underlying disease
Cystoscopy	Cardiac arrest	69	Chronic pyelonephritis
Thoracentesis	Ventricular fibrillation	76	Congestive heart failure
Esophagoscopy	Perforation	50	Cirrhosis
Barium enema	Cardiac arrest	89	Tuberculous peritonitis
Heparin (iv)	Retroperitoneal haemorrhage	66	Hypernephroma
Blakemore tube	Asphyxia	59	Cirrhosis
Digoxin	Ventricular fibrillation	40	Rheumatic heart disease
Sedatives	Staphylococcal pneumonia	73	Parkinsonism

Reproduced from *Quality & Safety in Health Care*, E M Schimmel. “The hazards of hospitalization”. 12, no. 1, 58–63, 2003, with permission from BMJ Publishing Group Ltd.

must be accepted as generally warranted by their benefits and should not preclude their useful employment. Until safer procedures evolve however, physicians will best serve their patients by weighing each measure according to its goals and risks, by choosing only those that have been justified, and by remaining prepared to alter the procedures when imminent or actual harm threatens to obliterate their good.

(SCHIMMEL, 1964: P. 100)

In 1981, Steel, Gertman, Cresenzi and Anderson set out to reassess Schimmel's findings in a medical service of a tertiary care hospital (Steel *et al.*, 1981). They noted that in the preceding 15 years the number and complexity of diagnostic procedures had increased markedly, the number of drugs in use had increased and the patient population had aged. Of 815 patients in their study, an incredible 36% suffered an iatrogenic illness, with 9% being major in that they threatened life or produced a major disability. Exposure to drugs was the main factor leading to adverse effects, with nitrates, digoxin, lidocaine, aminophylline and heparin being the most dangerous. Cardiac catheterization, urinary catheterization and intravenous therapy were the principal procedures leading to problems, with falls also a serious issue. Staying longer in hospital was associated with a higher risk of iatrogenic disease. Steel and colleagues stopped short of a direct assessment of preventability, stressing that their definition did not imply culpability. Nevertheless, by 1981, they were certainly willing to imply that many of the problems might be preventable. They called for monitoring of adverse occurrences, especially on medical wards, and educational programmes about iatrogenic disease. Thirty years on, iatrogenic disease and safety issues are still finding only a small corner in some medical and nursing curricula, but we are at least now recognizing incidents and adverse outcomes to a much greater extent.

Medical nemesis

'The medical profession has become a major threat to health.' This arresting sentence begins Ivan Illich's polemic 'Limits of medicine', subtitled 'Medical nemesis: the expropriation of health' (Illich, 1977). Nemesis represents divine vengeance on mortals who behave in ways that the gods regard as their own prerogative. Medicine, argued Illich, had sought to move beyond its proper boundaries and by doing so was causing harm. Illich's broader argument, expressed in a number of books, was that many institutionalized activities had counterproductive effects. In 'Deschooling society' for instance, he argued that formal, institutionalized education robbed people of their own intellectual curiosity and abilities, just as medicine robbed people of their own capacities for self care and autonomous living. Illich emphasized that medical harm was not just an unfortunate side effect of medical treatment that would eventually be resolved by technological and pharmacological advances; the only solution was for people themselves to resist unnecessary medical intervention and the medicalization of life.

Illich described three forms of iatrogenic effects:

- *Clinical iatrogenesis* – the direct harm done to patients;
- *Social iatrogenesis* – the excessive use of medicine to solve problems of living which encouraged people to become consumers of medicine, rather than actively involved in shaping their own health and environment;
- *Cultural iatrogenesis* – a deep culturally mediated sapping of people's ability to deal with sickness and death. Ordinary suffering and the experience of life and death then become commodities, illnesses that required treatment, rather than life to be lived and experienced – the 'paralysis of healthy responses to illness and suffering' in Illich's memorable phrase.

In the early 21st century, some aspects of this critique carry less force. Far from trying to medicalize life, doctors are now in retreat from the demands and unreasonable expectations thrust upon them. However, Illich's first theme of clinical iatrogenesis has proved remarkably farsighted, though we might now see the causes of iatrogenic harm as different from those suggested by Illich. He assembled a powerful set of charges against medicine and the medical profession, encompassing a critique of the lack of evidence for high technology medicine, evidence of useless or unnecessary treatment and doctor inflicted injuries. After reviewing the extant studies on the adverse effects of drugs, accidents in hospital and the hazards of hospitalization, he concluded that:

The pain, dysfunction, disability, and anguish resulting from technical medical intervention now rival the morbidity due to traffic and industrial accidents and even war-related activities, and make the impact of medicine one of the most rapidly spreading epidemics of our time. Amongst murderous institutional torts, only modern malnutrition injures more people than iatrogenic disease in its various manifestations.

(ILLICH, 1977: P. 35)

Illich's inflammatory language, and wholesale attack on the enterprise of medicine, hardly endeared him to the medical and nursing professions. Writing in 1997, John Bunker, who carried out some of the first studies on potentially unnecessary surgery, wrote that at the time he considered Medical Nemesis to be an ill-informed and irresponsible attack on the medical profession (Bunker, 1997). Bunker argued that Illich's more subtle, and more important message, about the dangers of social and cultural iatrogenesis, was perhaps misunderstood at the time. Illich's belief in the healing powers of friendship, personal autonomy, social networks and relationships and the importance of these factors in a fulfilled and healthy life now seems particularly prescient. There is now, as there was not in the 1970s, a huge literature on the importance of psychological and social factors in health and an acceptance on all sides of the importance of personal responsibility for health.

Illich's particular contribution to the gradually growing literature on medical harm was in the ferocity of his argument and the challenge he posed to medicine and the medical profession. Others had recorded and written about the hazards of drugs and therapeutics, but Illich went much further to suggest

that healthcare was actually a threat to health, comparable to that from traffic and industrial accidents. As we shall see in the next chapter, this claim, outrageous and inflammatory at the time, reappears in sober government documents towards the end of the 20th century.

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