

CHAPTER 1

Introduction to oncology and medical errors

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Medical errors have been defined as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.” Harmful medical errors are adverse events caused by medical errors. Attention to medical error has increased in recent years in medicine and oncology, building in good part on the 1995 Institute of Medicine (IOM) Report “To Err is Human,” which brought to the forefront of medicine the high incidence and healthcare consequences of errors that occur both in and outside of hospitals. [1] Researchers have studied the incidence of medical errors and estimated the numbers of injuries and deaths they cause. Patients and advocates are demanding greater safeguards against errors. Physicians and institutions have invested time and resources in patient safety training, procedures aimed at preventing errors, and efforts to change a culture of blaming and shaming physicians that yielded mainly denial, hiding, or the spreading of blame in the case of medical error. In addition, medicine and medical institutions have adopted ethical mandates to report errors and adverse events and disclose them to patients and family members, together with apologies. [2]

Research, educational, and programmatic efforts in oncology have been directed toward the prevention of errors through systemic improvements and new technology such as computerized tools for ordering different types of cancer therapies. Particular attention has been paid, in oncology as in other areas of medicine, to errors in one part of a complex system of care – a physician’s dosage error in prescribing a medication that is then sent to the hospital pharmacy, leading medication to the hospital pharmacy, leading, finally, to the administration of an incorrect dose to the patient. Another important area of research and practice is the accountability of medical teams balanced with the responsibility of individual team members. Attention to the early aftermath of error, including the

impact of physician disclosure or nondisclosure on patients and family member decisions on whether or not to pursue malpractice lawsuits, has also increased. [3–5]

Research has been conducted on physicians' emotional responses to error, and a number of narrative accounts supplement these studies; although, unfortunately, few of either in the field of oncology. The lived experience of committing or witnessing a medical error and the emotional–psychological difficulties associated with it are of major concern as we shift from a culture of singling out individuals involved in the commission of errors as incompetent or even morally deficient, to one in which we acknowledge the inevitability of medical errors while striving to limit their incidence. There is also a need to consider the role of mental health professionals in helping oncology professionals to face their medical errors and respond appropriately to patients and family members when these occur.

Our aim in this book is to discuss key aspects of medical errors in clinical oncology and provide recommendations for improvement in patient safety and reduction of medical errors. We also consider the impact of a medical error and lack of its aftermath – including proper or insufficient disclosure or its absence and lack of a heartfelt apology on patient–doctor relationships and trust. Table 1.1 below suggests key areas of attention in responding to medical error beyond clinical interventions to correct for their overall impact on cancer patients and their families.

In this book, we address key aspects of medical errors in oncology, a field in which treatments are complex and patients are exposed to multiple potential sources of adverse events and errors, from diagnosis to active therapy to long-term

Table 1.1 Responding to medical errors in oncology: areas for study and action.

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- Study of the epidemiology of errors in oncology
 - Analysis of specific causes of errors in oncology
 - Institutional disclosure policies and process incorporating a psychological understanding of the experience of error and attention to the lived experience of error for patients, family members, oncologists, and nurses
 - Clear ethical and professional standards for basic content of disclosure that respond to the tendency to hedge or redefine disclosure
 - Training in error disclosure, incorporating an understanding and response to the psychological and emotional aspects of disclosure for patients and family members
 - Training on the ethics of individual accountability even when errors stem from team or system failure
 - Education on the redemptive value of apology and forgiveness
 - Emotional support following errors for all parties
 - Building bridges among patients, family members, and oncology professionals after disclosure to restore trust in the patient–doctor relationship, institutions, and medicine
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survivorship, or palliative care and end-of-life stages. Cancer patients may be enrolled in clinical trials or receive relatively new drugs for which the knowledge of what constitutes an adverse event is lacking or preliminary, and in which a clear distinction between adverse events and medical errors can be, likewise, difficult to make. The use of detailed therapeutic protocols reduces the risk of harmful errors, yet the need for multiple concomitant medications or treatments may increase their occurrence. Similarly, the involvement of interdisciplinary teams in the care of cancer patients may increase the possibility of errors while, at the same time, contributing to the capacity to prevent or detect them early on due to multiple opportunities to intercept a mistake. Increasing use of electronic records and orders is believed to contribute to limit the risk of medical errors in clinical oncology, but this technology is not available or feasible for use in all countries or local contexts.

In addition to discussing error prevention and correction at individual, institutional, and system levels, we consider the impact of errors on cancer patients, their family members, and oncology professionals, and emphasize proper and empathic communication as a means of restoring trust in the patient–doctor relationship after an error has occurred. We also identify gaps and barriers to further progress in these areas. We first briefly review the contents of the individual sections and chapters in this volume below. We then add a few considerations of themes that, for lack of space, have not been systematically addressed in individual chapters, or that we explore from different standpoints: medical error, oncology patients and their family members; cultural attitudes and practices regarding disclosure; the impact of medical errors on oncologists; and medical errors, oncology, and the law. We also explore the ethical value of taking individual responsibility and accountability for medical errors, even while shifting from a culture of moral and legal blame to the more effective one of a system approach to patient safety.

Outline of the book

The first of three sections in this volume concerns the background and context of medical errors in oncology. Itzhak Brook, a physician writing as a cancer patient and survivor, describes in chilling detail the multiple medical and surgical errors he experienced in his treatment for hypopharyngeal squamous cell carcinoma, a serious form of throat cancer. Dr. Brook also offers practical recommendations for preventing errors in hospitals and medical offices and enhancing competent disclosure of errors to patients, while supporting healthcare professionals in doing so. He argues for the active collaboration of patients and families with oncologists and nurses in preventing medical errors or limiting their damage. He also refers with respect and gratitude to the many staff members who cared for him even in the context of multiple errors.

Drs. Mary Chalino, Evelyn Wong, Bradley Collins, and Richard Penson explore in depth the psychological and existential impact of medical error on oncology

professionals, including guilt and shame that, if unaddressed, can lead to burnout, compassion fatigue, and other negative consequences. The authors examine various models of personal coping with involvement in medical error, including spiritual and religious resources and mindfulness meditation in the context of individual resilience and the larger contexts of religion and spirituality, wisdom literature, and the humanities. Little attention has been paid in the research and scholarly literature to these aspects of how oncology professionals cope with the aftermath of medical errors – a void that this chapter contributes to filling.

Rounding out this first section, Drs. Michael Rowe and Antonella Surbone, editors of this volume, take a turn as chapter authors. We chose to contribute to our book with a report, based on in-depth interviews with patients and physicians facing a variety of medical scenarios, on why people who believe they or their loved one experienced a harmful medical error do *not* pursue malpractice litigation. We also add our own personal family and professional reflections to this research, including the relationship of errors to the erosion, and possible rebuilding, of trust in relationships between cancer patients and their oncologists and nurses.

The second section of this volume focuses on patient safety in clinical oncology practice. Dr. Martha Polovich gives the reader a bird's-eye, case-example rich, and scholarly perspective of the role of oncology nurses in preventing medical errors. Dr. Polovich's account emphasizes the complexity, and thus the ample room for error and lapses, of patient safety efforts in oncology care, and the integral involvement of nurses in these efforts. She discusses efforts to address potential threats to patient safety including recommendations for developing and implementing clearer procedures, the use of new medical technology to assist in reducing medical errors, and individual and collective practice in the context of a medical culture of patient safety.

Drs. Walter Baile and Daniel Epner offer a broad ranging review on disclosure of harmful medical errors. They review the histories of silence, individual blame, the lack of or misleading disclosure of harmful error to patients and family members, and a shift in medical culture toward correcting such deficient responses. They offer specific examples of "how" and "how not to" disclose, including disclosure statements and procedures. At stake in getting communication of medical errors right with patients and their families, the authors argue, are improvements in patient safety and the health of patient–doctor relationships.

Dr. Lidia Schapira, Joseph Betancourt, and Alex Green take up the impact of cross-cultural differences between caregivers and their patients and patient family members on patient safety, a critical topic in medicine and in the context of increasingly diverse societies worldwide. Using data and examples from the United States, the authors point out potential barriers to patient safety in cross-cultural care, including different cultural values and language and the challenges posed by low literacy among patients and family members belonging to

the non-dominant culture of the country in which they are treated. Addressing these concerns, they argue, requires increased knowledge and training for oncology professionals, the use of skilled interpreters, and institutional commitment to improving cross-cultural care in general and in relation to cancer patient safety.

In the third and final section of this volume we examine at the intersection of patient, professional, and institutional needs and realities with regard to patient safety and reduced medical error in oncology care. Dr. Eric Manheimer, writing of ever-larger and more complex medical institutions, discusses their historical and recent roles in causing medical error and undermining public safety. He places the tension between past failures and recent efforts to reform medical institutions in the immediate context of the Affordable Care Act in the United States. The applied theory of High Reliability Organization emerges, in his view, as the most promising model of future health care for the USA. Dr. Manheimer draws on his expertise as a medical director of large hospitals in which many cancer patients are treated and on his experience as a cancer survivor who has written about his own illness and recovery.

Drs. Patrick Forde and Albert Wu address the oncologist's professional and ethical responsibilities with respect to disclosure of adverse events and medical errors. Their chapter complements, in part, Drs. Baile and Epner's discussion of communication about medical errors. Here, the authors focus on ethical arguments for disclosure, such as the loss of autonomy and justice for patients who are not informed of adverse event and the potential for future or continued errors in cases where errors are not disclosed. They review the evidence for and against full disclosure, and the relevance of it and related issues to the special needs of cancer patients. They also present detailed case discussions to illustrate the fact that good communication between oncology professionals and cancer patients is dependent, and also can build, upon previously achieved mutual trust before a medical error occurs.

Dr. Juanne Clarke closes out this section with a reminder from a sociological perspective that the dominant forms of viewing and discussing medical error stem from a medical definition of error that is "not clear, objective, or self-evident." The definition and resulting efforts to address medical error and patient safety, she argues, are fueled by a *perspective* and a *theory* of error that are insufficiently aired and debated, given the medical perspective's dominant position, voice, and resources. Dr. Clarke considers the broader patient definition of error and the need for stronger patient-based and -oriented advocacy to enhance cancer patient safety.

In a concluding chapter, we briefly review the conceptual and practical implications of the contributions of our authors. We also suggest possible future directions for practice and research that may contribute to reducing medical errors and enhancing patient safety in oncology.

Medical error, oncology patients and their family members

Patients often have a broader understanding and definition of medical errors than physicians or researchers. They may, for example, include among medical errors the physician's failure to communicate effectively with them after the medical error has occurred. Individual physicians' or institutional arrogance, while not a constitutive element of the medical definition of error, has been described by many patients as contributing to their perception of medical errors and to the difficulty of repairing a breach in trust.

Patients and family members also may live with the physical and emotional consequences of the error for years, and lack of physician empathy and honesty in the aftermath of error can exacerbate their suffering. Yet most of the literature on medical error focuses on a narrower set of responses and time, including whether or not, and when, to pursue or forego a malpractice lawsuit. Education of all parties about the psychological–emotional consequences of adverse events and medical errors, and creation of new standards of practice in response to this extra-clinical domain of error, are needed. In addition, “near misses” that may be caused by excessive patient caseloads are also a cause of shame and fear for physicians, and are rarely addressed in terms of their emotional impact on doctors. [6]

Oncology patients, like others with serious or acute illnesses, are vulnerable due not only to their illness but also to the inherent power asymmetry between patients and oncologists. [7] Patients place their trust and lives in the expertise and person of their oncologists. From this perspective, disclosure is not only the right thing to do but follows directly from the fiduciary nature of the therapeutic relationship in clinical medicine. The practice of oncology, however, with its use of detailed protocols, multiple experimental medications, and interdisciplinary teams, along with the toxicity of the medications it offers, presents difficulties, at times, with regard to assessing whether an adverse event is a side-effect of treatment or the result of medical error. [8] These quandaries, in turn, can tempt oncologists to rationalize away some errors and question the need to disclose them to patients. [9, 10] On the other hand, oncologists may be so acutely aware of the depth of suffering of their patients that they refrain from disclosing errors, or offer only partial disclosure – especially when the error caused no permanent harm – in order to shield patients and their families from additional suffering and anguish. [9]

Cultural attitudes and practices regarding disclosure

Attitudes and practices of truth telling to cancer patients vary widely by culture and countries. Despite a sharp trend toward disclosure of diagnosis and prognosis worldwide based on respect for patient autonomy even in cultures oriented more to family and community values than individual rights, partial disclosure is still the

rule in many non Western countries. [11] It is difficult to disseminate and implement recommendations for error disclosure in cultures where cancer patients may be unaware, or only vaguely aware, of their illness status and prognosis.

In Anglo-American countries, with their traditions of providing extensive information to patients, a disclosure statement may be truthful yet not appropriate in a given context. In addition, examination of the nuances of truth telling in patient–oncologist relationships teaches the physician that statements of fact and truth telling are not synonymous. Oncologists may hide behind delivering a torrent of medical information that, while factually correct, may confuse patients rather than help them face the truth of their illness. [11]

Oncologists, more than most other physicians, must often communicate devastating news to their patients. The manner and content of the communication process can spell the difference between mere fact giving and truth telling. An oncologist may tell his patient that she has an aggressive form of cancer and has only months to live, or may essentially deliver this same message in the context of assuring her that he is committed to caring for her until the end and to offering all appropriate options, from antineoplastic treatments to palliative and end-of-life care. [12] The first statement voices the “plain truth” more forcefully than the second; the second provides an opening for dialog, giving the patient an opportunity and time to absorb the factual medical truth and prepare herself to face it together with her oncologist and her loved ones.

Perhaps the most striking gap in ethical approaches to medical errors and disclosure involves the “street-level” context of the ethics of medical care, in which competing interests and constituencies make collective and continuous decisions over time and interventions respond to earlier interventions, setting the stage for new ones. This model of decision making contrasts with that of the doctor who makes medical and ethical decisions on her own and in relation to generalized normative standards, but mostly in reference to the particular situation and patient in front of her. [13] Another gap in the ethical approach to disclosure involves the need to help patients, family members, and doctors come to terms with the impact of medical errors over time. Such an approach would involve addressing not only the lack of consensus among doctors, institutions, patients, and family members about what should be disclosed in the aftermath of adverse events, but what medicine’s roles and responsibilities are regarding the long-term impact of harmful error for patients and family members as well as for oncology professionals.

Regarding disclosure of medical errors, telling the truth to patients and their families and apologizing to them involves both ethical and psychological–emotional elements for physicians, in addition to legal and professional concerns. For patients and family members, the visceral experience of error and judgment of physicians’ and medical institutions’ violation of medical and ethical standards may be intermixed with the psychological–emotional elements of shock, grief, loss, survivor guilt, and sense of isolation. Other factors may include stigma associated with physical effects stemming from the medical error and a change in the patient’s potential role in the family due to reduced ability to work or

carry out other functions. In addition to the implications of being sued, which range from financial losses to professional reputation, physicians also suffer from subjective responses to medical errors that they have committed or witnessed. [14] A lingering belief in physician infallibility contributes to a culture of doctors' silence about error. Yet accompanying the message of infallibility are physicians' knowledge that errors do occur and the anguish they experience when the error is their own.

Studies and narrative accounts have examined the experience of medical error for physicians, including oncologists, who experience considerable distress in the aftermath of committing or witnessing medical errors. [14, 15] Errors negatively affect oncology professionals' self-confidence and afflict them with feelings of guilt, of being found out, and of fear of colleagues' ridicule. Such negative reactions, combined with fears of malpractice lawsuits and buttressed by traditional messages of silence from their institutions, leave doctors and nurses with few places to go to discuss and try to work through their feelings. Mortality and morbidity conferences or similar discussions of medical errors among team members focus on medical and surgical aspects of errors, and rarely are an appropriate setting for doctors to express their emotional response to errors and their need for support.

Oncologists, like physicians in other specialties who work with very ill patients over long periods, are especially prone to burnout. [16, 17] In oncology, the patient–doctor relationship occurs in the context of uncertainty over the course of the disease, the prospects for treatment effectiveness, and patients' physical and existential suffering. Uncertainty and existential suffering are common to oncologists as well. [18] For oncologists, the close relationships they develop with many of their patients may make error more difficult for them to bear and to confess to patients. At the same time, as noted above, severe illness and imminent mortality among their patients may tempt oncologists to withhold information on error or adverse events. [9] This temptation may persist even in the face of evidence that disclosure of error can reduce its psychological impact and that failure to disclose can heighten feelings of distress following errors and negatively affect oncologists' relationships with current and future patients. Thus, counseling oncologists and nurses regarding medical error and its aftermath should be a priority and dedicated psychological services should be made available to them.

Medical error, oncology, and the law

The legal–malpractice aspects of medical error have received much attention in the medical, ethical, and legal literature. [19] They appear to be perhaps less pressing in oncology than in many other medical disciplines and specialties. In the 2013 Medscape Malpractice Report, for example, the oncologist's risk of a malpractice lawsuit, at 4%, ranks well below internal medicine, family medicine,

obstetrics–gynecology, psychiatry, and cardiology, [20] with comparatively low malpractice premiums for oncologists as a result. [21] The Medscape finding may partly reflect the often-expected poor outcome of care in the context of aggressive forms of cancer in many patients. Still, based on these data, one in twenty-five oncologists can expect to be sued at some point in their careers. In addition, the Medscape report does not, nor does it claim to, take into account the potential damage to patient–doctor relationships in the care of the unknown numbers of cancer patients and family members who experienced dissatisfaction with their care, feel that errors or substandard care occurred, and/or may have considered or explored the possibility of a lawsuit.

Dr. Patricia Legant has written of the key risk areas for litigation in oncology care, among them delays in diagnosis, errors in chemotherapy dosing, pain control, and lack of, or poorly communicated, informed consent for surgical procedures. [21] Delays in diagnosis are most often laid at the door of primary care physicians, pathologists, and radiologists rather than oncologists, although oncologists are vulnerable to diagnosis-based lawsuits for missed or late diagnosis of late relapses or secondary tumors in cancer survivors. Regarding chemotherapy dosing errors, Dr. Legant notes a change in oncology care that increases the risk of error:

Until recently, oncologists would write and then communicate orders to office-based pharmacists and nurses, who would subsequently prepare and administer the drugs under their direct supervision. With recent changes in insurance reimbursement, however, drug preparation and administration are moving outside the office and into hospital outpatient departments. [21] Order transfers in general involve a risk of error, and this risk increases in the case of this relatively new scenario given the inexperience of hospital staff versus oncology office staff in handling orders.

Dr. Legant also discusses approaches for avoiding litigation. These include good patient–physician communication with time taken to listen and express sympathy with patients; good follow up through helping patients keep appointments and diligently monitoring key marker points for response to treatment such as x-rays and scans; good teamwork and communication among oncologists, nurses, pharmacists, and other staff; and sincere apologies and communication about steps that will be taken to address the results of medical errors. [21]

Dr. Daniel Morris notes a malpractice risk that is discussed in relation to the involvement of family members of oncology patients in questioning the appropriateness of care for their loved one. [22] Often, we think of family member dissatisfaction as stemming from close involvement in the patient’s care and concerns that may or may not have a factual basis and, like the patient’s response to his or her care, be influenced by the quality of the oncologists’ communication with both patients and family members. In some cases, however, dissatisfaction with care may come from the concerns or suspicions of family members who do not enter the picture until the patient’s death, having been absent during his or her care. While there are no clear “preventive” responses to this area of risk, improved

communication and other responses mentioned above are all the more important in these cases. [22]

Ethical implications of medical errors in oncology: responsibility and accountability

The Institute of Medicine report, "To Err is Human," and subsequent efforts to implement its directives have influenced a gradual movement away from a culture of blame and moral censure of health professionals who have committed a medical error toward a culture of systemic change based on openness and early disclosure, with clear policies and procedures to support this movement. While this shift is already producing positive results in the USA and other countries with similar approaches to medical errors, the role of individual responsibility and accountability, not only in legal but also in moral terms, remains key to effectively facing and preventing medical errors.

Bioethicist Edmund Pellegrino argued that prevention of medical errors is only possible through parallel organizational and systemic changes and a corresponding reinforcement of the sense of moral duty and accountability of each individual health professional who works in those organizations and systems of care. [23] "Medical errors," Dr. Pellegrino wrote, "take place in a nexus of intricate human relationships," and any system designed to protect patient safety must also foster in its individual members the ethical duty to possess and enact clinical competence and moral character to assure patient's safety. [23]

Reaffirming the moral nature of medical errors, inevitably associated with receiving and accepting blame, as well as with the classical moral tenets of accountability and personal responsibility, is especially important in oncology where many physicians, nurses, and other professionals work closely in teams. Often specific responsibilities are not assigned clearly and accurately enough at the onset, leading to some degree of confusion when a medical error occurs and to the potential loss of a sense of individual accountability of each team member. When multiple teams superimpose and interact in the care of cancer patients, the risk is even greater. When errors occur, there is a temptation to blame the team or the system, yet we as individual oncology professionals make up such teams and therefore carry a moral responsibility for medical errors of judgment or action even when those errors can be attributed, as well or mainly, to team or systemic lapses or gaps. [23]

The shift from a culture based only on moral and legal blame to a culture of system intervention based on open report of, and communication regarding, medical errors, must not lead us to lose sight of the physical and psychological suffering that an error causes to our cancer patients and their family and loved ones. Acknowledging the uncertainty of oncology practice and the inherent fallibility of medicine and of each one of us professionals should never be accompanied by a more or less

subtle “complacency and dulling of the moral sensibilities of the humans in the system.” [23]

Conclusion: humanity and humility in facing medical errors in oncology

Prevention and reduction of medical errors requires both system change and increased individual awareness and alertness. Patient safety is not an abstract concept referring to the universal category of “patients,” but a concrete praxis involving each cancer patient who has entrusted us with his or her medical care. The centrality of the patient in every clinical encounter and act requires our clinical competence, communication skills, and commitment to provide the best cancer care with expertise, humanity, and humility. [24] By contrast, arrogance can be a major component of medical error and is one attitude that patients often associate with errors that they personally suffered.

In 1980, Dr. Franz Ingelfinger wrote of his experience as a cancer patient facing the dilemma of what prophylactic treatment to have after surgery for an adenocarcinoma of the gastro-esophageal junction. [25] He described the contradictory advice he received from well intentioned colleagues and friends as making him and his “wife, son and daughter-in-law (both doctors) increasingly confused and emotionally distraught.” Those feelings were finally alleviated when “one wise physician friend said, ‘What you need is a doctor.’” Dr. Ingelfinger concluded that “a physician can be beneficially arrogant, or he can be destructively arrogant.” [25]

While he called “beneficially arrogant” those physicians who take charge of their patients and do not shy away from assuming their professional responsibilities in front of difficult treatment choices, Dr. Ingelfinger wrote at a time when the field of oncology was less well developed and sophisticated than at present, and many cancer patients were still ill-informed of their diagnosis and prognosis and not true partners in their own care. As Dr. Allan Berger writes, physician arrogance is, however, regrettably still common and “violates the benevolent spirit of medicine—its very soul—as well as the quality of medical care.” [26]

As we already mentioned, arrogance can be an important element of medical error, or the perception of it, for patients and family members either during the period of care, in reflection on it after the fact, or in the experience of the aftermath of error or suspected error. When a medical error has been committed, the beneficial meaning and effect of the physician’s apology, as several authors discuss in this book, is based on its being humbly heartfelt. As Dr. Nancy Berlinger writes, “Too often in a hospital setting, forgiveness is thought to be automatic—given if a physician makes the apology. But this is cheap grace: a forgiveness achieved without the participation of the injured party.” [27] The injured person’s distress may be exacerbated when physicians fail to disclose, apologize for, and make amends for harmful medical errors, or when they do it unilaterally, failing to consider the patient’s personal and cultural values and beliefs, for lack of knowledge or out of

arrogant attitudes of superiority toward their patients. [28] To restore trust and be granted forgiveness for our mistakes, we must acknowledge them in their moral dimension, not only in their systemic or legal one; disposing of the armor of arrogance and substituting humility and honesty, as well as our best medical judgment and care, in trying to reduce, as much as possible, the impact of having hurt a fellow human being already suffering from cancer and its treatments. Silence is never the right medical, ethical, or existential answer to medical errors. [10, 29]

Kathy Russell Rich was a journalist and writer who lived with cancer for many years, undergoing difficult treatments such as high dose chemotherapy with autologous bone marrow transplant. On December 19th 1999 she wrote, “You know what? A single expression of sorrow and regret would almost have changed everything.” [30] Kathy participated with us in the first ASCO session on medical errors in 2006. With our book, we wish to remember and honor Kathy and all those other patients with cancer who have suffered and endured medical errors during the course of their illness. We also hope to contribute to ongoing efforts to reduce errors in clinical oncology and their medical, psychological, and social consequences for all parties.

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