Improving Medical Outcome – Zero Tolerance
Series Editor: Petra Apell

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Fundamentals of Surgical Simulation

Principles and Practices

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The art of progress is to preserve order amid change and to preserve change amid order.

—Alfred North Whitehead
(15 February 1861–30 December 1947)

Foreword and Introduction of Authors

From a health care administrative perspective, poor quality is primarily associated with higher cost. From a medical staff perspective, poor quality is a cause of disappointment and frustration for individuals and teams wanting to provide best possible care. For a patient, poor quality may result in a medical error drastically changing their quality of life.

With 20 years of experience in life sciences, primarily in medical skills training and business development, I have met powerful and insightful individuals with groundbreaking ideas whose research has contributed directly or indirectly to patient safety. What often strikes me, however, is that despite evidence of more people dying due to medical errors than from motor vehicle accidents, AIDS, and breast cancer; and despite recent improvement initiatives with proven clinical effect, such as the WHO Surgical Checklist, few practical solutions have been implemented and our society still puts very limited resources into issues concerning patient safety. To increase awareness and perhaps catalyze change, the book series "Improving Medical Outcome – Zero Tolerance" has been created. Each book will tackle a specific area of quality and patient safety; and leading experts will share their expertise and personal views on quality improvement strategies.

In this book, Prof. Anthony Gallagher and Prof. Gerald O'Sullivan have combined and integrated their unique perspectives on surgical training to produce a scholarly volume on training, learning, and practice of modern surgery. Prof. Gallagher is an experimental psychologist of international renown and a highly cited researcher in the field of human factors, objective assessment, and simulation. Prof. O'Sullivan is internationally renowned for his work as a practicing surgeon, cancer researcher, and professional leader within Irish, European, and World surgery. Using their expertise to analyze why modern image guided surgery is difficult to learn and practice, they have concluded that the difficulties faced are not just related to human factors, but arise from fundamental problems associated with a century old way of training in surgery. Gallagher and O'Sullivan propose the current Halstedian apprenticeship approach to training surgeons should be supplanted with a systematic, evidence-based, quality-assured approach based on simulation and not on clinical exposure and experience alone. They propose using a metric-based, deliberate practice curriculum requiring trainees to objectively demonstrate a pre-defined level of skills before being allowed to implement and consolidate their skills in the clinical environment. The authors give a detailed account of the principles and practices of how this approach to training works, i.e., Proficiency Based Progression (PBP), including insights into a number of clinical trials utilizing this approach. Prospective, randomized, and blinded clinical trials have shown that proficiency-based progression trained surgeons perform significantly better than their traditionally trained counterparts.

The implications of this proficiency-based approach to the training of surgeons are profound. Appropriately trained surgeons and fellow medical staff team members can be expected to more reliably and uniformly provide the best possible care to patients. Improved care and less medical errors will lead to reduced costs. Most importantly, the ramifications of the proposed training approach will have a real impact on the quality of care and safety at individual level.

It is my wish that this book will become a true companion for individuals working with medical skills training and assessment. A companion, giving valuable advice or perhaps just make you think and act differently.

Petra Apell, M.Sc.

Disclosure: Mrs. Apell has held senior positions at Orzone AB, Mentice AB and Johnson & Johnson. Mrs. Apell is owner of Aproficio AB, holds shares in Orzone AB, and ensures she has not influenced the authors of this book to favor any of the companies in which she has financial interests.

Preface

The spectacular developments in surgery and procedure based treatments brought to the agenda concerns about the training and development of skills by young doctors and the acquisition of modern techniques by experienced surgeons. There is a widespread recognition that the traditional system of skill development in the operating room is no longer adequate. Many of the operations that were commonly performed and were used in whole or in part for basic training experiences are no longer in common usage. Forty years ago a third-year general surgical resident could expect, each week, under supervision to perform or significantly participate in several open abdominal "set piece" operations such as vagotomy and drainage, open cholecystectomy, and hernia repair. The cure of ulcers by medical treatment replaced vagotomy and the widespread adoption of minimally invasive surgery for cholecystectomy and hernia repair removed large and important educational opportunities fundamental to the basic training programs of most of the surgical specialties. In addition, the introduction of working time directives and the requirement to train more surgeons without commensurate expansion of services restricted the clinical experience of the individual trainee.

The introduction of minimally invasive surgery, particularly laparoscopic cholecystectomy, was accompanied by an increased frequency of complications, many life-threatening, particularly during the early experiences. That these problems could occur when experienced surgeons, well versed in open procedures and with knowledge of anatomy and pitfalls embraced new procedural practices heightened concerns about the training of novices who lacked such a background in open surgery. But the agenda was now set, surgery needed to develop new methods for training the novice in surgical approaches in general and for training experienced surgeons in the newer techniques. A series of high profile adverse medical events drew the attention of the general public to issues of clinical training. The societal response was best epitomized by The Bristol Inquiry – "there can be no more learning curve on patients." Surgery was forced to confront realities and to consider new approaches to surgical training – particularly the development and use of simulation to train and develop new techniques and procedures "off site." Surgeon Trainers were forced to engage with psychologists and computer engineers to develop new simulation technologies and to validate simulation based transfer of training to the clinic and operating room.

In *Fundamentals of Surgical Simulation* we attempt to provide a resource for program directors, surgical trainers, surgical trainees, psychologists, simulation engineers, and researchers. For trainers, this book gives explicit theoretical and applied information on how this new training paradigm works thus allowing them to tailor the application of simulation training to their program, no matter where in the world they work. For the trainee, it allows them to see and understand the rules of this new training paradigm thus allowing them to optimize their approach to training and reaching proficiency in as efficient a manner as possible. For the simulation researcher, engineer, and medical profession *Fundamentals of Surgical Simulation* poses some difficult questions that require urgent unambiguous and agreed answers.

This book is the product of a friendship and mutual respect between an experimental psychologist and a practicing surgeon/surgeon trainer. This friendship permits forthright exchanges of views and endures many agreements and disagreements particularly on the science and philosophy of surgical simulation, training, assessment, and validation. The outcome has been consensus, fellowship, friendship, and an abundance of (Irish) *craic*.

AGG
GCO'S

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Prof. George Shorten (Anaesthetics/Dean of Medicine, University College Cork): A new breed of medical leadership that understands the opportunities and threats offered by simulation based training.

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Anthony G. Gallagher
Gerald C. O'Sullivan

Contents

Chapter 1
Agents of Change

Halsted: The Beginning of the Modern Surgical Training Program

In August 1922, Dr. William Stewart Halsted returned to Baltimore from his summer retreat (High Hampton, North Carolina) with symptoms of choledocholithiasis. He had had his gallbladder successfully removed at Johns Hopkins Hospital in August 1919 and had remained symptom free until this occasion. However, despite a successful reoperation and attentive care by his colleagues he developed pneumonia and pleurisy of which he died on Thursday, 7 September 1922. Even at the start of the twenty-first century the stature of Halsted's contribution to medicine remains undiminished despite revelations about his private life. He was educated at Yale University (where there is no record of him ever borrowing a book from the library) and the University College of Physicians and Surgeons in New York, after which he took up a position as a house physician at the New York Hospital. One of his earliest contributions to patient care that still exists to this day is the introduction of the temperature, pulse, and respiration recordings to the patients chart. In 1884, Halsted commenced a series of experiments on himself and his colleagues investigating the anesthetic powers of cocaine. Unfortunately, during the process of these experiments Halsted and several of his colleagues became addicted to cocaine. Although hospitalized and treated for his addiction on at least two occasions it emerged after his death that his addiction had been treated by switching from cocaine to morphine, to which he remained addicted throughout his life. Most of his peers and colleagues assumed that his addiction to cocaine had been cured during his hospitalization in Rhode Island. However, private diary notes by Sir William Osler (the first chief of medicine at the Johns Hopkins Hospital), who was also Halsted's physician, clearly indicated that Halsted was never able to eliminate his daily use of morphine. Osler noted that Halsted could work comfortably and maintain his "excellent physical vigor" on three grains of morphine per day (about 180 mg). In later years (i.e., 1912), Osler noted that Halsted had reduced his consumption to about 1½ grains/day.

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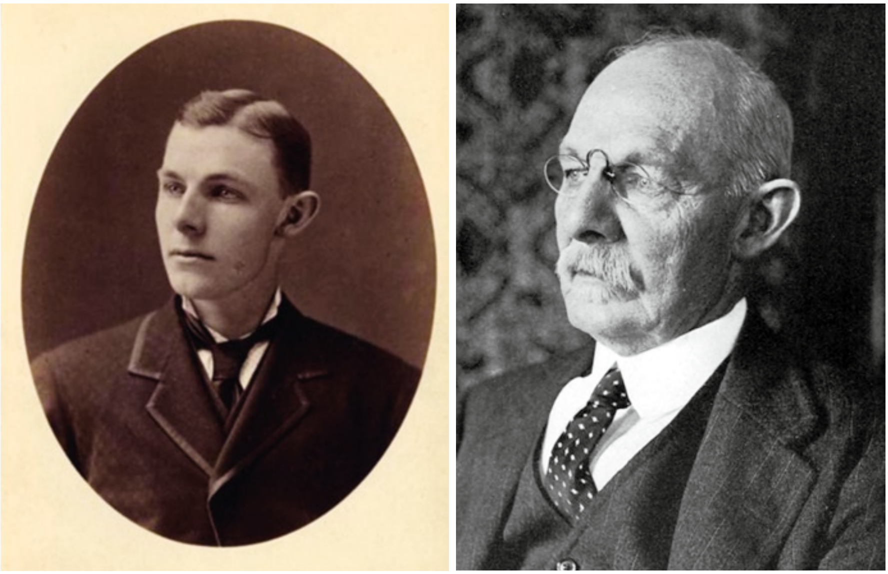

Fig. 1.1 Dr. William Stewart Halsted (1852–1922). Portrait of William Stewart Halsted, Yale College class of 1874 (Photograph courtesy of the Yale University Manuscripts & Archives Digital Images Database, Yale University, New Haven, CT)

During his time living and working in New York, Halsted was outgoing, gregarious, sociable, energetic, and vigorous. However, when he moved to Baltimore he led a quiet and scholarly life which bordered on reclusive. He appeared to be a solitary figure with few friends or close acquaintances at Hopkins throughout his career. Dr. John Cameron (1997) a subsequent Chairman of Surgery at Johns Hopkins speculated that this marked change in Halsted's demeanor probably resulted from his humiliation by his addiction. Despite this burden Halsted's contributions to surgery included recognizing the importance of submucosal suturing for intestinal anastomosis, development of radical mastectomy for cancer of the breast, and development of a surgical procedure for inguinal hernia repair. He was also the first surgeon to promulgate the philosophy of safe surgery by introducing rubber gloves into the operating room and advocating that the gentle handling of tissues, careful hemostasis, and the use of meticulous surgical technique. Even though general anesthesia had been introduced in the early nineteenth century, during Halsted's time most surgeons still operated rapidly with little concern for hemostasis (as though the patient was still awake during the procedure). By the time of his death the American surgical community had accepted his philosophy of safe surgery and took full advantage of the operative benefits anesthesia afforded for technical skills application during surgery. However, Halsted's (Fig. 1.1) single greatest contribution to modern healthcare was the development and implementation of the first system to train young surgeons.

Surgical Training

In the latter part of the nineteenth century there were no formal training programs in surgery. Individuals who were qualified or experienced in the practice of surgery were not particularly interested in training other surgeons who might then become competitors in private practice. Halsted devised a surgical training program at Johns Hopkins Hospital based on what he had learned from a number of well-known European surgeons. He established a surgical training program that was based on strict dedication to the bedside study of disease and graded responsibility with a clinical teacher. He also established that surgery was best learned by hands on experience and education within a hierarchical training program. His training program consisted of a 1-year internship, followed by 6 years as an assistant resident. If successfully navigated, this period culminated in 2 years as a house surgeon. The term (surgical) "resident" comes from Halsted's training program. His trainee surgeons were discouraged from marrying, lived in the hospital where room, board, and training were provided in exchange for service to the hospital 24 h a day, 7 days a week. This pattern of long work hours and service commitment was wedded (and indeed probably still is in some quarters) to the persona of becoming a surgeon.

The training system developed by Halsted at John Hopkins Hospital was based on the German system, and as such, it was autocratic and pyramidal in structure. Although eight residents entered training in first year, four of these positions were for only 1 year and of the remaining four, only one became a surgeon and the other three spent long periods of time with no guarantee of becoming staff surgeons. The system aimed at producing one outstanding surgeon that then went on to become a Professor (Grillo 2004). In this sense, the Johns Hopkins training model worked very well as graduating surgeons went on to establish training programs at other distinguished institutions such as Yale, Duke, and Brigham Hospital based on the Halsted training model.

One of the first major changes to this training system was introduced by Dr. Edward Delos Churchill (1895–1972) at Massachusetts General Hospital (MGH). Churchill was critical of the Halstedian training model for two reasons. The first was that the training model developed at Johns Hopkins unintendedly produced a number of poorly trained surgeons because they left training after completion of 1 year or shortly afterward. The second reason was that the training system was somewhat authoritarian in that it depended on the formation of a relationship between the dominant master surgeon and the docile trainee. Churchill believed that this was anti-intellectual (Pellegrini 2006). Churchill proposed a new training structure at MGH which intellectually and philosophically departed considerably from the traditional Halstedian approach to training. In the traditional MGH training structure there were eight residents, six of which were trained for 2 years with two being advanced to the 4th year level. The first change that Churchill advocated was that the total number of residents entering the training system in any given year should be decreased to six, with four of them obtaining a 4-year training (which meant they were fully trained) and two would remain in the hospital and might be destined to become master surgeons at MGH or go on to take up leading academic positions at other institutions. However, he also proposed that the residents should be trained by a group of master surgeons rather than a single dominant personality. One of his intentions in implementing this training structure appears to have been to minimize or obviate the self-aggrandizing and authoritarian relationship which was such an integral part of the apprenticeship model of training (Grillo 2004). The rectangular system proposed by Churchill would remain, with minor modifications, the core structure of the residency training systems in the USA until the end of the twentieth century. As Pellegrini (2006) points out, Churchill believed that the residency training structure should be implemented in such a way that it allowed for flexibility which enabled individual residents to follow up any specific interests they had and it also allowed the acquisition and development of proficiency. This idea of proficiency and flexibility in progression will be discussed further in Chap. 8.

The enactment of the servicemen's readjustment act of 1944 (or the GI BILL) was a defining moment for surgical training. It was created to train medical officers returning from World War II and marked the first time that surgical trainees in the USA received payment (Sheldon 2007). Although surgical trainees received some payment, the life of surgical trainees remained austere up until the 1970s. Just as in Halsted's era, they rarely left the hospital which provided them with meals, white uniforms, laundry, and somewhere to sleep. The next major change in surgical trainees' lifestyle was initiated by the Medicare and Medicaid Act of 1965 which provided a mechanism for surgical trainees to receive financial compensation for care that they had previously given for free (Sheldon 2007). Surgical trainees observed huge increases in their salaries as a result of this landmark health care legislation. Possibly as a result of these changes and changes in attitudes to work during the 1960s and 1970s, the restrictive lifestyle of the Halstedian training paradigm began to lessen. Trainees began to marry and move out of the hospital and were no longer available for service delivery 24 h a day (Wallack and Chao 2001). Despite these changes, surgical training remained arduous with the trainees working long hours, frequently on call every other night and going home only after the work was completed. Indeed, this work ethic and culture persisted in surgical training until the late twentieth century when the death of a young woman in a New York hospital brought into question the safety of having trainee doctors who had been on duty for long hours take care of sick patients.

Agents of Change

The Halstedian approach to training in surgery existed for the best part of a century, and despite its critics was effective. Indeed, it was so effective that the rest of medicine, more or less imitated the training program that had been pioneered at the Johns Hopkins and refined at MGH in Boston. However, all that was to change in the latter part of the twentieth century. Surgical training was about to undergo a paradigm shift in the way surgeons were trained and this revolution would impact on how *all* doctors were trained. Thomas Kuhn (1962) argued that science does not progress via a linear accumulation of new knowledge but undergoes periodic revolutions or so-called *paradigm shifts* in which the nature of scientific enquiry within a particular field is abruptly transformed. He also argued that paradigm shifts do not occur by accident, but instead are driven by agents of change. An agent of change can be something as simple as a growing body of evidence that demonstrates significant anomalies against an accepted paradigm or approach (such as the Halstedian approach to training). At some point in the accrual of this evidence the discipline is thrown into a state of crisis. During this crisis, new ideas, perhaps ones previously discarded are tried. Eventually, a new paradigm is formed which gains its own new followers and an intellectual battle takes place between the followers of the new paradigm and those who held on to the old paradigm. However, Kuhn (1962) argues that this is not simply an evolution of ideas, but a revolution. Furthermore, the new paradigm is *always* better and not just different. Paradigm shifts have occurred most frequently in the natural sciences and have always been dramatic, particularly in what appeared to be a stable and mature area of research and study. For example, Lord Kelvin in an address to an assemblage of physicists at the British Association for the Advancement of Science in 1900 famously stated that “there is nothing new to be discovered in physics now. All that remains is more and more precise measurement” (Smith and Wise 1989). Five years later, Albert Einstein published his paper on special theory of relativity which fundamentally challenged the bases of Newtonian mechanics (Pais 2005). In this chapter we will argue that the agents of change impinging on the discipline of surgery were worldwide, varied, pervasive and persuasive and cried out for a different and better way to prepare surgeons for operating on patients. The outcome of this revolution has been precisely that. In the coming pages, we will describe what we believe have been the agents of change.

The Libby Zion Case, USA

Libby Zion was an 18-year-old woman admitted to the New York Hospital, Cornell Medical Center, with fever, agitation, delirium, and strange jerking movements of her body on March 4, 1984 (Asch and Parker 1988). Within 8 h of admission, she was dead. The exact cause of her death was never conclusively demonstrated although it is widely suspected that she died because of serotonin syndrome. Her father, a lawyer and New York Times columnist, believed that she had died as a result of inadequate care from overworked and inadequately supervised medical residents. Her father conducted a very public and emotional campaign against the hospital and doctors and claimed that the death of his daughter was tantamount to murder. In 1987, the intern and resident who cared for Libby Zion were charged with 38 counts of gross negligence and/or gross incompetence. The grand jury considered evidence that a series of mistakes contributed to Libby Zion’s death including the improper prescription drugs and the failure to perform adequate diagnostic tests. Under New York law, the investigative body for these charges was the Hearing Committee of the State Board for Professional Medical Conduct. The hearing committee unanimously decided that none of the 38 charges against the two residents were supported by evidence (Spritz 1991). However, the final deliberations on this case rested with another body, the Board of Regents. In a surprise decision the Board of Regents voted to censure and reprimand the resident physicians for acts of gross negligence. Although the decision did not affect their right to practice as doctors and was overturned in the appeal Court in 1991, the decision of the Board of Regents caused considerable concern among practicing physicians in New York City and nationally.

As a result of a grand jury indictment of the two residents, the New York State Health Commissioner (David Axelrod) established a blue ribbon panel of experts headed by Dr. Bertrand M. Bell from Albert Einstein College of Medicine to address the problems in residency training. The Bell Commission put forward a series of recommendations that addressed several patient care issues one of which was resident work hours (Asch and Parker 1988). In particular, they recommended that residents could not work more than 80 h a week or more than 24 consecutive hours. In 2003 the Accreditation Council for Graduate Medical Education (ACGME) adopted similar regulations for all accredited medical training institutions in the USA (Philibert et al. 2002). These changes in training practices shook the medical establishment to its very roots and continue to reverberate. In general, both residents in training and attending surgeons thought that the quality of care given to patients had been negatively affected by the introduction of an 80 h work week (Whang et al. 2003) despite objective evidence that found no differences in the quality of care received by patients or quality of education experience received by trainees pre-and post the introduction of the ACGME work hour limit (Hutter et al. 2006).

European Working Time Directive

In the USA, pressures to reduce the number of hours worked by doctors in training emanated from an incident that occurred in medicine. However, pressures to reduce the number of hours worked by junior doctors in training in the UK and Europe derived from an entirely different source. The European Union Working Time Directive (EWTD) was first drafted in 1993 and was introduced to improve the living and employment conditions of workers within the European Economic Community. The most commonly known clause within the directive is that which is associated with a 48-h working week and the opt-out associated with it (Adnett and Hardy 2001). The directive, adopted in 1993 and amended in 2003 has been incrementally introduced in European nations with the final stage introduced on August 1, 2009. When first adopted in November 1993 the working time directive excluded the air, rail, road, sea, inland waterway and lake transport, sea fishing, offshore work, and the activities of doctors in training, as it was decided that these sectors required individual specific legislation to accommodate working time measures. A further directive covering these sectors, known as Horizontal Amending Directive was adopted on August 1, 2000. The entitlements in this legislation include:

- A limit of an average of 48 h work a week, up to maximum of 60 in any one week
- A limit of an average of 8 h work in 24, but no more than 10
- A right for night workers to receive free health assessments
- A right to 11 h rest a day
- A right to a day off each week
- A right to an in-work rest break if the working day is longer than 6 h
- A right to 4 weeks paid leave per year

It is fair to say that few issues have generated as much controversy or legal challenges as this directive, particularly within the medical profession. Doctors' leaders argued that if their American colleagues found it challenging to train doctors in the ACGME mandated 80 h/week, they would find it impossible within a 48-h time frame. When the legislation was first introduced there was some compromise with its implementation. However, in 2008 the European Parliament voted to end the right of individual doctors in member states to opt out of the directive. There is little doubt that the EWTD posed considerable organizational difficulties for its implementation in medicine. It was also widely believed that the directive compromised the training of future surgeons (Lowry and Cripps 2005) and as such was unpopular with UK trainee and trainer surgeons. In the UK, the implementation of the EWTD meant that doctors had to move to a shift pattern of working. This type of work practice allows important information loss about clinical care during the increased number of handovers. However, it should be remembered why this legislation was introduced in the first place.

The practice of working at night was made possible by Edison's commercialization of electric light in 1882. This extended the working day to 24 h a day, 7 days a week; fatigue caused by working longer hours and round-the-clock became a major social issue. The emerging labor movement in the early 1900s eventually influenced work hour regulations and laws and the concept of hours of service regulation emerged. As a result, the issue of workplace fatigue became intertwined with labor pay and rights issues and led to regulatory limits on work duration and minimums of off-duty time duration in all transportation modes by the middle of the twentieth century (Moore-Ede 1993). Research conducted in the late 1970s demonstrated that the brain's circadian clock exerted strong control over time, duration, and stages of sleep. Because of this circadian regulation of sleep, there was an important difference between sleep opportunity and the amount of sleep it was possible to obtain during that opportunity. For example, even under ideal sleeping conditions, individuals who slept 8 h when they went to bed at 11 p.m. would only sleep 6 h if they went to bed at 3 a.m., and only 4 h if they went to bed at 11 a.m. even though they had been kept awake all night (Åkerstedt and Gillberg 1986; Daan et al. 1984).

Around about the same time studies reporting on the link between sleep pattern, fatigue, and accidents started to appear in the scientific literature (Dembe et al. 2005; Samkoff and Jacques 1991; Schuster and Rhodes 1985; Wojtczak-Jaroszowa and Jarosz 1987). Furthermore, a series of major industrial accidents occurred between 1970 and 1990 where human operating errors related to fatigue were linked. These included:

- The Chernobyl nuclear reactor explosion in the Ukraine, where 237 people suffered from acute radiation sickness of whom 31 died within the first 3 months, 135,000 people were evacuated from the area (Hallenbeck 1994).
- Flixborough, where a chemical plant explosion destroyed an English Village on 1 June 1974, killing 28 people and seriously injuring 36.
- Piper Alpha North Sea oil platform which exploded and killed 167 people in 1988.
- In the city of Bhopal, India, December 3, 1984 a poisonous gas cloud escaped from the Union Carbide India Limited (UCIL) pesticide factory. The cloud contained 15 metric tons of methyl isocyanate (MIC) covering an area of more than 30 square miles. The gas leak killed at least 4,000 local residents instantly and caused health problems for at least 50,000 others.

These types of incidents led to in-depth analyses of how they occurred and precipitated the evolution of a systematic understanding of the relationship between human operative error and fatigue. These efforts have been greatly informed by the work of Prof. James Reason (1990) who had been an advisor to the Royal Air Force and NASA on human error. Reason pointed out that most major accidents are the result of multiple latent system errors and not just by the immediately obvious act of error by the human controller (Reason 1990). He suggested that many accidents were in fact not accidents but a series of events that set the occasion for an adverse event to happen. All that it took for these "accidents" to occur was the right set of environmental circumstances which invariably revolved around a person or persons. Avoidable human factors such as fatigue due to sleep deprivation which are known to be associated with increased probability of errors should not be allowed to happen, should be specifically anticipated and dealt with at a senior organizational level.

The relationship between errors in medicine and sleep deprivation was established in the 1970s (Friedman et al. 1971). Friedman et al., reported that interns made almost twice as many errors reading electrocardiograms after an extended workshift (i.e., 24 h or more) than after a night's sleep. More recent studies have shown that surgical residents make up to twice as many errors in the performance of a simulated laparoscopic surgical task after working overnight than after a night of sleep (Grantcharov et al. 2001). Although the literature as a whole suggests that sleep deprivation causes substantial decrements in physicians' performance (Gaba and Howard 2002; Weinger and Ancoli-Israel 2002) this is not accepted by some in the medical community. For example, Dr. Malcolm Lewis, Director of Postgraduate Education for General Practice at the School of Postgraduate Medical and Dental Education in Cardiff University (Wales) and chairman of the Committee of General Practice Education Directors, (a UK-based forum) has questioned the relationship between fatigue, work hours, and medical errors. In an interview for a Canadian medical Journal, he stated that "the perceived advantages [of the EWTD] are of less tired workforce and of improved patient safety as a result. This is of course theoretical and I am not aware of a body of evidence to support the perception" (Villaneuva 2010). It is of course possible that Dr. Lewis is unaware of the large volume of well-controlled, quantitative research that directly links decrements in performance to fatigue and sleep deprivation. However, what is less believable is that he is unaware of the results from studies in medicine, published in leading medical journals that have directly established a relationship between medical error, sleep deprivation, and fatigue. For example, Landrigan et al. (2004) investigated the effects of reducing intern work hours on serious medical errors in intensive care units, using a prospective, randomized study design. They compared performance of interns working according to a traditional schedule with extended (i.e., 24 h or more) work shifts every other shift (i.e., and every third night call schedule) and a schedule that eliminated extended work shifts and reduced the number of hours worked per week to 63 h. They found that interns made significantly more serious medical errors when they worked frequent shifts of 24 h than when they worked shorter shifts. Interns made approximately 21% more serious medication errors during the traditional schedule and they were also five times more likely to make a serious diagnostic error. Furthermore, the data for this study was from direct observation of the intern's performance rather than self-reported.

From the wealth of published data on the effects of fatigue on performance in a variety of industrial and occupational settings, the results are unambiguous, i.e., it significantly degrades human performance and considerably increases the probability that an error will be enacted. However, fatigue poses a particular and very real problem on a daily basis for particular types of surgical specialties such as neurosurgery, ophthalmic surgery, otolaryngology surgery, plastic surgery, or any type of surgery requiring a microsurgical techniques (e.g., tendon repair, vascular anastomosis, etc.). Physiological tremor arises from mechanical and neuromuscular sources and is made worse by a number of factors such as dehydration, caffeine, cigarettes, anger, fear, stress, and fatigue (Patkin 1977). Unfortunately for surgeons using this particular technique, increased hand tremor is a natural result of normal operating procedures and is a simple fact of the job resulting from muscle fatigue (Slack and Ma 2007). Surgeons who employ microsurgical techniques on a regular basis go to great lengths in an effort to control their hand tremor. These include biofeedback training, maintenance of a healthy lifestyle, ensuring they are well hydrated before operating, abstaining from coffee and nicotine, and sometimes resorting to taking beta-blockers (Elman et al. 1998; Ferguson and Jobe 2004; Harwell and Ferguson 1983). However, within these operators, fatigue is recognized as the most tremor producing factor and situations which induce fatigue prior to operating should be, where possible, avoided. Unfortunately, injuries which require the application of these types of surgical skills occur irregularly but commonly at inconvenient times such as during the night, in a patient admitted to accident and emergency as a result of a road traffic accident. The only safe approach to this type of scenario is for the surgeons to maintain a state of readiness, and that means minimizing surgical interventions by fatigued surgeons.

Other factors that need to be kept in mind are the findings from the 1960s, relating performance to levels of arousal and the presence of others, who would appear to have important implications for the practice of surgery. Scientific investigation of the effects of an audience dates back over a century. In 1904, a German researcher conducted experiments concerned with muscular effort and fatigue. He noted that the subjects were able to exert far more muscle effort on days that he watched as compared to the days on which they were not watched (Meumann 1904). However, Zajonc (1965) suggested that the situation was not that simple, and that the presence of others energized individuals and increased their drive level. An increase in drive strengthens the dominant response of the organism, i.e., the response most likely to occur. At the same time, an increase in drive weakens responses that already are weak. What this means is that under stressful conditions individuals will respond in a way that is very familiar or is easier for them. For example, in a simple or well-learned task, familiarity with what is required exists or the task has been practiced several times, thus the strongest and most likely response is the one that is appropriate and correct. In a complex and difficult task on the other hand, the strongest response is likely to be the wrong one. Complicating matters further is the Yerkes–Dodson law (Yerkes and Dodson 1908) which establishes an empirical relationship between arousal and performance. The law dictates that performance increases with physiological or mental arousal, but only up to a point. When levels of arousal become too high, performance decreases. The process is often illustrated graphically as a curvilinear, inverted U-shaped curve which increases and then decreases with higher levels of arousal. What this means for the practicing surgeon is that the skills which are very familiar and or well trained are more likely to be performed well in situations of stress whereas surgical skills which are unfamiliar and or novel to them will not be performed well. These predictions have profound implications for trainee surgeons, particularly in stress provoking situations such as in accident and emergency or in the operating room when unanticipated complications occur. This type of response is most likely to occur for surgical trainees (of *any* level of seniority) if the skills they are required to practice are novel, unpredictable, not under the control of the individual, and required to be practiced in the presence of an experienced evaluator (e.g., a more senior surgeon part of whose job is to appraise their performance). Lupien et al. (2007) have reviewed the evidence of the psychophysiological effects of stress hormones (glucocorticoids) on the process of forming long-term memory. They concluded that mildly elevated levels of glucocorticoids enhanced long-term memory formation. In contrast, long-term memory formation is impaired after adrenalectomy (which causes chronic low glucocorticoid levels) or after exogenous glucocorticoids administration (e.g., subcutaneous injection) thus demonstrating an inverted U-shaped performance reminiscent of the Yerkes–Dodson effect.

The Bristol Case, UK

In 1989 Dr. Stephen Bolsin moved from the Brompton Hospital in London to take up position as a consultant cardiac anesthetist at the Bristol Royal Infirmary. He very quickly formed the opinion that the Bristol Royal infirmary had significantly higher complication and mortality rates than what he was accustomed to, and probably higher than the national average complication rate. He identified that too many babies were dying during heart surgery and although he raised his concerns with senior hospital administrators, they refused to investigate. He eventually took his concerns to the media and the ensuing investigation became known as *The Bristol Case* (Smith 1998). The Bristol case centered around three doctors: Mr. James Wisheart, a former medical director of the United Bristol Healthcare trust; Mr. Janardan Dhasmana, a pediatric and adult cardiac surgeon; and Dr. John Roylance, a former radiologist and Chief Executive of the Trust. The central allegations against these individuals were that they knowingly allowed to be carried out or carried out operations on children, knowing that the mortality rates for these operations in the hands of the surgeons were higher than the national average. Furthermore, the operating surgeons were accused of not communicating to the parents the correct risk of death for these operations in *their* hands.

One of the earliest concerns raised by Dr. Bolsin was that Mr. Wisheart's operations took up to three times as long as those at the Brompton Hospital and were associated with more complications. By 1993, he had concluded a formal audit that showed that while national average mortality rate for repair of tetralogy of Fallot was 7%, Mr. Wisheart's was 33% and Mr. Dhasmana's was 25%. The audit also showed that while national average mortality rate for atrioventricular canal surgery was 10%, Mr. Wisheart's was 60% and Mr. Dhasmana's was 17%. By the time Mr. Wisheart had retired in 1995, seven of the last eight children that he operated on died. At about the same time Mr. Dhasmana began performing arterial switch procedures on neonates. Although he stopped after performing the procedure on 13 patients, 9 of them died and 1 of them had sustained serious brain damage. A team in Birmingham (87 miles north-east from Bristol) who were performing the same procedure had only 1 death in 200 patients. Mr. Dhasmana's results in older children were also cause for concern with a mortality of 30% compared to about 1% in centers of excellence.

Although Dr. Bolsin contacted the Department of Health in 1993, it was not until 1995 that a new consultant cardiac surgeon was appointed. The Bristol Royal Infirmary Inquiry was chaired by Professor Sir Ian Kennedy and was a landmark case in that it changed how medicine was learned and practiced in the UK (Bristol Royal Infirmary Inquiry 2001). Mr. Wisheart and Dr. Roylance were struck off the medical register and Mr. Dhasmana was disqualified from practicing pediatric cardiac surgery for 3 years. The enquiry concluded that a substantially and statistically significant number of excess deaths (between 30 and 35) occurred in children between 1991 and 1995. The mortality rate over the period was probably double the rate in England at the time for children under one and was even higher in children under 30 days (Bristol Royal Infirmary Inquiry 2001).

Dr. Richard Smith (1998) in his editorial in the British Medical Journal (BMJ) seemed to summarize very well the impact that the Bristol Case would have on medicine in the UK and the international reverberations from it when he said that medicine would be transformed by the case. It had thrown up a long list of important issues that British medical practitioners would take years to address which has proved correct. These included: