



On the quest for six sigma Donald W. Moorman, M.D., F.A.C.S.*

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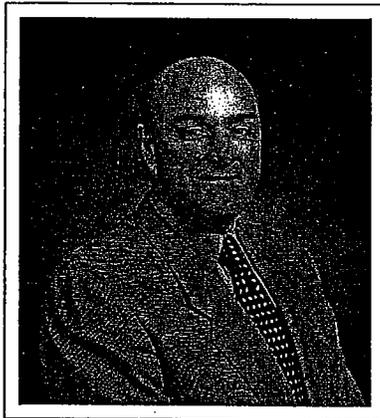
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Abstract

A review of patient safety from a surgical perspective with emphasis on erosion of hierarchy, human factors, and an institutional implementation of multidisciplinary team training to create highly effective dynamic teams. Suggestions include further opportunities to enhance patient safety in surgical patients. © 2005 Excerpta Medica Inc. All rights reserved.

Keywords: Patient safety; Team training; Quality; Dynamic teams; Patient care team



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I wish to gratefully acknowledge my fellow officers and the membership of the Midwest Surgical Association, and sincerely thank you for the opportunity to serve as your president. This association's strength is not only in bridging the worlds of academic and community surgery, but also our core value of family inclusion. It is always a joy to watch our Midwest Surgical family mature. As manifest in the reports we have shared here, the Association's objective of promoting high quality and effective surgical care also is being met.

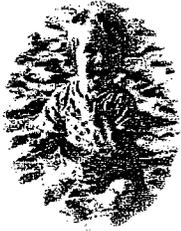
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Too often, however, our individual effectiveness as surgeons is diminished as we interface with the realities of reimbursement, mandates for intensive resource management, burgeoning technologic advances, and the onerous malpractice and surgical workforce issues now looming. But even with all these urgent issues, we must not overlook or deafen the cries from those afflicted with harm derived from our best efforts. As I reflect on the families of our Association, it is a reality that some of us may indeed suffer harm in our complex system. It is hard to believe that one of our beautiful children could befall the same fate as Josie King. A toddler, she suffered a scald burn. Josie did very well through her acute care, and then transferred to a pediatric floor at Johns Hopkins Medical Center. Through a series of unrecognized and subtle errors, culminating in an event of miscommunication, Josie died from dehydration and narcotic overdose. Josie King died despite her mother's every effort to communicate that her baby was dehydrated. Josie King died from an adverse event that is harm caused by medical error (Fig. 1) [1].

The reality of medical error causing significant system-wide harm emerged with the Harvard Medical Practice Study in 1991 [2]. Although previous studies had suggested that systematic flaws created a potential for harm, this study clearly indicated the possibility was a reality and in fact was prevalent. After random review of the medical records of over 30,000 patients receiving care in New York State, the investigators found that adverse events occurred in 3.7%. Extrapolating from the data, the investigators estimated that in 1984 throughout the entire state, there were more than

The Josie King Pediatric Patient Safety Program



"Among the great lessons of Josie's tragedy are the need for uniformly balanced communication between parents and care givers; constant awareness of the possibility of human and systems errors in the delivery of care; and the establishment of additional safeguards against errors."

— Tony and Sorrel King

www.josieking.org

Fig. 1. The death of Josie King highlighted awareness of the need for clear communication between all healthcare providers and patients and their families.

98,000 adverse events, with 2,550 leading to permanent total disability, and 13,451 deaths [2]. The investigators concluded, "The burden of iatrogenic injury was thus large." They further estimated that nationally the number of unnecessary deaths owing to iatrogenic injury was 180,000: realize this is equivalent to 3 jumbo jet crashes every 2 days. Yet, surprisingly, few responded with reform.

Lucian Leape [3], pediatric surgeon and patient safety pioneer, attempted to quantify why these injuries were occurring. By randomly analyzing over 30,000 hospital records, the team was able to identify 1,133 patients with disabling injuries. They were able to classify events and discover relative frequency, but, more importantly, they determined that 17% of events associated with a surgery were from negligence. Of the events not occurring with a surgical procedure, 37% were negligent [3]. The team concluded that although a significant number of disabilities from disease can be prevented only by further medical discovery, a huge proportion could be prevented readily with existing current knowledge, and a system of care redesign.

In 1994, Leape [4] published a seminal report in the *Journal of the American Medical Association* entitled "Error in medicine," in which he drew the parallel between human error science and medical error, an important realization. He concluded that our medical errors seldom were caused by irresponsible or unprepared individuals, but lay in the systems in which we work as latent errors, that is, accidents waiting to happen. He stated, "All humans err frequently. Systems that rely on error-free performance are doomed to fail" [4].

Still, there was little professional or public reaction until the Institute of Medicine (IOM) [5] liberated its 1998 report, "To Err is Human." In the analysis of these and other studies, the IOM concluded that between 44,000 and 98,000 Americans die annually from medical mistakes. The report estimated the cost of injury to be between \$17 and \$29 billion annually, over half of which was the direct cost of treating injury. The committee stated in the report, "Given current knowledge about the

magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years" [5].

Public attention, focused for the first time on this issue, lead to the creation of the Agency for Healthcare Research and Quality. Reporting systems, both voluntary and mandatory, emerged. Our hospitals were mandated to create patient safety agendas. The Leapfrog Group defined volume surrogates for quality and listed hospitals based on the likelihood of best outcomes. The Joint Commission on the Accreditation of Healthcare Organizations created patient safety initiatives. Subsequently, in 2001, the IOM [6] released a second medical error analysis, "Crossing the Quality Chasm," in which they created central recommendations for enhancing safety in health care institutions.

A young mother of 2 is admitted to a regional academic medical center with inflammatory response syndrome of unknown cause. Her case is confusing, until the computed tomography scan is performed, revealing a diffusely thickened stomach. Her liver has multiple lesions, and her laboratory tests curiously are insufficient to create a reasonable diagnostic assumption. Clearly, the team needs tissue, an esophagogastroduodenoscopy is performed, but unfortunately the biopsy specimen only has lymphocytic infiltration consistent with chronic inflammatory response. The team decides a liver biopsy examination is the way to go, but because her inflammatory response is worsening, the patient is moved to the intensive care unit (ICU). First case the next morning, she undergoes the biopsy procedure without apparent incident. Back in the ICU her pulmonary status worsens, and her blood pressure wanes. The medical resident on the case starts pressors and what he believes are judicious fluids. The patient's condition worsens; a hematocrit level decrease of 5% is documented. More fluid and another pressor are given. Finally, the realization 6 hours later that she is bleeding when she is found to have a hematocrit level of 14%, a pH of 6.75, a core body temperature of 34°C, and an international normalized ratio of 3.4. You know the rest: urgent surgical consultation, but at this point, even with the aggressive surgical response, nothing effectively controlled the downward spiral. The review: medical error: classify as a failure to rescue. But 2 small children with no mother, and a young life full of potential now lost forever. Could this happen in your institution? (This was a compilation of cases reviewed to show error chain leading to a too common outcome. This does not represent a single actual case.)

In 1998, the IOM gave us a 5-year mandate, and I am sure as you individually reflect, each of you can identify significant safety initiatives in your hospital or practice. Intravenous pump standardization, bar-coding systems, electronic medical records, physician online order entry systems; the list goes on and on. But, even though the efforts are apparent around each of us, little seems to have changed. Leape lamented in his keynote at the American College of Surgeons, that he has "not seen a big improve-

ment” in patient safety since the IOM report. Although we at Beth Israel Deaconess have done much, I am still seeing too much harm. Bill Grace [7], ethicist and leadership educator, has defined an essential mandate for those who lead. Simply stated, “Speak the truth and point toward hope.” I have spoken what I believe to be the truth, now let me point toward hope.

I refuse to believe any of us, surgeon, physician, nurse, or therapist, has anything but the noblest intent as we approach our daily tasks. We have been taught, drilled, and recurrently reminded of our personal mandate never to fail our patients. Each of us carries this as a central and core value in our very being; that is why we are able to do this job. Our patients are always our responsibility. None of us are average, how could anyone merely average open a human, expose them to the essential frailty of their existence, and bring them back better than when they started without total confidence in their ability? That central sense of responsibility for our patients is the essence through which we earn our patients’ trust. We never fail, therefore our patients are safe.

To that end, one would imagine we already would have succeeded at reaching the Six Sigma level of system performance. Six Sigma as a program is an industrial-quality program, the process defined by mathematic deviations and metric analysis to redesign systems. Six Sigma defines ultra high-quality manufacturing systems, in which only 3.4 defects occur per 1 million opportunities, a nearly perfect production rate of 99.9997% [8]. It also is used to define ultra-safe systems, such as European railways and commercial air transportation. Inherent in Six Sigma as a quality improvement tool is the realization that every human is vulnerable to increasingly definable human errors. We really cannot remember more than 5 to 7 digits when applying them to a task, and we really are prone to slips and lapses when we are distracted and overburdened. Pointing directly to this issue of propensity to err when overburdened and distracted, Aikens et al [9] studied error and mortality related to nurse staffing ratios, finding that when nurse-to-patient ratios were pushed beyond the normal staffing level for the institution, the 30-day mortality increased by 7% for each additional surgical patient. Failure to rescue was the most common associated cause. So in our environment of increasing hospital demand, and ongoing workforce shortages in nursing, the belief that we alone can create a safe environment for our patients is false.

Therefore, the essential mandate of the multidisciplinary team emerges. By creating freely thinking work groups who represent the problems and realities at the sharp end of patient care, we optimize our ability to improve. Autonomy, a value to many in our system, must be replaced by the culture of community.

Beth Israel Hospital and the New England Deaconess Hospital entered into a tumultuous merger in 1996. By 1999 the clinical services were combined, and the result was the progressive erosion of standardization and protocol-driven practice. Care rendered depended on confidence in self and individual freedom from error. Quality ebbed and personal energies dropped. A cul-

ture of blame was quick to emerge. Morale plummeted, and physician and nurse retention ebbed to new and unprecedented lows. A culture of safety? Probably not.

Many in Boston, New England, and nationally thought that with the disruption of staff and huge revenue losses we would falter. But even as we very nearly did, we were able to rally to a commonality of redesign teams. Today Beth Israel Deaconess is becoming financially healthy, and is focused on high-quality care, responsible resource management, and has set patient safety as a strategic priority. This has occurred not through the combined efforts of isolated individuals, but rather through the interdependent efforts of adaptive teams. Our cardiac surgery task force is a great example. Developed when we deemed our outcomes sub-optimal, their multidisciplinary analysis of care process allowed extraordinary improvement. As a concrete example, applying stringent serum glucose control and preoperative process standardization to the issue of deep organ space infections in cardiac surgery, the team virtually has eliminated the problem. To date, we have not had an organ space infection in 16 months. Ultimately, this collaboration has led to excellent outcomes. Although we still have not reached the six-sigma level, we must remember that the process of cardiac surgical care is quite different than manufacturing an automobile.

Tom Nolan [10], a scholar of quality improvement, has identified 3 critical preconditions for improvement: will, ideas, and execution. Armed with a strong will to improve, our redesign teams have approached their areas energized, and have used all existing knowledge to evaluate and discuss problems openly. These teams capitalize on the complexity theory realization that innovation occurs at the edge of chaos, and therefore all voices and ideas are heard and valued, and discovery and productive change is promoted [11]. We have energy to execute our ideas, but only with essential metrics for evaluation.

Highly functioning teams do not just happen. Particularly when we look at the pressures on today’s operating room teams, it is apparent that opportunities for failure are rampant. Care systems have less redundancy, and staffing is problematic at most medical centers. The Association of Operating Room Nurses (AORN) recently identified that fully one third of our operating room nurses in the United States are travelers (Bill Duffy, R.N., President AORN, personal communication). Nursing retention and staffing remain huge issues for most medical centers. Creating a team environment is, at best, challenging. Therefore, we must borrow from other industries to learn how to assemble a clearly communicating highly interdependent team quickly and consistently. Military and aviation crew resource management recognizes the value of each human resource, but also the potential for each human resource to at some moment be vulnerable to error.

On December 28, 1978, United Airlines flight 173 from Denver to Portland was piloted by one of their finest flight crews. The pilot was considered to be one of the most

reliable and best pilots in the fleet. As the aircraft, amply fueled and approaching the end of a near-perfect flight, was challenged by a warning light questioning proper deployment of the landing gear, the crew continued to circle, had indications that the gear was in fact functional, but in an effort to be absolutely sure, continued to scrutinize and check as they literally ran out of fuel. United Airlines flight 173 crashed into the forest 6 miles from the end of the runway. Of the 210 lives on board, 10 were lost, including the flight engineer who had warned the flight crew repeatedly of fuel shortage in the final minutes of the flight. Transcripts from the voice recorder and interviews with the surviving crew revealed that a lack of clear, concise, and assertive communication allowed this tragedy to occur. United Airlines undertook aggressive crew resource management after this incident, and now in simulation training, the major skill analyzed is the effectiveness of crew resource management and communication [12].

Based on these precedents, we at Beth Israel Deaconess have embarked in team training. In a Department of Defense-funded initiative, the Department of Obstetrics and Gynecology initiated team training in labor and delivery. This was considered an ideal starting point because labor and delivery constitutes a fairly narrow scope of practice, an easily identifiable team, was of a manageable size to implement and measure change, and represented an environment of high stress and demand. The labor and delivery project is well under way, and a multi-institutional validation study is in preparation for release in September of this year. But I can tell you 2 important results from our center. After formalized team training at Beth Israel Deaconess alone, team training has resulted in a 53% decrease in potential adverse outcomes in high-risk patients in the past 3 years. During the same time period, despite a national crisis in obstetrics because of skyrocketing malpractice costs, the BIDMC saw a halving of its claims, suits, and observation cases (Benjamin Sachs, M.D., Chair Ob/Gyn BIDMC, Principal Investigator Med Teams study, personal communication).

Therefore, we used the lessons learned from military and aviation crew resource management and developed a robust team-training program for surgery, now in initial phases of implementation in our operating rooms and surgical ICUs. This multidisciplinary program focuses on the dynamics of highly functioning teams, and with recognition of error science and the realization that any one team member may fail. It is not a warm and fuzzy presentation designed to placate the operating room personnel, but rather a focused training program to teach the essentials of team structure, formal communication techniques, and expectations. Training is multidisciplinary with surgeons of all disciplines, anesthesiologists, residents, nurses, technicians, and orderlies. Each session is conducted with a maximum of 30 multidisciplinary participants in every group.

Since we have implemented this program, we already have experienced early indicators of enhanced job satisfaction among our operating room personnel, and the surgeons

SHARED MENTAL MODELS

- A MENTAL MODEL is a mental picture or sketch of the relevant facts and relationships defining an event, situation, or problem
- The SAME mental model held by members of a team is referred to as a "SHARED MENTAL MODEL"

Fig. 2. A Team Dynamics in Surgery presentation slide depicting the definition of shared mental modes and the differentiation from traditional teams in which members work independently toward common goals.

involved have found the processes much less onerous than anticipated. Creating enhanced predictability has resulted in a decrease of overall workplace stress. Over the next 3 months we will complete the training of our 700 perioperative employees, physicians, and residents.

I would like to review a few of our program's highlights, so you more clearly understand what we are doing in this initiative. First, in module one, we validate the concept of team. This is not hard at our center because much work already has been done to erode the concept of autonomy and replace it with collaborative care models. I hope by now you can accept that health care is inherently risky, and we by ourselves simply cannot mitigate all potential errors and harmful events. We must rely on a team, and a team is in fact defined as 2 or more people who achieve a mutual goal through interdependent and adaptive actions, not a group, which achieves its goal through independent, individual contributions. In defining a team as such, the reality of interdependence becomes clear. Despite the fact that some of our surgeons rank among the very best in the world, they never could achieve their outstanding results without a true team, which manifests interdependency and adapts to situational needs. We define our teams, and the necessity for leadership within a team, and all understand the leader of the team may change in various situations. Surely the surgeon cannot lead when the issue is an anesthesia emergency, but in this case must use every team dynamic to allow the optimal response from the entire team in support of the anesthesia leader. We define responsible leadership and distinguish collaborative leaders from tyrannical autocrats, a personality we no longer tolerate because of the potential for disruption of safe and effective care processes. Finally, in this section we teach techniques of conflict resolution through communication, education, and collaboration.

Module two focuses on inherent potential for error, how to plan for its eventuality, and how to mitigate error before it can harm. In this module we review what constitutes a shared mental model and how to achieve it. The shared mental model creates commonality of effort and purpose (Fig. 2). Lack of a shared mental model is the most common

cause of conflict in our operating room environment. We define the elements of a preoperative team briefing, an initial checklist before every operative procedure. Additionally, in this module, we explore basic error science, and help all participants realize an error someday will be theirs. With this realization it becomes a great deal easier to accept the relevance of error prevention strategies, such as cross-monitoring and the communication techniques we teach to trap and mitigate error. We define individual and team competence and mandate clear communication when competence is a concern. We recognize that errors will occur, and although hopefully mitigated, we realize that latent errors may manifest, creating harm. We recognize how a patient harmed creates a second victim, a provider who through emotional response to the harmful event now becomes increasingly prone to error. We present accountability algorithms, and define the culture of just accountability in which we work. Finally, in this module we teach after-action analysis techniques, and caution our teams on the natural tendency to oversimplify in searching for a single cause.

Module three is a favorite, and in it we focus on communication techniques. Kicking off with a communication exercise conducted in pairs, our participants learn the deficiencies inherent in their communication. I marvel how a simple task can become so difficult when we must rely only on the spoken and interpreted words. We train that despite our best intentions, as Thomas et al [13] have shown, there is a communication chasm between nurses and physicians. We have capitalized on this recognition, creating a module in which we teach clear and concise techniques of information transfer. We have decided to use the SBAR (situation, background, assessment, recommendation) military communication technique as adopted by Michael Leonard, Doug Bonacum, and Suzanne Graham at Kaiser for standardized health care reporting (Fig. 3). We promote the use of the standard aviation CUS (concerned, uncomfortable, safety issue) words, and with their use, the specific message to be conveyed is clear (Fig. 4). Additionally, other key words, phrases, and actions are defined so that, when spo-

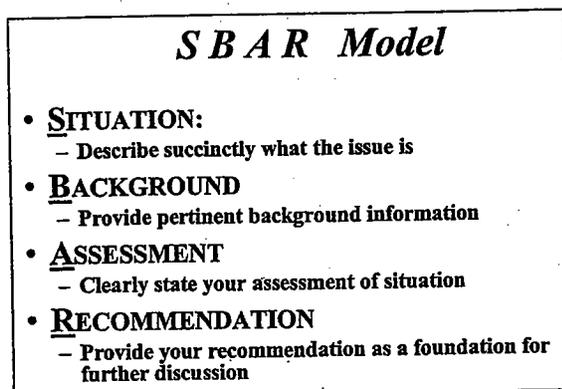


Fig. 3. SBAR is a communication technique developed by the nuclear navy as a model for clear, concise, and relevant communication. This is easily adapted to healthcare.

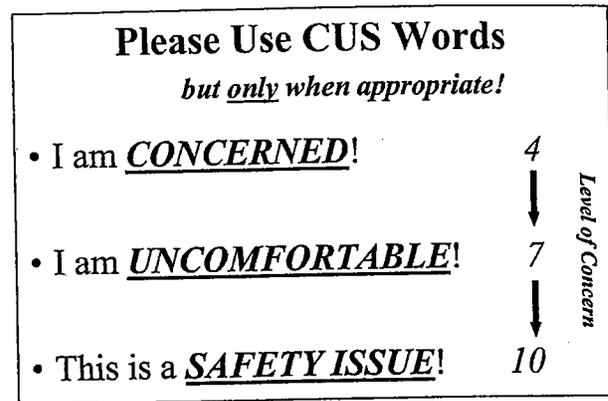


Fig. 4. These common aviation key words have been adapted for our operating rooms to clearly convey levels of concern around patient safety issues.

ken, all team members will understand clearly not only the issue, but also the magnitude of the issue. We teach assertiveness, active listening techniques, and the ways we can obtain and maintain situational awareness, not only for our individual operating room or ICU patient, but for all the demands around us. We review communication lessons learned in the cockpit to encourage problem-solving communication and have trained our personnel that the use of such communication allows the recruitment of the entire team's energies and capabilities to resolve a difficult situation. Last, we empower any member of the team to stop the line if they sense or discover an essential safety breach, an action never to be taken lightly, but requiring immediate cessation of process and resolution of the safety issue.

Module four is about workload management, and we have found that many of our personnel refuse to seek assistance when overwhelmed by tasks. As all of you know, error vulnerability is increased under stress, in high-task situations, and when fatigued. It also is enhanced when we are complacent in boredom, when we lose situational awareness, and when our vigilance is low. We teach the necessity for task prioritization. We teach when and how to appropriately delegate, and that when something is delegated to you, review of appropriateness comes only after the situation is resolved. Once again, a primary value of team is mutual assistance, and we ask all to monitor the workload of others, and offer assistance when they appear potentially overwhelmed.

Module five focuses on performance improvement, and includes techniques for immediate team evaluation and feedback, as well as training so our members become aware of evaluative techniques such as failure mode analysis. We provide the expectation for transparency and truth in such inquiry, and ask all to consider their role in any incident. We define improvement techniques for individuals and teams, which are applicable to units and departments. We recognize the process of change is slow, and the sustainability requires not only ongoing training and role modeling of expected behaviors, but a moral mandate to provide a safer environment of care.

Team dynamics in surgery has become passion for me, and I have invested significant energies in understanding the basics of team functioning and team advantage. It is clear to me when reading the lessons learned from the military and aviation, as well as the interactions I have had with those involved in aviation crew resource management, that erosion of our reliance on our autonomous inability to fail will alone provide significant energy toward creating a culture of safety. Although we still always must strive to do our best, we must rely on our teams.

Team training and collaborative care will have significant impact on outcomes and safety in medicine. Technologic advancements too will be an essential component. But even as these technologic advances promote a safety climate, we must avoid complacency in the technology. There is no quick fix to patient safety. I would reckon, as an example, given the impact of computerized online physician order entry, the schema for reliability ascension would appear roughly to reach three sigma performance (Fig. 5). Going to the next level will take a collage of technologies, but even more essential, the will by each of us to work in a culture of safety. I would offer an analogy for the vigilance we surgeons must adopt to that of a new parent, with a child just mobile. These parents constantly scan their child’s environment for hazards and potential for injury. We must hold the mandate for safety in the same way, with total commitment, and with great will to advantage our patients in safety.

Through my studies in patient safety and my immersion in the science of error prevention over the past year, it becomes clear to me that we really have much to do. I place a challenge on each and every one of you to evaluate your readiness for inevitable error. Can you reliably state your systems of care can trap and mitigate an error before creation of harm? Have you really embraced the mandate that we work diligently to eliminate errors and create an environment of safety? Can you erode the barriers inherent in

| Safety Initiatives and Prevention of Error | | | |
|--|----------------------------------|---|---|
| 1 Sigma | 2 Sigma | 3 Sigma | 4 Sigma |
| Hand Written Orders | Protocols & Standard Order Sheet | Computerize Physician Order Entry (CPOE) | CPOE with Aggressive Decision Support |
| Autonomy | Teamwork is important EDICT | Formalized Team Training-Behaviorally based | Integrated Teamliness as a “spiritual” obligation |

Fig. 5. An analogy of technologic and behavioral safety initiatives on the potential to attain Six Sigma performance. Each commitment of technology enhancement is to some degree additive. For team training to reach significant power, team behavior must become a personal obligation in providing safe care.

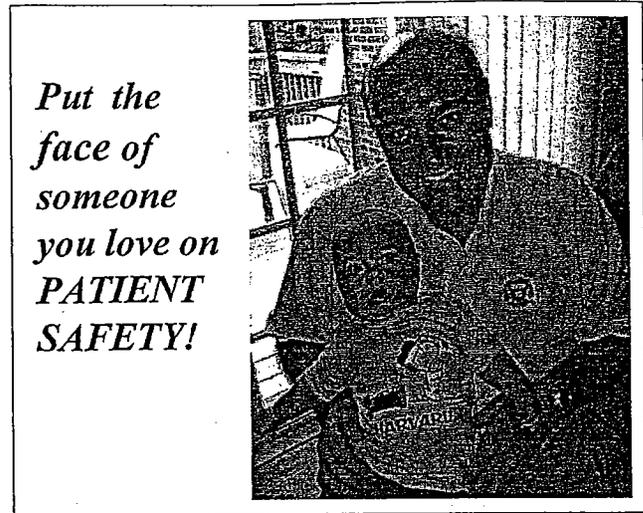


Fig. 6. Dr. Moorman and his new best friend, Spencer, age 3 months.

the rigid hierarchy we ourselves create? What of the numbers, does it really matter? Josef Stalin, minimizing the millions lost in Russia, said, “one death is a tragedy, a million deaths is a statistic” [14]. It does not take 98,000 deaths or even 185,000 deaths for us to act, the motivation of personal tragedy too often is lost. It takes only one. From this day forward do not forget the multitude harmed, but more importantly put a face on the next potential victim. Make that face someone you love. Then your passion will no longer allow complacency (Fig. 6).

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