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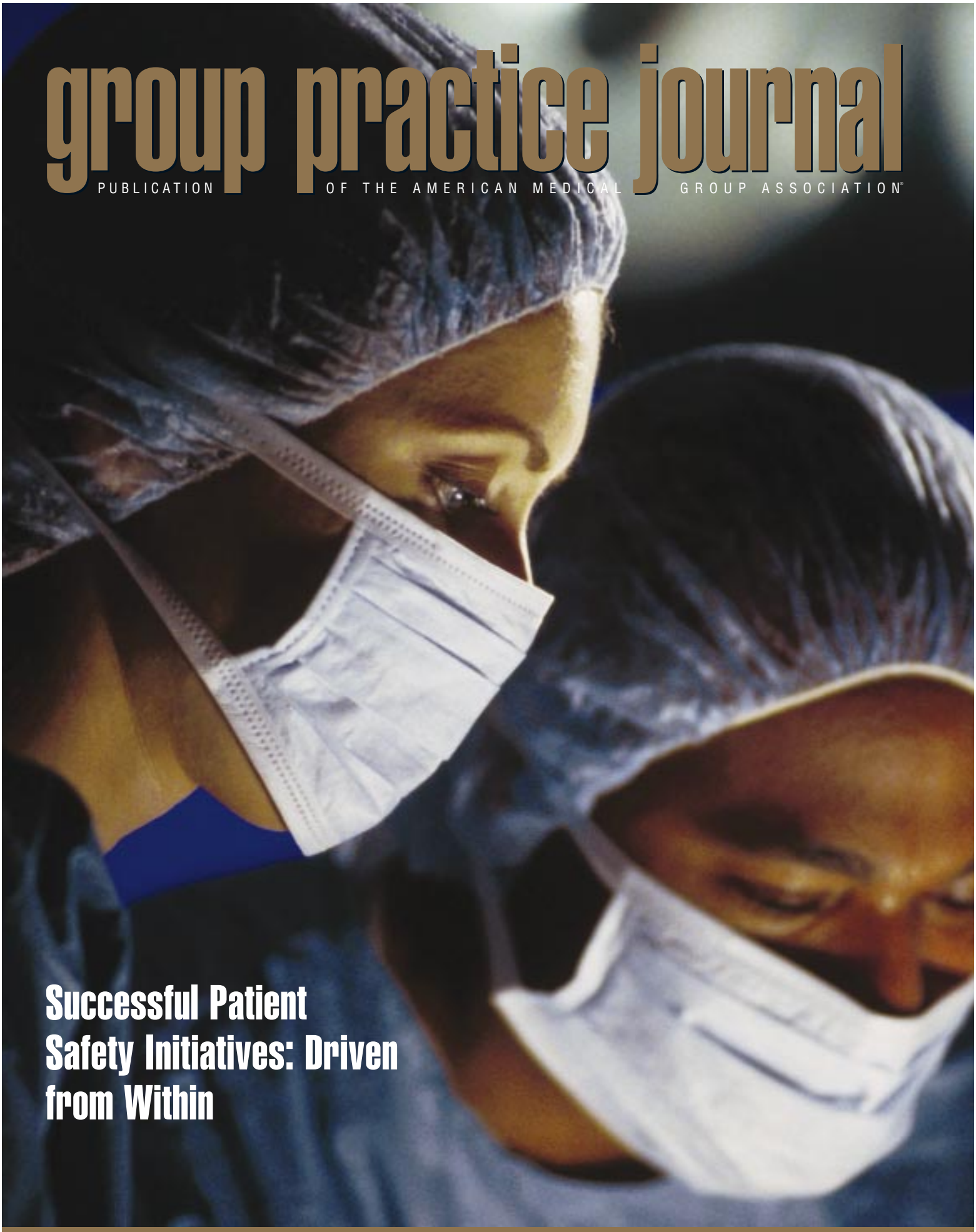

Successful Patient Safety Initiatives: Driven from Within

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Successful Patient Safety Initiatives: Driven from Within

BY ROGER M. MACKLIS, M.D.

Despite intensive publicity concerning medical errors and broad calls for new initiatives related to patient safety, relatively few authoritative reports documenting successful large-scale patient safety interventions have appeared. This disappointing pattern may be due in part to the fragmented nature of American health care and the wide variability in specialty-specific training backgrounds and accepted practices observed within medicine. The application of human factors research analyzed on a system-wide scale would suggest that sociocultural factors and task-specific "change management" principles may provide hints on the reasons that global "best practice" mandates and top-down reengineering are rarely successful. Large-scale health care process changes capable of longitudinal impact and self-amplification are likely to work best when they are designed and reinforced by champions from the specific task groups seeking to show improvement. As in many things, the messenger is an important part of the message. Change initiatives in health care should generally be local rather than global and internally driven by task group members with the standing to confer credibility.

CHANGE INITIATIVES IN HEALTH CARE SHOULD GENERALLY BE LOCAL RATHER THAN GLOBAL AND INTERNALLY DRIVEN BY TASK GROUP MEMBERS WITH THE STANDING TO CONFER CREDIBILITY.

To Err Is Human

By now it is widely accepted that American health care appears to trail many other enterprises in the areas of consumer safety and overall quality assurance. The sobering conclusions from the November 1999 Institute of Medicine (IOM) report entitled *To Err Is Human* included the fact that tens of thousands of American citizens perish each year through mistakes and poor operational performance.[1] These conclusions have been widely discussed and are considered to be an indicator of total system inadequacy rather than just the existence of a few "bad apples."[2] Although some controversy exists about the exact magnitude of the problem, no such controversy exists about the need to improve patient safety performance in both the inpatient and outpatient arenas. In essence, it seems apparent that the overall quality of the American health care product does not reflect the level of integrity and painstaking care that practitioners espouse and the public expects. Despite this concerning view, organized strategies by which to improve performance toward these goals are quite controversial and not yet widely adopted.[3] This lack of a clear consensus on how to intervene persists despite the occurrence of more than a dozen highly publicized regional and national meetings related to patient safety and medical error reduction which have occurred since the publication of the IOM report.

Virtually all of the wake-up calls and consensus statements produced at these patient safety conferences include the need to collect, analyze, and distribute examples of "Best Safety Practices" in medical operations. However, even with this sort of "expert teacher" model, the actual introduction of useful new technologies and infrastructure refinements in the area of medical error reduction is turning out to be a complex and somewhat frustrating experience.[4] Indeed, there is virtually no indication that American health care today has become safer and less error-prone compared to prior less sophisticated eras. As technology and specialization of treatment approaches improve, corresponding quality advances in the likelihood of error-free performance have not kept pace. The commercial realities and volume-driven incentives of the production model applied to the American health care enterprise are threatening to overwhelm a system which was not designed with a mission-critical performance mentality.[5]

This problem has certainly caught the attention of key stakeholders involved in the health care environment. Although newly organized medical error reduction initiatives now abound, a close inspection of what is actually being accomplished through these initiatives may unfortunately lead one to believe that many of these "quality" efforts are geared more toward a socially and legally defensible public relations stance rather than an actual attempt to produce lasting improvement in medical outcomes. Though one can point to the introduction of several specific technical and organizational changes which hold the opportunity to catalyze substantial gains within certain specific medical environments (for instance, computerized physician order entry [CPOE]

systems applied to pharmacy prescriptions[6]), it is difficult to correlate these *process* advances with true patient *outcome* improvements except in niche areas like anesthesiology. Many health care groups are now paying more attention to various quality indicators, but even in the most conscientious organizations it is difficult to document sustained large-scale improvements in objective health outcomes. There is thus concern that the opportunities for large-scale paradigm shifts in health care quality may be obscured by commercially slick technical advances which do not really represent exportable answers to system-wide performance problems.[7] Despite all the "change methodologies" and published analyses of "Best Practice" programs, mistakes in both judgment and in execution continue to occur in all sectors of the health care system. Is there some sort of fundamental disconnect that prevents the American health care system from effectively defining and instituting major process changes in health care delivery? Are we just nibbling around the edges of the core problems?

The sociologist and historian Paul Starr, in his Pulitzer Prize-winning monograph *The Social Transformation of American Medicine*, focussed on the inhomogeneous and multicultural origins of the patchwork of physician groups which ultimately came together to form American health care.[8] Starr traces the social evolution of the American physician and physician groups from an autonomous cadre of sovereign professionals to a set of loosely aligned professional guilds to the increasingly monolithic health care stakeholder groups portrayed today. Starr notes that the conflict between professionalism and a market economy poses difficult problems for self-regulating groups such as physicians who are used to setting and enforcing their own quality standards. Indeed, the original notion of a true medical professional as discussed by Starr involved a blunt *refusal* to allow external policing by either the consumer or external quality boards. As Starr recounts the social history, the public's confidence in the ability of physician groups to regulate themselves was somewhat shaken by the political movements of the last 30 years. However, as social unrest abated, physicians groups (as well as many health care institutions) regained fairly high confidence levels on the part of the consumer public. The IOM report thus came as something of a shock to consumers who had perceived physician groups as dedicated patient advocates in skirmishes with managed care regulations. The public at large still expects and generally assumes that American medicine should be safe, effective, and self-regulated. If there are problems, it is assumed that there must be a simple fix.

TECHNOLOGY BY ITSELF IS UNLIKELY TO ADDRESS FUNDAMENTAL PROBLEMS RESPONSIBLE FOR MANY OF THE MAJOR DANGER POINTS IN MEDICINE.

In reality, the appearance of unity and solidarity within American health care often disguises the fact that a collegial veneer plasters over dramatic differences in core competencies, training paths, incentives, and accepted specialty-specific subcultures. Each of these discrete subcultures has internalized certain specific ways of analyzing and achieving desired objectives, and each one has developed its own set of operational principles. The amalgam often comes together as an uncertain patchwork with fracture lines and error-prone operational gaps[9] readily apparent. It seems likely that the long-term solution to the problem of medical errors will involve an attempt to understand these cultural rifts and to plug these gaps with a judicious combination of new technology and novel infrastructure refinements which place more emphasis on change principles drawn from human factors research.[10]

Technology by itself is unlikely to address fundamental problems responsible for many of the major danger points in medicine. Defined cultural biases must be recognized. Several groups of investigators in the field are already working on promising theoretical constructs useful in grasping the problems at hand.[11] Their work begins with a tacit acceptance of cultural differences in the mindsets and process orientations of the participating health care groups. Each of these discrete medical subcultures participates in the overall enterprise within the background constraints of their own professional tribal lore. A solution that appears to plug a gap in one of these medical subcultures may expand and undermine a gap in a different medical subculture. Thus, what would appear to be a "Best Practice" developed in one branch of medicine may be an extremely poor fit for the culture of another branch. The quest for global solutions may therefore prove to be exceedingly difficult if not impossible. Generic "Best Practices" in medicine are turning out to be much more rare and brittle than more individualized culture-attuned lessons in how certain specific working groups learned to utilize their own backgrounds and strengths to optimize performance and safety.

Several investigators have examined the influence of sociocultural constraints and training paradigms on the likelihood of medical error.[12] Most of these investigations, however, examine these socioculture influences in the microcosm of a single small-group interaction such as an operating room team. Helmreich and colleagues have drawn attention to the fact that "interpersonal and communications issues are responsible for many inefficiencies, errors, and frustrations in this psychologically and organizationally complex environment." A careful analysis of the way that the different participants interact reveals

a striking segregation of the three major operating room groups involved (surgeons, anesthesiologists, and nurses) with respect to division of labor and the ways that each group chooses to accomplish their own portions of the tasks at hand. Attempts to break down this cultural process segregation are sometimes a hallmark of an unusually effective team but this cross-cultural cooperation can only occur if each member of the task group identifies with the success (or failure) of the group as a whole. The fact that this sort of cross-group interaction is an exception rather than the rule reinforces the view that sociocultural differences between various stakeholder groups in patient care may act as impediments to patient safety and as barriers to effective process change. This is especially true when change methodologies originate with an outside force and are therefore not "owned" by the group seeking change.

MOST OF THE WORKING GROUPS, EITHER CONSCIOUSLY OR SUBCONSCIOUSLY, UNDERSTOOD THE MAJOR RISK NODES ON THEIR OWN "THREAT MAPS" AND HAD ENGINEERED WAYS OF AVOIDING ERROR-PRONE BEHAVIOR.

From Within

An informative insight into this paradox is provided by the work of Jerry Sternin, a field director for the "Save the Children" organization who has worked for years in Vietnam and other third-world regions.[13] Sternin, who has a background in organizational change strategies and is a former Assistant Dean of the Harvard Business School, went to Southeast Asia to study the problem of childhood malnourishment. Earlier field workers had arrived full of plans to teach formal nutrition principles and tips on appropriate diet. The indigenous people listened to this advice politely and originally appeared to understand the need for more balanced nutrition rather than the conventional diet (which consisted primarily of rice with few edible additions). However, after making brief attempts to change traditional eating habits, the people soon resumed their prior ineffective practices. The net effect for the group was essentially zero. In contrast, Sternin realized that a small minority of the at-risk children were obtaining excellent nourishment despite the prevailing societal biases. The reason, he determined, involved the independent decision on the part of some of the mothers to include large amounts of tiny insect-sized crustaceans found in the roots of the local rice. Though not traditionally considered a reliable food-source, these parents cast aside commonly accepted practices in favor of experimenting with new sources of nutrition. With Sternin's help, these creative individuals, whom Sternin referred to as "Positive Deviants" (PDs), were able to commit their practices to a set of concrete teaching principles. Sternin and the PDs designed an intervention strategy which gave the group an opportunity to discover and practice the solution to the problem. This intervention involved multiple repeat sessions in which they answered the questions of the group and showed the group exactly how the solution could be applied.[14] With this sort of reinforcement, the new knowledge base and behavior patterns were successfully adopted by many of those who were initially skeptical. The fact that the solution was introduced with concrete suggestions and multiple sessions aimed at reinforcing the new behaviors was key. The solutions were developed *within* and by members of the subculture rather than introduced from the outside. This internal introduction helped to break through the sociocultural biases and erroneous beliefs embodied in the conventional teachings.

The relevance of Sternin's work for the problem of medical errors lies in his perceptions concerning the culture-bound nature of change strategies and the need for *change directed from within* a particular working community. Sternin realized that complex interlocking problems involving working groups with their own strongly held traditions and tightly defined processes may be extremely resistant to externally directed change strategies. In part, this resistance relates to the fact that the individual cultures under consideration have evolved over time a series of shared teachings and experiences which are not easily modified without threatening the entire cultural construct. Externally directed attempts at incorporating cross-discipline best practices, even when they are reasonable and useful, rarely stick and instead generate frustration at new problems brought on by the suggested practice changes. The "top-down" forcing function approach to best practice introduction may lead to grudging acceptance, but it is unlikely to yield long-term gains unless the group itself is incentivized to take ownership of the activity. Using Sternin's Positive Deviant approach, process changes are first distilled into concrete action steps rather than abstract discussions of how they might be applied. These steps are then discussed, amplified, and optimized from within. The creation of "local" operational autonomy led by a group member is critical. Only an internal member of the group will have the standing and cultural insights required to resolve the new complexities induced by the proposed changes. Thus, a cardiologist can demonstrate to other cardiologists how process improvements may take place, but the chance of the cardiologist teaching the same intervention to a neurosurgeon seems less likely.

In Vietnam, Sternin's principles provided a route to cultural acceptance of nutritional change because he utilized the group itself to lower the barrier to acceptance of the new ideas. This catalytic effect required concrete examples and reinforcement over time. In complex, multifactorial systems such as medicine and health

care, one might imagine that similar change-resistant traditions would be encountered. Abstract outside solutions may be rejected although individual, internally derived best practices (once their exact methodology is understood) may be embraced and transmitted. Sternin's breakthrough perceptions relate to the intuitive fact that new process pathways must be concrete and introduced by an internal change agent who has the standing within the group to demonstrate feasibility and convince others that change-related problems can be resolved. The change agent must understand and in most cases share the background, training, and experience constructs of the rest of the group. Longitudinal reinforcement is necessary.

POEMs Initiative

We have begun to use this theoretical approach as an underpinning for part of the Cleveland Clinic Foundation patient safety enhancement program which we call the Prevention of Errors in Medicine (POEMs) initiative. Like Helmreich and Sternin, we observed that many task-oriented working groups within the institution had developed, over time, their own rigidly defined sets of operational procedures. For the most part, these procedures proved efficient, robust, and reasonably successful in accomplishing their specific tasks. They were not, however, error-free. Although our POEMs group initially attempted to push for more uniformity in the way certain classes of tasks were accomplished throughout the institution, we soon came to the realization that these proposed global changes in accepted operating procedures may in many cases actually undermine rather than improve overall patient safety. The reason for this counter-intuitive effect involved the fact that most of the working groups, either consciously or subconsciously, understood the major risk nodes on their own "threat maps" and had engineered ways of avoiding error-prone behavior. In fact, a review of major closed claim and pending malpractice cases at our institution suggested that patient care interfaces in which responsibility for care is transferred from one group to another or from one environment to another are obvious danger points within the system. As long as a single working group was responsible for handling a task, major errors rarely were documented. We conjecture that one reason for this finding involves Cook's observation that working groups are constantly creating a fabric of safety within their own responsibility areas, but no single group is creating the same safety fabric at the interfaces.[15] Cultural interfaces are inherently error prone because the paradigms often change abruptly.

IDEALLY, WE WERE LOOKING FOR LOW-COST WAYS TO MAKE THE MISTAKE IN QUESTION ALMOST IMPOSSIBLE BECAUSE THE WORK PROCESS ITSELF WOULD PREVENT THE ERROR.

Recognizing the fact that individual working groups often recognize and attempt to fail-safe high risk areas in their own spheres of influence, we have recently enlisted the aid of dozens of individual groups to analyze the problems seen in their spheres. The POEMs task force asked the department chairs and section leaders from each of the major clinical operations units to identify one or two specific problems that they perceived as threats within their practice. After receiving these initial submissions, our POEMs group first attempted to identify those classes of problems which appeared to be common to multiple groups. We are now developing and instituting potential institution-wide fixes (in some cases, "technofix" strategies) for these sorts of global problems (e.g., difficulty obtaining the medical record at some key points of care). However, the great majority of the identified problem classes did *not* fall into this class and instead appeared to apply primarily to *specific* tasks performed by specific working groups. These more individualized classes of problems were logged, discussed, and then sent back to the working groups themselves with the suggestion that they brainstorm to identify, test, and then teach their own best practice solutions or workarounds to others in the group. We are thus utilizing the Sternin PD approach to encourage group buy-in.

Our charge to each of the clinical working groups involved a request to develop consensus opinions on the specific high-risk, high-frequency problems experienced (or narrowly averted) by their group and to take responsibility as a group for thinking of ways to engineer safety into the work process. Generic best practices are discussed but mostly as background. In many cases, the study of the "near misses" for that particular group provides some of the most useful insights on how the error class could be avoided on a global scale. Ideally, we were looking for low-cost ways to make the mistake in question almost impossible because the work process itself would prevent the error. This sort of mistake-proofing is much easier to engineer on a process-by-process basis rather than as a global enterprise-wide response. Only those groups with intimate working knowledge of the special error nodes under review will understand the underlying danger points or the opportunities for mistake-proofing. We thus believe that the most effective and efficient error reduction program will be inherently specialized rather than generalized. Although this might appear to be counter-intuitive, we believe that overall this approach bears a much greater chance of producing long-term beneficial change. In our POEMs initiative, we have now collected over 100 examples of the sort of task- and culture-specific

problems observed in different contexts by Sternin and Helmreich, as well as the groups' proposed tools for analysis and error reduction. The error nodes, as well as the proposed responses are being developed primarily by the working groups themselves, with some help from the institutional project management group set up to study and facilitate the interventions.

The resulting set of culture-defined best practices is currently being edited and prepared for internal distribution and ultimate publication. We expect to have further working group discussions at which both the selection of error classes and proposed solutions are reviewed and modified. We will then work with the groups to transplant these changes to others in the group. To accomplish this goal, we hope to train and utilize a cohort of patient safety officers (perhaps analogous to the "Black Belts" used in some corporations attempting to introduce "Six Sigma" quality initiatives) to monitor and facilitate these patient safety initiatives. The group of patient safety officers will itself form the data collection core of the reporting system and data management team. Based on the main campus responses to these interventions, we hope to repeat this process at other hospitals within our multi-hospital health system family, as well as at the other participating hospitals working with us in our quality initiatives. Each working group will participate in the training of their counterparts at the newly recruited site, thus amplifying the intervention leverage.

The point of the exercise is to make use of the observation that the process of health care and the groups engaged in it are neither uniform nor homogeneous. Rather than searching for arbitrary process uniformity, with the potential to limit creative "local" responses to the quality challenge, we might be better served by identifying and fine-tuning the operating procedures and the underlying assumptions utilized by each of the major working groups within our institutions. The processes utilized by these working groups are often highly evolved and the evolutionary process itself may uncover certain identifiable error nodes. Members of the working group will usually be best suited to identify these nodes and to identify potential solutions. The concept of universal best practices produced by an outside change agent should instead be replaced by a set of internally consistent best practice paradigms already being practiced and refined by "positive deviants" within the group. Successful interventions can be further optimized and amplified by others within the group. These improvements will leverage the creativity and specialized knowledge bases of the task groups to fuel the entire enterprise. As Helmreich noted, "Errors (as well as superior performance) have their roots in the backgrounds of the participants, the dynamics of the group, and the environment in which the activity occurs."[16] The same may be true about the solutions to these problems.[17]

WE MIGHT BE BETTER SERVED BY IDENTIFYING AND FINE-TUNING THE OPERATING PROCEDURES AND THE UNDERLYING ASSUMPTIONS UTILIZED BY EACH OF THE MAJOR WORKING GROUPS WITHIN OUR INSTITUTIONS.

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