PHD THESIS

FROM HIPPOCRATIC OATH
TO PATIENT SAFETY CULTURE

PARADIGM CHANGE ABOUT QUALITY AND SAFETY

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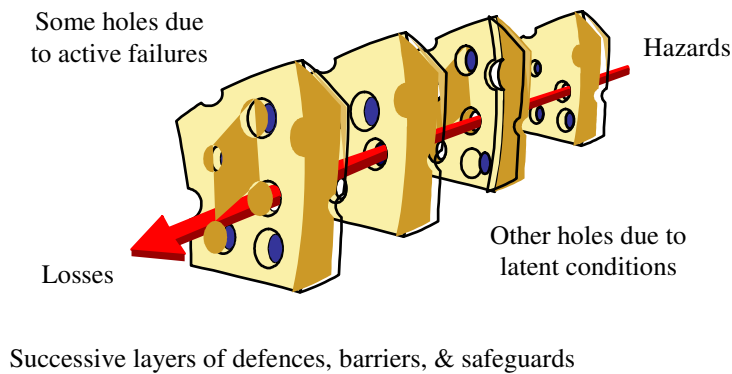DEPARTMENT OF PUBLIC HEALTH**

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1. INTRODUCTION

In recent years there has been an increasing recognition internationally that health care is not as safe as it could be and that patient safety outcomes can be improved. Patient safety is the freedom from accidental injury due to medical care or from medical error. The study of patient safety issues and interventions based on these studies is the process which allows an organization makes patient care safer.

Patient safety is central to quality health care as reflected in the Hippocratic Oath: "I will prescribe regimes for the good of my patient according to my ability and my judgment and never do harm to anyone…In every house whenever I come I will enter only for the good of my patient" (Excerpt from the Hippocratic Oath) The Hippocratic Oath guided doctors to do non-maleficience, beneficience, and justice for a long time. After establishing quality improvement practices patient safety science has been growing and searching for solutions, while describing methods to make patient care better. To reduce patient harm professional rules need to be simplified, and there is a need for system level arbitration to optimize safety and develop a culture of safety.

The Institute of Medicine formulated the dimensions of quality in healthcare as: 1) safe, free from harm; 2) patient-centered, organized around patient needs; 3) effective, use of evidence –based therapies; 4) efficient, eliminates waste; 5) equitable, quality is not influenced by race, gender, or religion; and, 6) timely, care is provided when needed.

In theory, quality and safety should not be a problem since medical professionals are educated and trained by the best to be proficient and error-free in their work. There is an expectation that health professionals are not likely to make mistakes. But human error is ubiquitous, and health care workers are not immune from the human proclivity for making errors. The 1999 Institute of Medicine report "To Err is Human" is the first public tabulation of the extent of patient harm and safety in healthcare setting. New concepts of human error were suggested to the healthcare industry based on the experiences in other high hazard industries, especially those from the aviation. A systematic approach based on proactive strategies involving the reporting of errors and adverse events was recommended, together with an admonition to identify and control latent conditions. Reason introduced the term latent conditions, referring to unsafe conditions which can exist unnoticed until an active failure happens. The relation of latent conditions and active failure is illustrated by Reason with a Swiss cheese model.

Some holes due to active failures

Hazards

Losses

Other holes due to latent conditions

Successive layers of defences, barriers, & safeguards

Figure 1 *Swiss cheese model of defences by Reason*

There is an increasing belief that an institution's ability to avoid patient harm will be realized when it engenders a culture of safety among its staff. The Institute of Medicine report, "Crossing the Quality Chasm" highlighted the need for improving patient safety, noting that patient safety emerges from systems that incorporate an understanding of human factors and safe design.

Culture can be defined as the collection of individual and group values, attitudes, and practices that guide the behavior of group members. Characteristics of a strong safety culture include a commitment of the leadership to discuss and learn from errors, communications founded on mutual trust and respect, shared perceptions of the importance of safety, encouraging and practicing teamwork, and incorporating non-punitive systems for reporting and analyzing adverse events. A culture of safety is the outcome that organizations reach through a strong commitment to acquiring necessary data and taking proactive steps to reduce the probability of errors and the severity of those that occur.

Cardiac surgery is a well established laboratory to study the outcomes of high risk patients and their provider teams. Cardiac surgery is a field in which performance and outcomes depend on complex individual, technical, and organizational factors and their interactions. The providers are highly trained, patients are high-risk, the procedures have a low error tolerance, and success requires a sophisticated organizational structure.

2. AIMS OF THE STUDY

To explore the cardiac surgery team members' attitudes, perceptions related to patient safety, and the impact of human factors and medical errors:

- Define a measurement of safety climate, define the dimensions (safety attitudes and impact of error), and factors (team climate, safety climate, stress recognition, impact of error, error management, risk modification, error burden on operating room staff) and validate a safety attitude survey.

- Explore team members' safety culture characteristics and safety attitudes in different cultural settings. Since we wanted to know whether, and to what extent, the characteristics and traits of the safety culture are generalizable, we choose to perform the study on two sites. The first was in the United States, which clearly has a well established quality management processes and carefully designed patient safety initiatives. Hungarian teams were studied as the second site, where healthcare service is at the beginning of a transformation. In Hungary quality assurance programs have been under development since 1997, including standards for accreditation, but hospitals do not suffer any consequences for not cooperating.

- Decide whether the main characteristics of the safety culture can be defined, explored with this survey tool, as:
    - Commitment to discuss and learn from errors, team work, and communication
    - Recognition of the inevitability of error
    - Proactive identification of latent threats
    - Incorporating nonpunitive systems for reporting and analyzing adverse events

- Determine whether this tool is useful to highlight safety improvement activities for organizational change.

3. METHODS

Questionnaire

Since safety culture survey results based on pre-formulated questions might lead respondents in particular directions, we choose a more complex and established methodology to increase study validity. The primary instrument we used was based on studies of the aviation experience. This experience was translated into terms and concepts appropriate for medicine by a University of Texas group and an error reporting system was developed to measure safety attitudes (Safety Attitude Questionnaire operating room version). Scaled questions were taken from this validated study to explore areas of known importance described in the safety culture literature. In addition, new areas were described and scaled questions were formulated based on the clinical experience of our research team members. The complete questionnaire included two separate domains. The first domain, Safety Attitude, represents caregiver attitudes on the scales of teamwork climate, safety climate, and stress recognition. The second domain, Impact of Error, relates to the organizational and personal burdens that are direct consequences of the making and the anticipation of making clinical errors. Respondents indicated the extent to which they agreed with each statement on a 4-point Likert scale consisting of "disagree strongly", "disagree slightly", "agree slightly", or "agree strongly." Respondents were expected to formulate agreement or disagreement with no neutral answer. Respondents were allowed, however, to select "don't know" as a possible answer.

A clinical scenario and a set of open-ended questions were added to the scaled questions to increase the validity and interpretability of the study.

Design and study population

Cardiac surgery teams from three urban academic health centers in the USA and four in Hungary agreed to participate in this study. IRB approval was obtained from each institution, and written informed consent was obtained from participating team members.

Statistical analysis

Items in each domain were submitted for an exploratory factor analysis. A confirmatory factor analysis was performed on each domain to measure the adequacy of final structure. The scalibility of the factor structure was evaluated, and the discriminant validity of the scales was evaluated by computing the correlation of each retained item with all scales within its domain. SAS® statistical package was used.

4. RESULTS

We studied surgery teams working in a high stress environment to assess attitudes and perceptions of team members toward patient safety.

We found that safety attitude questionnaire is a valuable tool to analyze a baseline safety culture and raise problems of system design which need to be solved.

Comparisons of the questionnaire results in the USA and Hungarian study groups

Comparison results were divided in three categories based on the significance level. Answers were as "Similar" for $p>0.05$, "Somewhat Different" for $0.01 \leq p \leq 0.05$, and "Clearly Different" for $p<0.01$.

In the *Team Climate* factor in the Safety Attitude Domain there is a clear difference between groups on four items. Significantly more of the Hungarian cohort report that they find it difficult to speak up and are unable to express disagreement. Also the Hungarians feel more strongly that the surgeons, anesthetists, and perfusionists do not maintain open communications. The groups are somewhat different on whether it is easy for the staff to ask questions when there is something they don't understand, with the Hungarian cohort in higher agreement. All of the other items in this factor are similar between the groups. Overall, it appears that the Hungarian teams find it more difficult to express disagreements but easier to ask questions.

In the *Safety Climate* factor of the Safety Attitude domain there is only one item on which there is clear disagreement. Significantly more of the Hungarians feel that nurses should not question attending than do their USA counterparts (80% to 5%). There are three items on which there is somewhat of a disagreement. These are on whether interruptions affect patient safety, whether the OR culture makes it easy to learn from the mistakes of others, and whether attending should always be in charge. The Hungarian cohort is in higher agreement on all three of these items than the USA cohort. All of the other items show similar responses. These responses seem to indicate a somewhat higher importance of the hierarchical structure to the Hungarian team members.

In the *Stress Recognition* factor in the Safety Attitude Domain all item responses are very close to each other between the USA and Hungary. All professional groups perceive high workloads, and when it becomes excessive they feel their performance impaired. From 75% to 80% agree that fatigue and excessive workloads impairs performance and about 50% believe that stress from personal life adversely affects

performance. These opinions are as to be expected and seem to lend validity to the responses.

In the *Error Management* factor of the Impact of Error Domain, six of the 1 items showed complete disagreement. Two of these referred to have and using a formal reporting system, which can be discounted as explained above. Of the remaining four items, three concerned information exchange about concerns with patient safety. In each of these items the Hungarian cohort had substantially lower responses than the USA group. The fourth item was on whether the lack of continuity of care adversely affects patient safety. Among the USA contingent 93% agreed that it did, while only 49% of the Hungarian respondents agreed. Only one item showed somewhat of a disagreement. This item concerned whether the staffing levels are sufficient. More of the Hungarians thought so (1% to 31%). In the area of *Error Management*, it appears that the Hungarian teams think that communications concerning patient safety are more lacking in their environment than do the teams from the USA.

In the *Risk Modification* factor of the Impact of Error Domain, there are two items which show completely different responses. One of these is that the respondent is afraid to reports for fear of punishment or loss of job, with 95% of the Hungarian team agreeing, while only 12% of the USA team did so. There are two items which show somewhat of an agreement. These are the feeling of safety in one's own OR and the feeling that errors due to lack of skill are rare. The Hungarians are in higher agreement on these two issues. All other items show similar responses. It would seem that although the atmosphere may seem more authoritarian in Hungary, the morale and respect for colleagues' skills might be higher.

In the *Error Burden* factor of the Impact of Error Domain, seven of the nine items indicate complete disagreement. Important among these is that the vast majority (31%) of Hungarian teams deny that they have either seen or committed errors while 92% say that OR personnel often disregard guidelines and 79% say that the same mistakes occur again and again. It may be that the respondents were making a distinction between "errors that can cause harm" and "mistakes", or there may be other underlying reasons for this seeming dichotomy.

Fictitious case of adverse event

The responses to the questions related to the clinical scenario were uniformly positive. Nearly all of the respondents agreed on the need to report the medication error

and on the need to discuss the error with colleagues, patient, or family. The five items relating to the reporting of error were summed to indicate the likelihood that the respondent would report the error. Nearly all of the respondents agreed on the need to report the medication error and to discuss the error with colleagues, but in Hungary only 11% of the respondents would tell it to the patient or family.

Open ended questions

Respondents were further asked to list any concerns that interfered with their sleep. The responses were collated into four categories, with multiple responses for some respondents (Table 1). Sleep problems were noted in all specialties at each of the participating institutions, and the most frequently reported concern related to provider competency and clinical skills.

Table 1 *Concerns Affecting Sleep Patterns*

	USA	H
	Respondents N=37(60%) Worries N=65	Respondents N=63 (72%) Worries N=93
1. Fear of making an error or not giving the best care e.g.: "forgetting to do something"; "making an error in clinical judgment that adversely affects patient health"; "we left the sponge in the patient"	30 (46%)	17 (18%)
2. Highly complex cases, patient outcome e.g.: "exact management of the complex critically ill patient"; "patient outcome"	11 (17%)	24 (26%)
3. Hectic schedule, heavy caseload e.g.: "unfair/unrealistic work assignments"	11 (17%)	21 (23%)
4. Other team members performance, stress during work, external factors e.g.: "too much stress at work"; "declining caseload"; "unprofessional behavior by others"	13 (20%)	31(33%)

In Hungary 72% and in the USA 65% of the respondents reported having difficulty sleeping because of job-related concerns (Table 1). In the USA study the leading cause of provider worries were fears related to their performance inadequacy, 46% worry about making error, closely followed by concerns over the complexity of the tasks faced (17%). 17% formulated problems with "unrealistic work assignments". Responses to this questions correlate with scaled question when more than 70% of the respondents feel that excessive workload and fatigue adversely affects their performance. The Hungarian study group at this point is less concerned about making an error (18%). They worry more about

the complexity of the cases (26%), the hectic schedule (23%), and worry the most about other team members' behavior, performance and stress during their work (33%).

Respondents were also asked to list three frequently occurring errors they had personally observed (Table 2). The reported errors were categorized by the type of error. In the USA study group the most frequent type was a medication error, miscommunication were also frequent. Equipment problems, not following clinical guidelines were less frequent. The observed errors by Hungarian study group were categorized by the same types but they do not detect as many medical errors (10%), and communication problems (7%). Most of the problems reported were related to standards are not followed, which is correlate with the finding that 92% responded that OR personnel often disregard rules and guidelines. As indicated above, the responses of the Hungarian teams may be making a distinction between errors with the potential to cause harm and simple "mistakes."

Table 2 *Frequently Occurring Errors Observed by Respondents*

Type of Error	USA	H
	Number of Errors Reported N=123 Respondents N=50	Number of Errors Reported N=124 Respondents N=60
1. Medication error	42 (34%)	13 (10%)
2. Equipment problems and misuse	28 (23%)	19 (15%)
3. Communication problem	28 (23%)	9 (7%)
4. Clinical standards are not followed	25 (20%)	83 (67%)

Finally, the respondents were asked to list up to three recommendations for improving patient safety. Fifty-one respondents articulated 130 recommendations and in the Hungarian study group 57 respondents listed 140 recommendations to improve patient safety. These included improving communications (USA 22% - H 15%), the need to follow and enforce clinical protocols (USA 21% - H 23%), appropriate staffing (USA 10%- H 19%), provide proper functioning equipment (USA 13% - H 14%), more education and training (USA 14% - H 14%), and better scheduling (USA 4%- H 5%). Both groups mentioned that they would like learn from mistakes, requested debriefing (USA 7% - H 6%), and wanted a calm respectful work environment (USA 7% - H 3%).

5. DISCUSSION

How much team members value patient safety?

On a positive note, we found that most team members value safety concerns and have an increasing awareness about these issues. But it is clearly demonstrated that in the USA, where the request for healthcare providers serve the patient is much stronger than in Hungary and quality and performance controls have longer and stronger traditions, team members' responses are closer to the desired culture. Among USA team members there was nearly unanimous support for the statement when errors are committed patient safety is important regardless of the patient outcome. This finding is confirmed by the responses to clinical scenario where nearly all responded in a way indicative of a concern for safety. This points out to the growing awareness to the need to report and learn from near miss opportunities. In contrast in Hungary only 14% thinks that committed errors are important in all circumstances, and eighty-six percent believes that a committed error is not important as long as the patient improves. The Hungarian responses reflect a possibly unacceptable level of awareness of error problems, and show we are at the beginning of this paradigm change about quality and safety. The error reporting scenario shows that most Hungarian team members do not support informing the patient or family about errors. However among the recommendations to improve patient safety no differences were found between USA and H team members. Both requested more briefing, debriefing, willingness to learn from errors.

Safety attitude of team members

Safety Climate we do expect the environment most likely to safe with open communication channels, well received questions from juniors and nurses if they do not understand something or perceiving a problem, and disagreements need to be solved.

The item responses in the Safety Attitude domain are perplexing. The teamwork climate was characterized as having open channels of communication –less open in Hungary-, but a substantial portion of the team feels that they are unable to express disagreement, and professional disagreements are not resolved. Only a small percentage of our respondents feel that it is easy to learn from their own mistakes, suggesting that many don't have the knowledge or the tools to analyze the causes of these errors. A troubling finding from the *Teamwork Climate* items is that 55-45% of respondents agreed that morale is low in their OR. Hungarians believe more strongly that attending surgeon should be formally in charge

of the OR, and a nurse should not question an attending. They report that they can ask questions if they don't understand something but not if they perceive a problem with patient care. These answers suggest that the old fashioned model, medical hierarchy, the person model is not replaced with the system model yet.

Human factors design reported by team members

Many of the errors and adverse events reported in both study sites relate to the need to address the human factors underlying these events. The fact that only 64% of the USA respondents would feel safe as a patient in their own operating room raises concerns and suggests that important underlying elements of a safe climate are perceived to be missing. This study demonstrated that team members perceive a high level of workload and more than 70% of the USA respondents feel that excessive workload and fatigue adversely affects their performance, which is of concern in a frequently high-risk context of cardiac surgery. Perhaps a lack of education on this issue can be the reason that in Hungary only 40% of team members realize the dangers of fatigue, workload, and stress.

Error perception, error burden

Perhaps the most troubling finding is the fact that respondents have seen the same mistakes occur repeatedly. The USA cardiac surgery team members perceive human error, both their own and that of others, to be ubiquitous. Respondents indicate that they know the proper channels to report patient safety concerns but often do not report these events. The H responses answers show that the system approach of error management has not yet been earned or taught. Interestingly about 90% sees the same mistake occur every day and report that operating room personnel often disregard rules and guidelines. Not having a hospital reporting system would seem to have slowed down the necessary change in healthcare organizations. This points out to a real failure of current systems to prevent errors from occurring again.

The recommendations to improve patient safety point to clear intervention opportunities, and interestingly USA and H team members share the same thoughts. They do want frequent team briefings before and after procedures, especially if the procedures included patient harm.

6. CONCLUSIONS

Healthcare providers pledge to practice medicine at its best according to the tradition of the Hippocratic Oath. There is no doubt that the healthcare service leaders and providers are fighting to find a way to improve quality and reduce possible patient harm. The pledge, the intention to do everything according to the beneficence and non-malpractice needs to be constantly shown. Patient safety science defines methods to get the desired results. To be able to apply our results about improved safety, the culture of blame and shame needs to change to a culture which includes system thinking. The characteristics of safety culture are seen more and more in the medicine. Our research explored the characteristics of the safety culture of operating room teams and confirms that bringing patient safety to the forefront of quality improvement work can help fulfill the promise to do no harm to patients.

- We used and validated a safety culture survey tool, derived from the Safety Attitude Questionnaire.
- The research explored same safety culture factors in the USA and in Hungary where economy is in transition.
- In both sites there is a commitment to discuss and learn from errors, and to learn from them. The recognition of the inevitability of the error is clearly stronger in the USA.
- The results from our safety attitude questionnaire can help identify learning opportunities through highlighting areas in need of improvement and developing strategies in which units can learn best practices from each other.

In conclusion, the findings suggest that cardiac surgery teams face significant barriers in enabling the conditions for safe outcomes. The perceived powerlessness of team members to prevent safety events must be addressed as part of an overall strategy to improve patient care outcomes. The study suggests that team members' safety attitude is related to actual level of patient safety, recommends the use of validated culture survey and highlights opportunities for safety improvement in the context of cardiac surgery teams. However, as Jeffrey R. Immelt, the Chief Executive Officer of General Electric pointed out: "It takes a decade to build the talent, culture, and tools, and to learn from our mistakes."[61]

7. AUTHOR'S RELEVANT WORKS

PUBLICATIONS

Bognar, A., Barach, P., Johnson, J.K., Duncan, R.C., Birnbach, D., Woods, D., Holl, J.L., Bacha, E.A., Errors and the burden of errors: attitudes, perceptions, and the culture of safety in pediatric cardiac surgical teams, Ann. Thorac. Surg. 2008. Apr; 85. (4):1374. -81. 85 (2008) 1374-1381 IF: 2.02

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PRESENTATIONS

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A. Bognar, M.D., M.B.A., R. Duncan, Ph.D., J. Johnson, Ph.D., D. Birnbach, M.D., P. Barach, M.D., M.P.H.: Assessing the Burden of Error Recognition on Patient Care in Surgical Teams; American Society of Anesthesiologists Annual Meeting, Chicago, IL, USA; Anesthesiology 2006; 105: A141

INVITED LECTURES

Bognár Ágnes: A nemzeti betegbiztonsági figyelő és adatgyűjtő rendszer kiépítése; A gyógyítás veszélyei – betegbiztonság konferencia, Budapest, 2008. június 15.

Á. Bognár: Experiences with Applying Safety Attitude Questionnaire; EU Developments in Healthcare; European Society for Quality in Healthcare, Autumn Workshop; Dublin, October 10 2009

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