PHD THESIS

FROM HIPPOCRATIC OATH TO PATIENT SAFETY CULTURE

PARADIGM CHANGE ABOUT QUALITY AND SAFETY

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SUMMARY

Healthcare is not as safe as it ought to be and healthcare workers are not immune the human proclivity of making errors. 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.

We assessed the perceptions and attitudes of surgical teams relative to the culture of safety, committing errors, the impact of errors and human factors. Cardiac surgery team members at seven academic centers were surveyed in the United States and Hungary. The survey included scaled, open-ended questions and a clinical scenario. Respondents were asked about the safety climate, team climate, stress recognition, and the impact of error as they relate to making and the anticipation of making clinical errors.

The response rate was high at both study sites. 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 in the USA and Hungary. Team members value safety concern, but many respondents felt unable to express disagreement and had difficulty raising safety concerns. Staffing levels, equipment availability, production pressures, and hectic schedules were concerns. Respondents admitted that errors occurred repeatedly and that guidelines and policies were often disregarded. The findings suggest that the safety attitudes among team members may impact team performance and need to be carefully taken into consideration.

The study confirms that bringing patient safety to the frontline of quality improvement works can help fulfill the promise to do no harm to patients.

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 [1]. 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 c. 300-400 BCE.) The Hippocratic Oath guided doctors to do non-maleficience, beneficience, and justice for a long time. This ethical guidance was expanded in the 20th century with a fourth element, the respect for autonomy -respecting decision making capacities of autonomous persons, enabling individuals to make reasoned informed choice [2;3].

Healthcare providers intend to preserve and maintain health, and to treat and manage illnesses while providing technologically advanced and excellent medical care by the best trained medical professionals. Hammurabi 1700 B.C.E. was the first who developed laws to control healthcare. Quality-of-care edicts in Hammurabi's Codex left no margin for error, outcome measurements were specifically identified in the Codex [4]. Semmelweis (1818-1865) was a "hero" [5] who did not accept as normal the 15-18% mortality rate after childbirth. During his work based on his observations he standardized hand washing with chlorinated lime solutions and the mortality rate was reduced to 1-2%. Semmelweis's experience was not immediately widely adopted, showing that the values of

scientific methods are not easy to define, and the use and spread of new methods is a difficult process. The American Surgical Association saw opportunities for improvement through measuring outcomes, and advocated changes [6]. As the 20th century ended, healthcare was undergoing a revolution in accountability. The intent and the striving to give quality care mentioned above was not enough. There was a diversion of significant amounts of control from the profession to others outside the profession. Managed care systems, government agencies, utilization review departments, and payers started supervising care, and asking doctors and hospitals to explain what they do and why they do it [7]. There were other concerns about variation in clinical practice at any level, as the increasing malpractice problem required finding a way to measure quality. A central tenet of quality improvement theory, that quality is not made by people but by process, flies in the face of the traditional view of healthcare- that quality is made by doctors. The quality improvement process was built on the experiences of accreditation. The Joint Commission on Accreditation of Hospitals started with a standardization program in the 1950s, and adopted optimal achievable levels of quality standards in 1970s (www.jointcommission.org). In the 1990s this organization, renamed as Joint Commission on Accreditation of Hospital Organizations, integrated into the accreditation process some outcome and performance measures. After establishing a sentinel events policy their mission statement was revised to explicitly reference patient safety. In the 1990s, besides accreditation, the theories and tools needed to cope with the problems of medical error and the effects of non-optimal system design were developed. In 1987 the National Demonstration Project on Quality Improvement on Health Care began to research the application of quality management methods to healthcare. The Institute of Medicine's (IOM) National Roundtable on Health Care Quality documents three types of quality problems – overuse, underuse, and misuse. The IOM publication "Crossing the quality

Chasm" gives detailed instructions and recommendations on how to redesign and improve care. To manage this learning process the Institute of Healthcare Improvement was founded in 1999 [8]. They now lead the research and applications on how healthcare service can be continuously improved and be made measurably better for patients. The IOM 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 they are not likely to make mistakes. There is a belief that errors come far and few between, errors are not "statistically" significant, and, besides, "it has not happened to me". But human error is ubiquitous, and health care workers are not immune from the human proclivity for making errors. Medical errors can go unseen and unrecognized if there is a prevailing traditional culture of blame, a hierarchical environment rooted in medical education and traditions, tolerance, and denial and complacency in handling problems and errors [9].

The 1999 IOM report "To Err is Human" is the first public tabulation of the extent of patient harm and safety in healthcare setting [10]. The report stated that annually 98,000 deaths occurred from medical errors, while 43,000 came from motor vehicle accidents and 42,000 from breast cancer [11;12]. This report initiated an international discussion about the role of organizational culture in the occurrence of preventable adverse events in healthcare. 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

[13;14]. 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 [15;16]. Latent conditions can arise from inefficient regulation, poor system design, or malfunctioning equipment. Active failures are characterized as those having a direct impact on patient safety. The relation of latent conditions and active failure is illustrated by Reason with a Swiss cheese model [9].

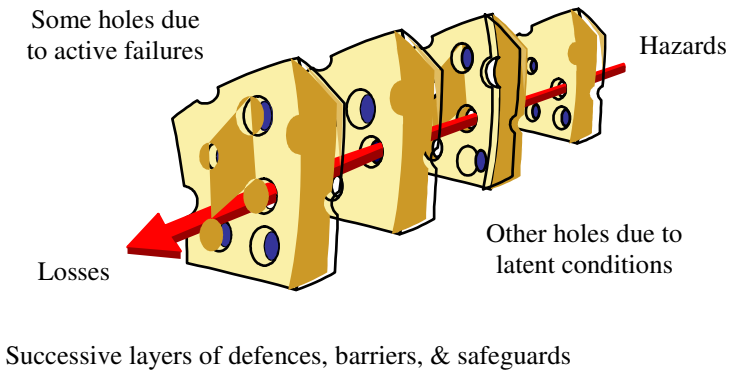

Figure 1 *Swiss cheese model of defences*

Health care organizations have become increasingly aware of the importance of assessing and transforming the organizational culture to realize potential improvements in quality and safety of care [17-21]. 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 members [22]. Safety is engineered through team training and supportive management [23-27], and by infusing the clinical microsystems with core safety elements [28]. These elements support the team's resilience (i.e., the ability to address potential patient harm situations in the face of error and impending patient harm) [28;29]. 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. The biggest challenge in moving toward a safer health system is changing the culture, as culture influences all aspects of healthcare. We need to move the culture in health care from one of blaming individuals for their errors, which are seen as personal failures, to one in which errors are seen as opportunities to improve the system [1].

Culture can be defined as the collection of individual and group values, attitudes, and practices that guide the behavior of group members [30-33]. 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 [34]. 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 [33]. The surface manifestations of a safety culture can be regarded as a safety climate discerned from the workforce's attitudes and perceptions at a given point in time [24;35]. A culture of safety recognizes the inevitability of error and seeks proactively to identify latent threats. Studies of safety culture in the literature focus mainly on discovering deficits in organization, communications, or personal skills with a view toward developing and tracking changes and interventions [23;36]. However, to improve patient safety it is necessary to understand the beliefs, attitudes, and behaviors regarding patient safety, and also to recognize the impact of the psychological and physical stresses of the ever-present threat of medical error on the members of the health care team. Individual team member's

feelings about, and reaction to, the stress over the professional demands and perceived lack of organizational support may increase the probability of medical error [37].

Cardiac surgery (CS) is a well established laboratory to study the outcomes of high risk patients and their provider teams [26;38-42]. 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. CS teams coordinate the efforts of several clinicians and support members and depend on a high level of cognitive and technical performance [38;43;44].

The intention of this study was to explore the cardiac surgery team members' attitudes, perceptions related to patient safety, and the impact of human factors and medical errors. 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 (USA), which clearly has a well established quality management processes and carefully designed patient safety initiatives [10;16;37;45-48]. Hungarian (H) 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 [4]. The Hungarian National Health Insurance, the only insurer in Hungary, owns a detailed national database for reimbursement purposes, but does not share quality indicators with the public, and does not ask any providers, hospitals, or doctors to explain what they do and why they do it. At this time there is no compulsory reporting of adverse or non-routine medical events to any authority [49].

Nosocomial infection surveillance and drug side effects reporting systems are set up but no results have been published in Hungary as yet. Medical universities' curricula do not include a course related to quality management and patient safety. The Euro Health Consumer Index 2009 shows Hungarian health service in the 20th place in Europe in the low middle range, recognizing this year that the improvement in patient rights and information services appears to be paying off. They conclude, "...60 years of publicly financed healthcare has resulted in a quite good coverage, but outcomes are still disappointing" [50]. We are interested in what it means for the team members to work in an environment where quality has been measured, and safety and patient centeredness have been important for a long time as contrasted to another setting where this has only recently been taken into account by the imposition of governmental standards.

We hypothesized that CS teams face challenges in current healthcare delivery systems and that these challenges influence professional, as well as personal activities, perceptions, and attitudes of individual CS team members [26;38;39;41]. These attitudes and perceptions may affect safety culture and medical outcomes. Previously published studies have highlighted the relationship between safety attitudes and team performance, but they have not explored the impact of the risk of error and its burden on individual team member's perceptions and performance [51]. The impact of psychological stress and distress have been noted in other high risk domains demonstrating decreased performance in the face of unmitigated stress [52]. We explored the impact of real and potential medical errors on CS team members in two study groups (USA, H) in an effort to better understand how these factors could influence the performance of individuals and their team.

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 attitudes and perceptions in different cultural settings
- Decide whether the main factors, characteristics of the safety culture [34] can be defined, explored with this survey tool:
  - 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. MATERIALS AND METHODS

3.1 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 [33]. 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. 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. A detailed description of the methods is given below.

3.1.1 Scaled questions

The questionnaire included 30 questions adapted from the Safety Attitude Questionnaire (SAQ) operating room version [53]. This validated questionnaire was a desirable source because it had been previously used to assess safety culture. We further formulated 28 new items that pertained to CS teams, not available on the SAQ, based on roundtable discussions, reviewing the literature, our clinical experience, and a previously partially validated study [54]. 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. These factors were described in an investigation of the psychometric properties of SAQ [55]. 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. Each domain contained existing questions from the SAQ as well as newly formulated questions.

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.

3.1.2 Fictitious case of adverse event

A clinical scenario based on an adverse event that involved the administration of a ten-fold overdose of heparin, causing excessive bleeding after cardiopulmonary bypass was also presented. The scenario was developed to provide an external correlate to the scales derived from the attitude questionnaire and designed to probe whether respondents would report an adverse event.

3.1.3 Open ended questions

In addition, four open-ended questions were created to allow the participants to give un-cued responses to correlate with the responses of the scaled questions. Respondents were asked to list errors that they had observed and whether job concerns affected their sleep. They were also asked to list any observed errors that they felt had been personal learning opportunities and those they would like to share with colleagues. Finally, respondents were asked to give recommendations for improving patient safety. Two of the researchers in the study coded the open ended questions using content analysis into themes that were developed inductively based on existing literature. Each researcher

independently decided on a content category and then categorizations were compared. Discrepancies in coding were reconciled through consensus, to determine the final classification.

The translation of the instruments into Hungarian was made by the author. One Hungarian physician researcher checked the translation and another physician researcher independent from the research group translated it back to English to confirm the translation.

3.2 Design and study population

CS 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 CS members. CS members were surveyed in 2004-2005 in the USA, and 2008 in Hungary. All participants were given paper copies of the questionnaire. Participants in the USA were provided with an online survey option. Surveys were introduced at CS team meetings. A local champion at each site assisted with hand delivery of surveys to CS members absent during these meetings. The web-based responses and paper form data were de-identified and information was entered into a computerized database (Microsoft Access) for subsequent analysis.

Approval to conduct this study was granted by the University Of Miami Internal Review Board Human Subjects Research Office, Protocol Number: 03/558B and the University of Szeged Ethical Committee (Szegedi Tudományegyetem Regionális Orvosbiológiai- és Kutatásetikai Bizottság) WHO No: 2318.

3.3 Statistical analysis

All analyses were carried out using the SAS® statistical package (SAS Institute, Inc., SAS/STAT® User's Guide, Version 6, Fourth Edition, Volume 1, Cary, NC: SAS Institute, Inc., 1989). There was consensus among the researchers that "don't know" responses could not be regarded as neutral, as opinions were being probed. Consequently, "don't know" responses were recoded as missing values. Percentages and mean values are based on non-missing responses. For all factor analyses the pair-wise covariance matrix was used for input.

Data from the first part of the study (USA) was used to validate our form of the safety questionnaire in detail based on prior validations of the instruments. A reduced validation process was used for the second part of the study. Items in each domain were submitted for an exploratory factor analysis (EFA). We used SAS PROC FACTOR to obtain the maximum likelihood estimates and an orthogonal (Varimax) rotation of factors. Items with factor loading above 0.4 in absolute value were retained. A confirmatory factor analysis (CFA) was performed on each domain to measure the adequacy of the final factor structure. Performing a CFA following an EFA may be somewhat self-fulfilling but, it does yield a sense of the adequacy of the factor structure [13]. An exploratory factor analysis was done with the 29 items proposed for the Safety Attitude domain. The items were pre-selected into the three proposed factors and predicated on the factor structure outlined for the psychometric properties of the SAQ questionnaire [53]. The initial analysis Factor 1, *Teamwork Climate,* comprised 14 items; Factor 2, *Safety Climate*, had 10 items; and, Factor 3, *Stress Recognition*, included five items. After eliminating items with either low factor loadings or substantial "cross-factor" loadings, or both, a final factor structure was produced.

The CFA fit indices were the similar to those applied in the validation of the psychometric properties of the SAQ [53]. The indices include the Bentler's Comparative Fit Index (CFI), Root Mean Square Residual (RMR), Root Mean Square Error of Approximation (RMSEA), and the model Chi Square. The scalability of the factor structure was evaluated by computing scale means, standard deviations, ranges, skewness, kurtosis, tests of normality, and Cronbach's alpha for the retained items. Items with a negative factor loading were recoded for positive valence prior to computing scale scores and Cronbach's alphas. A larger scale score indicates a more desirable outcome than a smaller scale score.

The discriminant validity of the scales was evaluated by computing the correlation of each retained item with all scales within its domain. We checked each item for "cross-loadings" above 0.4 with other factors, and examined cross correlations among scales within domains [13]. The scales within each domain were correlated with responses to the patient case scenario to assess external validity. The dependence of scale scores on medical specialty was analyzed by means of repeated measures of Analysis of Variance (ANOVA). Finally, multiple regression analyses of the scale scores were performed using the independent variables age, gender, and years in specialty, years at the current hospital, and loss of sleep due to provider concerns (worries). The analyses used backward elimination to find independent predictors of scale scores. Responses to individual scale items within factor are presented as the number of subjects responding mean ± standard error, and percent of respondents agreeing or disagreeing with the item.

The factor structure used for the second part of the study was based on our previous research [56]. The item answers given in Hungary were compared item by item with the answers given in the USA. The Hungarian responses to the open ended questions and the clinical scenario were analyzed as described above.

4. RESULTS

4.1 Respondent demographics

In the USA study group 61 of 89 CS team respondents completed the questionnaire, for a 69% response rate. Data from the three institutions were combined into one database to assure anonymity. The sample consisted of 24 anesthesiologists, 15 nurses (scrub, circulating, and one physician assistant), ten perfusionists, seven surgeons, and five persons who did not indicate a profession. This distribution of respondents is representative of the structure of most CS teams, and of the teams at the three participating institutions. Fifty-one percent of the respondents were female; 46% male; the gender of two respondents was not indicated. The average age of respondents was 41 years (SD = 8.5, Range 26-60); the average time in the specialty field was 12.4 years (SD = 9.07, Range 0.5-40); and the average time in their role at the current hospital was 10.1 years (SD = 9.19, Range 0.5-40).

In the Hungarian study group 84 of 109 CS team respondents completed the questionnaire, a 78% response rate. Data from the four institutions were combined into one database to assure anonymity. The sample consisted of 25 anesthesiologists, 21 scrub nurses, 14 perfusionists, 18 surgeons, and six persons who did not indicate a profession. This distribution of respondents is representative of the structure of most CS teams, and of the teams at the six institutions in Hungary. Fifty percent of the respondents were female; 45% male; the gender of four respondents was not indicated. The average age of respondents was 37.5 years (SD = 7.8, Range: 27-60); the average time in the specialty field was 14.1 years (SD = 8.5, Range: 2-39); and the average time in their role at the current hospital was 9.4 years (SD =7.2, Range: 0.2-39).

4.2 Psychometric properties of the Safety Attitude Questionnaire

4.2.1 Safety Attitude domain scale psychometrics in the USA group

Following the completion of the exploratory factor analysis and after elimination of items with either low factor loadings or substantial "cross-factor" loadings, or both, a final factor structure was produced. The items, descriptive statistics, and factor loadings are shown in Table 1. The items in the Safety Attitude domain derived from the SAQ showed up in the same factor as in the initial validation: six of the ten items in Factor 1, four of nine items in Factor 2, and four of four items in Factor 3, respectively, supporting the validity of our adaptation of the instrument [53][20]. Ulleberg and Rundmo [57] proposed a systematic approach to the use of a confirmatory factor analysis. The evaluation of the three factors in the Safety Attitude domain followed their approach as shown in the following paragraph.

The analysis yielded a CFI of 0.90, an RMR of 0.04, and an RMSEA of 0.07. The Chi Square for fit was 231.1, 253 df, p = 0.01. These parameters indicate a good fit of the data to the proposed model. A scale score was then computed for each factor in Table 1. Items with negative factor loadings were recoded as positive and mean response over all items in the factor of each subject were computed. The scale scores were all judged to be distributed normally by the Shapiro-Wilk test and by the measures of skewness and kurtosis. The Cronbach alphas are all large enough to reflect adequate scaling properties. Discriminant validity was evaluated in three ways. First, each individual item was correlated with each scale score. The highest correlations were found between an item and its own scale score. Only one item was correlated above 0.50 with another scale. Secondly, "cross-factor" loadings were checked by noting instances where difference in loading for an item on two factors was less than 0.15. No item was so cross-loaded. Thirdly, inter-

correlations among scales were low (0.35 or less), indicating adequate separation of the factors.

4.2.2 Impact of Error domain scale psychometrics in the USA group

The initial exploratory analysis of the Impact of Error domain yielded three factors. The first factor, which we named *Error Management*, included 12 items. The second factor, which we named *Risk Perception,* included eight items. The third factor, which we named *Error Burden,* included nine items. After eliminating items with either low factor loadings or substantial "cross-factor" loadings, or both, a final factor structure was produced (Table 4). A confirmatory factor analysis of the three factors in the Impact of Error domain yielded a CFI of 0.73, an RMR of 0.06, and an RMSEA of 0.09. The Chi Square for fit was 440.5, 294 df, $p < 0.0001$. With the exception of the CFI, these parameters indicate a good fit of the data to the proposed model. Attempts to confirm either a two-factor or a four-factor structure did not meet with success, yielding CFIs on the order of 0.60. The scalability and discriminant validity of the factors in this domain are not as good as those of the Safety Attitude domain. The scale score descriptive statistics and Cronbach alphas for the Impact of Error domain are displayed in Table 5. Unexpectedly, the Risk Modification scale was judged to be non-normally distributed by the Shapiro-Wilk test and demonstrates a large negative kurtosis. The distribution of scale values appears to be relatively flat across the range of item scores.

When looking at item correlations with scales, there were no instances of an item being correlated higher with another scale than its own. Cross-correlations, however, were frequently higher for *Error Management* items versus the *Risk Modification* scale and vice versa. Cross-factor loadings were within 0.15 of each other on three of the items for these factors. The overlap is borne out by the inter-correlations among scales, with *Error*

Management and *Risk Modification* correlated at the 0.54 levels. The scale responses of the different specialties represented in the sample to the factors in the Impact of Error domain are shown in Table 6. The responses of the specialties are different on the *Error Burden* scale ($F_{3,55} = 4.87$, $p = 0.0046$). In the pair-wise t-tests the nurses are significantly different from the anesthesiologists and perfusionists, but not the surgeons. There were no significant differences on the other two scales.

4.2.3 Safety Attitude and Impact of Error domains scales psychometrics in the Hungarian study group

The same questions were asked in the Hungarian study groups and a confirmatory factor analysis was performed in these two domains. The confirmatory data are listed in Table 1.

Table 1 *Confirmatory Factor Analysis of Hungarian Data*

Domain	Goodness of Fit Measure			
	CFI	RMR	RMSEA	Model Chi Square
Safety Attitude	0.76	0.069	0.095	321.1 (p<0.001)
Impact of Error	0.62	0.078	0.102	407.6 (p<0.001)

A Bentler Comparitive Fit Index (CFI) of 0.90 or greater indicates an excellent fit of the observed data to the proposed factor structure, while a CFI of 0.70 or greater indicates only a moderate fit. The Root Mean Square Residual (RMR) and the Root Mean Square Error of Approximation (RMSEA) should both be in the range of 0.08-0.10 for a good fit. The Model Chi Square, when significant, is an accepted measure of goodness of fit when the number of cases is between 75 and 200, as is the case here. In summary, the Safety Attitude domain shows a moderately good fit to the structure found among USA surgical teams, while the Error Burden domain fits the previous structure less well. In

order to see whether there was a better factor structure for describing the Hungarian data several exploratory factor analyses were performed. This included starting with all items and all responses, separating safety and error burden items, separating the respondents by age, and separating the respondents by profession. None of these approaches yielded as good a factor structure as that used following the USA experience. Thus, although the confirmatory factor analysis on the Hungarian data is not as strong as would be desired; the imposed factor structure seems to be the best the data can support.

4.3 Questionnaire results in the USA study group

In factor *Teamwork Climate* (Table 2), approximately 90% of the respondents agreed that surgeons, anesthesiologists, and perfusionists maintain open communication channels throughout the procedure. A total of 73% percent of the respondents indicated that disagreements in the operating room are appropriately resolved. Despite the open communication channels, 29% of the team members responded that they have difficulty speaking up if they perceive a problem with patient care, 41% feel unable to express disagreement, and only 44% report that briefings were routinely carried out before procedures, all of which suggests risks to reliable and safety oriented communication within a procedure. Only 45% of the respondents report that morale is high in the operating room (OR), lower than in other studies [22]. The correlations among these items are consistently high and statistically significant. These findings would be expected from the high factor loadings, indicating a true polarization among respondents on these issues.

In factor *Safety Climate* (Table 2), 82% agree that effective coordination of OR staff requires that the personalities of others be taken into account. Thomas et al, found that provider characteristics (personal attributes, reputation and expertise) influenced the ability of providers to work together [23].

Table 2 *Factor Analysis of the Safety Attitude Domain**

Factor 1 Team Climate	N	% Agreed	Mean ± SEM	Factor Loading
In our OR it is difficult to speak up if I perceive a problem with patient care	55	29	2.96 ± 0.14	-0.86
Surgeon and anesthetist maintain open channels of communication throughout the procedure	58	86	1.70 ± 0.11	0.79
Surgeon and perfusionist maintain open channels of communication throughout the procedure	59	93	1.39 ± 0.09	0.78
Nurse input about patient care is well received in the OR	54	65	2.22 ± 0.12	0.74
It is easy for our OR staff to ask questions when there is something that they don't understand	56	75	2.20 ± 0.12	0.73
Morale in our OR is high	55	45	2.60 ± 0.13	0.72
Disagreements in the OR are appropriately resolved (i.e., what is best for the patient)	52	73	2.10 ± 0.12	0.64
Senior staff encourage questions from junior medical and non medical staff during operations	52	65	2.27 ± 0.13	0.67
I am frequently unable to express disagreement with the attendings in our OR	56	41	2.75 ± 0.13	-0.60
OR staff are briefed before surgical procedures	50	44	2.56 ± 0.13	0.54
Factor 2 Safety Climate				
Debriefing after errors occur is common	48	29	2.92 ± 0.14	0.68
My patient safety is not reduced when I am interrupted	60	33	2.75 ± 0.09	0.67
The culture in our OR makes it easy to learn from mistakes of others	51	43	2.68 ± 0.13	0.65
My decision-making is as good in medical emergencies as in routine situations	60	78	1.88 ± 0.10	0.64
I receive appropriate feedback about my performance	55	62	2.20 ± 0.13	0.49
Nurses should not question decisions made by attendings	61	5	3.52 ± 0.08	0.49
The attending surgeon should be formally in charge of the OR during the surgical procedure	57	63	2.07 ± 0.16	0.47
Effective coordination of OR staff requires that the personalities of others be taken into account	56	82	1.86 ± 0.11	-0.43
It is difficult to discuss mistakes when they occur in the OR	52	60	2.42 ± 0.14	-0.41
Factor 3 Stress Recognition				
Fatigue impairs my performance during critical phases of patient care	60	73	2.16 ± 0.11	0.84
Stress from personal problems adversely affects my performance	61	46	2.77 ± 0.12	0.79
When my workload becomes excessive, my performance is impaired	55	75	2.04 ± 0.12	0.71
High levels of workload are common in our OR	53	94	1.60 ± 0.09	0.40

* Number of responses, percent agreed, item mean ± SE, and factor loadings; SEM=standard error of the mean

A further finding was that errors were difficult to discuss. Despite the reported open communication channels, only 29% reported that debriefing was common after errors, and only 43% agreed that it is easy to learn from mistakes in the OR. In addition,

60% reported difficulties in discussing mistakes, and only one third of the respondents indicated that debriefings occur after errors and patient harm.

There is little awareness of the impact of human factors on performance. Thirty-three percent reported feeling that patient safety is not reduced when they are interrupted. This is in contradiction to aviation, in which over 2/3 of pilots report that interruptions reduced flight safety. In factor *Stress Recognition* (Table 3), 94% agreed with the statement "that a high level of workload is common in the OR", and 73% felt that their performance was impacted by an excessive workload and fatigue. Interestingly 78% of respondents believed that their decision making was unaffected by emergency conditions. Both of these latter two statements suggest a lack of insight into the effects that fatigue and emergency has on provider performance, decreasing attentiveness and an accepted cause of error [16]. In the factors of *Error Management* and *Risk Modification* of the Impact of Error domain (Table 3) CS team members report insufficient resources. Only 31% feel that levels of staffing are sufficient and 69% report that problems with equipment are frequent including equipment that is uncalibrated, malfunctioning or not available. Only 47% report that equipment is adequate and only two thirds would feel safe being a patient in their own operating room.

Table 3 *Factor Analysis of Impact of Error Domain**

Factor 1 Error Management	N	% Agreed	Mean ± SEM	Factor Loading
My department provides adequate, timely information about events in the hospital that might effect my work	59	68	2.10 ± 0.14	0.82
I am encouraged by my colleagues to report any patient safety concerns I may have	59	78	1.94 ± 0.13	0.74
I know the proper channels to direct questions regarding patient safety in my department or work area	57	95	1.51 ± 0.09	0.67
Our levels of staffing are sufficient to handle the number of patients	52	31	2.79 ± 0.12	0.55
Trainees in my discipline (e.g., nurse, residents, etc) are adequately supervised	53	79	1.83 ± 0.11	0.53
I have used the hospital's reporting system for documenting medical errors	51	61	2.23 ± 0.19	0.52
Decision-making in our OR should include more input from other OR staff than it does now	50	74	1.96 ± 0.11	-0.51
Disruptions in continuity of patient care can be detrimental to patient safety	58	93	1.48 ± 0.08	-0.48
Problems with equipment are frequent in the OR	52	69	2.17 ± 0.14	-0.46
We have a confidential reporting system for documenting medical errors	47	85	1.65 ± 0.13	0.42
When medical errors occur they handled appropriately	53	85	1.77 ± 0.11	0.42
Factor 2 Risk Modification				
I am properly trained to use new and existing equipment in the OR	55	89	1.71 ± 0.11	0.77
Errors due lack of skill are rare in OR	52	58	2.23 ± 0.13	0.75
The OR equipment in our hospital is adequate	53	47	2.58 ± 0.15	0.72
Errors due lack of knowledge are rare in OR	54	59	2.24 ± 0.13	0.70
I would feel perfectly safe as a patient in our OR	59	64	2.08 ± 0.14	0.66
I am afraid to report adverse events as I might be punished or lose my job	60	12	3.57 ± 0.10	-0.53
I am reluctant to report adverse events as I might get a colleague in trouble	60	15	3.45 ± 0.09	-0.52
I expect to be consulted on matters that affect the performance of my duties	55	95	1.29 ± 0.08	0.40
Factor 3 Error Burden				
I have seen others make that had the potential to harm patients	58	91	1.59 ± 0.10	0.77
I am more likely to err in tenser hostile situation	60	85	1.75 ± 0.11	0.72
I have made mistakes that had the potential to harm patients	59	83	1.88 ± 0.11	0.58
I am ashamed when I make a mistake in front of other OR staff	55	75	2.07 ± 0.13	0.56
I have seen the same mistakes occur again and again	54	33	2.90 ± 0.15	0.55
Medical errors occur every day in our OR	49	41	2.75 ± 0.15	0.45
There are frequent changes to the schedules	54	91	1.52 ± 0.09	0.45
Errors committed during patient management are not important, as long as the patient improves	59	3	3.78 ± 0.07	-0.43
OR personnel often disregard rules or guidelines	56	39	2.89 ± 0.14	0.41

* Number of responses, percent agreed, item mean ± SE, and factor loadings; SEM=standard error of the mean

In the factor *Error Burden* of the Impact of Error domain (Table 3), 97% of respondents agree that errors are important regardless of patient outcome. Errors in this environment would appear to be omnipresent with 91% of the respondents stating they have seen errors, 41% report that medical errors happen every day, 83% respond that they have made a mistake that had the potential to harm a patient, and 75% report being ashamed of making an error in front of the OR staff. Seeing the same mistake occur repeatedly was reported by 33%. The perceptions of CS team members about the inadequacy of, and frequent problems with, equipments are reinforced by the 39% agreement with the statement that CS personnel "often ignore guidelines and have a generalized feeling of dread around safety errors" (Table 9).

4.4 Questionnaire results in the Hungarian study group

Responses of the Hungarian study group are presented in the same factor structure showing number of responses and percent agreement in Tables 4 and 5. In the same tables these responses are compared with USA item responses, and the results of z-test for proportions between the two groups are presented with the significance level.

In factor *Teamwork Climate* (Table 4), approximately 60% of the respondents agreed that surgeons, anesthesiologists, and perfusionists maintain open communication channels throughout the procedure, and indicated that disagreements in the operating room are appropriately resolved. According to this problematic answer, 69% of the team members responded that they have difficulty speaking up if they perceive a problem with patient care, 76% feel unable to express disagreement. Only 51 % report that briefings were routinely carried out before procedures. All of these suggest the lack of reliable safety oriented communication within a procedure. Strikingly, 55% of the respondents report that morale is high in the operating room. In factor *Safety Climate* (Table 4), 84% agree that

effective coordination of OR staff requires that the personalities of others be taken into account. Fifty-two percent reported feeling that patient safety is not reduced when they are interrupted.

Table 4 *Safety Attitude Domain: Comparison between Study Sites**

	USA		Hungary			
Factor 1 Safety Climate	N	% Agreed	N	% Agreed	z	p
In our OR it is difficult to speak up if I perceive a problem with patient care	55	29	83	69	5.03	0.00
Surgeon and anesthetist maintain open channels of communication throughout the procedure	58	86	80	64	-3.13	0.00
Surgeon and perfusionist maintain open channels of communication throughout the procedure	59	93	78	56	-5.67	0.00
Nurse input about patient care is well received in the OR±	54	65	83	80	1.91	0.06
It is easy for our OR staff to ask questions when there is something that they don't understand	56	75	83	89	2.08	0.04
Morale in our OR is high	55	45	74	55	1.13	0.26
Disagreements in the OR are appropriately resolved (i.e., what is best for the patient)	52	73	80	63	-1.22	0.22
Senior staff encourage questions from junior medical and non medical staff during operations	52	65	83	76	1.36	0.17
I am frequently unable to express disagreement with the attendings in our OR	56	41	80	76	4.31	0.00
OR staff are briefed before surgical procedures	50	44	79	51	0.78	0.44
Factor 2 Team Climate						
Debriefing after errors occur in common	48	29	78	40	1.28	0.20
My patient safety is not reduces when I am interrupted	60	33	82	52	2.32	0.02
The culture in our OR makes it easy to learn from mistakes of others	51	43	80	66	2.64	0.01
My decision-making is as good in medical emergencies as in routine situations	60	78	82	89	1.73	0.08
I receive appropriate feedback about my performance	55	62	79	48	-1.62	0.10
Nurses should not question decisions made by attendings	61	5	79	80	14.16	0.00
The attending surgeon should be formally in charge of the OR during the surgical procedure	57	63	87	82	2.50	0.01
Effective coordination of OR staff requires that the personalities of others be taken into account	56	82	76	84	0.30	0.76
It is difficult to discuss mistakes when they occur in the OR	52	60	82	72	1.43	0.15
Factor 3 Stress Recognition						
Fatigue impairs my performance during critical phases of patient care	60	73	83	73	0.00	1.00
Stress from personal problems adversely affects my performance	61	46	83	55	1.07	0.28
When my workload becomes excessive, my performance is impaired	55	75	83	73	-0.26	0.79
High levels of workload are common in our OR	53	94	83	89	-1.06	0.29

* Number of responses, percent agreed

A further finding was that errors were difficult to discuss. In correlation with the reported lack of open communication channels, 72% reported difficulties in discussing mistakes. In addition, 40% reported that debriefing was common after errors, and 66% agreed that it is easy to learn from mistakes in the OR. Eighty percent agreed that nurses should not question decisions made by attendings, and stated that an attending surgeon should be formally in charge of the OR during the surgical procedure.

In factor *Stress Recognition* (Table 4), 89% agreed with the statement "that a high level of workload is common in the OR", and 73% felt that their performance was impacted by an excessive workload and fatigue. Interestingly 73% of respondents believed that their decision making was unaffected by emergency conditions. As in the USA data both of these latter two statements suggest a lack of insight into the effects that fatigue and emergency has on provider performance, decreasing attentiveness and an accepted cause of error [16].

In the factors of *Error Management* and *Risk Modification* of the Impact of Error domain (Table 5) CS team members report insufficient resources. Only 51% feel that levels of staffing are sufficient and 60% report that problems with equipment are frequent including equipment that is malfunctioning, or not available. Seventy percent report that trainees are adequately supervised, and 49% reported that errors due to lack of knowledge is rare in the OR, but 76% agreed that errors due to lack of skills are rare. 94% agreed that when medical errors occur they handled appropriately. 50% feels that they are encouraged to report patient safety concern they might have.

Table 5 *Error Burden Domain: Comparison between Study Sites**

	USA		Hungary			
Factor 1 Error Management	N	% Agreed	N	% Agreed	z	p
My department provides adequate, timely information about events in the hospital that might effect my work	59	68	82	39	-3.57	0.00
I am encouraged by my colleagues to report any patient safety concerns I may have	59	78	68	50	-3.45	0.00
I know the proper channels to direct questions regarding patient safety in my department or work area	57	95	75	57	-5.93	0.00
Our levels of staffing are sufficient to handle the number of patients	52	31	84	51	2.38	0.02
Trainees in my discipline (e.g., nurse, residents, etc) are adequately supervised	53	79	82	70	-1.19	0.23
I have used the hospital's reporting system for documenting medical errors	51	61	65	6	-7.39	0.00
Decision-making in our OR should include more input from other OR staff than it does now	50	74	77	69	-0.61	0.54
Disruptions in continuity of patient care can be detrimental to patient safety	58	93	83	49	-6.84	0.00
Problems with equipment are frequent in the OR	52	69	81	60	-1.07	0.28
We have a confidential reporting system for documenting medical errors	47	85	56	18	-9.16	0.00
When medical errors occur they handled appropriately	53	85	80	94	1.61	0.11
Factor 2 Risk Modification						
I am properly trained to use new and existing equipment in the OR	55	89	84	79	-1.63	0.10
Errors due lack of skill are rare in OR	52	58	80	76	2.16	0.03
The OR equipment in our hospital is adequate	53	47	83	46	-0.11	0.91
Errors due lack of knowledge are rare in OR	54	59	83	49	-1.16	0.25
I would feel perfectly safe as a patient in our OR	59	64	82	82	2.38	0.02
I am afraid to report adverse events as I might be punished or lose my job	60	12	84	95	17.21	0.00
I am reluctant to report adverse events as I might gat a colleague/friend in trouble	60	15	80	25	1.50	0.13
I expect to be consulted on matters that affect the performance of my duties	55	95	78	35	-9.76	0.00
Factor 3 Error Burden						
I have seen others make that had the potential to harm patients	58	91	76	14	-14.07	0.00
I am more likely to err in tenser hostile situation	60	85	77	39	-6.37	0.00
I have made mistakes that had the potential to harm patients	59	83	81	31	-7.33	0.00
I am ashamed when I make a mistake in front of other OR staff	55	75	84	11	-9.46	0.00
I have seen the same mistakes occur again and again	54	33	84	79	5.90	0.00
Medical errors occur every day in our OR	49	41	78	49	0.89	0.38
There are frequent changes to the schedules	54	91	81	75	-2.58	0.01
Errors committed during patient management are not important, as long as the patient improves	59	3	81	86	18.65	0.00
OR personnel often disregard rules or guidelines	56	39	83	92	7.40	0.00

* Number of responses, percent agreed

The most striking finding in the Hungarian data is that 95% reported that they are afraid to report adverse event as they might be punished or lose their job. We are aware that in the participating university hospitals in Hungary there are no hospital-based confidential reporting systems. However these questions about reporting systems were left in the questionnaire to confirm validity of the responses. Based on the expectation, it is reassuring that 94% reported that they did not use the hospital reporting system. Also reassuring is that 82% would feel safe being a patient in their own OR in Hungary.

In the factor *Error Burden* of the Impact of Error domain (Table 5), only 3% of respondents agree that errors are important regardless of patient outcome. Errors in this environment would appear to be omnipresent [40] but only 14% of the respondents stated that they have seen others to make errors, and only 31% respond that they have made a mistake that had the potential to harm a patient. Only 11% report being ashamed of making an error in front of the OR staff. In spite of these responses, 49% report that medical errors happen every day, and seeing the same mistake occur repeatedly was reported by 79%. The perceptions of CS team members about the inadequacy of, and frequent problems with equipment are strongly reinforced by the 92% agreement with the statement that CS personnel "often ignore guidelines and have a generalized feeling of dread around safety errors" (Table 9).

4.5 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 (Tables 2 and 4) 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 (Tables 2 and 4) 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 (Tables 3 and 5), 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 (Tables 3 and5), 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. The other item is that the respondent expects to be consulted on performance issues, with 35% of the Hungarian team agreeing and 95% of the USA team agreeing. This appears to support the inference that there are more authoritarian issues at work among the Hungarian teams. 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 (Tables 3 and 5), seven of the nine items indicate complete disagreement. Important among these is that the vast majority 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.

4.6 Fictitious case of adverse event

The responses to the questions related to the clinical scenario (Table 6) 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. The overall scale score of the Safety Attitude domain significantly correlated with the summed score for reporting the error in the clinical scenario (r=0.26; p=0,042). The responses to the questions regarding reporting on events were also found to be significantly correlated to the *Error Burden* factor in the Impact of Error domain (r=0.33, p=0.009). These correlations suggest that the respondents most likely to report the error would also be those most likely to agree with the burden of error items in the factor.

Table 6 *Fictitious Case of Adverse Event*

	USA		**H**			
	N	% Agreed	N	% Agreed	z	p
Keep it to myself that the patient has received 10 times the prescribed level	61	3	77	4	0.34	ns
Write in the patient's case-record that the patient has received 10 times the prescribed level	53	85	78	74	-1.72	ns
Talk in confidence with a colleague about the incident	59	75	73	61	-1.83	ns
Talk to several colleagues about the incident	59	54	75	53	-0.12	ns
Inform my supervisor or the physician in charge of the patient	60	98	79	86	-2.85	ns
Tell the family/patient about the problem	53	57	72	11	-6.66	0.00

* Number of responses, percent agreed, ns: non significant

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.

4.7 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 7). 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 (e.g., “Forgetting to do something”, or “we left the sponge in the patient”).

Table 7 *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 7). 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%).

Among the USA teams the concerns about staffing and workload reflect items in the *Risk Perception* factor of the Impact of Error domain (Table 3 and 5). The only factor scale associated with loss of sleep was *Error Burden.* When adjusted for other factors in a stepwise regression, this relationship was statistically significant ($p<0.032$) (Table 8).

Table 8 *Regression Analysis of the Error Burden Scale in the Impact of Error Domain*

Variable	Parameter	SE	p
Intercept	3.303	0.367	< 0.0001
Age	-0.034	0.010	0.0014
Gender	0.284	0.124	0.0267
Hospital Years	0.021	0.010	0.0333
Loss of Sleep	-0.271	0.123	0.0320

The positive relationship of the scale score with the loss of sleep indicates that the respondents who agreed with the items in the factor were more likely to lose sleep from their concerns over patient welfare. Also, older participants, males, and those with a shorter tenure experience at their hospital were more likely to have higher scale scores on the *Error Burden* factor. The frequent presence of error and its psychological impact and

stresses from overwork suggest that these concerns impact clinicians even when away from work.

Respondents were also asked to list three frequently occurring errors they had personally observed. The reported errors were categorized by the type of error (Table 9). In the USA study group the most frequent type was a medication error (34%) (i.e., "wrong drug dose given", "wrong drug concentration"), and miscommunication (23%) (i.e., "discrepancies between colleagues") were also frequent. Equipment problems (23%), not following clinical guidelines (20%) (i.e., "no patient consent", "no blood available") were less frequent. These observations validate the concerns raised by the items in the *Risk Perception* factor in the Impact of Error domain (Table 4). 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 9 *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%).

The top two recommendations, improving team communications and increasing education and training, reflect the concerns expressed in both the *Teamwork Climate* and *Safety Climate* factors of the Safety Attitude domain (Table 2 and 4).

5. DISCUSSION

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, actions needed. We were researching the characteristics of the safety culture in the three academic centers in the United States and in four academic centers in Hungary. We were able to define the same traits of the culture in these two countries, however they have different features. A further finding was that the actuality and anticipation of clinical error imposes a measurable burden on the CS team. Since there is no ideal safety culture profile, and no database exists to compare results against organizations with the best safety practices [53], we chose to interpret our data following the methods of the safety culture study of 15 California hospitals [13]. We describe measures of safety climate based on the percentage of respondents with "problematic response" (i.e. answered a question with a score of 1 or 2, suggesting a lack of safety culture. This study indicated responses were "problematic" if they show a substantial percentage of responses in the undesired direction [13;54]. We believe that the items without a substantial agreement (75-85%) indicate the need for relevant interventions to improve patient safety.

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 (Table 2 and 4) 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. Our study found that the CS team's safety attitude have the same characteristics as safety culture studies describing other healthcare teams [58;59;]. 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. We found that only one-half of the respondents reported pre-surgery briefing, and only one third of the respondents indicated that debriefing occurs after errors and patient harm. 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. Clearly morale has many elements, but essentially reflects the emotional attitude of an individual to group expectations and loyalty to the group [59]. The high factor loading of the *Teamwork Climate* factor indicates that work is needed with respect to establishing better rapport among team members and setting realistic team expectations. 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 [15].

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. The perceptions of CS team members about the inadequacy of equipment are troublesome [40]. 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 CS. This

is in contrast to Sexton and co-workers [25] who found in their comparison of medicine and aviation that only 40% of medical respondents agreed with this question while 74% of pilots agreed. Perhaps the increased awareness and education regarding these issues in the ensuing years have altered these attitudes, or the high-risk profile of the CS environment increases the awareness of this vulnerability. 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. However in spite of all of these perceived problems 82% of Hungarian team members would feel perfectly safe in their own OR

Error perception, error burden

Perhaps the most troubling finding is the fact that respondents have seen the same mistakes occur repeatedly. The USA CS 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. This dissonance points to the reluctance providers feel about sharing these events with management and their colleagues. 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 OR 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. Only a small percentage of our respondents feel that it is easy to

learn from their own mistakes, suggesting that many may not have the knowledge or the skills to analyze the root causes of these errors. Educational sessions dedicated to root-cause analysis and safety science may provide another important opportunity.

We recognize several limitations to the study. The limited scope and sample size of cardiac surgical teams require that these findings be further validated. However, the successful fit of the confirmatory factor analysis based on a previously validated study [55] appears to lend credibility to the belief that relatively small sample sizes can be used to accurately measure previously described patient safety concepts. The validation of the hypothesized factor structure of the Impact of Error domain was more modest than for the established items, but still acceptable for identifying the attitudes and concerns of team members. Focusing on clinician perceptions based on pre-formulated questions may be a source of richness but also have unrecognized biases. Further development of the methodology to understand attitudes and their impact on actual provider performance, perhaps coupled with empirical and observational techniques [58], to measure these burdens would help confirm the generalizability of the results [60].

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. With this tool we were able to explore the factors of the safety climate and added the Impact of Error domain, which has not previously described in the literature. In this study Safety Attitude domain was defined using team climate, safety climate, and stress recognition factors. The Impact of Error domain consisted of error management, risk modification, and error burden factors.

- The research explored same safety culture domains and factors in the developed country, in the USA and in Hungary where economy is in transition. In spite of the many differences in circumstances in these two countries team members from both sites that discussion is limited and more staff input is wanted. They report that

knowledge and equipment are not always up to par. In the USA job stress is more often recognized as is its impact on performance. The possible result of these beliefs is that morale is not high. However when examining the differences we believe that a clear proof of the impact of applied quality research can be shown in the United States. Health professionals have commitment to discuss and learn from errors, while recognizing the inevitability of error. The sample institutions have incorporated nonpunitive systems for reporting and analyzing adverse events. Not having such reporting systems in Hungary may explain why that healthcare providers clearly stated that nurses cannot question decisions or point out problems, they deny that they or others make mistakes but report seeing the same errors again and again. In Hungary no positive attitude was reported about the importance of errors, rules, and guidelines. Team members are fearful of reporting errors. On a positive note in spite of all of the problematic responses in Hungary 82% of the respondents would feel perfectly safe as a patient in their own operating room.

- 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 nonpunitive reporting systems found in the Unites States and only at the discussion stage in Hungary. However we found that there are some professionals in the USA who say they are willing to report errors, and know the proper channels of reporting but say they do not use these opportunities. Changing these habits might prove to be difficult.

- 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. While safety attitude questionnaire may highlight areas in need of improvement, the implementation, measurement, and sustainability of a safety improvement program requires a committed leadership. Leaders need to set and communicate a clear and compelling safety vision, value and empower personnel to achieve the vision, engage actively in the hospitals patient safety improvement effort, lead by example, focus on system issues rather than individual error and continually search for improvement opportunities.

In conclusion, the findings suggest that CS teams face significant barriers in enabling the conditions for safe outcomes. These findings highlight the personal and professional burden that the fear and recognition of errors puts on team members and their impact on the performance and mindset of healthcare providers. 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

Barach, P., Johnson, J., Ahmad,A., Galvan, C., Bognar, A., Duncan, R.C., Starr, P., and Bacha, E.A., A prospective observational study of human factors, adverse events, and patient outcomes in surgery for pediatric cardiac surgery, J. Thorac. Cardiovasc. Surg., 136 (2008) 1422-1428. IF: 3.037

Bognar, A., Duncan, R.C., Birnbach, D., Bacha, E.A., Nagymajtenyi L.: Safety attitudes and perceptions in cardiac surgical teams in different cultural setting Qual. Saf Health Care, (submitted)

PRESENTATIONS

Deshpande, J., Throop, P., France D., Bognár, Á., Taylor, M., Churchill, K., Lynn,C., Deppen, S., Miles, P., Speroff, T. : Process Improvement Reduces Hospital Costs associated With a Novel Treatment (inhaled nitric oxide) Without Adversely Affecting Patient Outcome IHI National Forum, Orlando, FL, USA; 2002 Abstract book p:36

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A. Bognar, M.D., M.B.A., I. Nevo, M.D., J. Mohr, Ph.D., M.P.H., R. Duncan, Ph.D., P. Barach, M.D., M.P.H.: Safety Culture Survey - A Tool To Uncover Patient Safety Opportunities in the Operating Room; American Society of Anesthesiologists Annual Meeting, Atlanta, GA, USA; Anesthesiology 2005; 103: A1277

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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