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Article (Accepted for Publication)  
(Refereed)

*Original Citation:*

Steyrer, Johannes and Schiffinger, Michael and Clemens, Huber and Valentin, Andreas and Strunk, Guido (2013) Attitude is everything? The impact of workload, safety climate, and safety tools on medical errors: A study of intensive care units. *Health Care Management Review*, 38 (4). pp. 306-316. ISSN 1550-5030

This version is available at: <http://epub.wu.ac.at/4391/>

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## **Attitude is everything?**

The impact of workload, safety climate, and safety tools on medical errors: A study of intensive care units

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Final version published as:

Steyrer, Johannes; Schiffinger, Michael; Huber, Clemens; Valentin, Andreas; Strunk, Guido (2013) Attitude is everything?: The impact of workload, safety climate, and safety tools on medical errors: A study of intensive care units. *Health Care Management Review*, 38 (4): 306-316.  
doi: 10.1097/HMR.0b013e318272935a

## **Abstract**

*Background:* Hospitals face an increasing pressure towards efficiency and cost reduction while ensuring patient safety. This warrants a closer examination of the trade-off between production and protection posited in the literature for a high-risk hospital setting (intensive care).

*Purposes:* Based on extant literature and concepts on both safety management and organizational/safety culture, this study investigates to which extent production pressure (i.e., increased staff workload and capacity utilization) and safety culture (consisting of safety climate among staff and safety tools implemented by management) influence the occurrence of medical errors and if/how safety climate and safety tools interact.

*Methodology/Approach:* A prospective, observational, 48-hour cross-sectional study was conducted in 57 intensive care units. The dependent variable is the incidence of errors affecting those 378 patients treated throughout the entire observation period. Capacity utilization and workload were measured by indicators such as unit occupancy, nurse-/physician-to-patient ratios, levels of care, or NEMS scores. The safety tools considered include Critical Incidence Reporting Systems, audits, training, mission statements, SOPs/checklists and the use of barcodes. Safety climate was assessed using a psychometrically validated four-dimensional questionnaire. Linear regression was employed to identify the effects of the predictor variables on error rate, as well as interaction effects between safety tools and safety climate.

*Findings:* Higher workload has a detrimental effect on safety while safety climate – unlike the examined safety tools – has a virtually equal opposite effect. Correlations between safety tools and safety climate as well as their interaction effects on error rate are mostly nonsignificant.

*Practice Implications:* Increased workload and capacity utilization increase the occurrence of medical error; an effect that can be offset by a positive safety climate but not by formally implemented safety procedures and policies.

## **Key words:**

patient safety, safety tools, safety climate, workload, medical error, intensive care units

## Introduction

Reducing the number of medical errors as a means of improving patient safety has been in the spotlight for over a decade now (e.g., Kohn, Corrigan, & Donaldson, 2000). At the same time, hospitals, like other high-hazard industries, face the basic dilemma of “production versus protection” (Reason, 1997, p. 4), i.e., providing quick and (cost-)effective treatment while ensuring patient safety and avoiding medical errors. In addition, pressure on hospitals towards efficiency and cost reduction has risen over the last years (Hsieh, Clement, & Bazzoli, 2010), with potentially detrimental effects on safety (Hansez & Chmiel, 2010) as well as error-induced cost (van den Bos *et al.*, 2011).

One central determinant of medical error prevention consists in so-called safety culture (Naveh, Katz-Navon, & Stern, 2005), which is defined by a pioneer source as “the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organisation’s safety management” (International Safety Advisory Group, 1991, p. 23). A related construct is safety climate, which refers primarily to “the shared perceptions of employees concerning the degree to which safety is a top priority for employees within the organization” (Naveh, Katz-Navon, & Stern, 2011, p. 57).

Referring to the distinction made by Reason (1997) between error management tools (p. 130) and safety climate in the sense of shared values and attitudes (p. 194), we distinguish between two elements of safety culture – the abovementioned shared perceptions and attitudes concerning safety, hence termed safety climate (SC) and tangible, formalized safety procedures and tools (e.g., Critical Incident Reporting Systems (CIRS), checklists, barcodes, safety audits, or mission statements), hence termed safety tools (ST). This distinction between SC and ST is not always made in extant literature, with some authors seeing observable safety features as a part of safety climate both in theory on organizational culture and climate and empirical studies in healthcare and other fields (e.g., Katz-Navon, Naveh, & Stern, 2005; Neal, Griffin, & Hart, 2000; Ostroff, Kinicki, & Tamkins, 2003). Indeed, some ST like safety audits and mission statements are arguably quite closely related to the perception- and attitude-centered notion of safety climate, while others (e.g., checklists and barcodes) represent a much more tangible and procedural aspect of work design. One central distinction from SC, however, is that from a management perspective, all ST can be formally designed and implemented.

This difference applies to several similar distinctions in related fields, too, like that between hard and soft aspects of Total Quality Management (e.g., Wilkinson, Redman, Snape, &

Marchington, 1998) and/or organizational culture (e.g., the 7S-model, with strategy, structure and systems as “hard” aspects and skills, style, staff, and shared values as “soft” aspects; e.g., Waterman, Peters, & Phillips, 1980). It also relates to two different approaches to safety management in health care, where Neal et al. (2000) differentiate between *safety compliance*, which “involves adhering to safety procedures and carrying out work in a safe manner”, and *safety participation* consisting of “helping coworkers, promoting the safety program within the workplace, demonstrating initiative, and putting effort into improving safety in the workplace” (p. 101). In a similar vein, Khatri et al. (2006) contrast *control-based management* with *commitment-based management*. The former is characterized, among other things, by an “emphasis on compliance/obedience” (p. 119) and a “bureaucratic, rule-based culture” (p. 125), aiming at regulation and standardization by a centralized quality department (Khatri, Brown, & Hicks, 2009). By contrast, commitment-based management attaches importance to communication and teamwork, and makes “quality and safety issues permeate the entire organization” (Khatri et al., 2009, p. 318). In spite of all these dichotomies represented by the mentioned concepts, these aspects (climate vs. tools, soft vs. hard, control/compliance vs. commitment/participation) are arguably not mutually exclusive, which raises the question to what extent the potential effects of these approaches are independent, antagonistic or mutually reinforcing.

Based on these considerations, our study investigates the following research questions:

- 1) How strongly does production pressure (reflected in higher capacity utilization and/or staff workload) affect error rate?
- 2) To what extent do safety tools (see above) affect error rate?
- 3) To what extent do shared perceptions and attitudes among frontline staff concerning safety (safety climate) affect error rate?
- 4) Do safety tools and safety climate interact in affecting error rate?

In investigating these questions, our study contributes to extant research in three ways. First, while the effect of safety culture/climate on patient safety has been previously examined, the influence of staff workload/capacity utilization as factors that are thought to adversely affect patient safety has hitherto rarely been investigated let alone directly compared with safety climate/safety tools as elements of safety culture that are thought to positively affect patient safety. Second, it distinguishes between safety climate and safety tools as two elements of safety culture that represent different yet complimentary approaches to safety management and relates them to extant concepts of organizational and safety culture. Third, it consequently examines the main and interaction effects of these two elements (SC and ST) on patient safety as opposed to the influence of production pressure in a particularly error-prone medical specialty (intensive care).

## Framework and hypotheses

Regarding the abovementioned conflict between production and protection, there are several approaches that aim at improving both safety and efficiency via process optimization, like Six Sigma, Lean Healthcare etc., and while some sources suggest that the conclusion regarding the overall benefit of Lean Healthcare implementation is somewhat sobering (Grove, Meredith, MacIntyre, Angelis, & Neailey, 2006; Radnor, Holweg, & Waring, 2012), there are indeed successful instances in healthcare of reconciling these contradictory goals (Radnor, 2011, p. 4).

One central determinant whether such initiatives are beneficial to patient safety or not is arguably whether the modified processes lead to a reduction in workload for frontline staff (e.g., via less red tape, smoother handovers, etc.) or rather increase workload and production pressure on staff in an effort to “do more with less”. Several empirical findings suggest a tendency towards the latter in practice (Mehri, 2006; Schön, Bergquist, & Klefsjö, 2010), suggesting that while efforts for increased efficiency need not necessarily lead to increased workload, in practice they apparently do (see also Rasmussen, 1997), and indeed the premise that production pressure increases the rate of medical error is corroborated by several studies (e.g., Hansez & Chmiel, 2010; Valentin *et al.*, 2009). Hence, our first hypothesis:

*H1: A higher degree of capacity utilization and/or workload is associated with a higher error rate.*

Safety-related efforts, by contrast, contribute to increased safety margins (Rasmussen, 1997, p. 190) and should thus reduce the occurrence of errors. While this applies to both tools and climate, their pathways of effectiveness are arguably different (although not mutually exclusive). Procedural tools like checklists and barcodes serve as “technical” barriers against errors. Those tools that are closer to the perception-related notion of safety climate (safety audits and mission statement) primarily represent an “official” and observable reflection of the prevailing safety climate. Finally, training and Critical Incident Reporting Systems (CIRS) emphasize the learning aspect of a safety culture and mainly aim at a better recognition of and appropriate response to identified threats to safety and/or sources of error. Indeed, the notion that safety tools reduce medical error is supported by empirical findings (Shojania, Duncan, McDonald, & Wachter, 2002); specifically for CIRS (Valentin *et al.*, 2009), audits and mission statements (Ovretveit, 1999), or standard operating procedures for handovers (Catchpole *et al.*, 2007):

*H2: Implementation of safety tools (ST) is associated with a lower error rate.*

A good safety climate, on the other hand, establishes a priority for safety compared to efficiency goals (e.g., Zohar, 2000) and should thus contribute to less treatment errors as well, a notion supported by numerous studies (Clarke, 2006; Hofmann & Mark, 2006; Huang *et al.*, 2010; Katz-Navon *et al.*, 2005; Naveh *et al.*, 2005, 2011; Neal & Griffin, 2006; Singer, Lin, Falwell, Gaba, & Baker, 2009; Vogus & Sutcliffe, 2007):

*H3: A better safety climate (SC) is associated with a lower error rate.*

Concerning the respective effectiveness of these two safety culture elements (ST vs. SC), several sources suggest that a formalized, control-based approach might not be as important a determinant of (patient) safety as an approach emphasizing shared views and social norms concerning safety among staff (Podgórski, 2010), which applies to the medical field, too (Khatri, Halbesleben, Petroski, & Meyer, 2007; Waring, 2009). In addition, compared to other high-risk industries, work processes in health care depend to a greater extent on the decisions and discretion of frontline staff, with less reliance on automation and standardization (Gaba, 2000), which further underlines the importance of an emphasis on safety among frontline staff for error prevention:

*H4: SC reduces medical error more than ST.*

Finally, we argue that safety tools and safety climate reinforce each other. For the “technical barrier” type of tools (checklists and barcodes), a good safety climate enhances compliance with safety procedures, strengthening their effectiveness. Safety tools that focus on learning (training and CIRS) provide increased knowledge and awareness about important threats and errors, adding to the attitudinal aspect represented by climate. Finally, safety tools that represent the observable complement of a good safety climate may degenerate into mere rhetoric and pretense in case of a weak safety climate (Naveh *et al.*, 2011):

*H5: SC and ST interact in a mutually reinforcing way in their influence on error rate.*

## **Method**

### *Study design*

The study was conducted as a joint research project by the Austrian Center for Documentation and Quality Assurance in Intensive Care (ASDI), together with the Research Institute for Healthcare Management and complexity-research.com of Vienna University of Economics and

Business (WU). We drew on a sample of ICUs recruited by cooperating associations already in 2004 (apart from the ASDI these were the German Interdisciplinary Federation of Intensive Care Medicine and Emergency Medicine and the Swiss Society of Intensive Care Medicine) which have an explicit interest in patient safety and prior experience with the recording of medical errors for scientific studies (Valentin *et al.*, 2009; Valentin *et al.*, 2006). Required sample size was estimated beforehand based on expected effect sizes and validity of measures. Participating units could choose between two possible dates on which to begin a 48-hour observation period.

To avoid problems associated with the use of archive data (Clarke, 2006), this study used a prospective approach to error measurement. Medical errors that actually or potentially caused harm to a patient were recorded over a 48-hour period (which included change of shift for nurses and physicians), with safety climate measured during that time, too. To approach the problem of variation across specialties, we focused on a particular medical field: intensive care units (ICUs). Our choice was motivated by the fact that intensive care is particularly prone to error. The combination of complexity and potential for great harm makes it even more fraught with risk than other medical fields (Valentin *et al.*, 2009). A study of ICUs therefore seemed especially well-suited to investigating the research questions set out above.

### *Sample*

The final study sample consisted of 378 patients from 57 ICUs in as many (predominantly larger urban) hospitals. The data obtained during observation are summarized in Table 2, in which the values of continuous variables are expressed as mean +/- standard deviation and those of categorical variables as frequencies and percentages. It is noteworthy that the overall mean NEMS score of 35.5 ( $\pm 11.5$ ) score points per patient suggests a high level of treatment intensity.

Figures for the safety climate dimensions are based on responses from 549 nurses and 185 physicians, representing response rates of 41.4% and 35.2%, respectively. Response rate standard deviation across ICUs is 17.7 %. ICUs with less than five respondents for the safety climate survey were excluded from the analyses. The mean age of respondents was 37.5 ( $\pm 9.2$ ) years and their mean professional experience 14.4 ( $\pm 8.7$ ) years. Some 17% of respondents had managerial functions. The following results are based on those 378 patients who remained in an ICU throughout the entire observation period. An analysis of patients with an observation time of at least 12 hours (795 in total) led to similar results and is therefore not reported.



Table 1. Characteristics of 378 patients from 57 intensive care units

|   | <i>Count (%) or mean <math>\pm</math> SD</i> |
|---|--|
| <b>Patients</b>   |  |
| Age (years)   | 60.3 $\pm$ 19.1                              |
| Female (%)  | 141 (37.3)                                   |
| Male (%)  | 237 (62.7)                                   |
| No. of tubes, lines, drains, etc. per patient   | 4.7 $\pm$ 2.1                                |
| No. of medications (applications) per patient   | 49.4 $\pm$ 27.2                              |
| NEMS score (points) per patient   | 35.5 $\pm$ 11.5                              |
| <b>ICUs</b>   |  |
| No. (%) by type of unit   |  |
| Mixed   | 25 (43.9)                                    |
| Medical   | 16 (28.1)                                    |
| Surgical  | 12 (21.1)                                    |
| Pediatric   | 2 (3.5)                                      |
| Other   | 2 (3.5)                                      |
| No. (%) by unit size (beds)   |  |
| <8  | 13 (22.8)                                    |
| 8-12  | 27 (47.4)                                    |
| >12   | 17 (29.8)                                    |
| No. (%) by hospital size (beds)*:   |  |
| <400  | 17 (29.8)                                    |
| 400-900   | 23 (40.4)                                    |
| >900  | 14 (24.6)                                    |
| No. of physicians   | 12.6 $\pm$ 7.1                               |
| No. of nurses   | 41.6 $\pm$ 26.3                              |
| No. of patients (during 48h period)   | 6.6 $\pm$ 4.7                                |
| Safety climate total score  | 49.7 $\pm$ 19.0                              |
| Unit occupancy (0-1)  | 0.79 $\pm$ 0.19                              |
| Physicians to patient ratio (0-1)   | 0.35 $\pm$ 0.25                              |
| Nurses to patient ratio (0-1)   | 0.80 $\pm$ 0.43                              |
| Total no. of tubes, etc. per nurse  | 8.40 $\pm$ 4.60                              |
| Total no. of medications per nurse  | 66.79 $\pm$ 35.02                            |
| Total NEMS score (points) per patient   | 68.10 $\pm$ 35.60                            |
| ICUs with CIRS  | 33 (57.9)                                    |
| ICUs with regular safety audit  | 11 (19.3)                                    |
| ICUs with barcodes or other electronic measures designed to prevent medication errors | 14 (24.6)                                    |
| ICUs with checklists  | 51 (89.5)                                    |
| Error rate (no. of patients with errors / all patients)                               | 0.44 $\pm$ 0.32                              |

## *Data collection*

A study manual and all questionnaires were made available in German on the study website ([www.sifim.org](http://www.sifim.org)). Detailed handbooks as well as simulated training sessions were provided to all participants. Additional support and supervision was offered during data collection. Data collection itself was highly standardized in order to reduce the risk of errors. For each patient observed, basic demographic characteristics (age, sex) were recorded by staff on a form, along with the start and end of the individual observation period. Throughout that time, the form remained at the patient position and was used to record the occurrence of any of the predefined medical errors relating to the patient concerned, irrespective of the staff member recording them. Every contributor to the questionnaire could see all previous entries, making duplicate reporting highly unlikely. In addition, each ICU staff member was asked to fill in the safety climate questionnaire available on the study website. For both patients and medical personnel, data acquisition and reporting were anonymous. Last but not least, the characteristics of individual ICUs were reported by a designated coordinator, who was also responsible for briefing the unit staff, facilitating data collection, and transmitting information to the study database.

## *Measures*

Concerning the operationalization of “production pressure”, our measure of *capacity utilization* was constructed from three separate indicators expressing the relation between patient numbers and resources, as follows:

- Unit occupancy, defined as the ratio of “bed usage” (sum of all hours of patient observation) to “bed potential” (number of ICU beds times 48, the observation period duration in hours);
- Nurse-to-patient ratio, defined as “total nurse working hours” (mean number of nurses times 48) divided by “bed usage”;
- Physician-to-patient ratio, defined by analogy with 2.

Our *workload* measure was also composite and based on three indicators, in this case all concerned with the level of care provided per patient. They were:

- The number of medications received by patients in relation to nurse numbers
- The number of tubes, catheter, probes, lines and/or drains inserted into patients, again in relation to nurses.
- The so called Nine Equivalents of Nursing Manpower Use Score (NEMS; Reis Miranda, Moreno, & Iapichino, 1997), made up of: basic monitoring, intravenous medication, mechanic

airway, supplementary airway, singular vasoactive medication, multiple vasoactive medication, dialysis, specific interventions.

The composite variable showed no linear correlation with error rates, so its natural logarithm was used as a linear correction. The results obtained in both cases were similar.

On the “protection” side, the safety tools we included correspond to those most commonly used in German ICUs, the use of which was measured by means of six categorical (yes/no) indicators for each ICU: existence of a *mission statement* stressing patient safety; regular performance of *safety audits*; implementation of *CIRS*; regular *training* to improve patient safety as well as implementation of *checklists* for SOPs and/or *barcodes* or electronic tools to avoid medication errors, the latter two being safety tools directly related to daily medical tasks.

Concerning the measurement of *safety climate*, besides operationalizations of safety climate in general (e.g., Burke, Sarpy, Tesluk, & Smith-Crowe, 2002; Zohar, 2000), several instruments specifically referring to patient safety have been developed (e.g., Colla, Bracken, Kinney, & Weeks, 2005; Singer *et al.*, 2007). However, no reliable and valid instrument in German was available and a literal translation makes little sense from a methodological point of view (Coyne, 2001; Hambleton, Merenda, & Spielberger, 2005). This led to the development of the Vienna Safety Climate Questionnaire (VSCQ) in an iterative process using data from a total of 1,968 respondents and including multidimensional scaling ( $n = 61$ ), item selection ( $n = 954$ , including an EFA sample with  $n = 107$  and a first CFA sample with  $n = 847$ ), confirmatory factor analysis (second CFA sample, recruited after final item selection  $n = 761$ ), and validity (included in all samples). This process was completed before the current study was conducted.

Despite going beyond mere translation, the VCSQ is based on existing instruments for measuring safety climate (e.g., Colla *et al.*, 2005; Flin, Burns, Mearns, Yule, & Robertson, 2006; Schutz, Counte, & Meurer, 2007; Singer *et al.*, 2007; Weingart, Farbstein, Davis, & Phillips, 2004). Accordingly, the scales included in this study are closely related to extant dimensions of safety climate. For instance, taking the PSCHO by Singer and colleagues (e.g., 2007) as a reference, *Management Commitment to Patient Safety* largely corresponds to “Senior managers’ engagement”, *Organizational Learning* to “Learning”, *Communication and Cooperation regarding Patient Safety* to “Fear of shame” and “Fear of blame”, and *Attitude toward Safety Management* to “Overall emphasis on safety” and “Unit safety norms”.

Despite considerable intercorrelations of the VSCQ scales (see Table 3), a confirmatory factor analysis based on three samples (total  $n = 2,608$ , with the sample used in the present study included) supports the posited dimensions and item allocation, with  $RMSEA \leq .05$  and  $\chi^2/df < 3.6$  in all cases (Browne & Cudeck, 1993). The questionnaire has been successfully validated (Steyrer,

Latzke, Pils, Vetter, & Strunk, 2011), and the performance of the VSCQ on relevant psychometric criteria (see Table 1) is so satisfactory that it is now listed in the catalogue of safety culture instruments used in member states of the European Union compiled by the European Network for Patient Safety.

Although safety climate was ascertained individually it represents a construct on group and/or organizational level (here: ICU); the same ultimately applies to error rate (Neal & Griffin, 2006), with this study not focussing on the probability of an individual patient encountering a medical error but rather the performance of the whole ICU and its relationship to ICU-wide SC and ST. All analyses were therefore conducted at ICU level, with aggregated SC scale values. Table 1 shows the aggregation indices ICC(1), ICC(k) (notation follows McGraw & Wong, 1996), and the interquartile range for  $r_{WG(j)}$  for all scales. While using the uniform distribution as reference for the  $r_{WG(j)}$  calculations makes them upper bound values (LeBreton & Senter, 2008), these values as well as the ICC(k) values are well above the commonly cited threshold of 0.7, and ICC(1) well above 0.05 (Bliese, 2000; James, Demaree, & Wolf, 1993), suggesting that analysis on an aggregate level is appropriate here.

Table 2. Sample items and scale properties for the four VSCQ scales (different n apply to consistency and validity criteria as opposed to aggregation indices)

|  | n = 1,968 |     | n = 734           |            |
|--|-----------|-----|-------------------|------------|
| <b>1. Management Commitment to Patient Safety</b>  | Items     | 10  | ICC(1)            | .19        |
| “Management encourages the staff to report incidents” / “Most superiors know that they act as role models regarding safety issues”   | Alpha     | .91 | ICC(k)            | .81        |
|  | Validity  | .40 | $r_{WG(j)}$ (IQR) | .83<br>.92 |
|  |           |     |                   |            |
| <b>2. Organizational Learning</b>  | Items     | 10  | ICC(1)            | .18        |
| “After critical incidents we undertake major efforts to investigate the cause” / “We investigate critical incidents to draw new conclusions for our actions”                                 | Alpha     | .86 | ICC(k)            | .80        |
|  | Validity  | .43 | $r_{WG(j)}$ (IQR) | .83<br>.92 |
|  |           |     |                   |            |
| <b>3. Communication and Cooperation regarding Patient Safety</b>   | Items     | 10  | ICC(1)            | .17        |
| “If someone notices that a colleague makes a mistake it is no problem to address it” / “Mistakes are personalized and individual persons are charged” (-)                                    | Alpha     | .87 | ICC(k)            | .78        |
|  | Validity  | .37 | $r_{WG(j)}$ (IQR) | .80<br>.90 |
|  |           |     |                   |            |
| <b>4. Attitude toward Safety Management</b>  | Items     | 10  | ICC(1)            | .15        |
| “Process quality and error management are rather lip service than lived practice” (-) / “Sometimes it seems like a waste of time, which is taken for safety efforts without much effect” (-) | Alpha     | .82 | ICC(k)            | .76        |
|  | Validity  | .39 | $r_{WG(j)}$ (IQR) | .83<br>.90 |
|  |           |     |                   |            |

As regards our dependent variable, a *medical error* was defined, in line with previous studies on patient safety in ICUs, as an event that harmed or could have harmed a patient, whether by

omission or commission (Thomas *et al.*, 2000). We focused on intensive care routine processes and recorded errors in seven distinct categories, based on insights from two previous studies (Valentin *et al.*, 2009; Valentin *et al.*, 2006): administration of medication (wrong dose, time and medication, wrong means of administration or missed administration) and unplanned dislodgement of airways, arterial lines, central venous catheters, urinary catheters, enteral nutrition probes or drains. The *error rate* was the ratio of patients affected by errors in a given ICU to the total number of patients in that unit.

## *Analysis*

In several other studies on the relationship between safety climate and medical errors the occurrence of errors represents a count variable of rare events which is why the authors use poisson or negative binomial models to analyze their data (e.g., Hofmann & Mark, 2006; Katz-Navon *et al.*, 2005; Singer *et al.*, 2009). The distribution of our criterion variable, by contrast, does not correspond to a count of rare events, with a median and mean of .44 (s.d.  $\pm$ .32), a merely slightly positive skewness value (.23) and even a negative excess kurtosis (-.94), which is why OLS regression and correlations are employed in this study (as for instance in Naveh *et al.*, 2005).

Based on the correlation results presented in Table 3 we chose the predictors for the regression analyses, with a focus on keeping the models parsimonious and minimizing multicollinearity. In order to test H4 we conducted Steiger's Z-test (Steiger, 1980) comparing the (bivariate) effect of safety climate on error rate to that of the safety tools.

## **Findings**

Bivariate analysis reveals a high intercorrelation between capacity utilization and workload (0.72) and of both with error rate (capacity utilization: 0.25, workload: 0.40), which is why we only retained workload as a predictor for the following regression analyses. Similarly, while all safety climate scales are significantly correlated with error rate, the high intercorrelations of the VSCQ scales prompted us to choose *Attitude towards Safety Management* as safety climate proxy for the regression analyses, since this VSCQ dimension corresponds most closely to the definition of safety climate presented above.

Table 3. Overview of means, standard deviations, and correlations (ICU level)

|                                 | mean (SD)   | 1.   | 2.   | 3.   | 4.   | 5.   | 6.   | 7.  | 8.   | 9.   | 10.  | 11. | 12. |
|---------------------------------|-------------|------|------|------|------|------|------|-----|------|------|------|-----|-----|
| 1. Mgmt. Commitm. to Pat. Saf.  | -.02 (.58)  | --   |      |      |      |      |      |     |      |      |      |     |     |
| 2. Organizational Learning      | -.02 (.51)  | .85  | --   |      |      |      |      |     |      |      |      |     |     |
| 3. Comm. & Coop. reg. Pat. Saf. | -.00 (.54)  | .74  | .74  | --   |      |      |      |     |      |      |      |     |     |
| 4. Attitude tow. Safety Mgmt.   | -.00 (.53)  | .81  | .81  | .86  | --   |      |      |     |      |      |      |     |     |
| 5. CIRS                         | .58 (.50)   | .08  | .07  | .05  | .05  | --   |      |     |      |      |      |     |     |
| 6. regular safety audit         | .19 (.40)   | .17  | .06  | .10  | .12  | -.03 | --   |     |      |      |      |     |     |
| 7. barcodes                     | .25 (.43)   | -.08 | -.08 | -.06 | -.12 | -.01 | -.07 | --  |      |      |      |     |     |
| 8. SOP checklists               | .89 (.31)   | .22  | .17  | .07  | .10  | -.06 | .17  | .06 | --   |      |      |     |     |
| 9. training                     | .46 (.50)   | .24  | .25  | .12  | .12  | -.00 | .09  | .13 | .20  | --   |      |     |     |
| 10. mission statement           | .60 (.50)   | .36  | .37  | .19  | .19  | .02  | .04  | .05 | .19  | .54  | --   |     |     |
| 11. capacity utilization        | .63 (.42)   | -.19 | -.20 | -.05 | -.28 | .00  | -.05 | .26 | -.02 | -.02 | .12  | --  |     |
| 12. workload                    | -1.80 (.45) | -.04 | -.14 | -.03 | -.23 | .04  | .04  | .24 | .10  | .10  | .04  | .72 | --  |
| 13. error rate                  | .44 (.32)   | -.29 | -.36 | -.26 | -.44 | .16  | .13  | .19 | -.09 | -.08 | -.07 | .25 | .40 |

n = 57; correlations  $\geq .27$  are significant at the 5% level,  $\geq .34$  significant at the 1% level (two-tailed)

The intercorrelations concerning the use of safety tools are generally much lower, so we conducted separate analyses for each safety tool to assess the respective impact of workload, safety attitudes and each safety tool on error rate. We ran additional analyses including the number of safety tools as a predictor, but this was merely correlated with the individual ST and (like mission statements, albeit more weakly) with two SC scales (management commitment and organizational learning) but not with either capacity utilization, workload, or error rate. Based on the finding by Katz et al. (2005) that in contrast to “optimal” level of detail of safety procedures both scarcely and overly detailed safety procedures lead to a higher error rate, we checked for a curvilinear relationship between number of tools and error rate, too, but found none.

Table 4 presents the results of the regression analyses with error rate always the dependent variable, and workload, *Attitude towards Safety Management*, its interaction with the respective safety tool and the safety tool main effect as predictors. Both correlation and regression results support H1 and H3 (workload increases the error rate, safety climate reduces it) but strongly contradict H2: none of the examined safety tools significantly reduces error rate. More precisely, there was no significant relationship with error rate for any of the ST, except for a marginally significant (2-tailed  $p < .10$ ) main effect of safety audits opposite to the predicted direction.

Table 4. Regression model results (standardized beta coefficients)

| DV: error rate             | CIRS    | Audits  | Training | Miss. Stmt. | Barcodes | Checklists |
|----------------------------|---------|---------|----------|-------------|----------|------------|
| Workload                   | .31 **  | .27 **  | .32 **   | .30 **      | .37 **   | .33 **     |
| SC (Att. tow. Saf. Mgmt.)  | -.37 ** | -.43 ** | -.35 **  | -.36 **     | -.28 *   | -.35 **    |
| ST (see respective column) | .16 †   | .21 *   | -.06     | -.02        | .10      | -.08       |
| SC x ST                    | -.06    | -.18 †  | -.07     | -.15        | .24 *    | .03        |
| R <sup>2</sup>             | .32     | .34     | .30      | .31         | .34      | .30        |

\*\* p < .01 \* p < .05 † p < .10 (one-tailed)

Consequently, the regression results seem to support H4 as well (SC reduces the error rate more than ST). In order to properly test for significance we compared the correlation coefficients of SC and ST with error rate; in all instances the difference in favor of SC is significant at the 5% level (1-tailed; Steiger's Z ranges between 2.05 for checklists and 3.26 for CIRS). To check whether this difference in effect might be a statistical artefact due to the limited variation of a dichotomous variable as opposed to a scale variable, we performed a median split on all SC variables and entered them as well as the ST variables into an ANOVA. The respective eta square values yield the same picture as the effect size r, suggesting that the observed effects are not a result of different scale properties.

Concerning H5, the results do not support our assumption. There was just one merely marginally significant interaction with audits in the predicted direction (one-tailed p < .08), and even a "reversed" interaction with barcodes opposite to our assumption (two-tailed p < .07), suggesting that barcodes even contribute to an increased error rate in case of a good safety climate.

### *Limitations*

While the present study has some strengths, e.g., a prospective designs in which accidents were measured following the measurement of safety climate (Clarke, 2006), considering safety climate at the clinical area level rather than at the hospital level (Sexton *et al.*, 2006), an absence of common method variance, and the introduction of a now recognized German instrument for measuring safety climate that can relate to tried and tested instruments for measuring safety climate in English (e.g., Schutz *et al.*, 2007; Singer *et al.*, 2007), it has some shortcomings that should be considered when interpreting the results, too. First, it is not based on a random sample: units were self-selecting in that they chose to respond to the call for participation and had previous experience with external studies on medical error in ICUs (Valentin *et al.*, 2009; Valentin *et al.*, 2006), although not in connection with safety climate and/or tools. As a result, the possibility of

sample bias cannot be completely excluded, but such a bias should rather consist in more accurate reporting of errors and a better (and/or bounded below) safety climate compared to “average” ICUs, which would not weaken our results. Moreover, despite an ex-ante research design controlling for a range of variables and modeling the project on state-of-the-art studies in the areas of error and safety culture measurement which enabled us to include a great number of potential error rate predictors, some degree of distortion from omitted variables cannot be entirely ruled out. Concerning staff workload during the observation period, we were unable to record the precise number and time of individual treatments (i.e., the exact distribution of workload) and therefore have to assume that these were approximately evenly distributed.

Other conceivable causes of distortion lie in the methods we used to measure safety performance and safety climate. Our metric of the former was based on a limited set of error types. While these were selected for being the most important ones according to previous studies in ICUs (Valentin *et al.*, 2009; Valentin *et al.*, 2006), the inclusion of other types might have produced different results. In addition, error incidence was recorded by hospital staff, therefore it is possible that some over- or underreporting occurred, although the high values recorded make underreporting appear somewhat implausible. Similarly, the VSCQ relies on employees responding in a valid and truthful manner, something which cannot be guaranteed; on the other hand, the obtained values do not hint at any biases like social desirability or similar and the data were regularly verified and checked for any apparent inconsistencies during the execution of the study.

## **Discussion and Practice Implications**

Our findings for hospital care in ICUs support the notion of a production vs. protection trade-off in two ways. First, while it is arguably possible to implement measures that increase both efficiency and safety (as mentioned above in connection with Lean Healthcare), simply aiming at “doing more with less” obviously comes with a safety penalty, as reflected in the considerable effect of staff workload on error rate. Second, safety culture can apparently thwart the detrimental effects of increased workload on safety quite effectively. However, corroborating the findings by Khatri *et al.* (2007), a management approach relying on safety tools and procedures to compensate for the erosion of safety margins by increased production pressure might rather abet than abate medical errors.

Regarding any interaction between safety climate and safety tools, our findings were generally weak. For the two “climate-related” tools (mission statements and safety audits), only the



implementation of a mission statement was significantly correlated with some of the SC dimensions, and interactions with safety climate, although in the predicted direction, failed to reach statistical significance for our sample. The same applies to an even larger extent to the safety tools aimed at learning and increased awareness (training and CIRS), where no interaction was found at all. Concerning training as ascertained in our study, we argue that it consists mainly in off-the-job “ground school” lessons, representing individual “single-loop learning” which is just a precursor of “double-loop learning” that takes place and becomes effective on an organizational level (Argyris, 1982). CIRS, on the other hand, represents such double-loop learning, but still failed to interact with safety climate in the predicted way. One possible explanation for this is that CIRS in hospitals is still in a somewhat exploratory phase, especially that staff might not (yet) trust it to be positively anonymous and non-punitive, since it is administered and evaluated by management. A similar observation was made in another high-hazard industry, where the Aviation Safety Reporting System (ASRS), now a valued and effective safety tool, initially failed to work until its anonymity and non-punitive nature were clearly and credibly established by introducing a neutral organization functioning as a broker, with the supervisory authorities having strictly no access to any clues concerning the identity of the reporting persons (Stolzer, Halford, & Goglia, 2011, p. 57f.).

By contrast, checklists and barcodes address daily work routines in a highly structured and rigid manner. Here, the marginally significant interaction found in our data for use of barcodes (i.e., it lowers the error rate in case of a poor SC but contributes to an augmentation of errors in ICUs with a good SC) may hint at staff not using the implemented technology in case of a weak safety climate, therefore detecting less errors, while in case of a sound safety climate, staff may be more likely to use the available technology because they recognize its role in promoting safety, and, as a result, detect more errors. Another possible explanation relating to the finding by Katz-Navon et al. (2005) that overly detailed safety procedures increase the number of medical errors could be that in units with a firm safety attitude the implementation of barcodes represents an additional burden (despite falling slightly short of statistical significance for two-tailed testing, barcodes are the only ST with an appreciable relationship to workload and capacity utilization) but actually serves as a barrier against errors in the absence of such an emphasis on safety. The failure to find any comparable (or contrasting) effect for checklists might be largely rooted in the fact that almost all participating ICUs used checklists (see bottom of Table 2), making this safety tool more of a constant than a variable.

In conclusion, besides underscoring the importance of a sound safety climate to prevent a decline in patient safety resulting from increased production pressure, our findings support the

view that safety is created at the “sharp end” (Dekker, 2006), consequently strongly cautioning against a “shortcut” approach of trying to achieve safety via procedures and policies implemented top-down.

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## **Acknowledgements**

We thank the ICU teams and ICU study coordinators (see supplementary digital content) who participated in this study and were eager to contribute in an open-minded and dedicated fashion. This study was conducted as a joint research project and financed by the Austrian Center for Documentation and Quality Assurance in Intensive Care (ASDI) and the Interdisciplinary Group of Management and Organizational Behavior of the Vienna University of Economics and Business. The study was supported by the German Interdisciplinary Federation of Intensive Care Medicine and Emergency Medicine (DIVI) and the Swiss Society of Intensive Care Medicine (SSICM). Last but not least our thanks go to two anonymous reviewers and the editor for numerous valuable hints and suggestions which have contributed to equally numerous improvements throughout the paper.