

Measuring Patient Safety Culture in Romania Using the Hospital Survey on Patient Safety Culture (HSOPSC)

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ABSTRACT: Purpose To explore patient safety culture among Romanian staff, using the U.S. Hospital Survey on Patient Safety Culture (HSOPSC). Material and Methods: A cross-sectional study was carried out in six hospitals, located in four Romanian regions (Craiova, Cluj-Napoca, Bucharest and Brasov), based on staff census in the Units/hospitals which volunteered to participate in the study (N=1,184). The response rate was 84%. The original questionnaire designed by the American Agency for Healthcare Research and Quality was translated into Romanian (with back translation), pre-tested before application and psychometrically checked. It consists of 42 questions grouped in 12 categories, covering multiple aspects of patient safety culture (dimensions). Percentages of positive responses (PPRs) by question and category were analyzed overall and by staff profession. Results: Most respondents were nurses (69%). The main work areas were surgery (24%) and medicine (22%). The highest PPRs were for Supervisor/Manager Expectations & Actions Promoting Safety (88%), Teamwork Within Units (86%), Handoffs and Transitions (84%), Organizational Learning-Continuous Improvement (81%), Overall Perceptions of Safety (80%), Feedback & Communication About Error (75%). The lowest PPRs were for: Staffing (39%), Frequency of Events Reported (59%) and Non-punitive Response to Errors (61%). Nurses exhibited significantly higher PPRs than doctors. Conclusions: This small-scale study of staff's attitude towards patient safety in Romanian hospitals suggests that there is room for future improvement, especially within the doctor category. Further research should assess the relationship between patient safety culture and frequency of adverse events.

KEYWORDS: Patient safety culture, staff, hospital, HSOPSC, Romania

Introduction

Patient safety can be defined as "freedom for a patient from unnecessary harm or potential harm associated with healthcare" [1].

In the US, the 1999 Report of the Institute of Medicine "To err is human" [2] brought patient safety to public and political attention.

According to a survey carried out by the European Commission in 2005 medical errors were perceived as a prominent problem in Europe, as well. In line with the European average, the majority of the Romanian

participants in the survey (78%) ranked medical errors as an important issue in their country [3].

Thus, in 2009 the European Union (EU) Council recommended a series of strategic actions to improve the safety of patients such as: education and training of healthcare workers, reporting incidents and learning system, patient empowerment, policies and programs on patient safety.

Alongside this, several EU projects aiming to improve patient safety have been implemented, e.g. EUNetPaS (Setting up of the European Union Network for Patient Safety), LINNEAUS EURO-PC (Learning from International

Networks about Errors and Understanding Safety in Primary Care project), PaSQ (European Union Network for Patient Safety and Quality of care). As an EU member (since January 2007), Romania has taken part in all of these projects. Nevertheless, a recent EU assessment (2014), pointed out that Romania has not implemented any of the strategic actions recommended by the EU Council [4]. This suggests that most patient safety activities have been fragmented and at small scale, as there is currently no national policy/strategy for patient safety in this country. Despite its increasing importance in other countries across the world, patient safety remains low on the political agenda in Central and Eastern Europe (CEE) [5].

Continuous administrative reforms since the '90s, almost exclusive use of top-down decision-making strategies, chronic shortage of resources and supplies, and healthcare workers' migration have intensified the level of stress, rising serious concerns of the general population about the quality of healthcare in Romania [6-8]. This led to an impressive gap with respect to the other EU countries. In 2005, 58 % of the Romanian respondents (versus 40% in EU) were worried of suffering a serious medical error. The proportion of respondents confident that the healthcare professionals would not make a medical error that could harm patient was: 55% for dentists (versus 74% in EU), 56% for doctors (versus 69% in EU) and 44% for other healthcare staff (versus 68% in EU) [3].

On the other hand, several studies pointed out that Romanian staff perceive the healthcare system as a constant source of discontent, bitterness and doubts [6, 9-10]. The link between patient safety, healthcare staff well-being, and organizational culture has been repeatedly highlighted [2].

Little is known about the patient safety culture (PSC) among staff in Romanian hospitals in recent years [11].

This study explores PSC using for the first time the Romanian version of the US Hospital Survey On Patient Safety Culture (HSOPSC), previously validated for psychometric properties. The purpose of this study is to identify which PSC aspects are poor and need further improvement and to assess whether there are significant differences between doctors' and nurses' perceptions, in order to better target interventions. Inter-country comparisons with the US and other CEE countries are also provided.

Material and Methods

Method

A cross-sectional study was carried out in Romania using the HSOPSC. This questionnaire was designed by the Agency for Healthcare Research and Quality (AHRQ) in 2004 and was translated from English (with back translation) into Romanian. Preliminary pre-test on hospital staff with different professions was performed before distributing the survey to several hospitals and/or units which volunteered to participate in the study. Data was collected in February and October 2014.

Instrument

The US HSOPSC has 42 questions and measures 12 aspects of PSC, also called dimensions or composites. These are the following: *teamwork within units, supervisor/manager expectations & actions promoting patient safety, organizational learning-continuous improvement, management support for patient safety, overall perceptions of patient safety, feedback and communication about error, communication openness, frequency of events reported, teamwork across units, staffing, handoffs & transitions, non-punitive response to errors.*

The questionnaire also includes two outcome variables (*patient safety grade and number of events reported*). Most questions ask staff to give agreement or frequency answers, using a Likert scale from 1 ("strongly disagree" or "never") to 5 ("strongly agree" or "always"). Questions are also positively and reverse worded. For reverse worded questions, disagreement or low frequency indicate a positive response. All the original questions were kept in the Romanian version, except one. The question asking if the hospital uses "more agency/temporary staff that is best for patient care" is not applicable in Romania, since it is not common in the healthcare system to hire temporary staff.

Sample

The self-administered questionnaire was distributed to 1,184 staff from six hospitals in four different Romanian regions. Two hospitals were located in the South-West (Craiova), two in the South (Bucharest), one hospital in the Center (Brasov) and one in the North-West (Cluj-Napoca). One participating hospital was large (around 1,500 beds), one was medium (around 500 beds) and the remaining four hospitals were small (under 250 beds). Three hospitals conducted a census, involving all

hospital staff, while the other three administered the questionnaire to some units only. Overall, 999 questionnaires were returned (response rate of 84%).

Data analysis

Since the questionnaires were anonymous, we numbered them consecutively before the distribution to respondents. Thus, after the data input, we were enabled to quality check the electronic records using the original paper questionnaire. Records of respondents who answered less than one entire section of the questionnaire, fewer than half of the items throughout the entire survey or scored all the items in the same way were excluded (N=30).

Preliminary psychometric analysis was carried out to check to what extent the Romanian version of the HSOPSC was suitable for application in the hospitals participating in the study.

Descriptive analyses were computed to summarize the respondents' characteristics.

Percentages of positive responses (PPRs) were calculated for each item and each dimension. PPRs represent the percent of respondents who answered "Strongly Agree/Agree" or "Always/Most of the time" to positively worded items or who disagreed with those negatively worded. Ninety-five % confidence intervals (CI) were used to determine statistical significance of the differences found.

Results

The total number of respondents included in the analysis was 969. Most respondents were nurses (69%), followed by doctors (25%) and allied healthcare staff (6%). Ninety percent of the respondents had direct interaction with patients.

Fig. 1 shows the distribution of the 969 respondents included in the study, by work area.

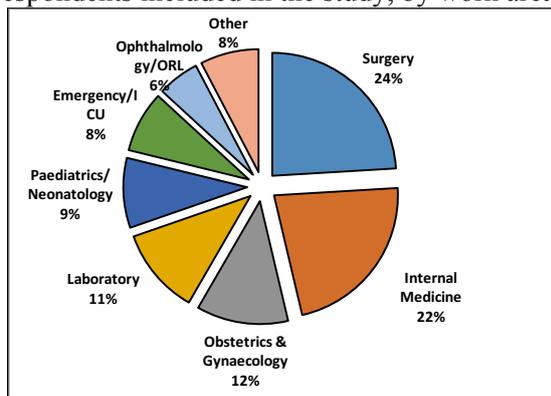


Fig. 1. Distribution of the respondents' work area

The most frequent work areas were surgery (24%), internal medicine (22%), obstetrics & gynecology (12%) and laboratory (11%).

Fig. 2 illustrates the perception of the staff about the patient safety grade. Seventy-one percent of the respondents perceived patient safety as very good/excellent and 27% as acceptable.

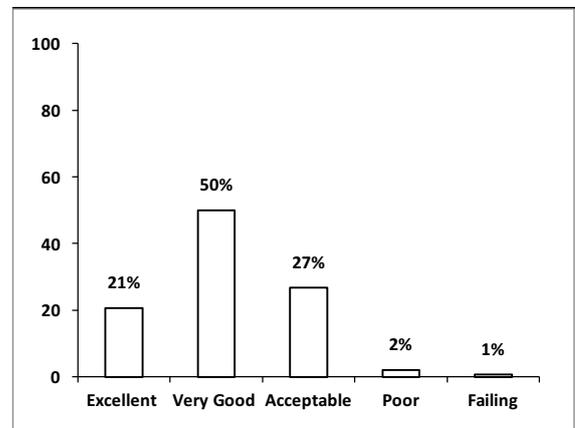


Fig. 2. Patient safety grade

Fig. 3 presents the frequency of the adverse events reported in the last year by the staff. Only a quarter of respondents have reported at least one adverse event in the last year.

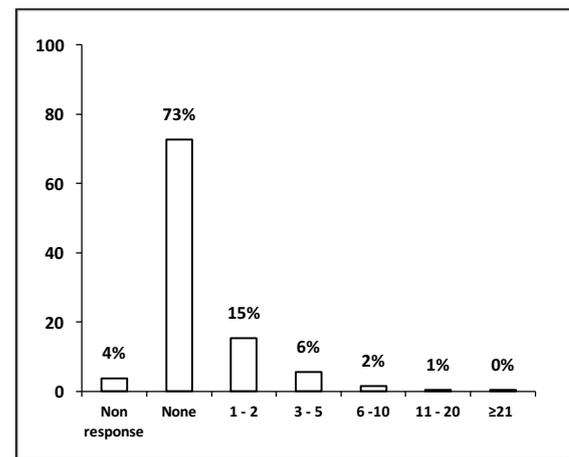


Fig. 3. Frequency of the adverse events reported in the last 12 months

Table 1 (a,b,c,d) illustrates the PPRs at item- and composite-level, by profession and overall.

Table 1a Percentage of positive responses (PPRs) with 95% confidence intervals: composites 1-3

Composites and items	Doctors	Nurses	Others	Overall
1. Teamwork Within Hospital Units	80.2 (77.7-82.7)	87.4* (86.2-88.7)	90.1* (86.2-93.9)	85.8* (84.7-86.9)
A1. People support one another in this Unit.	88.0 (83.9-92.1)	95.0* (93.4-96.7)	100.0*	93.6 (92.0-95.1)
A3. When a lot of work needs to be done quickly, we work together as a team to get the work done.	83.3 (78.6-88.0)	91.7* (89.7-93.8)	91.4 (84.2-98.6)	89.6 (87.7-91.6)
A4. In this Unit people treat each other with respect.	74.8 (69.3-80.3)	78.7 (75.6-81.8)	87.9 (79.5-96.3)	78.3 (75.7-80.9)
A11. When one area in this Unit gets really busy, others help out.	74.8 (69.3-80.3)	84.2* (81.4-87.0)	81.0 (70.9-91.1)	81.6 (75.7-80.9)
2. Supervisor/Manager Expectations & Actions Promoting Patient Safety	81.7 (79.3-84.1)	90.3* (89.1-91.4)	89.6* (85.7-93.5)	88.1 (79.2-84.1)
B1. My supervisor/manager says a good word when he/she sees a job done according to established patient safety procedures.	77.5 (72.2-82.7)	86.6* (84.1-89.2)	81.0 (70.9-91.1)	84.0 (81.7-86.3)
B2. My supervisor/manager seriously considers staff suggestions for improving patient safety.	80.7 (75.8-85.7)	93.2* (91.3-95.1)	98.2* (94.8-100.0)	90.4* (88.5-92.2)
B3r. Whenever pressure builds up, my supervisor/manager wants us to work faster, even if it means taking shortcuts.	81.0 (76.0-85.9)	88.4* (86.0-90.8)	84.5 (75.2-93.8)	86.3 (84.1-88.5)
B4r. My supervisor/manager overlooks patient safety problems that happen over and over.	87.7 (83.5-91.8)	92.8 (90.8-94.8)	94.8 (89.1-100.0)	91.6 (89.9-93.4)
3. Organizational Learning - Continuous Improvement	72.4 (69.1-75.6)	83.4* (81.8-85.1)	84.4 (79.0-89.8)	80.7* (79.3-82.2)
A6. We are actively doing things to improve patient safety.	85.5 (81.1-90.0)	96.1* (94.6-97.6)	91.2 (83.9-98.6)	93.1* (91.6-94.7)
A9. Mistakes have led to positive changes here.	59.5 (53.3-65.7)	66.0 (62.4-69.6)	72.4 (60.9-83.9)	64.8 (61.7-67.8)
A13. After we make changes to improve patient safety, we evaluate their effectiveness.	72.1 (66.4-77.8)	88.2* (85.7-90.6)	89.7* (81.8-97.5)	84.2* (81.9-86.5)

Notes: 1) An “r” associated to the item number indicates that items are negatively worded and reverse-scored when calculating percentage of positive scores. 2)*=statistically significant difference with respect to “Doctors”

Table 1b Percentage of positive responses (PPRs) with 95% confidence intervals: composites 4-6

Composites and items	Doctors	Nurses	Others	Overall
4. Management Support for Patient Safety	61.3 (57.8-64.8)	75.6* (73.7-77.5)	86.0* (80.9-91.2)	72.6* (71.0-74.2)
F1. Hospital management provides a work climate that promotes patient safety.	69.3 (63.5-75.1)	82.3* (79.4-85.2)	96.6* (91.9-100.0)	79.8* (77.3-82.4)
F8. The actions of hospital management show that patient safety is a top priority.	61.7 (55.6-67.8)	76.1* (72.8-79.3)	84.2* (74.7-93.7)	72.9* (70.1-75.7)
F9r. Hospital management seems interested in patient safety only after an adverse event happens.	52.9 (46.6-59.1)	68.5* (65.0-72.1)	77.2* (66.3-88.1)	65.1* (62.1-68.1)
5. Overall Perceptions of Safety	76.9 (74.2-79.6)	80.9 (79.4-82.4)	82.9 (78.0-87.8)	80.0 (78.8-81.3)
A10r. It is just by chance that more serious mistakes don't happen around here.	78.1 (72.9-83.3)	87.8* (85.3-90.3)	89.7 (81.8-97.5)	85.5 (83.3-87.7)
A15. Patient safety is never sacrificed to get more work done.	83.8 (79.1-88.4)	75.3 (72.0-78.6)	78.6 (67.8-89.3)	77.6 (77.5-82.5)
A17r. We have patient safety problems in this Unit.	77.5 (72.2-82.8)	80.9 (77.9-83.9)	80.4 (70.0-90.8)	80.0 (78.8-81.3)
A18. Our procedures and systems are good at preventing errors from happening.	68.3 (62.5-74.2)	79.7* (76.6-82.8)	82.8 (73.0-92.5)	77.0* (74.3-79.7)
6. Feedback and Communication about Error	71.3 (68.0-74.6)	75.6 (73.7-77.5)	78.2 (72.0-84.3)	74.7 (73.1-76.3)
C1. We are given feedback about changes put into place based on event reports.	70.5 (64.8-76.2)	74.4 (71.0-77.7)	74.1 (62.9-85.4)	73.4 (70.6-76.2)
C3. We are informed about errors that happen in this Unit.	65.7 (59.7-71.7)	67.3 (63.8-70.9)	74.1 (62.9-85.4)	67.3 (64.4-70.3)
C5. In this Unit we discuss ways to prevent errors from happening again.	77.8 (72.6-83.0)	85.1 (82.4-87.8)	86.2 (77.3-95.1)	83.3 (80.9-85.7)

Notes: 1) An “r” associated to the item number indicates that items are negatively worded and reverse-scored when calculating percentage of positive scores. 2)*=statistically significant difference with respect to “Doctors”

Table 1c Percentage of positive responses (PPRs) with 95% confidence intervals: composites 7-9

Composites and items	Doctors	Nurses	Others	Overall
7. Communication Openness	72.6 (69.3-75.8)	69.8 (67.8-71.9)	72.4 (65.8-79.1)	70.7 (69.0-72.4)
C2.Staff will freely speak up if they see something that may negatively affect patient care	74.5 (69.0-80.0)	74.8 (71.5-78.1)	74.1 (72.9-85.4)	74.7 (71.9-77.4)
C4.Staff feel free to question the decisions or actions of those with more authority.	66.8 (60.9-72.7)	62.1 (58.4-65.8)	69.0 (57.1-80.9)	63.7 (60.7-66.7)
C6r.Staff are afraid to ask questions when something does not seem right.	76.4 (71.1-81.8)	72.6 (69.2-76.0)	74.1 (62.9-85.4)	73.7 (70.9-76.5)
8.Frequency of Events Reporting	52.2 (48.6-55.8)	60.2* (58.1-62.4)	67.2* (60.3-74.2)	58.6* (56.8-60.4)
D1.When a mistake is made. but is caught and corrected before affecting the patient, how often is this reported?	51.2 (45.0-57.5)	61.8* (58.0-65.5)	63.8 (51.4-76.2)	59.2 (56.1-62.3)
D2.When a mistake is made. but has no potential to harm the patient. How often is this reported?	47.5 (41.3-53.8)	57.8* (54.1-61.6)	62.1 (49.6-74.6)	55.5 (52.4-58.6)
D3. When a mistake is made that could harm the patient, but does not, how often is this reported?	57.8 (51.6-64.0)	61.2 (57.4-64.9)	75.9* (64.8-86.9)	61.2 (58.1-64.3)
9. Teamwork Across Hospital Units	64.2 (61.2-67.2)	74.1* (72.4-75.7)	76.5* (71.0-82.0)	71.7* (70.3-73.2)
F2r.Hospital Units do not coordinate well with each other.	54.9 (48.7-61.2)	67.3* (63.8-70.9)	63.8 (51.4-76.2)	64.0 (60.9-67.0)
F4.There is good cooperation among Hospital Units that need to work together.	67.6 (61.7-73.5)	75.8 (72.6-79.1)	74.1 (62.9-85.4)	73.7 (70.9-76.5)
F6r.It is often unpleasant to work with staff from other Hospital Units.	64.7 (58.7-70.8)	70.2 (66.7-73.7)	80.7 (70.5-90.9)	69.4 (66.5-72.3)
F10.Hospital Units work well together to provide the best care for patients.	69.6 (63.8-75.4)	83.0* (80.1-85.9)	87.7* (79.2-96.2)	79.9* (77.4-82.4)

Notes: 1) An “r” associated to the item number indicates that items are negatively worded and reverse-scored when calculating percentage of positive scores. 2)*=statistically significant difference with respect to “Doctors”

Table 1d Percentage of positive responses (PPRs) with 95% confidence intervals: composites 10-12

Composites and items	Doctors	Nurses	Others	Overall
10.Staffing	32.1 (28.7-35.5)	40.9* (38.7-43.1)	47.7* (40.3-55.1)	39.1* (37.3-40.9)
A2.We have enough staff to handle the workload.	30.3 (24.4-36.1)	40.7* (37.0-44.4)	46.6 (33.7-59.4)	38.5 (35.4-41.5)
A5r.Staff in this Unit work longer hours than is best for patient care	16.7 (12.0-21.4)	26.7* (23.3-30.0)	46.6* (33.7-59.4)	25.4* (22.6-28.1)
A7r.We use more agency/temporary staff than is best for patient care	NA	NA	NA	NA
A14r.We work in "crisis mode" trying to do too much, too quickly.	49.4 (43.1-55.7)	55.5 (51.7-59.2)	50.0 (37.1-62.9)	53.6 (50.4-56.8)
11. Handoffs & Transitions	79.0 (76.4-81.5)	85.3* (84.0-86.7)	85.8 (81.2-90.3)	83.8* (82.6-85.0)
F3r.Things "fall between the cracks" when transferring patients from one Unit to another.	85.7 (81.3-90.2)	89.3 (87.0-91.7)	85.7 (76.5-94.9)	88.2 (86.2-90.2)
F5r.Important patient care information is often lost during shift changes	83.3 (78.6-88.0)	91.4* (89.2-93.5)	92.9 (86.1-99.6)	89.5 (87.5-91.4)
F7r.Problems often occur in the exchange of information across Hospital Units.	57.9 (51.7-64.2)	66.0 (62.3-69.6)	70.2 (58.3-82.1)	64.2 (61.1-67.2)
F11r.Shift changes are problematic for patients in this hospital	89.0 (85.1-93.0)	94.6 (92.8-96.3)	94.6 (88.7-100.0)	93.2 (91.6-94.8)
12. Nonpunitive Response to Error	59.1 (55.6-62.7)	61.0 (58.8-63.1)	67.8 (60.9-74.8)	60.9 (59.2-62.7)
A8r.Staff feel like their mistakes are held against them.	61.9 (55.8-68.1)	68.1 (64.5-71.6)	69.0 (57.1-80.9)	83.3 (63.6-69.6)
A12r.When an event is reported. it feels like the person is being written up, not the problem.	53.1 (46.8-59.4)	52.7 (48.9-56.5)	58.6 (45.9-71.3)	53.2 (50.0-56.3)
A16r.Staff worry that mistakes they make are kept in their personnel file.	62.4 (56.3-68.59)	62.2 (58.5-65.9)	75.9 (64.8-86.9)	63.1 (60.0-66.1)

Notes: 1) An “r” associated to the item number indicates that items are negatively worded and reverse-scored when calculating percentage of positive scores. 2) NA=not applicable, 3) *=statistically significant difference with respect to “Doctors”

Overall, across the individual questions, the range was from 25% (for the reverse worded question “A5r. Staff in this unit work longer hours than is best for patient care”) to 94% (for the question “A1. People support one another in

this unit”). At composite-level, the range was from 39% (staffing) to 88% (supervisor/manager expectations & actions promoting safety). Six composites had PPR >=75%: supervisor/manager expectations &

actions promoting safety (88%), teamwork within units (86%), handoffs and transitions (84%), organizational learning-continuous improvement (81%), overall perceptions of safety (80%), feedback & communication about error (75%). The composites with the lowest PPRs were: staffing (39%), frequency of events reported (59%) and non-punitive response to errors (61%).

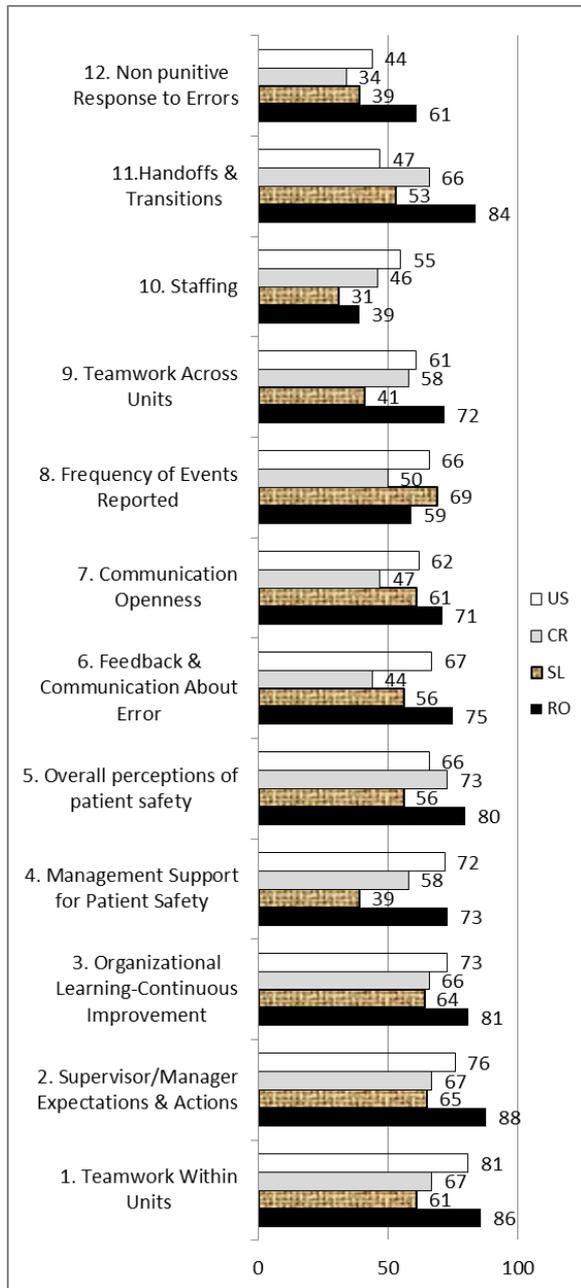


Fig.4. Benchmark of percentage of positive responses (%) between Romania (RO), Slovenia (SL), Croatia (CR) and the United States of America (US)

Both “Doctors” and “Nurses” professional groups exhibited the lowest PPR for *staffing* and the highest for *supervisor/manager expectations & actions promoting safety*.

Nurses exhibited significantly higher PPRs than doctors for most composites of the PSC: *supervisor/manager expectations & actions promoting safety* (90% versus 82%), *organizational learning-continuous improvement* (83% versus 72%), *teamwork within units* (87% versus 80%), *staff* (41% versus 32%), *Management support for patient safety* (76% versus 61%), *teamwork across units* (74% versus 64%), *handoffs & transitions* (85% versus 79%).

Fig. 4 shows an international comparison of PPRs by composite, between Romania, U.S. and other Central-Eastern European countries. PPRs in Romania (range: 39%-88%) and U.S. (range 44%-81%) were generally higher than in Slovenia (range 31%-69%) and Croatia (range 34%-67%) [12,13,14].

Five percent of the respondents provided open comments on patient safety (26 nurses, 19 doctors and 3 other healthcare staff). Half of them were positive comments on patient safety or constructive comments offering improvement suggestions. The other half were mainly complaints about staff and supply shortages.

Discussion

In this descriptive cross-sectional study we explored Patient Safety Culture (PSC) in Romania, using for the first time in this country the AHRQ HSOPSC. A hard copy of the questionnaire translated into Romanian was distributed to a sample of 1,184 staff in six hospitals across the country, based on a census in voluntary units.

A total of 969 valid questionnaires returned were analyzed. Nurses accounted for 69% of respondents. Overall, we found high positive response rates for most areas of PSC. The percentage of positive responses was low for two areas (*frequency of events reported* and *non-punitive response to errors*) and of serious concern for one area (*staffing*).

We found significant differences between nurses’ and doctors’ perceptions, suggesting more developed safety attitudes among nurses.

Insufficient human and physical resources (in 2013 the number of public hospital doctors fell to about 14,500 down from about 20,000 in 2011 [8], as well as poor funding (in 2014 the public health expenditure, expressed as % of Gross Domestic Product, fell to 4.5 down from 4.7 in 2010) have been more and more prominent in the Romanian healthcare system in the last years [10,15]. Some of our results were consistent with this national trend: *staffing* was the composite

with the lowest positive score and most respondents' open comments were complaints about staff shortages and poor supplies. In a recent study, Romanian staff pointed out that performance in healthcare may decrease as a result of lack of adequate medical supplies and stressful working conditions [7]. To achieve adequate performance, individual staff in our study might tend to compensate important shortages which increase complexity of their activity, by paying more attention to other components of patient safety that they can influence or manage more directly, such as teamwork, communication, continuous improvement, handoffs and transitions. Moreover, since the units included in this study voluntarily offered to complete the HSOPSC, we suppose that their staff were likely to be more open and positive in regard to most patient safety matters than staff in a differently selected sample. Several international studies observed that positive scores attributed by the staff to the PSC areas tend to be higher in small-medium hospitals (like those in our study), than in large ones [12,16].

All these reasons could lead respondents to attribute generally high positive scores to most PSC areas, even higher than in the US and other CEE countries with results available for benchmark [12,13,14].

The *frequency of events reported* and *non-punitive response to errors* were PSC areas lower positively scored with respect to the others. This is consistent with the fact that in Romania, reporting adverse events with the purpose of learning is not a current practice among the staff [11]. Both mandatory and voluntary reporting system are highly characterized by underreporting. Reporting hospital acquired infections (HAIs) is mandatory, but according to the study of Mada (2008) [17] Romanian hospitals report less than 10% of the real HAIs. Voluntary reporting systems should address suspected adverse drug reactions (ADRs) and/or other adverse events related to procedures/healthcare provided/etc. (AEs). The gap between Romania and Western countries in this field is impressive: the study of Farcas et al. (2008) [18] pointed out that, in 2006, the Romanian staff reported within the National Pharmacovigilance reporting system 351 ADRs only (versus 20,648 ADRs in France and 20,410 in England). The study of Paveliu et al (2014) [19] supports these findings: 73% of surveyed physicians in Romania admitted that they have never sent any report versus 39% in

Germany. The main causes were: lack of knowledge regarding the existence of a national spontaneous reporting system and of a National Pharmacovigilance Center, misunderstanding of the purpose of pharmacovigilance, and unawareness of the importance of a spontaneous reporting system [18]. An international pilot study, carried out to experiment an adverse events (AEs) voluntary reporting system, pointed out lower rates per 1,000 hospitalization days per month per setting reported in Romania than in Italy. (The corresponding rates were: 1 in the Romanian setting versus 3 and 15 in the two Italian settings in the study.) Most AEs reported were related to diagnostic (28%) and surgical (14%) procedures and patient falls (12%). [20]

Positive scores to the *frequency of the events reported* PSC area in the Central-Eastern European [13,14], as well as in some Eastern Asian countries [21,22] are systematically lower than in the Western countries, which suggests a different cultural approach to learning from HAIs/ADRs/AEs reporting systems. In a study based on CEE countries, Godycki-Cwirko et al (2015) pointed out that information about errors is collected when adverse events occurred, often in the context of legal actions against health professionals. Analyses of these medico-legal databases are scarce and therefore learning is limited [5].

Low positive score attributed by staff in our study to the *non-punitive response to errors* PSC area supports the hypothesis that they might be reluctant to report errors not only because of the shame of being named and blamed, but also for fear of disciplinary or legal action. Toraldo (2015) et al noticed that, in recent years, cases of real or presumed adverse events have been increasingly reported in the media, rather than in suitable scientific contexts. Thus, fear of the healthcare professionals of being blamed or low suited for malpractice comes before the opportunity of learning from near-misses or adverse events [23].

Our overall findings suggest high level of awareness of the hospital staff for patient safety and are encouraging for most areas referred to by the HSOPSC. This appears to contradict the opinions about patient safety expressed by the Romanian general population in parallel surveys. The extent to which such perceptions are based on individual or friends'/families' direct experience with healthcare professionals rather than on newspapers and television news should be established-frequently the media describes extreme cases as representative for the

healthcare system [23]. On the other hand, despite journalism's inherent limits, it is argued that it acts as a "watchdog to hold the medical profession accountable for improved safety and quality of care", increasing its awareness with respect to patient safety [24].

In accordance with other studies, based on the application of the HSOPSC [25] or different questionnaires [11,26], nurses rated the PSC higher than doctors for most areas, demonstrating higher safety awareness. Nurses are the most numerous staff in the hospital units and have more contact with patients. Moreover, they demonstrate better understanding and perception of patient safety. Therefore, nurses are deemed to have a critical impact on safety initiatives [27]. Although some studies have found evidence of relationships between patient safety culture and patient outcomes at the hospital and nursing unit level of analysis, the number of studies finding statistically significant correlations particularly using nurse-sensitive outcomes is limited [28].

This is the first time that the HSOPSC has been applied in Romanian hospitals. This small-scale study represents for managers of the participating units an insight in the staff's attitude towards patient safety and supports interpretation of current performance and quality indicators in their organizations. On the other hand, this study contributes to knowledge about patients safety in Central and Eastern Europe, based on data collected with the same questionnaire, which has been strongly recommended by the European Network for Patient Safety (ENPS) in its member states.

There are, however, several limitations to our study.

Firstly, although the participant hospitals were located in different Romanian regions, results cannot be generalized. To reduce selection bias, we distributed the survey to all the staff in the voluntarily participating units, independently of their clinical and non-clinical profile (staff census). Despite the relatively high response rate (84%), we do not know what would have been the patient safety perceptions of the staff who did not complete the questionnaire. Secondly, at this point in our research, there were no means to quantify nor to exclude socially acceptable responses. Thirdly, descriptive results presented in this paper refer to all 12 PSC areas (dimensions or composites) of the original US questionnaire. However, preliminary psychometric analyses of the

Romanian version pointed out good fit for less dimensions than the original US version.

Conclusion

Staff perceptions in the six hospitals participating in this study were positive for most patient safety culture areas. Patient safety culture was measured, for the first time in Romania, with the US HSOPSC. A shortage of human resources and materials, as well as low reporting of adverse events-likely due to staff fear of blame and punitive measures as a response to errors-are potentially threatening to the safety of patients and should be promptly addressed. We believe that it would be very hard to influence this in the short term. National policies for healthcare staff retention and motivation at work and medico-legal regulations encouraging learning from adverse events would be necessary in order to further improve quality and safety in healthcare.

Our study confirms previous findings which pointed out higher patient safety culture in nurses than in doctors. It is likely to reflect the fact that nurses spend more time than doctors with the patient and have more of a team-work approach in their profession in comparison to doctors, whose clinical work is more individualistic [11].

Since its release in 2004, the HSOPSC has been administered in 66 countries and translated into 31 languages [29]. However, the validity of this tool in measuring patient's safety culture outside the US should not be taken for granted.

Comparisons between Romanian hospitals and hospitals in other countries are interesting, and show higher scores in Romania than in other CEE countries. Nonetheless, these differences have to be interpreted with caution, taking into account the peculiarities of the healthcare system in each country and with the understanding that the psychometric validation of the Romanian version did not confirm all the dimensions of the original US questionnaire.

Future research should test the Romanian version of the HSOPSC on a larger dataset. The relationship between patient safety culture within hospital staff and healthcare outcome indicators should also be studied.

Abbreviation List

ADR = adverse drug reactions

AE= Adverse Event

AHRQ = Agency for Healthcare Research and Quality

CI = confidence interval

CR = Croatia
 ENPS = European Network for Patient Safety
 EU = European Union
 EUNetPaS = setting up of the European Union Network for Patient Safety
 HAI = hospital acquired infections
 HSOPSC = Hospital Survey on Patient Safety Culture
 LINNEAUS EURO-PC = Learning from International Networks about Errors and Understanding Safety in Primary Care project,
 PaSQ = European Union Network for Patient Safety and Quality of care
 PPR = Percentage of positive responses
 PSC = Patient Safety Culture
 SL = Slovenia
 US = United States of America

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