**Trends in the Staff’s Perception of Patient Safety Culture in Romanian Hospitals**

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**ABSTRACT:** Introduction. The IRIS-2 project (2019) expanded the application of the HSOPSC in Romanian hospitals, yet applied, for the first time in the country, in 2014 (IRIS-1). The aim is an update on patient safety culture for staff, by geographic region and overall, by year of survey. Materials and methods. A cross-sectional study was carried out in voluntary staff in four hospitals in four regions (n. 1,121 staff) and compared with a previous study based on six hospitals in four regions (n. 969 staff). The instrument was the Romanian version of the HSOPSC with 31 items and 9 dimensions. Statistics to analyze trend were computed using "R". Results No significant differences between the proportion of positive response (PPRs) by dimension were observed in IRIS-2 with respect to IRIS-1, with two exceptions: significantly lower PPR for “teamwork across hospital units” (65% versus 73%) and significantly higher PPR for “frequency of events reporting” (65% versus 59%). Four dimensions were well developed and five dimensions needed to be improved. The poorest PPRs were for the “teamwork across hospital units”, the “frequency of event reporting” and the “non punitive response to error” dimensions. Besides, one outcome indicator changed through time: the proportion of the staff who did not report any event significantly lower (64% versus 73%) and the proportion of the staff who reported “1-2 events” was significantly higher (21% versus 15%). Conclusion. Despite some small progress related to the frequency of events reporting, there is room for further patient safety culture improvement.

**KEYWORDS:** Patient safety, culture, Romania, trend.

**Introduction**

Patient safety is defined as the prevention of errors and adverse effects to patients associated with health care.

In European Union (EU) medical errors and health-care related adverse events occur in 8% to 12% of hospitalizations.

Twenty-three % of EU citizens claim to have been directly affected by medical error.

Eighteen % claim to have experienced a serious medical error in a hospital.

Hospital-acquired infections account for around 25% of these cases, while other adverse events are due to human error, medical device failures and other factors [1].

In Romania hospital acquired infections (HAIs) are under-diagnosed and under-reported and the public only become aware of the problem of HAIs when major incidents are reported by the mass media.

The reported incidence at the national level in 2016 was 0.44%, while the EU average was almost ten times higher (5.2%) [2].

Comprehensive systematic approaches to patient safety help prevent up to 70.2% of such unintentional harm to patients, but strategies to reduce harm are not implemented consistently across the EU [1].

HAIs can be prevented through correct application of environmental and individual hygiene measures, as well as through limitation
of the antibiotic multi-resistance. Hands are the main pathways of germ transmission during health care.

In a recent survey 68% of the Romanian nurses had an inadequate level of knowledge of the hand hygiene and HAIs prevention.

Thirty-nine % of Romanian nurses had insufficient level of knowledge [3].

Another survey carried out on doctors (dentists) pointed out a general compliance to hand hygiene of 77% of the participants. Efficient educational and training interventions are needed in order to support the knowledge and compliance to hand hygiene and to decrease the risk of health care associated infections [4].

On the other hand, Romania faces some of the highest levels of antibiotic multi-resistance and antibiotic consumption in Europe, ranking among the first five States in the EU [2].

The opinion of a healthcare organization on its safety issues inevitably depends on the method used to measure safety. A comprehensive picture can only be obtained by integrating several methods [5].

Systematic monitoring of staff perceptions about patient safety is a valuable method to raise awareness on the importance of preventing unintentional harm in all members of the organization.

Within the IRIS-1 project (2014) the Romanian version of the American HSOPSC (Hospital Survey of Patient Safety Culture) was used to establish a baseline assessment for patient safety culture in six hospitals in four regions [6,7].

The IRIS-2 project (2019) expanded the application of the HSOPSC to another four hospitals and two more regions, thus covering six out of the eight Romanian geographical regions. The aim of this paper is an update on patient safety culture for Romanian hospital staff, by geographic region and overall, by year of survey. The specific objectives of this recent study were the following:

1. Provide data that describe changes in patient safety culture over time in a specific geographical region, and at the national level;
2. Allow hospitals in a specific geographical region to compare their patient safety culture survey results with those of other hospitals in other geographical regions;
3. Provide decision makers with information to help identify strengths and areas with potential for improvement in patient safety culture at the national level.

Material and Methods

Methods

A cross-sectional study was carried out in Romania using the Romanian back translated version of the HSOPSC. This questionnaire was designed by the Agency for Healthcare Research and Quality (AHRQ) in 2004 [8].

Data were collected between October and November 2019 (IRIS-2 project) and compared with data collected in 2014 (IRIS-1 project).

Instrument

The original US HSOPSC had 42 items and measures 12 aspects of PSC, also called dimensions (composites). In a previous study we checked the Romanian version for psychometric properties and demonstrated that it was acceptable for application in Romanian hospitals, but with less items (31 versus 42) and dimensions (9 versus 12) [6].

The dimensions are the following: teamwork within units (4 items: A1, A2, A3, A11), supervisor/manager expectations & actions promoting patient safety (4 items: B1, B2, B3r, B4r), organizational learning-continuous improvement (3 items: A6, A9, A13), management support for patient safety (3 items: F1, F8, F9r), communication (6 items: C1, C2, C3, C4, C5, C6r), frequency of events reported (3 items: D1, D2, D3), teamwork across units (3 items: F2r, F4, F10), handoffs & transitions (2 items: F5r, F11r), non-punitive response to errors (3 items: A8r, A12r, A16r) [6].

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 (“r” associated to the item number), disagreement or low frequency indicate a positive response [8].

Sample

The questionnaire was self-administered and anonymously completed by voluntary staff in four Romanian hospitals.

Each hospital was located in a different geographic region: North-East (1,438 beds); South-East (1,206 beds), North-West (597 beds) and Bucharest or metropolitan region (913 beds).

One hospital opted for on-line application to staff in all hospital units (with a response rate of 23%), while the other hospitals opted for paper
application in voluntary units (with a range of the response rate between 74% and 94%).

After the quality data-check process, a number of 1,121 records were used for the final statistical analyses.

Data Analysis

Data analysis and graphing were performed in Microsoft Excel and the R language [9].

Descriptive analyses were computed to summarize the characteristics of the staff who responded to the IRIS-2 study.

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. PPRs for all 31 items were computed according to the hospital region and the average PPRs were compared. Then PPRs were grouped in 9 composites and analyzed for the entire IRIS-2 sample (data gathered in 2019 from 4 hospitals in 4 regions).

We reproduced the same analyses for the IRIS-1 sample (data gathered in 2014 from 6 hospitals in 4 regions) and compared the results. A difference of at least 5 percent point between PPRs was used for determining what differences to pay attention to. This thumb rule was proposed by Sorra et al. [10].

Results

The total number of records included in the analysis was n. 1,121, slightly higher than in the IRIS-1 project (n. 969).

Actuarial characteristics

The proportion of respondents per geographic region ranged from a min. of 24% to a max of 27% and appeared more balanced than in the IRIS-1 project (range: 10%-50%).

In both studies, the most frequent work area was” internal medicine” (about half of the respondents), the most frequent staff position was “nurse” (about two thirds of the respondents) and the great majority of the respondent declared to have direct interaction with patients. (Table 1)

Table 1. Actuarial characteristics of the participants, by year of survey.

| Characteristic                        | IRIS-1 (2014) | IRIS-2 (2019) |
|---------------------------------------|---------------|---------------|
|                                       | N=969   | %         | N=1121   | %         |
| Region                                |          |           |          |           |
| North-East                            | -       | -         | 283      | 25        |
| South-East                            | -       | -         | 264      | 24        |
| South-West                            | 480     | 50        | -        | -         |
| North-West                            | 223     | 23        | 275      | 25        |
| Center                                | 99      | 10        | -        | -         |
| Bucharest                             | 167     | 17        | 299      | 27        |
| Work Area                             |          |           |          |           |
| Internal Medicine                     | 417     | 43        | 600      | 54        |
| Surgery                               | 402     | 41        | 354      | 32        |
| Para-clinical specialties (lab, public health, etc.) /Non specified | 112 | 12 | 19 | 2 |
| Other (pharmacist, dietitian, etc.) /Non specified | 38 | 4 | 148 | 13 |
| Staff position in the Hospital        |          |           |          |           |
| Nurse                                 | 667     | 69        | 700      | 63        |
| Physician                             | 244     | 25        | 156      | 14        |
| Other /Non specified                  | 58      | 6         | 265      | 24        |
| Interaction with patients             |          |           |          |           |
| Yes, have direct patient interaction  | 875     | 90        | 1097     | 98        |
| No, do not have direct interaction with patients | 94 | 10 | 22 | 2 |

Overall patient safety culture

Figure 1 shows the average percent of positive response for patient safety culture (average PPR) by geographic region.

The average PPRs in the IRIS-2 project ranged from 72% (N-E region) to 78% (S-E region). This range is similar to the IRIS-1 project, i.e. from 74% (N-W region) to 79% (Center and Bucharest regions). Some regions contributed data from more than one hospital, i.e Bucharest region (3 hospitals) and the S-W and N-W regions (2 hospitals).

However, no significant difference of the average PPRs was observed between the participating hospitals within the same region, independently of the year of the survey.
Dimensions of patient safety culture

In Figure 2 PPRs are illustrated by patient safety culture dimension, overall (country level) according to the year of survey. In the IRIS-2 project the range of the PPRs by dimension was similar to the IRIS-1 project (58% to 90% versus 59% to 91%).

Four dimensions were well developed, while the other five dimensions needed to be improved. The poorest PPRs were found for the “teamwork across hospital units”, the “frequency of event reporting” and the “non punitive response to error” dimensions.

We found no significant differences between the PPRs by dimension in IRIS-2 with respect to IRIS-1, with the exception of the PPR for “teamwork across hospital units”-which was significantly lower (65% versus 73%)-and of the PPR for “frequency of events reporting” which was significantly higher (65% versus 59%).

![Figure 1. Distribution of the average PPR in IRIS-2, compared to IRIS-1 project (national level)](image)

Legend: 1) North-East, 2) South-East, 3) South, 4) South-West, 5) West, 6) North-West, 7) Center, 8) Bucharest

![Figure 2. Distribution of PPRs by dimension, overall.](image)

Legend: *means significant change.
Output Indicators

Figure 3a shows staff perception of the grade of patient safety. Patient safety grade was considered “very good” by half staff, “acceptable” by one third of the staff and “excellent” by 21% of the staff. No significant differences were found between the IRIS-2 and IRIS-1 results for this output indicator.

Figure 3b shows the n. of events reported in the last year by the staff. Most staff did not report any event. In the IRIS-2 project, the proportion of the staff who did not report any event was significantly lower than in the IRIS-1 project (64% versus 73%). However, the proportion of the staff who reported “1-2 events” was significantly higher (21% versus 15%). No significant differences were observed for the other response options to this output related question.

Figure 3a. Patient safety grade, overall.

Figure 3b. Number of events reported (in the last 12 months), overall.

Legend: *means significant change.
Discussion

In the IRIS-2 project (2019) we expanded the application of the Romanian version of the US HSOPSC.

Four different hospitals and two different regions were surveyed in addition to the IRIS-1 project (2014), where only six hospitals participated. We gathered 1,121 surveys from voluntary staff and compared results with the results of n. 969 surveys gathered in the IRIS-1 project, in order to detect if patient safety culture changed (geographic and time trends).

One of the main findings of the IRIS-2 project is that staff scored significantly higher the dimension “frequency of the events reported” with respect to the previous study (65% versus 59%).

This is consistent with a significant increase in the proportion of staff who declared that they reported 1-2 events in the last year (21% versus 15%) and a significant reduction of the proportion of staff who did not reported events in the last year (64% versus 73%).

This finding is encouraging, suggesting that hospital staff is currently more sensitive to reporting adverse events compared to staff in 2014.

This finding is convergent with data gathered by the National Register of Adverse Healthcare Associated Events, established by ANMCS in 2017, for reporting adverse healthcare related events with the purpose of learning from errors (based on 635 sanitary units with beds registered in the National Register, the n. of adverse events reported increased from 2,324 in 2017 to 5,132 in 2018 and to 5,879 in 2019) [11].

The National Authority of Quality Management in Health (ANMCS) is a public institution from public central administration which aims to ensure and improve the quality of health services and patient safety by standardizing and evaluating health services and accrediting sanitary facilities [12].

Another important finding of our study is that staff in IRIS-2 scored significantly lower the dimension “teamwork across hospital units”, with respect to the previous study.

This finding could be influenced by the different size of the hospitals involved in the two studies. While in IRIS-2 prevailed hospitals with more than 900 beds (3 out of 4 hospitals), in IRIS-1 prevailed hospitals with less than 500 beds (5 out of 6 hospitals).

Higher bed counts suggest greater work complexity and increased difficulties for staff to perform team activities with staff from other units.

Distribution of the average PPRs according to geographical region showed significant differences between some regions (range: 72% in North-East-79% in Center and Bucharest regions).

However, this finding should be interpreted with caution, as some regions are only represented by one hospital, and these differences are more likely to be hospital related, than region related.

No significant inter-hospital difference of the average PPRs was seen in the two regions which participated in the IRIS-2 and-1 studies with more than one hospital (North-West and Bucharest regions).

IRIS-2 confirms the need to invest in developing dimensions of the patient safety culture such as “non-punitive response to errors”, “frequency of events reporting”, “teamwork across units”, “management support for patient safety” and “communication”, which showed PPRs lower than 75% in both studies.

One strength of this study is that, for the first time, composites measures are computed according to the psychometrically validated Romanian version of the HSOPSC, with 9 composites.

Previously published results were obtained applying the HSOPSC before psychometric validation, and therefore were based on 12 composites [7].

Generally, imported tools developed by another country should be tested for psychometrics before extended application.

In our case, after psychometric analysis [6] 31 out of the 42 items of the original US HSOPSC only were kept in the analyses, and 9 out of 12 composites.

Other authors [13,14] also found that some items/composites were not psychometrically adequate for staff in their countries.

Another strength is that this study analyses, for the first time, geographical differences in staff’s perception of patient safety, according to the region of the hospital they work in.

Inter-regional comparison is important as national healthcare system might be heterogeneous.

For instance, when the ANMCS analyzed the first three causes for the adverse events reported in its National Register at regional level significant differences were observed.

The “non-compliance with universal and specific measures to prevent and control
Healthcare Associated Infections” (country average: 51%) had a range from 17% in the South-East to 83% in the Center; the “errors in the use of medicinal products” (country average: 19.3%) had a range from 2% in the Center to 62% in the South-East) and “falls” (country average: 14.2%) had range from 7% in the South to 27% Bucharest region [12].

The IRIS-2 study included two geographical regions (North-East and South-East) on which information was not available in the IRIS-1, leading to a coverage of six out of eight Romanian Regions.

Despite invitations to participate in the IRIS-2 study were sent to two hospitals in each one of the eight regions (in order to merge their data intra-region and avoid them to be recognized), our intent to cover all the Romanian regions failed. Most common reasons that hospital representatives claimed for their refusal were lack of time or worry about publicly sharing their results.

Missing information from hospitals in the West and South regions is one of the limitations of this research. Another limitation is that the samples used in IRIS-2 and IRIS-1 are convenience samples, based on voluntary participation of the hospital staff. Estimates based on self-selection may produce biased estimates of the population, therefore estimates are not representative for all hospitals in a region. Other major limitation is that none of the hospitals in this study participated in both IRIS-2 and IRIS-1 projects.

Thus, our results represent a baseline of the patient safety culture in the staff, without the chance to compare pre-and post-intervention results within the same hospital, like in other studies [15,16,17].

Systematic anonymous comparisons between high numbers of hospitals are carried out in the US, were there is a long tradition in the use of the HSOPSC.

According to the 2014-2016-2018 US comparative databases, the number of the US hospitals that submitted data more than once was: 55% out of 653 total hospitals in 2014 [18]; 48% out of 680 hospitals in 2016 [19] and 49% out of 630 hospitals in 2018 [20].

Time trend of staff perceptions about patient safety systematically measured within the same hospital might contribute to understand the effectiveness of the action plan for improving.

Conclusion
In conclusion, our research is a snapshot of patient safety culture in voluntary Romanian staff from four hospitals in 2019 compared with six hospitals in 2014.

Overall, these hospitals provide data from six out of a total of eight Romanian regions.

Our results pointed out that despite some small progress regarding the frequency of events reporting, there is room for further patient safety culture improvement, especially for non-punitive response to error.

Research in the field of patient safety is scarce in Romania with respect to other EU countries and major efforts are needed to fill this gap of information and to support hospitals in providing safer healthcare services.

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Conflict of interests
None to declare.

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