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Background Paper

**Patient safety initiatives in Central and Eastern Europe: A mixed methods approach by the LINNEAUS collaboration on patient safety in primary care**

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**KEY MESSAGE:**
- In most Central and Eastern Europe countries, patient safety has been addressed, but few changes have been implemented in primary care.
- A Polish demonstrator project showed that significant progress could be made in implementing patient safety initiatives in primary care through support by a co-coordinator of the external project and facilitation.

**ABSTRACT**

**Background:** Despite patient safety being recognized as an important healthcare issue in the European Union, there has been variable implementation of patient safety initiatives in Central and Eastern Europe (CEE).

**Objective:** To assess the status of patient safety initiatives in countries in CEE; to describe a process of engagement in Poland, which can serve as a template for the implementation of patient safety initiatives in primary care.

**Methods:** A mixed methods design was used. We conducted a review of literature focusing on publications from CEE, an inventory of patient safety initiatives in CEE countries, interviews with key informants, international survey, review of national reporting systems, and pilot demonstrator project in Poland with implementation of patient safety toolkits assessment.

**Results:** There was no published patient safety research from Albania, Belarus, Greece, Latvia, Lithuania, Romania, or Russia. Nine papers were found from Bulgaria, Croatia, the Czech Republic, Poland, Serbia, and Slovenia. In most of the CEE countries, patient safety had been addressed at the policy level although the focus was mainly in hospital care. There was a dearth of activity in primary care. The use of patient improvement strategies was low.

**Conclusion:** International cooperation as exemplified in the demonstrator project can help in the development and implementation of patient safety initiatives in primary care in changing the emphasis away from a blame culture to one where greater emphasis is placed on improvement and learning.

**Keywords:** Patient safety, safety culture, implementation, primary care, LINNEAUS collaboration

**INTRODUCTION**

Patient safety has not been defined specifically for primary care. The World Health Organization (WHO) defined patient safety as ‘freedom for patients from unnecessary or potential harm arising from healthcare’ (1). The WHO definition along with the Institute of Medicine and the Canadian patient safety dictionary were endorsed by the LINNEAUS Euro-PC project and provided the framework against which patient safety was investigated in the CEE countries which is the subject of this paper (2). Although
academic researchers have recognized the importance of patient safety as a component of quality, since the 1990s, it is only more recently that policy makers and patients have identified the problem as being important (3–5).

In 2006, the Directorate General SANCO of the European Commission published the Eurobarometer survey on the perception of medical errors by European citizens. It reported that 78% of respondents rank the issue as very or fairly important in their country; 23% said that they themselves or their family had been the victim of a medical error; 18% said this happened in a hospital, while 11% said they were prescribed the wrong medication; 98% of respondents felt that having national political support for patient safety was of high importance (6).

In 2006, The WHO’s World Alliance for Patient Safety approached member states and urged them to develop a coherent strategy for improving patient safety in their countries (7). However, despite these initiatives, patient safety remains low on the political agenda in several EU member states and especially in Central and Eastern European countries. For instance, despite the Warsaw statement on patient safety in 2005 (developed as part of the Polish Presidency of the EU), developing and implementing safety programmes in Polish healthcare have been a challenge because of difficulties with engagement of health professionals and government officials.

The problems in Poland exemplified the situation in many new ascension CEE countries with the emergence of patient safety initiatives. In these countries, there was no legal definition of patient safety and most activities related to patient safety were local and ad hoc, focused primarily on medication errors. Some data were collected on medical errors causing harm, based on patients’ (or their relatives’) claims or on relevant legal cases, when medical error was suspected. In those situations, legal procedures were initiated to assess guilt, damage and eventual compensation. There was no systematic monitoring of sentinel events, circumstances, near misses, or preventable events. There was also no detailed data and root cause analysis of incidents. A blame culture and a culture of ‘punishment’ prevailed.

Nevertheless, there is data suggesting that adverse events do happen in Poland. For example, data from the Superior Physicians Chamber of Poland showed that in the years 2006–2008 there were 8062 complaints related to medical errors and 5748 cases of professional mistakes were identified. Data from 2000–2008 showed that in 2747 cases physicians were found to be culpable suggesting that they were responsible for the fault (8).

We, therefore, felt that there was sufficient concern based on the Eurobarometer survey and on evidence from the medico-legal databases, to develop a national awareness programme about patient safety in primary care in Poland and other CEE countries: Albania, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Lithuania, Romania, Russian Federation, Slovakia and Slovenia.

In this paper, we review the situation regarding patient safety in these countries and then provide practical recommendations for further development and policies.

METHODS

A mixed methods design was used. We performed a review of literature, inventory of patient safety initiatives, interviews with key informants, an international survey, a review of national reporting systems and a pilot demonstrator project.

Review of literature

To analyse the engagement and differences in patient safety research in CEE countries, searches of four electronic databases (PubMed, BioMedCentral, ScienceDirect and EMBASE) were conducted in May 2013 searching for papers about patient safety in Central and Eastern Europe published from 1970–2013. The database search was restricted to English language and we used the keywords combinations ‘patient safety research,’ ‘primary care and medical errors,’ ‘primary care and medical mistake,’ ‘primary care and medical malpractice,’ ‘primary care and medical incident’ selected from the ‘glossary of patient safety’ (9).


Inventory of patient safety initiatives in CEE countries

We reviewed developments in patient safety in Poland in some detail, using published research, policy documents, unpublished data, and interviews with key informants. We also made an inventory of the status of patient safety in other Central and Eastern Europe (CEE) countries, using interviews and a survey amongst key informants from two conferences on patient safety in primary care organized by the LINNEAUS Euro-PC network (Manchester, 2010 and Warsaw, 2011). Representatives were present from Albania, Belarus, Bulgaria, Croatia, Czech Republic, Latvia, Lithuania, Romania, Russia, Slovakia and Slovenia.
Interviews with key informants

Representatives from these CEE countries took part in semi-structured telephone interviews to explore their views on patient safety in their countries. The interview guide consisted of two general questions: ‘Are there any patient safety activities in your country?’ and ‘Do you have any experiences in developing or implementing strategies to help health professionals participating in patient safety activities?’ These questions were then supplemented by 10 detailed questions, when relevant.

International survey

To assess the view of patient safety researchers on the value of patient safety improvement strategies, we repeated a survey carried out by the LINNEAUS Euro-PC partners from the Netherlands. This survey was initially carried out in eight EU states where there was already significant activity on patient safety in primary care (11). We wanted to get a wider picture and assess if there was any difference in the assessment of strategies for patient safety improvement by researchers in CEE countries. A survey was undertaken in an international panel of 13 CEE countries with a questionnaire, which consisted of 38 strategies to improve patient safety. The respondents were asked which of the strategies they use in daily practice in their countries and whether they considered them important.

Review of CEE reporting systems

An Internet search and consultations with countries key informants on reporting systems for patient safety incidents were performed.

Demonstrator project in Poland and networking

We carried out a demonstrator project in Poland as a means of testing the feasibility of implementing a series of patient safety activities in a CEE country. The purpose of the pilot implementation was to modify and test a series of instruments that had been developed by the LINNEAUS Euro-PC programme. We wanted to assess whether they could be used in situations where there was little activity on patient safety and identify the barriers to their use in CEE countries. Through a series of project activities, we developed and translated a patient safety ‘toolkit’ consisting of five elements relevant to patient safety in primary care: these included a thesaurus, taxonomy, register, assessment tools, and accreditation standards. The tool kit was tailored for use in the Polish primary healthcare setting by a Delphi process, field-testing in primary care settings, and a series of workshops and consensus conferences. At an early stage, we established an Internet-based anonymous patient safety incidents register ‘Bezpieczna Opieka Podstawowa’ (Safe Primary Care) (http://wnbikp.umed.lodz.pl/bop/index.php).

In 2011 in Warsaw, a CEE regional conference on patient safety in primary care took place with follow up CEE workshop in Lodz in 2012.

RESULTS

Review of literature

We found 1234 papers (787 in PubMed, 190 in BioMed Central, 169 in ScienceDirect and 88 in EMBASE). We then limited the search to the CEE countries and identified 19 papers. The abstracts of these papers were examined for relevant information and duplicates were excluded limiting it to 15 papers (listed in the Supplementary Appendix, available online only at http://informahealthcare.com/doi/abs/10.3109/13814788.2015.1043727).

We found no published patient safety research from Albania, Belarus, Greece, Latvia, Lithuania, Romania, or Russia. Poland and Serbia had each contributed two papers about primary care and patient safety and Croatia, the Czech Republic, and Slovenia had each produced one paper. Bulgaria and Croatia had additionally produced one paper each about primary care and medical errors. For comparison, the search for UK, the Netherlands, Denmark, Germany, Belgium, France, Italy, Spain, Portugal and Ireland together yielded 108 relevant papers.

Inventory in CEE countries

Primary care in most CEE countries follows the Siemaszko model developed in the former Soviet Union. It is based on multi-specialist polyclinics, without generalist gatekeeping and coordination of healthcare. In the 1990s, most countries started to introduce reforms, which were aimed at strengthening primary care so that GPs would play a key role (12–14). Because of these reforms, there was increasing recognition of the importance of patient safety in the primary care setting.

We found that in most of the CEE countries that we examined, issues related to patient safety had been addressed at the policy level although the focus was mainly in secondary care. However, most respondents reported that few of the policy recommendations had been implemented and that there was a dearth of activity in primary care. In some countries, information about errors is collected, often in the context of legal actions against health professionals when adverse events occurred. However, there have been few analyses of these medico-legal databases and remedial action were primarily aimed at disciplining doctors. Therefore, disciplinary actions have made health professionals reluctant to report errors; this has limited learning from them.

Summary comparative data for CEE countries are
presented in Table 1. Patient safety was not addressed in the ‘health care systems in transition’ reports for Albania, Czech Republic or Lithuania.

For comparison, the WHO Observatory review showed that most of the issues such as policy/strategy on patient safety, auditing patient safety, information on errors collected, patient safety indicators in use, professional liability, learning system for patient safety, were addressed in Belgium, Denmark, France, Italy, the Netherlands, Sweden and the UK.

International survey in CEE countries

We received responses from eight countries (Albania, Belarus, Croatia, Latvia, Romania, Russia, Slovakia and Slovenia). Our results showed that overall there was low use of patient safety improvement strategies (Table 2). Only one strategy was present in all eight countries: telephone facilities that allow quick access to the practice, particularly for urgent health problems.

In terms of patient safety management, only one strategy (‘hygiene protocols and guidelines present’) was present in Romania, Slovenia, Latvia, Russia and Albania. For comparison, the Dutch study showed that at least 18 different patient safety improvement strategies were used in countries such as Austria, Denmark, Germany, the Netherlands and the UK (11).

Interviews with key informants

Representatives from Albania, Croatia, Romania and Slovakia responded to the invitation to participate in this interview study. Albania and Croatia reported some experience of medical errors/incidents reporting systems, even if only on a small scale. In Albania, a National Centre for Accreditation and Policy has been established with an office and website, producing documents and papers but not yet disseminating anything. In Croatia there is a government Agency for Quality and Accreditation in Health and Social Welfare but it is not autonomous, and has no contact with GPs. Romania has no national strategy for patient safety, although a safety culture measurement tool is used in medical education. The National School for Public Health and Management is a partner in the EU Joint Action for Patient Safety and Quality of Care (PaSQ). In Slovakia, patient safety is recognized as being very important with the inclusion of patient safety indicators in its medical education programmes, but nothing has yet been done to promote safety in primary care.

The EUNetPAS project found that out of the EU member states in 2009 most of the involved CEE states (Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Poland, Romania, Slovakia and Slovenia) did not have any patient safety culture instruments in use. Poland introduced two instruments, the Manchester patient safety framework (MaPSaF) and modified Agency for Health Research and Quality (AHRQ) questionnaire in 2011, while participating in the EU project LINNEAUS Euro-PC (Table 3).

Review of national reporting systems for patient safety incidents

Our results listed in Table 4 are complementary to an earlier review (15). Out of all CEE countries, only Poland has started a patient safety incident reporting system in primary care: ‘safe primary care’ (in Polish) was introduced in 2011, as part of Poland’s participation in EU project LINNEAUS Euro-PC.

Table 1. Central and Eastern European (CEE) countries inventory data on primary care patient safety.

<table>
<thead>
<tr>
<th>Country</th>
<th>Patients who experienced an adverse event a (%)</th>
<th>Patients who reported an adverse event a (%)</th>
<th>Policy/strategy on patient safety b</th>
<th>Auditing patient safety b</th>
<th>Information on errors collected b</th>
<th>Patient safety indicators in use b</th>
<th>Professional liability b</th>
<th>Learning system for patient care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>?</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Belarus</td>
<td>?</td>
<td>?</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>15</td>
<td>?</td>
<td>?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Croatia</td>
<td>?</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>23</td>
<td>35</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Estonia</td>
<td>39</td>
<td>23</td>
<td>?</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>?</td>
</tr>
<tr>
<td>Latvia</td>
<td>43</td>
<td>15</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lithuania</td>
<td>36</td>
<td>16</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Poland</td>
<td>20</td>
<td>26</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Romania</td>
<td>16</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Russia</td>
<td>?</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Slovakia</td>
<td>29</td>
<td>26</td>
<td>?</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Slovenia</td>
<td>29</td>
<td>9</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

a Data from Special Eurobarometer 2010.

b Data from WHO Observatory.

? Indicates that information was not available.
As part of the continuing development of patient safety initiatives in CEE countries, we organized the first regional conference on patient safety in primary care in Warsaw in September 2011. We ran workshops for researchers and practitioners on quality of healthcare assessment and the development of accreditation systems for patient safety in primary care. A follow-up conference took place in May 2012 in Lodz to disseminate expertise in consensus development methods, safety culture measurement, significant events audit and medication errors, with a view to developing a research infrastructure for patient safety in primary care. This developing network has now been formalized into a regional Central European hub of healthcare professionals and researchers focusing on patient safety in primary care.

**DISCUSSION**

**Main findings**

This study found a shortage of research, information exchange and international cooperation in the development and implementation of patient safety initiatives in primary care in Eastern and Central Europe. Although there has been an attempt to develop healthcare policy relevant to patient safety in some countries (such as the National Health Program setting out health care priorities for the period 2005–2011 in Poland), the policies do

### Table 2. Central and Eastern European (CEE) countries' survey data on utilization of patient safety strategies in primary care.

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Number of strategies</th>
<th>In none of eight countries</th>
<th>In ≥50% of eight countries</th>
<th>In all of eight countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Facilities in the practice</td>
<td>9</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>2. Patient safety management</td>
<td>11</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Communication and collaboration</td>
<td>7</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>4. Generic conditions for patient safety in general practice</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>5. Education on patient safety</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>9</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

*aAlbania, Belarus, Croatia, Latvia, Romania, Russia, Slovakia, Slovenia

*bMethod adapted from Gaal et al. (11).

### Table 3. Countries key informants' data on patient safety culture instruments in European countries (2009). Based on EUNetPas project's report.

<table>
<thead>
<tr>
<th>Number of patient safety culture instruments</th>
<th>Country and year(s) of introduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>England, Scotland &amp; Wales (UK); Austria (2007; 2008); Finland (2007, 2007); Germany (2009; 2007); Norway (2006)</td>
</tr>
<tr>
<td>2</td>
<td>Belgium (2005/2007); France (2007); Hungary (research only); Iceland (2005); Italy (2005); Lithuania (pilot); Netherlands (2005); Portugal (2005); Sweden (2008); Switzerland (2006)</td>
</tr>
<tr>
<td>1</td>
<td>Bulgaria; Croatia; Cyprus; Czech Republic; Estonia; Greece; Ireland; Luxembourg; Latvia; Malta; Poland; Romania; Slovakia; Slovenia</td>
</tr>
</tbody>
</table>

*aIn primary care.

CEE countries are shown in bold.

### Table 4. Selected national reporting systems for patient safety incidents.

<table>
<thead>
<tr>
<th>Country</th>
<th>Year of introduction</th>
<th>Patron</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>2004</td>
<td>National Patient Safety Agency (NPSA)</td>
</tr>
<tr>
<td>Denmark</td>
<td>2004</td>
<td>National Board of Health</td>
</tr>
<tr>
<td>Spain</td>
<td>2005</td>
<td>Ministerio de Sanidad y Consumo</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>2006</td>
<td>Health Care Inspectorate</td>
</tr>
<tr>
<td>Norway</td>
<td>2006</td>
<td>Directorate of Health</td>
</tr>
<tr>
<td>Poland</td>
<td>2011</td>
<td>Medical University of Lodz</td>
</tr>
</tbody>
</table>
not address patient safety or accountability issues directly. The review of Ministry of Health documents showed a continuing reliance on a blame culture focusing on complaints, negligence, liability and promotion of patient rights rather than patient safety, risk management or system improvement.

Although there was some knowledge of how to approach improvement of health care safety in some of the CEE countries, there was a gap between awareness and practice, with a deficit in research, sharing of information, learning from adverse events and collaboration to make primary care safer. There was some data collection on events, injuries, adverse reactions, hazards, errors, and harm, but systematic monitoring of sentinel events, circumstances, near misses, preventable events, or detailed data about incidents, with root cause analysis, were missing.

When the EU supported the LINNEAUS Euro-PC collaboration, a decision was made to include countries like Poland where initiatives related to patient safety had been in a nascent stage. The examples of actions and interventions from EU countries where patient safety was in a well-developed state helped the process of engagement and in setting a framework for ongoing development in CEE countries. Key outcomes included a systematic review of publications on patient safety, the development of consensus procedures on classification systems and consensus on the use of safety culture evaluation tools. The programme also enabled the testing of many of these instruments in pilot studies in several CEE countries. All this work has been EU funded and supported by leading European centres, with support from experts from the United States and New Zealand. The sharing of this expertise enabled the Polish partner in the consortium to implement some initial actions on patient safety and shows the value of collaboration in such coordination actions. Project conferences and bilateral contacts with representatives of the CEE countries allowed us to share experiences and set up a formal network in the region.

**Barriers and challenges**

The process of patient risk improvement may face certain barriers, such as the need to engage all stakeholders to set priorities for safe practices and to address interdisciplinary teamwork with strong leadership and adequate financial resourcing (18). The success of patient safety improvement initiatives depends on motivated teams as well as patient and public involvement. Most of these facilitating factors are still absent in CEE countries, creating barriers to safety improvement, demotivation and frustration of healthcare professionals and patients.

There are specific challenges of improvement of safety in primary care related to mental care or childcare, which still have to be addressed in CEE countries. Electronic sources of information highlighting unsafe care and helping to identify potentially unsafe practices before incidents occur, used in the primary care context elsewhere are still very rare (19–21). The costs and benefits implementation strategies studied in some countries need time yet to be recognized in Central and Eastern Europe (22,23).

**Strengths and limitations**

This study provides valuable insights in the status of patient safety in primary care in Central and Eastern Europe. Additionally, it is the first study exploring CEE countries’ developments in clinical setting as well as research. The limitation was the use of only Polish and English publications owing to language barrier, as well as our main focus on reporting systems and safety culture evaluation. Still our results open a perspective for implementation and further research.

**Implications**

Participation in the LINNEAUS Euro-PC programme made clear to us that further research is required on how to overcome some of the barriers identified earlier, especially in health systems that are still developing concepts of patient involvement and a primary care focus. The importance cannot be underestimated of developing patient safety curricula for medical schools and vocational training, and strengthening patient safety components in quality assurance processes in primary care.

**CONCLUSION**

International cooperation in the development and implementation of patient safety initiatives in primary care in Eastern and Central Europe is needed, since continuing reliance on a blame culture focusing on complaints, negligence, liability and promotion of patient rights rather than safety culture, risk management or system improvement are dominant there. The process of improvement needs the engagement of all stakeholders to set priorities for safe practices and to address interdisciplinary teamwork with strong leadership and adequate financial resourcing.

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Supplementary material available online

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