



Patients' safety:
Round table
on
Reporting systems in health care

**29 September – 1 October 2010
Ljubljana, Slovenia**

ABSTRACT

Patient safety is a priority in many countries in the European Union. Experts and policymakers from the Czech Republic, Slovakia and Slovenia gathered in Ljubljana at the round table discussions on reporting systems in health care. The meeting was organized by the World Health Organization Regional Office for Europe and supported by the Slovenian Ministry of Health. The meeting allowed ample information exchange between participating countries, supported by additional international expertise. Common challenges were identified and a set of recommendations were developed. It has been recommended that participating countries priorities their actions and report on the progress made in a follow up meeting in one year time.

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Introduction

The round table on reporting systems in health care was organized by the World Health Organization Regional Office for Europe (WHO Europe) and supported by the Ministry of Health of Slovenia. It took place in Ljubljana, Slovenia between the 29 September and 1 October 2010.

The event aimed to provide an opportunity for exchanging experiences on reporting systems and patient safety in the Czech Republic, Slovakia and Slovenia, and identify opportunities for improvements through the lessons learned within other international settings. It additionally enabled exploration of existing interactions and possible integration of reporting systems established at various levels of health at national level.

It was attended by representatives from the three abovementioned countries, with a broad range of field experiences and backgrounds: experts from ministries of health, national competent authorities for specialized services, representatives of healthcare organizations, and other important partners in the healthcare system, such as professionals' associations and patients. On the second day of the meeting participation was also opened to all the patient safety officers from Slovenian hospitals.

Day 1

The meeting was opened by Dr. Dorijan Marušič, Minister of Health of Slovenia, who welcomed the participants and stressed the importance of the meeting in supporting actions towards improving patient safety. The Minister underlined the importance of quality and safety on the agenda of the Ministry of Health. He informed the participants about the National strategy on quality and safety that is about to be implemented and presented the current efforts to establish a system of accreditation in healthcare. The present meeting was described as very useful in supporting action on quality and safety - a priority in Slovenia.

Dr. Marušič agreed to act as chair for the first part of the event, with Dr. Seifert from the Institute of General Practice, Prague, Czech Republic as co-chair. The second day was co-chaired by Dr. Rems and Dr. Robida, from Slovenia; and the third day by Dr. Nagy, from the Ministry of Health of Slovakia. The reporter of the event was Dr. Poldrugovac, Slovenia.

The main features of reporting systems were presented by each participating country.

Reporting systems in Slovakia

One of the most important institutions in Slovakia responsible for monitoring data in health care is the National Health Information Centre (NHIC). NHIC collects information regarding both in-patient and out-patient activities and regularly reports on the findings. It has also an important role in the development of the information technology infrastructure at the national level. Recent changes in the legal framework require monitoring of indicators that the Ministry of Health and health insurance companies assess and represent the basis for granting incentives to organizations providing healthcare services.

Pharmacovigilance (vigilance of medicinal products) and materiovigilance (vigilance of medical devices) are nationally coordinated by the State Institute for Drug Control. The national Centre for Blood Transfusion is responsible for haemovigilance (vigilance of blood products). The Authority for Public Health of the Slovak Republic receives the mandatory reports regarding adverse events in vaccinations, while the Health Care Surveillance Authority (HCSA) receives the voluntary reports of adverse events that occur during provision of health care.

Reporting systems in the Czech Republic

In the Czech Republic healthcare organizations have a duty to report regularly to insurance companies, which in turn report to the National Reference Centre. Healthcare organizations also report to the Institute of Healthcare Information and Statistics. Where specific registries are in place, reporting is also performed to the national institution responsible for data collection in those areas.

Currently there isn't a unified reporting system regarding adverse events that occur during provision of health care to the patient. An adverse event reporting system is being piloted nationally and includes about 100 general practitioners. At the same time there is a strong internal reporting activity within healthcare organizations, particularly hospitals, as a reporting system is required in order to obtain accreditation of the health care institution.

Reporting systems in Slovenia

In Slovenia there are several institutions responsible for collecting data on adverse events nationally.

Haemovigilance is monitored by the Agency for medicinal products and medical devices (JAZMP), which is the competent authority. Analysis of the data and the ensuing reports are provided by the Blood Transfusion Centre of Slovenia. The first attempt to develop a standardized system for reporting transfusion reactions dates back to 1968, but the basic elements of the current haemovigilance system were established in 2002. The reporting of all adverse reactions is mandatory. It makes use of standard reporting forms that require reporters to grade severity and imputability. The system also involves the Rapid Alert System when necessary. Education being recognized as a key factor for implementation, the Blood Transfusion Centre developed a publication aimed at informing health professionals about haemovigilance. Gradually the scope of data collection has been expanded and it includes today near misses among other things. Those have been recognized in the course of the conference as particularly important in order to get a more comprehensive picture of potential sources of harm to the patient.

Adverse event reporting in the area of immunization has been seen as very important to assure the quality of the National Immunization Programme in Slovenia. Reporting is mandatory, and performed through the Adverse Event Following Immunization (AEFI). An AEFI register has been established and is managed by the national Institute of Public Health. An adverse event in this instance is defined as a medical incident that is temporarily associated with and could be (not necessarily) casually related to immunization. It works as a passive surveillance system. Its role in monitoring vaccine safety is essential in maintaining public confidence in immunization,

which has an important impact on immunization rates. It has been pointed out however, that sometimes increasing awareness of adverse events following immunization can have an effect that is opposite to the desired one. In 2009 for instance the number of reports increased following fears of adverse reaction to the pandemic influenza vaccine.

Pharmacovigilance in Slovenia is shared between JAZMP and the National Pharmacovigilance Centre. Medicinal products represent about 25% of the healthcare budget in Slovenia. There are 16 million prescriptions being filled out every year. A research study a few years ago came to the conclusion that approximately 10% of admissions to hospitals are drug related and 5 to 6% of admissions are due to adverse drug reactions. Eurobarometer data from 2006 show, that 78% of European Union (EU) citizens consider medical errors to be an important issue in their country. Different systems are in place to report adverse events ranging from adverse drug reactions to be reported within the national pharmacovigilance system to adverse events collected internally by hospitals and in some cases reported to the Ministry of Health. It has been pointed out that developments in this area in the past few years have been following the right path however the speed of change needs to be increased.

Materiovigilance in Slovenia is regulated by the new Medical Devices Act which came into force in 2010. The bylaw regulating the vigilance system came into force in July 2010. Experience in this area is therefore limited. The regulation is in line with EU requirements.

The Ministry of Health is responsible for the national adverse event reporting system, which has been established in 2002. The system requires hospitals to report a list of most serious adverse events, based on the model of the Sentinel Events developed by the Joint Commission for Accreditation of Healthcare Organizations. The system was aimed primarily at hospitals. To increase the number of reports, the Ministry of Health organized a series of conferences on the adverse event reporting system, for top and middle management of hospitals in 2009. Subsequently an increase in the number of reports has been observed. The mid-term view is to broaden the purpose of the adverse event reporting, which requires a redefinition of system's structure.

Data Collection and Quality Improvement in Health Care Organizations

The conference provided an equal opportunity for hospitals to present their perspective. All cases discussed showed an increasing concern for quality and safety at the hospital level. External accreditation and certification was considered important to the hospital, as the example of the National Institute for Cardiovascular Diseases (NICD) in Slovakia confirms. NICD is certified by 5 different standards, including ISO 9001. Care maps have been introduced to plan for the care of the patient. Those maps serve to monitor activities allowing the recognition of discrepancies. Systems to monitor non-compliance and corrective actions are in place. Monitoring performance takes place through a series of economic and healthcare indicators that is larger than the national mandatory set of indicators. The hospital for instance also reports voluntarily to the HCSA. Based on the data collected improvement activities take place, an example of which is the introduction of patient identification bracelets using colour codes.

Common Issues in Reporting

Comparison of all the presented reporting systems showed that numbers within each country are high. Some systems are in place in line with international requirements and EU directives. None the less a risk of fragmentation of information can be recognized. There seems to be room for better integration of information in two ways:

- a) Horizontally, among national bodies responsible for various reporting systems;
- b) Vertically, between organizations providing healthcare services and the competent national authorities they need to report to.

It has been noticed that underreporting is common to all adverse event reporting systems. Underreporting has been detected by comparing the data collected with the findings of national or international research studies that investigate the frequency of adverse event based on medical records. Differences can also be noted with respect to reporting systems in some other countries, where the actual occurrence of adverse events is not expected to be significantly higher.

The reasons for underreporting were discussed. In some countries reporting to a governmental body seems to be undesirable for fear of political use of the data. The establishment of independent institutions on the other hand is sometimes difficult to achieve. Making reporting mandatory as opposed to voluntary is also considered a possible action to increase the number of reports. However the value of mandatory reporting within a non-punitive system that therefore does not sanction a lack of reports has been questioned. It appears that a solution that would suite all the various systems and countries is impossible to define. What has emerged as the most important factor determining the appropriateness of the institution collecting the data is the trust it enjoys among the healthcare organizations. Caring for that trust is also the most important task of the institution in charge of a particular reporting system.

Informing and motivating those involved is also necessary in order to establish a successful reporting system. The publication prepared by the Centre for Blood Transfusion in Slovenia was mentioned, as well as the campaign organized in the Czech Republic concerning medication safety. The series of seminars on the Slovene Adverse Event Reporting System that took place in 2009 is another example of such campaigns.

A worrying trend of decreasing number of reports has been observed within some reporting systems in different countries. Possible approaches to reverse the trend have been discussed. It is very important to provide analysis and feedback to the reporting institutions. While many organizations provide yearly reports, direct and immediate feedback is not always present. It has been pointed out that it is necessary to constantly communicate with the providers of healthcare services from the very beginning of the system's establishment. Recommendations can be formulated drawing from foreign experiences even before national reports are produced and analysed.

The Czech Republic presented the successful experience with accreditation, which has stimulated hospitals to establish internal adverse event reporting systems in order to comply with accreditation standards. Compliance with standards is indeed mandatory for accredited institutions; however accreditation as such is not mandatory for hospitals and other healthcare organizations. In this case also the trust in the accreditation systems has been very important in spreading it.

Discussion over mandatory as opposed to voluntary reporting systems, as well as identifying the aims of the reporting system also pose the question of where the responsibilities for reporting and acting on those reports lie. It is clear that the responsibility is shared to a certain extent between single healthcare organizations and the competent national authority collecting all the data. The two types of institutions seem to lie at the opposite end of a spectrum. The task at hand is to recognize the competencies of each of the two. The dilemma can be shown in the example of primary care in the Czech Republic. Most of the healthcare services in primary settings are not offered by institutions owned by the state. Instead most general practitioners work as private providers within the public healthcare care system. The regulatory bodies must therefore make constant decisions, about how much autonomy to grant to the providers, thus allowing them to thrive the way the providers see best fit, and to what extent to impose solutions that are believed to be generally effective.

Providing proper incentives has been recognized as an opportunity to provide guidance for development without the lack of flexibility of a legal imposition. As has already been mentioned above, the standards in accreditation have been a very important incentive. Another one could be gaining credits towards licensing for physicians for each report filed. However in the latter case reconciling such a system with the need for anonymity and protection of those reporting adverse event can be a challenge.

Day 2

The second day of the conference was opened by Dr. Janez Remškar, Director General of the Directorate of Health Care at the Ministry of Health of the Republic of Slovenia, who welcomed all the participants and outlined some of the issues including getting reliable data and achieving required cultural change that were further discussed.

The second day was an opportunity to take a broader look at various policies and approaches to enhance quality and particularly safety in healthcare. Presentations by representatives from participating countries were complemented by presentations from other international experts, enriching the discussion with their experiences.

National Policies in Quality and Safety in Health Care

The representatives from the Czech Republic, Slovakia and Slovenia broadly outlined the approach of the respective countries to quality and patient safety. In general three areas for action could be recognized in all the presentations:

- 1) external assessment
- 2) clinical guidelines and standards
- 3) patient input in quality management

1) External Assessment

Supporting external assessment plays an important role in the activities outlined by all the presenting countries.

In Slovenia promoting certification or accreditation of healthcare facilities is one of the priorities listed in the National Strategy on Quality and Safety in Healthcare, due to the implementation phase initiated.

In Slovakia the insurance companies, which are the payers of healthcare services, may require external assessment in their contract with providers. Through the healthcare reform that took place recently, the preparation of quality plans was made mandatory for healthcare providers in Slovakia.

The rapid spread of hospital accreditation in the Czech Republic has already been pointed out. Current activities in this area include the establishment of an accreditation system in primary care, based on the National Standards for Primary Care issued in 2009.

2) Clinical Guidelines and Standards

The importance of including aspects of clinical treatment in fostering quality and safety has been recognized in many countries. In the United Kingdom the concept of clinical governance has gained importance over the last few years. In the Czech Republic and Slovakia defining and implementing guidelines has been emphasized as a priority. Accreditation represents a means for achieving not only better management from the organizational point of view, but also from the point of view of clinical work. A similar emphasis can be found in Slovenia in the National Strategy on Quality and Safety in Healthcare, where the development of systems to improve the efficiency of clinical work is listed as a priority.

3) Patient Input in Quality Management

In other sectors of the economy there is a general tendency to increase the role of the customer. Mechanisms for involvement of patients in the management and improvement of the healthcare system seem to be harder to define in the healthcare sector. However important changes have been recognized pointing to a trend that follows the example of other sectors. The Czech Republic is one of the first four countries to include patients in the pharmacovigilance system. The HCSA in Slovakia is an example of an institution that has established a very systematic approach to handling patients' complaints. A particularly interesting example of patients taking an active approach has been the establishment of a web page in the Czech Republic, where interested parties can check physicians' rankings, as voted by the patients themselves. The web page was an independent initiative where the regulatory bodies played no role.

The Importance of Data Collection

The availability of information, particularly in the form of sound statistical evidence, has been recognized as important in decision making at all levels. The most frequently reported adverse events in the care process appeared to be falls. Reporting of serious adverse events is less frequent than expected. Therefore, while the importance of reporting was stressed, it was also questioned whether the overall statistical data collected reflect the relative frequency of events correctly. The strong possibility of a bias has been recognized towards reporting smaller adverse events that do not result in harm to the patient and against more serious events.

The data from research studies investigating medical records has already been described as a potential benchmark to assess the effectiveness of data collection through reporting systems. The Ministry of Health, while recognizing a paucity of studies in this area in Slovenia, invited the safety officers present at the meeting to participate to such a retrospective study, which the Ministry of Health would be willing to co-finance.

Instruments for data collection were presented by WHO. In the area of adverse events in particular the instrument titled Assessing and Tackling Patient Harm, A Methodological Guide for Data-Poor Hospitals has been presented. The instrument, which will be available on the WHO web site in the near future, includes a series of tools to measure harm:

- 1) retrospective record review
- 2) record review of current inpatients
- 3) staff interviews on current inpatient
- 4) nominal group technique
- 5) direct observation and related interview

The publication will also include recommendations on how to select the most appropriate of these tools according to the objectives and the availability of resources of the facility performing the assessment.

WHO is also developing an indicators framework within the Patient Safety Indicators for Data-Poor Hospitals project. The project has multiple phases: identifying the most relevant patient safety issues, identifying the most relevant contributing factors within those issues and then exploring the availability of indicators in the recognized areas and the feasibility of data collection.

Root Cause Analysis

While data collection through the appropriate reporting structures is indispensable in order to recognize and address adverse events, the important aspect of the system is its ability to foster actual improvements in patient safety. In the course of the first day the importance of feedback from the national authorities to the reporting organizations has already been recognized. The discussion during the second day shifted to include actions to be taken after a report has been filed. Indeed reporting systems should be an opportunity to learn from past experience, also within the reporting organization. The most common tool to perform in-depth investigation of adverse events, aimed at systems' improvements, is the so-called root cause analysis.

Root Cause Analysis has been identified as the landmark of an organization that wants to learn. It has been portrayed as the element that allows a distinction between those organizations that report because they are asked to and those that collect information in order to learn from. Root Cause Analysis can be performed using various techniques recognizing that errors resulting in harm to patient have multiple causes. They also have the common aim of helping in the identification of weaknesses or failures in the processes, that if changed can prevent an adverse event from occurring again.

It has been also underlined that Root Cause Analysis is by its nature very deep and precise. It requires many hours of work by the many health care professionals involved and therefore it is fairly expensive. The costs of analysing adverse events can be reduced using other methods,

which have been identified by a European project on patient safety EuNetPas. More information is openly available on the website of the project.

It has been stressed that clearly identifying the reasons for adverse event reporting and learning is important. The primary motive for supporting such as system might be to foster safety culture among providers rather than developing recommendations. The latter are often made openly available by long established organizations running adverse event reporting systems or tackling patient safety.

Culture of Safety

Changing the culture in order to promote safer healthcare processes has been emphasized as the main issue in every effort to improve patient safety. Various definitions of a safety culture have been presented. Discussions on this topic are often met by a certain amount of scepticism, as the culture itself is an abstract concept. It has been shown that it reflects itself in patterns of behaviour that have a direct impact on safety.

The culture of safety of a healthcare organization can also be measured. Among the most famous survey tools to measure the safety culture is the one offered by the Agency for Healthcare Research and Quality. It has been pointed out that an evaluation of the tools openly available to measure the safety culture has been undertaken by EuNetPas. Considering the current efforts being made by the participating countries in the area of patient safety, measuring the safety culture in these countries has been presented as one of the most useful steps to be undertaken. Such a measurement may provide a useful starting point, against which to compare future results and thus provide a means for assessing the progress made through various initiatives in the future.

A just and fair reporting environment (accountable but no-blame culture) has been recognized as particularly relevant to promote adverse event reporting. If health professionals are expected to report adverse events, mechanisms must be in place, aimed at assuring that those reports will not be used in disciplinary or other punitive actions. More generally such mechanisms find an appropriate environment in organizations, where people can speak up and receive fair feedback, which constitutes part of the safety culture definition cited above.

The example of Denmark has been presented, where reporting adverse events cannot be used by law in a criminal investigation nor can it lead to the incrimination of the person reporting. As reporting is mandatory, this clause was necessary to assure that health professionals are not required to incriminate themselves. Individual responsibilities can still be assessed in a number of other ways, independent of the reporting system. One example of such a situation is the investigation that might follow a patient complaint.

Leadership has been recognized as playing a key role in building the safety culture. Leaders set patterns of behaviour that are then followed by the majority. A cultural shift, just as every other change, requires a critical mass of people is needed to modify the way activities are performed in a healthcare organization.

Competencies and skills in the area of quality and safety can also influence culture significantly by raising awareness and providing knowledge on the various techniques available to tackle

arising issues. Education and training should address various levels, starting from the formal undergraduate education and including the workplace.

The Role of the Patient

A system for patients' reporting of adverse events has been in place in Ireland for some time and offered the opportunity to discuss how patients perceive adverse events with respect to health professionals. The set of issues reported most often by patients is very different from those reported by the professionals, thus pointing at a very different understanding of adverse events by the two groups. The observation reveals the added value that a patient perspective can contribute to the decision making process when setting policies and priorities for action at all levels.

Patient should not be seen merely as passive elements at the receiving end of healthcare system. Instead they should be seen as allies in the process of improving quality and safety. Their role can be enhanced by giving them the opportunity to participate actively to the healthcare system. The potential range of roles they can take is very broad, going from raising awareness on a particular issue to supporting individual patients and their relatives.

The tension that often builds up in the relationship between patient and health professional when an adverse event occurs can be significantly reduced by a disclosure policy. Fully disclosing errors to the patient is not indispensable within an adverse event reporting system, yet it is necessary. Disclosure has been found to reduce litigations and claims for compensation, but primarily it is an ethical duty of the health worker and a very profound need of the patient.

Disclosure, just as a safety culture, must be actively promoted. The two are indeed closely linked by the principles of openness and fairness. It has also been recognized that disclosing incidents is often extremely hard for the health workers. A survey showed that health professionals may generally consider disclosing errors to the patients the right thing to do, and yet they might not actually do it when confronted with such a situation. Training can improve the communication skills of health professionals and their ability to tackle situations where adverse events need to be disclosed.

Day 3

Reporting adverse events within a healthcare organization

An example of how the policies and recommendations can be applied to a hospital has been presented by the University Medical Centre in Ljubljana (UMCL). UMCL has had the current internal safety reporting system in place since 2008. The system is the result of many years of experience targeted at improving safety, and it is worth noting some of its features. A nominated safety officer is responsible for the administration of activities to be performed when an adverse event is reported, but also for education and training of staff in safety of healthcare. The system is not limited to monitoring events occurring to patients, but also includes patient visitors, employees etc. In order to enhance the role of patients, UMCL established a patient council, which is a consulting body to the Medical council and has members in the expert assessment group. In 2010 progress has been observed in many instances: the detection of adverse events

has been more efficient, the motivation of employees has been rising, root cause analysis are more often performed and safer procedures are introduced.

Important International Networks

The meeting was concluded with a summary of the discussions and a comparative analysis of the current state of affairs in the three participating countries. The vital role of international networks has been emphasized, in particular: EuNetPas, the Organization for Economic Cooperation and Development (OECD) Health Care Quality Indicators (HCQI) project and the WHO Patient Safety Network. The Global Learning Community for Incident Reporting Systems established within WHO was also presented, with the aim of fostering exchange of information, success stories and lessons learned in the process of strengthening patient safety and better care .

Recommendations

Drawing from the rich presentations and discussions during the event, a number of possible areas for action have been identified in the final brainstorming session. For prioritization purposes, as well as considering their magnitude and impact, these have been divided into activities to be initiated in the short term and plans for the medium to long term.

Short term

- Communication between reporting institutions and integration of specific reporting (e.g. Blood transfusion centre Slovenia and UMCL; HCSA and Ministry of Health Slovakia)
- Cooperation with hospital quality managers
- Implementation of tools to identify the problem and define measures
- Development of action plans for implementation of existing legislation and guidelines
- Revitalization of activities to involve patients and improve communication between healthcare workers and patients
- Follow up conference/ awareness raising events
- Cooperation between stakeholders, involving patient organizations
- Meeting in 1 year time to monitor progress achieved as of today

Medium/ Long term

- Define the purpose of the reporting system – the vision
- Learning non punitive system but accountable, open to all for input
- Incentives – link to accreditation
- Strengthen quality and safety requirements at various health care levels
- Simple user friendly reporting at general practitioners' level with links to HT
- Patient safety in medical curricula

- Involve patients in reporting as allies in improving health care outcome
- Update/ develop supportive legislation (e.g. example of Denmark)
- Strengthening the safety culture and building trust to get feedback from patient

The following immediate steps have been commonly agreed by the participants:

1. Create a working/ steering group involving agencies receiving reports and professional/ patient associations to
 - identify 3 priorities for action to report on in 1 year time
 - research to evaluate harm (WHO patient safety selected methodology, Patient friendly hospitals/ health promoting hospitals)
 - Challenge professional societies for action to report on in 1 year time
2. Promote health literacy linked to public health interventions
3. Promote health care worker awareness/ education
4. Invitation to the Global learning community for incident reporting systems

It has also been recommended to have another international meeting to follow up on this one and report on the progress made in one year.

Annex 1

SCOPE AND PURPOSE

Patient safety is an integral component of the quality of care, which reflects the need for increased awareness and confidence in the system. Health care is becoming everyday more effective and more complex, with greater use of new technologies, medicines and treatments. Furthermore, times of financial crisis are likely to add pressure on health systems to further contain costs, and thus potentially affect service quality and patient safety.

European data, mostly available for the European Union Member States, consistently show that medical errors and health-care related adverse events occur in between 8% and 12% of hospitalizations. Integration and coordination of services, supported by patient/consumer involvement is proven to reduce these occurrences.

While a strong safety culture remains a mandatory background, the need for good reporting systems is recognized as part of the learning and improvement process. The experience of the already existing systems for reporting adverse events can be a good way of learning how to overcome barriers to communication, to support integrated databases and enhance responsive feedback to the patient/ consumer and the health-care provider/ health care facility.

Shared experience, information exchange and most of all joint knowledge and resources are needed to develop and build sustainable interventions to address reporting for patient safety, integrated within the existing structures and enforcement mechanisms on the ground.

Objectives and expected outcomes:

1. To provide a common platform for discussion and information exchange on actual practice, barriers and success factors to reporting safety failures in various health care related fields in Czech Republic, Slovenia, and Slovakia;
2. To explore the missing links and the potential for integration of current reporting functions/ systems for adverse event at various levels of care, including specialized services (i.e. blood services);
3. To use latest evidence, international experience and national know how to subsequently facilitate setting milestones for action.

Annex 2

PROGRAMME OF THE MEETING

Wednesday 29 September

<i>12:30 - 14:30</i>	<i>Registration</i>	
14:30 - 15:30	Opening address: Objectives of the workshop: Election of chair and reporter Introduction and expectations of participants	Dr Dorijan Marušič, Minister of Health of Slovenia Dr. Marijan Ivanusa, WHO CO Dr Valentina Hafner, WHO RO
<i>15:30 - 16:00</i>	<i>Coffee break</i>	
16:00 - 17:00	Reporting in health care (primary, secondary, tertiary care, palliative care) <ul style="list-style-type: none"> ▪ Reporting systems in Slovenia ▪ Reporting systems on Slovakia ▪ Reporting systems in Czech Republic Primary Health Care 	Dr Mircha Poldrugovac, Ministry of Health, Slovenia Dr Eugen Nagy, Ministry of Health, Slovakia Dr. Bohumil Seifert, Institute of general practice, Czech Republic
17:00 - 17:20	Reporting on blood transfusion (haemovigilance)	Prim Dr Marjeta Potočnik, WHO CC Ljubljana
17:30 - 18:15	Reporting on pharmaceuticals, devices & vaccines (pharmacovigilance & materiovigilance) <ul style="list-style-type: none"> ▪ Pharmacovigilance ▪ Materiovigilance ▪ Vaccine safety monitoring ▪ Safety vigilance 	Prof Dr Martin Možina, University Medical Centre, Slovenia Dr Vesna Koblar, Agency for Medicinal Products and Medical Devices, Slovenia Dr Alenka Kraigher, National Institute of Public Health, Slovenia Dr Peter Bandura, Health Care Surveillance Authority, Regional Office Prešov, Slovakia Dr Dagmar Kučerová, National Institute of Cardiovascular Diseases, Slovakia Dr. Bohumil Seifert, Institute of general practice, Czech Republic
18:15 - 19:00	Discussion & conclusions of day 1	

Thursday 30 September

9:00 - 9:15	Opening address:	Prim Dr Janez Remškar, Chief Medical Officer, Ministry of Health, Slovenia
9:15 - 10:10 includes discussions	Improving quality of care – a safety perspective (includes national report on addressing adverse events in hospital settings) <ul style="list-style-type: none"> ▪ National strategy on quality and safety in Slovenia ▪ National strategy on quality and safety in Slovakia ▪ National strategy on quality and safety in Czech Republic 	Dr. Biserka Simčič, Quality Department, Ministry of Health, and Dr Miran Rems, General Hospital Jesenice, Slovenia Dr Eugen Nagy, Quality Department, Ministry of Health, Slovakia Dr. Bohumil Seifert, Institute of general practice, Czech Republic
10:10 - 10:40	Tools to assess harm in health care settings	Dr Carmen Audera-Lopez, WHO patient safety programme
<i>10:40 - 11:10</i>	<i>Coffee break</i>	
11:10 - 12:30 includes discussions	The application and benefits of Root Cause Analysis within a patient safety programme The Slovenian experience in root cause analysis	Mr Keith Haynes & Dr David Watson, ECRI, UK Dr Andrej Robida, Slovenia
<i>12:30 - 14:30</i>	<i>Lunch</i>	
14:30 - 15:00	The Danish experience on reporting systems	Dr. Jørgen Hansen, National Board of Health, Denmark
15:00 - 15:30	Patient reporting systems	Ms. Mary Vasseghi, Sudden Cardiac Death foundation, Ireland
<i>15:30 - 16:00</i>	<i>Coffee break</i>	
16:00 - 16:45 includes discussions	Cultures of Safety - building an open reporting culture	Mr Keith Haynes & Dr David Watson, ECRI, UK
16:45 - 18:00 Panel led discussion	The role of the patient and public perception on health care related safety risks	Ms. Mary Vasseghi, Sudden Cardiac Death foundation, Ireland Dr. Jørgen Hansen, National Board of Health, Denmark Country representatives
18:00 - 18:30	General discussion and conclusions	

Friday 1 October

09:00 - 10:00	<p>Common barriers and success factors to identifying and addressing the (potential to) failure in health care provision</p> <ul style="list-style-type: none"> ▪ Hospital reporting systems: <i>practical solutions and reporting tools' experiences</i> ▪ Summary report of issues identified (days 1&2) 	<p>Prim Dr Dušica Pleterski, Jelka Mlakar, University Clinical Centre Ljubljana, Slovenia</p> <p>Dr Mircha Poldrugovac, Ministry of Health, Slovenia</p>
10:00 - 10:30	<p>Missing links and the resources for integration of current reporting practices for increased efficiency of data management</p>	<p>Dr Valentina Hafner, WHO RO</p> <p>Expert panel round table</p>
<i>10:30</i>	<i>Coffee break</i>	
10:30 - 12:00	<p>Conclusions, next steps and closure of the meeting</p>	

Annex 3

LIST OF THE PARTICIPANTS

Czech Republic

Bohumil Seifert
Institute of General Practice
First Medical Faculty of Charles University in Prague
Prague

Slovakia

Peter Bandura
Head of Regional Office Prešov
Health Care Surveillance Authority
Prešov

Eugen Nagy
Ministry of Health of the Slovak republic
Department of Health Care
Bratislava

Dagmar Kučerová
The National Institute of Cardiovascular Diseases
Bratislava

Slovenia

Suzana Baltič
General Hospital Izola
Izola

Milena Bergoč Radoha
Agency for Medicinal Products and Medical Devices
Ljubljana

Mirjana Bušljeta
Ptuj General Hospital
Ptuj

Danijel Globokar
Institute for Rehabilitation of the Republic of Slovenia
Ljubljana

Zdenka Gomboc
General Hospital Murska Sobota
Murska Sobota

Aleksander Grubišič
General Hospital Jesenice
Jesenice

Bojan Grulović
General Hospital Brežice
Brežice

Breda Hajnrih
Centre for Quality and Organization
University Medical Centre Maribor
Maribor

Bernarda Hostnik
General Hospital Celje
Celje

Simona Hotujec
Institute of Oncology Ljubljana
Ljubljana

Gordana Kalan Živčec
Medical Chamber of Slovenia
Ljubljana

Janko Kersnik
Quality Manager at OZG Kranj
Kranjska Gora

Darinka Klemenc
Nurses and Midwives Association of Slovenia
Ljubljana

Bojan Korošec
General Hospital Murska Sobota
Murska Sobota

Lučka Kosec
General Hospital Novo mesto
Novo mesto

Alenka Kraigher
Head of Centre for Communicable Diseases
National Institute of Public Health
Ljubljana

Robert Likar
Hospital Postojna
Postojna

Dorijan Marušič
Minister of Health
Ministry of Health of the Republic of Slovenia
Ljubljana

Jelka Mlakar
Safety Officer
University Medical Centre Ljubljana
Ljubljana

Martin Možina
Head of Department of Toxicology
University Medical Centre Ljubljana
Ljubljana

Kristijan Nedog
Psychiatric Hospital Ormož
Ormož

Nevenka Pavčnik
General Hospital Trbovlje
Trbovlje

Dušica Pleterski-Rigler
Safety Officer
University Medical Centre Ljubljana
Ljubljana

Mircha Poldrugovac
Ministry of Health of the Republic of Slovenia
Ljubljana

Marjeta Potočnik
Head of Centre for haemovigilance
Blood Transfusion Centre
Ljubljana

Miran Rems
Clinic for Abdominal Surgery
Jesenice General Hospital
Jesenice

Janez Remškar
Director General of the Health Care Directorate
Ministry of Health of the Republic of Slovenia
Ljubljana

Andrej Robida
Associate professor
Ljubljana

Tanja Romčević Gržetič
Hospital Sežana
Sežana

Dunja Savnik Winkler
General Hospital Nova Gorica
Šempeter pri Gorici

Biserka Simčič
Head of Quality Department
Ministry of Health of the Republic of Slovenia
Ljubljana

Andreja Sinkovič
University Medical Centre Maribor
Maribor

Branka Sušnik
Hospital for Gynaecology and Obstetrics
Kranj

Franc Svenšek
University Medical Centre Maribor
Maribor

Igor Švab
Head of Department of family medicine
Faculty of Medicine
Ljubljana

Ivan Tandler
General Hospital Slovenj Gradec
Slovenj Gradec

Rok Tavčar
Psychiatric Clinic Ljubljana
Ljubljana

Lilijana Vouk Grbac
Orthopaedic Hospital Valdoltra
Ankaran

Jerca Zupan
Psychiatric Hospital Begunje
Begunje na Gorenjskem

WHO temporary advisers

Jørgen Hansen
Senior Medical Officer
National Board of Health
Copenhagen
Denmark

Keith Haynes
ECRI Institute, European Office
Weltech Centre
Hertz
United Kingdom of Great Britain and Northern Ireland

Mary Vasseghi
Chairman of Sudden Cardiac Death in the Young
Support Group
C/o Irish Heart Foundation
Dublin
Ireland

World Health Organization

Headquarters

Carmen Audera-Lopez
Patient safety programme
Geneva, Switzerland

Regional Office for Europe

Valentina Hafner
Health care quality, Division of health systems and public health
Copenhagen, Denmark

Marijan Ivanuša
Head of Country Office, Slovenia

Marija Andjelković
Administrative Assistant Country Office, Slovenia