

Patient Engagement in Reducing Safety Risks in Health Care

**REPORT OF THE MEETING ON
PATIENT SAFETY AND RIGHTS
COPENHAGEN, 31 AUGUST 2011**

ABSTRACT

Patient safety, rights and resulting patient empowerment were reviewed from technical, legal and social points of view, at general level and in specified technical fields. Hand hygiene, elective surgery, blood transfusion safety and medication were selected as areas to explore exiting patient empowerment and its potential role to improve quality and safety of care. Enhancing patient involvement and health literacy appear to be incisive, but not easy to achieve, ways to improve patient safety.

Rapporteurs

Nataliya Tarasenko, Maria Gabriela Virone

Keywords

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Background

Both the topics of patient safety and patient rights are high on the health agendas of countries in the European region. This project aims to improve patient safety by enhancing patient empowerment and health literacy. The first coordination meeting set the main goal of producing guidance to support patient empowerment, focused on patient rights & safety. The preliminary chosen themes related to blood transfusion, hospital infections/ hand hygiene, and communication during patient handovers.

The national studies in selected technical areas were expected to address the potentially active role of the patient in risk management and safety control, and as co-producer of own health. This could lead to the identification of the most effective information to be provided to patients, in order to enhance health literacy, dialogue and patient engagement in improving quality and efficiency of care.

Introduction

The second Patient Safety and Rights expert group meeting was hosted by the WHO Regional Office for Europe in Copenhagen on 31st of August 2011. The meeting was co-chaired by Prof. Niek Klazinga, and Dr. Valentina Hafner. It was attended by more than 20 experts representing a variety of health care and patient organizations across the region.

The meeting was devoted to review the studies undertaken. Since the 2010 meeting, important progress has been achieved, leading to the development of 6 dedicated studies, 2 of a general nature, and 4 targeting selected technical fields (hand hygiene, elective surgery, medication prescription, blood safety).

The general studies addressed regulatory aspects and variable legal tools supporting patient safety and the right to safety (University of Amsterdam), with particular emphasis given to building knowledge and empowerment to contribute in the process of health promotion, protection and care. The role of patient participation in enhancing patient safety and the use of patient experience questionnaires as a tool to monitor progress of the team effort to reduce errors was detailed by the University of Tilburg team.

The four national studies conducted by institutional teams in Poland, Bulgaria, Portugal and France focused on the review of legislative aspects covering the specific technical area of work; review of key technical documents in use at the national level; review of health promotion/ health literacy related campaigns; and research on documented influence (retroactive) of patient intervention, informed choice, etc. in the reduction of safety failures occurrence.

Health 2020 and WHO European strategy on health systems and public health¹

Milestones set by the European legislation, recommend Member States to promote and emphasize the role of patients, improving quality and safety of health care². These are complemented by the dedicated World Health Assembly resolutions and continuous work of the WHO patient safety programme, in particular with its Patients for Patient Safety line of work.

¹ Presented by Dr Hans Kluge, Director, Division of Health Systems and Public Health, WHO Regional Office for Europe

² Recommendation No. R (2000)5 of the Committee of Ministers to member states on the development of structures for citizen and patient participation in the decision-making process affecting health care ; Recommendation Rec (2006)5 of the Committee of Ministers to member states on the Council of Europe Action Plan to promote the rights and full participation of people with disabilities in society: improving the quality of life of people with disabilities in Europe 2006-2015; Recommendation (2006)7 of the Committee of Ministers to member states.

The new European policy for health Health 2020³ based on the values and the conceptual framework of the Tallinn charter looks at the challenges of rapidly developing global and European trends through a focused lens. The operational approach to support Member States in health systems strengthening is expected to be driven by key health outcomes and global and regional strategies that should be easily adaptable in response to arising priorities. Improving core services, while preserving and reinforcing the values of solidarity, equity, sustainability, dignity and participation in the decision making process both what concerns personal health and the health of the society will remain a priority. This holistic and patient-centred approach to health care with increased focus on safety and quality improvement should be supported by the development of concrete policies and appropriate implementation mechanisms.

The legal dimension of patient safety – patient rights⁴

The first presented report mapped the evolution of regulatory frameworks and the current status of legal tool supporting patient safety and the right to safety in the European region. Key relevant international policy instruments, in addition to existing general human rights documents, treaties and recommendations, include: *European Union documents*, such as 2005 Luxembourg Declaration and Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections); *Council of Europe documents* (such as 2005 Warsaw Statement and Recommendation 2006/7 on the management of patient safety and the prevention of adverse events in health care); *WHO documents* (such as WHA55.18/2002 on Quality of care: patient safety; 2006 London Declaration,; 2008 Tallinn Charter, etc).

Many European countries have developed national legislation on patients' rights. In most cases these contain provisions dealing with the general rights of patients. Only few countries, e.g. Denmark and United Kingdom, have legislation addressing specific issues.

The most important rights mentioned in reviewed legislation directly or indirectly related to patient safety include: the right to health care that is safe and of good quality; the right to participate in policy making; the right to (outcome) information about the safety and quality of health services; the right to information with regard to the proposed treatment; the right to be informed about adverse events and medical errors; the right to participate in quality assurance schemes; the right to complain; the right to be compensated in case of damage; the right to be supported; the right to privacy. The key words for the existing legislation concerning patient safety are: *information, involvement and empowerment/support*.

Most of the existing patient safety legal rights reinforce one another. The right to information is crucial and constitutes the minimum level of patient protection as necessary to exercise their other rights. However, while legislation in many countries includes the right to informed consent and the right to be informed about adverse events, only some mention the patient's right to report such incidents. There is a collective dimension in the rights related to patient safety. For example, the right to complain is pivotal to individual compensation in case of damage, but also to identify quality and safety defects, and vice versa.

The collective dimension is especially strong in the right to participate in policy making. The tension between collective and individual dimensions underscore the importance of non-legal policy measures and the need to develop implementation mechanisms adapted to specific environments. Ability to make informal complaints should not be underestimated as a valid tool for improvement of quality of care.

³ http://www.euro.who.int/__data/assets/pdf_file/0007/147724/wd09E_Health2020_111332.pdf

⁴ Research was led and presented by Prof Johan Legemaate, Professor of Health Law, Academic Medical Centre, University of Amsterdam

The limits of legal measures in stimulating patient involvement are also evident in challenges experienced during patient participation programmes. These are due to variable level health literacy and to cultural factors. Patient involvement and especially empowerment and support presuppose certain competencies and skills enabling patients to exercise their legal rights. In this context, patient groups are especially vulnerable in shared decision making, as patients and health care providers come with different expertise in the process.

Legal instruments help define the level and modes of accountability of health care providers (professionals and institutions) in their interaction with the patients. The role of non-governmental organizations and industry is also important to consider. Cooperation between insurance companies and patients' rights associations, in particular, would promote further development of legislation and legal instruments reaffirming the patient status and the connected power of affirming patients' rights.

Discussion

Patient safety is increasingly included in the current educational curricula for all types of health care workers, which promotes the change in attitude and priority setting of the health care profession.

Insurance agencies can be strong partners in cooperation with health care institutions. In the Netherlands, for example, former private insurance companies start playing a crucial role in the development and implementation of prevention and quality improvement programmes at the hospitals, where they become part of the management.

Existing legislature does not seem to stipulate the obligation for patients to report adverse events and incidents. The Dutch legislation seems to imply such an obligation, but this is formulated in positive terms, and there are no possible sanctions for non-compliance. The mandatory connotation of reporting does not seem to work, which might explain why the obligation to report is not included in most national legislations.

There is some evidence indicating that introduction of informal systems of complaints can lead to improvement. Such an informal way of reporting is exercised best in an "enabling" environment. When patients feel comfortable about the health care personnel, they have a higher level of confidence to engage in dialogue.

The use of the word "citizen" instead of "patient" was discussed. Each term implies a different focus of intervention. In certain contexts it might be more appropriate to speak about citizens' rights instead of patients' rights. How to operationalize the concept of "citizen" might be examined also in the light of the Health 2020 policy. This links to issues of democracy and whether we are consumers or participants in the health care system. Patients might be reluctant to participate in safety or quality improvement programmes, while others might not have the possibility. The role of patients' relatives in particular has to be considered in relation to patients' rights.

Legal norms are important, but a part of the integrated approach required and not the only solution. Legal perspective deals with absolute concepts, but safety is relative. Experience from the only country (Denmark) that has explicit legislation on patients reporting systems indicate that it might generate additional challenges due to the required cultural change.

Patients' experiences and patient role with respect to safety⁵

Growing interest in patient involvement in and experiences with patient safety has recently led to several lines of research centered on the concepts of patient participation, patient-centered care, measurement of patient experiences, and the like. The report devoted to patient experiences presented the findings on patient roles with respect to safety derived from two recent systematic reviews (Hall et

⁵ Research was led and presented by Professor Delnoij, Tranzo department, University of Tilburg, Netherlands

al⁶ and Schwappach⁷) covering the period up to 2008 and supplemented by the review of the available literature related to patient participation and safety management for 2008-2011.

The results of the reviewed literature indicated that in general patients support a role in safety, but see their role as rather passive and consider patient safety as a professional responsibility. There is more support for traditional actions (e.g. giving information) than for challenging professional authority (e.g. asking about hand washing). In addition, it is easier for patients to challenge nurses than doctors.

The literature review was complemented by screening of patient experience surveys, which included the questionnaires of the Commonwealth Fund (US), Consumer Assessment of Healthcare Providers and Systems (CAHPS) questionnaires used by the Agency for Healthcare Research and Quality (US), Consumer Quality Index (CQI) questionnaires of the Dutch Centre for Consumer Experience in Health Care and questionnaires used by the Care Quality Commission in England⁸. The actual effects of patient involvement were examined and several examples follow.

In *hand washing* interventions, use of soap increased by 34-56% (91% of patients asked a nurse and 33% asked a doctor if they have washed their hands). However one study indicated that soap usage increased already in pre-programme period, mostly likely because the staff anticipated the question about hand hygiene from the patients.

In *wrong-site surgery* prevention, only 60-70% patients complied with the request to mark the site of surgery, and some made mistakes, which makes this method of patient involvement unreliable.

In other areas, *information campaigns* and patient safety video have increased patients' knowledge and level of comfort in speaking to staff about safety.

The overall conclusions point to an increased interest in the role of the patient in safety management, but patients themselves seem to be rather conservative in defining that role, e.g. they "follow instructions" and "expect competent care". In acute care setting the potential role of the patients should not be overestimated. Self-management is more important in the ambulatory care setting, particularly for chronically ill and for patients with multi-morbidities. Effects of actual involvement are often disappointing and more quality research of interventions in different settings is required. Research indicates that the "threat" of disclosure may be an effective way to encourage safe professional behaviour, so measuring and publishing of patients' experiences with safety is the right way to go.

Discussion

Studies of patient experiences in different patient groups indicate that capability and willingness to be involved are crucial. Relatives and in particular parents tend to be more involved than the patients themselves, in particular in maternity ward setting.

Existing tools for measuring patient experiences are moulded into the contexts of specific health care systems. Development of generic tool might not be feasible but general recommendations could be developed that would guide Member States in their own assessments, or a core set of questions that would allow cross-country comparison. The Organization for Economic Co-operation and Development (OECD) is currently concerned with the development of such core questions and recommendations in the three domains of communication, autonomy and access.

⁶ Hall, J., et al., Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review. *Quality & safety in health care*, 2010. 19(5): p.e10

⁷ Schwappach, D.L., *Review: engaging patients as vigilant partners in safety: a systematic review*. *Medical care research and review*: MCR, 2010. 67(2): p.119-48

⁸ For practical reasons, in this phase the work was limited to questionnaires available in English and Dutch

Some of the areas and examples discussed were beyond the scope and purpose of the current project. It was proposed that they could be included in the final paper in boxes, where linkages between the project work and these related or overlapping initiatives could be mentioned. *Patient story* as a part of patient experience has a great potential in raising political awareness, for example.

Increasing patient role in medication prescribing and pharmacotherapy safety in Poland⁹

Despite the many studies focused on medication safety, only few relate to pharmacotherapy and medicines use in primary care. The study on patient role in medication prescribing and pharmacotherapy safety in Poland included review of the relevant national legislation, focused pilot surveys and a specialist overview of the topic by the Regional Centre for Monitoring of Adverse Drug reactions (RCMADR), Krakow.

The existing Polish legislation emphasizes the duty of health care providers to deliver patient care according to the recent medical knowledge, with diligence and respect. The Law on the Profession of Doctor and Dentist (December 5, 1996, with Amendments) contains a stipulation obliging the doctor to report adverse drug reactions¹⁰ (ADR), while a separate Ministry of Health regulation covers standardized reporting. The Law on the Profession of Nurses and Midwives (July 5, 1996, with Amendments) lists the medicines a nurse (and a midwife) may administer without the doctor's order. The Law on Pharmacy (September 6, 2001, with Amendments) defines the content of product characteristics, e.g. indications, dosage and way of administration, counter indications, interactions and ADR. It also states that the hospital's pharmacy should participate in the reporting of ADR to the designated national Bureau.

The Law on Patients' Rights and the Ombudsman of Patient Rights (November 6, 2008, with Amendment) lists the patient right to obtain health care services in line with the recent medical knowledge, the right to get information and, having obtained it, to comment and present own view. The Law on Accreditation of Healthcare Institutions (November 6, 2008) addresses patients rights in medication safety through accreditation standards. Review of the agendas of, the Polish Patients Federation¹¹ and the Institute of Patient Rights and Health Education¹² (the two major patients' organizations in Poland) do not cover medication safety and/or provide the respective patient education.

Two pilot surveys "Patient Safety Rights and Medication Safety" focusing on ADR covered a group of 50 family physicians and 50 patients using primary care services from 5 cities in Southern Poland. In the anonymous patients' survey the inclusion criterion was continuous and repetitive use of medication (at least one medication taken for a chronic disease). The pilot intended to describe whether patient rights can improve safe pharmacotherapy. The pilot survey of physicians (all providing services within the public healthcare sector) intended to describe whether safe medication practices were being used in every day practice, while prescribing the new medication and continuing patient medicine treatment.

Only 39% of the interviewed patients knew names and dosages of medicines they take. This knowledge decreased for those who took more drugs. While 65% indicated that they discuss

⁹ Research led and presented by Dr Barbara Kutryba, WHO Collaborating Centre for Development of Quality and Safety in Health Systems, Krakow, Poland

¹⁰ Adverse drug reaction (ADR) is an event where the adverse effects can be defined as resulting directly from the medicine use. ADR should not be confused with adverse drug events (ADE) - any event related to medicine use leading to occurrence of adverse reactions, without (the possibility to define) the cause and effect relation

¹¹ www.federacijapp.pl

¹² www.prawapacjenta.pl

medication during every visit (although it is not known what exactly aspects are covered), only 6% state that potential interactions between different medicines taken were mentioned by the doctor. Only 1 respondent out of 50 stated that the doctor always asks about previous ADR. At the same time 82% of the respondents experienced ADR and 55% required subsequent treatment.

The results of the doctor pilot are no less alarming. The majority of doctors (62%) do not ask patients about over-the-counter medicines and diet supplements. While 82% of doctors expect the patient to present a list of medicines taken, with names and dosages, according to informal patients' comments this means that doctors seldom ask patients to prepare such lists, leaving it up to the patients' own initiative. The majority of primary care physicians have no practice of reporting ADR: 90% indicate seldom reporting, and 76% have never reported one.

Patient medication safety appears compromised by: 1) increased use of diet supplements susceptible to interactions, with no related research and no existing safety monitoring mechanism, 2) use of over-the-counter medicines, 3) use of off-label medicines, despite the availability of registered medicines for the same population or indication; 4) unsafe prescribing practices; 5) non-standardized content of patient history with low interest of professionals in patient medication history.

The continuous pharmacotherapy use calls for organization of the system of medication information centres for patients, doctors, pharmacists and other stakeholders. Wide implementation of the electronic Health Card, storing, among others, reliable information about medication taken, dosage, experienced adverse drug reactions could be a supportive tool. Health professionals need to be trained to use medicine information sources and to communicate about medicines with peers and patients. Particular attention is required by reporting ADRs to the designated and specialized centres for monitoring safety of pharmacotherapy. Patient organizations need to take an active role in providing the appropriate skills, knowledge, empowerment and encouragement to both individuals and organizations.

Discussion

The existing pharmacovigilance agencies in Poland deal mostly with the issues of side effects of medicines. Although some of them deal with issues of reporting, there are not many reports to date to allow dedicated research. The presented study provides a good starting point for engaging these agencies in the related research and could be a stepping stone towards a nation-wide discussion.

As the patient survey was conducted through personal interviews, no communication problems were experienced due to misunderstanding or inadequate knowledge on the part of respondents. If similar surveys are conducted in the form of postal questionnaires, more attention should be paid to providing adequate explanations easily understandable to laymen. Most of respondents were elderly people because they constitute the largest group of medicine consumers in Poland (65%). But since the patients' relatives could be present during the interviews, the old age of respondents was not considered to be a compounding issue.

It was suggested to include an additional question in similar studies: "How often medication plan is reviewed by doctors?"

Strengthening the role of patient in hand hygiene implementation in Bulgaria¹³

¹³ Research was led and presented by Dr. Rossitza Vatcheva Dobrevska, National HAI Reference Centre, National Centre for Infectious and Parasitic Diseases, Sofia, Bulgaria

The Bulgarian experience on implementing hand hygiene in health care facilities, reviewed the role that patients can play in the process and how this is supported by national regulations, medical staff attitude, education programmes and campaigns. A national point prevalence survey (PPS) conducted in 23 Bulgarian acute care hospital in 2006 confirmed an association of HAI with the risk factors, such as indwelling vascular lines, surgery and length of stay in a hospital. The results of the study underscored the need to effective measures aimed at enforcement of modern surveillance (including post-discharge surveillance), raising the awareness of both health care personnel and the general public about the social-medical burden of HAI and antimicrobial resistance, development and control of a more prudent use of antibiotics in Bulgarian hospitals and implementation of target oriented infection control interventions.

The most important piece of legislation in Bulgaria related to patient safety is the Health Law effective from 1 January 2005 that regulates activities and ensures quality control of health care. It regulates the rights and obligations of the patients in accordance with the Convention on the Protection of Human Rights and Human Dignity in the application of biology and medicine (Convention on Human Rights and Biomedicine) by Council of Europe, signed on 31 May 2001. The latest act related to infection control is the Decree No.39 from 26 August 2010 for endorsement of National Medical Standard on Prevention and Control of Healthcare Associated Infections, issues by the Ministry of Health that contains chapters on HAI prevention, hand hygiene, hand washing, hand disinfection and surgical hand disinfection.

The National Reference Centre for HAI prevention and control (NRC-HAI), a specialized unit at the National Centre of Infectious and Parasitic Diseases (NCIPD) was set up in 2007, with the support of the Ministry of Health and Swiss Red Cross. It was designated as the competent and authorized local structure for HAI. Main achievements of the NRC-HAI include the development of the “National Programme for Prevention and Control of HAI and restriction of AMR spread 2009-2011” and the development of the Medical Standard on HAI aimed at harmonizing the existing legislation with EU standards.

What concerns education, in Bulgaria there is an official specialty for nurses “Hospital hygiene/HAI prevention and control”, with currently 165 graduates. In 2010 a national training programme for infection control for doctors, based on IPSE Core Curriculum, was developed and a new special qualification “Prevention and Control of HAI” was introduced. The various existing training programmes on infection control include a chapter on patient safety and medical staff protection. The NRC-HAI, NCIPD have recently initiated a national campaign for Hand Hygiene 2011-2012 “Hand hygiene – an element of quality safe medical care” as part of the WHO Global Initiative “SAVE LIVES: Clean your hands”. The campaign is connected to implementation of “Council Recommendations on patient safety, including prevention and control of infections related to medical care “(2009), and is directed at health care personnel in constant contact with patients, as well as to hospitalized patients in both acute care hospital and long-term care facilities

A National Survey was conducted in 2011 by NRC-HAI, NCIPD on the basis of the WHO Self-assessment framework on Hand Hygiene as part of the on-going National Hand Hygiene campaign. The study was aimed at evaluation of the existing resources and the implementation of the WHO Hand Hygiene standards at the hospital level and their analysis at the national level. Thirty nine acute care hospitals.

In addition to the hospital survey at the national level, a questionnaire survey was conducted in two acute care hospitals with participation of 123 patients in June-July 2011. The 20 questions were developed and adapted based on the Y.Longtin et al. (2009)¹⁴ model. The results of the survey showed that 73% of patients considered HAI as a serious problem and 67.8% worried about the risk

¹⁴ Longtin, Y. et al., *Patients' Beliefs and Perceptions of their Participation to Increase Health Care Worker Compliance with Hand Hygiene*, 2009, 30,9, 830-839

of HAI, but only 30, 5% identified Hand Hygiene as hand disinfection with alcohol based hand rub. Hand hygiene of medical doctors was identified as a most important preventive measure by 89, 8% respondents. Totally 100% think that nurses clean their hands “always or most of times” and 98.3% think the same about doctors. Most of respondents (79, 7%) think that asking medical personnel to clean their hands would decrease the amount of hospital-related infections, but 50, 4% indicated that they would not feel comfortable if they had to ask the health care worker to clean hands. However an explicit invitation increased the intention of the patients to intervene from 52% to 82%.

This was the first study conducted in Bulgaria evaluating the patients’ opinions and knowledge on HAI, importance of medical staff Hand Hygiene and the patients’ intention to participate in the process of its strengthening. Its results indicate that it is important to extend the survey to other hospitals in Bulgaria. It is expected that the on-going national campaign on Hand Hygiene and the related research initiatives will improve hand hygiene practices in health care settings enhancing both medical staff protection and patient safety, increase patient participation in hand hygiene promotion, and raise awareness of society as a whole, important in terms of an epidemic and pandemic. This should have a long term positive effect on limiting the spread of infections associated with medical care, as an element of quality and safe patient care.

Discussion

The national study of hospitals shows that the impact of the Health Systems strengthening policies can be already felt in Bulgaria but the cultural aspects are still an issue. This is further underscored by the patients’ survey that indicates both on-going behavioural change and the importance of the change process in defining the patients’ role in enhancing safety and quality of care.

An interesting finding of the survey shows that the power of invitation, or permission, by the health care workers changes the dynamics of patient interaction. This underscores the leadership role of health care professionals in the process and the need for visual reminders in health care setting, such as posters and leaflets.

Patient engagement in elective surgery safety in Portugal¹⁵

This study was devoted to exploring the role that patients can play in preventing medical error during planned surgical procedures, based on the Portuguese experience. While improvement in surgical services has been achieved in the country due to emphasis given to safety, efficiency and patient satisfaction, 2.5% of the procedures in Portuguese hospitals can be related with adverse events¹⁶, of which 30-50% is preventable¹⁷.

The national legislation, such as Basic Law on Health, Patients’ Rights and Duties Charter, Portuguese Criminal Code and others, addresses issues of health literacy and right to safety in their clauses devoted to right for information about own health, informed consent, complaint and compensation, and safety. Some legislation, such as Basic Law on Health, the Organic Law of the Ministry of Health and National Health Services’ Users Guide, deals more specifically with patient engagement and safety. This issue is also addressed by Hand Hygiene National Campaign, Programme for nosocomial infections prevention, Programme of antibiotic resistance prevention and

¹⁵ Review was prepared and presented by Ana Mansoa, Intensive Care Nurse, Centro Hospitalar de Lisboa Central, Lisbon, Portugal

¹⁶ Mansoa, A, et al. *Eventos adversos na Prestacao de Cuidados Hospitalares em 2008 (Adverse Events during Hospital Care in 2008)*, Lisbon, 2009 (not published data)

¹⁷ Fragata JIG, *Erros e acidentes no bloco operatorio: revisao do estado da arte (Accidents and errors in the operation theatre: incidence and mechanisms*, Lisbon, Revista Portuguesa de Saude Publica, 2010, 10:17-25

National System of Health Evaluation (SINAS). National Incident and Adverse Events Notification System is being implemented and a Patient Safety Observatory is in the process of establishment. Regulation of surgical care includes Waiting List for Surgery's Integrated Management System – SIGIC ruled by the central Administration Services of the Ministry of Health (ACSS), and DGS's Normative circular document “Cirurgia Segura Salva Vidas” (Safe surgery saves lives) regulating the project implementation in all the operation rooms from 1 July 2010.

EUNetPaS 2010 report on “Diversified teaching programmes for Medical and Nursing Schools and continuing professional development across the EU” revealed that patient safety, as a mandatory module, is still rarely found in the medical school programmes within the EU¹⁸. The educational curricula of the Nursing School of Lisbon (ESEL) are accredited, and include health-care professional communication competencies, team-work, patients' rights to information and safety. The Strategic Plan for Nursing Education 2008-2013 aims at enhancing postgraduate training and research in nursing care quality. There are several postgraduate programmes in Portugal related to patient safety: Master in Patient Safety, Master in Quality Management, Master in Health Communication and post-graduate courses on Informed Consent.

A number of documents and codes of the professional medical associations in Portugal consider a bigger role of patients in the health care process and comprise issues of care quality and information given to the patient. Quality and accreditation in health care settings are addressed through Caspe Healthcare Knowledge Systems (CHKS) that is working with 28 Portuguese hospitals (over 40 indicators of patient safety). The recently adopted accreditation model of the Quality Agency of Andalusia (ACSA) is based on the main standards such as: citizen-centred health system; activity centred in the user; health-care professionals, development and education; support processes and results^{19 20}. Clinical risk policy, in Central Lisbon Hospital Centre (CHLC) in particular, is based upon a patient-centred culture and strong commitment in sharing the adverse events with the harmed patient²¹. A reporting system implemented in the hospital in 2002 is based on voluntary and confidential participation.

Several national studies in Portuguese surgical units conducted in 2005, 2007 and 2009 revealed insufficient consideration by health care providers of information dimension of the informed consent, and its heterogenic application in different unit and even in the same unit. Patient gender, literacy and previous hospitalizations seemed to have influence on the results. According to *2010 Euro barometer* survey on patient safety and quality of health care, 64% of the Portuguese Citizens believe that it is likely to be harmed by hospital health care, whereas 58% see a potential for surgical errors to occur. Out of the total number of Portuguese respondents who have reported that they or a member of their family underwent surgery in the last three years, 24% stated that written consent was never obtained, and 16% reported that it was only sometimes obtained.

Health promotion and health literacy related efforts by the Ministry of Health include patient information available on-line, patient education campaigns and national studies to evaluate user satisfaction during the process of consultation and auscultation²².

Patients' association in Portugal, such as Association of Health services users, have been active in organizing awareness campaigns like conferences, marathons and other events. The Association

¹⁸ Pinto, PR, *The training of doctors today. Challenges and Realities*. Sisifo, Educational Sciences Journal, 2007, 5: 77-92

¹⁹ Campos L., Saturno P. Carneiro A.V. *A qualidade dos cuidados e dos services (Health care and services quality)*, Lisbon, High Commissioner of Health, 2010

²⁰ *Manual de acreditacao de unidades de saude (Health care units accreditation handbook)*, Lisbon, Directorate General of Health, 2011

²¹ *Lage MJ Seguranca do Doente: da Teoria a pratica (Patient Safety meets clinical practice)*, Revista Portuguesa de Saude Publica, 2010

²² *Plano Nacional de Saude 2011-2016 – Qualidade em saude, versao discussao (National Health Plan 2011-2016 – Health Quality, discussion version)*, Lisbon, High Commissioner of Health, 2011

Plataforma Saúde em Diálogo (Platform Health in Dialogue) connecting patients associations, health-care workers, health promoters and users aims to assert itself as a partner in health policy design, through mediation with decision-makers.

The lack of information that seems to subsist in the Portuguese society asks for a real commitment in engaging and informing citizens on patient safety standards, risk and safety measures reduce or prevent errors and harm. TV remains the most powerful channel, while development of new instruments and tools of reporting and evaluation, in particular new computer based applications, would support campaigns based on the more traditional methods.

Discussion

Although informed consent is part of Portuguese legislation, this right cannot be utilized properly by the patients because of the way the system works. When signing the consent form, patients do not necessarily understand the implications of the surgical procedure. In Germany, for example, the form of informed consent includes a short introduction and a double that can be taken home. In this way an adequate level of understanding can be reached by the patients before they sign the form and they can easily access the signed agreement if they need a reminder.

Even though in Portugal there is a special body dealing with medical (and nurse) negligence, its impact on achieving safer surgery is limited because patients lack basic knowledge on what safe surgical procedures are and their rights in this connection. In order to avoid irrelevant complaints, professional bodies control the way complaints are filed in Portugal. Similar procedures are used in other countries, for example in Albania. Campaigns helping healthcare users to know their rights and what to expect in connection with surgical procedures would give them the necessary attitudes and skills to contribute to safer surgery.

The interaction between the patient and the health care provider requires increased efforts to enhance patient safety. Standardized forms, check lists, reminders etc. should support this process and not replace it. The topic could be considered also in the context of legislation as part of the current projects' report on legal tools and frameworks.

Blood transfusion safety in France: developing tools to support patients²³

The researchers analyzed the regulatory aspects and existing legal tools, and reviewed the grey literature in France on patient safety involvement in blood transfusion safety. Despite its high publicity, the topic of blood transfusion safety remains poorly explored with low emphasis placed on the potential role of patient as a user to improve transfusion safety (except from the donor side). At the same time research shows considerable potential for the role of patients in ensuring safe practice²⁴. The undertaken study is especially timely as the year 2011 was launched by the French Ministry of Health as a special «Year of patients and their rights».

The main actors in the field of blood transfusion in France are **EFS** – French Blood Transfusion organization, unique operator of blood transfusion since 2000 (collection of blood, biological qualification of samples, preparation of LBP and distribution), **Afssaps** – French Health Products Safety Agency (regulation and control of security, quality and efficacy of healthcare products),

²³ Research was conducted by the École des Hautes Études en Santé Publique (Dr Josselin Thuilliez and Ms Justin Bettinger, Département des Sciences Humaines et des Comportements de Santé) in close collaboration with the Etablissement Français du Sang (EFS) (Dr Yves Charpak, Director/Survey and Prospective)

²⁴ Davis R.E., Vincent A., Murphy M.F. *Blood Transfusion safety: the potential role of the patient*, Transfusion Medicine Reviews 25, no.1 (January 2011): 12-23

CSTA – Armed Forces Blood Transfusion Centre, and **LFB** – Laboratoire Français du Fractionnement et des Biotechnologies.

Patient safety activities and culture developed in France mainly after the blood contamination scandal in 1980ies. It led to improvement of the security of production and distribution chain of Labile Blood Product (LBOP), while numerous laws were passed and Afssaps was created in 1998. The national haemovigilance system established in 1994 has the overall goal of increasing safety and quality of blood transfusion. The nation-wide bodies such as EFS, CTSA, the National Haemovigilance Commission and Afssaps are in charge of the work of 155 transfusion sites under 18 regional Blood transfusion centres and 1600 healthcare centres under 29 Haemovigilance regional coordinators. In each health facility, a haemovigilance correspondent collects information and declares all adverse reactions in receiver and serious transfusion incidents, while a Transfusion Safety and Haemovigilance Committee (CSTH) is in charge of improving transfusion safety. The collected data are analysed at the national level and a summary report is produced by Afssaps every year that has to be adopted by the National Haemovigilance Commission.

The main legal document related to patients' rights and quality of healthcare system that became effective in 2002 (*Law n°2002-303 of 4th march of 2002*) stipulates that information to patient about his health is an obligation (to enable informed consent), and patients have the right to access their medical records. The French decree of February 2006 based on the European directive 2004/33/EC instructs that any information likely to compromise the quality and safety of LBP must be declared. From November 2006 the basic requirement of good transfusion practices prescribes that a post-donation document is given to the donor with the phone number of the establishment and the service to call. The decision published in December 2010 established the form, content and terms of declaring serious incidents, while a similar document describes the way adverse reactions must be reported²⁵.

Patients' rights in blood transfusion follow from the legal obligations of the prescriber to inform about: pre-transfusion (Circular DGS/SQ – 9 April, 1998) and post-transfusion (French public health code). Furthermore, the law requires that patients receive both written and oral information (Circular DGS/SQ 4 n°98-231) on the therapeutic procedure to be undertaken.

Despite the explicit regulation, and the safety and reliability of transfusion therapy in France quality of transfusion can vary due to the variability of practices. The causes of variability can relate to heterogeneity of knowledge, of know-how or hospital of organization, absence of update, non-formalization of practices, regional diversity, information system development and other factors.

Suggestions made by the experts towards an innovative approach to patient information and potential for active involvement include identity concordance, interaction with health care workers, health education, surveillance, associations and promotion, social epidemiology.

During the study conducted at the Blood Transfusion Centre of the city of Tours a questionnaire was distributed to all transfused adult patient during in the period of 1 to 15 July 2011. The results have shown for example that nearly all patients that know why they have been transfused but 4.5% don't know which blood component they have been transfused. Only 28.57 of respondents worried in connection with blood transfusion and all of them trust physicians for transfusion decision. About 33.33% received an information sheet before being discharged from the hospital and only 24% of respondents received written information on blood transfusion before being transfused. All of those who received the written information read it. Oral information was given to 59% of respondents: 62.5% received it from the physician, and 37.5% from both the physician and the nurse. Most of the respondents (88.89%) thought that it would be useful to give information on transfusion to a wider

²⁵ The French Public Health code discriminates between an *adverse effect/serious adverse effect* affecting donors or recipients and likely to be related to the administration of LBP, and an *incident* related to the administration of LBP that affects the safety or quality of the product which might result in an adverse effect

public. Half of the respondents who would like to be involved identified pre-transfusion part as the most important stage of involvement and 25% identified the stage during transfusion as such.

Based on the findings of the study, the researchers identified the most important strategies to further improve transfusion safety in France, which would include re-thinking communication on blood transfusion and co-producing an adapted and standardized patient information tool; upgrading doctors knowledge through continuous education programmes dedicated to communication with patients and further involvement of patients' organizations and pharmaceutical companies in safety processes.

Discussion

Differences in the use of blood components and products exist among the European countries, however it is difficult to establish whether they are caused by overuse in some countries or underuse in others. In average 1/3 of all patients receiving blood transfusion are over 65 years, and 2/3 are over 80 years. Considering the increasing average age of European citizens the demand for blood products is constantly growing. The other area of growing use of blood products is cancer therapy. Although patients associations ask for saving more blood products, the existing capacities cannot cope with the increased demand, which requires innovative solution and new modalities of citizens' involvement.

It should be noted that informed consent to blood transfusion is not yet legally regulated in all countries. In some countries signature of the form is only required if the patient objects to blood transfusion, and explicit consent is not obtained. This underscores the passive role of the patient. The general question also remains to what extent information given to patients transforms their relationship with the healthcare workers.

Other participating projects

Other projects that are complementary in their scope of work were briefly presented during the event.

The therapeutic patient education (TPE) competency framework²⁶ is currently being developed by the Institut National de Prévention et d'éducation pour la Santé (INPES) in France. The objectives of the TPE framework are to define the skills on TPE, propose shared definitions, and suggest a framework usable for initial/continuous training structures. Ultimately this could contribute to the validation of professional experience in this field of growing importance. A Technical Committee consisting of both French and European experts in health and social sciences and representatives of professional, patient associations and other relevant French institutions is responsible for the formalization and follow up of the project.

In the course of the project 96 interviews were conducted with medical practitioners in 9 chronic diseases and in 6 countries (Belgium, Italy, The Netherlands, Sweden, Switzerland, and United States). Different location practices were chosen as well as different contexts. The results were integrated through an extensive consultation process into three referential devised for three different roles: direct work with patients, direct work with TPE transversal teams, and direct work with institutions and partners. The referential were published on the INPES site with an online questionnaire and are expected to be finalized and published in December 2011.

The HANDOVER project is the first EU funded project on coordination and transitions of care devoted to studies of handovers in 6 participating European countries. Its initiation in 2008 was based on the growing recognition that adverse events are caused by informal non-standardized handovers

²⁶ INPES project was presented by Dr **Jérôme FOUCAUD**, Chargé d'expertise scientifique en promotion de la santé, Département formation et ressources, Direction de l'Animation des Territoires et des Réseaux (DATER)

and the movement of patients across countries. This multi-prospective study that aims to evaluate tools and education programmes towards improving the continuity of patient care through identification and implementation of novel patient handover processes in Europe.

During the project research, conducted in different medical settings and countries, all stakeholders agreed on the need for an active patient role facilitating communication and family members were perceived as of great importance to facilitate handover. A dedicated toolkit on required patient information is expected to be delivered by the project, complementing existing work.

Conclusions and the way forward

Drawing from the progress achieved so far and the findings of the presented reports, it was unanimously agreed that the reports give valuable perspectives on the core topic of the project and should be compiled into a final report.

The final outcome should consist of 140-200 pages with a foreword, 3 chapters (chapter 1: legal aspects, chapter 2: measuring patients' experiences, chapter 3: national studies) and a conclusion section.

The HANDOVER project, the INPES project and the WHO patient curriculum will be included as dedicated two pages boxes in the document, including relevant outcomes and web links. The alternative of more detailed annexes was also considered

The national studies will be finalized through a consultative process with the reviewers appointed for each chapter. Each national study should include recommendations on three levels: national system, healthcare workers and patients.

The following timeline was agreed upon:

30 September 2011 - reviewers to send their comments;

15- 30 October 2011 - authors to incorporate the reviewers' comments and complete their chapters

20- 30 November 2011 – final report ready for editing

20 December 2011 – report ready for publication

Annex 1**List of participants****Mr Martin E. BOMMERSHOLDT**

National Agency for Patients' Rights and Complaints
Denmark

Ms Justin BETTINGER

Département des Sciences Humaines
et des Comportements de Santé
École des hautes études en santé publique
France

Dr Yves CHARPAK

Director, Survey and Prospective
Etablissement Français du Sang (EFS)
France

Professor Diane DELNOIJ

Tranzo Department
Tilburg University
The Netherlands

Dr Jérôme FOUCAUD

Chargé d'expertise scientifique en promotion de la santé
Département formation et ressources
Direction de l'Animation des Territoires et des Réseaux (DATER)
France

Dr Anne ITEN

Médecin adjointe
Service Prévention et Contrôle de l'Infection
Hôpitaux Universitaires de Genève
Switzerland

Dr Isuf KALO

Director
National Center of Quality,
Safety and Accreditation of Health Institutions
Albania

Professor Niek KLAZINGA

Department of Social Medicine
Academic Medical Centre
University of Amsterdam
The Netherlands

Ms Claire KILPATRICK

Programme Manager
1st Global Patient Safety Challenge
WHO Patient Safety
Switzerland

Dr Barbara KUTRYBA

WHO Collaborating Centre for Development of
Quality and Safety in Health Systems
Poland

Professor Johan LEGEMAATE

Department of Social Medicine
Academic Medical Centre
University of Amsterdam
The Netherlands

Ms Ana MANSOA

Intensive Care Nurse
Centro Hospitalar de Lisboa Central
Hospital de Santa Marta
Portugal

Ms Margaret MURPHY

Lead
WHO Patients for Patient Safety
Ireland

Dr Piera POLETTI

Responsabile
CEREF - Centro Ricerca e Formazione
via T. Aspetti 38
35132 Padova
Italy

Professor Jane SANDALL

Programme Director (Innovations) NIHR
King's Patient Safety and Service Quality Research Centre
Department of Primary Care and Public Health Sciences
King's College London School of Medicine
United Kingdom

Dr Josselin THUILLIEZ

Département des Sciences Humaines
et des Comportements de Santé
École des hautes études en santé publique
France

Ms Britt WENDELBOE

Head of Office
Danish Society for Patient Safety
Denmark

Dr Rossitza VATCHEVA-DOBREVSKA
Head of National Reference centre for HAI
National Centre for Infectious and Parasitic Diseases
Bulgaria

Ms Maria Gabriela VIRONE
Researcher
Institute of Legal Information Theory and Techniques
Italian National Research Council
Italy

WHO Regional Office for Europe, Copenhagen, Denmark

Dr Valerie FLEMING
Policy Adviser
Nursing and Midwifery
Division of Health Systems and Public Health

Dr Valentina HAFNER
Programme Manager, a.i.
Health Care Quality
Division of Health Systems and Public Health

Dr Kees de JONCHEERE

Programme Manager
Health Technologies and Pharmaceuticals
Division of Health Systems and Public Health

Dr Hans KLUGE

Director
Division of Health Systems and Public Health

Ms Nataliya TARASENKO

Programme Assistant
Health Care Quality
Division of Health Systems and Public Health

REFERENCES

- Campos L., Saturno P. Carneiro A.V. *A qualidade dos cuidados e dos services (Health care and services quality)*, Lisbon, High Commissioner of Health, 2010
- Davis R.E., Vincent A., Murphy M.F. *Blood Transfusion safety: the potential role of the patient*, *Transfusion Medicine Reviews* 25, no.1 (January 2011): 12-23
- Fragata JIG, *Erros e acidentes no bloco operatorio: revisao do estado da arte (Accidents and errors in the operation theatre: incidence and mechanisms)*, Lisbon, *Revista Portuguesa de Saude Publica*, 2010, 10: p. 17-25
- Hall, J., et al., *Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review*. *Quality & safety in health care*, 2010. 19(5): p.e10
- Lage MJ *Seguranca do Doente: da Teoria a pratica (Patient Safety meets clinical practice)*, *Revista Portuguesa de Saude Publica*, 2010
- Longtin, Y. et al., *Patients' Beliefs and Perceptions of their Participation to Increase Health Care Worker Compliance with Hand Hygiene*, 2009, 30,9: p. 830-839
- Mansoa, A, et el. *Eventos adversos na Prestacao de Cuidados Hospitalares em 2008 (Adverse Events during Hospital Care in 2008)*, Lisbon, 2009 (not published data)
- Manual de acreditacao de unidades de saude (Health care units accreditation handbook)*, Lisbon, Directorate General of Health, 2011
- Pinto, PR, *The training of doctors today. Challenges and Realities*. *Sisifo, Educational Sciences Journal*, 2007, 5: 77-92
- Plano Nacional de Saude 2011-2016 – Qualidade em saude, versao discussao (National Health Plan 2011-2016 – Health Quality, discussion version)*, Lisbon, High Commissioner of Health, 2011
- Schwappach, D.L., *Review: engaging patients as vigilant partners in safety: a systematic review*. *Medical care research and review: MCRR*, 2010. 67(2): p.119-48
- The new European policy for health – Health 2020: Vision, values, main directions and approaches*. WHO Regional Office for Europe, 2011