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Patient Safety and Rights

**Developing tools
to support consumer health literacy**

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ABSTRACT

Both the topics of patient safety and patient rights are high on the health agendas of countries in the European region. Nevertheless, they are addressed differently: via policy oriented approaches focusing on legislation that reflects on patient rights, and via projects and activities addressing concrete safety risks implemented as part of the work on patient safety. These methods need to be linked in order to enhance patient understanding and active involvement in the process of health care improvement. One of the most important goals of the present research is to provide evidence based guidance on enhancing patient safety and rights through patient information and empowerment.

Keywords

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Patient Safety & Rights: developing tools to support consumer health literacy

Aim of the project

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 bridge the two approaches by trying to look at the links between patient rights and patient safety and more particular at means to improve patient safety by enhancing patient empowerment and health literacy.

Produce guidance and an applied tool supporting patient empowerment, focused on patient rights & safety around the themes of:

- blood transfusion,
- hospital infections/ hand hygiene, and
- communication during patient handovers.

Methodology

Patient rights are quite often shaped via policies and legislation strengthening the role and position of the patient (i.e. informed consent). From this perspective safety is considered as a justified expectation that the user of health care has from the provider of health care. Patient safety is often addressed via improvement activities related to concrete safety risks and awareness-raising as prevention mechanism.

This project plans to explore whether and how strengthening and empowering the patient can also become an important element of patient safety itself. Similar ideas are expressed in the recent article by Longtin et al (Mayo Clinic Proceedings 2010) that also introduces a conceptual model in which the patient is positioned as an active actor in risk management and safety control.

Changes from a passive approach of the patient to an informed pro-active role in improving quality and efficiency of own care and reducing safety risks imply:

- that the premises of patient safety right are shaped as realistic and informed expectations;
- that patient information on risks, involvement in decision making, and choice is provided at a level of details which are accessible;
- that patients are trained to be knowledgeable and vigilant in the same time, for maximum safety compliance, within and outside health care settings;
- that safety becomes a shared responsibility, with the patient co-producer of health;

It is proposed to apply the conceptual model on factors influencing patient participation presented in the article mentioned above to three selected areas of work, and define key elements/ listing of relevant activities that could help to

strengthen the position of the patient in the control of safety risks. This should allow identification of the most effective content and way to provide information to patients, identification of moments of risk and how the patient could intervene to reduce/ eliminate these. The development of an 'alert' checklist could be a practical longer term outcome of this exercise.

Project results are expected to be compiled in a background publication linking current legal tools supporting patient safety and rights and foreseen regional developments such as European Union (EU) dedicated directives and the WHO Regional Office for Europe new Health 2020 strategy.

Provisionally planned actions

September – October 2010: Electronic networking, shared background documents and preliminary agreement for the November meeting.

November 2010: Review and coordination meeting, Copenhagen, WHO Regional Office premises

March 2011: Finalize tools drawing on the above initiate piloting usability of tool in two BCA countries (including translation of tools in the national languages of the 'pilots')

June 2011: Deliver background publication in its final format (peer review to be undertaken prior to its finalization)

October 2011: Report on tool piloting in the selected countries and explore its expanded use

Meeting content

The Patient Safety & Rights coordination meeting was hosted by the WHO Regional Office for Europe in Copenhagen, on the 29th of November 2010. The meeting was co-chaired by Prof Legemaate from the University of Social Sciences in Amsterdam, Dr. Hans Kluge and Dr. Anja Bauman from WHO Regional Office for Europe. It was attended by a number of -----experts representing a variety of health care and patient organizations across the region.

During the meeting, experts focused their attention on the project background and content, being encouraged by the Chairpersons to share their opinions and comments, in particular on the conceptual model and its proposed applicability.

At the end of the working sessions, concrete next steps were agreed as detailed in the report

The legal dimensions of Patient Safety¹

The evolution of health care systems and supportive legal and regulatory frameworks towards patient centeredness was used to open the floor for further thinking. Health care is increasing its focus on patient safety, and reporting/

¹ The presentation was illustrated by Johan Legemaate, Professor of Health law, Academic Medical Centre/University of Amsterdam, Amsterdam, The Netherlands.

analysis of health care related incidents, accidents and near misses are used to reduce the number of occurrences and improve patient health and well being. The patient perspectives are increasingly being used to complement the health profession's standpoints at various levels (i.e. individual or lobby group, policy development etc)

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 the particular with its Patients for Patient Safety line of work

The patients' right to be informed and to be involved in the decision making processes³ of health care stay at the core of the current undertaking. However there is need to observe the non obligatory character of patient involvement as co-producer of his/ her own health. The degree of formalizing patient's responsibility for his/ her own health represents has to be carefully evaluated to avoid a possible counter effect.

The two faceted coin of empowerment involves health care services (profession, provision, regulatory, steering and financing aspects), and the patient/consumer community with its expectations, rights and obligations. It presupposes:

- focus on evidence based medicine,
- systems to monitor the quality and safety of health care;
- provision of adequate information;
- enhancement of accountability;
- fostering a culture where patients feel free to participate and report errors,
- including patient experiences/ views in medical guidelines, policy documents, legislation.

Seen from a legal point of view, engaging patients and their organizations in patient safety activities should focus on the right to be informed and the free right to actively participate (at all levels) in the process of health care improvement. Health professionals, health care systems and governments should stimulate this approach and create the necessary conditions for its expression.

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 Rec (2006)7 of the Committee of Ministers to member states

³ Regarding treatment, prevention of errors, policy development etc.

EU action on Patient Safety and Quality of Healthcare⁴

Existing evidence on the magnitude of health care related harm (8–12% of patients subject to health care related adverse events in the EU⁵), and its high degree of preventability initiated EU actions on patient safety and quality of health care. The comprehensive dedicated actions involved:

- collective work: setting up a working group on patient safety and quality of care,

The working group meets a number of times per year fostering information exchange, shared experiences, monitoring implementation mechanisms of dedicated directives, and defining strategic directions of work

- policy work: Commission Communication (2008) and Council Recommendation on patient safety, including the prevention and control of health care associated infections (2009);

The Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01) comprises two parts with a) seven recommendations addressing general patient safety issues, and b) two recommendations on prevention and control of healthcare associated infections⁶

- dedicated research: EU co-funded projects (38 research projects focused on patient safety and quality of healthcare).

Of particular relevance is the European network on patient safety 2007–2010 which established an umbrella network of EU Member States and stakeholders in the field of patient safety⁷. Its expansion into a Joint action exercise is under development.

The Joint Action on Patient Safety and Quality of Healthcare (2011–2014) under development is expected to contribute to the implementation of the Council Recommendation on patient safety; to establish and promote collaboration on aspects of quality of healthcare, including patient empowerment and the role of the patient in safety and quality improvement.

Factors influencing patient decisions to promote hand hygiene practices as part of patient safety movement⁹

Patient participation is increasingly recognized as a key component in the redesign of health care processes and is advocated to improve patient safety⁸. The first affirmation of consumers' rights, as the right to be safe, to be informed, to choose

⁴ The presentation was illustrated by Agnieszka Daval–Cichon, European Commission – Health and Consumers Directorate General – Health Strategy and Health Systems Unit, Brussel, Belgium.

⁵ As healthcare associated infections, medication–related errors, surgical errors, medical devices failures, errors in diagnoses, failure to act on the results of tests.

⁶ To classify, codify and measure patient safety; to share knowledge, experience and best practice at European level; to develop and promote research on patient safety.

⁷ <http://www.eunetpas.eu/> (last update: december 2010).

⁸ http://cordis.europa.eu/home_en.html (last update: december 2010).

⁹ The presentation was illustrated by Claire Kilpatrick, Programme Manager – First Global Patient Safety Challenge: Clean Care is Safer Care, WHO Patient Safety, Geneva, Switzerland.

and to be heard took place in the '60s. The current goal is reflected in patient empowerment: that concerns knowledge, skills, and a facilitating environment. to express their participation.

One of the push-pull factors in redesigning health care processes is the increase of the patient participation. The main result of this attitude is improving patient safety and interventions' efficacy. Patient active role in hand hygiene promotion and impact in preventing health care-associated infection was given as an illustrative example.

Participants were asked to focus their attention on the conceptual model by the Longtin at al team, and its applicability to the current project. This circular model includes key factors influencing participation of both health care worker and patient, and invites both sides to contribute to error prevention, as defined by the research group (figure 1).

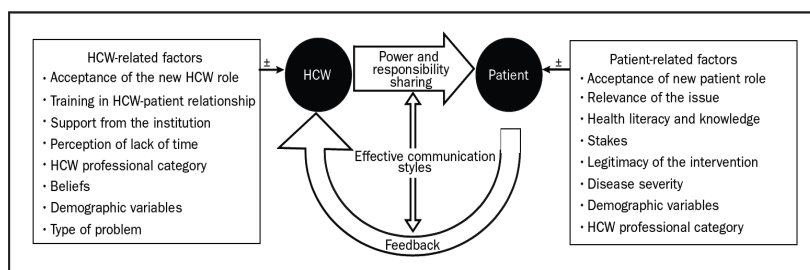


Figure 1/Conceptual model of factors that influence patient participation in preventing errors HCW = health care worker

The framework was extensively discussed, and the selection factors for listed criteria were considered mostly empirically than evidence based.

It has been considered that

- Socio-economical determinants need to be included in the model (beyond demographic variables); as well as psychological skills (beyond knowledge).
- The balance between health literacy and professional experience was also considered to require more attention.
- The institutional level of applicability should be defined, to identify the type of applicable legislation and to avoid a bureaucratic or formal system.
- The conceptual model needs to clarify methods, instruments, to address barriers. In many countries health care workers are organized in professional groups, and this often impacts on their direct communication with patients.

The experts suggested an equalitarian approach, looking at patient and family expertise related to their illness - the right to be active contributor in health care and not only the right to be 'marginally' involved.

Patient participation has been shown to improve many aspects of patient care and outcomes, but the success of patient participation programs cannot be measured uniquely through direct patient intervention. The circumstances in which patients

refrain from interacting with the health service is also an expression of their degree of health literacy and assumed empowerment.

The participants expressed their appreciation towards the “acceptance of the new patient role” on which the model is based. Higher education is allowing patients to be more responsible for their health safety and care. Therefore fulfilling the right to health care information will enable patients to know and to act with increased awareness and responsibility. This could be seen as a strength of future health care policies, programs and actions.

Converging projects under development

"HANDOVER"¹⁰

The HANDOVER project¹¹ is a 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.

The starting point for this project was that “poor continuity of clinical care, either at a patient’s referral to a hospital by a primary care specialist or at a patient’s discharge from the hospital as critical aspects of patient’s care. Incomplete handover to a secondary/tertiary care unit or discharge from hospital can lead to adverse events for patients that may ultimately lead to life threatening situations during treatment/surgery or re-hospitalization. Care transitions are especially important for vulnerable groups, as they are for high-risk patients with multiple co-morbidities¹²”.

The four objectives of the HANDOVER research are:

- 1) To identify the barriers to and facilitate effective handover in the social, linguistic and technological contexts in which they take place in different European settings;
- 2) To determine how variations in handover processes lead to “near misses” and adverse outcomes;
- 3) To identify and validate factors determining the success of integrating the patient care micro-system continuum;
- 4) To foster adoption of safe and effective practices based upon the findings among participating units and beyond, by creating generic tools and training for handover processes.

¹⁰ The presentation was illustrated by Barbara Kutryba, WHO Collaborating Centre for Development of Quality and Safety in Health Systems, Krakow, Poland.

¹¹ <http://www.handover.eu/> (last update: December 2010). The project is coordinated by the University Medical Centre, Utrecht (UMCU) and co-funded by the European Commission within 7th Framework Programme (FP7-HEALTH-F2-2008-223409). Project Leader: Paul Barach, MD, MPH; Project Manager: Loes Pijnenborg, MD, PhD.

¹² <http://www.handover.eu/> (last update: December 2010).

The main conclusions of the project to date are in line with the Patient Safety & Rights project: empowerment for patients has a vital role.

Discussions over the proposed conceptual model

The conceptual model of factors that influence patient participation in preventing health care related errors was discussed as the starting point of the current undertaking. Particular attention was given to its potentially creative use and adaptations that would enhance its application in the proposed target fields: blood transfusion, hospital infections/ hand hygiene, and communication during patient handovers.

The selection of the 3 technical areas for application is explained below.

- a) In the field of blood transfusion, patient empowerment would address double sided historical practices of applying (medical prescribing and patient requesting) transfusion therapy. These attitudes have a direct safety and economical impact on quality of care, and limitations in blood supplies. Up to date, attention in this field focused more on safe blood donation, accurate testing and producing good quality products, and less on the patient involvement as potential user side.
- b) In the field of preventing hospital infections the conceptual model was already applied to hand hygiene with good resulting evidence. This will allow further deepening and refining this research, and eventually expanding to other interventions such as antibiotic therapy use (antimicrobial resistance) providing a potential link to the medication aspect.
- c) In the field of handovers, the identified patient awareness on vital information that should accompany transfers or discharge would facilitate its availability as well as double-sided knowledge (HCW and patient) preventing related failures in a process which is getting increasingly frequent and complex.

The issue of medication errors was raised as potential field for this research. The area continues to receive already a lot of attention and dedicated work, therefore it was suggested that attention is oriented by lesser explored topics, with potentially high impact relevance, such as the ones mentioned above. These choices are not restrictive, but represent an initial piloting phase with the potential of wider applicability at a later stage pending on results achieved.

Some experts underlined the fact that patient safety is a general topic, so it could be more useful to focus attention on the global questions, such as the patients' skills and general frameworks. The counter-argument was that it might be more fruitful to address the issue applying a bottom up learning approach, from specific contexts which will also help validate the research tool proposed. In the meantime, work at global level is successfully led by the WHO patient safety programme in headquarters, with which working links are ensured.

Other comments related to the fact that

- the feedback received from patients should be seen as an effective way to change the system at both local and national levels. The recent antibiotics campaign in France directly engaging with the public is an example of such successful engagement of the civil society.

- it is necessary to differentiate between patients' groups, (e.g. type and degree of sickness). In Ireland, patients' involvement is being tackled through identification of patients' profession groups, for example engineers as prospective patients.
- Often patients and health care workers have different views on what error is, and a proper balance in estimating the role of patients' involvement must be observed, to ensure they are treated as more equal in the process of health care.

It was acknowledged that concrete initiatives for increasing the value of patients' involvement are necessary. In order to make a more meaningful contribution to the system the patients must have more knowledge of and access to medical evidence that would be instrumental in generating outcomes. In this respect, patients' organizations and the professional medical organizations should have parallel development and should be in constant dialogue. The Stanford Model United Nations Conference¹³ was mentioned in this connection, as it might give the inspiration for working out the tools applicable also to the patient safety area.

In what blood transfusion is concerned it was noted that the hazards associated with it, although rare, have a wide resonance in the public. This underscores the necessity to treat this issue very transparently. Currently there is no sufficient evidence about best blood transfusion practices, which differ from hospital to hospital and are not well documented. It would be real patients' empowerment if they played a bigger role in pushing for making such evidence available and accessible. For example, the cancer patients are normally given two alternatives for treatment, either surgery or chemotherapy. However they are not normally informed that blood transfusion is also part of the chemotherapy treatment. The change of health care workers attitude is an additional issue to be addressed.

An on-going qualitative study, planned for conclusion by June 2011, was mentioned, in relation to patients' involvement in the reduction of burden of disease. The study includes interviews with both patients and health care workers from 15-16 European countries (representative sample), and would be a much needed addition to the currently existing pool of examples, originating mostly from USA or EU countries. Clearly, while involving the patients, a methodological problem is associated with patients' knowledge of the issue to be tackled.

The communication aspects in addressing patient safety were underlined, such as the need to develop guidelines for *minimum* necessary patient information. This project is also expected to contribute in this direction.

The Chairpersons summarized the debate highlighting that the overall aim of the undertaking must be responsibility sharing rather than responsibility shifting. The challenge of the current project is to translate this big debate into concrete initiatives applied in the three selected areas. The application of the conceptual model in the field of blood transfusion safety represents also a symbolic step, especially because, in this area, people are not only patients but also donors.

¹³ <http://www.stanford.edu/group/sias/cgi-bin/smunc/>

Creating a balance between individual and collective responsibilities is another area for consideration. Building resistance is still continuing due to the lack of cooperation between health care workers and patients and the low level of nursing education (more frequent in developing countries).

There is a need to identify additional stakeholders that might be involved in the working group, more representatives from patients' organizations, but also more practitioners. For example medical doctors could give their direct feedback on the hospital needs. It is also important to create and encourage a membership network to share experiences on patient safety, to discuss and overcome difficult communications between health care workers and patients.

Coordination of this project with the EC patient safety and quality of care working group, WHO patient safety programme, European Patients Forum, Handover project etc has already been initiated, and remains to be expanded to include related initiatives. The long term strategy of the project is based on cooperation and partnership to enhance patient safety.

Conclusions

The added value of this project lies in the aspect of patient participation. The following statements briefly synthesize the working day results:

- a. the experts expressed interest for the use and application of the conceptual model to the project;
- b. all of them are convinced that it is essential to improve an approach based on patients empowerment and their involvement;
- c. it could be necessary to continue the debate on the three selected areas, for further clarification in relation to expected deliverables;
- d. evidence based research data need to be collected for health care workers, but also for patients.

It has been suggested as next steps:

- a. to continue reflecting and receive clarifications on the application of the conceptual model, specifying the best way of how to use it in the project;
- b. to prepare a briefing document fixing the roles, the methodology and the timelines for future steps, to be discussed through teleconference
- c. to convene and involve additional stakeholders (as patients representatives and medical doctors and nurses); The International Forum on Quality & Safety in Healthcare – “Better Health, Safer Care, Lower Costs”¹⁴, 5–8 April 2011 in Amsterdam, was mentioned as a potential opportunity for a follow up meeting on this topic – to be explored.
- d. to define the aim and content of the expected background publication

¹⁴ <http://internationalforum.bmj.com/>

Annex 1

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