



# Exploring patient participation in reducing health-care-related safety risks

## ABSTRACT

Patients' rights have been formulated in a number of documents and guidelines from various international bodies. Laws and declarations on patients' rights do not automatically make health care safer, but can help to empower patients. Empowered patients are in a better position to manage their own health and health care and to participate in efforts to improve safety. The report presents an overview of legal aspects influencing patient safety and describes examples of patient involvement. It highlights the need to strengthen a continuum of information between various levels of care, including patient experiences, health literacy and engagement. The work is expected to contribute to the wider process of evidence collation aimed at finding efficient ways to build realistic and informed expectations of health care, while encouraging patients to be vigilant and knowledgeable to ensure maximum safety standards. Recommendations are formulated with respect to the macro, meso and micro levels of health service delivery.

## Keywords

GUIDELINES

HEALTH MANAGEMENT AND PLANNING

PATIENT CARE – standards

PATIENT PARTICIPATION

PATIENT RIGHTS

SAFETY MANAGEMENT

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## Authors

- » Paul Barach, European HANDOVER project, University of Utrecht, the Netherlands
- » Justine Bettinger, Department of Human and Social Sciences and Health Behaviour, French School of Public Health, France
- » Yves Charpak, Director of Survey and Prospective, French Blood Transfusion Organization, France
- » Diana Delnoij, Tilburg School of Social and Behavioural Sciences, Tilburg University, the Netherlands
- » Valentina Hafner, Division of Health Systems and Public Health, WHO Regional Office for Europe
- » Halina Kutaj-Wąsikowska, National Centre for Quality Assessment in Health Care, WHO collaborating centre for developing quality and safety in health systems, Poland
- » Barbara Kutryba, National Centre for Quality Assessment in Health Care, WHO collaborating centre for developing quality and safety in health systems, Poland
- » Johan Legemaate, Academic Medical Centre, University of Amsterdam, the Netherlands
- » Agnes Leotsakos, Patient Safety Programme, WHO headquarters
- » Ana Mansoa, Central Lisbon Hospital Centre, Central Hospital de Santa Marta, Portugal
- » Willem Martinus Smid, Sanquin Consulting Services, the Netherlands
- » Josselin Thuilliez, House of Economic Sciences, Sorbonne Economic Centre, France
- » Erica van der Schrieck-de Loos, Netherlands Institute for Healthcare Improvement, the Netherlands
- » Rossitza Vatcheva-Dobrevska, National Reference Centre for Healthcare-Associated Infections, National Centre for Infectious and Parasitic Diseases, Bulgaria
- » Andrzej Warunek, National Centre for Quality Assessment in Health Care, WHO collaborating centre for developing quality and safety in health systems, Poland
- » Jarosław Woron, National Centre for Quality Assessment in Health Care, WHO collaborating centre for developing quality and safety in health systems, Poland

## Expanded expert group (also contributing to selected chapter reviews)

- » Benedetta Allegranzi, Patient Safety Programme, WHO headquarters
- » Anja Esther Baumann, Division of Noncommunicable Diseases and Health Promotion, WHO Regional Office for Europe

- » Martin Elhard Bommersholdt, Danish Agency for Patient Rights and Complaints, Denmark
- » Charles Bruneau, French National Authority for Health, France
- » Ana Paula Couthino, Division of Communicable Diseases, Health Security & Environment, WHO Regional Office for Europe
- » Agnieszka Daval-Cichon, Directorate-General for Health and Consumers, European Commission, Belgium
- » Gerald Dziekan, Patient Safety Programme, WHO headquarters
- » Jérôme Foucaud, Département Formation et Ressources, Direction de l'Animation des Territoires et des Réseaux, National Institute for Prevention and Health Education, France
- » Annemarie Hellebek, Clinical Pharmacology, University of Copenhagen, Danish Society for Patient Safety, Denmark
- » Kaisa Immonen-Charalambous, European Patients' Forum, Belgium
- » Anne Iten, Department of Infection Prevention and Control, Geneva University Hospitals, Switzerland
- » Eduard Kelley, Patient Safety Programme, WHO headquarters
- » Isuf Kalo, National Centre of Quality, Safety and Accreditation of Health Institutions, Albania
- » Claire Kilpatrick, National Health Service, United Kingdom
- » Iciar Larizgoitia Jaregui, Patient Safety Programme, WHO headquarters
- » Margaret Murphy, WHO Patients for Patient Safety Programme, Ireland
- » Piera Poletti, Research and Training Centre for Public Administration, Italy
- » Jane Sandall, King's Patient Safety and Service Quality Research Centre, Department of Primary Care and Public Health Sciences, United Kingdom
- » Mary Vasseghi, Sudden Cardiac Death in the Young Support Group, Ireland
- » Jan Vesseur, Netherlands Health Care Inspectorate, the Netherlands
- » Britt Wendelboe, Danish Society for Patient Safety, Denmark

#### **Peer reviewers**

- » Angela Coulter, Department of Public Health, University of Oxford, United Kingdom
- » Kees de Joncheere, Department of Essential Medicines and Health Products, WHO headquarters
- » Hans Kluge, Division of Health Systems and Public Health, WHO Regional Office for Europe
- » Yves Longtin, Infectious Diseases Research Centre and Centre Hospitalier Universitaire de Québec, Laval University Faculty of Medicine, Canada
- » Jose M. Martin-Moreno, University of Valencia Faculty of Medicine, Spain

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# LIST OF ABBREVIATIONS

ABHR	alcohol-based hand rub
ADE	adverse drug event
ADR	adverse drug reaction
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé [French Health Products Safety Agency]
BSI	bloodstream infection [bacteraemia]
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CME	continuing medical education
CoE	Council of Europe
CQC	Care Quality Commission [United Kingdom (England)]
CQI	Consumer Quality Index
CTSA	Centre de Transfusion Sanguine des Armées [Armed Forces Blood Transfusion Centre] [France]
DAI	determination of irregular antibodies [test]
DGS	Direcção Geral da Saúde [Directorate General of Health] [Portugal]
DUQuE	Deepening our Understanding of Quality Improvement in Europe [project]
ECDC	European Centre for Disease Prevention and Control
EFS	Etablissement Français du Sang [French Blood Transfusion Organization]
ERS	Entidade Reguladora da Saúde [Health Regulation Authority] [Portugal]
EU	European Union
EUNeTPaS	European Network on Patient Safety
FNHTR	febrile non-haemolytic transfusion reaction
GP	general practitioner
GVHD	graft-versus-host disease
HAI	health care-associated infection(s)
HAS	Haute Autorité de Santé [National Authority for Health] [France]
HBV	hepatitis B virus
HCV	hepatitis C virus
HCW	health care worker
HELiCS	Hospitals in Europe Link for Infection Control through Surveillance
ICT	information and communications technology
ICU	intensive care unit
IOM	Institute of Medicine
IPSE	Improving Patient Safety in Europe [project]
LBP	labile blood product
MARQuIS	Methods of Assessing Response to Quality Improvement Strategies [project]
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
NCIPD	National Centre for Infectious and Parasitic Diseases [Bulgaria]

NHS	National Health Service [Portugal, United Kingdom (England)]
NRC-HAI	National Reference Centre for Nosocomial Infections [Bulgaria]
OECD	Organisation for Economic Co-operation and Development
OR	odds ratio
OTC	over-the-counter [drugs]
PDI	post-donation information
PHC	primary health care
RAR	recipient adverse reaction
RCMADR	Regional Centre for Monitoring of Adverse Drug Reactions [Poland]
SDM	shared decision-making
SG	State Gazette [Bulgaria]
SINAS	Sistema Nacional de Avaliação em Saúde [National System of Health Evaluation] [Portugal]
SSI	surgical site infection
TACO	transfusion-associated cardiac overload
TRALI	transfusion-associated acute lung injury
TRIP	Transfusion Reactions in Patients [the Netherlands]
UTI	urinary tract infection

# FOREWORD



*Health is a social value and an individual right. It generates economic benefits for countries and is a prerequisite for national development and individual well-being.*

*Member States of the WHO European Region are addressing major health challenges posed by demographic and epidemiological change, widening socioeconomic disparities, limited resources, technological developments and rising public expectations. Evidence continues to show that addressing the quality and safety of care is one of the main entry points to strengthening health services and contributing to wider population access and coverage.*

*Regulation and targeted interventions focused on health service redesign are necessary, but not sufficient, to ensuring increased quality, better compliance with safety standards and a well-trained health workforce. Health technology assessments provide evidence of the clinical and cost-effectiveness of new operational tools and a wealth of information on health and health-related interventions and technologies is currently available for policy-makers, health professionals and the general public. Accurate understanding of this information can help patients and providers to prevent and cure disease through increasing treatment compliance and enabling recognition of safety failures in systems.*

*The new WHO European policy framework, Health 2020, supports action across government and society for health and well-being and emphasizes the role of good health in ensuring economic and social development. The capacity of each individual to contribute to improving his or her health status should drive effective dialogue with health professionals and create mechanisms for increasing safety and improving compliance with prevention and care interventions.*

*The WHO Regional Office for Europe is committed to supporting investment in health to address current and future challenges in maintaining and increasing the health status of populations, working in collaboration with national and international partners within the WHO global patient safety strategic framework. In this context, participation of the health-literate patient is seen as being at the core of the whole-of-society approach to better health that we encourage and promote.*

**Zsuzsanna Jakab**

*WHO Regional Director for Europe*

# PREFACE

At the start of the 21<sup>st</sup> century, the Institute of Medicine report *Crossing the quality chasm* portrayed health care systems as being motivated by payers and providers. The lack of focus on the patient was considered unacceptable and a call was made for greater patient-centred care and engagement.



We must accept that the roles of health care provider and patient have evolved over the last few years. Whereas the traditional model of care adopted a more paternalistic approach on the part of the health care professional, the role of the patient has changed to a more active one. Indeed, doctors today are continually greeted with patients who have downloaded Internet-based information or consulted so-called experts via email or social media on their health. Engaging patients intelligently in managing their conditions has been shown to improve clinical outcomes. Indeed, the health care systems of the future will be partnered with patients as coproducers of health, with each party actively involved in charting the patient journey towards achieving a healthy state. Moreover, as medicine continues to evolve, a greater repertoire of treatments and technologies will be offered for complex conditions and providing patients with tools to help in shared decision-making will be crucial to good outcomes. This key publication by WHO provides the reader with a global view on different approaches that have been taken to make patients equal partners in their health care decisions; the efforts range across different specialties, such as primary care and surgery.

In some countries, such as the United Kingdom, patient engagement is enshrined in the professional standards for health care professionals. Other countries have experimented with patient charters and bills of rights. Eventually, patient feedback could form part of a revalidation process for professionals. Indeed, these patients' rights and health care standards have been assessed in different settings throughout the report.

The principles of patient engagement have been less commonly addressed in patient safety than in (say) fields such as chronic disease management. It is surprising, however, to find many good examples in this document; the report serves as an excellent synthesis of studies of patient engagement in the reduction of health care risks, as well as an authoritative analysis of the concepts and debates that lie behind action programmes.

Despite these positive steps in Europe, greater efforts need to be made in creating a culture that allows for coproduction of health care outcomes by the health care professional and the patient. Educating both these parties on the merits of this approach is crucial to the delivery of safer, optimal care.

It is interesting to reflect that President John F. Kennedy in 1962 set out the rights of consumers generally. He identified four – the right to be informed, the right to be heard, the right to choose, and the right to safety – a vision that applies well to the subject of this report.

**Sir Liam Donaldson**

*WHO Patient Safety Envoy*



# CHAPTER I.

## PATIENTS' RIGHTS AND PATIENT SAFETY: INTRODUCTION

*Diana Delnoij, Valentina Hafner*

### Introduction

In the rhetoric of modern health care systems, the patient role has evolved from passive recipient of medical care to active, empowered and informed coproducer of health. This is reflected in the way health care professionals and patients measure quality of care, placing values such as patient centredness alongside effectiveness and safety. Contemporary definitions of quality of care incorporate these perspectives. The Institute of Medicine (IOM), for example, defines quality of care as: “doing the right thing, at the right time, in the right way, for the right person, and having the best possible results” (1). Several concepts, including safety, effectiveness, patient orientation, timeliness, efficiency and equity, are considered essential to quality.

The issue of safety in health care has received considerable attention over the last decade or so, fuelled by the publication in 2000 of the IOM report *To err is human – building a safer health system* (2). The IOM estimated that between 44 000 and 98 000 people in the United States died each year through medical errors and recommended that a comprehensive approach be adopted to redesigning the health care system at all levels to make it safer. Similar work has been carried out in several countries since the report's publication and national and international authorities have initiated patient safety programmes.

This renewed emphasis places safety high on the health care agenda. Indeed, provision of safe care has been a requirement for doctors since the early days of medicine. Physicians in antiquity pledged to keep the sick from harm and “injustice” through the Hippocratic Oath (3). The reference to “injustice” implies that patients had certain rights, but it took another 2000 years for physicians' obligations in relation to patients' rights to be reflected in charters and laws, with the recognition and codification of patients' rights arising from the patient emancipation movement of the 1960s. Longtin et al. (4) distinguish between humanist considerations (articulating the right to self-determination) and consumerism, and emphasizing customers' right to demand quality services.

Patients in Europe have rights that implicitly or explicitly regulate aspects of care such as access to safe care, provision of information about the risks and benefits of treatment to facilitate informed consent and the right to complain. Patients' rights may reflect structural aspects of care (such as availability and affordability), norms for the process of health care delivery (including informed consent) and situations in which either the process or outcome of care gives rise to complaints (5).

This report aims to explore the relationship between patients' rights and patient safety as a core concept in the contemporary quality improvement discourse. WHO believes the right to safety is an integral part of patients' health rights; the WHO Patient Safety Programme was launched in 2004 (6) and is summarized in Box 1.1.

### **Box 1.1. WHO Patient Safety Programme**

The WHO Patient Safety Programme includes a number of activities, programmes and campaigns that aim to coordinate, disseminate and accelerate improvements in patient safety worldwide. Launched in 2004 in response to a 2002 World Health Assembly resolution urging WHO and Member States to pay the closest possible attention to the problem of patient safety, its establishment underlined the importance of patient safety as a global health care issue. Its main areas of work – which in Member States that adopt them should have the potential to influence the patients' rights agenda – have included the action areas set out here.

#### **Global patient safety challenges**

Global patient safety challenges aim to identify a topic that covers a major and significant aspect of risk to patients receiving health care and which is relevant to every WHO Member State. Two such challenges have been launched to date, as described below. An important initiative on injection safety will be initiated in 2013.

##### **1. Clean Care is Safer Care**

Health care-associated infection (HAI) was chosen as the First Global Patient Safety Challenge, focusing on the theme "Clean Care is Safer Care". As part of this challenge, WHO developed guidelines on hand hygiene in health care with a set of complementary implementation tools.

##### **2. Safe Surgery Saves Lives**

Safer surgery was chosen as the Second Global Patient Safety Challenge, with the theme "Safe Surgery Saves Lives". The focus of the campaign is the WHO surgical safety checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: before the induction of anaesthesia ("sign in"), before the incision of the skin ("time out") and before the patient leaves the operating room ("sign out"). In each phase, a checklist coordinator must confirm that the surgical team has completed the listed tasks before they proceed with the operation.

#### **Patients for Patient Safety**

In the area of patient and consumer involvement, the "Patients for Patient Safety" initiative involves building a patient-led, global network of patients and patient organizations to champion patient safety.

#### **African Partnerships for Patient Safety**

This bidirectional initiative was launched in 2009, working with hospital-to-hospital partnerships between the WHO African Region and WHO European Region focusing on patient safety. The programme is framed around 12 patient safety action areas endorsed by the African Region. The partnership should provide a clear mechanism to translate policy on patient safety to action at the point of care. The programme is now working in 14 African and 3 European Member States.

#### **Research for Patient Safety**

This is undertaking global prevalence studies on adverse effects. Major research projects have been implemented in 13 developing and transitional Member States to understand the nature of patient harm and to develop measurement tools. Two rounds of the small grants for patient safety research, launched in 2008, involved 25 research projects in 22 countries, aiming to build capacity in this area. A global set of priority areas for additional research has been identified, as well as a series of methodological and training guides. The online series of patient safety research courses and materials has involved thousands of participants, being delivered in English, French, Spanish and Portuguese.

#### **International Classification for Patient Safety**

The International Framework for Patient Safety was developed to capture the dedicated knowledge domain and to serve as the basis for the International Classification for Patient Safety and other data-collection efforts. The classification aims to define, harmonize and group patient safety concepts into an internationally agreed taxonomy. This will help to elicit, capture and analyse factors relevant to patient safety in a manner conducive to learning and system improvement.



**Box 1.1. contd****Reporting and Learning**

This initiative aims to generate best practice for existing and new reporting systems and to facilitate early learning from information available. WHO has produced the draft guidelines on adverse event reporting and learning systems (7) and aims to produce guidance on an information model for patient safety based on the International Framework for Patient Safety and advance the draft guidelines. WHO currently hosts the WHO Reporting and Learning Community of Practice, jointly supported by the Canadian Patient Safety Institute.

**Solutions for Patient Safety**

This programme developed aide memoirs highlighting interventions and policy actions to improve patient safety, but is no longer being pursued.

**Eliminating central line-associated bloodstream infections**

WHO will ensure that the results of the work in Michigan, United States to eliminate central line-associated bloodstream infections (BSIs) are disseminated and the work replicated in other settings. This could change the lives of tens of thousands of patients worldwide, especially those in intensive care settings. The approach developed in the United States was adapted and tested successfully in Spain and the United Kingdom.

**Injection safety**

WHO has begun new work on injection safety in consultation with internal and external partners aiming to address the pressing issue of reuse of syringes and needlestick injuries in health care workers (HCWs).

**High 5s**

Based on the principle that standardization can lead to safety, the High 5s initiative developed and tested standardized approaches for improving organizational, team and clinical practices to advance patient safety. Following three years of implementation in eight countries, lessons learned about standardization will be disseminated to Member States interested in standardization and patient safety.

**Technology for Patient Safety**

This initiative focuses on opportunities to harness new technologies to improve patient safety. An initial set of priorities was identified for the broad areas of information technology for patient safety, design of safe new technology and making existing health care technology safer. The mapping was published in a special issue of the *BMJ Quality and Safety in Health Care* publication (8).

**Knowledge Management**

The Knowledge Management scheme works with Member States and partners to gather and share knowledge on patient safety developments globally, including the use of webinar technology. Courses have been produced in various languages, expanding significantly the reach of knowledge management activities. Additionally, WHO and the International Society for Quality in Health Care jointly run discussion forums on the society's knowledge platform.

**Capacity building and education for safer care**

A multiprofessional curriculum guide and other resources were developed for undergraduate and postgraduate health care providers and a guide to developing training programmes for patient safety research was produced in 2012 (9). WHO has developed training materials on 26 quality improvement and patient safety topics. E-learning will commence in 2014.

**Medical checklists**

After the success of the WHO surgical safety checklist (which has been shown to decrease morbidity and mortality by over one third), additional checklists are now being developed. The Safe Childbirth Checklist was developed in collaboration with three other WHO departments (Making Pregnancy Safer, Reproductive Health Research and Child and Adolescent Health). The Safe Childbirth Collaborative was launched in November 2012 as a platform for external partners in sharing implementation experiences. A trauma care checklist is also being developed in collaboration with the Department of Violence and Injury Prevention and Disability.

*Source:* WHO Regional Office for Europe (6).

WHO's view is that promotion of patient safety is connected to the development of consumer empowerment and patient involvement and participation (see Chapter 2) (WHO Regional Office for Europe, unpublished data, 2009) and that patients should

become active partners in improving the safety, quality and efficiency of health service delivery. The programme’s strategic directions continue to evolve in response to global developments and identified needs.

### Conceptual framework

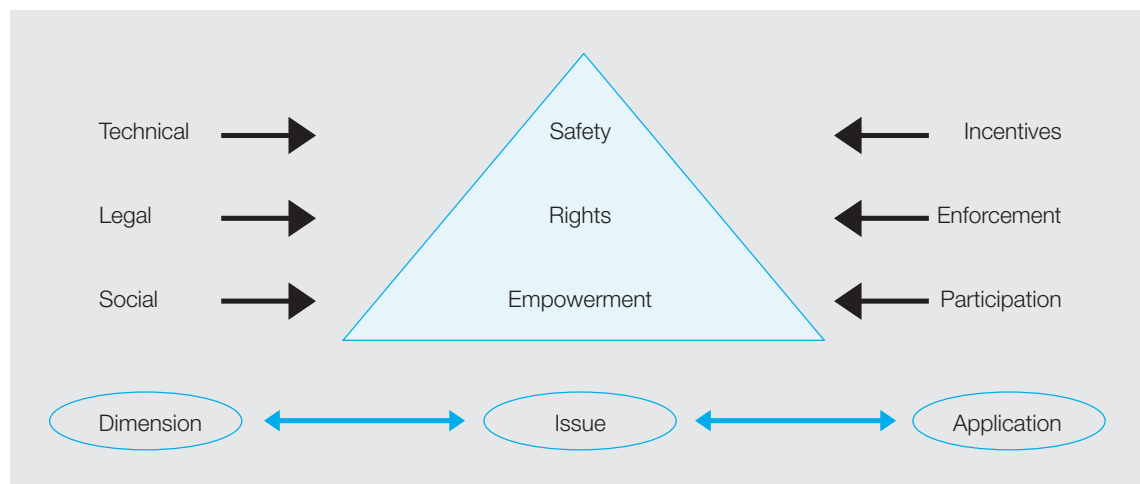
Articulating and implementing patients’ rights is a “good” and a goal in itself. Informing patients about their disease and treatment options, for example, demonstrates respect for their autonomy and dignity (see Chapter 4) (10). This report looks at the effect of patients’ rights legislation and the articulation of patients’ rights across various health-care safety declarations and charters. Laws and declarations on patients’ rights do not make health care safer by themselves but can help to empower patients, placing them in a better position to manage their own health and health care and participate in efforts to improve safety.

Empowering patients requires more than legislation alone, however. There is therefore a need to identify means to improve safety by enhancing patient empowerment through articulating patients’ rights in combination with policy instruments targeting other key dimensions of health care:

- » technical dimensions: the provision of safe care through, for example, tools that involve patients in promoting safety;
- » legal dimensions: patients’ rights, including the entitlement to safe and effective care and the right to complain about things that have gone wrong, and the extent to which the enforcement and implementation of those rights adds to patients’ empowerment; and
- » social dimensions: other policy tools, such as education campaigns, needed to increase patients’ empowerment and their ability to participate in decision-making in relation to their treatment and in preventing adverse events.

The entry points used to discuss patient safety, rights and empowerment and the potential mechanisms enabling their application are shown in Fig. 1.1.

**Fig. 1.1. The entry points to patient safety, rights and empowerment**

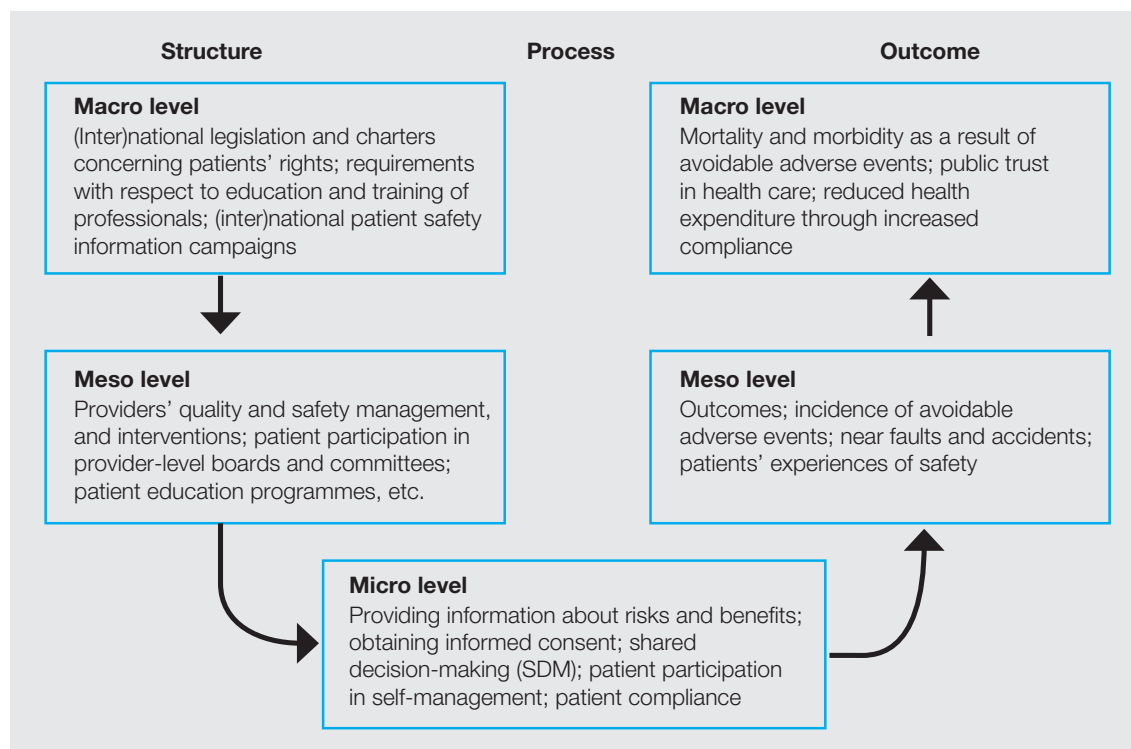


The causal mechanisms through which legislation on patients' rights and other policy tools can lead to patient empowerment, and how this empowerment may in turn increase patient participation in managing the safety of health care delivery, are explored in this report. This involves research into interactions between individual actions and collective phenomena (11). The design of health care system institutional (macro-level) structures affects:

- a) the way providers, third-party payers and patient organizations at meso level operate and interact;
- b) behaviour options for actors at micro level; and
- c) the primary process by which care is provided to individual patients.

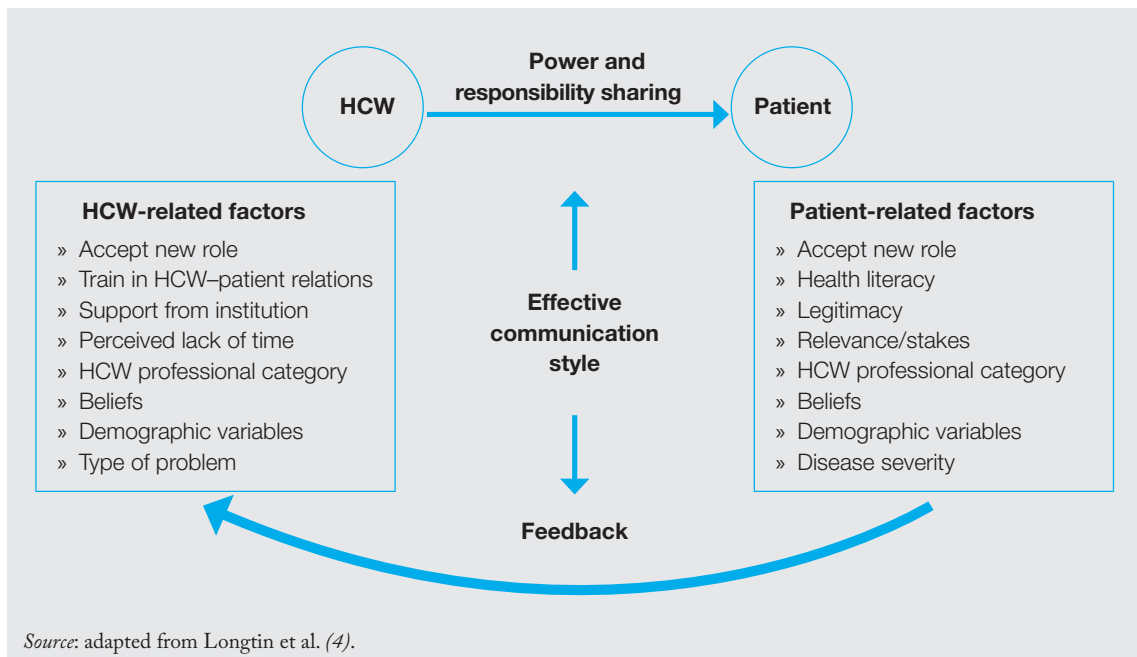
The sum of behaviour outcomes contributes to population health at aggregate level, ideally reducing morbidity and mortality. Fig. 1.2 visualizes this interaction.

**Fig. 1.2. Macro–micro relations between patients' rights and patient empowerment in health care safety**



Particular attention is given to the micro level, the primary process in health care in which individual patients are treated by (teams of) professionals and where opportunities can be created for patients to become coproducers of health and actively participate in decision-making, self-management and error prevention. Participation in error prevention is a topic of particular interest to this report, and Longtin et al. (4) have described a related conceptual model of influencing factors that takes the patient–provider interaction into account (Fig. 1.3).

HCW support is crucial to enhancing patient participation in error prevention. It implies the acceptance of patient participation and the need to encourage patient

**Fig. 1.3. Conceptual model of patient participation in error prevention**

contributions and be receptive to their input. Longtin et al. (4) suggest that a major education campaign is required to convince doctors and nurses of the value of patient participation. After securing professional support, patient education programmes will be needed to build understanding of their contribution's legitimacy and relevance. Several barriers to patient participation, including inadequate health literacy and lack of confidence, have to be overcome, however, and nonmodifiable factors such as old age or disease severity also need to be taken into account.

### How can patients contribute to safety management?

There is growing evidence that patients with the knowledge, skills and confidence to manage their health have better health outcomes (12); this could also apply to safety interventions and monitoring. Several hypotheses on the causal mechanism through which patients or their representatives (such as family members) can contribute to safety management exist. Hibbard et al. (13) suggest:

Patients and family members who are alert to the risk of errors can be more vigilant in monitoring what happens to them while in the hospital. By being informed and alert to their medication regimens, by ensuring medication accuracy on all orders, and by providing all pertinent information to staff, patients can be part of the team effort to reduce errors.

Peat et al. identify three routes through which patients can contribute to maintaining their own safety: helping to make sure that their treatment is appropriate by, for example, informing professionals about allergies or adverse reactions to medication; monitoring and ensuring safe delivery of treatment; and helping to improve systems by, for instance, participating in a safety committee (14).

Rathert et al. also describe various roles that patients could play in their own safety (15). Patients could:

- » be involved in routine monitoring and reporting of adverse events (via patient experience questionnaires);
- » check and double-check that they are given the correct medication, in the correct dose and at the correct time;
- » be informed about what to expect in terms of surgery and be encouraged to report any adverse event or complication;
- » observe and ask staff about hand washing practices; and
- » ensure they have been properly identified prior to treatment.

Similar suggestions are made by Davis et al. (16), who propose opportunities for patient involvement in safe blood transfusion. Patients can:

- » question the appropriateness of an intervention (in this case, of blood transfusion)
- » ask about risks, benefits and alternatives
- » ensure their identity is properly checked
- » ask questions about what they can and cannot do, and what to expect
- » ensure their observations are taken
- » monitor how they feel and report to staff if they think there is a complication.

Coulter provides a comprehensive list of examples of patient involvement in safer care (17). She suggests that patients could be involved by:

- » choosing a safe provider
- » helping to reach an accurate diagnosis
- » participating in treatment decision-making
- » contributing to safe medication use
- » participating in infection control initiatives
- » checking the accuracy of medical records
- » observing and checking care processes
- » identifying and reporting treatment complications and adverse events
- » practising effective self-care and monitoring treatments
- » providing feedback and advocacy to focus attention on safety issues.

Several examples of these ways of involving patients are described in this report.

## Definition of the main concepts

### *Patient*

The word “patient” is used in this report to refer to health care users, also known as health care “consumers” or “clients”. Although it refers to an individual, in reality it is often the patient system that participates in health care decision-making and safety management. Family members, such as spouses or children, are important actors who often accompany patients. They ask questions on their behalf and help them to remember the information provided, visit the patient when hospitalized and act as legal representatives when individuals are unable to give informed consent. Family members also often act as informal caregivers, including contributing to medication self-management. The word “patient” is therefore also used in this report in reference to the much broader patient system consisting of patients, representatives and informal caregivers.

### ***Patients' rights***

Patients' rights are seen as a subset of human rights and can be substantive (the right to information) or procedural (the right to complain). Legemaate (Chapter 2) makes a distinction between normative guidelines for health professionals and institutions that are not legally binding and legislation that is binding and can be enforced.

### ***Patient participation***

Patient participation is defined in the thesaurus of the United States National Library of Medicine as involvement in the decision-making process regarding health issues, but Longtin et al. (4) believe this definition is too narrow, as patients can participate in many other aspects of health care apart from decision-making. They conclude that terms such as "patient collaboration", "patient involvement" and "patient empowerment" are used interchangeably, and that the concept of patient participation is poorly defined. "Patient participation" in this report is understood to mean patient involvement in decision-making in advisory boards or committees at macro and meso levels of health care, but also to involvement at micro level in relation to:

- » decision-making on their own care and treatment (SDM);
- » administration of the treatment (compliance with prescriptions and self-management); and
- » safety management through, for example, general vigilance, participation in patient experience surveys or targeted interventions such as surgical-site marking or asking professionals about their hand hygiene.

The terms "patient participation" and "patient involvement" are used synonymously in this report.

### ***Patient activation***

Hibbard & Mahoney (18) discuss the concept of "patient activation". An activated patient has the knowledge, skills and confidence to self-manage their own health, be involved in treatment and diagnostic choices, collaborate with providers, select qualitatively good providers and, more generally, navigate the health care system.

### ***Patient empowerment***

"Empowerment" is an entry term in the United States National Library of Medicine thesaurus under "power", which is defined as the exertion of a strong influence or control over others in a variety of settings (such as administrative, social and academic). Patient empowerment could therefore be defined as the process by which patients gain more control over their health and health care. An operational definition used by WHO in a study of patients with tuberculosis described empowerment as patients' capacity to better control their health and life, to assist other patients in improving their lives (peer support) and to assist health care professionals (19). In other words, empowerment refers to the capacity that enables patients to participate – or be involved – in their own disease prevention and care.

### ***Patient safety***

It is generally agreed that patient safety can be defined as "freedom for a patient from unnecessary harm or potential harm associated with health care" (20). The intricate



relationships within the complex environment of health care practice are illustrated by eight direct definitions and seven complementary descriptions identified through the WHO International Classification for Patient Safety (21,22) that use safety as an entry point. The American Agency for Healthcare Research and Quality defines patient safety as freedom from accidental or preventable injuries produced by medical care (23). Injuries produced by medical care are also often described as “adverse events”, meaning they result from a medical intervention and not the patient’s underlying condition. While all adverse events result from medical management, not all are preventable: some are complications that cannot be avoided (2).

## Content of this report

This report presents six chapters in which the relationship between patients’ rights, patient participation and patient safety is explored. Following this introduction, Chapter 2 aims to shape the policy debate on how to link generic aspects of patient safety with a more proactive level of patient involvement, discuss legal aspects related to patient safety and rights and measure patient experiences. Four national studies identify existing best practice aimed at strengthening patient engagement in reducing health risks in selected technical areas: hand hygiene (Bulgaria); blood transfusion safety (France); medication prescribing and pharmacotherapy safety (Poland); and elective surgery (Portugal).

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# CHAPTER 2.

## PATIENTS' RIGHTS AND PATIENT SAFETY

*Johan Legemaate*

### Introduction

Attention to patient safety in health care has increased considerably since the turn of the century. Patient safety relates to the reduction of risk and is defined as “freedom from accidental injury due to medical care, or medical errors” (1). Patient safety is about managing this risk using a variety of policies and instruments including, but not limited to, building a safety culture, developing clinical guidelines, reporting and analysing adverse events, training doctors and other health professionals in quality and safety management and, last but not least, empowering patients.

The broader context of patient safety is clearly described by WHO Regional Office for Europe (2):

Patient safety is a serious concern all over the world, as a consequence of increased awareness of the issue. While health care has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments. Health services are treating older and sicker patients who often present with significant co-morbidities requiring increasingly difficult decision-making in health care prioritization. Economic constraints are leading to often overloaded and besieged health care environments. Reduced revenues and increasing expenditures in times of financial crisis are likely to further contain costs, and thus affect service quality and patient safety.

Patient safety is a global issue. Numerous initiatives have been put in place at national and international levels to develop sound patient safety infrastructures that aim to reduce the number of patients unintentionally harmed while receiving medical care (2). Data gathered from studies performed in the United States, Australia and a number of western European countries suggest that between 8% and 12% of patients admitted to hospital experience adverse events while receiving health care (3). The number may be even higher due to significant and widespread underreporting of adverse events.

This background chapter describes and analyses regulatory aspects of patient safety and, more specifically, the relationship between patient safety developments and patients' rights. The aim is to explore the legal context of patient safety with a focus on obligations and opportunities to increase patient involvement and participation in safety and quality of care issues. An analysis of the relationship between patient safety and patients' rights can help to identify legal issues that policy-makers should take into account when trying to reduce risks and unintentional damage in health care. These may include legislation and supportive measures and activities necessary to make legislation work.

The legal issues surrounding patient safety cannot and should not be isolated from the goals of health policy in general. The WHO Health 2020 policy framework (4), which further builds on the general framework and values of the *Tallinn Charter: “Health Systems for Health and Wealth”* (5), aims to promote and protect health, particularly for the most vulnerable segments of the population, and to ensure that appropriate care and support is available to those who are ill. The achievement of these goals depends, inter alia, on integrating health-related policy areas, acknowledging social determinants of health and linking public health and the health care system, all against a background of increased public involvement in health. Core values of the process include universality of the right to health and health care, equity, solidarity and the right to participate in decision-making relating to personal health and the health of societies in which people live (6).

The Health 2020 policy framework implies that health system performance should be enhanced to ensure equal access to care for equal need and appropriate patient-centred care, with a particular emphasis on participation and dignity (4). Information and knowledge systems should adequately reflect possible inequalities in health and their causes. Human rights and other legal interventions and policies should ideally support and strengthen these core values throughout health care, including the area of patient safety. Patients’ rights in relation to safety should not only be focused on trying to achieve the intrinsic goal of protecting patients against unwarranted interventions (the traditional legal role), but should also attempt to promote patients’ well-being and ensure equal access for all citizens to safe, good-quality, patient-centred care. Legal interventions that create barriers to this should be eliminated or diminished. The key issues are to empower and inform citizens and patients by involving patient organizations in policy-making, informing patients about standards, safety measures, remaining risks and complaints procedures, and developing core competences in safety for patients (7).

### Content of this chapter

The chapter provides an overview of international documents and guidelines on legal aspects of patient safety. Emphasis is given to dedicated flagship documents from the Council of Europe (CoE), the European Union (EU) and WHO. Some remarks on national legislative developments are also made. Patients’ rights directly or indirectly related to patient safety are analysed, taking into account a number of contextual factors when using legal interventions to promote or enforce patient safety and the division of responsibilities between key players in the area.

### Normative guidelines from international bodies

International bodies and organizations such as the CoE, the Organisation for Economic Co-operation and Development (OECD), EU and WHO have undertaken many activities in the area of patient safety in recent years, ranging from defining principles and strategic options to developing tools on specific and concrete intervention areas. This chapter does not present a comprehensive overview of these activities (2); instead, it aims to summarize these organizations’ normative views on key aspects of patient safety in relation to patients’ rights as described in some key documents produced over the last decade or so (7–10). These are not legally binding in a formal sense, but have a certified normative value by virtue of the organizations that produced them. They are therefore important normative “guiding lights” for national and international policy-makers.

**CoE**

Recommendation 2006/7 of the CoE outlines a comprehensive policy to improve patient safety (11) starting from the viewpoint that access to safe health care is the basic right of every citizen in all Member States. The recommendation states that patients should participate in decisions about their health care and recognizes that they should receive adequate and clear information about potential risks and their consequences to ensure informed consent to treatment. It is accompanied by an extensive appendix that provides a full technical and scientific background and rationale. The main legal features in the field of patient safety and patients' rights are set out in Annex 1 of this report.

The recommendation emphasizes the importance of protecting patients' rights. It promotes a comprehensive approach, including not only an adverse event reporting system, but also a fair and open complaints system, a just and adequate compensation system and an efficient and reliable supervisory system.

**EU**

The EU is engaging with a range of areas to facilitate improvement of patient safety (12). It has been regulating health care aspects of the safety of blood, tissues and cells over many years. More recently, patients' and health professionals' right to free movement has generated patient safety concerns at EU level.

The Council of the EU expresses a general view on patient safety in the EU context in its 2009 recommendation on patient safety and prevention and control of HAIs (7). The recommendation focuses on empowering and informing citizens and patients by:

- » involving patient organizations and representatives in developing policies and programmes on patient safety at all appropriate levels;
- » disseminating information to patients on patient safety standards and measures in place to reduce or prevent errors and harm (including best practice and the right to informed consent to treatment) to facilitate patient choice and decision-making;
- » outlining complaints procedures and available remedies and redress and the terms and conditions applicable; and
- » developing core competences in patient safety describing the knowledge, attitudes and skills required to achieve safer care for patients.

Annex 1 sets out some specific features of the EU recommendation.

**WHO**

The draft guidelines for adverse event reporting and learning systems (10) is the WHO document most relevant to legal aspects of patient safety and participation. This document, produced in 2005 by the World Alliance for Patient Safety, can be seen as a means to implement World Health Assembly resolution WHA55.18 on quality of care and patient safety (9). It focuses specifically on the role of reporting adverse events in enhancing patient safety (10):

In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health care systems to learn from their mistakes. Too often

neither health care providers nor health care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors. An effective reporting system is often seen as the cornerstone of safe practice and, within a hospital or other health care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

Different reporting systems (co)exist, and their effectiveness and efficiency may vary depending on the structure, scope and level (institutional, regional or national) of the system in question.

The WHO draft guidelines do not explicitly deal with the issues of patients' rights, but the underlying message is clear: patient-safety reporting systems play such a fundamental role that if such systems are not in place to allow multistakeholder-informed reporting of failure, it will be difficult (if not impossible) to realize patients' rights to good health care.

### **National legislation**

Many countries across the world have enacted legislation on aspects of patients' rights such as access to good-quality health care, information, informed consent, privacy, protection of vulnerable groups and the right to complain. Nys & Goffin's (13) overview of national legislation in Europe concludes that the way in which patients' rights are defined and implemented is largely determined by national law and differs widely from country to country. They emphasize that one of the challenges facing individual patients' rights is health care's increasingly international orientation, with patients, providers and services moving across the borders of EU Member States. They state that: "[W]hereas health systems, including the definition and organization of patients' rights, are still largely based on a national setting, they will increasingly have to deal with cross-border situations".

The relevance of general legislation on patients' rights in the area of patient safety is discussed later in this chapter. Several countries have enacted specific legislation regarding patient safety (14–16), including Denmark and the United States, whose legislation has a particular focus on improving the quality of care by reporting adverse events and regulating reporter protection.

The Danish act on patient safety in the health care system, introduced in 2004 (17), states that information on the incident reporter can be made available only to those responsible for its processing and analysis. The reporter's identity is not visible and reported information cannot be used in disciplinary or legal proceedings. Similarly, legislation on public access to information cannot be used as justification for granting access to information reported in this way. This is also the background against which Article 6 of the Danish act, which states that a reporter must not be subjected to disciplinary measures (by an employer or regulator) or to criminal legal proceedings as a consequence of the reporting, is viewed.

The 2005 United States act on patient safety and quality improvement (18) aims to strike an appropriate balance between encouraging the reporting of valuable information that will be used to save lives and safeguarding individuals' ability to access necessary information, enabling them to seek judicial redress when appropriate. As the Congressional Record notes:

[The act] would assure doctors and other health professionals that if they voluntarily report information to expert patient safety organizations, that information will be used for health care quality improvement efforts and will be kept privileged and confidential. This protection will encourage health care professionals to report and will result in the creation of valuable new information that can be used to identify best practices for eliminating errors and improving patient outcomes. We believe the bill will also help reduce the number of lawsuits resulting from medical errors. Information from medical records and other existing data sources will continue to be available for injured plaintiffs to pursue their claims in court, just as that information is available today (19).

### Patients' rights in the area of patient safety

In general terms, the relationship between legal rights and patient safety has been clearly summarized by WHO (WHO Regional Office for Europe, unpublished data, 2009):

The fulfilment of the right to health (a human and patient right) involves all health care actors: patients/consumers, governments and health care providers/stakeholders in rendering it concrete. All binding and non-binding international documents revised emphasize that international frameworks and policy instruments should be used to protect the fundamental human rights including patients' rights. In the quest towards strengthening political commitment of Member States, the WHO Declaration on the promotion of patients' rights in Europe and the *European Charter of Patients' Rights*, seek to render the right to health concrete, applicable and appropriate to the current transitory situation in health services across the region. Work towards a common European framework for action and international instruments for realizing national policies in the field of patients' rights recorded substantial progress according to reported data. Most of the European [Member States] have national dedicated policies and charters addressing patient rights. The implementation of local instruments as juridical legislation or extra juridical organisms (e.g. national or regional ombudsman) have to be encouraged and promoted to render effective the patient/consumer protection. The right to safety is a key point in the implementation of the right to health. Promoting patient safety is strictly connected with the development of consumer empowerment, and involvement in the process of health promotion and care, including participation in the policy-making process. It is expected to support the active partnership needed in the process of improving safety, quality and efficiency of health service delivery.

Patients' rights have been identified and elaborated in international documents and guidelines, national legislation, case law and deontological codes over decades. A number are relevant to patient safety. They can be separated into categories according to the level at which a right can best be exercised (for instance, collectively or individually) or based on their orientation (substantive or procedural). Such categorizations may be helpful in clarifying the content and legal strength of the rights in question, but not all patients' rights fit into a specific category, and some might belong to more than one. For that reason, the rights mentioned in the following sections are not categorized. They



have been placed in a kind of “natural order”, more or less following the phases a citizen who encounters a health problem goes through. Categorizations (collective, individual, substantive and procedural) are seen as dimensions of these rights and their relevance is discussed accordingly.

### ***The right to health care***

This fundamental human right can be found in many international treaties and guidelines and in national legislation (through constitutions or charters, or “translated” into specific national legislation on health care insurance). The WHO Constitution of 1946 (20) stated that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being”.

The right to health care has both collective and individual dimensions. At collective level, it stipulates that national authorities should strive to realize a health care system that is comprehensive (prevention, cure, care), accessible (geographically and financially) and of good quality (safe, state of the art). At individual level, the right to health care is embodied in citizens’ entitlements defined in national legislation. These entitlements may vary from country to country and over time depending on various factors, including the availability of resources.

### ***The right to safe and good-quality health care***

The *European Charter of Patients’ Rights* (21) states that: “each individual has the right to be free from harm caused by the poor functioning of health care services, medical malpractice and errors, and the right of access to health services and treatments that meet high standards”. The Luxembourg Declaration on Patient Safety (22) values access to high-quality care as a key human right, and the recommendations set out at the end of this chapter are based on the same assumption. Article 4 of the CoE’s biomedicine convention (23) stipulates that “any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards”. Several examples can be found in national legislation of provisions concerning the safety and quality of care. A clear example is Article 2 of a 1996 act on quality of care in institutions in the Netherlands (24), which states: “[T]he care providers offer appropriate care. Appropriate care implies care of a good level that is effective, efficient, patient centred and adjusted to the needs of the patient”.

Making an explicit distinction between the safety and quality of health services is not done commonly, but it is important. It can be argued that in health care, as in many others areas, different levels of quality exist and that the quality of the highest attainable level of care may vary according to circumstances. Even countries with well-developed health systems find it is not possible to deliver the best care theoretically possible to all patients. In most cases, patients are entitled to the care that is given to others in similar circumstances.

The right to safe and good-quality health care has collective and individual dimensions. At collective level, it instructs health authorities and health care providers (institutions and professionals) to provide safe, state-of-the-art care. At individual level, patients are free to express their opinion on the quality and safety of care received.

### ***The right to participate in policy-making***

It is broadly acknowledged that patients (or their organizations or representatives) should take part in developing health policies at all levels (national, regional and local). Patient-centred care can only be achieved if patients' views and experiences, along with other relevant sources of information, influence policy-making. Recommendation 2 of the European Council recommendation on patient safety stipulates that patient organizations and representatives should be involved "in the development of policies and programmes on patient safety at all appropriate levels" (7). There are many ways to realize this, varying from consulting national patient organizations on policy issues to creating a legislative basis for clients' councils in health care institutions (for more details, see (25)).

Clearly, this right has an overwhelming collective dimension. It implies that governments and health authorities stimulate and facilitate the establishment of well-informed patient groups and organizations. At patient level, it is important that individuals are free to participate in representative bodies and organizations and are supported if necessary to develop the relevant skills and competences.

### ***The right to information about the safety and quality of health services***

If circumstances allow citizens to make a choice between providers of health services, it is important that information about the safety and quality of the services rendered is available. The right to information about the safety and quality of health services has emerged as a consequence, allowing patients to choose the service provider that meets their wishes: this is especially relevant in market-orientated health care systems.

This can be seen as an individual right, but collecting the relevant information (through, for instance, performance indicators) can best be realized at collective level. Health service providers must define the data available, which should be valid, comparable and accessible through web sites, annual reports or other sources.

This right has a clear connection with the right to safe and good-quality health care, which cannot be fully exercised in the absence of relevant information. The implication is that health service providers must be transparent and accountable for the safety and quality of their services. The right is relevant at national and international levels due to increasing patient mobility and crossborder health care. Section 20 of the European Parliament and Council directive of March 2011 on the application of patients' rights in crossborder health care (26) stipulates:

In order to help patients to make an informed choice when they seek to receive health care in another Member State, Member States of treatment should ensure that patients from other Member States receive on request the relevant information on safety and quality standards enforced on its territory as well as on which health care providers are subject to these standards. Furthermore, health care providers should provide patients on request with information on specific aspects of the health care services they offer and on the treatment options.

### ***The right to information on proposed treatment (informed consent)***

The right to be informed about proposed treatment is one of the most crucial individual patients' rights (see, for example, (27)) (28). Valid informed consent for a medical

procedure can only be given if the patient has received clear information that is adequate to the purpose and delivered in an understandable way. The information has to focus on the nature of the patient's condition, the (possible) effects and side-effects of the proposed treatment, possible alternatives and the likely implications of no treatment.

The importance of the right to information on proposed treatment goes far beyond legitimizing consent. The patient cannot fully exercise other important rights (such as rights on refusing treatment, privacy and access to medical records) or exercise self-determination or personal autonomy without this information. Providing clear and adequate information may strengthen the relationship between the patient and health professional and consequently promote patient compliance. It is also relevant in a social context by enabling the patient to communicate with their family members and, if necessary, take care of work- or business-related issues, and plays an important role in managing expectations of possible outcomes and risks of health interventions. A well-informed patient knows what to expect and will be able to deal better with unexpected events, which may prove to be very important from a patient safety perspective.

This right has a very strong individual dimension. Relevant information must be provided to individual patients in the specific context of their health situation. The health professional responsible for conveying the information may be assisted by others and may use additional resources (such as brochures and web sites), but retains full responsibility for process and content.

### ***The right to be informed about adverse events and medical errors***

Health care aims to stabilize or improve the patient's health with minimum damage. Some forms of harm are unavoidable (wounding the patient to perform a surgical operation, for instance); others, such as adverse events and complications, may occur unintended, depending upon circumstances. Adverse events and complications are inherent to the delivery of health care and do not automatically constitute medical errors that justify compensation for damages. The patient should be informed about the nature, cause and consequences of the adverse event in all cases.<sup>1</sup>

The right to be informed about adverse events and medical errors is sometimes seen as an integral part of the right to information on proposed treatment. If there is a legal duty to inform the patient about prognostic aspects of a treatment decision, it is logical to assume that the patient must also be informed about an unintended or undesirable outcome of the treatment (regardless of whether it results from a medical error or not). The right to be informed about adverse events and medical errors can nevertheless also be seen as a legal right with its own foundation.

It is largely a right of an individual nature. Information provided under it enables patients to understand their situations and decide whether they wish to exercise their right to complain or take further (legal) action.

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1 It is commonly assumed that this right does not extend to so-called "near misses". "Near misses" should be reported in the context of the health provider's quality assurance scheme, but do not need to be reported to the patient.



### ***The right to participate in quality assurance schemes***

Responsibility for delivering safe and good-quality health care has to be fulfilled in the first instance by health care providers and cannot be transferred to the patient. Fulfilling this responsibility implies that patient views and experiences are collected in a systematic manner and that they are taken seriously. Article 3(c) of the European Council recommendation on patient safety (7) stipulates that patients, relatives and informal caregivers should be given opportunities to report their experiences. There are many well-developed and well-researched ways to collect patients' views and experiences in health care settings, including interviewing patients, using methods such as the Consumer Quality Index (CQI), analysing social media messages and enabling patients to report incidents and adverse events. If it is a legal obligation to deliver patient-centred health care that is adjusted to patients' needs (as suggested above), it is also necessary to develop a systematic way to collect and analyse the views and experiences of patients and/or patient organizations.

The right to participate in quality assurance schemes has both an individual and collective dimension. It aims to use patients' views and experiences derived at individual and group levels to improve safety and quality. At individual level, it is important to prevent the transfer of inappropriate (legal or medical) responsibilities to the patient. This right has to be distinguished from educating patients to improve their health condition and/or to be aware of factors that may threaten the safety or effectiveness of the health care they receive. These are very important issues, but tend to represent an obligation or challenge for governments and health care providers rather than being enforceable patients' rights.

### ***The right to complain***

The legal position of patients in health care should be based on three elements:

1. substantive rights (including access to health care, informed consent and privacy);
2. procedural rights (right to complain and other mechanisms to enforce patients' rights); and
3. adequate information about the existence and content of applicable substantive and procedural rights.

The right to complain is of vital importance in this context, not only as a tool to enforce compliance with existing rights, but also to create a forum in which rights and entitlements that have not yet been set out in legislation or case law can be debated. Seen from the perspective of the health care provider, complaints lodged by patients or their family can be used as indicators to evaluate and – if necessary – improve the safety and quality of care. Each complaint is free advice. It is inherent to the delivery of health care, as to any service, that patients may be dissatisfied with services offered. Health service providers have to respond to this in a constructive manner, avoiding defensive or legalistic responses. For that reason, the CoE recommendation requires “the existence of a fair and open complaints system” (8).

Patients' rights to complain can be shaped and implemented in various ways, ranging from the services of informal, easily accessible patient advocates or complaint officials

to an independent ombudsman and legal proceedings (29–31). A balanced complaint system should incorporate all these elements. European jurisdictions show wide variation in complaint systems, with variables such as the structure and organization of health care and the legal culture or tradition being influential. Research has shown that patients strongly favour informal and swift procedures to deal with dissatisfaction or complaints: only if a complaint cannot be solved at this level might a formal and/or independent authority, committee or court be required (32).

In the context of a patient safety management system, it is important to combine information from different sources, including:

- » incidents reported by health professionals and/or patients
- » complaints filed by patients with a complaints official or committee
- » claims for compensation for damages due to an alleged medical error.

An integrated analysis of these data may identify trends and developments in safety and quality of care that would otherwise be missed.

#### ***The right to be compensated in case of damage***

A “just and adequate compensation system” (8) should be in place to deal with damage that can be attributed to the delivery of health care. The traditional legal view is that patients are entitled to compensation in the case of culpable damage; in popular parlance, this means damage resulting from medical error. The traditional civil liability legal system has been supplemented in some European jurisdictions (Nordic countries, France and Belgium) with the potential to compensate patients for damage not caused by medical error, if certain conditions are met.

#### ***The right to be supported***

The patient’s right to be supported is embedded in everyday health care delivery. Patients may not always be in a position to claim or exercise their rights because of, for instance, inequalities in the relationship between patient and health professional, lack of knowledge or competences (health literacy), fear of being put at a disadvantage and vulnerability or disability as a result of their health condition. It is not realistic to expect that all patients are the autonomous agents legislation often presupposes.

Some of the rights mentioned above are intended to “compensate” for or prevent difficulties patients may experience in exercising their rights (such as the right to information). They consequently substantiate the right to be supported, but this right also requires specific measures and activities to be available, such as services:

- » empowering individual patients through education (not only to guarantee that patients’ rights are met, but also to broaden patients’ knowledge about health problems and to promote healthy living, disease prevention and ways of taking responsibility for their own health);
- » physically supporting patients who otherwise would not be able to exercise their rights;

- » engaging with patient representatives in cases where patients are not (fully) capable of voicing their wishes or exercising their rights because of (partial) incompetency or other reasons; and
- » appointing a patient advocate as part of a comprehensive complaint system.

### ***The right to privacy***

In an era in which information technology is rapidly expanding in health as well as in other parts of society, it is crucial to protect patients' privacy rights. Privacy in health care is traditionally realized through the legal and professional norms of medical confidentiality. As a general rule, health care professionals are supposed not to disclose patient information to other individuals or parties except when legitimized by patient consent, legal obligations or emergency circumstances.

Rules on medical confidentiality may create problems in the context of quality improvement when, for instance, quality improvement schemes require coded or identifiable patient information and medical confidentiality and/or privacy regulations prohibit this. The same problem may rise in national or international medical research into patient safety and quality of care. It is obvious that privacy protection is an important part of individual patients' legal position, but they (and patients of the future) may benefit from the outcomes of quality assurance schemes and patient safety medical research. It is important to balance the privacy interests of individual patients with societal interest in improving the safety and quality of health care, if necessary by allowing exceptions to the general rules on privacy and medical confidentiality. Adverse event reporting procedures, for instance, may underperform if approaches such as using identifiable patient data to check whether the reported information is complete or asking for more information from the health professional who reported the event are forbidden, at least in the first phase of the reporting process.

It can be assumed that, in general, patients do not object to their identifiable data being used for quality and safety-improvement purposes. Important preconditions are that patients receive general information about the possibility that their data may be used and are given the opportunity to object, identifiable data are only used when less intrusive options are not possible and adequate safeguards are put in place.<sup>2</sup>

### **Additional aspects**

Legal rights described in the previous section cannot be isolated from the context and circumstances in which they are to be exercised and implemented. It will be difficult to bridge the gap between legal provisions and the daily practice of health care if this connection is ignored. A number of additional aspects should be taken into account when working to empower patients through legal means.

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2 This will usually require legislation. See, for instance, Article 60 of the Health and Social Care Act 2011 from United Kingdom (England) (33) which, under certain conditions, allows the use of confidential patient information for quality protection purposes. A similar approach can be found in the United States' Patient Safety and Quality Improvement Act of 2005 (18). The Government of the Netherlands introduced a bill in Parliament with a similar provision in 2010. More extensive analysis of this legislation is provided by De Roode & Legemaate (34).

### *Awareness of the limits of the law*

There are good reasons to promote patients' rights in the area of safety and quality of care, but the effect of (and potential for) legal interventions should not be overestimated (35). Legal interventions may increase awareness of fundamental principles or values, but are unlikely to change undesirable behaviour. Daily practices often develop independently from legislators' and courts' intentions. However important the role of legal inventions in the regulation of social systems, these systems are also subject to other processes (social, cultural, political, financial and practical) influencing legal interventions' and other policy measures' effectiveness. Legal interventions are doomed to fail if their contents do not – at least to a certain extent – reflect the moral views of the professionals who have to implement patients' rights.

### *Vulnerable populations/health literacy*

As has been suggested above, not all patients are the autonomous agents legislation often supposes them to be. Patients may experience difficulties in being coproducers of their own health or effectively employing strategies to enforce their rights. This may be especially true in circumstances linked to migration or ethnicity, and lack of health literacy may pose problems from a more general perspective.

Making informed self-care decisions and participating in treatment decision-making are health contexts in which health literacy is important in empowering patients to manage their health. Health literacy represents “the cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health” (36). Motivation for, and barriers to, developing and practising health literacy skills should be explored in cases in which patients lack the ability to do so. This is not a legal strategy in itself but represents an important precondition to making legal rights and interventions work.

Nutbeam proposed a health literacy model that is now widely cited in the professional literature and is considered to be useful in analysing the literacy abilities required in various health situations. This model includes three sequential levels of health literacy. Level I – “functional literacy” – refers to the ability to apply basic literacy skills to health-related materials. Level II – “interactive literacy” – focuses on the development of advanced cognitive skills and the ability to operate in a social environment. Level III – “critical literacy” – builds on functional and interactive literacy and includes analytical skills that allow individual and group empowerment, supporting social action participation in health-related issues (37).

The increasing complexity of health care and health-related decisions is one of the reasons for the emergence of the health literacy debate (38):

The health sector is multifaceted and complex. Substantive literacy skills are needed to successfully navigate health and health care systems in today's societies. However, consumers are often provided with unnecessarily complex materials that do not function as the tools for action and aids for decision-making [that they are] meant to be. In addition, many health professionals have grown accustomed to writing and speaking a specialized language that relies on the jargon of their work rather than on the common words of everyday exchanges. Communication is often

hampered by the written and spoken word ... [A]ll reports indicate that health literacy is not independent of social factors and that population groups generally considered to be at risk for health issues (including the elderly, the poor, those without a high school degree, those who have limited resources, those who live in less resourced areas, and those who are members of minority populations) are also more likely to have limited health literacy proficiencies.

Health literacy requires an integrated approach that addresses not only individuals' skills, demands and assumptions, but also the social factors and contexts that shape skills and abilities.

### ***Patient participation in patient safety***

Increasing interest in encouraging patients and family members to contribute to ensuring their safety as they use health services has been accompanied by concerns about the appropriateness of safety-oriented patient activation initiatives and the limited circumstances in which they can be effective (39,40). Ideas about the relationship between health care staff and patients, including issues of trust and the allocation of responsibility, are emerging as particularly important for understanding the potentials and pitfalls of this process.

Patients' and family members' capability to contribute to their safety is strongly shaped by health care provision features, especially interpersonal relationships with staff. Patients and families are often unable or unwilling to adopt recommended behaviours to promote safety, such as monitoring their care and speaking up about concerns, because they appear (to them) to be challenging to, rather than collaborating with, health care staff. This problem arises particularly when staff behaviour indicates disinterestedness towards or mistrust of those patients, and when staff do not routinely engage patients in discussions and decision-making processes. Attempts to involve patients to ensure their safety as they use health services might risk shifting responsibility inappropriately to patients if the interventions used are insufficient in the circumstances to enable patients to act confidently and achieve the intended effects. While most patients may need more support than is currently given, this issue is particularly pertinent for people whose personal and social circumstances generally limit their capability for autonomy (40).

There is no requirement for patients to participate in patient safety activities. Many patients are not willing to be involved, and their reasons should be respected. It is important to invite and encourage patients to participate ("power of invitation"), but not to pressure them (see Chapter 7).

### ***SDM***

SDM is defined as patient involvement with providers in making health care decisions informed by the best available evidence about treatment and illness management options, potential benefits and harms, and that take patient preferences into account. SDM is important because many clinical decisions involve value judgements. Health care providers cannot automatically interpret what patients value. Clinical evidence and the patient's perspective can only be incorporated in decision-making through an explicit interaction between the health professional and the patient in which all relevant information is elicited and evaluated. In doing so, SDM recognizes the ethical value of



patient autonomy and the legal requirement of informed consent, and may also facilitate patients' contributions to their safety.

The concept of SDM is rapidly gaining support (41). Well-informed patients and providers using SDM can determine which option best matches what is most important to patients: delivering high-quality care that is both evidence based and patient centred.

Although SDM is a relevant model for the relationship between health professionals and patients, applying its principles seems to be difficult. Professionals and patients have identified many barriers, including the organization and prevailing culture of health care. Studies indicate that pushing clinicians to apply SDM is challenging. The question is how SDM can best be achieved: "patient pull, or clinician push?" (42).

The evidence in favour of SDM is reasonably strong, particularly when compared to most other initiatives aimed at changing behaviour. Marshall & Bibby's systematic review includes the results of 55 randomized controlled trials conducted over a period of 25 years (43). It shows that:

... patients involved in SDM are better informed than those who are not, and that they are less likely to be undecided about the best course of action at the end of a consultation. Patients are also more likely than their doctors to defer or decline surgical intervention, with no measurable adverse impact on health outcomes or satisfaction, and with the potential to reduce costs. Patients also seem more likely to adhere to treatment regimens and less likely to sue their doctor.

See also King et al. (44).

The concept of SDM makes it necessary to rethink current laws on informed consent by establishing "a system that enables patients to have access to the information pertinent to their personal values and beliefs in order to make an informed decision" (45).

### ***Importance of implementation***

Implementation programmes require a balanced strategy addressing three levels: legislation, patients and their organizations, and health professionals and institutions. Contextual conditions should be given due attention. The mere fact that information is a cornerstone of patients' rights does not guarantee a problem-free implementation process.

Recognizing or legislating on patients' rights in relation to safety and quality of care is not enough. The wording of these rights is often very general and requires interpretation. The real issue is how patients' rights can best be implemented. Legal interventions will always need to be embedded in, or supplemented by, non-legal policy measures, including a broad, multidisciplinary and well-conceived implementation policy. This also applies to other policy measures.

### ***Division of responsibilities***

Many parties are involved in promoting patient safety. It is important to identify the focus, as well as the limits, of their responsibilities. Making responsibilities explicit allows policy-makers and legislators to optimize the division of responsibilities,

prevents misunderstandings and shapes expectations. It goes beyond the scope of this report to present an extensive analysis of this theme, but a brief outline of some of the general issues involved in relation to national or regional government, health insurance companies, health institutions, health professionals and the patient and family is presented in the sections below.<sup>3</sup>

### ***National or regional government***

The main responsibility of government, based on international human rights standards and/or national constitutions or bills of rights, is to create a health care system that is fair, accessible and of good quality. The realization and implementation of every citizen's right to health depends to a large extent on the normative, organizational and financial preconditions created by national or regional governments. The actual involvement of the government in the health care system varies from country to country, ranging from national health systems under government control, to entirely privatized health systems, to a mixture of these models.

Either way, a strong orientation at governmental level towards internationally accepted standards and values on the right to health care is instrumental in turning this right into a reality. It requires sufficient financial resource allocation (which may be problematic due to demographic and/or economic situations) and a broad range of additional policy measures, including (but not limited to):

- » introducing legislation on patients' rights;
- » initiating a monitoring or supervisory system;
- » promoting the development and dissemination of standards and systems on the quality and safety of care; and
- » regulating health professional training and registration.

Importantly, government should assume responsibility for undertaking or promoting activities such as collecting and analysing patient safety data<sup>4</sup> and output indicators at national level, making the aggregated results available for comparison and improvement activity.

### ***Health insurance companies***

Health insurance companies' role varies from country to country. It will be limited (or even nonexistent) in countries with a government-oriented national health system, but private health insurance companies in systems that are more market-driven can play a dominant role in ensuring insured citizens' entitlements are met.

Traditionally, health insurance companies tend to focus more on the availability and price of health care they supply and less on the quality and safety of health care they contract. Quality and safety may profit from health insurance companies' proactive policies in health systems in which they deliver or contract services; this may include

3 Several other relevant parties can be identified, such as patient organizations, nongovernmental organizations and the wider industry; they may play an important role in enhancing patients' rights and safety in a number of countries.

4 See, for instance, the Danish act on patient safety in the health care system which came into force in 2004 (briefly described in the section on national legislation above) (17).

action being taken against health institutions or professionals who underperform. Companies should actively solicit the opinions and experiences of the citizens they insure and incorporate them into their policies.

### ***Health care institutions***

Health care institutions' primary obligation and responsibility is to provide services that reflect prevailing national and international quality and safety standards. They should facilitate health professionals to respect patients' rights and fulfil their other professional obligations. It is crucial that health care institutions operate a comprehensive safety management system that leaves room to incorporate information obtained from patients and their organizations.

### ***Health care professionals***

Health professionals' responsibilities overlap with those of health care institutions. They are expected to deliver state-of-the-art care. Article 4 of the CoE's biomedicine convention (23) stipulates that "any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards". This obligation is particularly directed towards health professionals. Professional obligations and standards include patients' rights and prevailing norms on the quality and safety of care.

Health professionals should undertake necessary activity to keep their knowledge and experience up to date through continuing medical education (CME), which is encouraged or even mandated by (re)certification schemes in many countries. Current professional obligations include the willingness to report incidents and adverse events and to otherwise participate in activities and systems to improve the quality and safety of care. Health professionals should remain open to their patients' views and experiences and create a climate that encourages patients and their families to be sensitive to quality and safety issues and to flag these when necessary. By identifying factors that might influence patients' preferences for involvement, health professionals may be more sensitive to individual patients' preferences and provide better patient-centred care (46).

### ***The patient (and family)***

Patients do not have formal obligations or responsibilities. They can refuse medical treatment and may choose to ignore advice given to them, thereby taking the risk that their health situation does not improve or may deteriorate. As long as they are deemed competent, uninformed patients may make unwise or even damaging decisions.

As has already been suggested above, "activating" patients for the sake of their safety is not an easy task and requires a comprehensive and well-balanced approach. Attempts to involve patients should not result in an inappropriate shift of responsibility from health care provider to patient. Patient participation in safety issues must be realized by providing clear and adequate information, by raising awareness and by promoting the development of skills and competences. Formal mechanisms, including formulating legal obligations for patients to monitor their own health or health situation, will be counterproductive and are incompatible with the fundamental principles of autonomy and self-determination.



Health care providers should nevertheless encourage and empower patients to take responsibility for their own health and safety situation, portraying the responsibility as an opportunity rather than a duty. Patients can act as safety “buffers” during their care, but core responsibility for their safety must remain with health care professions (47). Research shows that “patients would like health staff to be more attentive and proactive and that they expect to be taken seriously and to be consulted in accordance with their competences, resources, and knowledge” (48). This may also apply to the patient’s family members.

## Recommendations

An internal WHO report on human rights and patient safety (WHO Regional Office for Europe, unpublished data, 2009) identified the following key statements.

Patient safety is an issue of increasing concern in health care systems all over the world. It involves at the same time various actors, with the patient/consumer at its core. Only an informed and empowered consumer can actively contribute to improving communication as well as health care outcomes.

The right to safety is one of the fundamental patients’ rights, as are the right to informed consent, the right to participate in safety promotion, and the right to fair procedure.

It is necessary to introduce an integrated approach, with patient safety at the core of high-performing health care systems, by bringing together all factors which can potentially impact the quality and safety of processes.

Promoting patient empowerment and involvement in the process of health promotion and care will support the active partnership needed in the process of improving safety, quality and efficiency of health service delivery.

The patients’ rights described and analysed in this chapter underpin and fuel these key statements. Legal rights and developments cannot be isolated from contextual aspects and influence. For this reason, the scope of this chapter has not been limited strictly to legal developments and legal rights. Similarly, the recommendations outlined in the following sections are not limited to legal questions and solutions, but cover a broader area of activities and interventions.

### ***Recommendation 1 – Regulate patients’ substantive rights***

It is important to acknowledge the rights of patients in relation to patient safety and to regulate them through national legislation in such a way that patients are able to use and enforce them. Specified rights to information at individual level form the core of the individual patient’s legal position. Other rights lose their meaning or become ineffective in the absence of adequate information.

### ***Recommendation 2 – Encourage quality and safety improvement systems***

Patients have a right to safe and good-quality health care. This right underpins health care providers’ responsibility to develop and implement quality and safety improvement systems. It is important that these systems receive input from all relevant sources. Barriers to reporting incidents and adverse events to these systems must be minimized.

***Recommendation 3 – Provide individual patients with relevant information***

Information and communication are key words in this process. Patient participation starts with the availability of valid, clear and relevant information at various levels, including information related to:

- » the basis on which patients can differentiate between (the quality and safety of) health care providers;
- » the patient's health situation, available treatment options and potential risks to the patient's safety; and
- » how to get involved in patient safety activities.

Availability and accessibility of such information is an important precondition for patient participation in patient safety activities. Good information is a first and very important step towards patient involvement. Content, availability and timing of information are all of crucial importance.

***Recommendation 4 – Stimulate the participation of patients in patient safety activities***

It is important that health care providers invite, encourage and empower patients to take part in patient safety activities and try to eliminate barriers. By doing so, patients can contribute to their own safety and to the safety of future patients.<sup>5</sup> Adverse event reporting systems should allow patients or their families to report adverse events. Patients should be clearly informed about how to report into the system.

***Recommendation 5 – Minimize barriers to patient participation (health literacy and SDM)***

Some individual patients or groups may have insufficient health literacy to participate in patient safety activities, lacking the necessary knowledge, skills and competences. Health literacy problems should be actively detected, monitored and remedied. Patients can claim a right to be supported. Important aspects include:

- » improving access to information;
- » training health care providers in effective communication;
- » developing and implementing systematic support for patients with insufficient health literacy; and
- » making information available in other languages or providing translation/interpreting services.

SDM should be one of the tools to improve patient participation.

***Recommendation 6 – Stimulate the policy involvement of patients and their organizations***

Patients and their organizations have a right to participate in policy development at various levels. Policy-makers at all levels should actively seek the involvement of patients and their organizations.

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<sup>5</sup> Research has shown that an important motive for patients to file a complaint is to prevent other patients experiencing the same situation (see, for example, Vincent et al. (49) and Bismark et al. (50)). This finding indicates that the possibility of improving general quality and safety may be an important motivator for participation in patient safety activities.

***Recommendation 7 – Encourage the availability of complaints procedures***

Apart from patients' substantive rights, their procedural rights should also be recognized and implemented. Patients should be able to signal dysfunctions in health care and report adversities that have occurred. It is important that available complaint options meet patients' expectations. Many patients are dissatisfied with the way in which their complaints are handled, a phenomenon that exists in a number of countries and which is not well understood. Fair complaints handling is highly significant in restoring patients' trust in health care and in renewing their commitment to the health care provider or organization (51). Complaints procedures should function in such a way that the outcomes of complaints proceedings are integrated within the health provider's quality and safety improvement system.

***Recommendation 8 – Combine information from different sources***

It is important to combine information from different sources in a patient safety management system, including incidents reported by health professionals or patients, complaints filed by patients with a complaints official or committee and claims for compensation for damage due to an alleged medical error. An integrated analysis of these data may identify trends and developments in safety and quality of care that would otherwise have been missed.

***Recommendation 9 – Include safety issues in health professional curricula***

Sufficient attention should be given to patient safety issues in relation to the rights of patients in education and training curricula for (future) health professionals.

***Recommendation 10 – The importance of implementation***

Patient safety is similar to other areas in that new policy measures in the area, whether with a legal background or not, should be supported by a well-conceived implementation programme. Implementing policy measures is an art in itself.

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# CHAPTER 3.

## PATIENT PARTICIPATION IN HAND HYGIENE IN BULGARIAN HEALTH CARE

*Rossitza Vatcheva-Dobrevska*

### Introduction

Ensuring safety for everyone who comes into contact with health services is one of the most important challenges to the health care system today. Safety consciousness is supported by the reporting and analysis of medical errors as part of a learning culture designed to prevent patient harm. It is well recognized that “access to high-quality health care is a key human right, recognized and valued by the European Union” (1). Accordingly, patients should expect every effort to be made to ensure their safety as users of preventive and curative health services.

HAIs are a major patient safety issue worldwide. They are linked to failures in systems, processes and to the behavioural practices of HCWs, patients and the general public within and beyond the health care environment. More than 1.4 million people around the world become seriously ill from such infections annually. It is estimated that 5–10% of hospitalized patients in industrialized nations acquire one or more infections and that 15–40% of those admitted to critical care are affected. Approximately half of HAI-attributable deaths are caused by the seven most common multidrug-resistant bacteria and occur in the four main types of HAIs: urinary tract infections (UTIs) (27%), lower respiratory tract infections (including pneumonia) (24%), surgical site infections (SSIs) (17%) and BSIs (primary bacteraemia) (10.5%).

The European Centre for Disease Prevention and Control (ECDC) presented data showing that HAIs are responsible directly for approximately 37 000 deaths annually and contribute to a further 110 000 deaths across the EU. The burden on health care systems is immense, resulting in an additional 16 million days of hospital stay per year. Assuming the average daily cost of hospital stay is €334, the total annual health care cost for the 27 countries belonging to the EU since 2007 can be estimated at €5.5 billion. This figure does not, however, include the indirect costs linked to loss of income or the hidden costs associated with physical and emotional suffering (2).

### Content of this chapter

Bulgaria supports the development of measures aimed at limiting the spread of HAIs and antimicrobial resistance and to improving quality and patient safety in line with the 2009 European Council recommendation on patient safety (3), which includes HAI prevention and control (4). The aim of this chapter is to present an overview of the Bulgarian experience of implementing hand hygiene through core preventive interventions in health care facilities, including patient participation, and to highlight how this is supported by national regulations, medical staff attitudes, education programmes and campaigns.

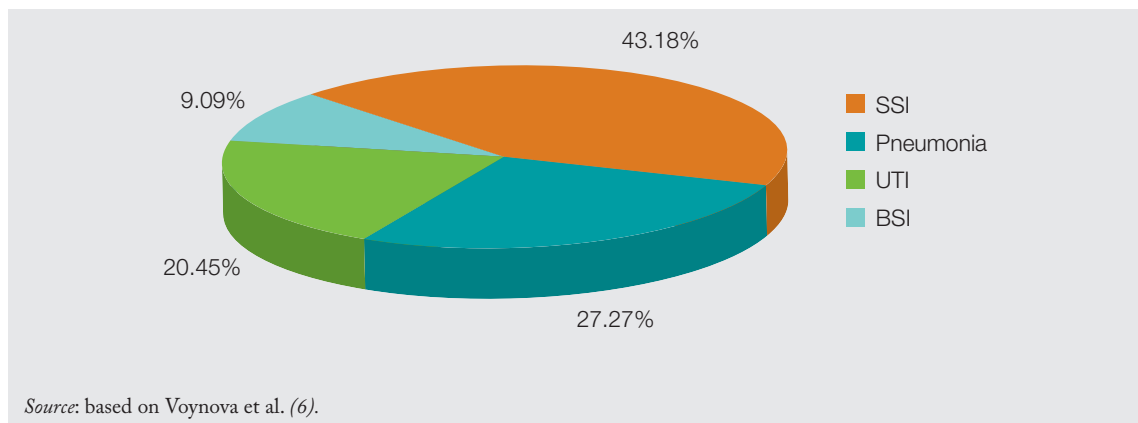
### Bulgarian data on HAI-related morbidity and the role of hand hygiene

A national point prevalence survey was conducted in 23 Bulgarian acute care hospitals in 2006. Prevalence of the four major nosocomial infections – SSIs, BSI, UTIs and pneumonia – and various risk factors were estimated using Hospitals in Europe Link for Infection Control through Surveillance (HELiCS) methodology and Centers for Disease Control and Prevention case definitions. The overall HAI prevalence rate in a representative sample of 3624 patients was 2.43%, with prevalence rates between hospitals varying from 0% to 8.2% (5). The low prevalence rate was explained by the short hospital stays of patients included in the study. The highest prevalence rates were found in intensive care units (ICUs) (15.2%) followed by surgical wards (4.1%).

Multivariate analysis confirmed a statistically significant association of nosocomial infection with risk factors such as indwelling vascular lines, urinary catheters, surgery and length of hospital stay. Catheterization rates of patients with peripheral venous catheters were extremely high, reaching 48.4%. Contaminated and dirty wounds and an American Society of Anesthesiologists score of >3 were shown to be predictors of SSI, with urology, gastroenterology and trauma patients in surgical wards more likely to acquire SSI compared to other surgical patients (6).

SSIs were the most common type of HAI recorded, amounting to 43.18% of the total, followed by pneumonia at 27.27%, UTIs (20.45%) and primary bacteraemia (BSI) (9.09%) (5). Results are summarized in Fig. 3.1.

**Fig. 3.1. Types of HAI in Bulgarian hospitals**



Most of the 3624 patients included in the survey were hospitalized in medical (42.5%) and surgical (36%) wards, followed by obstetrics and gynaecology (10.9%), paediatric units (7%) and ICUs (3.4%) in acute care hospitals. The largest single proportion was in the 65–74 age group (20.58%) followed by 55–64 (20.25%).

This was the first prevalence survey of nosocomial infections in Bulgaria to follow internationally accepted criteria and to be carried out by specifically trained Bulgarian teams. It underlined the need for effective measures directed towards enforcing modern surveillance (including post-discharge surveillance), raising medical staff and public

awareness of the sociomedical burden of HAIs and implementing target-oriented infection control interventions (5). The survey also supported the decision-making process for improving infection control and optimizing hospital infrastructure and provided a valuable instrument to support ongoing surveillance and control systems.

Total HAI incidence reduced from 12.7 per 1000 discharged patients in 2007 to 11.2 in 2008 and 10.2 in 2009. Recorded incidence decreased significantly (about 10%) compared to the late 1990s. Morbidity in university hospitals declined from 13.7 per 1000 discharged patients in 2003 to 10.7 in 2009 and from 11 to 9 in primary municipal hospitals. In secondary hospitals, where morbidity varies more widely, a substantial decline from 13 to 8 per 1000 discharged patients was recorded (7).

Preventing HAI was identified as a fundamental priority and the core topic of the First Global Patient Safety Challenge, “Clean Care is Safer Care” (8–10). Implementation strategies include integrating multiple interventions related to blood, injection and clinical procedure safety, water, sanitation and waste management, and promoting hand hygiene as a cornerstone of safe health care.

### **Bulgarian legal and regulatory framework on preventing HAI and involving patients**

The legislative framework covering this topic comprises several documents, described in this section.

The Law on Health of 10 August 2004 (State Gazette (SG) No. 70 of 10 August 2004; updated by SG No. 54 of 17 July 2012), effective from 1 January 2005, regulates dedicated activities and quality control measures relating to health care, consequently covering patient safety aspects. The act regulates patients’ rights and obligations in accordance with the Council of Europe’s biomedicine convention of 1997 (11).

The main law on infection control organization is the Ordinance of the Ministry of Health No. 13 on Organization of Hospital Infections Prevention and Control (SG No. 95/1998r.), issued in 1998 and updated in 2005 by Ministerial Ordinance No. 2 of 10 January 2005 on the Organization of Prevention and Control of Nosocomial Infections (SG No. 8 of 21 January 2005).

The National Medical Standard on Prevention and Control of Healthcare Associated Infections was endorsed by the Ministry of Health with Ordinance No. 39 of 26 August 2010 (SG No. 69 of 3 September 2010). It includes chapters on HAI prevention, hand hygiene, hand washing and hand disinfection. This act discusses the indications, elements and techniques of hand hygiene.

The National Reference Centre for Nosocomial Infections (NRC–HAI) was set up in 2007 to support the prevention and control of HAIs. This is a specialized unit at the National Centre for Infectious and Parasitic Diseases (NCIPD) established with support from the Ministry of Health and Swiss Red Cross via the hospital hygiene programme. NCIPD is the competent and authorized local organization for HAI prevention. An expert council for infection control has been created as an advisory

body to the Minister of Health to support higher decision-making levels in the health care system.

The national programme for prevention and control of HAI and restriction of antimicrobial resistance spread, which ran from 2009 to 2011, was based on European Commission (12) and Improving Patient Safety in Europe (IPSE) initiatives. Several surveys were carried out in health care facilities to assess the efficiency of programme interventions in limiting the spread of HAI.

Strengthening active surveillance systems will improve HAI recognition rates. These will provide evidence and incentives to decision-makers and professionals to enhance implementation of measures for improving patient, personnel and visitor safety in health care establishments, including containment of HAI and antimicrobial resistance. Bulgaria has committed to the World Alliance for Patient Safety (13) First Global Patient Safety Challenge, “Clean Care is Safer Care” (14), to meet the goal of ensuring patient safety across health care settings. Different initiatives, including awareness campaigns, have been launched in support of this aim.

## **Prevention of HAI: the Bulgarian context**

### ***Education and training on hand hygiene and HAI prevention***

National campaigns have maintained momentum on hand hygiene as a focal point. The “Hand hygiene – what do we know?” campaign targeted HCWs between 2004 and 2006 through press releases and posters, a multicentre questionnaire study on hand hygiene in hospitals (discussed in more detail in the next section) (15), national training programmes and through invited speakers from other countries. No data on the auditing of compliance with hand hygiene or use of alcohol-based hand rub (ABHR) are currently available (16).

The national campaign for hand hygiene 2011–2012, called “Hand hygiene – an element of quality and safe medical care”, was launched by NRC–HAI, with operational activities coordinated by NRC–HAI, NCIPD and the Public Health Directorate of the Ministry of Health. It is based on the WHO multimodal strategy to improve hand hygiene and aims to raise medical professionals’ awareness of the importance of hand hygiene as a critical factor in limiting spread of infections (in hospitals and community) and of the serious health, economic and social burden HAI presents. The campaign targets medical professionals who are in regular contact with patients and all hospitalized patients in acute and long-term facilities. Activities have been initiated to assess existing information and resources to support the development of a comprehensive operational approach to patients’ involvement in promoting hand hygiene in health care establishments.

It is expected that the campaign will contribute effectively to improving hand hygiene practices (including the use of ABHR) at various points of medical care (14) as a simple mechanism to prevent transmission of nosocomial infections and enhance patient safety and medical staff protection. The campaign is also expected to raise societal awareness

and promote a health-and-safety culture in the population, which will be an important factor in epidemic or pandemic prevention and control.

Patients will be targeted with leaflets, posters and other measures to raise their awareness and will be asked to complete questionnaire surveys to assess baseline and outcomes (17). National goals will also include an audit of compliance with hand hygiene and use of ABHR.

### ***Formal infection control education***

Nurses in Bulgaria can specialize in hospital hygiene/HAI prevention and control by taking a basic training course. Currently, there are 165 graduates.

The national infection control training programme for doctors uses the IPSE core curriculum. It was developed in response to Ordinance No. 34 of 29 December 2006 on the Acquisition of Specialty in a Healthcare System (SG No. 7 of 23 January 2007; updated by SG No. 50 of 3 July 2012), which identifies “prevention and control of HAI” as a new medical postgraduate qualification. Medical doctors with a therapeutic, surgical, clinical diagnostic or prophylactic specialist background can take the programme.

HAI training for clinical medical and nursing staff is part of the CME system. Training courses regularly held for clinical specialists and nurses include:

- » seminars in health care facilities and national symposia with training modules;
- » courses on diagnostic methods, risks for staff and patient safety in organ transplantation (provided by the National Agency for Transplantation); and
- » training in infection control based on the IPSE core curriculum for infection control practitioners.

Patient safety and HCW protection are included in the curricula of these courses.

Existing infection control training programmes will be further developed by expanding coverage and addressing additional target audiences such as medical students (medical/dental, medicine/pharmacology) and primary health care (PHC) professionals.

Initiatives to raise public awareness of, and provide education about, patient safety and prevention of HAIs are scheduled to be started in schools and within communities.

### ***Survey using hand hygiene self-assessment framework in hospitals***

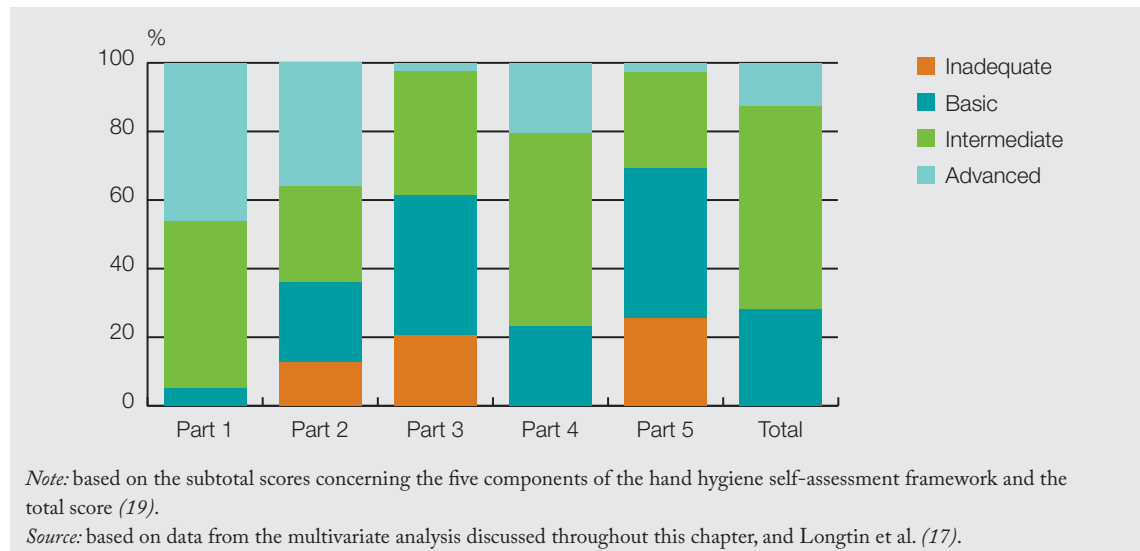
NRC-HAI organized a national survey (18) based on the WHO self-assessment framework on hand hygiene (19) as part of the 2011 national hand hygiene campaign. Its aim was to evaluate existing resources and implementation of the WHO hand hygiene standards at hospital level. Thirty-nine acute care hospitals participated. The overall results indicate that work on hand hygiene is progressing at hospital level, with 59% of participating hospitals in the survey’s “intermediate or consolidation” category.

The hand hygiene self-assessment framework (19) looks at: system change (part 1); training and education (part 2); evaluation and feedback (part 3); reminders in the

workplace (part 4); and an institutional safety climate for hand hygiene (part 5). Results were evaluated according to these categories as applied to the health care facilities.

The 39 participating hospitals were analysed according to the subtotal scores for the five components of the hand hygiene self-assessment framework shown in Fig. 3.2.

**Fig. 3.2. Categorized distribution of 39 Bulgarian hospitals**



The highest percentage of hospitals with an inadequate subtotal score (level) received this evaluation in part 5 on “institutional safety climate for hand hygiene” (26%), followed by part 3 on “evaluation and feedback” (20%) and part 2 on “training and education” (13%). “Basic” subtotal scores have the largest proportions in part 5, “institutional safety climate for hand hygiene” (44%) and part 3, “evaluation and feedback” (41%). The largest proportions for health care facilities receiving “intermediate” scores occurred in part 1, “system change”. The highest percentage of “advanced” scores was obtained for “training and education” (36%) and “reminders at workplace” (20%), reflecting the ongoing attention given to upgrading knowledge and skills and educational resources, and disseminating and enforcing information. WHO technical documents on hand hygiene are being translated into local languages and one of the main goals is the implementation of hand hygiene compliance evaluation.

The self-assessment survey also contained a question about patient involvement in hand-hygiene promotion. Only one of the participating hospitals received the highest possible evaluation score of 10 points; around 46% scored 5 and approximately 51% scored 0.

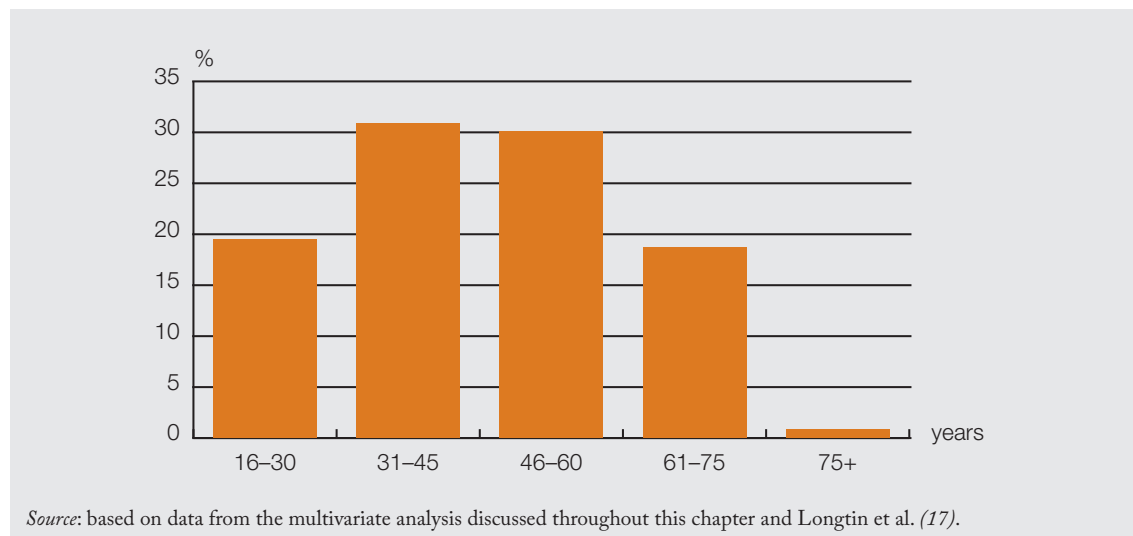
### Survey of patients’ knowledge and intention to support strengthening of hand hygiene in hospitals

A survey was carried out with 123 patients (100% response rate) in two Bulgarian acute care hospitals during June and July 2011. The patients (40% males and 60% females) were interviewed at the bedside by an infection control nurse or chief nurse in the ward using a 20-item questionnaire (adapted from the work of Longtin et al. (17)). Hospital psychologists supported the process for older patients.



The age distribution of respondents is shown in Fig. 3.3. The largest proportion (31%) were in the 31–45 years group, followed by 46–60 (30%) and 75+ (1%).

**Fig. 3.3. Distribution of respondents by age**



Main results from the survey are summarized in the tables below.

The association between patients' characteristics and their intention to ask their nurses and physicians whether they washed their hands (Table 3.1) shows lower involvement with increased age, with substantially reduced intention to ask (72% less for patients aged between 45 and 60 and 89% less for the age group 61–75 years) compared to younger age groups.

Patient knowledge levels about HAIs proved to be quite advanced (Table 3.2), with 44.1% able to correctly name the type of infection patients can acquire in hospitals, 73% considering HAI to be a serious problem and 67.8% worried about the risk of contracting a HAI. Medical staff hand hygiene was identified as the most important HAI preventive measure (89.8%) and 83.1% indicated the same for patients' hand hygiene. All patients thought that nurses wash their hands "always or most of the time" and 98.3% said the same for doctors. Among those who answered "Yes" to the question "Are you worried by the risk of HAI?", the intention to ask their nurses whether they performed hand hygiene was about 70% lower than in the group who answered "No". In the group of patients who answered "Yes" to the question "Do you think that HAIs are a serious problem?", the intention to ask their nurses whether they performed hand hygiene was about 77% lower than in the group who answered "No". The odds ratios (ORs) in the other comparisons were not significant.

Data on patients' willingness to participate in the process of improving medical staff hand hygiene are summarized in Table 3.3. Most respondents (79.7%) considered that asking HCWs to wash their hands would prevent the acquisition of an infection in hospital, but more than half stated they would not feel comfortable asking a nurse or physician to clean their hands. An explicit invitation from HCWs significantly increased the intention to ask nurses/physicians from 52% to 86.2%.

**Table 3.1. Association between patients' characteristics and their intention to ask HCWs whether they performed hand hygiene**

Characteristic	Intend to ask nurses					Intend to ask physicians				
	Proportion (%) of respondents <sup>a</sup>	OR	95% CI <sup>b</sup>		p <sup>c</sup>	Proportion (%) of respondents	OR	95% CI		p
			Lower	Upper				Lower	Upper	
<b>Gender</b>										
Male	44.1	1.000	–	–		41.7	1.000			
Female	55.9	0.762	0.370	1.567	0.459	58.3	0.921	0.448	1.892	0.823
<b>Age (years)</b>										
16–30	25.4	1.000				28.3	1.000			
31–45	33.9	0.667	0.235	1.892	0.446	38.3	0.631	0.211	1.886	0.410
46–60	23.7	0.365	0.126	1.055	0.063	25.0	0.281	0.094	0.842	0.023
61–75	15.3	0.386	0.119	1.251	0.112	8.3	0.114	0.030	0.430	0.001
>75	1.7	1x10 <sup>9</sup>	0.000	–	1.000	0.0	0.000	0.000	–	1.000
<b>Level of schooling</b>										
Primary	11.3	1.538	0.407	5.815	0.525	10.9	1.062	0.283	3.984	0.928
High school	64.2	1.538	0.661	3.580	0.318	60.0	1.002	0.436	2.302	0.997
University	24.5	1.000				29.1	1.000			
<b>Profession</b>										
Worker	40.0	0.476	0.040	5.671	0.557	42.3	2.316	0.194	27.590	0.507
Employee	56.0	0.452	0.039	5.256	0.526	55.8	1.933	0.166	22.497	0.599
Medical staff	4.0	1.000				1.9	1.000			
Retired	15.3	0.706	0.277	1.799	0.466	10.0	0.326	0.118	0.902	0.031
<b>Have you been hospitalized previously?</b>	81.4	1.112	0.455	2.721	0.816	80.0	0.941	0.386	2.296	0.894
<b>Have you ever acquired an HAI?</b>	6.8	1.091	0.260	4.574	0.905	6.7	1.054	0.251	4.417	0.943
<b>Have any of your relatives ever acquired an HAI?</b>	10.2	0.692	0.230	2.078	0.511	6.7	0.338	0.101	1.127	0.077

<sup>a</sup>100% response rate, except for “Level of schooling” (91.9%) and “Profession” (83.7%).

<sup>b</sup>Confidence interval.

<sup>c</sup>Probability.

Source: based on data from the multivariate analysis discussed throughout this chapter and Longtin et al. (17).

The main reasons for not intending to ask HCWs whether they performed hand hygiene (summarized in Table 3.4) were given as trust in HCWs, followed by consideration for HCW knowledge and feelings of embarrassment or awkwardness about challenging.

Results from the multivariate analysis of factors associated with patients' intention to ask their nurses and physicians to perform hand hygiene are summarized in Table 3.5. Age, the availability of information on HAI and perception of the risk of acquiring HAI had a direct influence on patients' intention to ask about hand hygiene. Patients' intention to ask their nurses about hand hygiene decreased with age, with almost 98% less intention in the 61–75 age group than the youngest groups. In the group of patients

**Table 3.2. Association between patients' beliefs and knowledge about HAIs and infection control strategies and their intention to ask HCWs whether they performed hand hygiene**

Beliefs and knowledge	Intend to ask nurses					Intend to ask physicians				
	Proportion (%) of respondents	OR	95% CI		p	Proportion (%) of respondents	OR	95% CI		p
			Lower	Upper				Lower	Upper	
<b>Can you name the type of infection patients acquire in hospitals?</b>										
Incorrect answer	55.9	1.000				50.0				
Nosocomial or HAI	44.1	0.839	0.412	1.706	0.627	50.0	1.333	0.655	2.714	0.428
<b>Have you received information about HAIs?</b>										
No	45.8	1.000				45.0				
Yes	54.2	1.624	0.796	3.314	0.183	55.0	1.739	0.851	3.553	0.129
<b>Are you worried by the risk of an HAI?</b>										
No	32.2	1.000				26.7				
Yes	67.8	0.301	0.120	0.755	0.011	73.3	0.582	0.245	1.383	0.220
<b>Do you think that HAIs are a serious problem?</b>										
No	27.1					23.3				
Yes	72.9	0.228	0.077	0.670	0.007	76.7	0.411	0.153	1.103	0.077
<b>Hand hygiene includes:</b>										
hand washing with water and soap	54.2	1.046	0.514	2.126	0.902	53.3	0.975	0.480	1.981	0.944
hand disinfection with ABHR	30.5	1.568	0.697	3.529	0.277	28.3	1.265	0.564	2.836	0.568
both	57.6	0.816	0.396	1.681	0.581	53.3	0.571	0.276	1.185	0.133
<b>What is the most important measure to prevent HAIs?</b>										
Hand hygiene of medical staff	89.8	1.085	0.343	3.436	0.890	88.3	0.797	0.252	2.524	0.700
Hand hygiene of patients	83.1	1.017	0.397	2.604	0.972	80.0	0.667	0.258	1.720	0.402
Others	15.3	1.740	0.579	5.228	0.324	13.3	1.231	0.417	3.633	0.707
<b>Before caring for a patient, nurses wash their hands ...</b>										
never or sometimes	1.7	1.086	0.066	17.767	0.954	1.7	1.051	0.064	17.188	0.972
always or most of the time	100.0	–	–	–	–	100.0	–	–	–	–
<b>Before caring for a patient, physicians wash their hands ...</b>										
never or sometimes	1.7	1.086	0.066	17.767	0.954	1.7	1.051	0.064	17.188	0.972
always or most of the time	98.3	0.000	0.000	–	1.000	100.0	2x10 <sup>9</sup>	0.000	–	1.000

Source: based on data from the multivariate analysis discussed throughout this chapter and Longtin et al. (17).

who answered “Yes” to the question “Have you received information about HAIs?”, their intention to ask nurses/physicians was four times higher than for the group of patients who answered “No”. For the question “Have you ever reminded a physician to wash her/his hands?”, 100% responded “No”, which may indicate that communicating with nurses appears to be easier.

**Table 3.3. Association between beliefs related to patient participation to improve HCWs' hand hygiene compliance and patients' intention to ask HCWs whether they performed hand hygiene**

Beliefs	Intend to ask nurses					Intend to ask physicians				
	Proportion (%) of respondents	OR	95% CI		p	Proportion (%) of respondents	OR	95% CI		p
			Lower	Upper				Lower	Upper	
Do you think that <b>patients asking caregivers</b> to wash their hands would prevent the acquisition of infection in the hospital?										
No	20.3	1.000				25.0	1.000			
Yes	79.7	2.511	1.118	5.637	0.026	75.0	1.610	0.737	3.515	0.232
Do you <b>intend to remind</b> your physician/nurse to wash her/his hands the next time you observe that (s)he had forgotten to do so?										
No	32.2	1.000				31.7	1.000			
Yes	67.8	3.509	1.667	7.388	0.001	68.3	3.753	1.777	7.926	0.001
If your physician/nurse <b>asked you to remind</b> her/him to wash her/his hands the next time you observe that (s)he had forgotten, would you intend to do so?										
No	8.5					8.3				
Yes	91.5	3.600	1.226	10.567	0.020	91.7	3.745	1.275	10.994	0.016

Source: based on data from the multivariate analysis discussed throughout this chapter and Longtin et al. (17).

**Table 3.4. Reasons for not intending to ask HCWs whether they performed hand hygiene**

Reason	No intention to ask nurses		No intention to ask physicians	
	No. of responses	%	No. of responses	%
Belief that this task is not the patient's role	36	56.3	35	55.6
Feeling of embarrassment or awkwardness	44	68.8	43	68.3
Perception of being impolite, disrespectful, dishonest	43	67.2	41	65.1
Belief that caregivers know or should know	46	71.9	42	66.7
Fear of reprisals	36	56.3	33	52.4
Perception of not knowing when to intervene or not knowing the indications for hand hygiene	32	50.0	30	47.6
Belief that HCWs can be trusted	48	75.0	48	76.2
Refusal to judge caregivers' work	34	53.1	33	52.4
Perception that this intervention is too "daring"	43	67.2	41	65.1

Source: based on data from the multivariate analysis discussed throughout this chapter and Longtin et al. (17).

It is important to note that there were no interventions promoting patient participation in the health care settings at the time of the study. This explains the results and underlines the need for immediate action in this area.

Objectives for future work are to extend activities aiming to implement a safety culture, including:

- » developing training programmes and modules for patients (including the role of hand hygiene for HAI reduction);
- » encouraging caregivers to use the model of "an explicit invitation" to enhance their role; and

**Table 3.5. Multivariate analysis of factors associated with patients' intention to ask HCWs to perform hand hygiene**

Characteristic	Intend to ask nurses (n=59, 48.0%)				Intend to ask physician (n=60, 48.8%)			
	OR	95% CI		p	OR	95% CI		p
		Lower	Upper			Lower	Upper	
<b>Age (years)</b>								
16–30	1.000				1.000			
31–45	0.372	0.101	1.367	0.136	0.363	0.103	1.277	0.114
46–60	0.150	0.038	0.592	0.007	0.123	0.032	0.472	0.002
61–75	0.110	0.023	0.530	0.006	0.034	0.006	0.180	0.000
>75	6x10 <sup>8</sup>	0.000		1.000	0.000	0.000	–	1.000
<b>Do you have information about HAI?</b>								
No	1.000				1.000			
Yes	3.990	1.473	10.812	0.007	4.094	1.550	10.816	0.004
<b>Are you worried by the risk of HAI?</b>								
No	1.000				1.000			
Yes	0.143	0.041	0.492	0.002	0.236	0.072	0.779	0.018
Do you think that <b>patients asking caregivers</b> to wash their hands would prevent the acquisition of infection in the hospital?								
No	1.000				1.000			
Yes	3.638	1.334	9.921	0.012	1.857	0.729	4.729	0.195
Have you <b>ever reminded a nurse</b> to wash his/her hands?								
No	1.000				1.000			
Yes	1x10 <sup>9</sup>	0.000	–	0.999	3.580	0.549	23.348	0.182
Have you <b>ever reminded a physician</b> to wash his/her hands?								
No	1.000				1.000			
Yes	–	–	–	–	–	–	–	–

Source: based on data from the multivariate analysis discussed throughout this chapter and Longtin et al. (17).

- » preparing and distributing leaflets and other information materials on hand hygiene (implementation of guidance on engaging patients and patient organizations in hand-hygiene initiatives).

## Recommendations

Infection control specialists work to inform medical staff and wider society about basic solutions to the problem of HAI. Many infection prevention and control measures, including hand hygiene, are simple, low-cost and effective, but they require staff accountability and behaviour change. The main actions required to reduce HAI are:

- » ensure core elements for infection control are in place at national and health care setting levels;
- » improve reporting and surveillance systems;
- » ensure minimum dedicated resources and training;
- » implement hand hygiene best practice and standard precautions at the bedside every day; and
- » improve staff knowledge, awareness and compliance.

The following recommendations are based on the findings presented in this chapter of the first Bulgarian study to evaluate patients' opinions on, and knowledge of, HAI.

***Recommendation 1 – Educate patients on hand hygiene***

Appropriate patient information can play an important part in the process of active patient engagement in hand hygiene implementation. Development and extension of patients' education on hand hygiene, patient safety and reduction of HAI are key interventions that can be achieved through training and education programmes. Preparation and distribution of materials to raise hand hygiene awareness supports these interventions.

***Recommendation 2 – Educate HCWs on patient involvement in safe care***

The survey shows that patients are much more likely to ask about hand hygiene if explicitly invited to do so, highlighting the need for full HCW support for the process. Patient participation in hand hygiene could be further enhanced through HCWs' education, focusing on promotion and advocacy for patient participation in safe care and using explicit invitations from HCWs as guidance.

***Recommendation 3 – Stimulate cultural change among the general public and medical profession***

Many institutions score "inadequate" for patient participation in the self-assessment tool, showing that the culture of safety is not fully implemented in hospitals. Identified links between age, profession and beliefs, and the perception of patients' direct involvement in reducing HAIs provide additional evidence for the necessary cultural change for the general public (safety and quality expectations) and medical profession to enhance health care provider and patient dialogue at hospital level.

***Recommendation 4 – Monitor progress and provide evidence***

The study described in this chapter should be extended to other health care facilities to validate the data on a wider national scale and promote their further use in informing related decision-making mechanisms. Dedicated indicators should be used to monitor progress and ensure that planned actions are implemented and patient engagement in wide-scale hand hygiene compliance is ensured and effective.

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# CHAPTER 4. BLOOD TRANSFUSION SAFETY IN FRANCE: DEVELOPING TOOLS TO SUPPORT PATIENTS

*Justine Bettinger, Josselin Thuilliez, Yves Charpak<sup>6</sup>*

## Introduction

This chapter addresses the link between patient safety and patients' rights in the specific context of transfusion and blood safety. The French experience is presented, reflecting the recognized expertise and fundamental reform of the blood transfusion service and the special "year of patients and their rights" launched by the Ministry of Health in 2011. Attitudes towards historical transfusion therapy practices, from the perspective of health care professionals (prescribing and administering transfusion therapy) and patients (requesting transfusion therapy, adopting a "zero-risk" assumption) have direct safety and economic effects on quality of care and availability of blood supplies.

The major challenge in the 1980s was to improve security of the production and distribution chain of labile blood products (LBPs) after the French HIV blood-contamination crisis. Consolidation of a safety culture among medical actors and patients is the next challenge in the blood transfusion field, reflecting the fact that the epidemiology of blood transfusion risks has evolved and the average age of patients transfused has also changed (with a shift towards older recipients). The evolution of the role of the individual in the health care system also highlights the potential of information (for the general public and patients) as a means to enhance safety cultures.

Clinical risks associated with blood transfusion include transfusion-transmitted infections, unexpected clinical complications, adverse effects due to error and suboptimal care during the transfusion process; all have been well documented (1). In special circumstances, transfusion absence and delay may also represent a risk to health. Davis et al. (2) suggest that there is considerable potential for patients to assume a positive role in ensuring safe practice.

Several questions have previously been raised in this field of research (2), including the following.

- » How willing are patients to be involved?
- » What could they reasonably be expected to do?
- » Might their involvement be affected or curtailed by individual characteristics?

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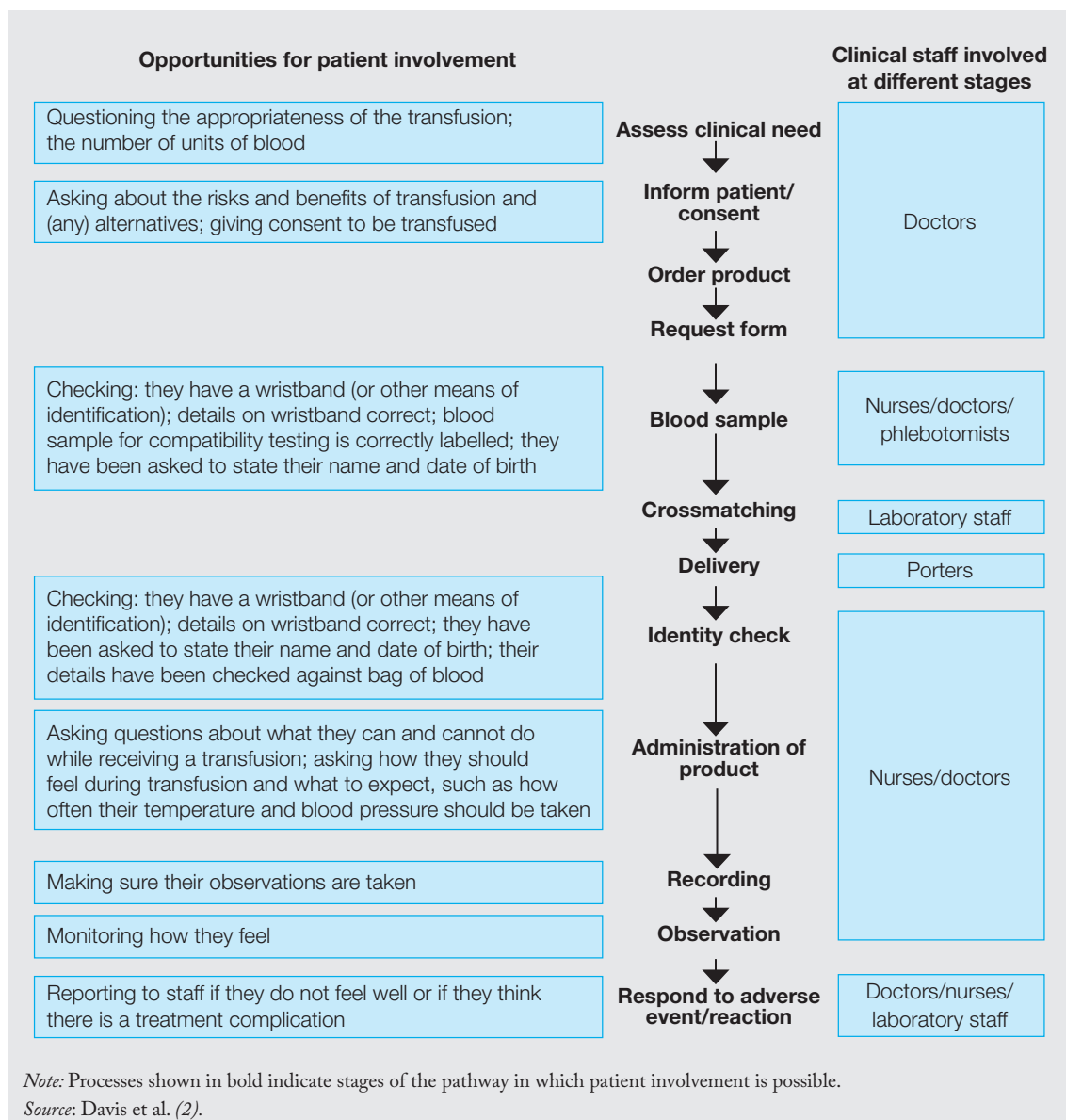
6 The study in Chapter 4 was undertaken by the École des Hautes Études en Santé Publique [School of Public Health] in close collaboration with the Établissement Français du Sang [Blood Transfusion Organization].

Some answers and proposals have been provided in response to these initial questions, but first, patients who could potentially participate in the process need to be identified. Such patients must:

- » have knowledge of how to be involved (studies have shown that many patients have a very limited understanding of the risks and benefits of transfusion);
- » have the physical and cognitive capacity to be able to participate – this will lead to some patients being omitted; and
- » be willing to participate – very few studies provide information on the profile of patients who are willing to participate.

Several opportunities for patient involvement were identified by Davis et al. (2), including before, during and after transfusion, showing the direct impact potential of an informed and engaged patient in improving safety throughout the transfusion process (Fig. 4.1).

**Fig. 4.1. Patient involvement in the transfusion process**



Other questions can also be raised at this stage.

- » Does patient involvement really have a positive effect on transfusion safety? There is little information on the effectiveness of initiatives that aim to inform patients and improve their willingness to participate.
- » Does providing safety-related information produce any adverse effects?
- » What are the implications for clinical practice?
- » What legislative framework is needed to ensure safety becomes a shared responsibility, with the patient as a coproducer of health?

### Content of this chapter

The chapter provides a brief overview of blood transfusion and patient safety in France and presents a critical analysis of legislative and applied tools supporting patient empowerment (with a focus on patients' rights and patient safety) in relation to blood transfusion. Theoretical and legislative aspects are compared to clinical practice and their consequences for patient safety, drawing from interviews with experts (particularly haemovigilance experts) and prescribers and complemented by a case study conducted at the Etablissement Français du Sang (EFS) [French Blood Transfusion Organization] centre in the city of Tours. The concluding section summarizes the potential benefits of patient involvement in the blood transfusion process to improve patient safety and offers recommendations for moving forward, with suggestions for future research. A list of relevant legislation is presented at the end of the references section.

### Blood transfusion and patient safety in France

#### *Blood transfusion: organization and transfusion-related data, including number of adverse events*

##### Organization of blood transfusion in France

The EFS was set up on 1 January 2000 (following Law No. 98-535 of 1 July 1998), gathering in one unique institution the previous blood transfusion centres and taking responsibility for some of the tasks of the former French blood agency. Regulation and control tasks were given to the Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) [French Health Products Safety Agency],<sup>7</sup> which was created by the same law, and the Institut National de Veille Sanitaire [Institute for Public Health Surveillance] (3). The main actors in the field of blood transfusion in France today are (4):

- » the EFS, which is in charge of the collection of blood, the biological qualification of donations, preparation of LBPs and their distribution at national level; its activities fall under the control of the AFSSAPS;
- » the Centre de Transfusion Sanguine des Armées (CTSA) [Armed Forces Blood Transfusion Centre], which is responsible for supplying armed forces in the field and military hospitals with LBPs;

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7 AFSSAPS was replaced on 1 May 2012 by Agence Nationale de Sécurité du Médicament et des Produits de Santé [National Security Agency of Medicines and Health Products] under the Law of 29 December 2011 on the Strengthening of the Safety of Medicines and Health Products.

- » Laboratoire Français du Fractionnement et des Biotechnologies, a biopharmaceutical manufacturing company that is in charge of blood plasma fractionation; and
- » the AFSSAPS, responsible for evaluating and managing the security, quality and efficacy of health care products.

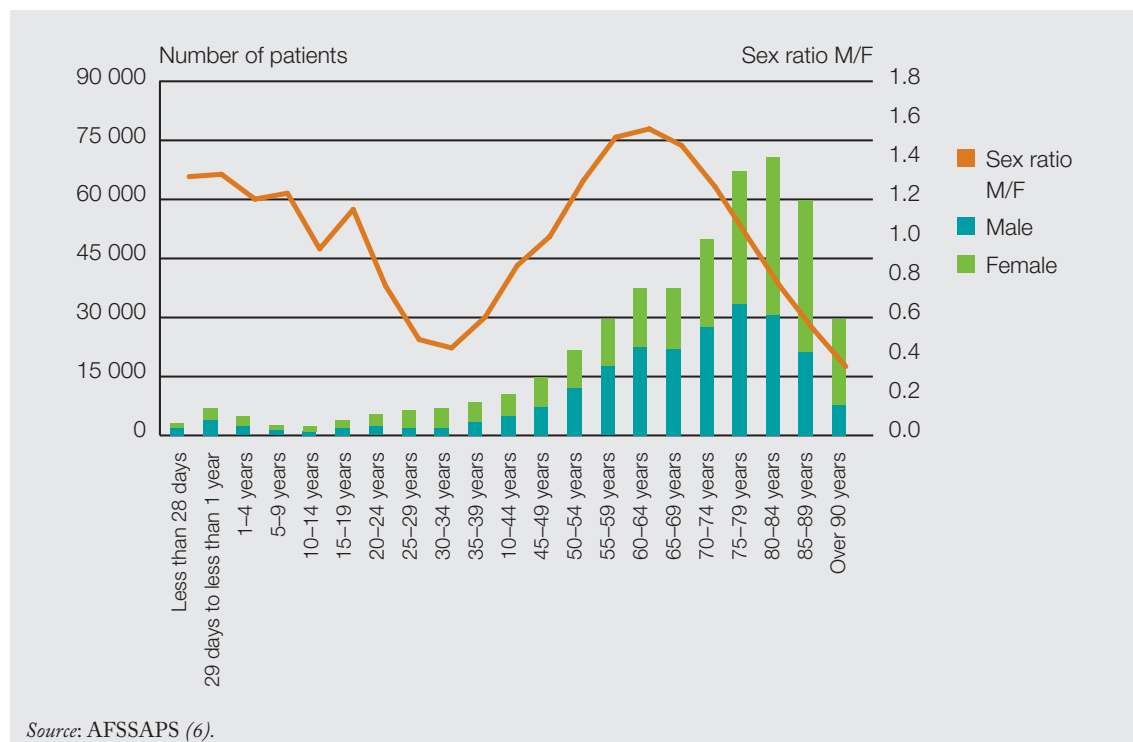
The Institute National de la Transfusion Sanguine [National Institute of Blood Transfusion] web site provides a description of other important actors in the blood transfusion field, along with further information (4).

#### Current transfusion data and blood transfusion procedures

The three main groups of pathologies that give rise to transfusion are haemato-oncology (52.7% of prescriptions), surgical procedures (23.99%) and intensive care and medicine procedures (21.92%) (5). In 2009, 2 979 117 LBPs were distributed – 79% red blood cells, 9% platelets and 12% plasma – with almost all being homologous products.

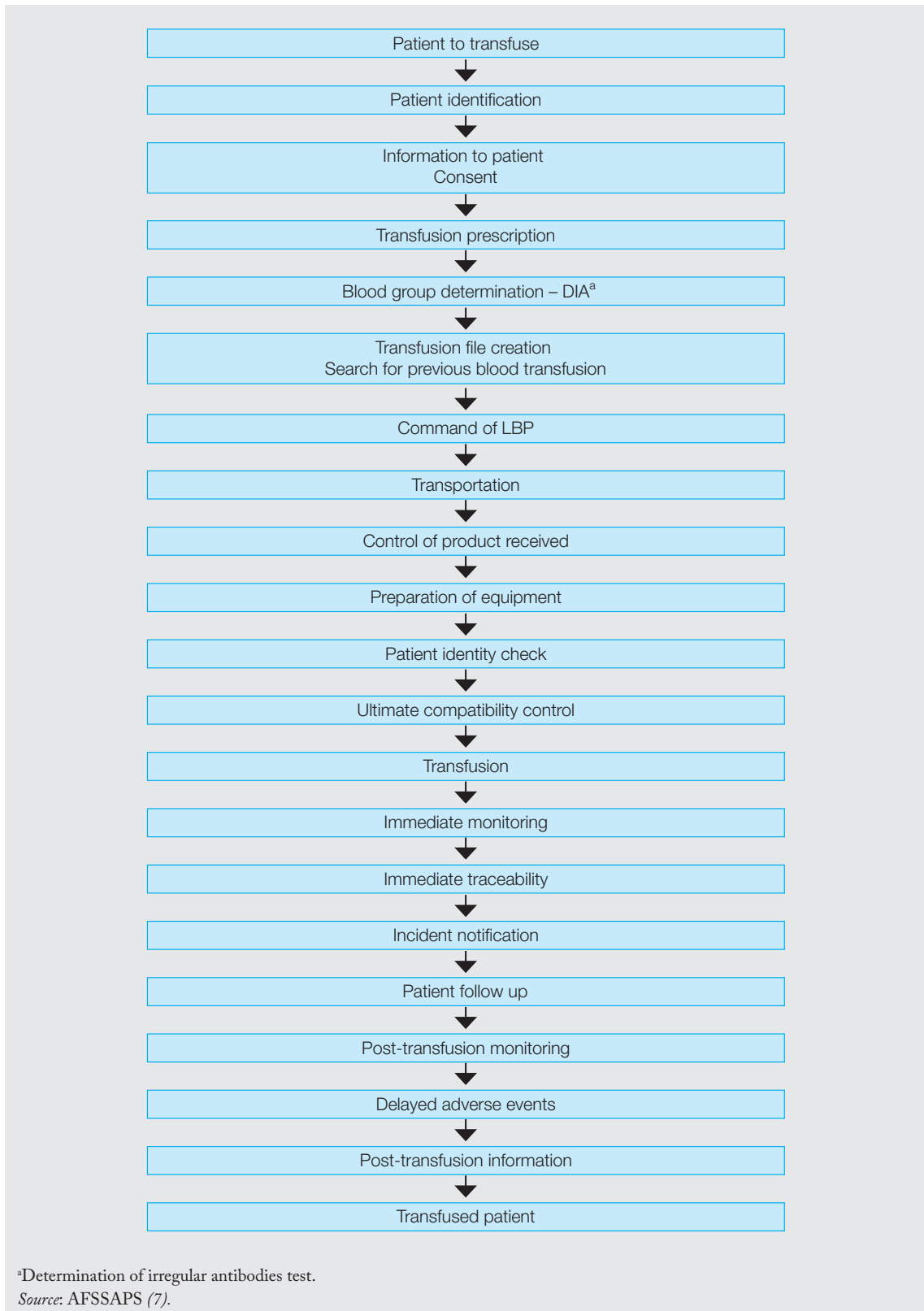
The number of transfused patients has increased since 2006 (6). According to the AFSSAPS, the number of donors rose to 1 773 374 in 2009 (1.7 donations per donor), representing 4.1% of the population, with equal gender representation. The number of transfused patients was estimated at 538 506 (52% women, 48% men), with a ratio of transfused patients of 8.3 per 1000 inhabitants, although it varied greatly with age (Fig. 4.2).

**Fig. 4.2. Transfused patients by age and gender, 2011**



The generic steps covering the transfusion procedure are presented in Fig. 4.3, along with the entry points for provision of patient information. These appear to relate mainly to informed consent and post-transfusion information.

**Fig. 4.3. Transfusion procedure steps**



#### Adverse events and transfusion-related incidents

Blood transfusion involves some risks that can relate to the quality of the blood products, the clinical profile of the recipient or the health care organization. Adverse effects are defined in the French Public Health Code (8) (Box 4.1).



### Box 4.1. Definitions of adverse effects and incidents in French law

The definitions listed here apply to the application of article R1221-23 of the French Public Health Code.

1. **Adverse effect:** a harmful reaction affecting donors, related (or likely to be related) to the blood collection; or affecting recipients, related (or likely to be related) to the administration of a LBP; a **recipient adverse reaction (RAR)** is a harmful reaction affecting a recipient, related (or likely to be related) to the administration of a LBP.
2. **Serious adverse effect:** an adverse event resulting in death or danger of death, resulting in disability or incapacity, or provoking or prolonging hospitalization or any other morbid condition.
3. **Incident:** an incident related to the collection of blood, biological qualification of donations, preparation, storage, distribution, issue or use of a LBP, due to an accident or error, likely to affect the safety or quality of the product and result in adverse events.
4. **Serious incident:** an incident likely to result in serious adverse effects.

**Severity of RARs** is defined by different grades:

- » Grade 4: death of the recipient
- » Grade 3: immediate danger of death
- » Grade 2: long-term morbidity
- » Grade 1: absence of immediate or long-term danger of death
- » Grade 0 (introduced in 2002–2004): isolated dysfunction without clinical or biological manifestation.

**Imputability of RARs** is defined as the probability that an adverse reaction affecting a LBP recipient be attributed to the products transfused, or that an adverse effect affecting a blood donor be attributed to the collection of blood or blood components; by definition, imputability does not apply to chain incidents. For each adverse effect declaration, a case-by-case analysis should enable a causal link to be established between the transfusion of the LBP and the occurrence of the adverse effect.

The imputability levels are classified according to the following criteria.

- » **Imputability 4** – certain: the tests prove that the adverse event was caused by the transfusion.
- » **Imputability 3** – likely: the adverse event does not appear to be accounted for by a concurrent cause and diagnostic information that suggests the adverse effect was caused by the transfusion remains.
- » **Imputability 2** – possible: the adverse effect could be accounted for either by the transfusion or a concurrent cause without it being possible to decide at the current stage of investigation.
- » **Imputability 1** – doubtful: the adverse event does not seem to be fully accounted for by the administration of the LBP, although it is not possible to totally exclude this.
- » **Imputability 0** – excluded: it was proven that the LBP was not involved in the occurrence of the adverse effect.

The AFSSAPS is responsible for the compilation of haemovigilance data. According to the 2009 annual haemovigilance report (6), 7808 adverse reactions occurred among recipients of blood, representing 2.6 per 1000 LBPs. A typology of the different risks and latest available data are given in Table 4.1.

Fig. 4.4 provides additional information about the distribution of adverse reactions related to blood transfusion; further figures can be found in the AFSSAPS 2009 annual haemovigilance report (6).

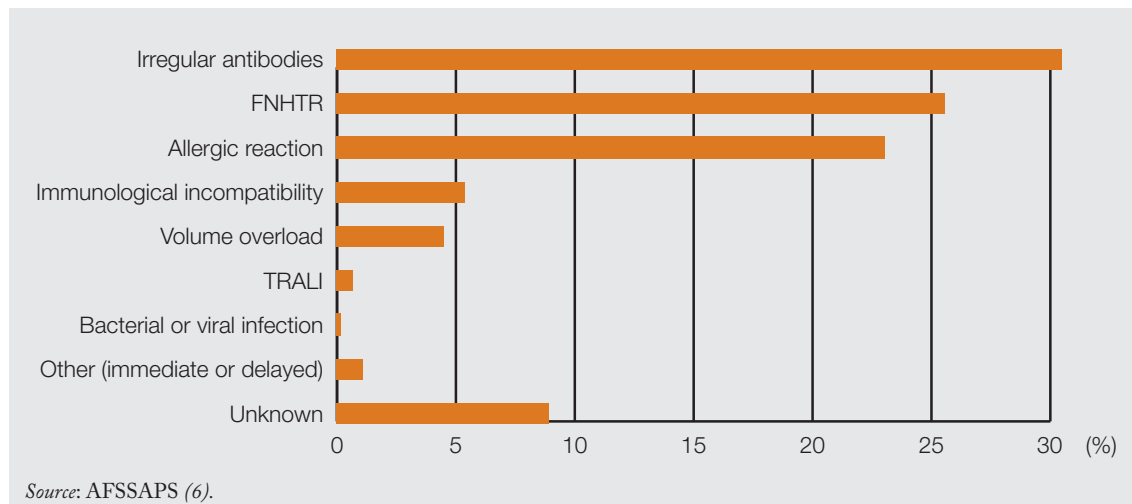
The frequency of adverse events increases with age, with 60% of the grade 3 or 4 adverse reactions declared in 2009 in patients aged over 60 years and 24% in those over 80.

### *Patient safety in France: an overview*

Patient safety is defined as being free from unnecessary or potential harm associated with health care.

**Table 4.1. Typology of risks**

<b>Risks linked to the blood product itself</b>	
Transmission of main viruses	<p>The risk of viral transmission has been consistently reduced since the early 1990s as a result of: blood donor selection; serologic tests; and viral genome testing for HIV-1 and hepatitis B virus (HBV) (9).</p> <p>Between 2002 and 2004, residual risks of viral infection were:</p> <ul style="list-style-type: none"> <li>• HBV: 1/1.45 million LBPs (average: 2 infected LBPs per year)</li> <li>• HIV: 1/2.35 million LBPs (average: 1 infected LBP per year)</li> <li>• hepatitis C virus (HCV): 1/7.7 million LBPs (average: 1 infected LBP in 3 years).</li> </ul> <p>Between 2000 and 2009, for 26 million transfused LBPs in France, there were:</p> <ul style="list-style-type: none"> <li>• 40 declarations of HCV infection (none since 2004)</li> <li>• 16 declarations of cytomegalovirus (average of 1 to 2 per year)</li> <li>• 2 declarations of HIV infection (none since 2002) (6).</li> </ul> <p>Residual risks of viral infection are mainly due to blood donation sampled during serological window.</p>
Bacterial contamination	<p>There were 10 suspected bacterial infections in 2009 (6).</p> <p>Platelets are the blood product most exposed to bacterial contamination, mostly for reasons of temperature.</p>
Other threats (9)	<ul style="list-style-type: none"> <li>• Malaria: 2 declarations between 2000 and 2009, and none since 2006 (6).</li> <li>• West Nile virus: no transmission by blood transfusion has been reported.</li> <li>• Chikungunya virus: to date, no case of transmission through transfusion has been confirmed (nor for dengue virus).</li> <li>• Chagas' disease: several human cases appeared recently in French Guiana, leading to the interruption of blood collection. No transfusion-related transmission has been reported in the rest of France.</li> <li>• Variant Creutzfeldt-Jakob disease: the risk of transmission of the prion via blood transfusion is real, but the incubation period is unknown and there is no way to test blood donors. No post-transfusion cases have been reported in France.</li> </ul>
<b>Risks linked to the recipient's clinical profile</b>	
Viral risks	<p>A high number of blood donors are asymptomatic carriers of viruses that are very widespread in the general population and are not systematically searched for in blood products. The risk is mainly for immune-depressed blood transfusion recipients who can develop severe conditions after primary infection by these viral agents through transfusion (9).</p>
Febrile non-haemolytic transfusion reaction (FNHTR)	<p>FNHTR is one of the most common complications of transfusion, but is normally not severe. In 2009, 1508 FNHTRs were reported (25.6% of all RARs) (6).</p>
Allergic reactions	<p>Allergic reactions represented 23.1% of all transfusion events reported to the haemovigilance network in 2009 (6). Most patients respond well to treatment (9).</p>
Transfusion-associated cardiac overload (TACO)	<p>In 2009, 267 TACOs were reported (4.5% of the RARs) (6). TACO was the most common cause of transfusion-related death between 2000 and 2004 in France (9).</p>
Transfusion-associated acute lung injury (TRALI)	<p>In 2009, 42 TRALIs were diagnosed (6). Reporting of TRALIs was introduced in September 2001, but the filing procedure appears to be still insufficiently understood by clinicians (9).</p>
Graft-versus-host disease (GVHD)	<p>No case of GVHD has been reported to the haemovigilance network (9).</p>
Immunological incompatibility	<p>A total of 316 immunological incompatibilities were reported in 2009, representing 5.4% of all RARs (6).</p>
<b>Risks mostly linked to the organization of health care</b>	
Risks linked to identification errors	<ul style="list-style-type: none"> <li>• Blood component ABO incompatibility very often results from an error in transfusion practice. Eleven ABO incompatibilities were reported in 2009, representing 0.2% of the total number of RARs (6).</li> <li>• Errors in identity control have been reported in 60% of grade 0 incidents (that is, an inappropriate blood transfusion due to one or several failures without immediate clinical or biological consequences for the recipient).</li> <li>• The biological test failed in 6% of cases (9).</li> </ul>
Delay and/or defect in transfusion	<p>Problems of delay and defect in blood transfusion mainly result from:</p> <ul style="list-style-type: none"> <li>• a lack of awareness by health authorities and blood transfusion settings</li> <li>• organizational malfunctioning in the availability and transportation of blood products</li> <li>• the absence of systematic assessment of transfusion-related emergencies (9).</li> </ul>

**Fig. 4.4. Distribution of adverse reactions, 2009**

Patient safety activities in France were mainly implemented after the HIV blood-contamination crisis (contaminated blood was administered to people with haemophilia during the 1980s). This highlighted the failure of safety culture and barriers designed to protect individuals and the system from errors at all levels of the health care supply chain. Consequently, patient safety activities became product-oriented and politically driven through numerous laws. The AFSSAPS was created in 1998 to evaluate and manage the security, quality and efficacy of health care products, provide surveillance and health care product safety recommendations and disseminate alerts. Fig. 4.5 shows the different institutes involved in patient safety in France.

The EFS and Haute Autorité de Santé (HAS) [National Authority for Health] reinforced their cooperation on 26 May 2010 by means of an agreement that formalizes sharing of knowledge to improve transfusion safety.

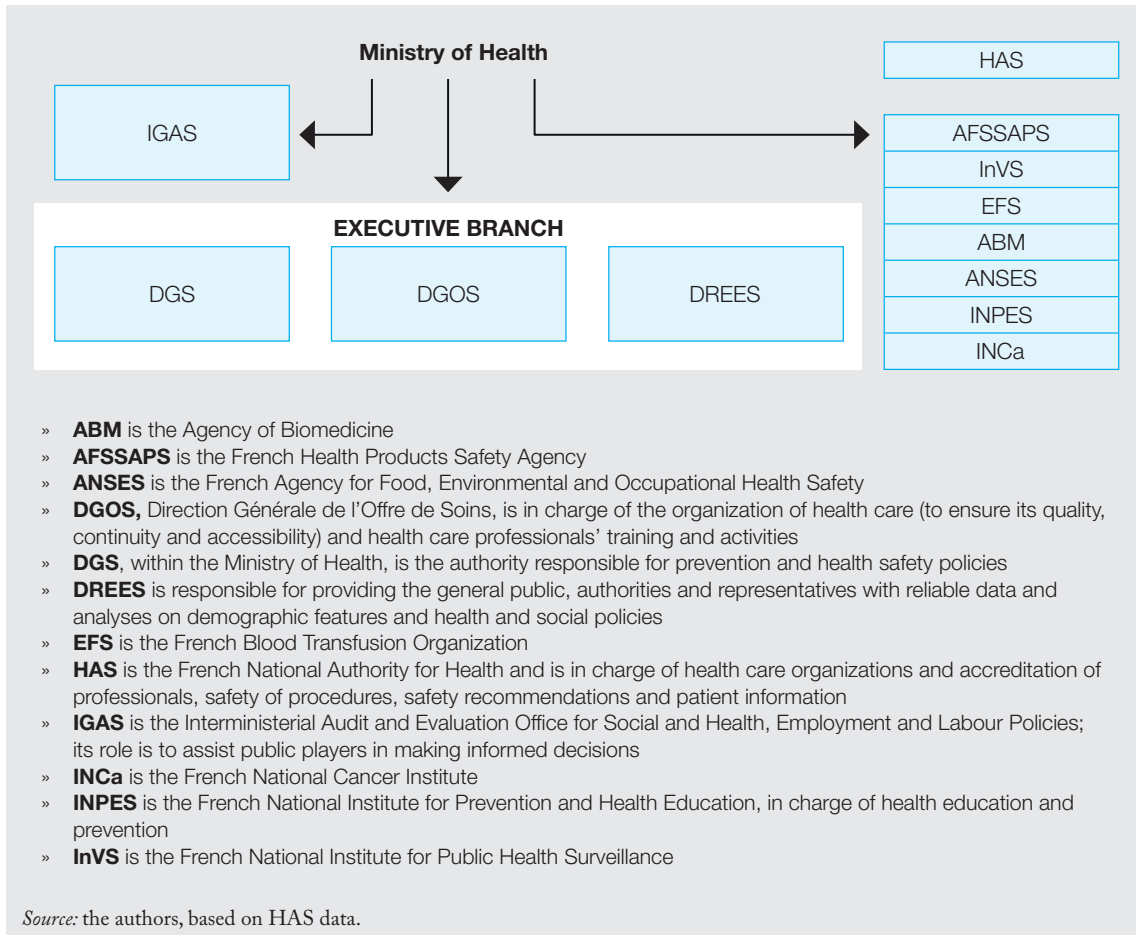
#### The “year of patients and their rights”

The official “year of patients and their rights” in France was 2011. The initiative originated from political will, sensitized to the existing gap between legal requirements and the practical reality of patients’ rights. It aimed to give more visibility to patients’ rights and safety and quality of services, and to facilitate the development of technologies. The idea was also to support patients’ organizations in their efforts to encourage patients to be more involved in their own care.

Reports published to mark the year highlight four key elements that must be present to guarantee patients’ rights and their place in the health system:

- » health care professionals’ involvement in promoting patients’ rights
- » particular vigilance with respect to new technologies and new health care modalities
- » the promotion of transparency in health care supply
- » the promotion of health democracy.

Concrete responses, such as a project on promoting patients’ rights and initiation of work on health democracy, were put in place. The new national health conference

**Fig. 4.5. Patient safety in France**

body was set up, chaired by a representative of patients' organizations, with the aim of influencing decision-making and policy-making processes, and a new health information web site is being developed.

It is worth noting that patients' common rights, including informed consent, provision of information and access to medical records, also apply to blood transfusion.

#### Transfusion and haemovigilance organization in France

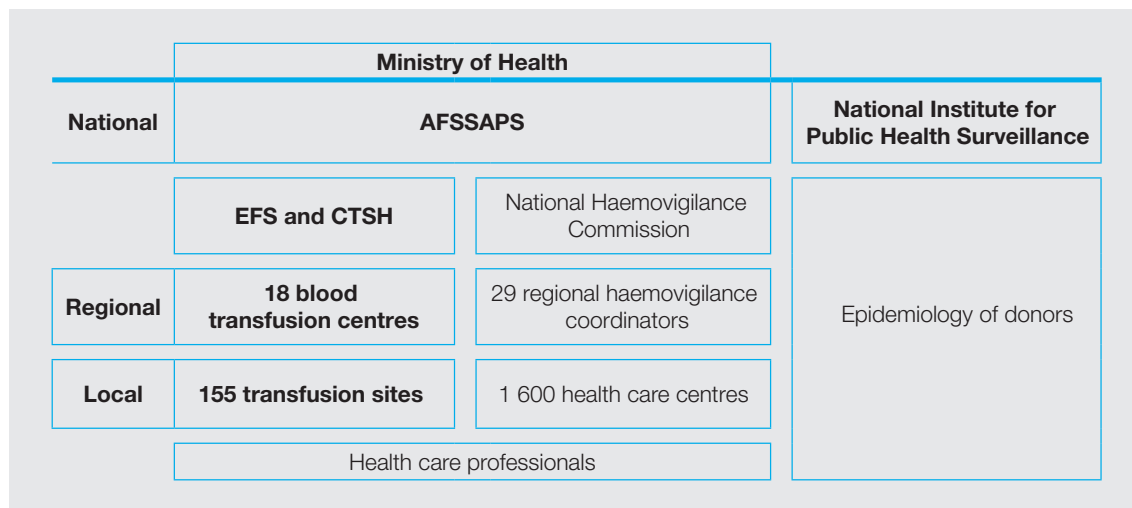
The overall goal of haemovigilance is to increase the safety and quality of blood transfusion (Article R1221-22). According to Decree No. 2006-99 (1 February 2006) relating to the blood transfusion centres and haemovigilance and modifying the Public Health Code (Article R1221-24), the national haemovigilance system consists of:

- » AFSSAPS;
- » National Haemovigilance Commission;
- » regional haemovigilance coordinators (mentioned in Article R1221-32);
- » EFS and the CTSA;
- » National Institute for Public Health Surveillance; and
- » health care facilities and armed forces hospitals (haemovigilance correspondents), transfusion safety and haemovigilance committees or facility medical commission

subcommissions; under Article R1221-43, a haemovigilance correspondent in each health facility must declare all adverse reactions in transfusion recipients and serious transfusion incidents and collect information mentioned in articles R1221-40 and R1221-2.

A simplified depiction of the transfusion and haemovigilance system at national, regional and local levels is shown in Fig. 4.6 (6).

**Fig. 4.6. Organization of transfusion and haemovigilance in France**



The transfusion safety and haemovigilance committees, created in 1994, are responsible for improving transfusion safety through research and consequent recommendations. Their duties at local level are to improve safety for transfused patients, monitor the application of haemovigilance regulations and manage the training of staff members dealing with blood transfusion processes (10).

Any health care professional who observes or becomes aware of an adverse effect or a serious incident must report it within eight hours. Analysis of haemovigilance data is carried out at national level.

## Regulatory aspects and legal tools supporting patient safety and the right to safety in France

### *List of official legislative documents*

Law No. 2002-303<sup>8</sup> on patients' rights and quality of the health system came into force in 2002. This law gives the right to every hospitalized individual over 18 years of age to name a trustworthy person who will back them during their stay and defines the right for patients to access their medical records. In relation to blood transfusion, the 11 January 2006 bill<sup>9</sup> (repealed on 1 October 2006) abolished the systematization of pre- and post-serological transfusion checks on LBP recipients.

8 Loi No. 2002-303 du 4 Mars 2002; see the list of legislation at the end of this chapter.

9 Circulaire DGS/DHOS/SD3/2006/11 du 11 Janvier 2006.

### Haemovigilance

Article R1221-27 of the Public Health Code (8) states that AFSSAPS should produce an annual summary report on haemovigilance, which has to be adopted by the National Haemovigilance Commission.

European Commission Directive 2004/33/EC (11) stated the need to increase donors' awareness about the importance of post-donation information (PDI). This necessity is reflected in the Decree of 1 February 2006<sup>10</sup> on haemovigilance: any information likely to compromise the quality and safety of the LBP must be declared. A document describing the basics of good transfusion practices<sup>11</sup> specifies that a post-donation document should be given to the donor with a phone number to call to provide any relevant information. The decision published in December 2010<sup>12</sup> establishes the form, content and terms for transmitting the serious incident declaration. A similar decision about adverse reactions occurring among blood recipients was made public in January 2007.<sup>13</sup> A 2003 bill<sup>14</sup> sets out the correct behaviour in the case of a suspected transfusion incident by bacterial contamination.

### Patients' rights

Providing information to patients about their health is obligatory under Article R1112-2. The patient has to be informed by the prescriber when possible and before the transfusion.<sup>15</sup> The patient's informed consent has to be obtained by the doctor before the transfusion procedure (8,12).

Article L1111-4 of the Public Health Code (8) stipulates the following points:

- » physicians must respect a patient's will after informing them about the consequences of their choices;
- » when the patient is not able to express a decision, no intervention can be carried out without the family or legal guardian's agreement, except in emergency cases; and
- » consent of individuals who are either under 18 years or are under the responsibility of a guardian has to be sought consistently, whenever possible.

Patients can access their medical records (Article L1111-7) and consequently the list of transfusion procedures they have undergone (Article R1112-2). Any patient who has received a LBP should be informed of this in writing during their stay (Article R1112-5).

### ***Patient information on blood transfusion: the prescriber's legal obligations***

Informing the patient about blood transfusion is a legal obligation under the Law of 4 March 2002.<sup>16</sup> Information is given by the prescribing doctor to the greatest extent possible before the transfusion procedure.<sup>15</sup> The French Society of Anaesthesia and Intensive Care

10 Décret No. 2006-99 du 1er Février 2006.

11 Décision du 6 Novembre 2006.

12 Décision du 24 Décembre 2010.

13 Décision du 5 Janvier 2007.

14 Circulaire DGS/DHOS/AFSSAPS n° 2003-581 du 15 Décembre 2003.

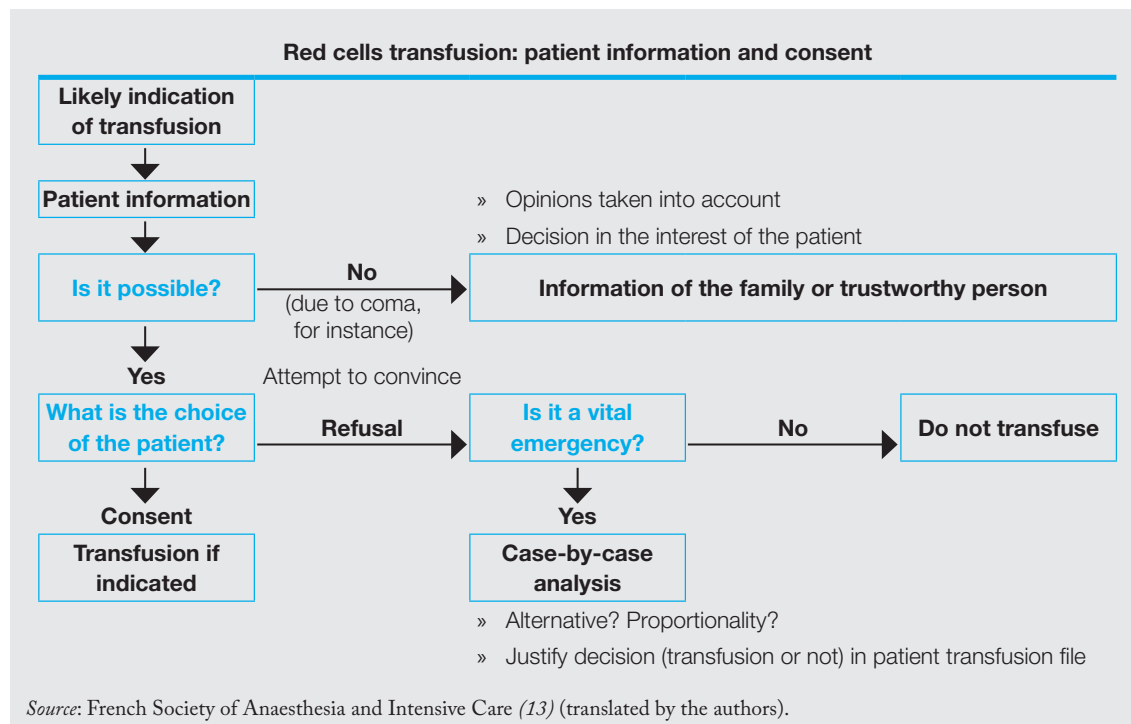
15 Circulaire DGS/DHOS/AFSSAPS n° 2003-582 du 15 Janvier 2003.

16 Loi No. 2002-303 du 4 Mars 2002.



has published on its web site a decision tree (Fig. 4.7) to guide anaesthetists on the process of informing patients about blood transfusion (13).

**Fig. 4.7. Decision-making tree to guide anaesthetists**



#### Legal content relating to information given to transfused patients

According to French law,<sup>17</sup> patients must be informed about the nature of the treatment to be administered and about confirmed and potential risks. Hergon et al. further describe the legal content of information that is to be given to patients at different stages of the blood transfusion procedure. Pre-transfusion information for patients should include “the idea of the necessity of the use of transfusion treatment due to the patient’s clinical and/or biological state and [on] immuno-haematologic tests necessary for the transfusion; adverse effects linked to transfusion treatment, their frequency and the measures taken to avoid them” (14). Prescribers have been required to inform patients about severe risks since 1998,<sup>17</sup> including those that are exceptional and potential. Professionals are not obliged to inform patients about minor and rare risks (15).

Provision of post-transfusion information has also been made compulsory (Article R 710-2-7-1 of the Public Health Code (8)). This must include the quantity and nature of transfused blood products, a reminder of the importance of the post-transfusion test for irregular antibodies (DIA), and donor deferral (facultative). Post-transfusion serological tests have not been compulsory since 2006.<sup>18</sup>

17 Circulaire DGS/SQ\_4 n° 98-231 du 9 Avril 1998.

18 Circulaire DGS/DHOS/SD3/2006/11 du 11 Janvier 2006.

### The format of information given to patients

The law requires that both written and oral information be given to patients. A written information sheet has to be provided, with a copy retained in the patient's file.

The complementarity of written and oral information and the importance of combining them has been discussed in the literature. Written information's advantages in assisting patients to remember verbal information are highlighted by several authors (16). It also enables patients to reflect and allows traceability of the information provided (15). Written forms of information are more likely to be homogeneous and validated by specialist institutions.

Verbal information presents several additional advantages over written. Oral information is described as "the only way to personalize information, to adapt it to the individual's questions and to create a trustful environment" (16). A similar suggestion, particularly in relation to the importance of dialogue between patient and doctor, is posited by Hergon et al. (14). Wargon et al. (17) explain that written information accompanied by verbal information can facilitate patients' understanding.

Although written information has become compulsory by law, the written form is not systematically used by prescribers, who often express a preference for communicating verbally to allow them to adapt better to the needs of each patient.

## Patient information: the link between legislation, medical practice and recipients' safety

### *Methodology*

This section is based on the results of face-to-face interviews with experts.<sup>19</sup> General and specific questions were asked, depending on the expert. Permission to quote the experts was obtained and the transcripts of the interviews were sent to each expert for validation. A list of the main standardized questions asked is provided in Box 4.2.

#### *Box 4.2. List of questions asked during expert interviews*

- » Is there a consensus on the practice of blood transfusion?
- » How is pre-transfusion information given to patients?
- » Have guidelines been created to help health care professionals inform patients?
- » What training on patient information is given to health care professionals?
- » What is the role of the haemovigilance correspondent in this field?
- » How is post-transfusion follow up organized?
- » Do you believe that giving better information to patients could help in reducing adverse events?
- » Do you think it could be useful to inform a wider public about blood transfusion, rather than only informing patients before they are transfused?
- » Is the post-transfusion information sheet systematically given to patients after transfusion?
- » Do you think it could be beneficial for patients to become further involved in the blood transfusion process, and how do you think they could?
- » Do you think that further involvement of patients would only have a positive impact, or could it also have a negative impact on care?
- » What kind of information system is used in your health care centre to report adverse events? Does it work well?
- » How are relations with the EFS organized, particularly in relation to dealing with adverse events?

19 The interviews were conducted in French and transcriptions translated into English.

## *The heterogeneity of situations and practices*

### Context

As with any medical procedure, blood transfusion entails a degree of risk. Transfusion therapy in France is safe and reliable, but several assessments have shown that the quality of transfusion can vary due to inconsistencies in the practices of different actors. Causes of variability are diverse but include heterogeneity of knowledge and nonformalization of practices, organization and information systems development. These can lead to failures that generate potential risks for patients and underline the importance of implementing an ongoing process of quality improvement and risk containment (18). It is also important to implement rational methods to share efficient evaluation tools designed to improve transfusion-related security.

### Heterogeneity of knowledge and know-how

A 2006 multicentre study based on 14 state-run hospitals concluded that medical staff had inadequate knowledge of blood transfusion. Results were drawn from the analysis of 694 questionnaires including various transfusion topics, and the situation was acknowledged by the medical staff involved (19). The rate of correct answers ranged from 47% to 78% for 7 of the 9 essential safety questions, and 9% of wrong answers related to the interpretation of final bedside compatibility tests (indicating incompatible blood and therefore invalidating transfusion).

According to Fialon et al. (20), pre- and post-transfusion testing<sup>20</sup> are still insufficiently implemented and control tests are not always carried out. This could result in patients being insufficiently or not informed of check-up results and about blood transfusion.

Heterogeneity of practice and knowledge around pre- and post-transfusion follow up was also highlighted by the experts. For instance, the DIA return rate was generally low and variable (usually less than 25%) and there was no real consensus about the utility of this test which, while recommended by law, is not compulsory. Differences between recommendations and reality were also highlighted in relation to transfusion thresholds: “AFSSAPS recommendations for blood transfusion procedure are followed but there is a tendency in the hospital to transfuse from a lower threshold than recommended” (Expert 7).

Participative action linking health care services and transfusion services has been undertaken to reduce the variability of practices. For instance, since the creation of regional health agencies, regional haemovigilance coordinators have provided expertise on how to improve transfusion safety for patients and organize a coordinators’ network-wide day for haemovigilance annually. Nearly all experts identified the need to further involve general practitioners (GPs) in transfusion follow up.

Experts believed that television documentaries on blood transfusion should be made to show progress in relation to safety and existing risks.

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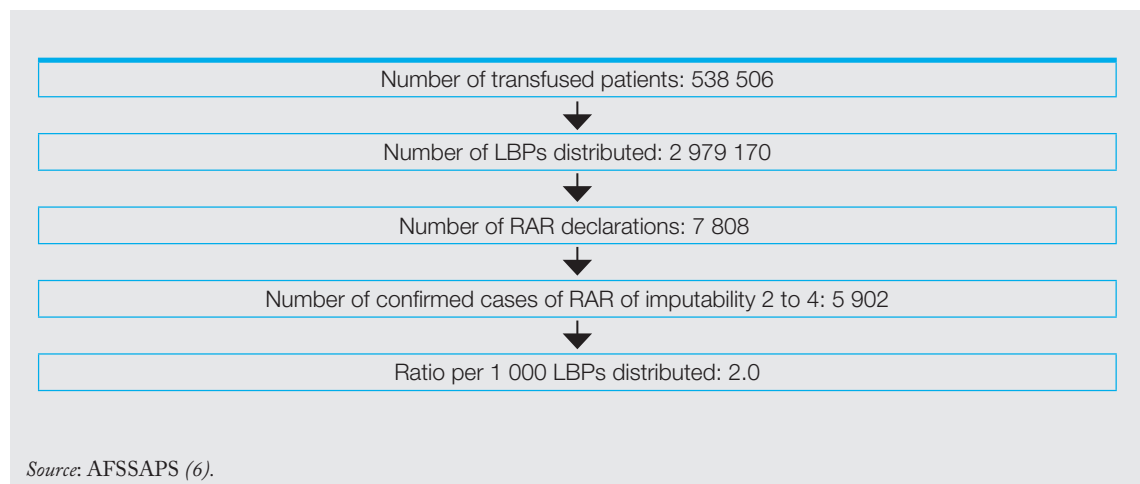
20 Circulaire DGS/DHOS/SD3/2006/11 du 11 Janvier 2006.

### Information system

Rieux & Nguyen (21) suggest the allocation of human resources to haemovigilance varies depending on the hospital. In everyday practice, haemovigilance correspondents in hospitals are often compelled to carry out activities beyond their scope (notably transfusion safety activities).

Health care facilities' haemovigilance correspondents have been able to declare RARs directly via an electronic system (Fig. 4.8) since 2004: there were 271 such declarations in 2009, constituting 60% of all RARs from the dedicated electronic database (6).

**Fig. 4.8. Number of health facilities declaring at least one transfusion adverse event through the established declaration process, 2000–2009**



Huge efforts have been made to computerize transfusion files, despite difficulties, but outcomes remain highly variable. Securing the improvement and computerization of data exchange between the EFS and hospitals constitutes a priority for the haemovigilance network. Haemovigilance correspondents should have access to all the information they need in the transfusion chain (21). It is also important to define the number and nature of undeclared adverse events.

Another important limitation of haemovigilance systems is the difficulty associated with capturing information on transfusion-transmitted infections that have prolonged latency periods. New strategies need to be developed to try to capture comprehensively this type of adverse event (22). The development and systematization of medical information is probably a key element for users' participation in health care systems, as it can give individuals the means to express their preferences and to negotiate their own care pathway (with the health care organization and with their GP) (23).

Management of PDI is also of vital importance in blood safety. PDI comprises any information about the donor declared or discovered after a donation that can affect recipient safety or the quality of the LBP. In 2009, 14 809 LBPs were destroyed following PDI reports indicating problems with the blood donor. The number of PDI declarations has multiplied five-fold since 2003, reaching 1295 in 2009. The rate of

declaration reached to date is 3.9 per 10 000 samples. The information covered includes transmissible disease markers, risky donor behaviour, clinical or biological anomalies, and nonconventional transmissible agent transmission risks.

The declaration of certain donor-related information obtained after donation is not regulated but is covered by an agreement between the AFSSAPS, the French blood agency and CTSA. The recommended deadline varies from 48 hours to 15 days after obtaining the information. The declaration is only submitted to the AFSSAPS if the LBPs from the donations in question have left the blood agency.

Traceability enables the link between the delivered LBP and the recipient, while preserving the confidentiality of the donor and the medical anonymity of the recipient. In the case of adverse events, the investigation moves in an “upstream” direction through the different steps of the transfusion chain, identifying potential causes and taking corrective measures.

### ***The crucial role of information: theoretical aspects***

Context: a strong social request for information

Information is ubiquitous nowadays, triggering what Lienhart & De Traverse (16) have described as a “strong request” for information from the public. According to Expert 13, the Head of the School of International Languages, Literatures and Cultures, patients want increasingly more information. Thieblemont et al. (24) talk about a “new exigency for information” and associate this movement with the development of information technologies and the abundance of medical web sites. What is missing in this abundance of sources, however, is information that is reliable and referenced (Expert 10).

The role of information in the evolution of the patient–doctor relationship

According to Noirez (25), information can have two very different goals: to legally protect medical doctors in a medico-legal context, and to involve patients in their care decisions. Informing patients is a fundamental step in this direction: for Ghadi (26), informing patients is “a way to respect their autonomy and dignity”.

The growing importance of information has progressively transformed the relationship between patient and doctor. Critical thinking about medicine has developed within the general public, leading health authorities to start considering patient participation in therapeutic decisions with doctors, who hold medical knowledge and legal responsibility. The evolution of the patient–doctor relationship and the decline of what was known as the “paternalist model” have mainly been triggered by the increasing role of information in society. According to Ghadi (26), the active involvement of patients in their care is a necessary condition of a truly trustful relationship with health care professionals and the health care system. Further patient engagement in health care is strongly supported by patients’ organizations.

Adapting information given to patients

A study carried out in 2002 (17) which assessed patients’ understanding of information on transfusion and related risks showed a gap between their perception and the actual

level of understanding of the information provided, although the value of written documents was confirmed.

Experts identified several barriers to patient understanding, including language (experts 1 and 9). This problem has begun to be addressed in Bichat University Hospital by translating the information sheet into six different languages. The issue of vocabulary in the information sheets was also cited by Expert 14. Patient information files have been suggested,<sup>21</sup> but these are not synchronized between hospitals are often created in medical academic settings or directly by the haemovigilance unit or hospital administration staff. Experts 11 and 15 described the format of information tools given to patients as being similar to medico-legal documents, which are legally competent but not specifically designed to communicate with patients. Expert 6 stated that in his university hospital, a decision was made to create an information file focused more on security than on risk, with the objective of “humanizing” the information.

Medical information needs to be adapted to the patient’s profile and given at the right moment to enable patient autonomy (25). The way risks are presented by doctors can affect the decisions patients make (24). Thieblemont et al. underline the need for doctors to be aware of the issues individuals refer to when evaluating risks and adapt the information accordingly. Several experts pointed out the fact that information on blood transfusion given at the same time as the diagnosis is often not remembered by the patient. It is necessary to balance the information given to patients so it is understandable and adequately quantified, without creating stress or overload for them (experts 1, 3 and 6).

As recalled by Noirez (25) and by several experts (3, 15, 6 and 11), patients sometimes prefer to rely on doctors to make final decisions and do not want to be informed. This choice should be respected, in the light of the core duty of doctors to protect their patients. According to Expert 3: “There needs to be a balance between giving patients the opportunity to get involved in their care and letting them rely on doctors if they want to”.

#### Availability of information to patients

The expert interviews highlighted the rates of information-giving on blood transfusion. Provision of pre-transfusion information appeared to vary from 0% to 94% in the examples provided.

An unpublished study carried out in Nantes University Hospital on health care professional knowledge showed that 94% of prescribers informed the patient every time a transfusion was carried out, but only 40% checked that written information had been given (Expert 6).

A study conducted in 2003 disclosed that 14 recipients out of 29 did not know they were being transfused, and 9 responded that they had been given an information card (18). Only 31% confirmed that they had received the pre-transfusion information document.

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21 Circulaire DGS/SQ.4 n° 98-231 du 9 Avril 1998.



Although the global trend of patient information delivery is quite low, practices differ between care settings. Expert 12 provided some detail on these differences: “Information is given in a more systematic way (up to 80%) in private hospitals for planned surgeries. In public hospitals, overall information is provided less, even though information given in a preoperative setting by anaesthetists is more systematic. Post-transfusion information is not sufficient, except for paediatrics and haematology units.”

Most of the experts stated that general transfusion information given to patients is to some extent not adapted to their needs. Several obstacles hindering efficient patient–provider communication and information must therefore be addressed, such as:

- » lack of time (experts 1, 3, 11)
- » health care professionals’ work overload (Expert 1)
- » medical doctors’ difficulty in talking about risks (Expert 15)
- » ignorance over the responsibility to inform (Expert 9)
- » lack of financial and human resources (Expert 14)
- » lack of training (Expert 14).

Expert 6 explained that “health care professionals should learn how to inform better and to adapt information, which otherwise could lead to stress”.

Expert interviews revealed differences in the training of nurses and medical doctors in the field of patient information applied to blood transfusion. Nurses appear to be trained on the modalities of patient information in this field, while this is automatically considered “part of doctors’ culture to inform patients about each medical procedure” (experts 2, 6 and 7). While interns are reminded of the importance of providing information to patients before starting practice (Expert 3), it appears to be difficult to train doctors on this issue and it is not considered a priority (Expert 9). Consequently, doctors tend to adopt an approach largely focused on pathology rather than on the individual (experts 8 and 13). The need to enhance doctors’ training on the modalities of information provision to patients (experts 6 and 12) and on the relational aspects of care was highlighted by several experts. Thieblemont et al. (24) support the idea that training for doctors on the communication of risks to patients should be developed.

Such initiatives are already being developed and/or implemented locally, with guidelines on patient communication (Expert 6) and conferences and meetings (mostly directed at anaesthetists and haematologists (experts 7 and 9)) being introduced to fill identified gaps. Provision of information to patients will soon become a compulsory part of medical doctors’ curriculum (Expert 4).

#### Suggestions to improve information provided to patients

An innovative approach to compiling and providing information to patients is needed. This would imply starting with patients’ needs (patient centredness), coproducing the information (which can be shared with all actors in the health care chain) and encouraging patients to become involved in their care. Information tools need to be validated by users (Expert 10). Coproduction of information tools with patients’ organizations, health care professionals and patients (experts 10, 8, 14 and 11) seems

to be fundamental to improving the development, use and understanding of these documents by all actors. To create a good information tool for patients, it is necessary to meet those who have received a blood transfusion, see the documents they received, evaluate their knowledge and investigate the problems/information presented to them. Only after such an assessment can a useful tool start to be (co)produced (Expert 8).

Experts made several suggestions for making patient information more appealing and efficient (Box 4.3). The need to renew information on blood transfusion given to patients is heightened by the fact that medical knowledge is evolving fast and blood transfusion is still associated with fear by some patients.

#### *Box 4.3. Experts' main suggestions to improve information on blood transfusion provided to patients*

*"Too much information kills information. What is important is to work on the impact of information, to catch people's attention" (Expert 11).*

- » General information on blood transfusion could be **broadcast through television** at the patient's bedside before receiving transfusion (Expert 11).
- » Use of **podcasts** or **videos** telling patients' stories (Expert 11).
- » **Documentaries** on blood transfusion should be made to show progress in the area of safety (Expert 1).
- » The **hospital orientation booklet** should state the idea that patients to be transfused must receive related information and, if not provided, they should ask for it (Expert 3).
- » A **public campaign** on questions over the safety of blood transfusion could be initiated (Expert 2).
- » The **Internet** can be used to inform about risks, treatment alternatives and medical procedures (Expert 14).
- » Educational and pictorial information on blood transfusion could be provided via the **Internet** (maybe as part of the EFS web site) using **short, informational films** (Expert 10).
- » A **web site** could be used to provide patients with stories from LPB recipients; various videos involving medical staff, EFS staff and patients; a list of frequently asked questions on blood transfusion; a forum, and so on (Expert 8).
- » The general public should be informed about blood transfusion via **blood donation organizations**.
- » Information could be given **at school**; children are a good way to transmit information (experts 9 and 12).
- » Focus should be placed on **human specificity of LBP**s and not only on risks, with blood transfusion being part of a human chain, from blood donation to transfusion (Expert 12).

### ***Patient involvement***

#### Context

Working with patients, giving them responsibilities and informing them of goals and strategies used could improve adherence, quality and safety of treatments and outcomes (27). Most of the adverse effects of blood transfusion are due to errors and suboptimal care during the transfusion process, and patients could play a significant role at this stage (2).

According to Expert 15, the French law dealing with modernization of the health care system introduced in 2002<sup>22</sup> put an end to medical paternalism. Patients have increasingly become able to question doctors and, as a consequence, public authorities have started to consider how patients could take part in medical decisions. The most involved patients are generally highly active in patients' organizations.

22 Loi No. 2002-303 du 4 Mars 2002.

However, patient engagement in their own care requires preparation, follow up and evaluation to ensure a balanced approach to improving patient safety, supported by constructive dialogue with health care providers. In other words, implementation of “health democracy” requires time.

#### Involving patients in their own care

Patients’ involvement in their own process of care depends on many individual and contextual factors, including age, level of education and pathology. Family history and cultural background, level of health literacy and emotional support are very important in the patient–doctor dialogue and directly affect the degree of active patient involvement in care. It seems important to understand the gap between “seeking information” and “getting involved”. Durand (27) adds that patients’ commitment will depend on their cognitive capacities, psychological state and what they hear from the message delivered by health care professionals. In addition, beliefs (linked to illness, the role of professionals and so on) play a significant role in the choices patients make. Language and understanding remain important barriers.

Better informed patients are more likely to be able to talk about treatment risks and to take care of themselves. Provision of general information by health care professionals is only the first step in patient involvement. In the blood transfusion process, different ways in which patients could get involved include (2):

- » giving informed consent to receive blood (information on risks, benefits and alternatives);
- » contributing to reducing identification errors, with active patient involvement in identity checks; and
- » reporting transfusion-related adverse events (immediate and delayed side-effects) – further involvement will enable patients to ask relevant questions and will lead to shared responsibilities and care decisions.

The expert interviews revealed various opinions, a common element of which was the fact that further involvement of patients would certainly have a positive effect on the outcomes of care and patient satisfaction (Box 4.4).

### **Case study – the example of one blood transfusion service: qualitative and quantitative interviews of recipients**

#### ***Method***

A questionnaire-based pilot survey (see Annex 2) was performed at the EFS centre in the city of Tours between 1 and 15 July 2011. The objectives were to evaluate the understanding of written and oral information on transfusion for a limited number of patients and to seek advice on enhancing communication and patient involvement in the transfusion process.

The questionnaire was distributed to transfused adult patients treated for chronic conditions in the chosen location and was completed on site. As a pilot survey,

**Box 4.4. Experts' main suggestions to increase patient involvement**

- **Identity verification**
  - » Patients need to be aware (and be informed) that they will be asked to repeat their name several times for safety reasons before and during transfusion.
  - » Patients will need to be made aware of the importance of maiden name (for women), married name and birth date as part of identity checks.
  - » Patients should ask health care professionals if their identity and suitability for the product to be transfused have been checked.
  - » Health care professionals should explain to patients the importance of the blood group card and encourage them to produce this card upon arrival at the hospital.
  - » Extended use of computerized tools is still being debated.
- **Listening to the patient**
  - » It is essential to establish if patients want to get involved in the process of their own care and to understand the reasons (positive and negative) for their choice.
  - » When possible, the fact that patients want (or do not want) to get involved in the process of their own care should be formalized.
- **Information and risks**
  - » Patients could get more involved by asking questions about the risks and benefits of transfusion, particularly about how to identify (post-)transfusion adverse events.
- **Health education**
  - » The development of health education will promote patients' involvement.
  - » It is necessary to inform the general population about the process of blood transfusion.
  - » It is essential to explain and document the progress made in enhancing the safety of transfusion treatment and clinical procedures to strengthen positive views.
- **Surveillance**
  - » Patients should be encouraged to participate in their own surveillance of undesirable side-effects; efforts should be sustained and scaled up to delay side-effects and post-transfusion adverse effects to minimize incidents.
- **Patients' organizations**
  - » Health care structures could help patients to identify organizations that bring transfused patients together and through which they can participate and benefit from additional support.
  - » Patient organization members and blood transfusion recipients should promote blood donation among their relatives and friends.
- **Social epidemiology**
  - » Research is needed to better understand the mechanisms of active patient involvement in reducing transfusion safety risks.

conclusions are restricted to this case study, and it is to be noted that not all questions were answered by all patients, which is reflected in the analysis.

***Descriptive analysis***

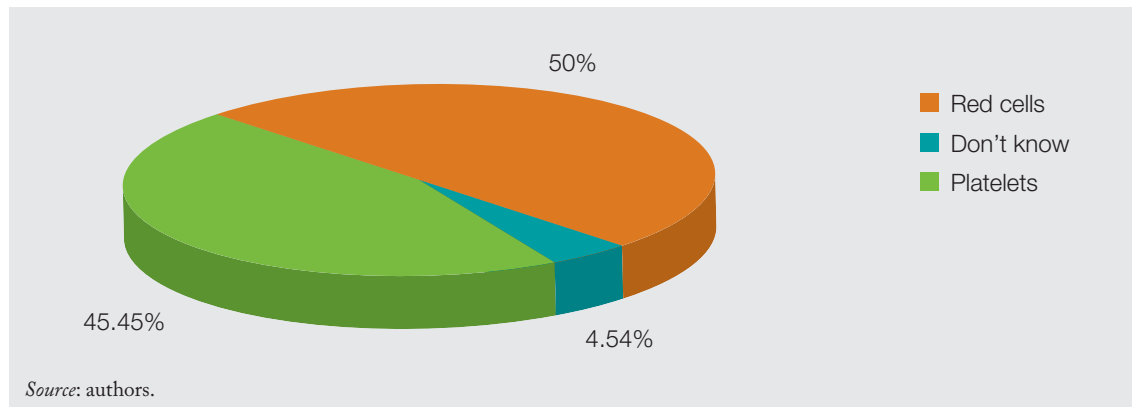
The questionnaire was answered by 24 patients (56.5% female and 43.5% male). One individual considered the questionnaire too difficult. The average age was 63.4 years, but only 47% answered the question relating to their age. All answered questions 3 and 4: 82.6% were hospitalized more than 3 times and 91.3% were transfused more than 3 times.

**Knowledge and blood transfusion process**

Almost 70% of patients did not know about their rights in the field of blood transfusion (question 5). Half thought that blood transfusion presented severe potential risks (question 6); 27% did not think it presented severe risks, and 23% did not know.

Nearly all patients knew why they have been transfused (only 2 missing values), but 4.5% did not know which blood component they had received (Fig. 4.9).

**Fig. 4.9. Patient responses to the question “Do you know with which blood component you have been transfused?”**



#### Patient information and satisfaction

Only 28.6% of respondents had been worried when informed that they would be given a blood transfusion and all of them stated that they trusted physicians to make transfusion decisions (questions 18 and 19).

Just over 57% were accompanied by a relative for their hospitalization, but 50% said that the relative had not helped them to understand information given on blood transfusion. Only 33.3% indicated that they received an information sheet before being discharged from hospital.

Only 24% (91% response rate) received written information on blood transfusion before being transfused (question 10); of these, all had read the information.

Fifty-nine per cent received oral information related to transfusion treatment, of whom 62.5% received it from a physician and 37.5% from a physician and nurse. Just over 69% considered the information to be sufficient. For those who considered the information insufficient, lack of information was related to risks linked to transfusion and to post-transfusion follow up. Twenty-four per cent received information on post-transfusion follow-up tests (question 8).

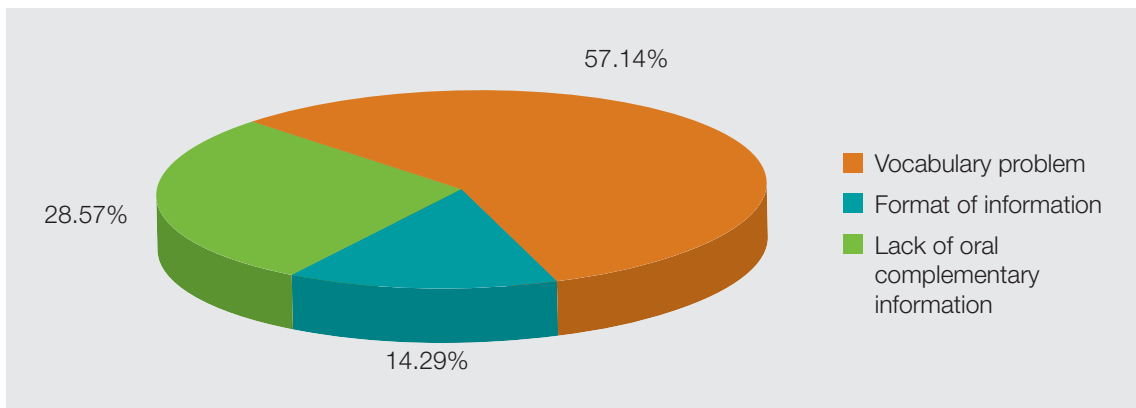
Among those who received information on transfusion, only 28% declared that they had difficulties understanding the information given. Cited difficulties mainly related to the vocabulary used (Fig. 4.10).

#### Respondents' feedback on information and involvement

Fifty-five per cent (78% response rate) highlighted the importance of oral information. Only 5% indicated their preference for both oral and written information.

Just under 90% considered it useful to give information on transfusion to a wider public than transfused patients only.

**Fig. 4.10. Reasons given for patients' difficulty understanding the information provided on their transfusion**



Only 47% showed an interest in increased involvement in their transfusion treatment. Fig. 4.11 indicates the level of preference for patients to being involved in their transfusion treatment.

**Fig. 4.11. Patients' degree of interest in being involved in their transfusion treatment**

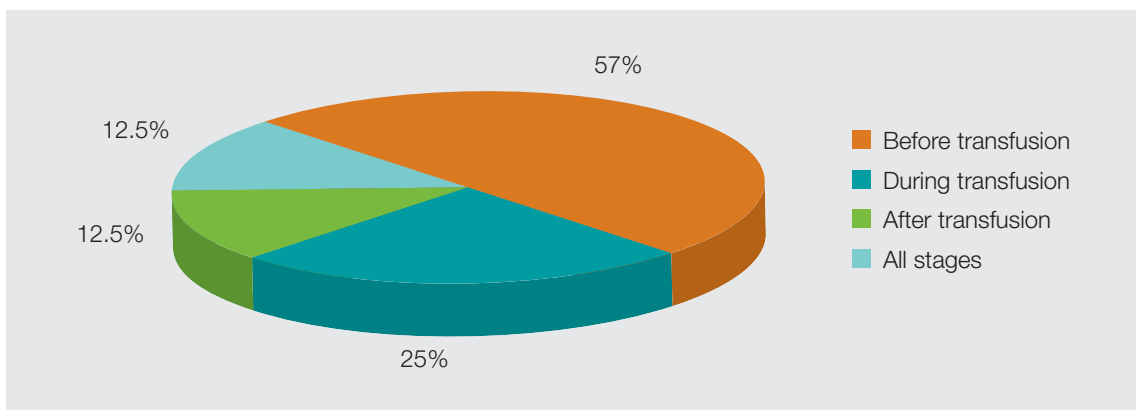


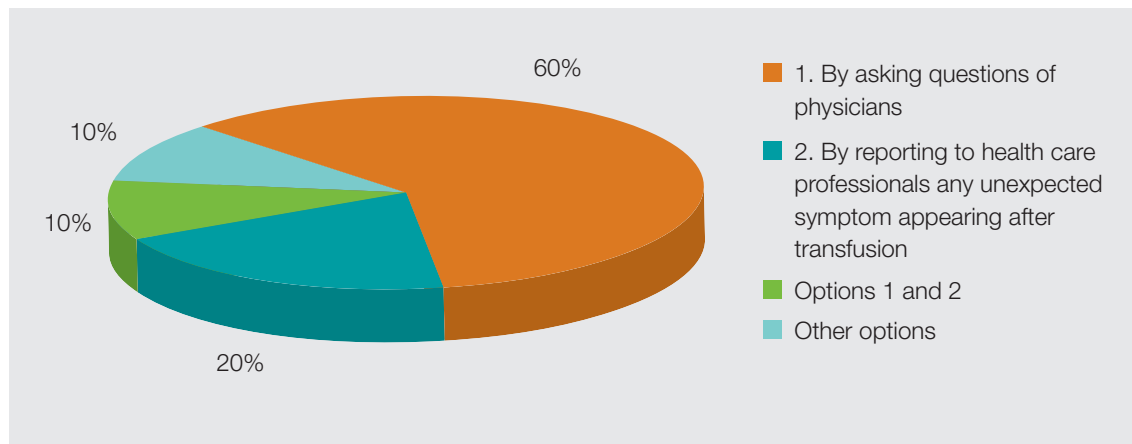
Fig. 4.12 shows patients' preferred methods of active involvement in their transfusion treatment, according to the respondents questioned in the pilot survey. The main methods identified were asking questions of physicians and reporting to health care professionals any unexpected symptom appearing after transfusion.

### Recommendations

Blood transfusion was highly publicized in France in the 1980s following the transmission of HIV to patients through contaminated blood products. The negative public image associated with blood transfusion was linked to a limited understanding of related safety challenges and the potential of system failure in blood transfusion organizations. The sector has recovered through a very formal and regulated process for collecting, processing, testing, monitoring, delivering and tracing blood products from the donor to the treated patient/recipient.

Emphasis was placed on product safety, aiming to ensure zero risk and 100% safety, particularly in terms of cross-match (compatibility) issues. Interaction with donors



**Fig. 4.12. Patients' response to the questions on how they would prefer to get involved**

and patients on the safety of blood products, both legal and medical, has centred on verifying and following closely the lack of microbiological transmission (post-donation and post-treatment seroconversion) and identity issues. Despite explicit regulations, safety and reliability of transfusion therapy in France can fluctuate due to variability of practices at delivery level. These can relate to the heterogeneity of knowledge, hospital organization, outdated and/or nonformalized practices, regional diversity, information system development and other factors.

Some aspects of blood safety have been less thoroughly explored, and there is relatively little emphasis placed on the potential role of the patient in improving transfusion safety. Patients are seldom involved in discussions on the need for transfusion treatment and the benefits and risks, apart from selected population groups refusing transfusion (Jehovah's Witnesses, for example) or patients with rare blood diseases who are in need of regular transfusion. At the same time, research shows considerable potential for the role of patients in enhancing safe transfusion practice.

The French Ministry of Health launched a special “year of patients and their rights” in 2011, giving political support and visibility to the need for increased patient safety and rights, including patients' involvement in their own health preservation and care. Recommendations to increase patient involvement were also made by the experts interviewed in this study (Box 4.4, Table 4.2).

***Recommendation 1 – Strengthen patient identity checks (and of the units to be transfused)***

The importance of individual identifiers such as maiden name (for women), married name and birth date should be properly understood as additional measures aiming to reduce the risk of failure. Patients need to be aware (and be informed) that they will be asked to give their name several times for security reasons before and during transfusion. They should be encouraged to ask health care professionals if their identity and suitability for the transfusion product have been checked.

***Recommendation 2 – Upgrade doctors' communication skills***

This could be achieved by rethinking communication on blood transfusion and upgrading doctors' knowledge through CME programmes dedicated to communication

Table 4.2. Experts' opinions on main themes of the questionnaire

Experts		Opinions on main themes														
		Haemato-oncologist	Anaesthetist	Anaesthetist and haemovigilance correspondent (private hospital)	Haemovigilance correspondent	Haemovigilance correspondent	Haemovigilance correspondent	Regional health centre, Ile de France	EFS	DGOS	Association de Soutien et D'Information à la Leucémie Lymphoïde Chronique et al Maladie de Waldenström	Association Française des Hémophiles	Communication adviser	EmPatient organization	Laboratoires Internationaux de Recherche	Association Le Lien
<b>General information on blood transfusion and haemovigilance</b>																
1. Blood transfusion procedure strictly follows recommendations			±	±	+	+	+	+								
2. Post-transfusion DIA rate is very low (% when available)			±	+	++	++	++	++	25%							
3. DIA return rate needs to be improved			±	-	±	±	±	±								
<b>Information given to patients and relationship between doctor and patient</b>																
1. Written information on blood transfusion is systematically given to patients			-	+	-	-	-	-								
2. Poor information rate is mostly due to time constraints			++		+	+	+	+								
3. Doctors need to be trained on information modalities			+	-	-	-	-	-								
4. The way information is given is somehow not adapted					+	+	+	+								
5. Patients have problems understanding given information			++		+	+	+	+								
6. Doctors see more information as a constraint and sometimes ignore their responsibility to inform			+		+	+	+	+								
<b>Information system</b>																
1. Patient's transfusion file is computerized			+	+					++							
2. Information exchange between health care facility and EFS is efficient					-	-	-	-	++							
3. Information system is working well					-	-	-	-	±							
4. Information system insufficiencies create important problems					++	++	++	++	±							
5. Information system needs to be further developed			++		++	++	++	++	+							
<b>Adverse events, reactions and incidents</b>																
1. Reporting system for adverse events and incidents works well			+	++	±	±	±	±	+							
2. Identification controls must be strengthened			++		++	++	++	++	++							
3. Identify error is a health care management issue				+	+	+	+	+	+							
3. Lack of culture of notifying about grade 0 incidents					++	++	++	++	+							
4. Identification wristbands should be developed					++	++	++	++	+							
5. It is sometimes hard to know which incidents require notification			+		+	+	+	+	+							
<b>Patient involvement means:</b>																
1. involving patients in identity checks			++	++	++	++	++	++	+							
2. participating in monitoring of side-effects				++	++	++	++	++	+							
3. asking questions				++	++	++	++	++	+							
4. a positive role/effect																
5. not everybody wants to get involved			+													
			++	++	++	++	++	++	++							

Notes: ++ strongly agree; + agree; ± neither agree nor disagree (nuance); - disagree; -- strongly disagree. Source: authors.

with patients. The key point is to listen to patients to understand whether they want to be involved or not. Where possible, the fact that the patient wants to be involved (or not) and/or to receive information (or not) should be formalized.

***Recommendation 3 – Develop information tools for patients with patients***

It is important to produce, adapt and standardize patient information tools with patients' involvement to ensure the tools can be used to the fullest extent possible. Barriers such as language, vocabulary and – last but not least – health literacy should be taken into account. Where possible, it is recommended that the process of patient involvement be formalized.

***Recommendation 4 – Educate patients***

It is necessary to inform the general population on how the transfusion process works and to explain progress made in the field as part of building a safety culture. The development of health education and chronic condition self-management will promote patients' involvement.

***Recommendation 5 – Engage patients in surveillance***

Participation of patients in their own surveillance of the transfusion process, related clinical procedures and potential undesirable side-effects of the transfusion treatment should be promoted. It is expected that this would help to reduce incidents and increase patients' confidence in their shared responsibility for their own health outcomes.

***Recommendation 6 – Promote patient organizations and peer groups***

Patient organizations could give additional voice and support to transfusion recipients and help in the process of increasing health literacy and public information campaigns. Health care providers should help patients to identify these organizations.

***Recommendation 7 – Study patients' attitudes***

Research is needed to better understand which patients are willing to get involved. This includes shared responsibility in the decision-making process and safety compliance, but also involvement in donor promotion campaigns among relatives, friends and communities.

A summary discussion of patient involvement in blood transfusion in the Netherlands is provided in Annex 3.

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### Related legislation

Article L1111-4 du Code de la Santé Publique.

Article L1111-7 du Code de la Santé Publique.

Article R1112-2 du Code de la Santé Publique.

Article R1112-5 du Code de la Santé Publique.

Article R1221-22 du Code de la Santé Publique.

Article R1221-24 du Code de la Santé Publique.

Article R1221-27 du Code de la Santé Publique.

Article R1221-40 à R1221-42 du Code de la Santé Publique.

Article R1223 du Code de la Santé Publique.

Article R710-2-7-1 du Code de la Santé Publique.

Circulaire DGS/SQ 4 n° 98-231 du 9 Avril 1998 relative à l'information des malades, en matière de risques liés aux produits sanguins labiles et aux médicaments dérivés du sang, et sur les différentes mesures de rappel effectuées sur ces produits sanguins.

Circulaire DGS/DHOS/SD3/2006/11 du 11 Janvier 2006 abrogeant la circulaire DGS/DH n° 609 du 1er Octobre 1996 relative aux analyses et tests pratiqués sur des receveurs de produits sanguins labiles.

Circulaire DGS/DHOS/AFSSAPS n°2003-581 du 15 Décembre 2003 relative aux recommandations concernant la conduite à tenir en cas de suspicion d'incident transfusionnel par contamination bactérienne.

Circulaire DGS/DHOS/AFSSAPS n° 2003-582 du 15 Janvier 2003 relative à la réalisation de l'acte transfusionnel.

Décret n° 2006-99 du 1er Février 2006 relatif à l'Établissement Français du sang et à l'hémovigilance.

Décision du 6 Novembre 2006 définissant les principes de bonnes pratiques prévus à l'article L. 1223-3 du Code de la Santé Publique.

Décision du 24 Décembre 2010 fixant la forme, le contenu et les modalités de transmission de la fiche de déclaration d'incident grave.

Décision du 5 Janvier 2007 fixant la forme, le contenu et les modalités de transmission de la fiche de déclaration d'effet indésirable survenu chez un receveur de produit sanguin labile.

Loi No. 98-535 du 1 Juillet 1998 relative au renforcement de la veille sanitaire et du contrôle de la sécurité sanitaire des produits destinés à l'homme.

Loi No. 2002-303 du 4 Mars 2002 relative aux droits des malades et à la qualité du système de santé.

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# CHAPTER 5.

## PATIENT SAFETY, RIGHTS AND MEDICATION SAFETY IN PRIMARY CARE IN POLAND

*Basia Kutryba, Jarosław Woron, Halina Kutaj-Wąsikowska, Andrzej Warunek*

### Introduction

Many studies focus on medication safety as one of the fundamental areas of patient safety. Adverse drug events (ADEs) are the most frequent type of adverse events. There is often confusion, however, between ADEs and adverse drug reactions (ADRs). They are defined, respectively, as follows:

- » ADE – every adverse event related to medicine use (pharmacotherapy); there is not necessarily a cause–effect relationship involved; and
- » ADR – every event has a cause–effect relationship resulting from medication use; the relationship between cause and effect can be determined as resulting directly from the medicine use – anaphylactic shock during penicillin administration, for example.

ADEs therefore include ADRs and other adverse events related to medication use, prescribing, storage and design.

Several national multicentre studies of adverse events in different countries reveal that between 6.3% and 12.9% of hospitalized patients suffer at least one adverse event during their admissions and that between 10.8% and 38.7% are caused by medicines. Between 30.3% and 47% of these ADEs appear to be consequences of medication errors and may therefore be considered to be preventable.

Available data show that the morbidity and mortality associated with medication errors in Europe are of a similar magnitude to those in the United States and other countries. The reported incidence of preventable ADEs in European hospitals ranges from 0.4% to 7.3% of all hospitalizations. European evidence on medication errors is presented in the following sections in the format of the different European studies on ADEs, but the review of the research literature shows that only a few studies are related to pharmacotherapy and the use of medicines in PHC.

These studies reveal that ADEs are mostly caused by errors in prescription and drug administration or lack of patient compliance and are probably more frequent than in hospital settings because drug consumption in PHC is greater, although data on this are scarce and fragmented.

The European research on preventable ADEs occurring in primary care and leading to hospital admissions has shown that between 0.9% and 4.7% of all hospital admissions

to internal medicine wards and ICUs are caused by medication errors. Many studies mention that the problem of medication safety is addressed by the CoE in its recommendation on management of patient safety and prevention of adverse events in health care (1), specifically in the section on “Medication safety – a specific strategy to promote patient safety”.

Most research in this area concentrates on the hospital sector, with the majority of studies on medication safety relating to tertiary hospital care and focusing on the process and design of care or on health care staff. As yet, not much international research relating to patient involvement in medication safety at different levels of care delivery has been carried out. Such studies tend to be widely dispersed, located within legislation, accreditation manuals, patient information leaflets and aids, and address patients’ rights to access their own medical records, to provide informed consent regarding medical treatment and diagnostics, to receive visitors or to make a phone call.

The aspects of patient safety rights at EU level do not appear to be addressed by EU-funded research projects focusing on quality strategies and performance at hospital level (Methods of Assessing Response to Quality Improvement Strategies (MARQuIS), Deepening our Understanding of Quality Improvement in Europe (DUQuE), or the European Network on Patient Safety (EUNeTPaS)). Patients’ rights and medication safety are not directly addressed in the European Council recommendation on patient safety, including the prevention and control of HAIs (2), nor in the European Parliament and Council directive on the application of patients’ rights in cross-border health care (3). The EU questionnaire on the transposition by Member States of measures in the directive relates mainly to the mutual recognition of prescriptions and refers to the legislation and not to medication safety and patients’ rights per se.

The two initiatives in which the National Centre for Quality Assurance was involved – the MARQuIS and EUNeTPaS projects – explored the hospital level. MARQuIS included patient interviews in three countries but, due to the project focus, questions related mostly to the quality and organization of care provided for foreign patients and did not refer to medication practices. The EUNeTPaS project provided a compendium outlining the implementation of “good medication safety practices in Europe”.

The DUQuE project addressed the problem of patient responsibility in managing their own health care through a patient experience survey for those admitted with acute myocardial infarction, hip fracture, stroke and in labour (childbirth). It interrogated understanding of the reasons for taking each medication and investigated whether the patient needed to receive help on reading instructions, pamphlets or other written material from the doctor or pharmacy.

Research related to patient and family involvement in the safety of their own care – which results in evidence that patient empowerment is a factor that contributes to safer care and less harm – is growing continuously, although it is not yet as extensive in central and eastern Europe as elsewhere. Even less visible are presentations of the needs and expectations and/or rights related to patients’ and families’ empowerment in medication practices at PHC level, including patients’ and providers’ views of safe

medication practices and how these relate to patients' rights in terms of enhancing the safety of their own care.

This contributes to the message that patients should be encouraged to take an active role in their treatment as a means of safeguarding themselves from possible harm. Providers should be educated on how to communicate with patients in an empowering way to involve them in care self-management through an active partnership, enabling them to become “lay experts” in relation to their own health care condition(s) and symptoms. Such statements position patients' needs at the centre of good medicine practices.

### Project description

The Polish study on patient safety rights and medication safety (see annexes 4 and 5) focused on the primary care level, mainly due to the fact that medication use at this level of care considerably exceeds the scale of medicine use at hospital level (4). Experience of participation in the MARQuIS and DUQuE international research projects on the quality of hospital care suggests using field-based methodology<sup>23</sup> for patient surveys might result in bias and low response rates. The study focused on exploring patient safety throughout the spectrum of patient–doctor communication on medicines, ADRs, polypharmacotherapy and drug interactions. Issues related to medicine prescribing, packaging and administration were not covered in the study due to organizational and time limitations.

### Content of this chapter

The chapter consists of the following elements:

- » a review of legislative documents and legal acts<sup>24</sup> and of the agendas and programmes of patients' organizations in Poland;
- » analysis of a focused pilot survey;
- » an overview from the specialist Regional Centre for Monitoring of Adverse Drug Reactions (RCMADR) in Kraków; and
- » conclusions and recommendations.

### Legal dimension and patient education

The review of binding legislation included an overview of the major acts regulating and overseeing the performance and delivery of care by doctors, nurses and midwives, pharmacists and health care organizations in relation to patients' rights and medicines safety at national and local levels. Existing legislation emphasizes the duty of providers (medical doctors and nurses) to deliver patient care according to up-to-date medical knowledge, with attention and respect. The Law on the Profession of Doctor and Dentist (regulating the principles for the medical profession) emphasizes in Article 31 the doctor's obligation to provide clear, understandable patient information about the

23 Field-based surveys are both interview and questionnaire based and therefore depend to a large extent on the competences of the operator.

24 Law on the Profession of Doctor and Dentist (5 December 1996, with amendments); Law on the Profession of Nurses and Midwives (5 July 1996, with amendments); Law on Pharmacy (6 September 2001, with amendments); Law on Patients' Rights and the Ombudsman of Patients' Rights (6 November 2008, with amendment); Law on Accreditation of Healthcare Institutions (6 November 2008).

state of health, diagnosis, suggested diagnostic methods and treatment, expected results and prognosis. The same regulatory aspects are formulated for nursing care. Article 45a states that the doctor is obliged to report ADRs to the National Bureau for Registration of Medicinal Products. There is a separate Ministry of Health regulation related to the standardized method of reporting and the design of the reporting formulary. The Law on the Profession of Nurses and Midwives lists the medicines a nurse (and a midwife) may administer to a patient without instruction by a doctor.

The Law on Pharmacy defines the content of the “summary of product characteristics”, including factors such as indications, dosage and method of administration, contraindications, drug interactions and ADRs. Article 86 states that hospital pharmacies must also participate in reporting ADRs to the National Bureau for Registration of Medicinal Products.

The Law on Patients’ Rights and the Ombudsman for Patients’ Rights lists the rights to obtain health care services in line with recent medical knowledge and receive information on the process of care, covering the principles listed in Article 31 of the Law on the Profession of Doctor and Dentist. Patients have the right to receive this information and, having obtained it, to comment and present their own viewpoint. They also have the right to obtain information about patients’ rights.

The Law on Accreditation regulates the process of accreditation of hospitals and primary care facilities. Accreditation programmes developed for these two levels of patient care address patients’ rights in medication safety by setting accreditation standards. Patients’ rights at both levels are therefore concurrent with those listed in the Law on Patients’ Rights and the Ombudsman of Patients’ Rights. The accreditation standards do not refer directly to patients’ rights in terms of medication safety, nor do they define the standardized content of a checklist or patient history.

The two main patient organizations –the Polish Patients Federation (5) and the Institute of Patients’ Rights and Health Education (6) – do not deal with medication safety and/or provide related patient education.

### **Focused pilot survey: “patient safety rights and medication safety”**

#### ***Methodology***

The survey was designed for the specific purposes of the study and focused on ADRs at PHC level. It covered 50 family physicians and 50 patients using PHC services. Respondents from both groups were located in five cities in southern Poland: Kraków, Wieliczka, Nowy Targ, Zakopane and Krzeszowice.

Inclusion criteria for participation in the patients’ survey (Annex 4) were continuous and repetitive pharmacotherapy (the use of at least one medication taken for a chronic disease). The pilot aimed to describe whether patient safety rights can influence and improve safe pharmacotherapy. Patients were asked to mark the appropriate response for each of the questions. From the group of 50 patients approached, 49 completed the survey.



The physicians were providing services within the public health care sector (with contracts with the public purchaser, the National Health Fund) and were randomly selected (Annex 5). The pilot aimed to discover whether safe medication practices were being used in everyday practice, including when prescribing new medication and during continuing patient medicine treatment. The response rate was 100%.

The pilot study was anonymized: respondents were assured information obtained would be used solely for the purpose of the pilot survey. The only personal features were respondents' gender and age, along with (in the doctors' survey) the degree of specialty.

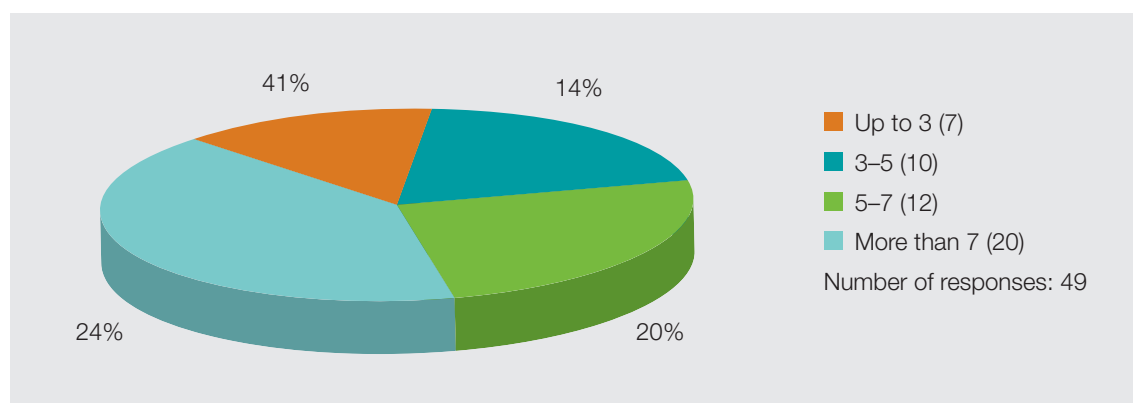
Both pilots consisted of 12 multiple choice and dichotomous questions. Collected data were stored in an SQL<sup>25</sup> database that enabled their distribution on simple pie and bar charts; however, more specific methods for data analysis were also used (histograms, cross analyses).

### *Results of the “patient” pilot*

All patients were subject to continuous and repetitive pharmacotherapy as a result of chronic disease and most were women (71%). The respondents were elderly, with an average age of just under 65 years (women 65.3 years; men 63.8).

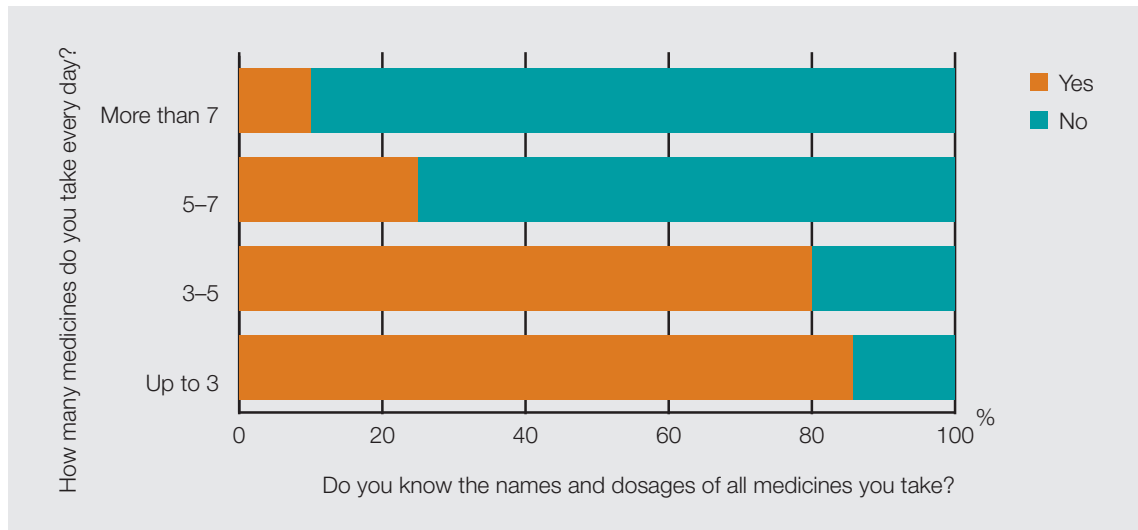
Regarding the number of medicines taken each day, 25% were taking from 5 to 7 and 41% over 7 (Fig. 5.1): 65.3% (62.8% of women and 71.4% of men) were therefore taking more than 5 medicines daily. Attention should be focused on these two groups of respondents, as there is evidence that pharmacotherapy consisting of 7 or more medicines taken in parallel always results in drug interactions. In addition, in the group of patients taking 5–7 medications, adding an over-the-counter (OTC) drug or a supplement to the medicines might contribute to the medicine–medicine and/or medicine–dietary supplement interaction.

**Fig. 5.1. Number of medicines per patient per day**



Only 39% of patients knew the names and dosages of the medicines taken (64% men and 60% women). Understanding of one's medicines – including their names and dosages – decreases with the number of medicines taken (Fig. 5.2).

25 Structured Query Language.

**Fig. 5.2. Relationship between patients' knowledge and the number of medicines taken**

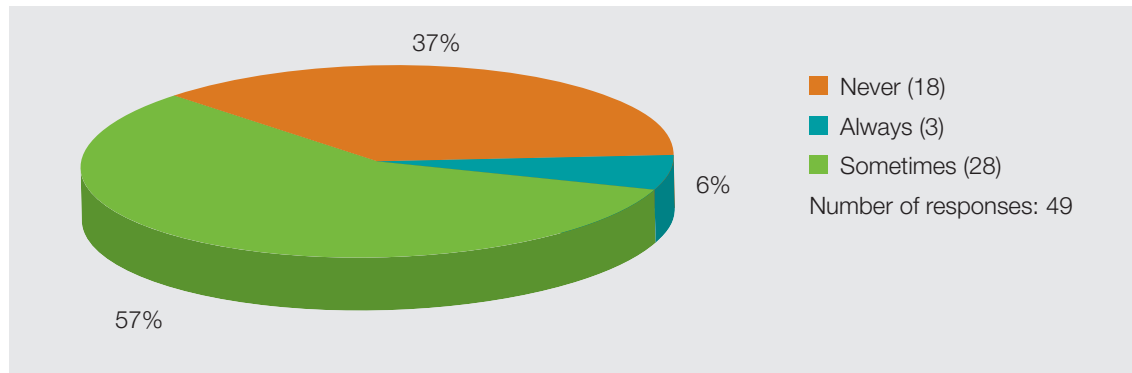
Almost two thirds said they discussed their medication during every visit to the doctor, but it is not known what aspects of pharmacotherapy were covered in these discussions (for example, does the patient obtain answers to all their questions, does the doctor provide clear and patient-friendly information and does the patient understand the answers?).

Regarding discussions about medicines taken, most (93%) claimed they, their family or an accompanying person initiated such conversations during medical visits. This clearly shows there are problems related to drug use that require explanation and clarification. Only 7% of respondents (all women) stated that conversations had been started by the physician, which indicates insufficient pharmacotherapy surveillance and monitoring by physicians and suggests that patients are rarely asked about ADRs. It seems that doctors mainly refer to the written information in the patient's file.

Only 6% of respondents stated that the doctor mentioned or discussed potential interactions related to the medicines being taken: 94% of patients may therefore not be aware that prescribed drugs might have interactions with other medicines or with OTC drugs and/or dietary supplement(s).

The survey results suggest that few doctors were interested in their patients' medication history. Only 6% of patients stated that their doctor always asked about medicines being taken before prescribing a new one (Fig. 5.3): over a third (37%) reported that it "never happens" and more than half (57%) that it was "sometimes" discussed. This implies that almost 40% of patients are at risk of adverse interactions, as the doctor – unless he or she has thoroughly consulted the patient's file and the recorded information is complete – will not be aware of which medicines have been taken recently and will not knowledgeably manage the risk of potential interactions.

Only one respondent indicated that the doctor asked about previous ADEs when prescribing a new medication. Over a third (37%) confirmed that this "sometimes" happened but 61% (30 respondents) claimed the doctor never asked about this.

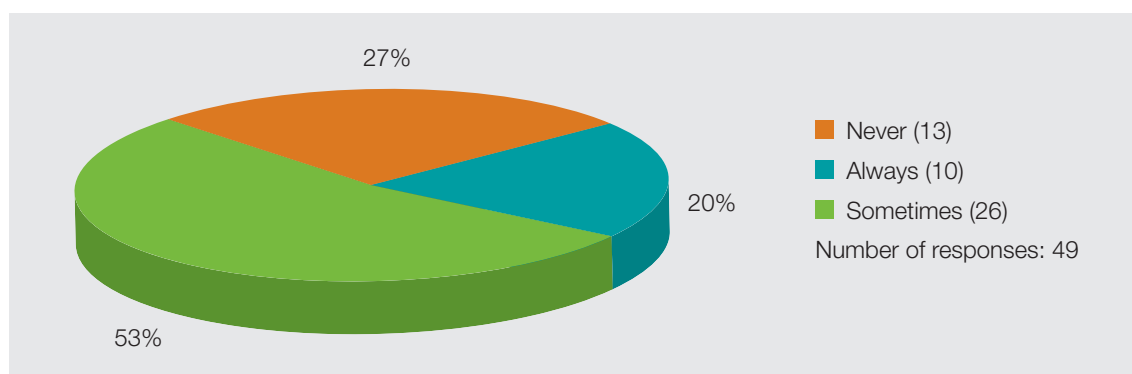
**Fig. 5.3. Frequency with which doctors inquire about medication history**

Twenty-six per cent confirmed that they had refrained from taking a prescribed medicine having learnt about contraindications from the medicine's information that the doctor had not mentioned.

Most respondents (82%) confirmed that they had experienced an ADR. This indicates the probability of pharmacotherapy not always being adequately monitored and not including the proper contraindications, limitations and risk of interactions. In light of previous findings related to doctors' lack of interest in patients' medicines history and experience of ADRs, this might be a result of limited interest, but could also be due to lack of time.

More than half of the patients (55%) stated that they had required treatment after experiencing an ADR. This might imply that patients' right to safe treatment is being compromised in an era of health care cost reductions.

Fig. 5.4 makes it clear that only 20% of patients stated they always asked about safety and potential drug interactions when buying OTC drugs and/or dietary supplements. Just over a quarter (27%) claimed they had never done so, and just over half (53%) confirmed that they "sometimes" did. Eighty per cent of respondents therefore seldom used potential sources of information about drug safety outside of the doctor's office. This might contribute to the level of pharmacotherapy complications.

**Fig. 5.4. Frequency with which patients ask about interactions between OTC and prescription medicines**

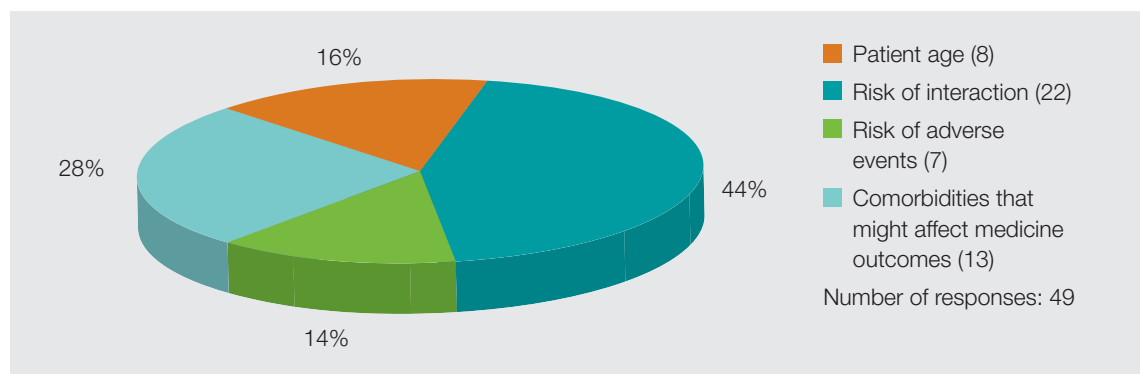
**Results of the “doctor” pilot**

Most of the 50 doctors<sup>26</sup> participating in this study (62%) had the highest level of specialization, and 22% had no specialty degree (general physician). Sixty-six per cent were females and the average age of respondents was 49 years.

All doctors (with the exception of one) indicated that they expected patients to provide detailed information about medications they were currently taking at the first visit. Eighty-two per cent expected the patient to present a list of medicines taken, with names and dosages. Although most doctors expected this, it is clear from patients’ informal comments that doctors seldom asked them to prepare such lists and, in most cases, the lists were created on the patients’ own initiative, reflecting the level of their health literacy. Such a discrepancy between the assessments of patient and doctor might reflect the perceived dimension of the doctor–patient dialogue in terms of medications, in which the doctor is likely to rely mainly on information in the patient’s file while the patient expects a different level of involvement.

The doctors were asked to list the most important factors to be considered in drug prescribing. It is worth noting that epidemiological data identify the possibility of avoiding approximately 30–40% of ADRs (7) if doctors acknowledge risk factors before prescribing. Results are presented in Fig. 5.5. The risk of interactions between medicines and dietary supplements taken simultaneously was listed as the most likely risk occurrence (44%). This is significant, as the background research shows that interactions between recently taken medications are the major contributing factors to ADRs. Existing comorbidities that can change the performance of the drugs taken already (26%) were indicated as next most likely.

**Fig. 5.5. Most important risk factors regarding drug prescribing, according to doctors**

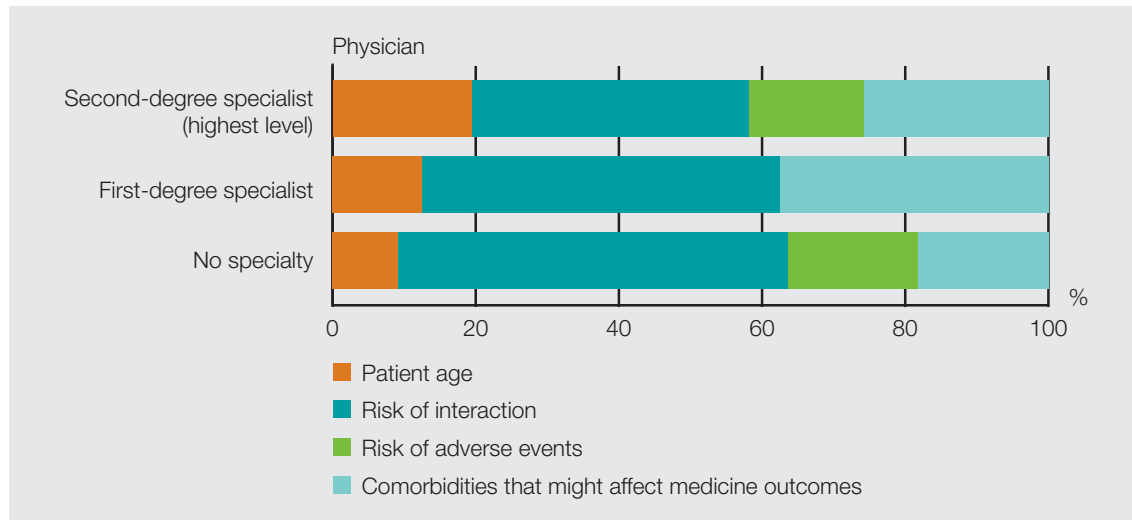


Only 16% indicated patient age as an important agent, despite it being generally understood that the process of ageing considerably affects pharmacokinetics of medicines and increases the risk of ADRs: 14% of respondents recognized the increasing risk of ADR in the elderly patient population.

<sup>26</sup> It is important to note that in Poland, medical doctors practising in PHC are GPs or paediatricians who have specialized in family medicine.

Fig. 5.6 shows a link between the degree of specialization and how much attention the doctor paid to the risk of drug interactions. Looking at this from the viewpoint of doctors' qualifications, those with no specialty degree indicated the risk of interaction as the major contributing factor when prescribing medicines; the highest (second-degree) category of specialists claimed to pay most attention to patient age.

**Fig. 5.6. Relationship between specialization and importance of risk factors**



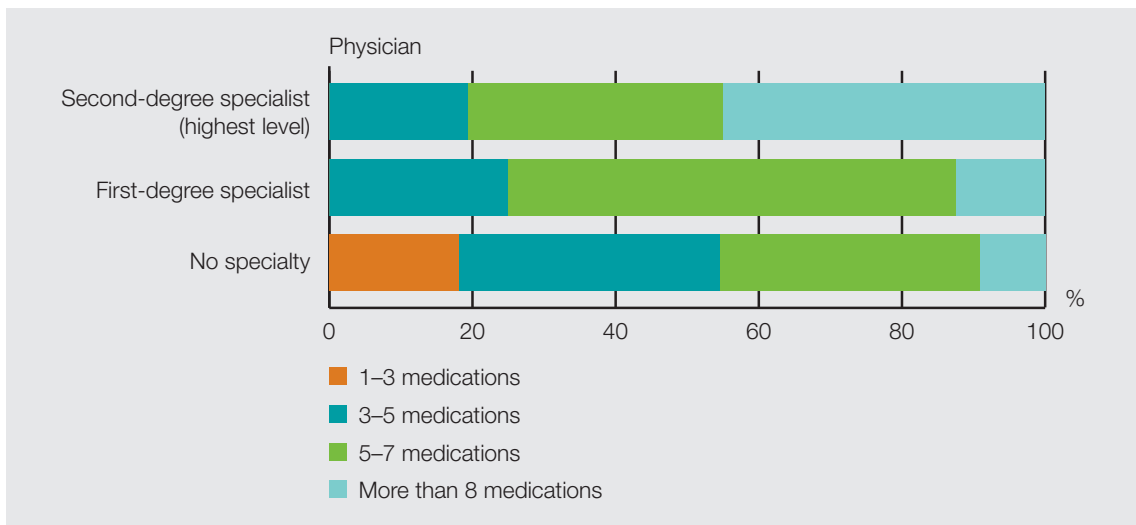
The majority of doctors (62%) stated that they do not ask patients about OTC drugs and diet supplements, which makes comprehensive risk assessment of drug interactions difficult. However, almost all doctors confirmed that they ask their patients about the names of the medicines they take – this prevents polypharmacy and drug interactions in polypharmacotherapy. The few negative responses to this line of questioning (6%) came from the doctors with no specialist degree.

When asked if they have treated patients for ADRs, 90% confirmed that they had seen patients experiencing ADRs due to OTC preparation use. This indicates the need for patient education on the boundaries of safe self-medication. Only doctors with the first or second degree of specialization claimed to have treated patients with ADRs resulting from supplements or herbal remedies.

Although 76% “sometimes” asked patients about their medications to establish the possibility of ADRs before prescribing a new medication, only 10% indicated that they had never asked. Only the second-degree specialists inquired about ADRs when prescribing a treatment, but all doctors regardless of specialty level (with one exception) claimed that they reflected on potential drug interactions when prescribing.

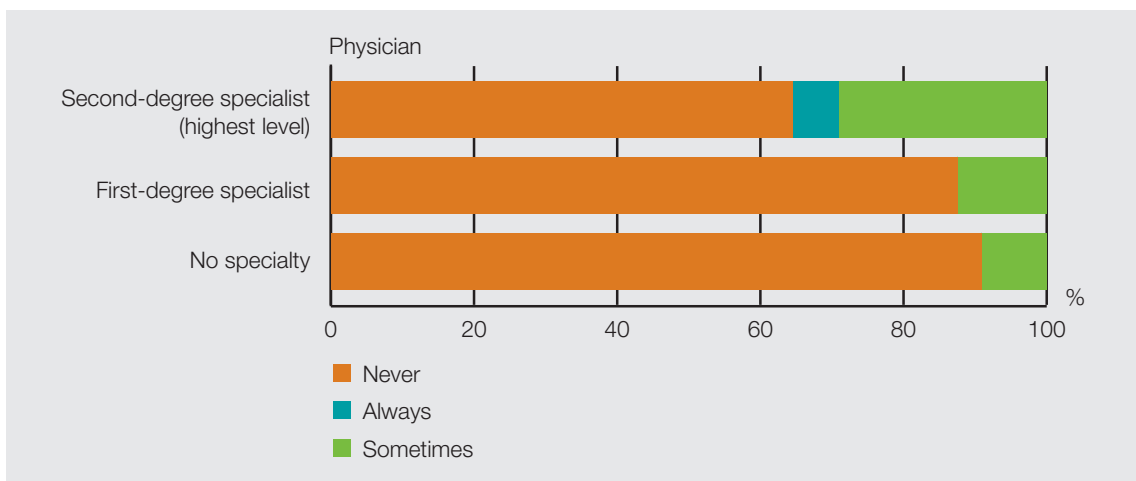
When asked about the number of simultaneously taken medicines, 40% claimed that a 5–7 drug combination presented a demonstrated statistical risk for clinically expressed interactions. Thirty-two per cent, mostly those in the highly specialized category, indicated that certainty of drug interactions reaches 100% when more than 8 medications are taken simultaneously, which has also been scientifically proven (7) (Fig. 5.7).

**Fig. 5.7. Number of simultaneously taken medicines for which the risk of interaction is certain, according to doctors**



The primary care physicians consulted in this survey had no practice of reporting ADR occurrence to the designated and specialized centres for monitoring safety of pharmacotherapy: 96% indicated they had seldom (“never” or “sometimes”) and 74% had “never” reported an ADR. Such responses are alarming not only in the light of the existing legislation,<sup>27</sup> but also considering the results of the pilot study: 90% of doctors claimed to treat patients with ADRs resulting from OTC drug interactions, and 38% indicated that additional treatment had been required due to ADRs caused by dietary supplements or herbal medicines. This indicates a lack of adequate awareness and inappropriate practice on the reporting of ADRs, which hampers rational and safe pharmacotherapy and may place individual patients at risk from unsafe medications. ADRs were most frequently reported by the highly specialist medical practitioners (Fig. 5.8), which might suggest the need to revisit the process of CME at PHC level.

**Fig. 5.8. Frequency of reporting ADRs to designated authorities by doctors’ degree of specialization**



27 Law on Pharmacy; Law on the Profession of Doctor and Dentists; Decree of Minister of Health regarding Monitoring of the Safety of Medicinal Products (17 February 2003).



## Report from the RCMADR in Kraków (1 January 2004–31 December 2010)

The analysis covers ADRs reported to the regional centre in Kraków from 1 January 2004 to 31 December 2010. The total number of reports was 2619. Detailed analysis of these included ADRs that resulted from the following (Table 5.1):

- » drug interactions in polypharmacotherapy;
- » medicines–dietary supplement interactions;
- » OTC drugs and prescribed medicine interactions; and
- » medication errors: prescribing/administering a medication with contraindications or existing limitations.

**Table 5.1. Number of ADRs reported per year per category, 2004–2010**

Year	Drug interactions in polypharmacotherapy	Dietary supplements interactions	OTC drugs and prescribed medicines interactions	Medication errors	% of reports in relation to all reports sent in a given year
2004	42	1	18	16	68.14
2005	89	2	26	25	60.68
2006	118	3	41	46	74.82
2007	186	4	48	68	79.48
2008	295	10	62	82	82.99
2009	276	12	73	91	87.25
2010	295	28	62	104	88.90

*Source:* authors' own compilation based on data collected by the RCMADR.

Analysis of the ADRs confirms a continuous increase resulting from the numerous pathologies in pharmacotherapy. This observation stems from the growing practice of polypharmacotherapy not preceded by rational risk assessment oriented towards potential ADRs. In addition, the Polish health care system does not provide an objective and reliable source of patient medicine information, and treatment is usually provided by different providers at primary and specialist care levels. These professionals have no established practice for consulting the literature on medicines and often have little knowledge of the characteristics of medicines prescribed by another specialist. This makes the prevention of drug interactions and ADRs an impossible challenge in patients who are subject to collaborative medication treatment.

Patient medication safety is also compromised by the increased use of dietary supplements that are susceptible to interactions, with no research covering the risk of interaction. The safety of dietary supplements is not monitored in Poland, making it difficult to obtain an objective opinion about the safety and risks of their interactions.

The number of ADRs due to interactions between OTC drugs and prescribed medicines is increasing. This might be related to low patient awareness of medicines interactions or may indicate restricted access to competent sources of information on medicines (physicians, pharmacists); it may also result from a lack of willingness to read and understand patient information leaflets.

The number of reported ADRs has increased since 2004 due to unsafe prescribing practices that do not observe the necessary limitations on use of medicines. Research indicates that medicines have been prescribed to populations known to be susceptible to a certain type of ADR.

The fact that 38% of the doctors that responded to the survey treated patients with ADRs resulting from use of dietary supplements or herbal remedies points to a problem with the commercial information on dietary supplements in patient information leaflets. These may emphasize the anticipated advantages without highlighting the potential risks (adverse reactions that might result from medicines interactions and the ADRs these supplements may induce). A similar observation relates to herbal medicines. These are commonly considered to be very safe, yet research proves this assumption to be untrue, as herbal substances may modify the performance of other medicines and also induce serious ADRs (8).

An additional reason for ADRs and drug-induced illness can be the nonstandardized content of a patient's medical history, alongside medical professionals' characteristic lack of interest in the patient's medicine profile. This can lead to unacceptable repeated exposure to certain drugs in patients in which interactions and previous drug hypersensitivity have already been recorded.

## Recommendations

The study results point to two main findings:

1. **poor medicine practices** existing at PHC level, in terms of: doctors' interest in patients' medicine profiles; quality of medicines information provided to patients during visits; content of communication regarding patient medicines; and ADR reporting rates; and
2. **poor quality and low volume of patient education** concerning pharmacotherapy and the inadequate use of potential sources of medicines information, as well as the absence of patient- and provider-focused medication information centres.

These findings – if validated on a larger scale – require urgent communication with appropriate authorities and stakeholders to determine initiatives required to improve pharmacotherapy safety at PHC level.

The recommendations that follow are made with respect to: (a) the health care system level; (b) the professional level; and (c) the patient level.

### ***Recommendation 1 – Organize medication information centres (health care system level)***

Continuous pharmacotherapy use calls for a system of medication information centres to be set up for patients, doctors, pharmacists and other stakeholders. Such centres would provide broad-scale, reliable information about medicines, indications, contraindications, interactions and the principles of safe and effective polypharmacotherapy. Added value would be attributed by learning to link medications in a rational way, using their complementary performance mechanisms and limiting polypharmacy (linking medications that do not contribute to increasing joint therapeutic effects, but rather

raise the risk of ADRs). Such a system would also prevent the linking of medications with a similar profile of adverse reactions, consequently reducing the risk of increasing drug toxicity during the combined use of medicines. An alternative might be for on-call family doctors to provide information on medicines use.

***Recommendation 2 – Implement an electronic health card (health care system level)***

There is a need for the wide-scale implementation of an electronic health card, storing reliable information about medications taken, dosage and ADRs experienced. Lack of knowledge about medicine names and doses can result in serious consequences in emergency situations and/or sudden hospital admissions – it is crucial that hospital/emergency staff know what medicines patients have recently taken. Some unexpected incidents such as hypotension, collapse, loss of consciousness, convulsions and heart rhythm disorders resulting in emergency admissions to hospital can also be the result of ADRs. The increasing complexity of polypharmacotherapy might lead to errors in terms of overdose or medicine withdrawal symptoms, because the more medicines taken, the less patients appear to know about their names and appropriate dosages. This is especially important in patients over the age of 65 years, who represent 14% of the Polish population and consume over 40% of all medications prescribed. It is therefore crucial to verify the perception of doctors' instructions regarding medications for this population group (9).

***Recommendation 3 – Improve professional competences (health professional level)***

All health professionals should recognize the value of patient involvement and have access to sound basic-level and continuing education that covers clinical knowledge and medicine therapies, clinical guidelines, communication skills, human relationships and safe medication practices. Professional competences should be regularly evaluated. Information needs of different populations and special groups, such as older people, children, disabled people, migrants and individuals with low levels of health literacy, should be taken into account. Information on medicines provided to patients needs to include the choice of the most appropriate treatment for their health problem, including “non-drug” options – it should be comprehensive and understandable information about the expected therapeutic effects, potential ADRs and instructions for taking the medicine. Health professionals need to be trained to use medicine information sources and communicate about medicines with peers and patients to induce compliance during long-term pharmacotherapy. In addition, there is a need not only for education, but also for enforcement mechanisms (including incentives) relating to the practice of reporting ADRs to the designated and specialized centres for pharmacotherapy monitoring safety.

***Recommendation 4 – Provide medication information in an understandable way (health professional level)***

Professionals are expected to provide information on the names of drugs, dosages and timing of medicines administration in an understandable manner, with letters and numbers clearly distinguishable. The patient's understanding of the doctor's orders should always be verified. Safe medication practice would require that the patient obtains information about what common medicines should be taken in case of headache, toothache, diarrhoea or heartburn, particularly when prescribing drugs with a high probability of interaction.

***Recommendation 5 – Pay specific attention to patients with a history of ADRs (health professional level)***

Significant attention should be paid to patients' medication history, with a focus on previously experienced ADRs (including those involving OTC drugs and dietary supplements): these are crucial factors in safe pharmacotherapy.

***Recommendation 6 – Educate patients (patient level)***

There is a clear need for patient education, not only to improve health literacy, but also to facilitate communication with health care professionals on medicines prescribed and treatment courses followed (such as checklists like the Institute for Safe Medication Practices model, medicines memos and medicines lists). Doctors should articulate their expectations relating to patients bringing along their lists of medications with updated names and dosages, and patients should be made aware of the necessity of compiling a list of the medications they take. In addition, there is a need for patient education on the use of OTC drugs and the boundaries of safe self-care and treatment. Patients should be encouraged to use all potential sources of information about all medicines, including prescribed medicines, OTC drugs, dietary supplements and herbal remedies, as this contributes to medication safety and reduction of potentially related complications.

***Recommendation 7 – Involve patient organizations (patient level)***

Patient organizations need to play an active role as advocates and promoters of safety-culture changes. Enhancing appropriate developments includes raising awareness and strengthening knowledge relating to the potential and expected roles that patients can play in reducing medication-related safety risks, as well as providing empowerment and encouragement for the individuals and organizations in this participative process (Annex 6).

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# CHAPTER 6.

## PATIENT PARTICIPATION IN ELECTIVE SURGERY SAFETY IN PORTUGAL

*Anna Mansoa*

### Introduction

The complexity of health care services all over the world presents new challenges in assuring service quality and safety (1). Patient safety is an important aspect of public health and a recognized key issue in establishing and delivering accessible, cost-effective and responsive health care (2,3).

It has already been shown that medical errors and health care-related adverse events occur in between 8% and 12% of hospitalizations within EU Member States (1), with a large percentage being considered preventable (3). HAIs are the most frequent adverse event threatening patients' safety worldwide, with an estimated prevalence of 7.1% in Europe (1,4).

Enhancing patient safety, defined as “freedom for a patient from unnecessary harm or potential harm associated with health care” (1,3), and assuring the protection of patients' rights is high on national and international health agendas. Patient participation, a key component in the redesign of safe health care, is advocated as a means to improve patient safety in several areas, such as the management of chronic diseases (5). It is consequently being promoted by WHO as a means to improve well-being and increase the efficiency of the health care system through enhanced communication between patients and health care providers.

“Patients for Patient Safety”, one of WHO's main actions involving work with a global network of patients, consumers, caregivers and consumer organizations, launched the *London Declaration* in 2006 (6). This advocates for the reduction of health care errors as a basic human right and emphasizes the importance of strengthening patient engagement (1). Patients can contribute to safer health care experiences by being involved in, and informed about, their treatment (7). Fewer adverse events are likely to occur when patients and HCWs become partners in health care, sharing important information, managing systemic risks and dealing with adverse events (8).

Even if more evidence on the role of patient participation in preventing medical errors is needed, existing research shows that patients can influence and substantially modify HCWs' behaviour. However, the efficacy and implementation of patient participation in preventing medical errors and increasing staff adherence can be influenced by a multitude of cultural and environmental factors (5). The acknowledgment that only an informed patient can be really engaged in his or her own health care and contribute to the quality of services brought the importance of effective policies promoting health literacy to the international agenda (5).

Exploring the key role that patients can play in preventing medical errors in surgery safety is the domain approached in this chapter. The study draws from the conceptual model proposed by Longtin et al. (5) (see Chapter 1), in which several factors (relating to HCWs and patients) that influence patient participation in improving patient safety are considered.

### Content of this chapter

The chapter is focused on the experience of Portugal, taking into account improvements in surgical services and the emphasis placed upon increasing safety, efficiency and patient satisfaction. Elective surgery is discussed, starting with definitions of surgery and elective surgery.

### Morbidity related to surgical care

WHO defines surgery as: “any procedure involving the incision, excision, manipulation, or suturing of tissue that usually requires regional or general anaesthesia, or profound sedation to control pain” (9). Surgery is among the most complex and expensive types of health service (10). It is believed that major surgery is now occurring at a rate of 234 million procedures per year – 1 for every 25 people (9).

The tremendous progress made in terms of effectiveness and complexity of surgical care has brought new challenges to improving the performance of the surgical system and enhancing a strong commitment to quality and safety of services, from the preoperative evaluation to surgical intervention and postoperative care (11). Major surgical complications occur in 3–22% of inpatient surgical procedures in industrialized countries, with a death rate of 0.4–0.8%: almost half of the adverse events recorded are deemed to have been preventable (9). Technique-related complications, wound infections and postoperative bleeding are probably responsible for around half of all surgical adverse events (12). Estimates show that 1 in every 20 hospital patients contracts HAI every year, and SSIs are the third most common type of infection (17%). UTIs (27%), lower respiratory tract infections (24%) and BSIs (10.5%) are the other most common types of HAI (1). Methicillin-resistant *Staphylococcus aureus* (MRSA) is isolated in approximately 5% of all HAIs (1).

Although the global incidence and costs are unknown, SSIs are assumed to be a major cause of death and disability. Infection occurring during a surgical procedure or during wound healing is expected to complicate approximately 2% of clean surgery and 10% of contaminated operations (10).

Despite the undeniable improvements in safe practice, complications relating to anaesthesia remain a substantial cause of death during surgery globally (9). Hypoxia due to respiratory suppression, injuries due to manoeuvres to control the airway, aspiration, inadequate resuscitation, hypo- and hypertension, cardiac depression and elevation, and medication reactions and interactions are all potential life-threatening problems (10).

Three decades ago, a healthy patient undergoing general anaesthesia had an estimated 1 in 5000 chance of dying from complications (9,11). Today, the risk has dropped to 1 in 200 000 in the industrialized world with improved knowledge and basic standards of care (9–11), and efforts are targeting further risk reduction.

The report published on 28 March 2011 by the Unidade Central de Gestão de Inscritos para Cirurgia [Central Unit of the Surgical Waiting List] states that the annual volume of surgery in Portugal increased by 37.6% between 2006 (345 321 episodes) and 2010 (475 293) (12,13). These official data only relate to patients undergoing elective<sup>28</sup> or deferred<sup>29</sup> surgery (13–15).

National evidence concerning the quality and safety of services in Portugal is lacking, and information about adverse events is currently very limited and difficult to access (16). Fragata, however, believes that about 48% of all adverse events occur in operating theatres and that 30–50% of cases are assumed to be preventable (17).

A Portuguese study from 2008 (18) reported that 2.5% (n=41 191) of procedures performed in Portuguese hospitals<sup>30</sup> could be linked to one or more episodes of adverse events. The authors of the study expected the average length of stay to be 11 days longer for individuals harmed by adverse events during medical or surgical procedures than those not affected by adverse events.

According to the ECDC, Portugal reported 4201 SSIs in 2008. Of patients staying more than 48 hours in the ICU, 391 acquired pneumonia, with the most frequently isolated microorganisms being *Pseudomonas aeruginosa* (23.5%) followed by *Staphylococcus aureus* (17.6%). Two hundred and nine cases of ICU-acquired BSI were also reported: the most frequently isolated microorganism was coagulase-negative staphylococci (23.9%) (19).

Another study of adverse events was carried out by the National School of Public Health at three hospitals in Lisbon in 2009. The incidence of adverse events was 11.1%, of which 53.2% were considered preventable. Just over 60% did not harm the patients or resulted in minimal impairment, but 10.8% resulted in death. The average length of stay was 10.7 days longer for patients who experienced an adverse event (20).

The 2009 national survey on prevalence of infection carried out by the National Infection Control Programme in 144 hospitals showed an HAI prevalence of 9.8% and a community-acquired infection prevalence of 20.3% among inpatients. The most frequently isolated microorganisms were MRSA, *Escherichia coli* and *Pseudomonas aeruginosa* (21). Pina and colleagues believe that 5 in 100 inpatients may have acquired an HAI (22).

In 2009, Portugal was one of 19 countries applying patient safety indicator rates from the set of 7 indicators<sup>31</sup> selected by the OECD's Patient Safety Expert Subgroup. From

28 The “lista de inscritos para cirurgia” [waiting list for surgery] (13,14) does not include: patients undergoing minor surgery, unless general or loco-regional anaesthesia and the use of an operating theatre are necessary; patients undergoing surgery outside of the ambulatory or conventional surgery room; and patients undergoing urgent surgery (not scheduled) in the emergency operating theatre (13).

29 Deferred urgency is “[W]hen the patient in an acute crisis situation is offered surgery, deferred in time, using elective surgery resources” [translated from Portuguese] (14).

30 According to administrative data from the reimbursement system based on diagnosis-related groups.

31 Based on hospital administrative databases (most of the participating countries use a reimbursement system based on diagnosis-related groups).

the indicators reported by OECD, Portugal had the second highest rate of postoperative sepsis (1.493%) and the lowest rate of postoperative pulmonary embolism or deep vein thrombosis (0.108%). The country reported low rates of catheter-related BSI (0.057%) and accidental puncture or laceration (0.116%), but the report stated that underreporting is likely in countries with low rates for these indicators. The averages for obstetric trauma (vaginal delivery with (1.698%) and without (0.632%) instruments) were also close to the minimum rate, and no foreign bodies were reported to have been “left behind” during surgical procedures (23).

### **National legal and regulatory framework on surgery safety and patient engagement**

This section focuses on the existing legal and regulatory documents that relate to health literacy, patient engagement and safety. Most set out broad regulations for health care and are applicable to surgical care. Documents that regulate surgical practice alone are also considered.

#### ***Health literacy and the right to safety***

Patients must be able to read, understand, evaluate and use health information effectively to be involved in, and truly contribute to, improving the quality of health care services and reducing medical errors (24). Their lack of understanding can contribute to failures in health care and in turn may represent a hazard to patient safety.

Standards on patients’ right to information and to safety are based on several European documents (25–28). Patients’ rights are also articulated in Portuguese law. Article 64 of the Portuguese Constitution (29) states that: “[E]veryone has the right to the protection of health and the duty to defend and promote health”. To ensure the right to health protection, the state is charged with: “disciplining and inspecting entrepreneurial and private forms of medicine and articulating them with the National Health Service (NHS), in such a way as to ensure adequate standards of efficiency and quality in both public and private health care institutions” (29).

Although broadly regulated and encompassed in diffuse legislation (30), some requirements related to health literacy and the right to safety are stated in the Basic Law on Health (31),<sup>32</sup> specifically in articles V (citizens’ rights and duties) and XIV (consumers’ statute) (Table 6.1).

The right to personal integrity is also reflected in the Portuguese Constitution (Article 25) (29). The Basic Law on Health gives important rights to citizens as users of health services. According to this law, patients have the right to be cared for by appropriate means, with technical quality and respect. Article XIV of the same law states that a patient has the right to be indemnified for injuries caused (31). Lobato de Faria (32), however, considers that the norms relating broadly to patients’ rights “... are too vague and general to be of practical use. There are no specific regulations to guide the health provider on the detailed contents of the declared rights of a patient” (30). It would

32 The Basic Law on Health (Law No. 48/90 of 24 August 1990) (31) also comprises the revisions inducted by Law No. 27/2002 of 8 November 2002.

be desirable to have a special statute concerning patients' rights (de Oliveira, personal communication, 2012).

The increasing awareness of this subject among Portuguese legislators is noticeable, as illustrated by the Parliamentary discussions on the 2008 Bill No. 788/X (which focused on the right to be informed and informed consent) (33) and the special concern expressed by the 10th Health Parliamentary Commission. Several bills have been introduced in the Portuguese Parliament to replace the Basic Law on Health (No. 48/90 of 1990) (31) with more detailed legislation regarding patients' rights (Table 6.1).

Three charters providing for protection of patients' rights within the NHS have been developed. Although they are not legally binding, these tools represent an important commitment on the part of the Portuguese Government in this field.

The Ministry of Health published a charter of patients' rights and duties in 1997 (34).<sup>33</sup> Its main goals are to assert the citizen's role as the main actor in the health system and to (re-)assure fundamental human rights in health care provision, especially in terms of protecting human integrity and dignity, as well as the right to "autodetermination" (34).

Among other rights, the patient has the right to be informed about available health services, the competences and levels of care available within them (Article 5), and to be informed in a clear way about diagnosis, prognosis, treatment possibilities and risks (Article 6). Patients also have the right to access information in their own clinical file (Article 10) and to a second opinion about their health condition (Article 7), and to give or refuse their consent before any medical or research procedure (Article 8). The right to safety is vaguely stated in Article 1 (right to human dignity) and Article 3 (right to be treated in a proper way) (Table 6.1).

A charter on inpatients' rights and duties, based on this charter, was published in 2005(36),<sup>34</sup> with HCWs as its main target.

A charter for hospitalized children (38) approved in 1988 in Leiden was published in Portugal in 1998 by the Portuguese Child Support Institute. The charter declares that children and families have the right to receive appropriate information about a disease and its treatments, with the purpose of being able to take part in the decision-making process. It also states that hospitals should respond to children's needs, assuring safety, proper equipment and professional care.

The Entidade Reguladora da Saúde (ERS) [Health Regulation Authority], an independent public entity responsible for overseeing access to health care and for the maintenance of quality and safety of health services, published a technical report and presented the concept of a charter of consumers' rights for public consultation and discussion on 2 June 2011 (39).

33 Founded on the Portuguese Constitution (29); the Basic Law on Health (31); and the Hospitals Statute (35).

34 Founded on the Portuguese Constitution (29), the *Convention on Human Rights and Biomedicine* (26), the Basic Law on Health (31), the *Charter of Fundamental Rights of the European Union* (37) and the *Charter of Patients' Rights and Duties* (34).



***Information about health and safety***

Patients are more likely to be involved in their health care when thoroughly informed (5), enabling them to make appropriate health decisions. Legally, the right to information about one's own health is part of the right to informed consent (30) (Table 6.1).

According to Portuguese law, health information is any information directly or indirectly linked to the present or future health status of a person, either living or deceased, including clinical and family history (40). Article XIV of the Basic Law on Health, which regulates patients' rights and duties, states that a patient has the right to be informed about their condition, possible treatment options and the possible evolution of the condition (31). The inclusion of the right to know the risks and secondary consequences of treatment, as well as the risks and consequences of refusal of the intervention or of different options, should also be addressed, as suggested by the ERS (41).

The Portuguese legal framework (30) states that patients' access to their personal health data should be granted through an authorized physician and cannot be used for any purpose other than health care and research (30,31). The Health Systems Observatory objects to the fact that patients can only access their personal data in the presence of a physician (42).

The duty of health care professionals to explain the diagnosis, intervention/treatment and consequences to the patient is indicated in the Portuguese penal code (43), except for instances when this information can represent danger or harm to the patient (Article 1.157). The right not to know is not specified in Law No. 12/2005 of 26 January 2005 on Personal Genetic Information and Health Information (40), but is set out in the *European Charter of Patients' Rights* (27), Article 4, which states that "a patient has the right to refuse information about his or her health status".

***Informed consent and safety***

Informed consent is one of the many processes used to ensure that patients are engaged in their own health care, especially in relation to surgical procedures. Seeking informed consent offers a "prime opportunity for patient education, engagement and involvement that can lead to better, safer and more effective care" (44).

The Centre for Biomedical Ethics and Law of the Catholic University of Leuven states that the right to informed consent appears in different ways in Portuguese law and sometimes with different legal bases (30) (Table 6.1). Information provided to patients is usually verbal (41). Portuguese law does not require written informed consent except for the following laws: Law No. 46/2004 of 19 August 2004 (Clinical Trials with Medicinal Products for Human Use) (45); Law No. 12/2005 of 26 January 2005 (Personal Genetic Information and Health Information) (40); Law No. 32/2006 of 26 July 2006 (Medically Assisted Procreation) (46); and Law No. 22/2007 of 29 June 2007 (Harvest and Transplant of Human Organs and Tissues) (47).

The ERS suggests the implementation of a legal framework that changes the non-obligatory nature of written informed consent (41). According to the penal code (43), consent can be freely revoked and any treatment performed without previous consent of the patient can be sanctioned. In the field of informed consent, the Direcção Geral



da Saúde (DGS) [Directorate General of Health] of the Ministry of Health advises that, despite having no legal basis for the requirement, if the hospital or unit clinical director requires the use of informed consent forms, the physician has a duty to fulfil this formality (48). Written consent should be obtained in this case, not due to legal obligation, but to hierarchical bureaucracy (41, 48). The DGS also states that physicians in private practice must enforce laws that impose written consent (48).

### ***Complaint and compensation***

Patients' right to complain about the way they are treated is provided in the Basic Law on Health (Article XIV) (Table 6.1) (31). The penal code (43) also provides for the right to complaint and compensation in Article 1.156 (on medicosurgical interventions and treatment without consent), under which prosecution depends on the user's complaint.

Aiming to improve patient-centred health care and enhance patient participation, the DGS recently created the NHS users' suggestions and complaints management system, "Yes citizen". This is a network system that involves all public health care institutions in the NHS and collects, lists, analyses and processes all complaints in the "livro amarelo" ["complaints book"] or through citizens' offices. It is recognized by the Ministry of Health as a good example of citizen-centred health policy and is available to all citizens anywhere within the national territory (49). Regional disciplinary councils of the Portuguese Medical Association are responsible for dealing with complaints submitted through its patients' office (50–52).

### ***Patient engagement and safety***

The Basic Law on Health states in Article V that patients are responsible for their individual and community health and have a duty to promote and protect it (30,31). Patients are expected to cooperate with HCWs, providing information regarding their health situation (31). They also have the right to form entities to represent them, to defend their rights and cooperate with the health system (Article XIV). The law encourages citizens and communities to participate in defining and planning health policies and in monitoring how health services function (Article II). As the Ministry of Health consulting body, the National Health Council represents all stakeholders involved in the working process of health care entities, including patients (Article VII) (31,40).

The DGS publishes an NHS users' guide annually (53). This document aims to keep citizens informed about available health services, relevant regulations and their rights and duties so that they can act as partners in efforts to improve health quality (53).

Aiming to ensure protection of health service users' rights (particularly in relation to the right to information and right to choose), the ERS introduced the Sistema Nacional de Avaliação em Saúde (SINAS) [National System of Health Evaluation] in 2006. The aim of the SINAS is to evaluate health care institutions according to ratings within different parameters, such as clinical excellence (already implemented), patient safety, infrastructure, and – in future – patient satisfaction and comfort (not yet implemented). Seven clinical areas are currently being evaluated: orthopaedics, gynaecology, obstetrics, paediatrics, stroke, heart attack and ambulatory surgery (39).

**Table 6.1. Key legislation and regulatory documents related to health literacy and the right to safety**

Right to ...	information about own health	informed consent	complaint and compensation	safety
Convention on Human Rights and Biomedicine	Chapter III, Article 10	Chapter II, articles 5 and 8	Chapter VIII, articles 23 and 24	Chapter I, articles 1, 2 and 4
European Charter of Patients' Rights	Article 3	Article 4	Article 13 (Complaint) Article 14 (Compensation)	Article 8 (Observance of quality standards), Article 9 (Safety)
Basic Law on Health, Law No. 48/90 of 24 August 1990	Article XIV – Consumers' statute	Article XIV – Consumers' statute	Article XIV – Consumers' statute	Article XIV – Consumers' statute
Portuguese Penal Code, DL No. 48/95 of 15 March 1995	Article 1.150 (Medicosurgical interventions and treatment) and Article 1.157 (Duty of clarification)	Article 1.150 and Article 1.156 (Medicosurgical interventions and treatment without consent) and Article 1.157	Article 1.156	Articles 1.144–1.150 (Crimes against physical integrity)
Other national legal documents	Law No. 12/2005 of 26 January 2005 (Health information and personal genetic information) Bill No. 788/X of 2009 (Right to be informed and informed consent)	Law No. 46/2004 of 19 August 2004 (Clinical trials for medicines: Article 6, No. 1, paragraph d) Law No. 12/2005 of 26 January 2005 (Personal genetic information and health information: Article 19, No. 5) Law No. 32/2006 of 26 July 2006 (Aided medical procreation: Article 14, No. 2) Law No. 22/2007 of 29 June 2007 (Harvest and transplant of human organs and tissues: Article 8, No. 6) Bill No. 788/X of 2009 (Right to be informed and informed consent)		Dispatch No. 256/2006: Transfer of National Infection Control Programme to the DGS  Dispatch No. 14178/2007: Approves the National Programme of Health Care-associated Infection Prevention and Control  Dispatch No. 18052/2007: Rules on the infection control commissions
Charter of Patients' Rights and Duties	Article 6 (Information) Article 10 (Access to data)	Article 8	Article 12 (Complaint)	Article 1 (Right to human dignity) Article 3 (Right to be treated in a proper way)

Despite all this, Portugal took last place in the subdiscipline “Patients’ rights” within the Euro Health Consumer Index in 2009 (54), achieving a score equivalent to “not so good/not available” in seven of the nine indicators. The low score in the subdiscipline “Information” (24th position) prompted reconsideration of national information legislation (55). One of the main recommendations from the evaluation carried out by WHO of the national health plan for 2004–2010 was that “health system stakeholders should be engaged early, broadly and consistently in the development of the next plan, and communication should be fostered” (56).

### ***Elective surgery safety***

Some documents within the Portuguese legal and regulatory framework set out particular regulations for surgical practice, particularly elective procedures. According to Portuguese law (13,14), surgical intervention is “one or more surgical acts performed by one or more surgeons in an operating room” (14). The DGS added to this definition: “... with the same therapeutic and/or diagnosis purpose, under general, loco-regional or local anaesthesia, with or without an anaesthetist” (57,58).

Elective surgery is defined in Portuguese law as being “performed in the surgery room with a previous scheduled date, not including minor surgery” (14).

The need for regulation of surgical services was recognized in Council of Ministers resolution No. 79/2004, published 27 April 2004, and through the establishment of an integrated management system for the surgical waiting list (14,59) regulated by the central administration services of the Ministry of Health. The goals of the integrated management system are to improve service, ensure equity in access, increase efficiency and enhance knowledge and transparency of surgical care (elective surgery and deferred urgency) (13). Regulation of the integrated management system (14) sets out some definitions of information documents, such as consent forms, surgical proposals and treatment proposals. The third section of the regulation establishes users’ rights and duties, specifically related to the right to complain, the right to access information related to the waiting list and other administrative issues (14).

Beyond the normative documents concerning health care safety in a broad sense, the DGS also publishes regulatory documents on surgical practice. The DGS regulatory memorandum No.16/DQS/QDCO of 22 June 2010, based on the WHO guidelines on safety of surgical care (10), regulates implementation of the “Safe Surgery Saves Lives” initiative in all NHS operating theatres effective from 1 July 2010 (60). It recommends the implementation of two specific tools: the surgical safety checklist (before induction of anaesthesia, before skin incision and before the patient leaves the operating room) and the surgical Apgar score, which considers the intraoperation estimated blood loss, lowest mean arterial pressure and lowest heart rate (60).

### **HCWs and patient engagement**

Health care institutions, HCWs and their associations have an important role to play in guaranteeing patient participation in enhancing health care safety. This requires deep commitment at education and professional levels.

This section focuses on provision for communication with, and involvement of, patients in professional training programmes at all levels and in ethical guidelines. It also addresses professional associations’ and health care institutions’ involvement in raising awareness in this field.

### ***Undergraduate and postgraduate education***

The strategic plan for training in the health sector, presented in 2003 by the national health task force nominated by the Council of Ministers (61), was expected to be a tool to support health professional education (62,63). According to the last published

evaluation conducted by the Health Systems Observatory (dated September 2003), concrete information about the development of the strategic plan was not available (63).

The current national professional accreditation agency is the Agency for Evaluation and Accreditation of Higher Education, created by means of Decree-Law No. 369/2007 of 5 November 2007 (64). Several nursing and medical schools have submitted their curricula for accreditation from this agency, the evaluation and accreditation policies of which are set out in Law No. 38/2007 of 16 August (65).

### ***Medical education***

The systemic nature of patient safety and the importance of communication, cooperation and organizational learning are considered key to medical doctors' education on patient safety (66). A report launched in 2010 under the auspices of EUNetPaS provided teaching programmes for medical and nursing schools and continuing professional development across the EU. Good practice examples in medical curricula were presented by the Comité Permanent des Medecins [Standing Committee of European Doctors], according to whom the issue of patient safety is still rarely to be found as a mandatory module in medical school programmes within EU Member States (66). Several internal and external evaluations have been carried out in Portuguese medical schools by national and international commissions and efforts have been made to update curricula in relation to science content and health care professionals' attitudes within their relationships with patients and their families, other professionals and wider society (62).

### ***Nursing education***

The European Federation of Nurses Associations presented in their strategic plan for nursing education 2008–2012 the current state of play from the nursing perspective, based on examples provided by 32 nursing leaders of allied associations such as the European Federation of Nurse Educators. The strategic plan – developed by the Portuguese Nursing Association – stated that a more qualified workforce would increase consumer safety and the quality of care (67). Patient safety is a fundamental aspect of the nursing curriculum and is likely to feature in the strategic plan's implementation in an integrated way.

### ***Deontological codes and professional organizations***

Portuguese professional associations recognize the importance of knowledge-based clinical practice as a fundamental means of promoting health care quality and safety, with patient safety being part of the responsibility of the professionals they represent (68). Ethical codes should serve as guidance to the different aspects of human relations that HCWs establish in their professional activity (69).

The Portuguese Medical Association's ethical code (70) assigns the patient a key role in the health care process and articles in the Medical Association Rule No. 14/2009 provide specific guidance on surgical safety (69). Article 44 notes patients' rights to detailed information from the physician on diagnosis, treatment and prognosis of their disease, taking into account patient emotional status and ability to comprehend. Article 45 provides details on patients' informed consent following substantive medical advice and reflection, and Article 26 affords the Association the opportunity to perform

inspections of surgical services to ensure that quality and safety conditions for surgical care are met.

The nurses' ethical code is part of the Nurses Association Statute set out in Law No. 111/2009 (71), which includes provisions regarding patients' right to information (Article 84), patients' right to life and quality of life, respecting cultural and spiritual integrity (Article 82) and the duty of professional excellence, adjusted to patients' needs (Article 88).

The Nurses Association has been implementing a nursing care quality standards programme since 2005 (72). Recommendations include nurses establishing partnerships with the "consumer" in the health care planning process and engaging the patient's family in his or her health care (72).

### ***Health care institutions***

Health care institutions' safety standards involve clinical and non-clinical aspects (39), as stated in law and mandated by different accreditation processes. The hospitals accreditation process started in Portugal in 1999 with the King's Fund model in the Fernando da Fonseca Hospital, and the Caspe Healthcare Knowledge Systems is currently working with 28 Portuguese hospitals. Its indicator set consists of over 40 patient-safety indicators drawn from clinically endorsed measures of safe practice (73). Release of safety information through the reporting of adverse events is highly recommended in all health care organizations with external accreditation processes (74). The DGS quality department recently adopted an accreditation model promoting patient-centred health services (75,76).

The Central Lisbon Hospital Centre provides an example of organizational commitment to enhancing safety information and reducing clinical risks through a systematic approach. A voluntary and confidential reporting system was implemented in 2002 (74). According to Lage, the hospital centre's safety policy is based on a patient-centred culture and strong commitment to sharing information about adverse events with patients who have experienced harm (74). Patient participation in preventing medical errors seems to be shaped by the complaints management process (77) and specific guidelines on obtaining informed consent before carrying out medical procedures (78). There is no information available on patient participation in this reporting system.

### ***National studies***

Informed consent is a recognized ethical and legal requirement for surgical procedures, denoting a decision-making partnership between the surgical team and the patient (or surrogate).

There is a lack of national evidence on the reality of patient-centred informed consent in surgical practice, but some studies aim to clarify the quality of informed consent in Portugal. In a 2009 report, the ERS quoted Almeida's dissertation, produced in 2005 and focusing on two cardiothoracic surgical units in the city of Porto. The author's view was that health care providers did not always take into account the information dimension of consent (41).



The ERS developed a study in 2007 that aimed to describe the national state of affairs concerning the application of informed consent at operational level. Public and private entities were requested to send their informed consent forms as part of the study, and 120 valid answers were received (41). The results showed that the application of informed consent was heterogeneous among the different health care units and, in some circumstances, even within the same unit. Moreover, some health care units did not even have policies related to informed consent (41).

In a study of informed consent quality carried out in 2009 in the surgical unit of the Porto Hospital Centre, Santo Antonio Hospital, 63.5% of respondent patients underwent elective surgery. Of these, 73.7% had a low level of education, 51.1% were men and 62% were retired. The authors reported that 86.1% of patients undergoing surgery received information about surgery-related issues; this information was provided by the surgeon in 62.8% of cases. Just over 50% received the information minutes, hours or days before the surgery, while 49.2% received it weeks or months before. Just over 30% did not receive information about other treatment options but 81.4% considered that they had received sufficient information. Relationships with the surgeon and participation in SDM independently influenced each patient's satisfaction with the informed consent process (79).

### Patient engagement and surgical safety

Elective surgery gives the patient the opportunity to improve the quality of care received by understanding treatment options and working with HCWs to make the surgery as safe as possible (80). Surgery consists mostly of elective procedures and most of the available data reflect this. The majority of patients in the Porto study mentioned above did not know the meaning of informed consent, even though all had given their informed consent before surgical procedures or important diagnostic tests. Patient gender, literacy and previous hospitalizations seemed to exert an influence on the results (41).

According to the 2006 Eurobarometer survey of medical errors, 18% of Europeans and 16% of Portuguese citizens had experienced a serious medical error in a hospital. Most Portuguese citizens (66%) thought it was unlikely that a hospital patient could have any influence on avoiding a medical error and only 23% believed that a hospital patient could actually help in their prevention (81). Increased awareness is nevertheless perceptible in the 2010 Eurobarometer survey of patient safety and quality of health care, in which 50% of Europeans and 64% of Portuguese believed that being harmed by hospital health care was "likely". When asked to state their views of the likelihood of occurrence of specific adverse events, 67% felt that HAIs were likely to occur and 58% saw a potential for surgical errors (82).

The 2010 Eurobarometer survey revealed that 17% of European health consumers who reported that they or a member of their family had undergone surgery in the previous three years stated that written consent was never obtained. In Portugal, 24% stated that written consent was never, and 16% only sometimes, obtained (82).

The WHO Second Global Patient Safety Challenge, "Safe Surgery Saves Lives", recognizes the importance of the patient undergoing surgery as a member of the team (9). During the treatment process, the surgical team "contributes information about



diagnosis, prognosis, and treatment options, with risks and benefits, and frequently provides a medical opinion and a treatment recommendation”, while patients “contribute their unique set of values, preferences, and health care goals through which they interpret the treatment recommendation” (83). The readiness of HCWs and patients to do this, however, also depends on awareness and literacy.

### Health promotion/health literacy-related campaigns

The Ministry of Health and health care institutions provide several tools to improve health literacy and patient participation, based on the new role of the citizen and the whole community as partners in the decision-making process (84).

#### *Ministry of Health*

Some Ministry of Health tools contribute to enabling patient engagement in assuring health care quality through information, education and consultation projects: these are also applicable to surgical practice. Describing the national news coverage in the domain of health literacy, the technical office of the national health plan 2011–2016 lists the following as the Ministry of Health’s information sources: the Ministry of Health web site (85), Linha Saúde 24 (a 24-hour health phone line) (86) and Linha do Cidadão Idoso (a phone line for older people) (87).

All Ministry of Health institutions have a web site, with areas designed to inform patients (51). The health portal (85) is a good example, providing information about organizations and policies, health topics and access to services. This web site has 250 000 visits monthly and around 8220 daily. It also provides general information on issues such as patients’ rights and available services. In the section “Users’ rights and duties”, citizens can access the *Charter of Patients’ Rights and Duties* (34), the *Charter of Inpatients’ Rights and Duties* (36) and the NHS users’ guide (53). A link to the “Yes citizen” platform is also available, which aims to collect, register and analyse all suggestions and complaints from NHS users (49).

The Ministry of Health web site also provides specific information related to surgical practice. The results of some service indicators relative to elective surgery, such as the number of surgeries carried out and waiting lists, and links to related legislation are available in the “Registered surgery list” section.

Linha Saúde 24 (86) is a permanent health line focused on counselling and guidance for patients. It receives on average 2500 calls daily (2009) (84).

The Justice Ombudsman web site (88) informs citizens about their rights and benefits in the health field and provides information about opportunities to complain. Two help lines have been created, one for children and one for older people (cited above), and a “disability citizen’s line” is being trialled (88). There is no available information about number of visits to the Justice Ombudsman’s web site.

One of the Ministry of Health projects is the “More Health” television channel. The aim of this project, coordinated by the High Commissioner for Health, is to improve citizens’ health literacy and empower them through information and the broadcasting of positive and creative content related to health promotion and disease prevention, in

accordance with the national health plan (89). The channel is displayed in the waiting rooms of some health units and selected content is available on the High Commissioner for Health web site (90), on YouTube and Twitter.

Several national studies are usually performed to evaluate NHS users' satisfaction. Citizens' satisfaction with hospitalization, hospital appointments and emergency care is evaluated as being between 2.29 and 2.81 out of a maximum of 5.0 (84). Quality and satisfaction evaluation in national hospitals shows that HCWs are aware of quality issues, but long waiting times persist and the level of response to complaints is inadequate (84).

The national health plan 2012–2016 was subject to consultation with the public and health system stakeholders. Meetings with citizens and media are being taken forward, along with information technologies (91). Citizens can comment on technical documents on several topics relating to the health plan on its web site (92).

### ***Health care institutions***

The national institute of statistics, Statistics Portugal, and the Agency for the Knowledge Society published the results of a national survey of information and communications technology (ICT) in public and private hospitals in 2004 (93). One of the relevant facts is that 90% of the national hospitals' web pages listed information on the health services they provided and 80% offered an e-mail address to receive messages, information requests, suggestions and complaints. Over 23% also had information about health care and health prevention on their web sites. It is clear, however, on examining activities developed by the hospitals through the Internet, that communication with citizens was less-well established (11.4%) (93).

Another Statistics Portugal study on ICT in hospitals (94) revealed that 88.1% had an Internet presence, with 97.1% of web sites containing institutional information, 82.1% displaying information about available services, 61.4% prevention and health care and 31% procedures in case of medical emergency, but only 8.2% allowed appointments to be made online.

### ***Social networks and patient organizations in Portugal***

The Association of Public Services Users (95) aims to bring together hundreds of users' commissions and associations that exist all over the country, organizing and coordinating their actions. The Association of Health Services Users, which is part of the bigger association, mounts awareness campaigns through conferences, marathons and other events in partnership with other patients' associations (96).

Although some associations for patients with chronic diseases, such as the National Association for Cystic Fibrosis, provide general information about surgical care, it is not possible to identify within the scope of this study any association providing information for patients undergoing elective surgery.

### **Patients and ICT**

The influence of ICT (such as e-health, health information systems and media) in the improvement of health literacy in modern societies is unarguable (93). It is believed

that major progress in the use of information in the health system, in doctor–patient relationships and in health care performance is related to the enormous amount of health and medical information available on the Internet (93), but the quality of such information is being discussed in different settings and by different stakeholders (governments, policy-makers, HCWs and citizens). Specialist analysis of ICT was carried out by a group of national experts as part of preparations for the national health plan 2011–2016, with the High Commissioner for Health publishing findings in September 2010. They reported that the topic was still being approached only cautiously and was sparsely documented in national studies and analyses (93).

Increasing use of ICT as a health information resource by Portuguese citizens and families seems, nevertheless, to be consistent with the international picture (93). In the “Network society in 2006” inquiry, 19.6% of Internet users stated that they searched for online health information. This represented a 3% increase from the 15.9% recorded in 2003 (97). There seemed to be a correlation in the 2003 study with users’ age, literacy and gender, with individuals who looked most for health information being between 25 and 44 years (97). A decrease in ICT skills was the reason for the rate decrease in older ages, but more women (22%) searched for health information than men (17.6%).

In relation to the type of information researched on the Internet, 70.1% of respondents looked for information/advice about a health issue and 28.2% used the Internet as a complementary information platform following a medical appointment. People searched mainly for information about diseases and treatments (11.4%), health insurance (8.3%), hospitals (8.2%) and the NHS (7.9%). They were mostly concerned about public health issues: 16.2% looked for information about keeping in good shape and exercising, and 11.7% researched nutrition. A further 6.8% wanted to know about heart disease.

In another study carried out in 2007, 49% of Portuguese citizens accessed the Internet, of whom 62% used it for health information research (30% of the total sample) (98).

### *Media*

Television is still the preferred popular medium in Portugal, with coverage reaching 99.5% of the national population (99). In 2010, Portuguese people spent almost 3.5 hours daily watching television (100), preferring news programmes (48.5%) and series (15.9%). Health information is mostly available through informative and fiction programmes (soap operas and series). Health and social services topics correspond to 4% (in time) of the total national news coverage (99). Currently, the Portuguese public television provider (channel RTP1) provides a weekly debate programme entitled “Health Service” (101), which provides a platform for discussion and reflection that brings together health professionals, health care institutions, patients and their families. The programme “Civil Society” (on RTP2) (102) is a network connecting citizens with partners such as health professionals’ associations, universities and patients’ associations.

### **Recommendations**

Concern about patient safety in Portugal has become more apparent in recent years, bringing with it the opportunity to develop a national strategy for patient safety capable

of being implemented locally (103) and which involves patients and their organizations. The following recommendations can be made.

***Recommendation 1 – Involve all stakeholders in patient safety***

Enhancing the participation of all health stakeholders, including patients, in the development of national policies and programmes on patient safety (3,104) and in the design and evaluation of health services (2) could lead to stronger engagement of, and commitment from, patients. Merging the three existing patients' charters that define individual and societal responsibilities could be a way to clarify the national commitment to assuring patients' rights to be informed and to informed consent.

***Recommendation 2 – Develop national guidelines***

Developing national guidelines on quality information (addressed to HCWs) will allow homogeneity of information presented to patients across similar settings (such as surgical units) within different health care institutions.

***Recommendation 3 – Design instruments to enhance patient involvement in safe surgery***

Designing and enforcing instruments to assist the patient to become truly engaged in the process of safe surgery could also be suggested, following existing experience. Various good examples of this can be found in the relevant international literature (Box 6.1).

***Box 6.1. Examples of instruments that help patients to be involved in safe surgery***

- » A good example is the consumer fact sheet developed by the National Patient Safety Foundation, which is based on five steps to help patients to become involved in the process of safe health care (7).
- » A 2002 campaign by the Joint Commission on Accreditation of Healthcare Organizations and the Centers for Medicare and Medicaid Services urges patients to play a part in preventing medical errors (105). Through posters, brochures, videos and other promotional materials, the Speak Up™ campaign encourages patients to:
  - speak up about any concerns they have
  - pay attention to their health care
  - educate themselves about their illness or condition
  - ask for help from an advocate
  - know the medications they take
  - use a high-quality health care facility
  - participate in decisions about their health care.
- » The Speak Up™ brochure entitled *Speak up: help avoid mistakes in your surgery* gives the patient important tips to help him or her to make the surgery safer by being an involved and informed member of the health care team, before and after the surgery (106).
- » Another tool, developed by the New Mexico Medical Review Association, encourages patients to talk with the surgical team and to ask specific questions before surgery, enabling them to play an active role in improving surgical safety by avoiding infection, blood clots and heart attacks (107).
- » The information booklet (also available on the Internet) entitled *Having surgery? What do you need to know?* (80) developed by the Agency for Healthcare Research and Quality aims to help patients undergoing elective surgery and their families by giving them some questions to ask to the primary care doctor and the surgeon. This tool should help patients to know more about the surgery, anaesthesia, recovery process, alternatives, costs, benefits and risks, as well as how to obtain a second opinion.

***Recommendation 4 – Design an education campaign for health care professionals***

Acknowledging that HCW-related factors contribute to patient participation in enhancing health care safety, it is important to understand the level of acceptance and

readiness of the actors involved to embrace the new role of the patient. More research could contribute to the real awareness, commitment and experiences of HCWs and health care institutions in relation to patient safety and patient engagement in the domain of surgical care. Institutions and HCWs must be prepared to accept the new role of the patient and to improve HCW–patient relationships (5). A large-scale and well-designed education campaign following the proposal of Longtin et al. (5) may help physicians, nurses and all HCWs to recognize the value of patient participation.

***Recommendation 5 – Ensure that patient safety receives proper attention in training***

Considering the *Luxembourg Declaration*, which focuses on patient safety (108), and European Council recommendations (3), the Kraków statement on quality and safety education (109) promotes the idea that ensuring patient safety receives proper attention in higher education curricula (undergraduate and postgraduate education) and training of all HCWs (including work-based training) supports the development of core competences in patient safety (3,109). Based on this assumption, WHO published a patient safety curriculum guide for medical schools (8) in 2009 and, in 2011, a multiprofessional version (110).

***Recommendation 6 – Apply targeted incentives to encourage professionals’ acceptance of the new patient role***

The application of incentive schemes (beyond financial encouragement)<sup>35</sup> may also contribute to improving health care professionals’ participation and acceptance of the new role of patients. Access to education and training, effective supervision and monitoring, and an approach to lifelong learning and personal development are nonfinancial incentives highly valued by health care professionals (111).

***Recommendation 7 – Disseminate information on patient safety via mass media***

The lack of information that seems to exist in Portuguese society (81,82) demands a real commitment to engage with and inform citizens by disseminating information on patient safety standards, risks and safety measures to reduce or prevent errors and harm (3). Bearing in mind that television remains the preferred method for transmitting to Portuguese citizens, enhancing television awareness campaigns – adjusted to users’ ages, literacy levels and gender – may also contribute to global consciousness of the new role of the patient. Enhanced research on the use of ICT could also support the development of new campaigns by allowing know-how to reach the health care user.

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# CHAPTER 7. PATIENTS' EXPERIENCES AND PATIENT SAFETY

*Diana Delnoij*

## Introduction

Patients' health care experiences are being measured in several European countries as part of national programmes of performance measurement and public disclosure of performance indicators. These programmes often exist alongside national patient safety programmes, but with little or no interaction. They are commonly run by different agencies or different departments within one agency supported by different research groups, and the link between patient experiences and patient safety is not always well established, even within health care facilities.

There is nevertheless growing interest in the role patient participation can play in enhancing patient safety and in the use of patient experience questionnaires as a tool to monitor (factors that contribute to) safety risks. Rathert et al. argue that perceptual measures of patient safety and quality can help to identify areas in which there are higher risks of preventable adverse events (1), not only because patients interpret lapses in service quality (such as delays in care, lack of coordination or poor hygiene) as risks to their safety (2), but also because patients may be more perceptive about safety problems than they have been given credit for. Taylor et al. (3), for example, showed that poor coordination of care, poor interpersonal skills and unprofessional behaviour were associated with the occurrence of adverse events, "close calls" or low-risk errors. The authors provide two possible explanations for this finding. One is that patients' experience of harm may increase their vigilance and critical assessment of service quality. The other is that general attributes of the organization, such as the quality of inter-professional and patient-clinician communication, may lead to service quality problems as well as adverse events and errors (3).

The initiative "Patients for Patient Safety" was established as one of the action areas of the WHO World Alliance for Patient Safety (Box 7.1). It aims to involve all actors, including patients and families, in reform initiatives and safety improvements (4). It is argued that patients ought to be seen as partners alongside health care providers in efforts to improve patient safety and that self-reporting of adverse events provides useful information for safety management (5). Patients themselves may be hesitant to assume a leading role in ensuring safety, however: research indicates that patients – at least in the acute care setting (that is, hospital) – believe they should be able to trust that they will receive safe care delivered by competent HCWs (6).

## Content of this chapter

This chapter explores patients' various roles in safety management, as described in Chapter 1. These roles include:

- » being involved in monitoring and reporting adverse events;
- » checking and double-checking that they are given the correct dose of the correct medication at the correct time;
- » being informed about what to expect in terms of surgery;
- » being encouraged to report any adverse event or complication;
- » observing and asking staff about hand washing; and
- » ensuring they are properly identified prior to treatment (6).

Three specific questions are addressed in this chapter.

1. What are patients' attitudes towards their involvement in patient safety?
2. What are the actual effects of involving patients in safety management?
3. What are the experiences of patients with respect to:
  - the occurrence of adverse events;
  - safety management in health care facilities (such as receiving information about the appropriateness of interventions, risks, benefits and alternatives, as well as identity checking); and
  - being actively involved in safety management and feeling safe?

Questions 1 and 2 are addressed in a short overview of the relevant literature on patient participation in patient safety. Question 3 is answered by means of analysis of patient experience surveys and data collected.

#### ***Box 7.1. "Patients for Patient Safety" – action area of the WHO World Alliance for Patient Safety***

The World Alliance for Patient Safety was launched by WHO in 2004. The perception of patients and families as an untapped resource was officially acknowledged by the global medical community within this initiative, as was viewing the patient experience as a learning tool. Patient and consumer involvement – in the form of the programme entitled "Patients for Patient Safety" – was designated as one of the original six action areas of the Alliance.

The "Patients for Patient Safety" agenda promotes the perspective of patients and their families in planning and delivering care as being:

- » crucial to articulating the reality and identifying the gaps between patient safety measures that can be achieved and the levels of safety being experienced by patients;
- » necessary to ensure services are driven by patient need and are genuinely patient centred;
- » a useful validation tool for implementing guidelines, processes and protocols; and
- » an enabler to making the patient voice heard in the global arena of health care.

By 2011, the "Patients for Patient Safety" network already comprised 214 patient safety champions representing 51 countries. Collaborative agreements had been signed with 13 supporting organizations, while the development of an "associate member" tier was under way.

For more information on WHO activities with respect to patient safety, see Annex 6 and the WHO web site (7).

## **Method**

### ***Literature on the relationship between patient participation and patient safety***

Two systematic reviews from 2010 looked at patient involvement in safety (8,9). Both included studies published up to the year 2008. An additional search has been conducted

for 2009–2011 using a combination of the medical subject headings “participation, patient” and “safety management”, and search limits “humans”, “abstract” and “English”. This resulted in 32 references, including the two systematic reviews. The 32 references have been screened on the basis of their abstract. This resulted in the identification of three additional references in which empirical findings were presented (6,10,11).

#### Screening of patient experience surveys

The following patient experience questionnaires have been screened:

- » Consumer Assessment of Healthcare Providers and Systems (CAHPS) questionnaires used by the American Agency for Healthcare Research and Quality;
- » questionnaires of the Commonwealth Fund;
- » CQI questionnaires of the Dutch Centre for Consumer Experience in Health Care; and
- » questionnaires used by the Care Quality Commission (CQC) in United Kingdom (England).<sup>36</sup>

Findings of surveys in which these questionnaires have been used are presented. Findings from a European Commission survey focusing on patient safety and quality of health care (12) are also described.

## Results of the literature review

### *Patient attitudes towards involvement in safety*

Schwappach (9) reviewed 21 publications that investigated the participation of individual patients in safety-related actions or prevention strategies. Of these, 13 assessed patients’ attitudes towards systematic engagement in safety. Schwappach concludes that generally, patients and the public support an active role for patients in error prevention, but that patients’ attitudes towards specific error-prevention strategies vary. Patients are more likely to support traditional actions, such as ensuring information transmission from patient to provider, rather than actions that require them to challenge medical authority. For example, the majority of people in one of the studies reviewed by Schwappach stated that they would be “likely” or “very likely” to find out about the results of a test at the hospital in the event that they had not been informed, but were “not likely” or “not at all likely” to ask HCWs whether they had washed their hands (13). Patients are more willing to communicate with or complain about nurses than about physicians (9) (see also the section below, “Patient participation in error prevention: hand hygiene”) and tend to overestimate health care professionals’ capacity to address and solve all issues that might arise. Schwappach refers to the study by Abbate et al. (14) in which patients were asked whether they would stop providers who were not wearing gloves. They were most willing to intervene if they had never been exposed to a provider not wearing gloves: in other words, they thought they would intervene if they had not yet experienced how difficult it can be in practice to confront a provider.

36 For practical reasons, the work has been limited to questionnaires in English and in Dutch. The Norwegian Knowledge Centre for Health Services runs a national programme to measure hospital patients’ experiences with patient safety. However, these surveys and the reports are only available in Norwegian (Øvind Andresen Bjertnæs, Director of the Norwegian Knowledge Centre for Health Services, personal communication, 2012).

Other studies on patient attitudes towards involvement in safety have been published since Schwappach's review. Rathert et al., for instance, analysed patients' responses to an open-ended survey question: "Please tell us what you believe is the patient's role in patient safety". Questionnaires were sent to 1040 patients who had experienced an overnight stay in 1 of 3 acute care hospitals. The response rate was 33%. The comment that was mentioned most frequently (by 23% of respondents) was "the patient role is to follow instructions", followed by "patients should expect competent care" (8%). Examples of other comments included the patient "should listen", "ask questions", "be cooperative" and "monitor things". Rathert et al. conclude that many patients view their role as passive and do not see patient safety as being their responsibility. Differences between age groups were minor, but there were interesting differences between the comments of patients who had been hospitalized themselves and the parents of hospitalized neonates, with the latter being more likely to assume an active role (6).

### ***Medication safety***

The review by Hall et al. (8) covers interventions with respect to medication safety. Of the 15 studies included, most (8) described interventions aimed at improving the safety of medication self-management, often in an outpatient setting or focusing on discharge from the hospital. The other studies evaluated interventions aimed at improving medical record-keeping with respect to medication history or more general patient education guidelines about medication safety. Hall et al. conclude that the methodological quality of most of the studies was poor, making it difficult to draw conclusions with respect to the safety benefits of the interventions, but with one exception: interventions aimed at self-management of anticoagulation resulted in a reduction of deaths and thromboembolic events (15).

One of the studies in the review by Hall et al. was also included by Schwappach: a prospective randomized controlled trial in which hospitalized patients received individualized medication information that was updated every three days, as opposed to the standard care consisting of general drug safety information (16). There were no statistically significant differences between the control and intervention groups in relation to adverse events, preventable adverse events, "close calls", patients' awareness, and so on. A similar more recent study, published after the review, looks at the effects of introducing a patient-friendly daily medication schedule for hospitalized patients. Patients' feedback on this system suggests they found it useful, that they understood the medications they received in the hospital setting better and that it helped to identify mistakes (10).

### ***Patient participation in error prevention: hand hygiene***

The Schwappach review includes three studies in which hospital patients were encouraged – individually, via a health educator, and via a patient brochure and supportive materials – to ask staff: "Did you wash your hands?" (17–19). The intervention was replicated in various settings. Schwappach (9) presents results that are weighted for sample sizes in the different settings. Eighty-three per cent of patients had read the brochure. Fifty-seven per cent reported that they had asked staff to wash their hands: of these, 91% had asked a nurse but only 33% a doctor. Use of soap in the three studies increased by 34–56% between the control and intervention periods, although increase in soap usage had already occurred in the pre-programme period in one study: in other



words, staff already anticipated the need to increase hand washing before patients were actually instructed to question them about hand hygiene.

***Patient participation in error prevention: wrong-site surgery***

Schwappach's review includes a study by DiGiovanni et al. (20) of a preoperative instruction for surgical patients to clearly mark the extremity that was not to be operated on to prevent wrong-site surgery. The study was conducted in a foot-and-ankle clinic and 100 consecutive patients were observed. Of these, only 59% were compliant in correctly marking the site.

After Schwappach's review was published, Bergal et al. (11) presented a study in which 200 orthopaedic patients were instructed during their preoperative visit to mark the word "YES" (using a standard blue marking pen) at the site of surgery before arriving at the preoperative area on the day of their surgery. The purpose of the study was to evaluate factors affecting patients' compliance with site marking to see if this could provide a useful tool to prevent wrong-site surgery. Of the 200 enrolled patients, 135 (68.2%) made a mark, 63 made no mark and 2 were lost to follow up. Of the 135 patients who made a mark, 2 marked the wrong site. Time between enrolment and surgery negatively affected compliance, and compliant patients were younger and used English more often as their primary language. Other patient characteristics, such as gender or level of education, were not related to compliance. The authors conclude that "patient involvement in surgical site marking is unreliable and may not help in decreasing the chances of wrong-site surgery" (11).

***Patient participation in error prevention: other***

Schwappach describes a study by Anthony et al. (21) in which a patient safety video was shown to patients who visited the ambulatory surgical areas of a community hospital. Patients' knowledge and levels of comfort in talking to staff about safety had slightly increased after watching the video. Two further studies in Schwappach's review focused on information campaigns targeted at patients in the United States (22) and Ontario, Canada (23). Only the latter study evaluated the level of patient involvement in error prevention, only after the introduction of the campaign, and only in convenience samples. The campaign ("Your health – be involved") included brochures, posters and a DVD for hospital television. Hospitals implemented the campaign in various ways. The study showed that 17% of patients involved had heard about the campaign and that 7 out of 15 reported that they had changed their way of communicating with health care staff as a result.

## Measuring patient experiences

***Background***

The IOM defines quality of care in terms of six core aspects: safety, effectiveness, patient centredness, timeliness, efficiency and equity (24). There are two important sources of information relating to these aspects of quality of care: registration of clinical data by health care providers; and patients' reports, collected through surveys.

Patients have specific experiential knowledge that is seen as being crucial for the advancement of high-quality care. Patients know what it is like to live with a specific disease and have much experience with health care providers and treatments.



Information about patients' experiences is therefore vital (25). That aside, there is evidence that patients with myocardial infarction who report better experiences in terms of patient centredness have higher rates of survival after 12 months (26). Patient reports are cited in the relevant scientific literature as, for example, patient-reported outcome measures – measures of the way patients perceive their health and the effect that treatments or adjustments to lifestyle have on their quality of life. These include measures of patient outcomes (in terms of health or quality of life) as well as measures of patients' experiences or their satisfaction with health care.

Patient satisfaction had become a frequently used outcome measure in clinical trials by the last decades of the 20th century, with satisfaction surveys frequently used to measure quality of care from the patient's perspective. In the second half of the 1990s, however, it became clear that patient satisfaction surveys were not very useful as a tool for quality improvement. It was argued that for quality assurance purposes, it would be more useful to look at specific experiences (27–29). This led to the development of new types of patient surveys with an emphasis not on evaluation of satisfaction, but on collecting detailed reports of what actually happened to patients during a hospital stay or a visit to the doctor. Examples of these consumer-experience surveys are the CAHPS questionnaires in the United States (30–37), the questionnaires used by the Commonwealth Fund (38–45), those developed by the Picker Institute (46,47) (now used by the English CQC) and the Netherlands CQI (48–58).

### ***Construction of questionnaires***

Construction of surveys is usually based on qualitative research through, for example, focus groups in which a small convenience sample of people are brought together to discuss a topic or issue with the aim of ascertaining the range and intensity of their views (see, for example, Damman et al. (55)). A focus group discussion leads to quality of care being put into practice from the patients' perspective and is aimed at ensuring the validity of the questionnaires' content. Focus groups result in lists of possible questionnaire items. These topics are then used to formulate questions about, for example, the degree or frequency with which experiences met quality standards. Examples of this degree or frequency focus are shown in Box 7.2.

#### ***Box 7.2. Examples of degree and frequency foci in questions***

##### **Degree**

In the past 12 months, did doctors listen carefully to what you had to say? (Response categories such as: “yes, completely”; “yes, definitely”; “yes, to a certain extent”; “no”.)

##### **Frequency**

How often in the past 12 months did doctors listen carefully to what you had to say? (Response categories such as: “never”; “sometimes”; “usually”; “always”.)

Topics covered in a patient survey vary but may include: fast access to reliable health advice; effective treatment delivered by trusted professionals; participation in decisions and respect for preferences; clear, comprehensible information and support for self-care; attention to physical and environmental needs; emotional support, empathy and respect; involvement of, and support for, family and carers; and continuity of care and smooth transitions (59).

Questionnaires almost always address process aspects of health care quality, such as information, communication and interpersonal contact. Whether they also cover aspects of patient safety is analysed in the sections below.

### ***Data collection***

Patient experience surveys such as the surveys of the Commonwealth Fund are used to measure the performance of a health care system as a whole; CAHPS, CQC and CQI surveys measure the performance of health care providers; and CQI looks at the experiences of patients with a certain disease. Depending on the unit of analysis, samples are drawn from the general population (Commonwealth Fund) or from the patient populations of health care providers (CAHPS, CQC and CQI). Sample sizes depend on factors such as the reliability of the questionnaire, the expected response rate and the aim of the survey. In studies comparing patient experiences across countries, sample sizes are usually 1000–2000 citizens/patients per country. Studies comparing patient experiences between hospitals usually work with sample sizes of at least 500 patients per hospital. Data are collected mostly by postal questionnaires but also through face-to-face interviews, telephone interviews or online surveys. The best method depends on the study population and financial resources available for the survey. Face-to-face and telephone interviews require more human resources than postal surveys and are therefore usually more expensive. Online questionnaires are comparatively cheap but can only be used in populations with good access to, and experience with, the Internet. At present, this makes online surveys less appropriate for use with older populations.

### ***Purpose and use***

There is growing interest in Europe in measuring patients' health care experiences (60). Surveys are being carried out in several European countries to map the quality of care as perceived by patients. In a number of these countries (Denmark, Norway, United Kingdom (England) and the Netherlands), such surveys are part of a systematic programme of work that takes place at regular intervals.

Patient experience surveys often serve multiple purposes. Surveys in the NHS in United Kingdom (England), for example, aim to provide comparative information for the CQC and the public. They are used for external accountability purposes and to inform consumer choice, but providers also use the results for internal quality improvement. The Picker Institute, which develops and conducts these surveys, consequently offers providers so-called "guides to improvement". Recently, the CAHPS Consortium in the United States has also developed a "CAHPS improvement guide" for providers seeking to upgrade their performance in the domains of quality measured by CAHPS surveys.

According to Berwick et al. (61), measuring quality indicators can improve the quality of care along two lines: selection or change. Selection takes place if public reporting of quality indicators stimulates individual consumers or their agents to choose providers that perform better over those that perform less well. Change takes place if (internal) feedback on performance stimulates providers to engage in quality improvement activities. Fung et al. (62) reviewed experiences with public reporting of performance indicators in the United States. They found that evidence of a relationship between public reporting of performance indicators and the quality of patient care was scant. The

available evidence suggests that individual consumers do not often use this information (yet) to select better-performing providers over those performing less well (see, for example, Faber et al. (63)), but that publicly releasing performance data stimulates quality improvement activity at hospital level. Improvement of publicly released performance scores have also been demonstrated for the CQI in the Netherlands (64).

### Results of screening patient experience questionnaires

Questions have been identified on:

- » the occurrence of adverse events as reported by patients in patient experience questionnaires;
- » the occurrence of factors that are known to contribute to or to prevent adverse events (safety management);
- » safety as an experience (trust; the concept of “feeling safe”); and
- » actual involvement in safety management.

#### *CAHPS surveys in the United States*

The CAHPS programme is a public–private initiative to develop standardized surveys of patients' experiences with ambulatory and health care facility-level care. CAHPS results are used to assess the patient centredness of care, to compare and report on performance, and to improve the quality of care (65).

The following surveys have been reviewed for this study:

- » CAHPS Health Plan Survey, which asks enrollees about their recent experiences with health plans and their services;
- » CAHPS Clinician and Group Survey, about recent experiences with physicians and their staff;
- » CAHPS Surgical Care Survey, about surgical care, surgeons, their staff and anaesthetists;
- » CAHPS Hospital Survey, about experiences with inpatient care in medical, surgical or obstetrics departments;
- » CAHPS In-centre Haemodialysis survey, about experiences with haemodialysis;
- » CAHPS nursing home surveys, which include three separate instruments – a personal structured interview for long-term residents, a postal questionnaire for recently discharged short-stay residents and a postal questionnaire for residents' family members; and
- » CAHPS Item Set for Addressing Health Literacy.

The Health Plan Survey, Clinician and Group Survey (adult specialty care and adult primary care) and the Item Set for Addressing Health Literacy do not include items that are related to patient safety. Items relating to safety are found in the In-centre Haemodialysis Survey, the Nursing Home Survey and the Surgical Care Survey.

#### Items related to safety in the CAHPS In-centre Haemodialysis Survey

“In the last three months, how often did dialysis center staff check you as closely as you wanted while you were on the dialysis machine?”

“Ha[s] any dialysis center staff [member] ever told you how to get off the machine if there is an emergency at the centre?”

“In the last 12 months, were you ever unhappy with the care you received at the dialysis center or from your kidney doctors?”; followed by: “In the last 12 months, did you ever talk to someone on the dialysis center staff about this?”

“In the last three months, how often did dialysis center staff change their gloves between patients?”

The last question is supplemental. In all cases, the response categories are “never” “sometimes”, “usually” and “always”. The question about changing gloves also includes the response category “don’t know”.

Data collected with these survey instruments have not been published in scientific literature. Some information has been presented at a CAHPS user meeting: 3% of the patients reported that staff “never” or only “sometimes” changed gloves between patients (33).

Item related to safety in the CAHPS Nursing Home Survey

“What number would you use to describe how safe and secure you felt in the nursing home?” (response categories 0–10).

No data are reported in scientific publications; one publication describes the development of the questionnaire (35).

Item related to safety in the CAHPS Surgical Care Survey

“Did this surgeon or a health provider from this surgeon’s office warn you about any signs or symptoms that would require immediate medical attention during your recovery period?”

No data are reported in scientific publications; one publication describes the development of the questionnaire (36).

### ***Commonwealth Fund surveys***

The Commonwealth Fund is a private foundation that aims to promote a high-performing health care system with better access, improved quality and greater efficiency, particularly for low-income people, the uninsured, minority Americans, young children and older adults. The Fund achieves this through supporting research, including an extensive programme of patient/consumer surveys on health care issues, both in the United States and internationally (66).

Questions related to patient safety have been asked in two surveys: the Commonwealth Fund Survey of Public Views of the US Health Care System and the Commonwealth Fund International Health Policy Survey of Sicker Adults. Commonwealth Fund surveys are conducted in national languages via telephone interviews with residents of the countries included in the surveys.

### Adverse events

Respondents from the United States were asked about the occurrence of adverse events in the Commonwealth Fund Survey of Public Views of the US Health Care System 2011. Thirteen per cent said that they or a family member acquired an infection or complication as a result of medical care and 15% reported experiencing a surgical or medical error or mistake, including incorrect drug dosage or laboratory results (67).

The 2008 Commonwealth Fund International Health Policy Survey of Sicker Adults was conducted in eight countries: Australia, Canada, France, Germany, the Netherlands, New Zealand, United Kingdom and United States. Patients with chronic disease who had been hospitalized in the previous two years were included. Of these patients, between 7% (France) and 18% (United States) reported that they had been readmitted to hospital or went to the emergency room because of complications during recovery (68).

Of all the patients with chronic disease who participated in the survey:

- » 6% (the Netherlands) to 14% (United States) reported that they had been given incorrect medication or doses;
- » 8% (United Kingdom and France) to 17% (Australia) reported a medical mistake in treatment; and
- » 1% of those who had been subject to laboratory tests in the Netherlands to 7% in Australia and the United States reported having been given incorrect results.

Most errors in medication, treatment or laboratory testing occurred outside the hospital.

### Safety management

Of the hospitalized patients in the 2008 Commonwealth Fund International Health Policy Survey of Sicker Adults, 8% (United States) to 17% (United Kingdom) reported that they had not been given instructions about symptoms and when to seek further care. Forty per cent (Canada) to 68% (France) who regularly took prescription medicines reported that doctors or pharmacists sometimes/rarely/never reviewed and discussed all the medications they were using.

### *Netherlands CQI*

The CQI was introduced by the Netherlands Ministry of Health, Welfare and Sports in 2006 as the national standard for measuring patient experiences with health care providers and health plans. The CQI is a registered trademark that is owned by the Centre for Consumer Experience in Health Care, which coordinates the development of CQI surveys and collects emerging data. CQI questionnaires measure patient experiences rather than patient satisfaction (53). Patient experience questionnaires ask whether certain processes and events occurred, combined with questions about values and expectations with regard to health care.

Currently, 22 sets of questionnaires have been developed, covering health and social care literally from the cradle (perinatal care) to the grave (palliative care). CQI questionnaires cover services such as long-term care for older people, home care, mental health care, general practice, physiotherapy, hospital care, elective surgery, haemodialysis and

rehabilitation. Results of CQI surveys are used for public reporting, providing consumer information and improving the quality of care, among other things.

The Centre for Consumer Experience in Health Care has an online database of all the individual items in CQI questionnaires that was used to identify questions about experiences with patient safety, adverse events, trust, and so on. After identifying these questions and their location (within, for example, a specific CQI questionnaire), publications were searched to find empirical data collected with the questionnaires. This resulted in the findings reported in the sections below.

#### Adverse events

Sixteen per cent of Netherlander breast cancer patients reported that they had experienced infections after their surgery (69). Six per cent of those who had total-hip or total-knee replacement reported that they needed a second operation because of a complication or infection.

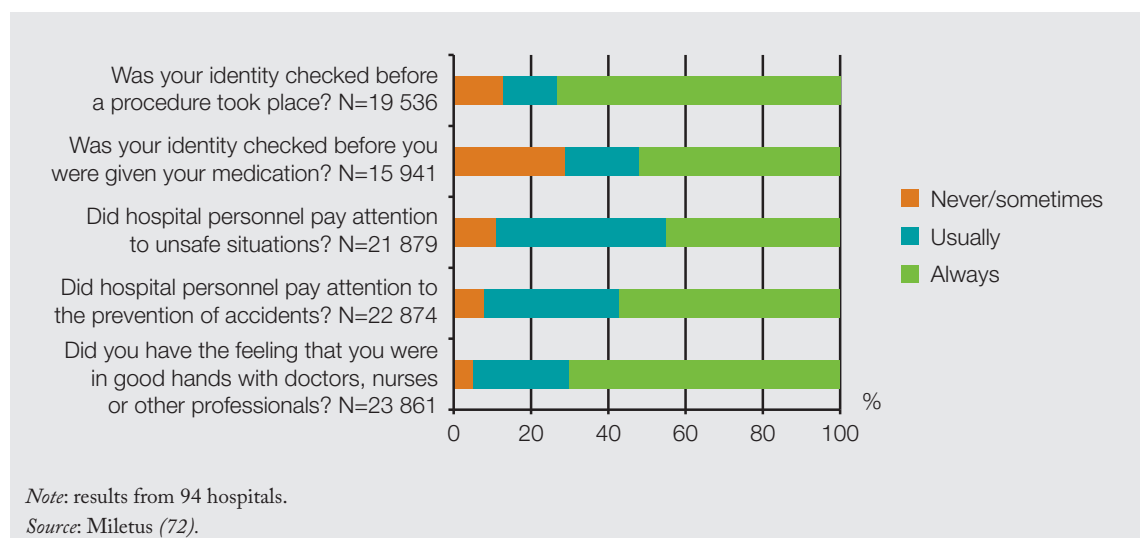
Three per cent of cataract patients reported that they had been reoperated on within three weeks (70) and 13% reported that they experienced complications (71).

#### Safety management

Twenty-three per cent of cataract patients reported that they were not told what to do in case of emergency; 46% reported that hospital personnel did not ask them if they were allergic to iodine; and 40% said that hospital personnel did not ask them if they were allergic to any other drug (71).

Twenty-nine per cent of hospital patients reported that their identity was “never” or only “sometimes” checked before they were given their medication, and 13% that their identity was “never” or “sometimes” checked before a procedure was performed (72) (Fig. 7.1).

**Fig. 7.1. Patient experiences with safety management – inpatient hospital care in the Netherlands, 2009**



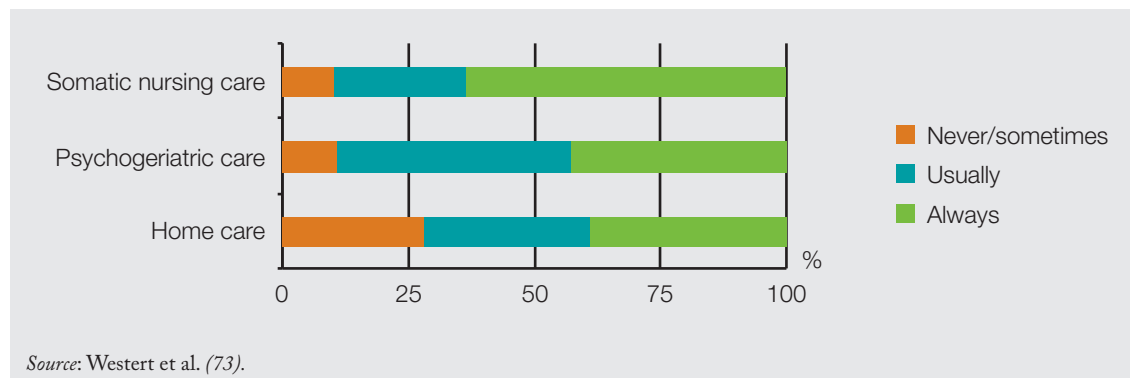


### Feeling safe

Five per cent of hospital patients reported that they “never” or only “sometimes” felt safe in the hands of doctors and nurses during their hospital stay (72) (Fig. 7.1).

Ten of the nursing home clients questioned reported that they “never” or only “sometimes” experienced competent and safe care; 11% of families of clients on psychogeriatric wards reported that they “never” or only “sometimes” experienced competent and safe care; and 44% of home care clients “never” or only “sometimes” experienced competent and safe care (73) (Fig. 7.2).

**Fig. 7.2. Clients experiencing competent and safe care – nursing homes and home care in the Netherlands, 2006**



### Being actively involved

Thirty per cent of cataract patients reported that their ophthalmologist was never/sometimes willing to talk about things that had gone wrong (71). Thirty-three per cent of breast cancer patients reported that their health care providers were never/sometimes willing to talk about things that had gone wrong (69).

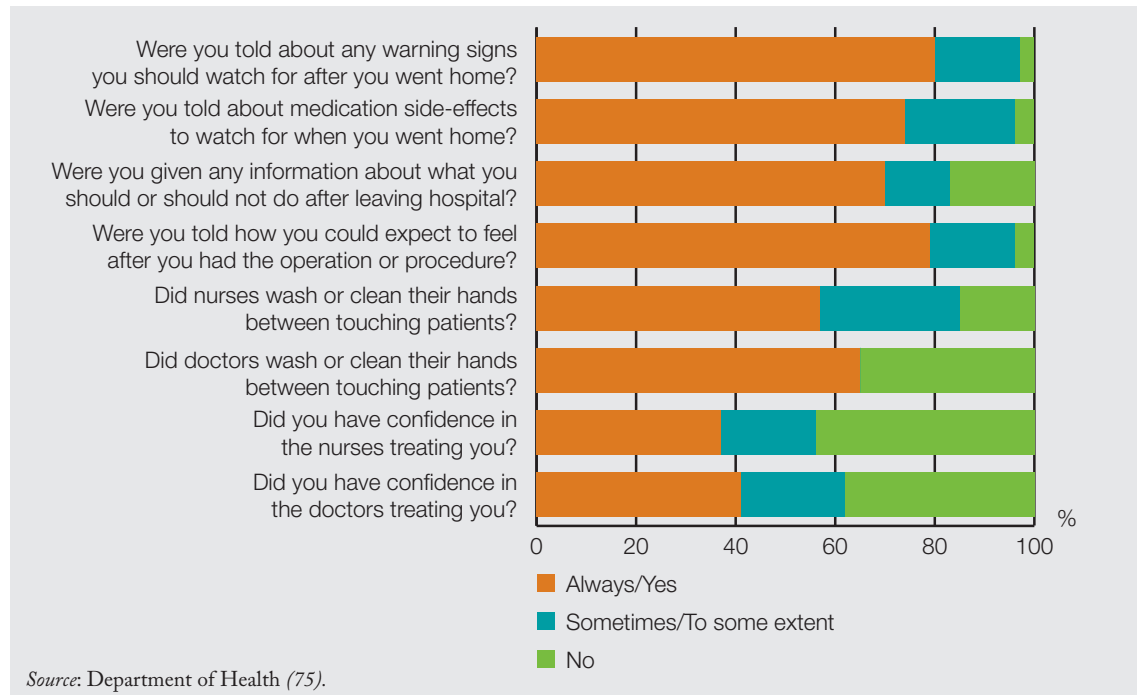
### Surveys of the CQC

The CQC in United Kingdom (England) coordinates patient surveys and collects feedback on individuals' experiences in using a range of health care services provided by the NHS. Several questions in the adult inpatient survey are related to patient safety. Data are reported on the CQC web site (74).

### Safety management

Seventeen per cent of patients who were given medication to take home with them said they received an explanation “to some extent”, but an additional 9% said that a member of staff did not explain the purpose of the medicines. Forty-four per cent reported that they were not informed about medication side-effects that could occur at home (Fig. 7.3). Thirty-five per cent said they were not given written or printed information about what they should or should not do after leaving hospital and 38% were not told about any danger signals they should watch for after they went home.

When asked about hand washing, 78% of respondents said that as far as they knew, doctors “always” washed their hands between touching patients, while 7% said that this

**Fig. 7.3. Inpatient experiences in NHS hospitals, 2010**

did not happen (as far as they knew). For nurses, the percentages were 79% (“always”) and 4% (“never”).

#### Feeling safe

Seventeen per cent said they “sometimes” and 3% “never” had confidence and trust in the doctors treating them. For nurses, the percentages were 22% and 3% respectively. Ten per cent felt that there were “rarely or never” enough nurses to care for them during their hospital stay (Fig. 7.3).

#### Being actively involved

Eighty-eight per cent of respondents were not asked to give their views on the quality of their care while in hospital and 58% did not see posters while in hospital explaining how to complain about care they received.

#### ***Eurobarometer: patient safety and quality of health care***

The European Commission has been monitoring the evolution of public opinion in EU Member States since 1973. Public opinion is monitored through the “Eurobarometer”, which consists of standard and special surveys. Special surveys take place for in-depth studies and are integrated in the standard Eurobarometer polling waves.

A special Eurobarometer survey was carried out in 27 EU Member States in September and October 2009. The survey focused on Europeans’ perceptions of patient safety, their attitudes toward the quality of health care in their country and their actual experiences regarding adverse events. This special Eurobarometer was part of wave 72.2 of the Eurobarometer surveys (12) covering the population of the respective Member States. Residents aged 15 years and over were sampled via a multistage random design, with a

probability proportional to population size and density. The respondents represented the whole territory of the countries surveyed, according to the distribution of the resident population. Interviews were conducted face to face in people's homes and in their national language. A total of 26 663 interviews were completed (12). The findings in relation to actual experiences of Europeans are described in this section.

#### Adverse events

Twenty-six per cent of respondents said that they or a member of their family had experienced an adverse event when receiving health care. Percentages were highest in Sweden (49%), Denmark (43%), Latvia (43%) and the Netherlands (42%) and lowest in Austria (12%), Portugal (13%), Italy (15%) and Bulgaria (15%).

More adverse events were reported by respondents who were aged between 40 and 54 years and were educated to a higher level, who worked as managers (compared to other occupational groups) and who frequently had problems paying their bills.

#### *Patients' attitudes, involvement and experiences*

There is increased interest in the role of the patient in safety management. Three questions have been addressed in this chapter.

1. What are patients' attitudes towards their involvement in patient safety?
2. What are the actual effects of involving patients in safety management?
3. What are the experiences of patients with respect to:
  - the occurrence of adverse events;
  - safety management in health care facilities; and
  - being actively involved in safety management and feeling safe?

#### Attitudes

Patients seem to be rather conservative in defining their role. "The patient role is to follow instructions" and "patients should expect competent care" are the two most frequently mentioned comments in the qualitative study by Rathert et al. (1), although it should be noted that this study was carried out among patients who had been in hospital. The potential role of patients in an acute care setting such as a hospital should not be overestimated. Many are not capable of active involvement, not even when they are explicitly invited to be involved in, for instance, marking a surgical site or questioning staff about hand washing. The studies described in this chapter show that it is possible to stimulate a certain group of patients to ask about hand washing or mark a surgical site, but confronting medical professionals and questioning medical authority is something that many patients find difficult. In the experiments that have been described in the relevant literature, about 91% of patients asked a nurse about hand washing, but only 33% "dared" to ask a doctor. Netherlands patients, among whom roughly one third stated that their doctor was never/sometimes willing to talk about things that had gone wrong, also reported such responses. It should be borne in mind that people are at their most vulnerable in a hospital setting and it is questionable whether they should be encumbered with the additional burden of being responsible for ensuring their own safety. Participation and involvement should not imply that professionals devolve responsibility for safety to patients.

In the ambulatory care setting, where HCWs are not present on a 24-hour basis, self-management is much more important, particularly for chronically ill patients and for those with comorbidities. Chronically ill patients often welcome opportunities to be more actively involved in care and also, therefore, in patient safety. They have become experts in dealing with their own disease(s), therapies and medications and know how to navigate the health system and deal with a variety of health professionals.

For chronic patients in an outpatient setting, safety issues often revolve around medication safety. Patient involvement in medication safety has been studied by Hall et al. (8). As was noted above, they concluded that the methodological quality of most of the studies in this field was poor, making it difficult to draw conclusions about the safety benefits of interventions. More research is needed in this area on, for instance, medication safety as a joint responsibility of patients and pharmacists (76–79).

#### Effects of patient involvement

Various innovative interventions have been studied with respect to patient involvement in the safety of hospital care. Interestingly, in one of the experiments concerning hand washing, it turned out that the increase in soap usage by staff had already occurred in the pre-programme period. Staff had anticipated the need to increase hand washing before patients were encouraged to ask about hand hygiene. This shows that many improvements are not discrete, single “before–after” changes, but instead follow an evolutionary path in which the context of implementation is important (80,81). It also shows that the threat of embarrassment which follows disclosure of unsafe behaviour is apparently a positive incentive to improve hand hygiene. This resembles a phenomenon that has also been demonstrated for public reporting of performance data. Public disclosure of substandard performance triggers professionals and managers to improve the quality of care (62). This is related to the fact that safety performance is an important attribute that determines patients’ choice of a hospital for elective procedures, such as cataract surgery or hip or knee replacement (82).

A potential role for patients in safety management therefore lies in asking them to report the occurrence of adverse event and to measure their experiences of safety management.

#### Patient experience surveys

The review of patient experience questionnaires showed that, despite the emphasis that has been placed on safety after the IOM publication *To err is human – building a safer health system* in 2000 (83), the CAHPS questionnaires contain only a few items related to patient safety. Results of surveys in which these items have been used are scarcely available in the public domain. Safety issues are nevertheless included in Commonwealth Fund surveys conducted not only among the United States population, but also in samples of chronically ill individuals in eight industrialized countries. A European survey in the Eurobarometer series showed that on average, 26% of respondents stated that they or a member of their family had experienced an adverse event while receiving health care (12).

Surveys conducted by the CQC and those of the CQI show that surveys provide a useful tool in measuring patients’ experiences of various aspects of health care safety. This is promising, as adverse events are generally underreported in complaints, claims and incidence reports. In addition, there is little overlap in adverse events covered by health

care professionals' and patients' reports: both groups report different adverse events and, consequently, patient reports can complement professionals' reports (84).

Of course, patient surveys only provide the patients' perspectives on safety. Many aspects of safety management take place "behind the scenes", out of sight of patients. This is also true of some of the safety aspects that are currently covered in patient experience questionnaires, such as items relating to hand washing by doctors and nurses. Patients' reports should therefore always be used in combination with other sources of information in public reports on the safety of care provided in health care facilities.

### *Limits to patient participation*

Although there seem to be possibilities for patients to be involved in safety management, it is essential to also be aware of the limitations. Not everyone is capable of being involved. Even tasks that seem rather straightforward at first glance, such as marking a surgical site, can be difficult for many patients. It is not altogether clear why and how such things are problematic. Watt (85) concludes that:

[F]ew of the interventions have been evaluated for effectiveness or acceptability, many appear to be 'knee jerk' reactions to adverse events and their theoretical basis has not been established. There appears to have been little consideration of the mechanism of effect and of what conditions and circumstances are required for patients to adopt safety roles.

The findings described in this chapter show that compliance with the request to mark a surgical site is lower if more time elapsed between enrolment and the surgery, in older patients and in those who do not use English as their primary language (11). This suggests that some patients forgot the instructions given to them and that others were not able to comprehend them in the first place.

On a more general level, difficulty in achieving patient involvement in how their care is being delivered arises from a variety of aspects:

- » patients are at their most vulnerable and least assertive in the acute care setting;
- » the attitudes and behaviours of individual health care professionals may pose difficulties;
- » it is not often habitual to invite patients to be partners in their care; and
- » fear for the real or imagined possibility of being labelled a "difficult" or "over-anxious" patient also comes into play.

The degree to which patients are confident and competent to participate in safety management and in reporting on safety in patient experience questionnaires is related, among other things, to (health) literacy. Health literacy is "the ability to read, understand, and act upon health information" (86). Apfel et al. (87) state:

Health literacy skills include basic reading, writing, numeracy and the ability to communicate and question. Health literacy also requires functional abilities to recognize risk, sort through conflicting information, make health-related decisions, navigate often complex health systems and 'speak up' for change when health system, community and governmental policies and structures do not adequately serve needs.

Health literacy is an important precondition for reading and understanding patient information about risks and benefits of medical procedures, about the course of a certain disease and symptoms to watch for, about side-effects of interventions or medication, and about safety management in general. A recent United States study showed that about 60% of medical inpatients have limited health literacy. Patients in the lowest literacy group were significantly older, were less educated and had a lower income (88).

Although limited health literacy is problematic in an inpatient setting, it is even more so in outpatient, chronic care. Patients are willing to participate in safety management in an inpatient setting, but health care professionals are ultimately responsible for the delivery of safe care. In ambulatory care, however, patients must adhere to medication regimes and follow instructions about self-care without the constant presence of a health care professional. Patients must assume responsibility for their own “quality control”, for implementing medical instructions and for making health decisions (89).

Adherence to medication instructions among chronic patients is often as low as 50% and is related to patient knowledge. It has been shown that consumer understanding of prescription drug information and self-management skills are lower for people with lower health literacy rates (87,90). The relationship between self-management, adherence to medication instructions and literacy is well known, but it still seems to be difficult to develop tools to address the problem (91). Wolf & Cooper Bailey suggest improving provider–patient communication, improving the readability of health materials such as information leaflets and putting in place sustainable processes to routinely identify and track patients who may be struggling to properly comply with medical instructions (89).

Generally speaking, the crucial counterpart of the empowered patient is the “patient-literate” health professional. It is necessary to improve the communication and listening skills of health professionals. Patients can be involved in providing feedback on doctors’ communication skills (92). As a means of providing systematic feedback, the CAHPS Consortium has developed a set of questions that measure patients’ perspectives on how well health care professionals communicate health information (93). Examples of questions from the CAHPS Health Literacy Item Set include: “In the last 12 months, how often did this doctor use medical words you did not understand?”; and: “In the last 12 months, how often did this doctor use pictures, drawings, or models to explain things to you?” Questions such as these are useful for monitoring professionals’ efforts to empower patients and improve their self-management skills.

Another measure to assess health literacy and self-management skills is the Patient Activation Measure developed by Hibbard et al. (94–99). Studies of its use show that chronic patients’ activation levels can be improved and that this leads to better self-management. Hibbard concludes that by encouraging small and realistic steps toward improving health, it is possible to improve self-management (98).

Although the patient–professional relationship is crucial when it comes to enhancing patient involvement, this also places demands on health care systems. The Patient Involvement in Patient Safety Research Group states that it should be made easier for professionals to enable patient involvement in safety by, for example, ensuring a reasonable workload. The



group recommends that patient involvement in health care safety should be facilitated not only by an emphasis on patient roles, but also by amending health care systems and supporting health care professionals to develop better relationships with patients (85).

## Recommendations

The following recommendations can be made.

### ***Recommendation 1 – Take patients' vulnerability into account***

The findings suggest that patients are willing to be involved in safety management insofar as this encompasses actions that patients are traditionally used to taking, such as informing doctors about certain allergies to medication. Actions that require patients to assume new responsibilities, such as marking a surgical site, are found by a substantial group of patients to be more difficult to perform. Patients might not have the cognitive or psychological competences to be actively involved, lacking health literacy. In addition, there are ethical issues to consider, especially in an inpatient setting: should the burden of being responsible for safety issues be assigned to patients at a time at which they are most vulnerable? Interventions aimed at engaging patients should take these considerations into account.

### ***Recommendation 2 – Hospitals should provide tailor-made discharge information***

In patient surveys of the CQC in United Kingdom (England) and in the Netherlands CQI, various items refer to patients' experiences with safety. The results of those surveys suggest that inpatients' experiences with safety management are generally positive. There are, however, some areas of concern. For example, being told what to do in case of emergency at home or being told what signals or side-effects to look out for after hospital discharge are aspects of safety management that leave room for improvement in hospitals in both countries. Information should be tailored, in the sense that it should refer to specific conditions or treatments.

### ***Recommendation 3 – Measure and publish patients' experiences with safety management***

A way to improve hospitals' performance in these areas might be the public disclosure of patients' experiences with these aspects of care. Disclosure of substandard performance triggers professionals and managers to improve the quality of care, and it encourages patients to choose safe hospitals. The examples of the surveys described in this chapter show that it is possible to measure patients' experiences with various aspects of health care safety.

### ***Recommendation 4 – Combine patient experience surveys with other sources of information about safety management***

Patient surveys only provide the patients' perspectives on safety. Many aspects of safety management take place "behind the scenes", out of sight of patients. Patients' reports should therefore always be used in combination with other sources of information in public reports on the safety of care provided in health facilities.

### ***Recommendation 5 – Monitor professionals' efforts to improve self-management skills***

While professionals are responsible for patient safety in hospitals, patients are responsible for their self-management and adherence to medication instructions in ambulatory care. People with low levels of health literacy have difficulties in assuming that responsibility. They need help through readable health materials and in the form of tailored instructions.

Providing these is the responsibility of professionals. Again, patient experience surveys can be used to monitor professionals' efforts to empower patients and to improve their self-management skills. The CAHPS Item Set for Addressing Health Literacy or the Patient Activation Measure serve as good examples of these kinds of surveys.

***Recommendation 6 – Combine quantitative data with qualitative narratives***

It should be borne in mind that the least-literate patients are also least capable of filling out questionnaires. It is obvious that a certain level of literacy is required for patients to be able to complete questionnaires about their experiences with health care safety. Even when older people respond, they have higher rates of missing items (100). Questionnaires can be difficult to understand for patients with low literacy levels. King et al. therefore suggest that future patient reporting systems should balance closed-ended questions for cause analysis and classification, and open-ended narratives to allow for patients' limited understanding of terminology (101). Patient stories are not only a rich source of information, they can also serve as a powerful tool to influence and change professionals' behaviour (85).

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# CHAPTER 8. CONCLUSIONS AND RECOMMENDATIONS

*Diana Delnoij, Valentina Hafner*

## Introduction

Patient safety is an issue of increasing concern in health care systems all over the world. It involves in the same time various actors, with the patient/consumer at its core. Only an informed and empowered consumer can actively contribute to improve communication as well as health care outcomes (WHO Regional Office for Europe, unpublished data, 2009).

The aim of this report is to identify means to improve patient safety by articulating patients' rights and enhancing patient empowerment. Several dimensions of health care provision have been touched upon, ranging from technical and legal to social dimensions. We have tried to unravel the causal mechanisms along which legislation and various charters describing patients' rights at macro level lead to patient empowerment and participation, and how this empowerment and participation in turn can help organizations at meso level, individual patients and professionals in the primary process (micro level) to improve the safety of health care delivery.

Patient roles in strengthening patient safety have been explored, including:

- » involvement in monitoring and reporting adverse events;
- » checking and double-checking that they are given the correct medication, in the correct dose and at the correct time;
- » being informed about what to expect in terms of surgery;
- » being encouraged to report any adverse event or complication;
- » observing and asking staff about hand washing; and
- » ensuring they have been properly identified prior to treatments.

The previous chapters focused on the following topics.

- » In Chapter 2, an overview of international documents and guidelines from the CoE, the EU and WHO with respect to legal aspects of patient safety were presented. Patients' rights that are directly or indirectly related to patient safety were described in some detail and contextual factors that may influence the effectiveness of legal interventions were analysed.
- » Chapter 3 included discussion of a study of hand hygiene in Bulgaria. Results were presented from a survey of patients in two Bulgarian hospitals that explored patients' knowledge of HAIs and their willingness to participate in hand hygiene compliance in health care.
- » In Chapter 4, the focus was on blood transfusion safety in France. It presented: an overview of the literature in this field; a description of the legal rights and responsibilities of the different actors involved in blood transfusion; and the results

of a small-scale patient survey addressing understanding of written and oral information on blood transfusion and patients' recommendations with regard to their involvement in the transfusion process.

- » Chapter 5 described medication safety in Polish primary care. The study included a review of legal documents and legal acts, and a survey of doctors' and patients' knowledge of medication safety. An overview of data from the RCMADR in Kraków was also presented.
- » In Chapter 6, Portuguese legislation and ethical codes relevant to elective surgery safety were described. Portuguese data on surgical safety were also reviewed.
- » Chapter 7 addressed three questions.
  1. What are patients' attitudes towards their involvement in patient safety?
  2. What are the effects of involving patients in safety management?
  3. What are the experiences of patients with respect to the occurrence of adverse events, feeling safe and being actively involved in safety management?
 The questions were answered through a study of the literature and a review of patient experience questionnaires and related survey data.

In this final chapter, general conclusions are drawn and recommendations formulated, addressing macro, meso and micro levels of health care. The conclusions and recommendations are based on the evidence presented in the previous chapters.

### Macro level

Many countries in the WHO European Region have adopted laws and regulations in which patients' rights are described. In Chapter 2, Legemaate refers to a recent overview of national patients' rights legislation in Europe by Nys & Goffin (1). The authors conclude that the way in which patients' rights are defined and implemented is largely determined by national law and differs widely from country to country. In addition to general legislation on patients' rights, Legemaate describes specific legislation regarding patient safety that has been implemented in, for example, Denmark and the United States. The legislation of these two countries focuses on reporting adverse events and regulating reporter protection.

No matter how important the definition of patients' rights, Legemaate cautions readers as to the limits of the law (2). Legal interventions are useful in increasing awareness, but the law does not always reflect daily practice, as has been demonstrated in several chapters of this report (see Box 8.1 for a summary). Legemaate argues that daily practices often develop rather independently from the intentions of legislators and courts and are subject to social, cultural, political, financial and practical processes. These processes influence the effectiveness of legal interventions to improve the patient's position. Legemaate therefore stresses the importance of implementation. This is not the same as more regulation and (further) juridification.<sup>37</sup> An example of juridification is the obligation in French law to provide written information, when in fact patients seem to prefer oral information (see Chapter 4). The right to information, according to Legemaate, forms the core of the individual patient's legal position: "Other rights lose their meaning or become ineffective in the absence of adequate information" (see Chapter 2). Information is the key to patient

37 Referred to here as a process of increasing legal intervention.

involvement in safety issues in, for instance, the area of medication safety. Yet patients often lack the most basic information about the medicines they are taking (see the section on the micro level below).

### *Box 8.1. The limits of the law*

#### **Chapter 4 (Blood transfusion safety in France)**

- » Despite the law, patients and the general public mostly ignore their rights.

Even though written information is compulsory by law, the written form is not systematically provided by prescribers of blood transfusion. Prescribers, but also patients, expressed their preference for oral information.

#### **Chapter 5 (Patient safety, rights and medication safety in primary care in Poland)**

- » Doctors are legally obliged to report ADRs to the National Bureau for Registration of Medicinal Products. However, 74% of the primary care doctors involved in the survey had never reported an ADR at the time at which it occurred.

#### **Chapter 6 (Patient engagement in elective surgery safety in Portugal)**

- » Informed consent application differs among health care providers. Thirty per cent of patients in the surgery unit of a Portuguese hospital had not received information about other treatment options.

One of the problems in relation to implementation of patients' rights is that patients are often dependent on providers to effect and enforce their rights. If patients' rights are not mirrored by providers' obligations, difficulties may arise. As discussed in Chapter 1, the Hippocratic Oath forms a good starting point in the development of professionals' codes with respect to patient safety. According to Legemaate (Chapter 2), professional obligations and standards include the rights of patients as well as the prevailing norms regarding the quality and safety of care. Present-day professional obligations of health professionals include a willingness to report incidents and adverse events and to otherwise participate in activities and systems to improve the quality and safety of care. Similarly, patients' right to information is reflected in professional codes, such as the Portuguese Medical Association's ethical code (see Chapter 7). According to Article 44 of this code: "[T]he patient has the right to receive and the physician the duty to provide clarification on the diagnosis, treatment and prognosis of his disease".

However, if a health professional does not have sufficient communication skills or views the duty to inform the patient as a non-medical but legalistic obligation, the goals embodied in the rights of patients will not be adequately met (Legemaate, Chapter 2). In most of the chapters of this report, therefore, recommendations are made with respect to the curricula and CME of professionals (Box 8.2).

### **Meso level**

The meso level involves health care institutions, such as hospitals. The primary obligation and responsibility for quality and safety lies at this level. As Legemaate argues in Chapter 2, health care institutions should facilitate health professionals to respect patients' rights and fulfil their other professional obligations; they should put in place an effective and comprehensive safety management system in which there is room to incorporate information obtained from patients and their organizations. Kutryba also recommends involving patient organizations in providing the appropriate developments, skills, knowledge, empowerment and encouragement for patients (Chapter 5).

**Box 8.2. Curricula and CME****Chapter 2, Recommendation 9 – Include safety issues in the curricula of health professionals**

- » Sufficient attention should be given to patient safety issues in relation to the rights of patients in education and training curricula for (future) health professionals.

**Chapter 3, Recommendation 2 – Educate HCWs on patient involvement in safe care**

- » Patient participation in hand hygiene could be further enhanced through HCWs' education, focusing on promotion and advocacy for patient participation in safe care and using explicit invitations from HCWs as guidance.

**Chapter 4, Recommendation 2 – Upgrade doctors' communication skills**

- » This could be achieved by rethinking communication on blood transfusion and upgrading doctors' knowledge through CME programmes dedicated to communication with patients. The key point is to listen to patients to understand whether they want to be involved or not. Where possible, the fact that the patient wants to be involved (or not) and/or to receive information (or not) should be formalized.

**Chapter 5, Recommendation 3 – Improve professional competences**

- » All health professionals should recognize the value of patient involvement and have access to sound basic-level and continuing education that covers clinical knowledge and medicine therapies, clinical guidelines, communication skills, human relationships and safe medication practices. Professional competences should be regularly evaluated. Information needs of different populations and special groups, such as older people, children, disabled people, migrants and individuals with low levels of health literacy, should be taken into account.

**Chapter 6, Recommendation 4 – Design an education campaign for health care professionals**

- » Acknowledging that HCW-related factors contribute to patient participation in enhancing health care safety, it is important to understand the level of acceptance and readiness of the actors involved to embrace the new role of the patient. More research could contribute to the real awareness, commitment and experiences of HCWs and health care institutions in relation to patient safety and patient engagement in the domain of surgical care.

To articulate and defend patients' interests in the policy arena, however, patient organizations should have information at their disposal about what patients find important, detailing their experiences with safety management. Examples in Chapter 7 show that it is possible to use patient surveys as a tool to measure patients' experiences with various aspects of health care safety. Patient surveys form part of a systematic programme of work that takes place at regular intervals in several European countries. This is certainly the case in Denmark, Norway, United Kingdom (England) and the Netherlands.

Patient experience surveys often serve multiple purposes, including use in internal quality improvement activities. In most countries, however, surveys also aim to provide comparative information for the public. Delnoij (Chapter 7) recommends publishing the findings of patient experience surveys because public disclosure triggers professionals and managers to improve the quality of care and encourages patients to choose safe hospitals. Legemaate also recommends providing patients with this kind of information (Box 8.3).

In Chapter 2, public disclosure is defined in terms of patients' right to information about the safety and quality of health services. This is an individual right from the patient's point of view, but collecting information about performance indicators can best be realized at a collective level, as the information is not comparable without consensus about definitions and data collection methods.



### *Box 8.3. Public consumer information*

#### **Chapter 2, Recommendation 3 – Provide individual patients with relevant information**

Information and communication are key words in this process. Patient participation starts with the availability of valid, clear and relevant information at various levels, including information related to:

- » the basis on which patients can differentiate between (the quality and safety of) health care providers;
- » the patient's health situation, available treatment options and potential risks to the patient's safety; and
- » how to get involved in patient safety activities.

#### **Chapter 7, Recommendation 3 – Measure and publish patients' experiences with safety management**

A way to improve hospitals' performance might be the public disclosure of patients' experiences with aspects of care. Disclosure of substandard performance triggers professionals and managers to improve the quality of care, and it encourages patients to choose safe hospitals. Examples in Chapter 7 prove that it is possible to measure patients' experiences with various aspects of health care safety.

Consumer web sites offer a means of communicating information about health care providers' performance. Consumer information about the quality and safety of health care providers in the Netherlands is presented on various web sites (see Chapter 2). In Portugal, a national health care institution evaluation system – the SINAS – is being developed. The intention behind the SINAS is to evaluate health care institutions according to ratings within different parameters, such as clinical excellence (already implemented), patient safety, infrastructure, and – in future – patients' satisfaction and comfort (see Chapter 6).

As is the case in the Portuguese example, information about the performance of health care providers with respect to patient safety should be derived from a variety of sources. After all, patient surveys only reflect patients' perspectives on safety: many aspects of safety management take place “behind the scenes”, out of patients' sight (see Chapter 7). Legemaate (Chapter 2) therefore recommends combining information from different sources: incidents reported by health professionals or patients, complaints filed by patients with a complaints official or committee, claims for compensation for damage due to an alleged medical error, and so on.

Safety management of care delivered by chains of providers presents a difficult problem. Almost all the experts interviewed about blood transfusion safety in France, for instance, identified a need to involve GPs in follow-up tests because there is a lack of awareness on the part of GPs about the importance of post-transfusion check-up tests (see Chapter 4). Similarly, the authors of Chapter 7 demonstrate that there is room for improvement in discharge management in hospitals in United Kingdom (England) and the Netherlands, particularly in relation to telling patients what to do in case of an emergency at home or what signals or side-effects to look out for after hospital discharge. The question arises as to who is responsible for integrated safety management. In social insurance systems, health insurers could play a role in this process, including being responsible for integrated care and safety. To be able to fulfil that role, health insurers should actively solicit the opinions and experiences of their enrolees (see Chapter 2).

### **Micro level**

The micro level refers to the primary process in which health care provision and consumption takes place. It is important to make a distinction here between care that



is provided through interaction of a patient with health care professionals and patient self-management.

### ***Patient–professional interaction***

There is information asymmetry between health care professionals and patients: consequently, the professional acts as the patient’s agent. This implies that the professional is responsible for the patient’s safety, but also allows room for patient involvement. In theory, patients can also stake a claim in terms of responsibility for their safety, but self-confidence and knowledge are required to question professional authority. The Bulgarian study presented in Chapter 3, for example, shows that most respondents believed that asking HCWs to wash their hands would prevent HAIs, but more than half stated they would not feel comfortable asking their nurses or physicians to clean their hands. Questioning authority is more difficult with doctors than nurses (see Chapter 7). It may even seem easier to switch to another care provider when disagreement or dissatisfaction arise or, if that is not an option, to simply not follow the doctor’s orders: this is referred to as “nonadherence” or “noncompliance” and is a highly undesirable outcome of patient–professional interaction. Health care professionals should therefore at least stimulate patient involvement from the medical point of view, if not from an emancipator perspective.

There is evidence that patients with myocardial infarction who receive patient-centred care have higher rates of survival after 12 months (see Chapter 7). It is not altogether clear what the causal mechanism behind this is, but avoiding noncompliance may have something to do with it.

Involving patients in decisions about their care and treatment is often referred to as SDM (see Chapter 2). SDM is defined as the involvement of patients with their providers in making health care decisions that are informed by the best available evidence about treatment and illness management options and potential benefits and harms, and which consider patient preferences. This is a necessary precondition to guaranteeing informed consent. To provide consent, a patient needs clear and adequate information that focuses on the nature of the condition, the (possible) effects and side-effects of proposed treatment, possible alternatives and the likely implications of not treating. Legemaate argues in Chapter 2 that the importance of the right to information goes beyond legitimizing consent; it may also strengthen the relationship between the patient and the health professional and thereby stimulate patient compliance.

So, patient involvement is essential for many reasons. The question, however, is: do patients want to be involved? The findings from the literature reviewed in Chapter 7 suggest that on a general level, patients and the public support an active role for patients in error prevention. That said, patients are more likely to support traditional actions, such as ensuring information transmission from patient to provider, rather than actions that require them to challenge medical authority. Patients expect competent care and many patients view their role as passive: they do not see patient safety as their responsibility.

In practice, many patients have difficulties in assuming an assertive and active position. Patients are often unable or unwilling to speak up, particularly when HCWs behave in ways that indicate they are disinterested in, or distrustful of, their patients, and when

they do not routinely engage patients in discussions and decision-making (see Chapter 2). Even tasks that seem rather straightforward at first glance, such as marking a surgical site, appear to be difficult for some patients. It should be borne in mind, therefore, that patients are at their most vulnerable and least assertive in the acute inpatient setting (see Chapter 7). Very few studies to date have provided information on the profile of patients who are willing to participate (Chapter 4).

### ***Self-management***

Patient safety in the inpatient setting is first and foremost the responsibility of professionals, although examples describing how patients can be involved as coproducers of safe care are given in this report. Patient involvement is crucial. Patients in ambulatory care are expected to adhere to medication regimes and instructions about self-care without the constant presence of a health care professional. They or their family members must assume responsibility for their own “quality control” (see Chapter 7). They need comprehensive information, backed by scientific knowledge, to assume that role, because adherence to medication instructions among chronically ill patients (for example) is related to health literacy. The patient survey described in Chapter 5 revealed that 65% of patients surveyed took more than five medicines every day, but that only 39% knew the names and dosages of the medicines they took. Knowledge of medicines’ names and dosages appeared to decrease with the increasing number taken.

Although the relationship between self-management, adherence to medication instructions and literacy is well known, it is difficult to develop tools to address the associated problems. Recommendations on patients’ health education are presented in several chapters (Box 8.4).

The most promising combination of approaches is probably to work not only on improving patients’ health literacy, but also to address the “patient literacy” of health care professionals. There is a need to improve health professionals’ communication and listening skills. Patients can provide feedback on doctors’ communication skills (see Chapter 7). It may be useful to monitor professionals’ efforts to empower patients and to improve patients’ self-management skills through surveys such as the CAHPS Health Literacy Item Set or the Patient Activation Measure. Studies involving the latter have shown that chronically ill patients’ activation levels can be improved and that this leads to better self-management (see Chapter 7).

### **Conclusion**

Milestones – set by European legislation – recommend that Member States promote and emphasize the role of patients to improve quality and safety of health care (3–5). These are complemented by the dedicated World Health Assembly resolutions and continuous work of the WHO Patient Safety Programme, particularly through its work on “Patients for Patient Safety”, and supported by the new WHO European health policy framework (6).

The studies presented in this report show that patient safety and patient involvement need to be addressed at different levels and from different perspectives. However, there is as yet limited evidence for the effectiveness of patient involvement in safety

### Box 8.4. Patient education

#### Chapter 2, Recommendation 5 – Minimize barriers to patient participation (health literacy and SDM)

Some individual patients or groups may have insufficient health literacy to participate in patient safety activities, lacking the necessary knowledge, skills and competences. Health literacy problems should be actively detected, monitored and remedied. Patients can claim a right to be supported. Important aspects to focus on include:

- » improving access to information;
- » training health care providers in effective communication;
- » developing and implementing systematic support for patients with insufficient health literacy; and
- » making information available in other languages or providing translation/interpreting services.

#### Chapter 3, Recommendation 1 – Educate patients on (their potential role in) hand hygiene

Appropriate patient information can play an important part in the process of active patient engagement in hand hygiene implementation. Development and extension of patients' education on hand hygiene, patient safety and reduction of HAI are key interventions that can be achieved through training and education programmes. Preparation and distribution of materials to raise hand hygiene awareness supports these interventions.

#### Chapter 4, Recommendation 4 – Educate patients

It is necessary to inform the general population on how the transfusion process works and to explain progress made in the field as part of building a safety culture. The development of health education and chronic condition self-management will promote patients' involvement.

#### Chapter 5, Recommendation 6 – Educate patients

There is a clear need for patient education, not only to improve health literacy, but also to facilitate communication with health care professionals on medicines prescribed and treatment courses followed (such as checklists like the Institute for Safe Medication Practices model, medicines memos and medicines lists). Doctors should articulate their expectations relating to patients bringing along their lists of medications with updated names and dosages, and patients should be made aware of the necessity of compiling a list of the medications they take. In addition, there is a need for patient education on the use of OTC drugs and the boundaries of safe self-care and treatment. Patients should be encouraged to use all potential sources of information about all medicines, including prescribed medicines, OTC drugs, dietary supplements and herbal remedies, as this contributes to medication safety and reduction of potentially related complications.

#### Chapter 6, Recommendation 7 – Disseminate information on patient safety via mass media

The lack of information that seems to exist in Portuguese society (81,82) demands a real commitment to engage with and inform citizens by disseminating information on patient safety standards, risks and safety measures to reduce or prevent errors and harm (3). Bearing in mind that television remains the preferred method for transmitting information to Portuguese citizens, enhancing television awareness campaigns – adjusted to users' ages, literacy levels and gender – may also contribute to global consciousness of the new role of the patient. Enhanced research on the use of ICT could also support the development of new campaigns by allowing know-how to reach the health care user.

management. This multidisciplinary field of research has only just begun to develop. It is important to strengthen crossfertilization and cooperation among the different areas of investigation. Patients' experiences with health care are usually measured as part of national programmes of performance measurement and public disclosure of performance indicators. These programmes often exist alongside national patient safety programmes, but have little interaction and may be administered by different agencies or departments. Even within health care facilities, the link between patient experiences and patient safety is not always well established. The emancipatory patients' rights movement can serve as a bridge between the worlds of quality, safety assurance and patient involvement and stimulate research in this field.

Two initiatives that have particular relevance to patient safety, the HANDOVER project addressing pathways between levels of care and research into the role of the consumer in patient safety in the Netherlands, are briefly described in Annex 7 and Annex 8.

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# ANNEX I.

## QUOTATIONS FROM INTERNATIONAL LEGISLATION

### *1 – Council of Europe, Recommendation 2006/7*

From the recommendation

Recommends that governments of Member States, according to their competencies:

- (i) ensure that patient safety is the cornerstone of all relevant health policies, in particular policies to improve quality; [...]
- (iii) promote the development of a reporting system for patient safety incidents in order to enhance patient safety by learning from such incidents; this system should:
  - (a) be non-punitive and fair in purpose;
  - (b) be independent of other regulatory processes;
  - (c) be designed in such a way as to encourage health care providers and health care personnel to report safety incidents (for instance, wherever possible, reporting should be voluntary, anonymous and confidential);
  - (d) set out a system for collecting and analysing reports of adverse events locally and, when the need arises, aggregated at a regional or national level, with the aim of improving patient safety – for this purpose, resources must be specifically allocated;
  - (e) involve both private and public sectors;
  - (f) facilitate the involvement of patients, their relatives and all other informal caregivers in all aspects of activities relating to patient safety, including reporting of patient safety incidents;
- (iv) review the role of other existing data sources, such as patient complaints and compensation systems, clinical databases and monitoring systems as a complementary source of information on patient safety (...)

From the appendix to the recommendation

D.1.2. Incident reporting systems are not intended to identify and punish the individual staff members involved in patient safety incidents.

D.1.11. When designing patient safety incident reporting systems it may be an advantage to have in place a complaints system, a patient compensation system and a supervisory body for health professionals. These should complement the patient safety incident reporting system, and together these systems would form an overall integrated system for managing risks – both “clinical” and “non-clinical”.

J.3. Legal approaches regarding patients’ rights should:

- (a) ensure that complaints, criticisms or suggestions made by patients or their representatives are taken seriously and handled appropriately;
- (b) ensure that patients are immediately informed of an adverse event and of any events entered into the patient's medical file;
- (c) ensure that patients that have been harmed by a patient safety incident are entitled to receive financial compensation;
- (d) ensure the presence of an efficient and sufficiently capable supervisory system to identify and manage cases of malpractice;
- (e) take into consideration the fact that any incident can have multiple legal consequences, depending on the nature and severity of the incident and the causal relationship between the process of care and an adverse event.

J.4. It may appear difficult to establish a patient safety reporting system without compromising patients' rights. However, if the public is ready to accept the presence of a confidential, anonymous, non-punitive reporting system, the public must be assured that their legal and financial rights will be protected. The existence of a fair and open complaints system, a just and adequate compensation system and an efficient and reliable supervisory system will certainly make the process easier and politically more acceptable. Promoting a "no-blame" culture is not intended to diminish the effective legal protection of patients.

## ***2 – Council of the European Union, Recommendation of 9 June 2009***

From the preamble

- (9) Patients should be informed and empowered by involving them in the patient safety process. They should be informed of patient safety standards, best practices and/or safety measures in place and how they can find accessible and comprehensible information on complaints and redress systems.

From the recommendations

- (3) Support the establishment or strengthening of blame-free reporting and learning systems on adverse events that:
  - (a) provide information on the extent, types and causes of errors, adverse events and near misses;
  - (b) encourage HCWs to report actively through the establishment of a reporting environment which is open, fair and non-punitive; this reporting should be differentiated from Member States' disciplinary systems and procedures for HCWs and, where necessary, the legal issues surrounding HCWs' liability should be clarified;
  - (c) provide, as appropriate, opportunities for patients, their relatives and other informal caregivers to report their experiences.

## ***3 – WHO draft guidelines for adverse event reporting and learning systems***

- (1) Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying systems factors.



- (2) When designing adverse event reporting and learning systems, the responsible parties should clearly set out:
  - the objectives of the system
  - who should report
  - what gets reported – mechanisms for receiving reports and managing data
  - sources of expertise for analysis
  - the response to reports
  - methods for classifying and making sense of reported events
  - ways to disseminate findings
  - technical infrastructure and data security.
- (3) HCWs and organizations should be encouraged to report a wide range of safety information and events.
- (4) HCWs that report adverse events, near misses and other safety concerns should not be punished as a result of reporting.
- (5) Reporting systems should be independent of any authority with power to punish the reporter.

## ANNEX 2.

# PATIENT QUESTIONNAIRE ON BLOOD TRANSFUSION

This questionnaire is anonymous. Please note that the results of this questionnaire are confidential. To answer, please circle the answer you choose. Several answers are sometimes possible.

<b>I. Personal information</b>					
1) Sex	F	M			
2) Age					
3) How many times have you been hospitalized?	0	1	2	3 and +	I don't know
4) How many times have you been transfused?	0	1	2	3 and +	I don't know
<b>II. Knowledge on transfusion</b>					
5) Do you know about patients' rights in France in the field of transfusion?	Yes	No			
6) Do you think blood transfusion presents severe potential risks?	Yes	No	I don't know		
7) Do you know why you have been transfused?	Yes	No			
8) Have you got information related to post-transfusion follow-up tests to be carried out 3 months after transfusion?	Yes	No	I don't know		
9) Do you know with which blood component you have been transfused?	Red cells	Blood platelets	Plasma	I don't know	
<b>III. Satisfaction and appreciation</b>					
10) Did you receive any written information on blood transfusion before being transfused?	Yes	No			
11) If yes, did you read it?	Yes	No			
12) Did you receive oral information on blood transfusion before being transfused?	Yes	No			
13) Who gave you this information?					
14) According to you, was the given information sufficient?	Yes	No			
15) If no, what would you have liked more information on?	Risks linked to transfusion	Possible alternatives to transfusion	Post-transfusion follow up	The actual process of transfusion	
16) Did you experience any difficulty in understanding the information given on transfusion?	Yes	No			

17) If yes, do you think this was mainly due to:	a vocabulary problem (too complex) – oral or written form	a problem of information format	a lack of oral information to complement the written information		
18) Have you been worried about being given a blood transfusion?	Yes	No			
19) Do you trust doctors to make the transfusion decision?	Yes	No			
20) Were you accompanied by a relative during your hospitalization?	Yes	No			
21) If yes, did they help you to understand the information given on blood transfusion?	Yes	No			
22) Before being discharged from hospital, did you get an information sheet concerning transfusion?	Yes	No	I don't know		
23) If yes, did you keep it?	Yes	No			
<b>IV. Suggestions</b>					
24) How would you like to be informed on blood transfusion?	In writing	Orally			
25) Other suggestions:					
26) Do you think it is useful to give information on transfusion to a wider public than only transfused patients?	Yes	No			
27) Would you like to play a more significant role in the blood transfusion process?	Yes	No			
28) If yes, at what stage(s) of the blood transfusion process would you be prepared to get more involved?	Before transfusion	During transfusion	After transfusion		
29) Specify how you would be prepared to get further involved:	by asking questions of doctors (e.g. on risks, etc.)	by helping health care professionals during the last compatibility control before transfusion	by reporting to health care professionals any unexpected symptom appearing after transfusion	by carrying out post-transfusion follow-up tests 3 months after transfusion	
30) Other suggestions:					

# **ANNEX 3.**

## **PATIENT INVOLVEMENT IN BLOOD TRANSFUSION IN THE NETHERLANDS**

*Willem Martinus Smid*

### **Organization of blood transfusion in the Netherlands**

The catalyst for the merger of all blood banks and the Central Laboratory of the Red Cross Blood Transfusion Service in the Netherlands was an evaluation report carried out by the Ombudsman. The evaluation was initiated following a series of complaints from patients receiving plasma products in the 1980s. The conclusion was that although no wrongdoing was found, the supervision system in place under the Ministry of Health, Welfare and Sports was complex, involving more than 20 independent organizations.

As a result, Sanquin was formed and authorized by the Ministry of Health, Welfare and Sports in 1998 as the sole organization responsible for blood supply in the Netherlands.

### **Development of blood transfusion in line with legislation**

EU legislation was transposed in the Netherlands legal texts, with provisions supporting the position of the patient. In the blood transfusion field, a good example is the case of Jehovah's Witnesses refusing blood transfusion therapy. For legal procedures, the courts followed the reasoning of the individual patient's right to choose for him or herself; more recently, however, there has been a tendency towards considering the duty of HCWs to deliver what is considered by professionals to be "standardized care", particularly in situations in which a life is at risk.

Most legislation had an effect on blood banks, given its focus on the quality and safety of blood and blood products. In hospital settings, the quality of patient care focused mainly on developing and implementing processes and procedures to prevent adverse transfusion reactions. The contribution of the patient to transfusion safety has been limited.

### **Remaining risks of blood transfusion**

Haemovigilance in the Netherlands is organized quite differently from the way it is delivered in France. The Netherlands national haemovigilance office, Transfusion Reactions in Patients (TRIP), is an independent organization managed by representatives of professional societies involved in blood transfusion. Hospitals report transfusion reactions (Box A3.1 and Box A3.2) to TRIP and reports are subsequently compiled.

In 2009, there were 30 reports involving administration of the wrong blood product, occurring as a result of identification errors (1). A study in 2010 involving automated registration of the transfusion process in an academic hospital found one case of incorrect blood product administration in 590 transfusions (1 in 790 for red cell concentrates and 1 in 365 for platelet concentrates). The study involved 33 000 transfusions of blood components and blood products (Huyhn et al., unpublished data, 2010).

### **Box A3.1. Reporting procedure**

Reports of transfusion reactions are sent to TRIP on a voluntary basis and are treated confidentially. Data analysis and reporting are anonymous. Reporting to TRIP is separate from the regular communication methods between hospitals and the supplying Sanquin blood banks about transfusion reactions or incidents.

#### **Who**

- » The hospital submits a report if a reaction has been noted in the hospital.
- » The Sanquin blood bank submits a report if a problem has been detected by the blood bank after delivery of a blood component to a hospital. TRIP's point of contact in each of the four supplying divisions is the manager of the clinical advisory service.
- » TRIP checks for double reporting by comparing product numbers.

#### *Responsible persons at hospital level*

- » Haemovigilance officer, a staff member officially responsible for reporting to TRIP, nominated by the Blood Transfusion Committee and preferably officially appointed by the hospital board.
- » Haemovigilance assistant, who prepares the report to TRIP (visits ward, collects and collates information), assists the haemovigilance officer and provides education and training on blood transfusion.

#### **What**

##### *Transfusion reaction (TRIP definition)*

- » Any undesired medical event (symptom, sign or diagnosis) or worsening of a pre-existing medical condition during and/or after a blood transfusion.
- » Period: from the ordering of the transfusion until an unlimited time after administration of a blood component.
- » Imputability: rating the likelihood that the undesired event was due to the transfusion of the blood component.
- » More: categories of reactions that are to be reported to TRIP.<sup>1</sup>

#### **How**

##### *How to report*

##### *Department where reaction is detected*

- » Treat/act according to hospital protocol; discuss with the consultant in charge.
- » Treating team sends report to blood transfusion laboratory.

##### *Blood transfusion laboratory*

- » Further tests according to hospital procedures.
- » Report to supplying blood bank if appropriate.

##### *Report to TRIP (hospital haemovigilance officer)*

- » Report to TRIP, generally after conclusion of investigation.
- » Send in completed reports at least every three months.
- » Please do not "save up" reports of grade II reactions (or higher), but instead submit when results of investigations are complete.

#### **Publication of results**

##### *Communication with hospitals (currently 110 addresses)*

- » TRIP confirms receipt of reports to the submitting party.
- » Each hospital receives a preliminary overview of (national) reports to date every six months and (if there has been no communication) a "nothing to report" card to confirm participation.
- » Personal contacts are maintained through regional meetings and visits to individual hospitals where possible.

##### *Annual report*

The submitted reaction reports are reviewed by an expert panel of board members. Any discrepancies in the assignment to a particular category of reaction, grading or classification of imputability are resolved by discussion with the reporting party. The annual report is sent (with analyses and recommendations) to the reporting haemovigilance officers, blood transfusion committees and governing boards of the hospitals, to the other participating organizations and to the Ministry of Health, Welfare and Sports. A summary in English is made available on request.

Publication in relevant scientific journals is envisaged.

<sup>1</sup> See Box A3.2 and the TRIP web site for more details (2).

### *Box A3.2. Categories of reactions*

#### **Categories of reactions**

##### **FNHTR**

Increase of body temperature of  $\geq 2^{\circ}\text{C}$  (with or without rigors) during or in the first two hours after a blood transfusion, if no other cause for the fever can be found and haemolysis has been excluded. Exclusion of bacteriological or blood group serological causes and TRALI.

##### **Acute haemolytic transfusion reaction**

Signs starting within minutes or up to 24 hours after commencing transfusion, due to (usually complement-mediated intravascular) destruction of red blood cells. Most often caused by transfusion of ABO-incompatible blood components, sometimes by irregular erythrocyte antibodies or occasionally by transfusion of a haemolytic red blood cell concentrate or infusion of hypotonic fluids.

##### **Delayed haemolytic transfusion reaction**

Immune-mediated destruction of red blood cells occurring  $>24$  hours after, and as a result of, transfusion of a blood component.

##### **TRALI**

Clinical picture of adult respiratory distress syndrome: dyspnoea, hypoxia and a finely mottled appearance on chest X-ray with onset up to six hours after administration of a (plasma-containing) blood component, if other causes, such as anaphylaxis, infection and circulatory overload, have been excluded.

##### **Circulatory overload**

Onset within a few hours of transfusion of dyspnoea, orthopnoea, cyanosis, oedema of dependent parts, raised central venous pressure, with congestive picture on chest X-ray.

##### **Anaphylactic reaction**

Serious allergic reaction with onset within seconds to minutes of commencing transfusion, with signs such as airway obstruction, circulatory collapse or gastrointestinal signs as well as minor allergic manifestations.

##### **Other allergic reactions**

Within minutes to hours of starting transfusion, occurrence of allergic signs such as itching, erythema and urticaria, without serious allergic manifestations.

##### **Post-transfusion purpura**

Severe temporary thrombocytopenia arising roughly 9 (1–24) days after a transfusion of red blood cells and/or platelets, usually in a patient who has previously had a blood transfusion or been pregnant.

##### **Bacterial contamination**

Bacterial septicaemia that can be traced to a transfused blood component. May be difficult to distinguish from a haemolytic transfusion reaction. Confirm diagnosis by bacteriological culture on the patient and the blood component and/or another blood component resulting from the same donation.

##### **Viral infection**

Any viral infection that can be traced to a transfused blood component (hepatitis A, HBV, HCV, non-ABC, HIV, human T-cell lymphotropic virus, Epstein-Barr virus, cytomegalovirus etc.)

##### **Post-transfusion hepatitis**

Significant rise in transaminases between 14 and 180 days after transfusion or a serologically confirmed new infection with HBV or HCV in a patient who has been transfused. Transfusion-associated cytomegalovirus infection A (probably) – primary cytomegalovirus infection in a recipient of a blood component should be reported.

##### **Transfusion-associated graft-versus-host disease reaction**

Reaction 1–6 weeks (usually 8–10 days) after a T-cell blood component is administered, with (initially central) erythema, watery diarrhoea, elevated liver enzymes and pancytopenia – generally involving a high risk of mortality and caused by an immunological reaction of the donor's T lymphocytes to the tissues of the recipient (who had suppressed immunity).



**Box A3.2. contd****Haemosiderosis**

Haemosiderosis in a multiple-transfused patient.

**Development of new antibody against blood cell antigen**

Detection, after a transfusion, of a clinically relevant antibody (irregular erythrocyte antibody, human leukocyte antigen antibody or human platelet antigen antibody) against a blood cell antigen where that antibody had never previously been detected (to the extent of the hospital's knowledge).

**Other transfusion reactions**

- » Rigors without fever
- » Post-transfusion malaria
- » Other parasitic infections in a transfusion recipient
- » Transfusion refractoriness

**Mild febrile reaction (optional reporting by sentinel hospitals)**

Rise in body temperature of  $>1$   $<2^{\circ}\text{C}$  during or in the first two hours after a transfusion without further relevant symptoms or signs and with no apparent cause other than the transfusion.

**Wrong blood component transfused**

Any case where a patient received (all or part of) a blood component that did not meet all the requirements of an appropriate blood component for the patient, or was intended for another patient. These are to be reported even if no harm results for the patient.

**Seriousness of reactions**

Grade 0: no morbidity; Grade I: slight morbidity, no risk of mortality; Grade II: moderate to serious morbidity, with or without mortal risk; Grade III: serious, life-threatening morbidity; Grade IV: death as a result of blood transfusion.

**Imputability of a reaction to a blood transfusion**

Certain: clinical picture and  
clear temporal relationship with transfusion and  
confirmatory laboratory results and  
other possible causes excluded

Probable: clinical picture, but  
temporal relationship not clear-cut or  
absence of confirmatory laboratory findings or  
another cause possible

Possible: clinical picture, but  
no temporal relationship and  
absence of confirmatory laboratory findings and  
another cause possible

Improbable: clinical picture, but  
no temporal relationship and  
absence of confirmatory laboratory findings and  
another cause more probable

Definitely not: demonstrable other cause

As yet uncertain: insufficient information available at present but will be forthcoming

Infection risks have substantially diminished due to developing safety measures and technologies, and increased attention is now also being given to immunological risks. It is noteworthy that identity errors are becoming one of the main causes of adverse outcomes of blood transfusion, in the prevention of which patients can play an important role.

## Patient involvement in the blood transfusion process

Limited attention has been paid to date to the patient contribution to improving the blood transfusion process. The blood supply part of the transfusion chain – from the blood donor to the resulting blood components/products – is the responsibility of the blood supply organization and the Ministry of Health, Welfare and Sports. The patient is covered by specific technical standards and considerations and is subsequently not expected to contribute to any part of the chain (except as a potential donation promoter). In hospital care, a number of steps can be distinguished, however. First, the patient should be informed of the decision by the physician to prescribe blood products. The next steps involve selection of the appropriate product and compatibility checks. Correct patient identification and administration of transfusion therapy – with post-transfusion follow up – represent the final steps of the process.

Providing information to patients who have an indication for transfusion therapy is now considered to be part of standard care. Information should also include a description of possible adverse reactions and treatment alternatives. This approach is part of the guidelines on blood transfusion for the Netherlands (3); however, there are limiting factors in its application. These include lack of time and the fact that transfusion is often only one part of the patient's treatment. To support this process, Sanquin has developed a patient information leaflet that is available to hospitals.

A well-informed patient can contribute to a positive transfusion outcome if he or she is aware of the importance of identification and immediate evaluation as part of the process of the therapy. Interestingly, and illustrating the cultural differences in perception, professionals considered that identification wristbands would be regarded as an impersonal additional safety measure, while these have been easily accepted by patients.

Important scientific and technological progress has been achieved in improving the outcomes of blood transfusion therapy. This continuous improvement process is now evolving towards increased contributions from patients. The so-far rather cautious steps in patient engagement need to be more clearly defined and further developed.

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# ANNEX 4.

## PATIENT QUESTIONNAIRE ABOUT MEDICATION SAFETY

### PATIENT SAFETY RIGHTS AND MEDICATION SAFETY WHO Patient Safety Rights Project

The questionnaire intends to describe whether patients' rights affect medication safety and can improve safe pharmacotherapy. Please mark the appropriate choice for each of the questions below. This survey is anonymous and information obtained will be used solely for the purpose of this study. Please just indicate your sex and age at the final page of the questionnaire. Thank you for your input and cooperation.

**1. Do you take medicines for chronic diseases?**

YES       NO

**2. How many medicines do you take every day?**

A Up to 3       B 3–5       C 5–7       D More than 7

**3. Do you know the names and dosages of all medicines you take?**

YES       NO

**4. Do you discuss the medicines you take every time you visit your doctor?**

YES       NO

**5. If yes, who initiates talking about drugs?**

Doctor       Me/Accompanying person

**6. Does a doctor tell you about the possible interactions/lack of interactions between the medicines you take?**

YES       NO

**7. Does a doctor ask about the medicines you take before prescribing a new drug?**

NEVER       ALWAYS       SOMETIMES

**8. Does a doctor ask about the previous adverse drug reactions you might have had related to the medications you take, before prescribing the new drug? (Adverse drug reaction includes, e.g.: allergies; stomach problems; skin exanthema; discomfort of alimentary tract; respiratory system disorders; blood pressure disorders, etc.)**

NEVER       ALWAYS       SOMETIMES

**9. Have you ever not begun taking a prescribed medication because you have read the leaflet that presented counter-indications that were not mentioned by the doctor during the visit?**

YES       NO

**10. Have you ever experienced adverse drug reaction(s)?**

YES       NO

**11. In case of the adverse drug reactions, did they require treatment?**

YES       NO

**12. While buying OTCs at the pharmacy, do you ask about the possible interactions between the OTC drug and medicines you already take?**

NEVER       ALWAYS       SOMETIMES

**SEX**

FEMALE       MALE

**AGE**

Years

# ANNEX 5.

## DOCTOR QUESTIONNAIRE ABOUT MEDICATION SAFETY

<b>PATIENT SAFETY RIGHTS AND MEDICATION SAFETY</b>	
<b>WHO Patient Safety Rights Project</b>	
The questionnaire intends to describe whether safe medication practices are being used in everyday practice while prescribing the new medication and continuing patient medicine treatment. Please mark the appropriate choice for each of the questions below. This survey is anonymous and information obtained will be used solely for the purpose of this study. Please just indicate your sex and age at the final page of questionnaire. Thank you for your input and cooperation.	
<b>1</b>	<b>Physician</b>
<input type="checkbox"/> No specialty <input type="checkbox"/> 1st degree specialist <input type="checkbox"/> 2nd degree specialist (highest)	
<b>2.</b>	<b>Do you expect patients to provide detailed information about recently taken medication at the first visit?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>3.</b>	<b>Please describe which of the factors below are most important regarding drug prescribing:</b>
<input type="checkbox"/> A Patient age <input type="checkbox"/> B Risk of interaction <input type="checkbox"/> C Risk of adverse events <input type="checkbox"/> D Comorbidities that might affect medicines outcomes	
<b>4.</b>	<b>Do you ask your patients about the OTC drugs and/or dietary supplements they might be taking?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>5.</b>	<b>Do you always ask your patients about the names of medications they recently took?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>6.</b>	<b>Have you treated a patient/patients who have appointments due to adverse drug reaction to an OTC drug?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>7.</b>	<b>Have you treated a patient/patients who visit due to adverse drug reaction to a dietary supplement or herbal medicines?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>8.</b>	<b>Do you ask patients about possible adverse drug reactions before prescribing new medication?</b>
<input type="checkbox"/> NEVER <input type="checkbox"/> ALWAYS <input type="checkbox"/> SOMETIMES	
<b>9.</b>	<b>Do you reflect upon the possible undesired interaction with medicines already taken before prescribing a new drug?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>10.</b>	<b>Please define the number of simultaneously taken medicines for which the statistical risk of drug interactions results in certainty.</b>
<input type="checkbox"/> A 1–3 medications <input type="checkbox"/> B 3–5 medications <input type="checkbox"/> C 5–7 medications <input type="checkbox"/> D More than 8 medications	
<b>11.</b>	<b>Do you expect the patient to have a list of their medication names and doses?</b>
<input type="checkbox"/> YES <input type="checkbox"/> NO	
<b>12.</b>	<b>In case of adverse drug reaction, do you report this to the designated authorities?</b>
<input type="checkbox"/> NEVER <input type="checkbox"/> ALWAYS <input type="checkbox"/> SOMETIMES	
<b>13.</b>	<b>SEX</b>
<input type="checkbox"/> FEMALE <input type="checkbox"/> MALE	
<b>14.</b>	<b>AGE</b>
Years	

## ANNEX 6.

# WHO PATIENT SAFETY PROGRAMME

The WHO Patient Safety Programme includes a number of activities, programmes and campaigns that aim to coordinate, disseminate and accelerate improvements in patient safety worldwide. Launched in 2004 in response to a 2002 World Health Assembly resolution urging WHO and Member States to pay the closest possible attention to the problem of patient safety, its establishment underlined the importance of patient safety as a global health care issue. Its main areas of work – which in Member States that adopt them should have the potential to influence the patients’ rights agenda – have included the action areas set out here.

### Global Patient Safety Challenges

Global Patient Safety Challenges aim to identify a topic that covers a major and significant aspect of risk to patients receiving health care and which is relevant to every WHO Member State. Two such challenges have been launched to date by WHO, as described below. The third challenge on Medication Safety will be initiated in 2013.

#### 1. *“Clean Care is Safer Care”*

HAI was chosen as the First Global Patient Safety Challenge, focusing on the theme “Clean Care is Safer Care” (1). As part of this challenge, WHO guidelines on hand hygiene in health care were developed, along with a set of complementary implementation tools.

#### 2. *“Safe Surgery Saves Lives”*

Safer surgery was chosen as the Second Global Patient Safety Challenge, with the theme “Safe Surgery Saves Lives” (2). The focus of the campaign is the WHO surgical safety checklist. The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: before the induction of anaesthesia (“sign in”); before the incision of the skin (“time out”); and before the patient leaves the operating room (“sign out”). In each phase, a checklist coordinator must confirm that the surgical team has completed the listed tasks before it proceeds with the operation.

#### 3. *Medication safety*

The safety of medicines is not a new area of activity for WHO, but the WHO Patient Safety Programme will be building on positive work done in medicines regulation and management of counterfeit medicines to develop the Third Global Patient Safety Challenge in “Medication Safety”. This area will develop advocacy messages as well as technical tools for improving medication safety across the spectrum of health care settings.

### “Patients for Patient Safety”

In the area of patient and consumer involvement, the initiative “Patients for Patient Safety” (3) involves building a patient-led global network of patients and patient organizations to champion patient safety.

### **African Partnerships for Patient Safety**

African Partnerships for Patient Safety, a bidirectional initiative working with hospital-to-hospital partnerships between the WHO African Region and Europe, focusing on patient safety, was launched in 2009. The programme is framed around 12 patient safety action areas endorsed by the WHO African Region. Partnership experiences are utilized to stimulate national system change through close working with ministries of health. The partnership provided a clear mechanism to translate policy on patient safety to action at the point of care. The programme is now working in 14 African and 3 European Member States.

### **Research for Patient Safety**

Research for Patient Safety (4) is undertaking global prevalence studies on adverse effects and developing a rapid assessment tool for use in developing countries. Major research projects have been implemented in 13 developing and transitional Member States to understand the nature of patient harm and to develop measurement tools. Two rounds of the Small Grants for Patient Safety Research, launched in June 2008, involved 25 research projects in 22 countries, aiming to build capacity in this area. A global set of priority areas for additional research has been identified, as well as a series of methodological and training guides. The online series of patient safety research courses and materials has involved thousands of participants and is delivered in English, French, Spanish and Portuguese.

### ***International Classification for Patient Safety***

The WHO Patient Safety Programme developed the International Framework for Patient Safety to capture the knowledge domain for patient safety and to serve as the basis for the International Classification for Patient Safety and other data collection efforts (5). The classification aims to define, harmonize and group patient safety concepts into an internationally agreed classification. This will help to elicit, capture and analyse factors relevant to patient safety in a manner conducive to learning and system improvement.

### ***Reporting and Learning***

The Reporting and Learning initiative aims to generate best practices for existing and new reporting systems and to facilitate early learning from information available across organizations running reporting systems. WHO has produced draft guidelines on adverse event reporting and learning systems (6). Based on the International Framework for Patient Safety, WHO aims to produce guidance on an information model for patient safety, which will advance the draft guidelines on adverse event reporting and learning systems. WHO currently hosts the WHO Reporting and Learning Community of Practice, jointly supported by the Canadian Patient Safety Institute.

### ***Solutions for Patient Safety***

The Solutions for Patient Safety programme (7) developed aide memoirs highlighting interventions and policy actions to improve patient safety. This patient safety programme is no longer being pursued.

### ***Eliminating central line-associated BSIs***

WHO will ensure that the results of the work in the State of Michigan (United States) to eliminate central line-associated BSIs are disseminated and the work replicated in other settings. This could change the lives of tens of thousands of patients worldwide,



especially those in intensive care. The approach developed in the United States was adapted and tested in Spain and the United Kingdom, with successful results. Lessons from this experience will help understanding the conditions for effective implementation. A process evaluation of the Spanish experience has been conducted by WHO and will be released shortly.

### ***Injection safety***

WHO has begun new work on injection safety in consultation with internal and external partners to address the pressing issue of reuse of syringes and needlestick injuries in health care workers.

### ***High 5s***

Based on the principle that standardization can lead to safety, the High 5s initiative (8) developed and tested standardized approaches for improving organizational, team and clinical practices to advance patient safety. The initiative focused on learning of what works and does not work using standardized protocols to reduce patient harm. Following three years of implementation in eight countries, lessons learned about standardization will be disseminated to more Member States interested in standardization and patient safety.

### ***Technology for Patient Safety***

The initiative entitled Technology for Patient Safety focuses on opportunities to harness new technologies to improve patient safety. The initiative sets out an initial set of priorities for WHO and its partners in the broad areas of information technology for patient safety, designing safe new technology and making existing health care technology safer. This mapping was published in a special issue of *BMJ Quality and Safety in Health Care*.

### ***Knowledge Management***

The Knowledge Management scheme works with Member States and partners to gather and share knowledge on patient safety developments, including through the use of webinar technology. WHO has developed a training programme using webinars (visual training materials displayed on the web) to raise capacity on patient safety in developing and transitional countries. Courses have been produced in various languages, expanding significantly the reach of these knowledge management activities. Additionally, WHO and the International Society for Quality in Health Care have jointly run discussion forums on the society's knowledge platform and WHO is hosting an increasing number of communities of practice to facilitate cross sharing and learning.

### ***Capacity building and education for safer care***

A multiprofessional curriculum guide (9) for undergraduate and postgraduate health care providers and other resources were developed within the framework of capacity building and education for safer care. A new guide for developing training programmes for patient safety research was produced in 2012 (10). WHO has developed training materials on 26 quality improvement and patient safety topics for building capacity and knowledge of health care educators, leaders, managers and providers. Education and training are delivered through workshops and e-learning will commence in 2014.

### **Medical checklists**

After the success of the surgical safety checklist developed by the WHO Patient Safety Programme in 2009, which was shown to decrease morbidity and mortality by over one third, additional checklists are being developed.

As part of WHO's response to the influenza A H1N1 pandemic, the WHO Patient Safety Programme developed a checklist for HCWs treating patients with H1N1. The programme has developed the Safe Childbirth Checklist in collaboration with three other WHO departments (Making Pregnancy Safer, Reproductive Health Research, and Child and Adolescent Health). The Safe Childbirth Checklist Collaborative was launched in November 2012 as a platform for external partners joining WHO in the production of additional evidence about effective checklist implementation. The WHO Patient Safety Programme is also developing a Trauma Care Checklist in collaboration with the Department of Violence and Injury Prevention and Disability.

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# ANNEX 7.

## HANDOVER PROJECT

*Paul Barach*

### Introduction

When a patient's transition from hospital to home is less than optimal, the repercussions can be far-reaching – hospital readmission, an adverse medical event, and even mortality. HANDOVER,<sup>1</sup> which focuses on improving the continuity of patient care in Europe through identification and implementation of novel patient handover processes, is the first major European study to assess patient transitions. The goal of the study is to identify and study patient handover practices and create standardized approaches to handover communications in six European countries (United Kingdom (England), Italy, the Netherlands, Poland, Spain and Sweden).

This project addresses the challenges of transitioning patients to and from the hospital to their home and other health care facilities. Without sufficient information and an understanding of their diagnoses, medication and self-care needs, patients cannot fully participate in their care during and after hospital stays. WHO, Joint Commission International and other lead regulatory bodies in the United States, Australia, Canada and across Europe have identified ineffective handovers of patients as a major public health problem. Poor coordination of care across and between European border settings can result in costly, potentially harmful, and often avoidable rehospitalizations. This three-year, EU FP-7<sup>2</sup> collaboration is the first major European study to assess the coordination and outcomes of patient transitions and develop new ways to address patient readmissions. Ineffective and unsafe handover practices consume resources and lead to much wasted work. Poor coordination of care has a severe effect on patients and their well-being, health care delivery and the rising costs of health care. Additionally, poorly designed discharge processes create unnecessary stress for medical staff, causing failed communications, rework and frustrations. Safer and more coordinated handovers could increase efficiency and cost-effectiveness of health care interventions and patient satisfaction.

The objective of the HANDOVER project<sup>3</sup> and the European Research Collaborative is to better understand how to enhance communication among health care providers, improve support for patients and families, engage organizations across the continuum of patient care, track process and outcome measures, and refine the clinical workflow at the primary care–hospital interface.

1 The participating members of the European HANDOVER Research Collaborative include: Loes Pijnenborg, Julie Johnson, Beryl Göbel, Cor Kalkman, Richard Lilford, Nicola Novielli, Yen-Fu Chen, Semira Manaseki-Holland, Basia Kutryba, Halina Kutaj-Wasikowska, Ewa Dudzik-Urbaniak, Marcin Kalinowski, Francesco Venneri, Giulio Toccafondi, Antonio Molisso, Sara Albolino, Hub Wollersheim, Gijs Hesselink, Lisette Schoonhoven, Myrra Vernooij, Marieke Zegers, Helen Hansagi, Mariann Olsson, Susanne Bergenbrant, Maria Flink, Gunnar Ohlen, Carola Orrego, Rosa Sunol, Oliver Groene and Jerry Andriessen.

2 The EU's Seventh Framework Programme for Research.

3 More information is available on the European Handover Research Collaborative web site (1).

## Key objectives

The objectives of the European HANDOVER research collaborative were to:

- a) identify the barriers and facilitators in the medical, social and technological contexts in which patient handover takes place;
- b) identify key strategies and tactics for reducing readmissions that could be applied across Europe;
- c) understand actionable strategies for engaging community organizations across the continuum of care;
- d) strengthen patient involvement and understanding of their care;
- e) develop and assess tools and training programmes for implementing patient handover training; and
- f) assess the cost-effectiveness of handover interventions.

## The principles of the HANDOVER study

1. **A systematic qualitative multimodel study** using content analysis was performed using grounded theory of hospital and primary care physicians and nurses, patients and caregivers in five countries. One hundred and ninety-two individual interviews and 26 focus group interviews were conducted in five EU countries with patients or caregivers, hospital physicians, hospital nurses, GPs and community nurses.
2. **Clinical foci:** to properly address the health care continuum, several clinical conditions which represent the entire chain of care (primary care – referral – hospital – discharge – aftercare by primary care physician) were identified. These include chronic illnesses such as diabetes, heart disease, asthma, chronic obstructive pulmonary disease and polypharmacy (>6 drugs per patient).
3. **Patient groups:** the HANDOVER project included attention to the patients and their carers, especially in terms of care of older patients (60+ years), and handovers of patients with multiple conditions. In addition, attention was paid to minority groups such as people with communication problems due to language barriers and/or hearing/sight impairments. For example, the project in Spain focused on communication challenges with non-Spanish-speaking minorities and how to address their crossborder care needs.
4. **Microsystems:** HANDOVER used the clinical microsystem at the primary care-hospital interface as the unit of analysis.
5. **Applied quality improvement methods:** the prospective, multimodel study was conducted applying sophisticated quality improvement tools such as process maps, surveys, interviews, focus groups, observations, artefact analyses and Ishikawa diagrams to directly assess patient handovers and shadow physicians and nurses providing care following patient handovers.

## What has been learned as a result of the initiative?

While the prevailing handover practices differ across Europe, many of the identified referral and discharge barriers and facilitators appear to be similar in the different countries and settings. The key themes underpinning the barriers and facilitators for patient discharge and referrals that emerged from the analysis include: communication content, process, tools; attitudes; organizational factors; community resources; patient awareness; and patient empowerment.

***(a) Provide new insight into the role of organizational culture as an important context for unsafe hospital discharge***

A number of themes emerged relating to organizational culture. The handover interface is fragmented and care provision dominates handover administration, as well as attitudes towards reflection and improvement. Hospital and primary care providers have different and often incompatible values and beliefs. Providers demonstrate a strong focus on self, professional “here-and-now” working and give less priority to ensuring proper patient follow up. Furthermore, there is scepticism towards the value of feedback and integrating new practices, and handover practice is often ruled by habits that are left unchecked. Poorly designed discharge processes create unnecessary stress for medical staff, causing failed communications, extra work and frustration. The study suggests that the safety of hospital discharge is determined to a large extent by the manner in which care providers – in particular within the hospital – value the importance of handovers at discharge. Those who see it as an important aspect of clinical work aiming to ensure continuity of care are subsequently able to integrate these practices into their everyday work. The study points to the need to directly address organizational culture as a key factor in efforts to improve the handover of patients at hospital discharge.

***(b) Identify key strategies and tactics for reducing readmissions that can be applied across Europe, using practical strategies for engaging community organizations across the continuum of care***

Important and intricate relationships exist among the people, processes, technology and clinical settings in which handovers occur. These relationships have the potential to facilitate or impede the handover process and directly affect patient outcomes. A fragmented care delivery model and culture at the interface between the hospital and primary care, conflicting professional values and, in some countries, the organization’s identity played a key role in hindering effective handover practices.

***(c) Strengthen patient involvement in, and understanding of, their care***

All stakeholders, including patients, agreed on the need for an active **patient role** in the handover process. The extent to which patients (and carers) are aware of their own important role and are sufficiently empowered to act accordingly affects the quality and safety of handovers, both positively and negatively. Multiple factors – such as the lack of direct contact between professionals, involvement of multiple professionals and the lack of feedback – make it difficult for GPs to fulfil this role properly and to be accountable. The study worked with the WHO Patients for Patient Safety Committee to develop a series of tools and guidance to help empower patients and strengthen patient involvement and understanding of their care. This is an ongoing process that will be evaluated over the next few years.

***(d) Professional awareness and respect***

A comprehensive and reliable discharge plan along with post-discharge support could help to reduce readmission rates, improve health outcomes, increase efficiency and ensure quality transitions. Community care providers are often not informed sufficiently and within a reasonable time period about patient outcomes, and handover problems often remain unspoken with possible opportunities for improvement overlooked. In the eyes of physicians, nurses and patients, the lack of a collaborative attitude between



hospital and primary care is a serious barrier to effective and safe discharge, especially with complex patient care in which continuity of care is essential. The lack of awareness of different professional perspectives inherent within primary and secondary professional domains seems to influence roles and responsibilities in patient diagnosis and treatment. Though most professionals think they carry a shared responsibility in this respect, in practice they do not. Because of multiple assigned roles and unclear responsibilities, especially for nursing professionals, barriers to effective handover also exist at patient discharge. It is common for the GP to play an essential part in the coordination of patient care. However, as already mentioned, multiple factors make this role difficult to fulfil.

#### **(e) Barriers to success**

Current interventions aimed at improving patient handover at the hospital–primary care interface fall short in terms of addressing the large number of barriers and facilitators that influence effective handover. However, effective handover interventions are mostly aimed at improving organizational and technical aspects of the handover process.

#### **(f) Quality improvement tools**

The effectiveness and efficiency of various methods and tools used in the first major European study to improve patient handovers were determined. The triangulation of multimodal improvement science methods in this study – including analyses of barriers and facilitators using Ishikawa diagrams and process maps, as well as analyses of roles and responsibilities, near misses and so on – is innovative and has applications across Europe, which could facilitate crosscountry learning to advance the quality of care.

### **Future**

The HANDOVER Toolbox initiative<sup>4</sup> has been successfully piloted and is ready for implementation. This interactive online platform has been successfully developed to encourage a community of users to design and share ideas and best practices concerning effective handover of patients. The European HANDOVER Research Collaborative is committed to continuing this work.

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4 See the European Handover Research Collaborative web site for more details (2).



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# ANNEX 8.

## ENHANCING THE PATIENTS' ROLE IN PATIENT SAFETY IN THE NETHERLANDS

*Erica van der Schrieck-de Loos<sup>1</sup>*

### Objective

In 2009, the Netherlands Organization for Health Research and Development asked the Institute for Healthcare Improvement to conduct research into the role of the consumer in patient safety. The purpose of this international research and its recommendations on how patients/consumers and health care professionals can together improve patient safety (with patients as partners within health care teams) is to report on existing knowledge and problems. The focus is on developing recommendations for the potential and desired role of the client based on current insights, highlighting necessary further research in the area and suggesting any further practical developments.

### Method

The timeline for this qualitative exploratory research was six months. The main question was about **how to give consumers a role in patient safety to improve their safety in health care**, based on four subquestions.

1. What is known about effects, risks and factors when engaging patients?
2. What is known about interventions (initiatives) on the role of consumers in patient safety?
3. What opinions do health care professionals, patients and policy-makers have about making consumers members of the health care team to improve patient safety?
4. How can existing gaps in the development of a further role for consumers in patient safety be addressed?

The study consisted of four steps:

1. an international literature review was carried out using 20 keywords in 4 databases, resulting in 541 articles (research covering the period 1999–2009); 38 articles were selected and analysed by a matrix of 4 subquestions;
2. an international web search resulted in 24 concrete interventions to engage clients and to educate professionals on engaging clients in patient safety; these interventions were analysed by a matrix;
3. 21 semistructured interviews with 24 national patient safety experts (cure, care, patient and policy organizations) were analysed by a matrix of 4 subquestions; and

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1 The work of Van der Schrieck-de Loos et al. (1) supports this annex.

4. conclusions and recommendations were discussed in an expert meeting with 9 national patient safety experts and disseminated by means of a report, various publications, a press release and presentations at (inter)national conferences (from 2009 to present).

## Results

The research shows that the consumer has a unique perspective on the care process, which is a valuable addition to professional knowledge. Care provision is less than optimal without consumers' contribution, as they are the ones who experience the care intervention or process.

The way in which the consumer can fulfil a role is still unclear at the moment and depends on the degree to which he or she is willing and able to participate and has the necessary skills to do so. The consumer role is always voluntary (not all consumers are able or willing to play a role in patient safety). It may serve as an additional verification step in the care process, where the consumer can act as adviser to, or supervisor of, their treatment process, but the health care professional retains ultimate responsibility for the consumer's safety.

The professional's attitude and skills are also crucial factors in giving further substance to the consumer's role. The creation of an open culture is essential and starts with the relationship between the professional and the consumer. Consumers need to be equipped with the right information in terms of knowing what patient safety means, what risks exist and how they can contribute to the care process to enhance their own safety.

The unique perspective of the consumer must also be considered in the drafting of guidelines, protocols, care standards and patient safety policy. This contributes to the development of a transparent and reliable care system that is clear and understandable to all parties.

International research into the effect of interventions with regard to the role of the client in patient safety remains limited. Existing (inter)national interventions are mainly aimed at information and "tips" for the patient and their family or representative, a common example of which is the patient safety card. Few interventions have yet been developed that support the professional in this process. To ensure a positive effect of interventions, it is important to target the relationship (and the dialogue) between health care professional and consumer. A clear link between interventions targeting professionals and existing legislation and regulations increases motivation for their use.

The Netherlands is leading the way in terms of patient/consumer collectives (councils and representatives), but the role of the patient/consumer councils in health care facilities is currently underutilized. The professionalization and facilitation of patient/consumer collectives makes it possible to involve the perspective of the consumer in the (annual) safety policy of health care facilities and redesign of care processes. At the same time, discussion of incidents and the development of how (former) victims of patient safety-related issues are dealt with – including the organization of aftercare for such (former) victims – are very important factors in the creation of an open safety culture.

The gaps in developing the role of the patient/consumer in patient safety are visible in:

- » the current organization of care (insufficiently transparent and reliable);
- » lack of insight into the values, knowledge, attitudes, needs, ideas and readiness of patients/consumers to play a role in patient safety; and
- » insufficient attention being given to the communication and health literacy skills of professionals and patients/consumers.

Motivating professionals is a guiding principle for supporting and encouraging patients/consumers to play a role in patient safety.

## Conclusion

The relationship between the health care professional and the patient/consumer is the key to developing the role of the latter in patient safety. The first prerequisite is shared awareness of the fact that a role for the patient/consumer is possible, accompanied by the motivation and skills to enable the activation of this role. A number of themes affect the relationship between the professional and the patient/consumer and are important for developing the integrated approach required:

- » professionalization and facilitation of patient/consumer collectives (councils and representatives) so that they can fulfil a role in care policy and primary care process redesign;
- » research into the effect and importance of, and the interaction between, the five context factors on which the fulfilment of the role of the patient/consumer depends:
  1. the specific patient (knowledge and opinions)
  2. the illness (phase and characteristics)
  3. the professional (knowledge, opinions and “inviting” behaviour)
  4. the setting
  5. the type of safety behaviour the client exhibits;
- » research into existing initiatives (interventions) in terms of their effects, including development, innovation and extending them to other settings;
- » developing a national information and knowledge centre for all parties involved in health care, with public information, tools and education packages to give substance to the role of the patient/consumer in patient safety;
- » setting up a training programme (such as a patient safety officer programme) for health care organizations, focusing on leadership, culture and structure;
- » evaluating and optimizing the legislation and regulations relating to the role of the patient/consumer; and
- » involving the insight of the client in guidelines, indicators and standards of care and making health care options clear and understandable to the patient/consumer.

In the long term, it is essential that patients’ perspectives be incorporated at four levels:

1. the individual care process and organizations
2. the national health care organizations
3. the national health care system
4. laws and regulations.

This is only possible when initiatives are based on the relationship between patients and health care professionals to create an active dialogue about safety. This integrated approach is expected to make sustainable implementation of the role of the patient/consumer in patient safety possible.

## Reference

1. Van der Schrieck-de Loos E, Posma E, Salfischberger Y. *The role of the client in patient safety. A necessity, not a desirability*. Utrecht, CBO (ZonMW), 2009 (<http://www.cbo.nl/en/Patient-Safety/Patient-engagement-empowerment/>, accessed 1 May 2012).

