



EFN INPUT TO THE HIGH LEVEL PATIENT SAFETY WORKING GROUP – 12 SEPTEMBER 2008

EFN COMMENDS ON THE FUTURE COUNCIL RECOMMENDATIONS ON PATIENT SAFETY AND HEALTHCARE ASSOCIATED INFECTIONS

EFN welcomes the Commission ongoing work on the Council Recommendations on Patient Safety and Healthcare Associated Infections (HCAI). Taking into account EFN discussion to date on the Patients' Rights in Cross-Border Health Care Directive proposal, EFN believes that the Council Recommendations on Patient Safety and HCAI are a crucial step forward in making health systems safe for patients, families and staff.

"What is good for patients is good for nurses!"

The Council Recommendations create a European framework to assist resolving causes of infections so that patients, families and staff are assured a safe and worry-free hospital environment across the European Union. In achieving this, EFN believes that the main pillars of these future recommendations should be the development of a national strategy, the creation of multidisciplinary specialist Infection prevention and Control teams, establishing effective reporting and surveillance systems and implementation continuous professional development for healthcare workers.

The development of a dedicated multidisciplinary committee to coordinate implementation of the national strategy supports a 'stakeholder approach' to ownership and management of this important issue. Nurses are sympathetic to the complex multi-factorial issues which surround HCAI's and are an important stakeholder group who are ideally placed to assist successful implementation of the Council recommendations into practice.

EFN appreciate that the future Recommendations should not be seen in isolation. There is an important link with the EU Patients Rights Cross-Border Healthcare Directive, the forthcoming Green Paper on the European Workforce and the early work of DG Sanco on Health Care Standards.

Therefore, EFN calls on the National governments to:

1. Involve National Nurses Associations in developing a National Strategy for the prevention and control of HCAIs;
2. Strengthen Patients Rights in the prevention and control of HCAIs;
3. Develop and implement multidisciplinary and evidence based national standards for healthcare associated infection control to ensure best practice at member country level.
4. Establish appropriate staffing levels to assist better management of workloads and maintenance of staff/training competence to prevent HCAIs;
5. Provide the proper investment for more infection prevention nurses and stronger surveillance/reporting mechanisms; and,
6. Support nurses to participate in CPD initiatives.

To conclude, EFN believes the High Level Working Group on Patient Safety, led by the representative of the UK and Poland, is making enormous progress to address key challenges for the EU health systems.

12 September 2008

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During the EFN 88th General Assembly, held in Copenhagen on 10-11 April 2008, EFN members demonstrated their commitment to Patient Safety by provide data for the "reality check", discussing extensively the future Council recommendations on HCAI initiative and commissioning the Workgroup of European Nurse Researchers (WENR), EFN's sister organisation, a research mapping on "Patient Safety in Europe: Medication Errors and Hospital-acquired Infection" to support the EFN Policy Statement on Patient Safety.

A. GENERAL COMMENTS TO DG SANCO INITIATIVE ON HEALTHCARE ASSOCIATED INFECTIONS (HCAIS)

- A far reaching initiative – but stresses the importance of the problem and future challenges
- The content of this draft is directed towards hospitals, although in some countries there may be more healthcare associated infections in non-hospital care.
- EFN Members provided input to the following questions:
 - How many infection control nurses are there per hospital bed? This should be calculated by the number of hours pertaining to beds.
 - What is an infection control nurse – how long is their education? Are there other professionals working with infection control?
 - Where are the infection control nurses employed?
 - What is the average salary for the infection control nurse in each MS?
- DG Sanco should explore with DG Regio how the Structural & Social Cohesion Funds can be used for Patient Safety.
- The importance of involving professional organisations in the **National Strategic Plan**
- The positive impact of developing multidisciplinary Committees and infection control teams.
- Development and implementation of multidisciplinary and evidence based national standards for healthcare associated infection control to ensure best practice at member country level.
- Standards to ensure infected healthcare workers do not infect other staff or patients. Should be developed
- Standards on the appropriate use of antibiotics should be developed.
- Terminology - Reference to hospitals or non-hospital institutions; the use of home healthcare, nursing homes, primary health care etc should not be used unless it is absolutely necessary. If these terms are used they must be defined in the glossary.
- The term healthcare professionals should be used with deletion of use of the term "workers".
- Suboptimal staff to patient ratios must be clarified.
- Improving Communication on HCAIs between hospital settings & non-hospital settings is central to success of the recommendation, e-health could support this.

B. EFN MEMBERS DATA AND REFLECTIONS ON HCAI/INFECTION CONTROL NURSES

Firstly, in relation to **numbers of Infection Control Nurses (ICN's) and the ratio of ICN's to acute in-patient beds:**

- The traditional model of Infection Control teams (ICT's) consisting of an Infection Control Doctor and nurses is changing as a result of healthcare development and needs of healthcare organisations.

The role of Infection Control Doctor and Infection Control Nurse is still relevant, especially in the "new" Member States, however these teams are expanding to now include audit and surveillance staff and specialist data support and epidemiology posts.

Not all members of ICT's are therefore nurses, or if they are nurses have not the word 'nurse' in their role title. This can mean practical problems in trying to identify exact numbers of nurses working in the field.

The role of Health Protection Nurse, which includes elements of Infection Control, in the community, also highlights the multi-specialism of some nurse roles which cross over boundaries with other safety roles such as radiation and chemical/deliberate release incidents.

- It might be worth considering how the elements of ICT's vary across Europe and of those teams, how many nurses are employed and in what roles, as this will have a direct impact on how the number of Infection Control Nurses are allocated per hospital/healthcare organisation.

This could be calculated on a per in-patient bed basis or at a population level for the community.

The traditional figure of **1 ICN to 250 beds** (based on the 1980's work in the USA) is no longer considered a valid comparison or resource due to changes in healthcare and patient acuity, BUT within the EU Member states far from achieved: even 1 ICN per hospital (800 bed) is not achieved in old and new MS. In Cyprus there is only **one Infection Control Nurse in each major District hospital** (there are 5 District hospitals in the Island). In the other 3 **smallest hospitals there aren't full time working Infection Control Nurses.**

The outbreaks of *C. difficile* in Canada which led to the Aucoin report publication recommended **1 ICN to 100 beds** in order to **undertake both proactive work rather than a reactive service as a result of lack of investment.**

In many Member States, like **UK**, many organisations are looking to expand the number of ICN's however there is a shift in emphasis in the ownership and management of Infection Control from the ICT to individual sectors in health care e.g. divisions or directorates such as paediatrics, obstetrics etc in hospitals. This has led to the development of '**Link nurses**' who work clinically in these local areas but who undertake roles at the direction and discretion of the ICT at a local level. Such staff is not considered part of the ICT but are a vital component of a proactive IC programme.

Belgium has a recent law (KB 26 April 2007 attached) but the implementation is not effective. Therefore reference is made to the work of Dr Gordts from the AZ Brugge. As an example: Brugge has 1.9 fulltime equivalents ICN officially but in reality working with 2.75, partially not financed in the hospital budget. Dr Gordt stresses the importance of region approach in which hospital care and community care (elderly care) are working together to combat MRSA. As a second example, the Free University Brussels, with 700 beds, there is 1.8 ICN, but they have currently other responsibilities, like wound care.

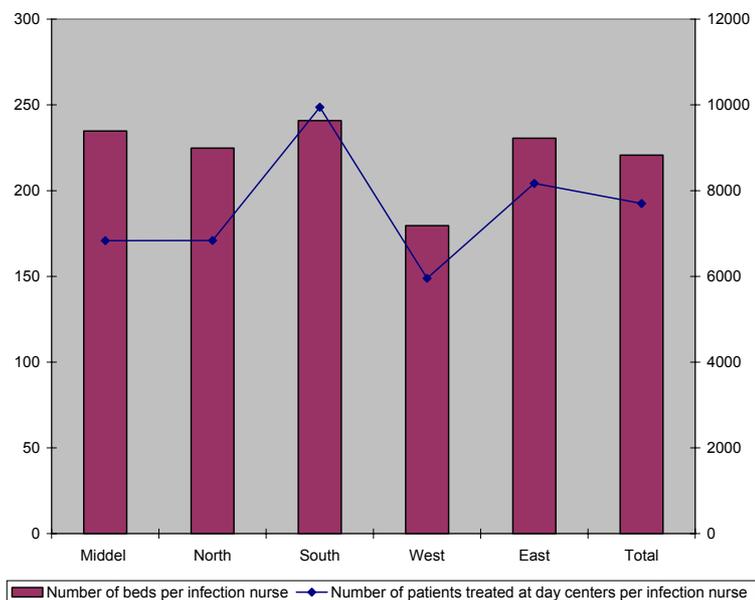
In **Italy** there are no laws that establish the presence of infection control nurses. Usually each hospital has an infection control nurse. In small hospitals, ICN have other responsibilities which should not be the case.

Slovenia has approximately one infection control nurse per 250 hospital beds/patients. They have a responsibility for clinical standards and practice related to infection prevention. UKC Ljubljana has 8 infection control nurses on full time job and 92 of them are infection control link nurses for assist in the implementation of infection control policies. Slovenia has nearly one hundred (100) ICN with post diploma education at the University Medical Centre Ljubljana, maybe the biggest hospital in EU with nearly 7000 employees and 2400 beds. It is 15 years lasting process, supported by nursing management and with great efforts of some enthusiastic nurses, especially assistant chief nursing officer for infection control.

Norway provided EFN with detailed data on ICN:

Norway							
	Total number of infection nurses	Total number of beds	Number of beds per infection nurse	Total number of day care treatment	Total number of out patient clinics per infection nurse	Number of patients treated at day centers per infection nurse	Total number of patients treated per infection nurse
Middel	9	2113	235	61500	544080	6833	67521
North	7	1574	225	47862	397020	6837	63779
South	14	3372	241	139274	779963	9948	65901
West	15	2694	180	89336	665370	5956	50493
East	18	4150	231	147046	1064204	8169	67522
Total	63	13903	221	485018	3450637	7699	62691

III



In **Denmark** the ratio is 0,25 Infection Control Nurses per hospital bed. The education has a duration of 30 weeks combined theoretical and clinical education. To be admitted to the education you have to have an education as registered nurse, which is at bachelor level and you need to have 2-3 years of relevant clinical experience of management and leadership. The education is controlled by the National Board of Health. For the moment there are great difficulties in recruiting to the education which means that we are expecting a shortage in infection control nurses in the years to come. There are no Danish controlled studies to support the connection between the rate of infections and the number of infection control nurses.

In relation to **the cost of Infection Control teams** and the effect on rates of Infections this is a very challenging question to address at a European level.

- As you may be aware many countries use different surveillance systems and therefore it is almost impossible to compare the effect of ICT's on infection rates. This is further complicated by issues raised in the first question relating to how ICT's are constructed and what population they serve (e.g. acute hospital, community, mental health or independent sector).
- The **average salary** of an Infection Control Nurse is the **same as the salary of the other nurses** in Cyprus and is according to the post and the years in Service. In **Belgium**, the infection control nurses gained the salary of the head nurses (1.700 euro net) but combines this job with other responsibilities such as management of the unit, quality assurance or wound care. The salary in **Italy** depends on many factors (years of work, degrees) and is about 1200 euros. The average salary for an ICN in **Slovenia** is 900 euro. In **Norway**, the infection control nurse has one school year of education at college level. The yearly salary of an infection control nurse is from 37.200 euros to 43.292 euros. Infection control nurses work for the most part in hospitals in Norway, although some large communities have understood the importance of this knowledge and therefore hired infection an infection control nurse. In **Denmark**, the average salary of infection control nurses is not fixed.
- EFN suggestion would be to establish links with IPSE (Improving patient safety in Europe) who may be able to provide some specific information to help further develop questions that the Commission may wish to consider in order to provide them with useful information. IPSE have been undertaking valuable work on surveillance and anti-microbial resistance in Europe. The website address is: <http://helics.univ-lyon1.fr/> and the contact is Ian Russell Ian.Russell@adm.univ-lyon1.fr. IPSE is interested in looking at Infection Control education which is a critical issue for ICT's who need to undergo specialist training. There is currently huge variation both within and between member countries in relation to this, which will inevitably mean that the quality and ability of ICT's to undertake their role will vary across the EU.

C. EFN urges action on Healthcare Associated Infections (HCAIs) in an event at the European Parliament

EFN urges action on Healthcare Associated Infections (HCAIs) in an event the European Parliament – 17 October 2007

On 17 October 2007, Health First Europe, of which EFN is a member, held an event in the European Parliament, Brussels on the issue of HCAIs to call for EU level action on this pressing issue. According to the Commission there are approximately three million HCAIs and 50,000 attributable deaths in the European Union each year. EFN believes this to be a health crisis requiring pan-European leadership and co-ordination from the European Commission in co-operation with the Member States, aims to push this item up higher up the EU agenda. According to the European Centre for Disease Prevention and Control's (ECDC) First European Communicable Disease Epidemiological Report identifies there is much that can be done to tackle HCAIs, indeed up to 30% of HCAIs are preventable.

At a lunch hosted by MEPs Avril Doyle (Ireland, EPP-ED) and Liz Lynne (UK, ALDE), decision-makers met with nurses, doctors, patients and industry to both investigate the extent of the problem in all 27 Member States and to proffer solutions as to how it could be best addressed. Liz Lynne's introductory comments focused on the gravity of the situation, stating as an example that in the UK 90 patients had recently died of the HCAI - C.Dif - a bacteria that causes diarrhea and more serious intestinal conditions such as colitis. C. Dif. has now overtaken MRSA as the main cause of hospital-acquired infections in the UK.

In their speeches, Professor Rossolini from the University of Siena (Italy) highlighted that tackling HCAIs was a complex and multifaceted task, while Paul De Raeve from the European Federation of Nurses Associations noted the importance of continuous professional development of healthcare staff as an important factor tackling HCAIs. During the course of the lunch a lively debate was chaired by former MEP and HFE Honorary President, Mary Banotti. Themes debated included the cleanliness of hospitals and the supervision of healthcare staff by 'matrons', hand washing, the reuse / reprocessing of medical devices and sterilisation, and effective prescription of antibiotics by doctors.

Avril Doyle in her concluding remarks noted that while the European Commission, Member States and the ECDC had dedicated many resources to tackling the possible pandemic of avian flu, but simply not enough was being done to tackle the current epidemic of HCAIs – a real and present problem that is affecting many patients everyday. The lunch was well attended, and included participation by the ECDC, a Cabinet member of Health Commissioner Markos Kyprianou and MEPs – all of whom made spontaneous and passionate contributions to the discussion.

At the close of the lunch, the doctors, nurses, patients and experts attending from 9 different Member States at the invitation of HFE were then divided into 7 national teams (the UK, Germany, France, Spain, Italy, Portugal, Poland) and went on to meet with national MEPs and health attaches, with a view to exploring existing best practices in the Member States, and what action can be taken by all stakeholders involved. There is in fact much expertise in Europe and examples of best practice that need to be effectively assessed, communicated and their urgent adoption actively encouraged.

MEPs were very interested in the stories and experiences that participants had to relate on the issue of HCAIs. A number of MEPs have since offered to raise this matter in the course of their daily parliamentary work and are liaising directly with HFE members in this respect. HFE has since drafted a letter to MEP Jan Andersson, Chair of the European Parliament's Employment and Social Affairs Committee, expressing support for a possible hearing on HCAIs with respect to nurses and care givers (proposed by MEP Liz Lynne) to be added to his Committee's work programme.

Throughout afternoon an information point on HCAIs was manned by the HFE Secretariat on the ground floor of the European Parliament buildings and passers-by were invited to stop and learn more about the serious problem of HCAIs. Information in the form of a brochure, containing HFE's key messages, and on the most prevalent types of HCAI were distributed to approximately 250 people, while approximately 150 people, including several MEPs took part

in the 'HCAI lottery'. The lottery, taking as its basis the fact revealed by the European Commission that one in ten patients going into hospital will contract a HCAI, enabled those willing to take a chance, to draw at random a ping-pong ball from a bag to see if they were that one in ten people who contract an infection whilst in hospital. While the vast majority of participants escaped with a caution and an 'I survived the Healthcare Associated Infections Lottery – but I might not be so lucky next time' HFE sticker, 35 people did go on 'contract' an HCAI, illustrating just how real a risk patients and healthcare staff face in hospitals everyday.

MEPs participating in the event included: Liz Lynne MEP (ALDE, UK), Avril Doyle MEP (EPP-ED, IE), Linda McAvan MEP (PES, UK), Irena Belohorska MEP (NI, SK), Peter Liese MEP (EPP-ED, DE), Holger Krahmer MEP (ALDE, DE), Bernadette Vergnaud MEP (PES, FR), Anne Ferreira MEP (PES, FR), Elisabeth Morin MEP (EPP-ED, FR), Alejandro Cercas MEP (PES, SP), Cristina Gutiérrez-Cortines MEP (EPP-ED, SP), Pier Antonio Panzeri MEP (PES, IT), Iles Braghetto MEP (EPP-ED, IT), Malgorzata Handzlik MEP (EPP-ED, PL), Jan Jerzy Kulakowsky MEP (ALDE, PL), Lidia Geringer De Oedenberg MEP (PES, PL), Marios Matsakis MEP (ALDE, CY)

Other decision-makers participants included: Mr Erginel, Cabinet Member of the Health Commissioner, John O'Toole, from the European Centre for Disease Prevention and Control (ECDC), Todd Weber, from the US Centre for Disease Prevention and Control, Marco Castellina, Italian health attaché

HFE participants included: Mary Banotti, HFE Honorary President; Juliane Bruderek, Infection Control Nurse from Hannover Medical School; Dr Ilona Nowak, Hospital manager and member of the board of BDPK, the German Federal Association for Private Hospitals; Christophe Debout, President of the "Groupement d'Interêt Professionnel en Soins Infirmiers" (GIPSI) and of the "Association nationale des infirmiers et infirmières diplômés d'état" (ANIIDE) ; Judy Birch, HFE Advisory Committee Member and Chief Executive of the Pelvic Pain Network; Camille Perdigou, Project Manager at BAQIMEHP (Bureau de l'Assurance Qualité et de l'Information Médico-Economique de l'Hospitalisation Privée); Annette Jeanes, Infection Control Office Department of Microbiology Windeyer Institute of Medical Science; Rafael Vicente Reig Recena, General Secretary of SATSE, Spanish Nurses Association; Esther M^a Reyes Diez, from SATSE, the Spanish Nurses Association; M^a de los Angeles Pineda Alegre, from SATSE, the Spanish Nurses Association; Prof. Sierra, Prof. of Microbiology and Preventive Medicine, Regional Vice Minister Canary Islands; Prof Rossolini, from University of Siena; Carlo Ramponi, Head Responsible for Quality in the Lombardia Region and Managing director of Joint Commission International; Antonella Mastretti, Health Director of San Donato Hospital; Vincenzo Costigliola, Member of HFE Advisory Committee and representing the European Medical Association; Beata Jagielska, from the European Association for Medical Oncology; Dorota Kilańska, President of the Polish Nurses Association and lecturer at the Medical University in Lodz; Mariola Bartusek, Doctor in Economics Studies at the Medical Academy in Katowice; Geert Bailleul, from Sint Jan Hospital in Bruges; Ms Charlotte Pauwelyn, from Pro Medicis in Brussels; Lieve Blommaert, Hospital Hygienist at AZ VUB Jette; José Robalo, Deputy Director General of Health; Jacinto Oliveira, Vice-President of the Portuguese Nurses Order; Raul Fernandes, from the International Affairs Office of the Portuguese Nurses Order; Prof Martin Fried, Surgeon and Executive Director of the International Federation for the Surgery of Obesity; Mark Grossien, from the European Medical Technology Industry Association; Anna Ludwinek, from the European Medical Technology Industry Association; Roy Bridges, Member of the HFE Executive Committee and representing the Medical Technology Group, UK; Zeger Vercouteren, Member of the HFE Advisory Committee and representing the European Medical Technology Industry Association; Mark Grossien, HFE Treasurer and representing the European Medical Technology Industry Association; Anna Ludwinek, from the European Medical Technology Industry Association; Bert Van Caelenberg, Member of HFE Executive Committee and Secretary General of the European Federation of Public Service Employees; Femke Beumer, from the European Federation of Public Service Employees; Paul De Raeve, Member of HFE Executive Committee and Secretary General the European Federation of Nurses Associations; Paolo Giordano, Member of HFE Executive Committee and General Delegate of the European Union of Private Hospitals; Maya Parikh, HFE Secretary General.

D. WENR – Patient Safety in Europe

EXECUTIVE SUMMARY

This Report was commissioned by the European Federation of Nurses Associations (EFN) in November 2007 in order to support its policy statement on Patient Safety. In that statement the EFN declares its belief that European Union health services should operate within a culture of safety that is based on working towards an open culture and the immediate reporting of mistakes; exchanging best practice and research; and lobbying for the systematic collection of information and dissemination of research findings.

This Report addresses specifically the culture of highly reliable organisations using the work of James Reason (2000). Medication errors and hospital-acquired infections are examined in line with the Report's parameters and a range of European studies are used as evidence. An extensive reference list is provided that allows the EFN to explore work in greater detail as required.

The Workgroup of European Nurse Researchers (WENR) argues that that a systems approach to patient safety medication should be adopted throughout the European Union (EU), particularly given the differences in error reporting across the EU and that EFN should champion this approach.

There is a vast literature aimed at improving hand hygiene compliance. The World Alliance for Patient Safety has produced WHO guidelines on Hand Hygiene. The Workgroup of European Nurse Researchers argues that EFN should work with these strategies and encourage interventions that are behaviourally-focused, multi-disciplinary in nature, evidence-based with specific outcomes measured and audited for sustainable success.

Finally reference is made throughout the Report regarding the variability of evidence at local, national and governmental levels.

Abbreviations

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CDC	Center for Disease Control and Prevention
DoH	Department of Health
EFN	European Federation of Nurses
EU	European Union
HCWs	Healthcare Workers
HAI	Hospital Acquired Infection
HCAI	Healthcare-associated Infection
HRO	Highly Reliable Organisation
NHS	National Health Service
UK	United Kingdom
USA	United States of America
WENR	Workgroup of European Nurse Researchers
WHO	World Health Organisation

DEFINITIONS

Patient safety: The UK National Patient Safety Agency (2003) defines patient safety as “the process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimize the risk of them recurring”.

Adverse events: Adverse events are incidents in which a patient is unintentionally harmed by medical treatment and adverse incidents in which patients are harmed by medical treatment (Vincent et al 1998). Brennan et al (2004) define an adverse event as an injury that was caused by medical management (rather than the underlying disease and that prolonged hospitalisation, produced a disability at the time of discharge or both).

1. Medication

Drug related problems: Included are medication errors (involving an error in the process of prescribing, dispensing or administering a drug, whether there are adverse consequences or not) and adverse drug reaction (any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function (van den Bemt et al 2000). Drug related problems are classified into two categories: medication errors and adverse drug effects (Fijn et al 2001).

Medication errors: The American Society of Hospital Pharmacists (1982) defines a **medication error** as a ‘dose of medication that deviates from the physician’s order as written in the patient’s chart for from standard hospital policy and procedures’. They qualify this by pointing out that, except for errors of omission, the medication dose must actually reach the patient (O’Shea 1999). Wolfe (1989) defines **medication errors** as ‘mistakes during the prescription, transcription, dispensing and administration phases of drug preparation and distribution’. A **medication error** is a discrepancy between the dose ordered and the dose received. It excludes errors in prescribing (Barker et al 2002). A **medication error** is ‘any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer (American National Coordinating Council for Reporting and Prevention 2001).

Near miss: is used to describe situations that did not cause harm to patients, but could have done.

Medication preparation: Is ‘the phase in which the nursing professional, based on the medical prescription, separates, organises and prepares the medications the patient in the work will receive’ (Anselmi et al 2007).

Medication administration: Is the phase in which the nursing professional administers the previously prepared medication to the patients in the work unit. It is considered that the medication has been applied once the patient has effectively taken/ingested/received the drug (Anselmi et al 2007).

Adverse drug reaction (ADR): Is any noxious, unintended and undesired effect of a drug, excluding therapeutic failures, intentional and accidental poisoning and abuse [World Health Organization 1986].

2. Hand Hygiene Practices (WHO Definitions in Whitby et al 2007)

Hand hygiene: A general term referring to any action of hand cleansing.

Hand cleansing: Action of performing hand hygiene for the purpose of physically or mechanically removing dirt, organic material or micro-organisms.

Handwashing: Washing hands with plain or antimicrobial soap and water.

Hand antisepsis: Reducing or inhibiting the growth of micro-organisms by the application of an antiseptic hand rubs or by performing an antiseptic handwash.

Handrubbing: Action of applying an alcohol-based hand rubs. Alcohol-based hand rubs is an alcohol-containing preparation (liquid, gel or foam) designed for application to the hands to reduce the growth of micro-organisms. Such preparations may contain one or more types of alcohol with excipients, other active ingredients, and humectants.

Inherent hand hygiene practice: Instinctive need to remove dirt from the skin when hands are visibly soiled, sticky or gritty. Likely to be established in the first 10 years of life and to drive the majority of community and HCW hand hygiene behaviour throughout life. For example, among nurses, it occurs after touching an 'emotionally dirty' area (axillae, groin or genitals).

Elective hand hygiene practice: Attitude to hand cleansing in more specific opportunities not encompassed in the inherent category and more frequently corresponding to some of the indications for hand hygiene during healthcare delivery. For example, among HCWs, it includes touching a patient such as taking a pulse or blood pressure, or having contact with an inanimate object in the patient environment.

Patient Safety in Europe: Medication Errors and Hospital-acquired Infection

1. Introduction

Patient safety has become a major concern for both society and policymakers and arguably is one part of the quality improvement movement. Patient safety is a complex issue with many factors that include human suffering and financial costs. Fitzpatrick (2006) has identified patient safety indicators and 'setting-specific' patient safety research in the following areas: medication errors, falls and injury prevention, hospital-acquired infections, patient safety in hospital acute-care units, medications in the perioperative environment and home visit programs for the elderly.

Even if patient safety is a major concern, hospitals are inherently unsafe given the nature of their business. Approximately 10% of all hospitalisations in the Industrial World incur an adverse event that results in injury, delayed recovery and sometimes death. In the United Kingdom (UK) reports indicate that approximately 10% of patients "have experienced an adverse event contributing to approximately 72,000 deaths" [<http://www.patientsafetyresearch.org/>]. The World Health Organisation (WHO) estimates that in developing countries, 50% or more of medical equipment is unsafe while 77% of counterfeit and substandard drugs are to be found in poorer countries [<http://www.patientsafetyresearch.org/>].

The American Institute of Medicine (IOM) report (Kohn et al 1999) on the quality of patient care entitled "To Err Is Human" drew international attention to the occurrence, clinical consequences and cost of adverse drug events in hospitals, which is estimated at \$2 billion and up to 98,000 deaths annually in the United States (USA) (Barker et al 2002, Flynn et al 2002). In the UK, the Department of Health (DoH) commissioned a report on 'An Organisation with a Memory (DoH 2000) which according to Tighe et al (2006) covered similar ground to the IOM report and led to the establishment of the UK National Patient Safety Agency whose objectives are to collect and analyse information on adverse events; to learn from these events and ensure feedback to practice; and to identify risks and produce solutions. Page and McKinney (2007) report that the Audit Commission (2001) pointed out that medication errors account for about 20% of deaths due to all types of adverse events in hospital and that this cost the UK National Health Service (NHS) around £500 million a year leading to an average 8.5 additional days in hospital. Two further reports, 'Building a safer NHS for patients' (DoH 2001) in which the UK Government stated its aim to reduce by 40% the number of serious errors in

the use of prescribe drugs and ‘Building a safer NHS for patients- improving medication safety’ (DoH 2004) further emphasise the commitment to making drug treatment as safe as possible in the UK.

Of the nine Patient Safety Solutions approved by WHO April 2007, four relate directly to medication error while one is related specifically to hospital acquired infection through poor hand hygiene [<http://www.jcpatientsafety.org/>].

In the European Union (EU), patient safety is being addressed through three processes; first in collaboration with national ministries of health and stakeholders; secondly through the European Commission's patient safety working group of the High Level Group on Health Services and Medical Care and the Commission patient safety policy initiative 2008; and thirdly the EU is promoting patient safety through the health research theme of the 7th Framework Programme for Research.

2. Report remit

The remit for this work was agreed with the European Federation of Nurses Associations (EFN) November 2007. The context was EFN's “input to the DG Sanco High Level Group Project EuNetpas and the European Parliament initiatives” and its work in 2008 on key issues of which “Healthcare related infection [is the] top priority – relate[d] to [the EU's] health and safety directive”. In particular the “focus on medication errors and infections is key.”

Project parameters

The evidence-based and grey literature on Patient Safety is vast and ever-increasing. There are dedicated Patient Safety websites (Appendix III), conferences and government agencies some of which include clinical research guidance and ethics approval as for example in the UK's National Patient Safety Agency [<http://www.npsa.nhs.uk/>].

Consequently the project parameters were set with care given the remit, timeframe, volume of literature and that this work was unfunded. The literature was surveyed initially on a geographical basis as set out below with each working group member taking primary responsibility for one area while recognising there would be some crossover. As we were unable to identify specific Finnish studies that met the entry criteria, we made direct email contact that indicated there is ongoing work but it is not yet published.

- Sweden & Finland
- Ireland, Northern Ireland, other EU countries
- Iceland, The Netherlands, Denmark, Norway
- UK excluding Northern Ireland and theoretical background

Given that EFN's raison d'être is to be the voice of Nursing in the European Commission, inclusion criteria were set as follows:

- published research studies conducted by nurses and/or
- with a focus on nurses or nursing practice
- hospital-based studies
- adult-focused
- published from the year 2000 onwards
- limited to Swedish, Finnish, Icelandic, Danish, English, Norwegian, Dutch languages
- related to medication errors and hospital-acquired infections (HAIs) as agreed with EFN.

Non-nursing studies addressing specific hospital infection outbreaks, the operationalisation of infection surveillance, the incidence of hospital infection, screening among health care workers, infection related to surgical procedures were excluded as were all community-based studies.

This is a snapshot of current work in the European areas surveyed. In the next sections, a brief outline of the ‘highly reliable organisation’ with reference to systems theory is presented. Patient safety as related to medication error and hospital acquired infection are described in two separate sections. Search strategies are detailed in the Appendices along with specific web addresses related to patient safety. A comprehensive reference list is provided if further details of specific studies are required by EFN.

3. The Highly Reliable Organisation (HRO)

Arguably two approaches to human fallibility exist; that of the ‘person’ approach or that of a ‘systems’ approach (Reason 2000). The person approach “focuses on the errors of individuals, blaming them for forgetfulness, inattention or moral inattention” while the systems approach focuses “on the conditions under which individuals work and tries to build defences” [systems] to prevent or lessen the impact of the effects. Patient safety is directed at establishing ‘a high reliability organisation’ where mistakes occur but their incidence or frequency is limited and systems are designed that can “better tolerate the occurrence of errors and contain their damaging effects” (Reason 2000).

Five key concepts are critical to the successful HRO (Hines et al 2008)

1. **Sensitivity to operations.** Hospital leaders and staff need to be aware of and alert to the systems and processes affecting patient care. “Awareness is key to noting risks and preventing them.”
2. **Reluctance to simplify.** While simple processes are good, simplistic explanations for failure (unqualified staff, lack of training, communication failure, etc.) are “risky” as they deny the complexity that is care delivery.
3. **Preoccupation with failure.** ‘Near-misses’ should be viewed as evidence that the system is working effectively rather than necessarily as proof that the system needs to be improved to reduce further risk.
4. **Deference to expertise.** Leaders and supervisors must “listen and respond to the insights of staff who know how processes really work and the risks patients really face.” Without such cultural openness, the highly reliable organisation is not achievable.
5. **Resilience.** All “leaders and staff need to be trained and prepared to know how to respond when system failures do occur.”

As noted in the Porto Patient Safety Conference (2007) report, “Errors by clinicians are only part of the problem of patient safety. Research shows that when there is an error, there is a cause, and failures in the way the system functions are at the heart of most problems. Patient safety is an issue in all health care settings including hospitals and community care, the home and in medical, nursing and technical practice” [<http://www.patientsafetyresearch.org/>].

4. Patient Safety: Medications

Introduction

Studies on medication safety and nursing are few; are heterogeneous in design making comparability between research reports difficult; and have a lack of evidence for effect despite literature reviews, descriptive studies and reports on implementation of guidelines. Few studies describe nurses’ reactions to medication errors although there may be a significant impact on personal and professional development (Schelbred & Nord, 2007).

Size of problem

Reported, potentially life-threatening medication errors range from 3% to 21% while clinically significant errors range from 3.3% to 31% (Tissot et al 1999, 2003, Taxis & Barber 2004). A UK and German study reported error rates of 26% in the preparation of 337 intravenous medication doses and 34% in the administration of 278 doses with the majority of medication errors having a potentially moderate or severe outcome (Wirtz et al 2003). Another German study reported a global error rate of 48% (preparation - 19%; administration - 23%) in intravenous medications (Taxis & Barber 2004). One study looked at errors across the whole medication process in medical and surgical departments and found a 43% opportunity for errors (Lisby et al 2005).

Errors in the delivery of medications

An adverse drug event (ADE) is an injury due to medication. ADEs can be classified according to preventability, ameliorability, disability, severity, stage of the process, and person or group responsible. ADEs are not necessarily the result of a medication error. If a medication error is present, both the stages of the process where the error occurred, and the person responsible for the error, should be considered as set out in Morimoto et al's (2004) model below:

- ordering (physician, nurse practitioner, or physician assistant);
- transcribing (a secretary or a nurse);
- dispensing (pharmacist);
- administration (nurse, pharmacist, or patient); and
- monitoring (physicians or patients).

Specifically medication errors can occur at many levels within the delivery process and include the following: timing errors, wrong administration rates, preparation errors, wrong administration techniques, physiochemical incompatibility, dosing errors which include omission errors, unauthorised and wrong dose errors, labelling errors including ambiguous labelling of commercial drugs (Cousins et al 2005, Guchelaar et al 2004, Taxis & Barber 2004, Tissot et al 2003, Wirtz et al 2003). 'Wrong time' errors appear to be either the most or second most common type of error: Ireland (O'Hare et al 1995); France (Tissot et al 2003, Prot et al 2005); UK (Cousins et al 2005); Germany (Taxis et al 1999).

Causation of errors

It is extremely difficult to extrapolate a clear picture of causation given the many and sometimes confounding variables (Armitage and Knapman 2003). However factors include:

- knowledge deficits (Tissot et al 1999, Schneider et al 1999)
- workload factors (Tissot et al 2003)
- organisation issues, complex medication systems, labelling issues (Cousins et al 2005, Wirtz et al 2003, Tissot et al 1999, Taxis et al 1999)
- illegible or incomplete medicine orders (Tissot et al 2003)
- distracting environments (Wirtz et al 2003, Deegan 2001)
- an organisational culture of fear (Deegan 2001, Delandey 2006, Kirke et al 2007, Kirke & Delaney 2007).

Medication error information can be collected via (1) practice data (patient note reviews, computer-based triggers), (2) soliciting incidents from health professionals (self-reports), and (3) surveying patients for drug related events. These methods are complementary and a combination may be useful (Morimoto et al's 2004).

Summarised below are a number of reported, evidence-based strategies aimed at improving drug medication safety.

Some tested strategies for improved medication safety

1. Improving drug infusion safety requires a systems approach that is informed by a nonpunitive culture of drug error and near miss reporting (Bucknall 2007, Burdeu et al 2006) and provides feedback to the organization and/or individual (Handler et al 2006).
2. The reporting of medication errors may be increased when paired with a high level of trust in the manager or the use of care pathways (Vogus & Sutcliffe 2007).
3. Shared charts for prescription and drug administration can aid safe and rational medical treatment (Heier et al 2007, Bourke et al 2002).
4. Protocols appear to improve drug safety administration but they need to be systematically implemented and monitored (Egerod et al 2005).
5. Pharmacy-provided protocols for the preparation of parenteral drugs can improve safe administration (van den Bemt 2002).
6. Multidisciplinary, intervention programs that promote the correct administration of drugs via enteral feeding tubes can reduce medication error (Van den Bemt et al 2006).
7. There needs to be a readily available medication error reporting system (Handler et al 2006).
8. Online reporting systems should be explored in greater detail (Ashcroft & Cooke 2006).
9. Clear labelling of drugs could reduce medication errors (Guhelaar et al 2004).

Conclusion: medication error

The benefit of reporting systems is the gaining of knowledge of what errors have been made and the frequency with which they occur. In order to prevent drug errors and enhance patient safety we need to identify the types of errors and under what circumstances they occur.

Future research should capture the environmental and human context of error including the particular experiences of those who have made errors. Large-scale, multicentred surveys, sufficiently powered to provide statistically significant results, using multidisciplinary samples, are required to evaluate existing definitions of errors (Armitage & Knapman 2003). Qualitative research is required into how HCWs who have committed serious medication errors cope with the event and its consequences and that take on the behavioural aspects of the medication delivery process.

In summary a multi-layered strategy to medication errors is required that recognises inadequacies in existing approaches to medication errors; that moves away from the blaming culture to one where there is improved error reporting with opportunities for enhancing performance and understanding behaviour within the process of medication use (Moyen et al 2008).

A systems approach to patient safety medication, that includes an open culture, should be adopted throughout the EU, particularly given the differences in error reporting across the European Union.

5. Patient Safety: Hospital Acquired Infection (HAI)/Nosocomial Infection/Healthcare Associated Infection (HCAI)

The problem

There is general acceptance that a global hospital approach to hospital acquired infection (HAI) is required (Brusaferro et al 2003) such as that described by Schecker et al (1998). This involves minimum appropriate surveillance systems, the definition and implementation of specific policies for infection control and the presence of dedicated and trained health care personnel (e.g. physicians, nurses). However, surveys of Italian NHS teaching hospitals have revealed that the infrastructure for infection control is sub optimal when compared with international guidelines and surveys in other countries (Moro et al 2004, Brusaferro et al 2003).

Prevalence and/or incidence rates of HAI vary internationally, within countries (Doherty et al 2007, Creedon et al 2005, Whyte et al 2005), and in how they are reported (Brusaferro et al 2006). Most HAIs are endemic and result from cross-transmission related to inappropriate patient care practices (Pittet 2004). While there is much agreement on the importance of nosocomial infection and surveillance priorities, there are no agreed basic minimum standards for the resources and facilities necessary for HAI control and prevention (Cunney et al (2006).

The variation in HAI reporting across Europe is illustrated by the following statements: HAI prevalence rates of 4.9% in 45 Irish hospitals (National Disease Surveillance Centre 2006); an overall infection incidence-rate of 11.8 per 1000/patient-days in long-stay facilities in Italy (Brusaferro et al 2006); a MRSA prevalence rate of 14.0/100,000 population in the Republic of Ireland (ROI) compared to a rate of 11.4/100,000 in Northern Ireland (Burd et al 2003, McDonald et al 2003, Mc Donald et al 2002); surgical site infections (SSI) from 1.9% in Southeast France (Couris et al 2007) to 22.7% in Serbia (Maksimovic et al 2008); an overall HAI prevalence rate in north-Danish hospital wards of 5.2% - 7.1% with a bed occupancy rate of 93.7% - 98.9% (Scheel et al 2008).

The cost of HAI

HAI is a costly problem for patients and health services (Pirson et al 2008, Brusaferro et al 2006, Pirson et al 2005, Humphries & O'Flanagan 2001). For example: Patients who developed MRSA infection post head and neck surgery in Ireland had on average, a hospital stay 3-times longer than those who did not develop MRSA, with the costs of their first hospital stay, three times greater (Watters et al 2004). Patients with bacteraemia in a Belgian hospital had significantly higher mortality, a longer hospital stay and greater costs (€ 12,853) compared with controls (Pirson et al 2005). Three years later that figure was increased to €19,301 per patient (Pirson et al 2008).

Healthcare associated infection (HCAI) represents one of the most common adverse events affecting patients admitted to acute hospitals. HCAI affects hundreds of millions of people worldwide, complicates the delivery of patient care, contributes to patient deaths and disability, promotes resistance to antibiotics and generates additional expenditure to that already incurred by the patient's underlying disease. (Pittet & Donaldson 2005b). In particular multi-resistant bacteria such as MRSA present a significant challenge to healthcare institutions globally (Eveillard et al 2001, Burd et al 2003). In Ireland, MRSA is endemic in many hospitals (Doherty et al 2007, Creedon 2006, 2005). Eveillard et al (2001) suggest that in Europe the proportions of strains of MRSA vary from 1% in Scandinavian countries to 30% in Southern countries.

WHO has identified hand hygiene as a major patient safety issue in relation to HCAs and there is general agreement that effective hand hygiene remains the most important initiative in the control of infection (Tavolacci et al 2007, Moret et al 2004, Barrau et al 2003, Burd et al 2003).

Risk factors

Risks factors related to HAIs include length of hospital stay, presence of an invasive device, a Norton's pressure sore risk of more than 12 and being bedridden (Brusaferro et al 2006); rapid patient turnover, leading to increased work and overcrowding (Cunningham et al 2005); a lack of dedicated specifically trained infection control nurses, inadequate dissemination of information and insufficient production and updating of guidelines (Brusaferro et al 2003), residing in a longterm care facility (CDC 2008). Elsewhere protocols to prevent exposure to blood and body fluids that are not tailored to the differences in knowledge, risk perception and practical needs of different professional groups, increase risk (van Gemert-Pijnen et al 2006). In one Norwegian study, it was found that wearing a single plain finger ring by healthcare workers (HCWs) did not increase the total bacterial load on the hands, nor was it associated with an increased rate of carriage of Staph aureus but plain rings were associated with an increased rate of Enterobacteriaceae (Fagernes & Nord, 2007).

Hand hygiene and nursing

Preventing microbial pathogen cross-transmission and healthcare-associated infections is most effectively managed by hand hygiene (Whitby et al 2007). Handwashing is therefore a core element of

patient safety for the prevention of health care-associated infections and the spread of antimicrobial resistance (Sax et al 2007, Pittet et al 2006, Barrau et al 2003, Hejazi et al 2000).

However, health care worker compliance is problematic worldwide with most practising hand hygiene less than 50% than they should (Abbate et al 2008, Sax et al 2007, Creedon 2005, 2006, Larson et al 2005, Arenas et al 2005, Pittet and Donaldson 2005a, Barrau et al 2003, Girard et al 2001, Pittet et al 2001). Factors associated with non-compliance include skin irritation (Larson et al 2006), a lack of knowledge of guidelines (Tavolacci et al 2006, Nobile et al 2002), psychosocial factors (Moret et al 2004), workload (Arenas et al 2005, Wendt 2004), being a physician (Tavolacci et al 2006), poor aseptic technique in practice (Cousins et al 2005, Wirtz et al 2003). While nurse compliance rates tend to be higher than physicians (Wendt et al 2004), non-compliance by nurses is a significant patient safety issue. In order to improve compliance with recommended practice, it is recommended that infection control teams should learn from behavioural science (Pittet 2004, Creedon 2005, 2006) using theoretical frameworks such as Azjen's Theory of Planned Behaviour.

The First Global Patient Safety Challenge 'Clean Care is Safer Care', launched by the WHO World Alliance for Patient Safety October 2005, developed new WHO Guidelines on Hand Hygiene in Healthcare with the specific aim of dealing with large-scale healthcare-associated infection. Since 2005 the Alliance has expanded educational and promotional tools developed initially for the Swiss national hand -hygiene campaign, for worldwide use (Sax et al 2007, Larson 2006).

Examples of project-based outcomes where HAIs have been reduced

Below are examples of a number of different European projects that have sought to reduce HAI.

- a significant reduction of the incidence of ventilator assisted pneumonia can be achieved by relatively simple changes in the nurse pulmonary care protocol (Wallis De Vries et al 2002);
- a randomized clinical trial on the effectiveness of teaching patients basic principles about the care of central venous catheters on the frequencies of CVC-related infections found a significant reduction in infections in the intervention group (Møller et al 2005).
- HCAI rates can be reduced by up to one third (Creedon 2005) if HCWs comply with HCAI guidelines issued by the Centre for Disease Control and Prevention (CDC) (Pittet et al 2000).
- education has been shown to increase compliance and reduce skin-irritation in Switzerland and Germany (Widmer et al 2007, Schwanitz et al 2003).
- implementation of barrier precautions is sufficient to ensure the control of HCAI in a large hospital Eveillard et al (2001)
- a French programme focused on barrier precautions and education led to a decrease in the incidence of MRSA by 17.9% and Entero bacteriaceae producing extended-spectrum β -lactamases (ESBL) by 54.9% (Eveillard et al 2001).

Some strategies for improved avoidance of HAIs

Human behaviour is complex, dynamic and multi-faceted. It is therefore critical to the success of any strategy to improve hand hygiene compliance, that the design and implementation of an intervention be grounded in an understanding of human behaviour (Whitby et al 2007). We should not be surprised when single interventions fail to produce sustained improvement in healthcare worker behaviour over time (Whitby et al 2007). Interventions must recognise behavioural complexity.

Creedon (2006, 2005) reports on the successful implementation of a multifaceted interventional behavioural hand-hygiene programme that resulted in a significant improvement in compliance with hand hygiene guidelines from 51% to 83%. Björholt & Haglind (2004) evaluated the costeffectiveness of an 'Intensive MRSA Control Programme' in a large teaching hospital and found the programme was successful, eradicating an epidemic outbreak of MRSA with the programme demonstrated to >24 months of implementation. The 2nd Irish National Acute Hospitals Hygiene Audit indicates there has been a change in culture with hospitals more proactive and innovative in their approach in to improving hygiene standards compared to the first audit 6-months earlier.

In each of these cases, the approach adopted to HAI was multifactorial, required multidisciplinary solutions and specifically trained nurses and doctors.

Future research: hand hygiene

The WHO Global Patient Safety Challenge task force on behavioural considerations for hand hygiene practices has identified the following areas for future research in the understanding of and compliance with hand hygiene protocols (Whitby et al 2007).

- “Confirmation that behavioural determinants of hand hygiene can be generalized to other healthcare occupational groups in addition to doctors and nurses, and in varying ethnic and professional groups;
- Identification of which predictor has the greatest impact on hand hygiene for all groups of HCWs(HCWs) regardless of their ethnic origin to design the most cost-effective motivational programmes suitable for both high- and low-resource healthcare settings;
- Development of an alcohol-based hand rubs that does not leave a residual smell of alcohol to facilitate use of hand rubs by those HCWs from cultural and religious backgrounds where the use of alcohol is discouraged;
- Assessment of ethnography as a research tool for exploring hand hygiene barriers in diverse cultures;
- Assessment of market research methods to improve hand hygiene in HCWs in high, transitional and low-resource facilities;
- Refocusing of school-based hand hygiene programmes away from a self-protection practice towards a practice for the benefit of self and others;
- Assessment of the acceptance of adult patient engagement (not critically or mentally impaired patients) and their families from culturally diverse backgrounds in prompting HCWs to perform hand hygiene in a manner that does not offend;
- Effectiveness of an overt annual or biannual hand hygiene audit as a means of motivating hand hygiene behaviour with an evaluation of acceptance of short programmes using a peerpairing system to prompt performance of hand hygiene in preparation for the annual overt hand hygiene audit.
- Further assessment of the influence of workload or staffing level on hand hygiene behaviour.”

6. Patient Safety: What do Patients and the Public Want?

In the UK patients and the public as key stakeholders in healthcare have become pivotal in patient safety policy and implementation. As reported by Coutler and Ellins (2006), patients want more transparency and openness regarding medical errors. Patients want to be informed about the event, to receive information on what and why it happened, how its consequences can be mitigated and how to prevent any other recurrences can be prevented. In an increasingly litigious environment, ‘honest disclosure’ can increase patients’ trust and satisfaction while reducing the risk of legal action (Mazor et al 2004).

7. Conclusion

As has been noted elsewhere an organisation which is transforming requires a workforce that is flexible, dynamic, open to change and possesses transferable skills and these are critical to delivering the Patient Safety agenda (Basford & Kershaw 2008).

The 10 point recommendations to emerge from the EU Patient Safety Conference (Porto 2007) provide a rational basis for a way forward.

Recommendations: EU Patient Safety Conference Porto 2007

- Target funding for patient safety research at European Union institution and member state levels
- Promote a joined-up system of local, national and international patient safety research supported by all stakeholders in Europe and ensure it is linked to evidence-based policies and practice
- Promote multidisciplinary research and the integration of disciplines relating to patient safety research
- Develop the effective use of IT for data collection and systems which promote safety and reduce adverse events
- Establish a pan-European electronic collection of patient safety research findings, readily accessible for both researchers and policy-makers
- Agree and fix a minimum data collection criteria for patient safety across Europe , building on the WHO International Classification for Patient Safety
- Provide healthcare professionals with a new culture on patient safety issues, more training opportunities on patient safety research and advice based on clinical evidence
- Develop indicator and monitoring systems within Europe to identify a whole range of healthcare incidents and risks
- Foster networks and joint research across the European Union, neighbouring regions and developing and transitional countries
- Develop strategies to involve patients in patient safety research programmes and activities

In the EU, health care is strongly influenced by the concept of subsidiarity wherein national governments retain direct control of national health care systems (Craig & Smith 2008). Nevertheless 'Patient Safety' has allowed the EU to comment on a range of health-related measures and both recommend and legislate in matters that affect member states' health policies. Medication errors and infection control are two such examples.

Patient safety research should be multidisciplinary and of sufficient scope and scale that it can 'make a difference'. While we have shown that patient safety can be improved and adverse events reduced by improving the organization of care, it is equally vital that research is required to understand system failures. As argued by the Porto 2007 Patient Safety Conference, "The role of patient safety research is to measure the extent of the problem, identify causes, to work with clinicians and policy-makers in developing solutions using scientific evidence, and to evaluate the effectiveness of interventions."



To cite this Report:

Smith, LN (Ed), Burke, J, Sveinsdóttir, H, Willman, A (2008) Patient Safety in Europe: Medication Errors and Hospital-acquired Infection. Amsterdam, Workgroup of European Nurse Researchers.