eHEALTH FOR SAFETY

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1 Introduction

eHealth for Safety is a European study addressing RTD needs concerning the (potential) contributions of ICT to patient safety and risk management. It had the following overarching goals:

- Identification of key issues, topics and challenges where ICT applications can have a high impact on improved patient safety

- Development of both a ten year vision/strategy and concrete recommendations for RTD measures (within the EU's 7th Framework Programme) and for longer term research activities

Within this study we take ***a broader look* at the general contribution ICT tools can make to higher quality of care, increased patient safety and better risk management** (and not just reduction of errors and adverse events). Thereby we apply a broad definition of risk management to optimise patient safety in a holistic fashion **across the whole health value system,** first of all through (better) *information and prevention*, and if this is not sufficient and *diagnosis and treatment* become necessary, *optimise* (often minimize) the number, processes and severity of interventions including surgical procedures, drugs etc., and the same applies to biomedical and clinical *research, training and education, and* the whole *public health* domain.

Work package 1 of the *eHealth for Safety* study laid the foundation for all further work to come. It fed directly into WP 2, the execution of empirical information gathering, and together with WP 3 - the analysis of all the material collected, helped to structure and organise WP 4, final reporting and roadmapping.

This report synthesises all the work done over the course of the project. After briefly re-visiting relevant definitions, evidence on the dimension of the patient risk and safety is presented. Next, the most important findings from the desk research in WP1 are exposed, followed by the findings from the empirical work in WP2. The result of the analysis of this data is a vision and a number of recommendations for future research efforts as presented in the last chapter. The recommendations have already found their place in the preparations for the first call of the EU's 7th Framework Programme and will continue to guide the EC in further calls related to the field of patient safety and risk management in healthcare.

2 Definitions

This section gives an overview of the definitions of key terms, as referred to and used in this report.

2.1 Defining "Patient Safety"

According to Baker and Norton[1], there is ***no standard listing of the topics and areas included under "patient safety."*** The topic can be defined narrowly to include only research specifically related to the study of adverse events and their prevention, or, more broadly to include any aspect of health care and health services that may lead to patient injury, and any interventions, including clinical, organizational and policy changes to reduce injury. These interventions could include improved reporting of adverse events, efforts to reduce the likelihood of injury or lower the impact of injuries that do occur, and policy and research initiatives related to patient safety and healthcare error.

The patient safety movement has galvanised itself in recent years in many developed countries, and globally through the recent initiative led by the World Health Organisation[2] and known as the "World Alliance for **Patient Safety".**. The rate of development of patient safety programmes and initiatives is increasing to the point that patient safety appears to be one of the most important common issue in health care internationally. For example, an internet search for "patient safety" in February 2004 revealed just over 500,000 results, the same search in March 2005 revealed 2,680,000 results – a five fold increase. Whilst many less tangible quality issues can be open to debate, improving patient safety through reducing the incidence of potentially preventable harm appears to have become difficult to argue against.

The following are the ***elements of patient safety*** that most developed countries have identified in their strategies for improving patient safety:

- A 'just' or 'fair' culture that encourages a reporting and questioning culture; Systems for reporting and analysing incidents both locally and nationally;

- A good in-depth analysis process to establish root causes for selected individual incidents and aggregate incident reviews, thus enabling learning;

- A process to ensure that actions are implemented and corresponding improvements in patient safety and quality of care can be demonstrated; and

- Effective processes for sharing information at various levels – nationally, organisationally and clinically – for learning and improvement.

- Redefinition of compensation systems (punitive or non-punitive) and their impact on the patient safety culture and achievements.

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[1] Baker GR, Norton P. Patient Safety and Healthcare Error in the Canadian Healthcare System (2002) A Systematic Review and Analysis of Leading Practices on Canada with Reference to Key Initiatives Elsewhere. A Report to Health Canada. Ottawa: Health Canada.

[2] ibid, p. 67

In order to improve understanding of the extent and impact of patient safety incidents a number of research projects have been carried out in various countries. As a result patterns and trends are starting to emerge. Indeed, Neale et al. collated information on international studies involving retrospective reviews of patient records to determine the incidence of patient safety incidents. These studies refer only to inpatients. This found that the average incidence was 8.9 per cent and the average incidence of potentially avoidable adverse events was 3.4 per cent. The variation in data can in part be explained by differences in the underlying methodologies for screening records to determine patient safety incidents.

International comparisons of organisational learning for patient safety are presented as well as *summary information on aspects of patient safety programmes and initiatives* in selected countries. Given that tremendous differences in health care provision can exist within individual countries, this information needs to be interpreted with caution.

In his article "The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human'", Wachter[3] pointed out that ***improving safety requires a multidimensional approach***. He identified five major areas of activities and initiatives that have marked the past five years. Although some of the efforts may be seen as cross-cutting, they fall into the following broad categories: (1) regulation, (2) error reporting systems; (3) information technology; (4) the malpractice system and other vehicles for accountability; and (5) workforce and training issues.

Reviewing the key initiatives in several countries, Baker and Norton[4] conclude that "considerable activity is underway in Australia, the United States and the United Kingdom to reduce the incidence of adverse events and medical errors. Each of these countries has established a high profile committee with a mandate to examine the issue, improve reporting, and develop recommendations to address system deficiencies. These efforts have included strong support from the federal governments (and state governments in Australia). In addition, a variety of professional groups, employers, regulators and healthcare providers have initiated a wide range of efforts to address this issue."

2.2 Defining Medical Errors

Medical errors are the **failure of a planned action to be completed as intended, or use of the wrong plan to achieve an aim.**[5] Medical error reduction is an international issue (see the section dealing with international activities below), as is the implementation of patient care information systems (PCISs) as a potential means to achieve it.[6] The serious problem of medical errors is not new, but in the past, the problem has not gotten the attention it deserved.

Errors occur not only in hospitals but in other health care settings, such as physicians' offices, nursing homes, pharmacies, urgent care centres, and care delivered in the home. Unfortunately, very little data exist on the extent of the problem outside of hospitals although many errors are likely to occur outside the hospital. For example, in a recent investigation of

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[3] Wachter, Robert M. (2004): The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human' - Amid signs of progress, there is still a long way to go. Health Affairs, 30 November 2004.

[4] Baker GR, Norton P. (2002): Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices on Canada with Reference to Key Initiatives Elsewhere. A Report to Health Canada. Ottawa: Health Canada. p. 16

[5] Jill Rosenthal and Trish Riley (2001): Patient safety and medical errors: a roadmap for state action. National Academy for State Health Policy.

[6] Ash et. al (2004): Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. Journal of the American Medical Informatics Ass. 11_104-112

pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the State.[7]

As already mentioned, available data suggest that error in medicine is frequent and results in substantial harm. **General recommendations** for a reduction of the frequency and consequences of errors in medical care are

- to implement clinical decision support judiciously,
- to consider consequent actions when designing systems,
- to test existing systems to ensure they actually catch errors that injure patients,
- to promote adoption of standards for data and systems,
- to develop systems that communicate with each other,
- to use systems in new ways,
- to measure and prevent adverse consequences,
- to make existing quality structures meaningful, and
- to improve regulation and remove disincentives for vendors to provide clinical decision support.

Specific recommendations are

- to implement provider order entry systems, especially computerized prescribing,
- to implement bar-coding for medications, blood, devices, and patients, and
- to utilize modern electronic systems to communicate key pieces of asynchronous data such as markedly abnormal laboratory values. [8]

2.3 Defining "Quality Assurance and Improvement"

Many of the issues discussed in this deliverable sometimes also appear under the heading quality assurance (QA) and quality improvement. In fact, patient safety, quality assurance and risk management overlap considerably and therefore all three categories are discussed in this paper, with special emphasis on patient safety, as the focus of the study and current international research.

The underlying rational of QA is that the health **system must deliver the best possible outcomes for patients within the constraints of available resources.** People expect the best possible health care. Quality and safety in patient care is a fundamental and primary obligation of all health services. Health care provision is complex and carries risks of patient harm. Improving the quality and safety of care for people and the clinical governance systems are essential for a health organisation that wishes to reduce harm and waste.[9] Care cannot be considered to be of high quality unless it is safe.[10]

Appropriate collection analysis and feedback of health information is essential to the building of a safer, better health system. The development of an electronic health record is complex,

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[7] AHRQ (w.d.) Medical Errors: The Scope of the Problem. Fact sheet, ttp://www.ahrq.gov/qual/errback.htm

[8] Bates et al (2001): Reducing the Frequency of Errors in Medicine Using Information Technology, in Journal of the American Medical Informatics Association Volume 8 Number 4 Jul / Aug 2001

[9] Health Care Complaints Commission (2003) Investigation Report. Campbelltown and Camden Hospitals. Macarthur Health Service. Part 7: Systems for quality and safety http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf

[10] Moss F./ Barach (2002): Quality and Safety in Health Care: a time of transition, in:Qual Saf Health Care 2002;11:1, BMJ Publishing Group, (www.qualityhealthcare.com)

but is an essential resource for safe, knowledge based health care.[11] Quality and safety for patients also depends on robust:

- process and system design for clinical care and supports
- risk management across all governance processes
- monitoring and action based upon real data relating to organisation performance and identified community needs

Quality improvement and assurance has been an important focus in Australia. Accreditation by the Australian Council on Health Care Standards was developed in 1974, with a focus on improving the structures, processes and outcomes within the health system. The evolution through quality assurance to continuous quality improvement led to the notion of clinical governance emerging in the 1990s, all with the fundamental purpose of improving the quality and safety of care in the health system.

Improving the quality and safety of health care in locally, nationally and internationally has been recognised as a key priority. The Australian Department of Health has set up a quality and clinical policy branch, which supports its framework for managing the quality of health services in New South Wales. The Mac Arthur Health Service Investigation report found that the effectiveness of key quality and safety systems, such as incident reporting and complaints management, had been limited and made ineffective by a range of factors, such as

- a variability of reporting due to the culture and behaviour of different professional groups
- a culture that does not consistently encourage reporting of quality and safety problems
- a culture of blame reported by some staff
- a lack of feedback when reports are made
- delays in reviewing reports and implementing remedial action
- a failure to monitor and evaluate the implementation and effectiveness of any remedial action recommended
- inadequate resourcing of key quality and safety systems and personnel.[12]

The effectiveness of many **quality improvement interventions** has been studied, and research suggests that most **have highly variable effects which depend heavily on the context in which they are used and the way they are implemented.** This has three important implications.

Firstly, it means that the approach to quality improvement used in an organisation probably matters less than how and by whom it is used. Rather than taking up, trying, and then discarding a succession of different quality improvement techniques, organisations should probably choose one carefully and then persevere to make it work.

Secondly, future research into quality improvement interventions should be directed more at understanding how and why they work - the determinants of effectiveness - rather than measuring whether they work.

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[11] Barraclough B.: NHIMAC 2nd Annual Health Online Summit (2003): The Role of Health Information in Improving Safety and Quality in Health Care"

12 Health Care Complaints Commission (2003) Investigation Report. Campbelltown and Camden Hospitals. Macarthur Health Service. Part 7: Systems for quality and safety http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf

Thirdly, some element of evaluation should be incorporated into every quality improvement programme so that its effectiveness can be monitored and the information can be used to improve the systems for improvement.[13]

2.4 Defining "Risk Management"

There is a range of definitions for risk management which are derived from the commercial work environment as well as from health care and reflect the approach to risk management that is taken. The Joint Australia/New Zealand Standard (2004) defines risk management as "the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects".[14] When applied to healthcare this definition helps to dispel some misconceptions:

- Risk management is not primarily about avoiding or mitigating claims; rather it is a tool for improving the quality of care

- Risk management is more than simply reporting patient safety incidents. Risks also have to be analysed, treated and monitored

- Risk management is not only the business of service managers but also concerns working clinicians

Risk management therefore addresses the following basic questions[15]:

FIGURE 2: BASIC QUESTIONS IN RISK MANAGEMENT

Basic questions	Risk management contribution
What could go wrong?	Risk identification
What are the chances of it going wrong and what would be the impact?	Risk analysis and evaluation
What can we do to minimise the chances of this happening or to mitigate damage when it has gone wrong?	Risk treatment. The cost of prevention is compared with the cost of getting it wrong
What can we learn from things that have gone wrong?	Risk control; sharing and learning

Source: Royal College of Obstetricians and Gynaecologists (2005)

Reid et al.[16] argue that one needs to differentiate between different levels of risk, such as

- **Individual or patient risks:** potential compromises to the health of an individual caused by some action of the system.

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[13] Walshe K., Freeman T. (2002): Effectiveness of quality improvement: learning from evaluations, in:Qual Saf Health Care 2002;11:85-87, BMJ Publishing Group, (www.qualityhealthcare.com)

14 Standards Australia and Standards New Zealand (2004) Risk Management, AS/NZS 4360:2004. Strathfield, Risk Management Standards (Third edition).

15 Royal College of Obstetricians and Gynaecologists (2005) Improving Patient Safety: Risk management for maternity and gynaecology. Clinical Governance Advice No 2 (revised October 2005) p. 2/9

16 Reid et al. (2005: 42) Builinding a better Delivery System: A New Engineering / Health Care Partnership - Patient Safety and Risk Management Tools ; in: National Academies Press

- **Care team member risks:** occupational risks, such as exposure to disease, physical duties, and workplace hazards (e.g., exposure to toxic substances, radiation, and equipment malfunctions).

- **Healthcare organizations**[17]:

    - operational risk, which includes all risks associated with the delivery of services

    - competitor risk, such as the potential of losing market share to competitors

    - financial risk, such as the risk of non-payment or reduced payment for services or the risk of significant financial liability

    - environmental risk, such as the risk of damage by forces external to the organization

    - model risk, that is, the risk that the models used for evaluating other types of risk are not accurate

- At the **socio-economic level**, risks are incurred not only by individual organisations but also from the interaction between organisations, lack of adaptability of organisation and the misalignment of objectives.

Risk management thus involves the analysis and assessment of risks, as well as the development of strategies to reduce risk, protect against losses, and ensure that risks transferred from one agent to another are compensated fairly.

As Knox (2002) points out, managing risk in healthcare organisation is more about corporate design and improvement and changing systems of work rather than simply a staff function assigned to an office or someone labelled "risk management". Integrating the work of risk into organizational and managerial culture and making it an explicit step in the decision making process is critical to future successful management of corporate healthcare risk.[18] As an example the Figure below provides a suggested trigger list for incident reporting in maternity[19].

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[17] McDonough, J.E., R. Solomon, and L. Petosa. 2004. Quality Improvement and Proactive Hazard Analysis Models: Deciphering a New Tower of Babel. Attachment F. Pp. 471–508 in Patient Safety: Achieving a New Standard of Care. Washington, D.C.: National Academies Press. Qtd.in Reid et al. (2005: 42) Builinding a better Delivery System: A New Engineering / Health Care Partnership - Patient Safety and Risk Management Tools ; in:National Academies Press,.

[18] Knox G. E. (2002): Risk management or safety first? in:Qual Saf Health Care 2002;11:116, BMJ Publishing Group, (www.qualityhealthcare.com), p. 116

[19] Royal College of Obstetricians and Gynaecologists (2005) Improving Patient Safety: Risk management for maternity and gynaecology. Clinical Governance Advice No 2 (revised October 2005). P. 4/9

FIGURE 3: SUGGESTED TRIGGER LIST FOR INCIDENT REPORTING IN MATERNITY

Box 4. Suggested trigger list for incident reporting in maternity		
Maternal incident	**Fetal/neonatal incident**	**Organisational incident**
Maternal death Undiagnosed breech Shoulder dystocia Blood loss > 1500 ml Return to theatre Eclampsia Hysterectomy/laparotomy Anaesthetic complications ITU admission Venous thromboembolism Pulmonary embolism Third/fourth degree tears Unsuccessful forceps or ventouse Uterine rupture Readmission of mother	Stillbirth > 500 g Neonatal death Apgar score < 7 at 5 minutes Birth trauma Fetal laceration at caesarean section Cord pH < 7.05 arterial or < 7.1 venous Neonatal seizures Term baby admitted to neonatal unit Undiagnosed fetal anomaly European Congenital Anomalies and Twins (Eurocat)[30]	Unavailability of health record Delay in responding to call for assistance Unplanned home birth Faulty equipment Conflict over case management Potential service user complaint Medication error Retained swab or instrument Hospital-acquired infection Violation of local protocol

Source: Royal College of Obstetricians and Gynaecologists (2005)

One way of identifying prospective risks is through a tool called Failure Mode and Effects Analysis (FEMA) which will be discussed in chapter 6.3 as a key tool in systems engineering and human factor research. For an after the fact approach to identifying what could have gone wrong the London Protocol is a useful tool in this respect, outlining 7 key steps[20]:

1. Identify incident and take decision to investigate
2. Select members of investigation team
3. Gather data and relevant physical incidents
4. Determine the chronology of incidents
5. Identify care delivery problems (unsafe acts, e.g failure to act, incorrect decision)
6. Identify contributory factors (e.g. inadequate training, lack of supervision)
7. Devise an action plan

In the risk analysis stage (see above figure), the risk is assigned a score and depending on that score it is decided in the risk treatment stage whether the appropriate course would be elimination, substitution or acceptance of the risk.

How risk is communicated to patients is also of considerable importance. One study[21] found that patients preferred health risks to be framed in absolute terms, using bar graphs, and calculated over their expected lifetime. There was no clear preference for presenting a treatment's effect on multiple outcomes.[22]

On the European level DG Health and Consumer Affairs (SANCO) is working to identify, encourage and support the post-graduate training and scientists working in the public risk assessment area. [23] We will return to the issue of how to manage risk in chapter 6, where we analyse the contributions of different non-medical fields to risk management.

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[20] S. Taylor-Adams, C.Vincent (2004) Systems Anaysis of Clinical Incidents: the London Protocol. Clin. Risk 10: 211-220.

Quoted in Royal College of Obstetricians and Gynaecologists (2005) Improving Patient Safety: Risk management for maternity and gynaecology. Clinical Governance Advice No 2 (revised October 2005). P. 5/9 FN 23

[21] Of a small, self-selected population of women who were more likely to be interested in health-related activities.

[22] Fortin Jennifer M. et al: Identifying patient preferences for communicating risk estimates: A descriptive pilot study, in: http://www.biomedcentral.com/1472-6947/1/2

[23] DG SANCO (2005): Maximising the Contribution of Science to European Health and Safety.

3 Patient risk and safety in practice

Since the publication of two IOM reports, *To Err Is Human*[24] (2000) and *Crossing the Quality Chasm*[25] (2001) patient safety issues have received considerable attention. The first report included an estimate that systems failures in healthcare delivery (i.e. poorly designed or "broken" care processes) were responsible for 44000 to 90,000 deaths each year. The second report revealed a wide "chasm" between the quality of care the health system should be capable of delivering today (given the astounding advances in medical science and technology in the past half century) and the quality of care most Americans should receive.

The risks that people are exposed to when entering the healthcare systems are intuitively underestimated. This was shown by research comparing contacts with the healthcare system to other potentially risky activities. Travel by rail in Europe and commercial air travel are actually among the safest activities, with less than one in 100,000 fatalities per personal encounter or trip. Driving is far more dangerous: about 42,000 people die each year in the EU in automobile accidents. It is no surprise that, statistically, mountain climbing and bungee jumping are among the most dangerous activities. The most striking result of all is that there are more deaths per encounter with the healthcare system than for any of these other activities.[26]
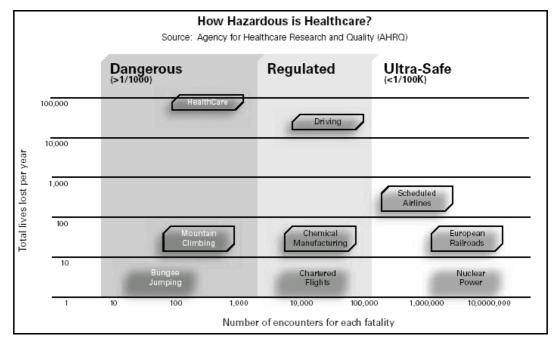
FIGURE 1: RISK OF FATALITY IN DIFFERENT DOMAINS

Source: AHRQ, 2005

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[24] Kohn LT, Corrigan JM, Donaldson MS (eds.) (2000). To err is human: Building a safer health system. Institute of Medicine, National Academies Press: Washington D.C. http://books.nap.edu/books/0309068371/html/index.html [accessed March 2007]

[25] Committee on Quality of Healthcare in America (2001). Crossing the Quality Chasm: A New Health System for the 21st Century, Institute of Medicine, National Academy Press: Washington D.C. http://books.nap.edu/catalog/10027.html [accessed March 2007]

[26] Scott Young (2005) The Role of Health IT in Reducing Medical Errors and Improving Healthcare Quality & Patient Safety. PowerPoint. Agency for Healthcare Research and Quality. http://www.ehealthinitiative.org/assets/documents/Capitol_Hill_Briefings/Young9-22-04.PPT

Most of the available evidence on patient safety comes from the United States**.** In Europe, the above cited IOM study often serves as a benchmark to extrapolate from micro-level results in order to arrive at an estimate of the overall incidence of adverse events on the national level.

3.1 The size of the problem

The incidence of adverse events, resulting in injuries or other types of harm is widespread. In the United States more than one million patients suffer injuries each year as a result of broken healthcare processes and system failures.[27,28] In the United Kingdom the Department of Health estimates that one in ten patients admitted to NHS hospitals will be unintentionally harmed[29] **Patient surveys also reveal a worryingly large incidence of medical errors**. In a recent international survey released by "The commonwealth fund"[30], patients were asked whether they believed they experienced a medical mistake in treatment or care, were given the wrong medication or dose, were given incorrect test results, or experienced delays in receiving abnormal test results. Thirty-four percent of U.S. respondents reported at least one error. Thirty percent of Canadians asked also claimed at least one such error while 20 percent of those in Australia, 25 percent of New Zealanders, 23 percent of Germans and 22 percent of those in the United Kingdom made similar allegations. Although these numbers are striking, they once again highlight the problem of patient safety definition. If a "medical error" approach to patient safety is chosen, patient safety incidents are much more common. If however, an adverse event approach is chosen, the numbers will most likely be smaller. The effect of extensive inclusion criteria on patient safety statistics is illustrated in Table 1.

TABLE 1: ADVERSE EVENTS IN ACUTE HOSPITALS IN SEVEN COUNTRIES

Study	Number of acute care hospitals	Date of admissions	Number of hospital admissions	Adverse event rate (% admissions)
California Insurance Feasibility Study	23	1974	20864	4.65*
Harvard Medical Practice Study (HMPS)	51	1984	30195	3.7
Utah–Colorado Study (UTCOS)	28	1992	14052	2.9
Quality in Australian Health Care Study (QAHCS)	28	1992	14179	16.6
United Kingdom	2	1999	1014	10.8
Denmark	17	1998	1097	9.0
New Zealand	13	1998	6579	11.2
France**	7	2002	778	14.5
Canada	20	2000	3745	7.5

*The California study assessed 'potentially compensable events'.
**Figures from France are from the pilot study not the full study.

Source: Vincent (2006), p. 42

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[27] Kohn LT, Corrigan JM, Donaldson MS (eds.) (2000). To err is human: Building a safer health system. Institute of Medicine, National Academies Press: Washington D.C. http://books.nap.edu/books/0309068371/html/index.html

[28] Starfield B (2000) Is US Health Really the Best in the World? Journal Of The American Medical Association 284(4):483-5.

[29] National Audit Office/NAO (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1

[30]Schoen C, Osborn R et al. (2005) Taking the Pulse of Health Care Systems: Experiences of Patients with Health Problems in Six Countries, Health Affairs Web Exclusive W5-509.

Here, the Australian data are surprisingly high. This can be accounted for by the wider range of adverse events included in the study. For example, adverse events occurring outside the hospital were also included and the overall focus of the study was on the quality of care delivered and not on negligence. Thus, minor complications such as wound infections, skin injury or urinary tract infections were included; elements which were discarded by the American studies.[31] It has been also said that better information gathered from the Australian medical records could have explained the differences.

3.2 The problem of measuring Adverse Drug Events (ADEs)

Adverse Drug Events (ADEs) are the subject of many studies and represent a major subgroup of patient safety issues. ADE studies have to be distinguished from the larger category of medication error studies, which may or may not lead to an adverse drug event. While medication error studies assess whether a drug was prescribed and administered correctly (with or without actual or potential harm to the patient), ADE studies focus on the harm that might or might not have been caused by an error.[32]. Assessing the true extent of adverse drug events remains difficult. The first reason concerns the overemphasis on the inpatient sector in most of the studies. A second problem concerns differences in the types of incidents reported, either focusing on ADEs acquired while in hospital care, or including ADEs which led to hospital admission. Further problems can arise when the focus of the study is on a particular age group, for example the over 65 year olds. A literature review study on hospital ADEs from 2003 dealing with 10 studies found the median incidence of preventable Adverse Drug Events to be 1.8% with a range of 1.3% to 7.8%.[33] This figure is in line with estimates from the Netherlands where the number of hospitalisations for adverse drug reactions (ADR) were analyzed in a 2001 study. It found that 1.83% of all hospitalisations were related to adverse drug reactions.[34] A more recent study from 2006 (HARM study), which covered 21 out of approximately 100 Dutch hospitals over a 40 day period found that medication related admissions amounted to 2.4% of all admissions and 5.6% of all emergency admissions.[35]

A study of hospital admissions in the UK, published in 2004, found that 6.5% of people admitted to hospital had experienced an ADE and that in 80% of those, the ADR was the direct cause of the admission. The same study found that patients with ADEs occupy 4% of NHS hospital bed capacity.[36] Preliminary data from an ongoing study at the Royal Liverpool University Hospital has indicated that about 16% of patients suffer an ADR as hospital inpatients. Many ADRs are experienced by patients when they are being treated in primary care or as outpatients. It is difficult to quantify the actual prevalence of ADRs and there has been little research into the incidence of ADRs in patients treated in primary care.

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[31] Vincent C (2006), Studies of errors and adverse events in healthcare: the nature and scale of the problem, chapter 3 in Vincent C, Patient Safety, Churchill Livingstone. p. 42

[32] Vincent C (2006), Studies of errors and adverse events in healthcare: the nature and scale of the problem, chapter 3 in Vincent C, Patient Safety, Churchill Livingstone.

[33] Kanjanarat P, Winterstein AG, Johns TE et al. (2003), Nature of preventable adverse drug events in hospitals: A literature review, American Journal of Health-System Pharmacy, 60(17):1750-59. p. 1753

[34] van der Hooft CS, Sturkenboom M, vn Groothest K et al. (2006), Adverse Drug Reaction-Related Hospitalisations: A Nationwide Study in the Netherlands. Drug Safety 29(2): 161-168. p. 164

[35] van den Bemt P & Egberts T (2006), Hospital Admissions Related to Medication. Final Report, Utrecht Institute for Pharmaceutical Sciences. p. 30

[36] Pirmohamed M, James S & Meakin S et al (2004) Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ 329: 15-9. Quoted in BMA Board of Science (2006) Reporting adverse drug reactions. A guide for healthcare professionals.

The overall rate of preventable adverse drug events in the United States was estimated at 1.5 million preventable ADEs each year. In hospitals, figures vary between 380.000 and 450.000 preventable ADEs per annum, based on conservative estimates.[37] In ambulatory care 530,000 preventable ADEs have been projected for outpatient Medicare alone.[38] A meta-analysis of ADRs in hospitalised patients in the USA found the overall incidence of serious ADRs (on admission and experienced while in hospital) to be 6.7% and of fatal ADRs to be 0.32%.[39] In line with above mentioned preliminary data from the UK, a small study in the USA found that around 25% of outpatients had experienced an ADR and that in many instances they were preventable or ameliorable.[40]

In Spain, a National Study of Adverse Events related to Healthcare in Hospitals (ENEAS) estimated that medication related AEs accounted for 37.4% of all AEs.[41] In both the Dutch and Spanish studies, the vulnerability of older patients to adverse events in general and adverse drug related events in particular, was highlighted. The above mentioned HARM study found that 65+ patients have a two times higher frequency of drug related hospitalisations than younger patients. The Healthcare Quality Report for the Netherlands found that one in five of the independently living elderly is annually prescribed at least one potentially hazardous medication. This may concern medicines that are unsuitable for elderly or that should be prescribed in a smaller dosage.[42] The particular, vulnerability of patients aged 65+, who were two times more likely to be victim of an adverse event, was confirmed in the ENEAS study.[43] These findings should not come as a surprise, given that older peoples' medication regime often involves more than one drug.

In sum, the available evidence suggests that Adverse Drug Events should be a cause of serious concern. Although there are important methodological difficulties, the available evidence suggests that roughly between 2% and 8% of hospitalised patients will experience an adverse drug event. Elderly people have a risk which is twice as high as those of younger age groups. (comment : difficult to get a clear idea between ADR during the hospitalisation and ADR prior to the hospitalisation. We should clearly separate :

- ADR during patient stay at the hospital due to in prescription

- ADR as a cause of hospitalisation due to errors of prescription or administration

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[37] Classen et al (1997) Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality. Journal of the American Medical Association 277(4):301-306.

Bates et. al (1995) Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. Journal of the American Medical Association 274:29-34.

Qtd. in IOM (2006) Preventing Medication Errors. Committee on Identifying and Preventing Medication Errors. Board on Health Care Services. Prepublication Copy. p. 3

[38] Gurwitz et al (2003) Incidence and preventability of adverse drug events among older person in the ambulatory setting. Journal of the American Medical Association 289(94):1107-1116.

Qtd. in IOM (2006) Preventing Medication Errors. Committee on Identifying and Preventing Medication Errors. Board on Health Care Services. Prepublication Copy. P. 3

[39] Lazarou J, Pomeranz BH, Corey PN (1998) Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies, Journal of the American Medical Association 279(15):1200-1205.

[40] Quoted in BMA Board of Science (2006) Reporting adverse drug reactions. A guide for healthcare professionals.

[41] Aranaz JM, Aibar C, Vitaller J, Ruiz P (2006) National Study of Adverse Events Related to Healthcare in Hospitals [English Summary], ENEAS 2005, http://www.who.int/patientsafety/research/RESUMEN.ENEAS_INGLES.pdf [accessed March 2007]

[42] Westert GP, Verkleij H (eds) (2006), Dutch Healthcare Performance Report, Bilthoven: National Institute for Public Health and the Environment, p. 63

[43] Aranaz JM (dir.) (2006) National Study of Adverse Events Related to Healthcare in Hospitals, p. 48, ENEAS study, [full version], https://www.who.int/patientsafety/information_centre/reports/ENEAS-EnglishVersion-SPAIN.pdf [accessed March 2007]

3.3 Estimating the costs of adverse events

Measuring the cost of patient safety related incidents is extremely difficult, because costs affect not only the care providers in terms of prolonged hospital stays or increased readmission rates, but also society as a whole through lost earnings due to disability etc. If patient safety related incidents are conceptualised as one manifestation of bad care processes, resource waste, poor communication etc., then an estimated thirty to forty cents of every United States' dollar spent on healthcare, or more than half a billion dollars per year, is spent on system failures, unnecessary repetition, poor communication, and inefficiency"[44]. Costs for hospital ADE errors are estimated at between 2.3 billion USD (1993 value) and 3.5 billion US$ (2006 value) and at 887 million USD for ambulatory care related ADEs. However, these calculations do not take important cost factors like costs of morbidity and mortality as well as lost earnings and compensation payments into account and are thus likely to be underestimates. [45]

In the United Kingdom, **patient safety incidents cost the NHS an estimated £2 billion a year in extra bed days**; hospital acquired infections add a further £1 billion to these costs. The cost of settled clinical negligence claims in 2003-04 was £423 million and provisions for outstanding clinical negligence claims as at end of 2003-04 were in excess of £2 billion. Adverse Drug Reactions in the NHS create annual cost to the NHS of £466 million.

In the Netherlands, a study carried out by WINAP (the scientific institution of pharmacists in the Netherlands) showed that costs arising from over 90,000 hospital cases of errors in medication amounted to 300 million euros each year[46]. Extrapolated cost **estimates for adverse drug events in the Netherlands put the costs at €76 million a year**.[47]

3.4 Preventable adverse events

Kanjanarat and his colleagues point out that few discussions exist on "whether errors are by definition preventable or whether every preventable adverse event is necessarily associated with an error."[48] Most studies assume though that a distinction can be made between adverse events which are the result of an error and thus preventable and adverse events which "cannot be prevented given the current state of knowledge."[49] Given the high costs and the high incidence of adverse events it is startling to note the preventability ratios of adverse events. For example, the Department of Health in the UK estimates that one in ten patients admitted to NHS hospitals will be unintentionally harmed*[50]*, a rate similar to other developed countries. Around 50 per cent of these patient safety incidents could have been avoided, if only lessons from previous incidents had been taken into account. [51] Another small study in the USA found that around 25 per cent of outpatients had experienced an ADR and that in many instances

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[44] Proctor P. Reid, W. Dale Compton, Jerome H. Grossman, and Gary Fanjiang, Editors, (2005): Building a Better Delivery System: A New Engineering/Health Care Partnership. Committee on Engineering and the Health Care System, National Academies Press, 276 p., http://www.nap.edu/catalog/11378.html

[45] IOM (2006) Preventing Medication Errors. Committee on Identifying and Preventing Medication Errors. Board on Health Care Services. Prepublication Copy. P. 4 for these calculations

[46] www.nictiz.nl

[47] Data from English abstract of HARM study, kindly provided by Mr. Michael Tan, NICTIZ, Netherlands.

[48] Kanjanarat et al. (2006), p. 1751, op cit.

[49] Quality Interagency Coordination, Glossary of Terms "unpreventable adverse event", http://www.quic.gov/report/mederr8.htm [accessed April 2007]

[50] NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1

[51] NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1

they were preventable or ameliorable.[52] The Spanish ENEAS study found that 42.8% of all the adverse effects under scrutiny were avoidable.

The Dutch HARM study on Hospital Admissions related to Medication found that medication related admissions amounted to 2.4% of all admissions and 5.6% of all emergency admissions.[53] Of these hospitalisations, 46% were assessed as being potentially preventable. If the results of this study are extrapolated to all Dutch hospitals, 41,000 hospitalisations annually are drug related; 16,000 drug related admissions are preventable. A retrospective study of patient records in two English hospitals found 10.8% of patients experienced an adverse incident; of which around half were judged to have been preventable. [54]

3.5 Estimating the number of deaths caused by adverse events

The most extreme effect of adverse events in healthcare is death. The United States Commission on Systemic Interoperability in its recent report "*Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*"[55] pointed out that medical errors are killing more people each year than breast cancer, AIDS, or motor vehicle accidents together.[56] The US Institute of Medicine (IOM) in its groundbreaking report "To Err is Human" estimated that systems failures in healthcare delivery (i.e. poorly designed or "broken" care processes) were responsible for 44000 to 90,000 deaths each year.[57] In surveys, 42% of US adults said that they, or a member of their family, had experienced a preventable medical error in their care, 10% said it led to a death.

In the United Kingdom, the analysis of trust surveys found that 169 trusts were able to provide data on the number of deaths as a result *of patient safety incidents*. This showed that in 2004-05 there were some 2,181 deaths recorded but it is acknowledged that there is significant under reporting of deaths and serious incidents. *[58]* The available evidence on deaths related to adverse drug events in the United Kingdom indicates that over 2% of those patients who were admitted to hospital with an ADE died.[59] In a population based review of medical records in two US hospitals concerning preventable adverse events, the authors found that 4.65% of patients aged 16 to 64 died as a result. In line with previous observations, the death rate was twice as high for patients aged 65+, namely 10.44%.[60]

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[52] Quoted in BMA Board of Science (2006) Reporting adverse drug reactions. A guide for healthcare professionals.

[53] van den Bemt P & Egberts T (2006), Hospital Admissions Related to Medication. Final Report, Utrecht Institute for Pharmaceutical Sciences. p. 30,

[54] NAO 2005, A Safer Place for Patients, op. cit. p. 26

[55] Commission on Systemic Interoperability (2005): Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology, U.S. Government Printing Office, Washington, October 2005, 249 p., http://endingthedocumentgame.gov/PDFs/entireReport.pdf

[56] Institute of Medicine, Centers for Disease Control and Prevention; National Center for Health Statistics: Preliminary Data for 1998 and 1999. 2000.

[57] Kohn LT, Corrigan JM, Donaldson MS (eds.) (2000). To err is human: Building a safer health system. Institute of Medicine, National Academies Press: Washington D.C. http://books.nap.edu/books/0309068371/html/index.html [accessed March 2007] Starfield B (2000) Is US Health Really the Best in the World? Journal of the American Medical Association 284(4):483-5.

[58] NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.1

[59] Pirmohamed M, James S & Meakin S et al (2004) Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ 329: 15-9. Quoted in BMA Board of Science (2006) Reporting adverse drug reactions. A guide for healthcare professionals.

[60] Thomas EJ, Brennan TA (2000), Incidence and types of preventable adverse events in elderly patients: population based review of medical records, British Medical Journal 320:741-744.

3.6 Causes and solutions

The role of incomplete or missing information as well as organisational factors have to be taken into account if one wants to arrive at a complete explanation of the causes of adverse events. In fact, most of the research on the causes of adverse events places a high responsibility on deficiencies in system design, organisation and operation rather than on individuals. Factors to be aware of include an organisation's strategy, its quality management tools and its capacity to learn and adapt.[61] The critical role of information is highlighted in particular when it comes to medication related adverse events. According to the United States Institute of Medicine, over a half million people are injured each year because of adverse drug events, many of which could be avoided if healthcare providers had complete information about which drugs their patients were taking and why.[62] Similar observations were made in the Dutch Healthcare Performance Report of 2006. With regard to out of hour pharmacies, the report noted a lack of access to the patients' complete medical history. As a consequence, the level of care delivered was substandard and increased the risks of adverse drug reactions.[63]

In a 2002 survey, two reasons for medical errors were given by American physicians and the public: shortage of nurses (53% of physicians, 65% of public) and overworked, stressed and fatigued healthcare providers (50% vs. 70%). The public also cited too little time with physicians (72%) and not working as a team or insufficient communication (67%).[64]

The IOM study suggests that several possibilities exist for reducing the ADE rate. In a hospital setting this includes Computerised Physician (Professional) Order Entry (CPOE), Decision Support System (DSS), and bar coding applications. In particular, electronic prescribing and monitoring for errors in all care settings is essential. However, in addition to these technical components, improved provider-patient communication is a key component.[65] A consensus has also emerged on possible solutions to improve patient safety. Hospital executives in Australia, Canada, New Zealand, the UK and the US have outlined the following suggestions for improved quality of care, many of which prominently feature ICT tools[66]: Bar coding medications was considered a very effective measure by a considerable majority of respondents, ranging from 62% in the US to 36% in Australia. Standard treatment guidelines found the highest support among respondents. Between 43% and 59% of respondents considered this a very effective measure. Similar high levels of support were found for computerised ordering of medications and electronic medical records.

Available studies about the impact of various ICT tools on patient safety indicate that these tools improve patient safety in three ways: first by preventing errors and adverse events, second by facilitating rapid responses after an adverse event and finally by tracking and providing feedback about adverse events.[67] As an example, Computerised Physician Order Entry Systems (CPOEs) in a controlled trial have been found to reduce serious medication errors by

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[61] WHO (2002), Quality of care: patient safety: Report by the Secretariat, 55th World Health Assembly A55/13, 23 March.

[62] Agency for Healthcare Research and Quality, Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs. Research in Action: Issue 1. March 2001

[63] Dutch Healthcare Performance report, op cit., p. 64

[64] reported in Canadian Institute for Health Information (2004) Health Care in Canada, p.30

[65] compare IOM (2006) Preventing Medication Errors. Committee on Identifying and Preventing Medication Errors. Board on Health Care Services. Prepublication Copy. p. 5-10.

[66] The Commonwealth Fund, Harvard School of Public Health, Harris Interactive, Inc (2003) Commonwealth Fund International Health Policy Survey of Hospital Executives, Survey Charts (Powerpoint), in particular slides 26 to 30. http://www.cmwf.org/surveys/surveys_show.htm?doc_id=233227 [accessed April 2007]

[67] Bates DW, Gawande AA (2003), Improving Patient Safety with Information Technology, New England Journal of Medicine 348(25):2526-34.

55%.[68] On a more fundamental level, ICT tools help to address failures of communication, which remain the most common factor contributing to adverse events.[69]

Although these insights have by now entered the mainstream, a status report on patient safety efforts five years after the publication of the IOM's report found that Computerised Physician Order Entry Systems (CPOEs) were only fully implemented by 34.2% of the survey hospitals. However, a substantial number had implemented medication safety systems to address problems related to look-alike, sound-alike or spelled-alike drugs. Surprisingly, 9% of hospitals did not have a written patient safety plan at all.[70]

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[68] Bates DW, Leape LL, Cullen DJ et al. (1998), Effect of computerized physican order entry and a team intervention on prevention of serious medication errors, JAMA 280(15) :1311-6, cited in Bates DW, Cohen M, Leape LL et al. (2001), Reducing the Frequency of Errors in Medicine Using Information Technology, Journal of the American Medical Informatics Association 8(4):299-308.

[69] Bates DW, Gawande AA (2003), Improving Patient Safety with Information Technology, New England Journal of Medicine 348(25):2526-34.

[70] Longo DR, Hewett JE, Ge B, Schubert S (2005), The Long Road to Patient Safety A Status Report on Patient Safety Systems, Journal of the American Medical Association 294(22):2858-65.

4 ICT applications in healthcare benefiting patient safety and risk management

4.1 ICT in healthcare: review of the evidence

4.1.1 Electronic Health Record (EHR) implementation

One of the most important developments in eHealth in recent years in many countries has been the ongoing spread of activities concerned with the implementation of Electronic Health Records (EHR) on the national, regional and local level. The IOM has advised that *moving from a paper to an electronic based patient record system would be the single step that would most improve patient safety.*

In the UK, the National Programme for Information Technology in the NHS being delivered by the Department's agency, *NHS Connecting for Health*, has begun to roll out its National Care Record system and expects it to have full functionality by 2010. Most trusts foresee that this will help them to ensure that **patient records are no longer lost** and there are **better controls over prescribing** (both issues have led to significant numbers of patient safety incidents). The UK National Audit Office (NAO) has underlined the **key role IT should play in improving patient safety** not only in *avoiding medication errors* but in *supporting retrospective audit* and *providing information to professionals*. The NAO notes that Connecting for Health (CfH), the agency charged with delivering the National Programme for IT (NPfIT), has asked the *National Patient Safety Agency* (NPSA) to help assure the programme's specifications and *ensure that patient safety is an inherent **feature of the system***. Here, technology is seen as an important facilitator. In its evaluation of the activities conducted so far in the UK the report states that "the *National Care Record has significant potential to improve safety as lost or poorly completed records are a major contributory factor to patient safety incidents."*[71]

In the United States, the concept of the **national health information infrastructure (NHII)** was created to overcome the ICT deficit in healthcare. The NHII must be a secure, reliable, and adaptable national infrastructure capable of connecting and supporting highly distributed, varied, independently managed, multi-tiered, intra-institutional, clinical information/communications technology systems and applications. While the implementation of comprehensive EHR systems has lagged behind, in the US progress in certain areas, such as computerized reporting of laboratory results, has been made. Two cases of the use of EHRs have been documented by Reid et al.[72] The **Veterans Health Information Systems and Technology Architecture (VistA)** supports a continuum of care, from intensive care units and other inpatient areas, to outpatient care settings, long-term care settings, and even home care environments. Additionally, the Veterans Health Administration (VHA) Computerized Patient Record System (CPRS) provides a single interface where health care providers can review and update patients' medical records, as well as place orders for medications, special procedures, x-rays and imaging, nursing care, dietary requirements, and laboratory tests. The second example is the **Automation of the Clinical Practice (ACP) Project at Mayo Clinic** (Jacksonville, Florida) which was initiated in 1993 and had the objective to switch to the "pa-

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[71] NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.9

[72] Proctor P. Reid, W. Dale Compton, Jerome H. Grossman, and Gary Fanjiang, Editors, (2005): Building a Better Delivery System: A New Engineering/Health Care Partnership Committee on Engineering and the Health Care System, National Academies Press. P.69

perless" practice of medicine to improve patient safety and physician effectiveness and reduce expenses. The last paper based record was circulated in the clinic in 1996 and in 2002, 445,000 patient visits were conducted with the computer-based patient record.

It is likely that these developments of eHealth infrastructure in many countries will lead to broader implementation of other well known ICT tools, like the ones addressed below. In the following sub sections we provide a detailed review of important ICT components and their application, starting with decision support systems.

4.1.2 Decision Support Systems (DSS)

Decision support systems (DSS) are broad solutions which **incorporate a variety of eHealth applications.** In particular CPOE (see section below) and decision support systems complement each other and should ideally be incorporated in one solution. Due to the broadness of the term, several definitions of decision support system have been brought forward. On a general level DSS can be described as "computer based support for management decision makers who are dealing with semi-structured problems."[73] There are two types of decision support systems – business and clinical- which different significantly in intent and content but which, at the same time, also share many common elements which potentially allows useful synergies to be established by integrating clinical decision support (CDS) with business decision support (BDS).[74]

According to Liu et al. (2006) *'decision tool'* "is an active knowledge resource that uses patient data to generate case-specific advice which support decision making about individual patients by health professionals, the patients themselves or others concerned about them."[75] This definition is an updated and more general version of Wyatt and Spiegelhalter's 1991 definition of computer decision aids ("active knowledge systems which use two or more items of patient data to generate case-specific advice").[76]

Safety in the clinical environment is firstly based on structures that reduce the probability of harm, secondly on evidence for increasing favourable outcomes and thirdly on explicit directions. **Explicit computerised decision support tools** standardise clinical decision making and lead different clinicians to the same set of diagnostic or therapeutic instructions. **Simple computerised algorithms** generate reminders, alerts, or other information; **protocols** that incorporate more complex rules reduce the clinical decision error rate. When explicit computerised protocols are driven by patient data, the protocol output (instructions) is patient specific, thus preserving individualised treatment while standardising clinical decisions. The expected decrease in variation and increase in compliance with evidence-based recommendations should decrease the error rate and enhance patient safety.[77]

Since decision support systems go back as far as 1974 **several reviews of the evidence collected** so far have taken place, the most important of which are introduced below. Firstly, Hunt et al's review (1998) [78] concludes that **clinical decision support systems can enhance**

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[73] P.G.W. Keen and M.S. Scott Morton (1978) Decision support systems: an organizational perspective. Reading (Mass.): Addison-Wesely. For a variety of definition of DSS see http://en.wikipedia.org/wiki/Decision_support_system

[74] cf Oliveira Jason (2002) A Shotgun Wedding: Business Decision Support Meets Clinical Decision Support. Journal of Healthcare Information Management — Vol. 16, No. 4

[75] Liu J, Wyatt JC, Altman DG (2006) Decision tools in health care: focus on the problem, not the solution. BMC Med Inform Decis Mak. 2006 Jan 20;6:4

[76] Wyatt JC, Spiegelhalter DJ. Field trials of medical decision-aids: potential problems and solutions. Proc Annu Symp Comput Appl Med Care. 1991:3–7.

[77] see for instance Morris, A.H. (2002) Decision support and safety of clinical environments. Qual Saf Health Care 11: 69-75.

[78] Hunt et al. (1998): Effects of computer-based clinical decision support system on physicians performance and patient outcomes: a systematic review. JAMA 280: 1339-1346

clinical performance for drug dosing, preventive care and other aspects of care but not convincingly for diagnosis. In this review 68 controlled trials in variety of different subject areas were analysed. Fifteen studies assessed systems designed to assist with **drug dosing,** eight of which addressed the dosing of intravenous medications, with 6 finding improvements with the use of DSS. Four trials also evaluated patient outcomes and only one found a significant benefit compared with usual clinical practice. 19 Studies of CDSS providing **preventive care** were also analysed by Hunt et al. All of the studies evaluated clinician performance and 14 (74%) found a benefit for at least one of the processes of care measured.

Open Clinical also lists several evaluation studies of decision support systems, the most important of which are listed below:

- Sintchenko et. al[79] (2004) note that the use of DSS plus microbiology report improved the agreement of decisions by clinicians with those of an expert panel from 65% to 97% (p=0.0002) or to 67/ (p=0.02) when only antibiotic guidelines were accessed. They conclude that when used computer-based decision support **significantly improved decision quality**

- In their assessment of computer-based cardiac care suggestions Tierney et al (2003)[80] found that the intervention had **no effect on physicians' adherence to care suggestions.** Physicians viewed guidelines as providing helpful information but setting limits to their practice. They suggest that future studies must weigh the costs and benefits of different (perhaps more Draconian) methods of affecting clinician behaviour.

- Van Wijk et al (2002)[81] determined the compliance of such general practitioners with recommendations for bloods test orders. A guideline based decision support system, Blood Link, was integrated in the electronic medical record of 31 general practitioners in 23 practices. **71% of orders used the decision support software rather than the paper order forms.** The most frequent type of non-compliance was the addition of tests. This may be the case, the authors conclude, because practitioners already apply new insights that have yet to be included in the official guidelines

- Rousseau et al. (2003)[82] report **primarily negative comments about a DSS.** The three main concerns voiced by clinicians were: timing of the guideline trigger, ease of use of the system and helpfulness of the content

Similarly, Kawamoto et al. (2005)[83] review seventy studies and **conclude that decision support systems significantly improved clinical practice in 68% of trials.** For five of the system's features interventions possessing the feature were significantly more likely to improve clinical practice than interventions lacking the feature. The commonest types of decision support system were computer based systems that provide patient-specific advice on printed encounter forms or on printouts attached to charts (34%), non-electronic systems that attached patient-specific advice to appropriate charts (26%) and systems that provided decision support with computerised physician order entry systems (16%).

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[79] Sintchenko et al. (2004) Comparative impact of guidelines, clinical data and decision support on prescribing decision: an interactive web experiment with simulated cases. J Am Med Inform Assoc 11 (1) 71-7.

[80] Tierney et al. (2003) Effects of computerized guidelines for managing heart disease in primary care. J Gen Intern Med 18 (12): 967-76.

[81] Van Wijk et al. (2002) Compliance of general practitioners with a guideline-based decision support system for ordering blood tests. Clin. Chem 48(1): 55-60.

[82] Rousseau et. al (2003) Practice based, longitudinal, qualitative interview study of computerised evidence based guidelines in primary care. BMJ. 2003 Feb 8;326(7384):314.

[83] Kawamoto et al. (2005): Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ, April 2, 2005; 330(7494): 765.

Most notably, **75% of interventions succeeded when the decision support was provided to clinicians automatically, whereas none succeeded when clinicians were required to seek out the advice of the DSS. Similarly, systems that were provided as an integrated component of charting or order entry systems were significantly more likely to succeed than stand alone systems (rate difference 26%, 2% to 49%).** Systems that **prompted clinicians to state a reason** for not following advice were more successful than those that allowed the system to be bypassed without having to give a reason (rate difference 41%, 19% to 54%). Systems that **provided a recommendation** were significantly more successful than systems that provided only an assessment (rate difference 35%, 8% to 58%), Of the six features shown to be important by the univariate analyses, four were identified as independent predictors of system effectiveness by the primary meta-regression analysis.

This analysis **confirms the critical importance of automatically providing decision support as part of clinician workflow** (P < 0.00001). The other three features were providing decision support at the time and location of decision making (P = 0.0263), providing a recommendation rather than just an assessment (P = 0.0187), and using a computer to generate the decision support (P = 0.0294). Among the 32 clinical decision support systems incorporating all four features, 30 (94% (80% to 99%)) significantly improved clinical practice. In contrast, clinical decision support systems lacking any of the four features improved clinical practice in only 18 out of 39 cases (46% (30% to 62%)) analysis.[84]

In Garg et al's systematic review of controlled trials of DSSs, **about two thirds of these are effective** at narrowing knowledge gaps, improving decisions, clinical practice or patient outcomes[85], but many are not (e.g. computer-based guidelines on the management of angina and asthma).[86] Why did one third of the computerised DSSs that were sufficiently mature to be exposed to a randomised trial fail to influence clinical actions in Garg et al's systematic review? Reasons why this might have happened include:

- Failure of clinicians to use the DSS e.g. because they did not understand what it was for, the prevailing clinical culture was against it, their patients or peer group objected to it, it was too slow, or was not linked to the Electronic Patient Record (EPR).

- The DSS did not produce an effective output in time to influence their decision: e.g. the output was not available in time; they could not understand the output.

- The output was not convincing enough to persuade the users to change their practice: e.g. the output showed poor accuracy, was badly worded, users had never before heard of this drug and required more details.

- The output was available and was convincing enough to influence user decisions, but the user was unable to change their practice: e.g. the drug was too expensive to prescribe, there was adverse peer or patient pressure, the user was missing some vital information, equipment or skill that they needed before being able to enact their decision.

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[84] Kawamoto et al. (2005): Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ, April 2, 2005; 330(7494): 765.

[85] Garg et al. (2005) Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA. 2005;293:1223–1238.

[86] Eccles et al. (2002) , McColl E, Steen N, Rousseau N, Grimshaw J, Parkin D, Purves I. Effect of computerised evidence based guidelines on management of asthma and angina in adults in primary care: cluster randomised controlled trial. BMJ. 2002;**325**:941–944. doi: 10.1136/bmj.325.7370.941.

- The performance of the clinicians was already optimal, given the circumstances and patient case mix.

Each of these potential reasons for failure needs to be considered carefully by DSS developers before they start work. This means that DSS developers need to start with the steps necessary to bring about the intended user actions or behaviour, not with the improvement of the quality of user decisions or the accuracy of the DSS itself. Those wishing to improve clinical practice and patient outcomes need to analyse the steps necessary to bring about the intended change and accept that, quite often, a DSS will not be the solution, as the long list of issues above demonstrates. Liu et. al. (2006) thus advocating that the development of decision support systems need to shift from being technology led to problem led, and that a new mindset is needed to encourage this.[87]

Complementary with this information Ash et. al. (2004)[88] identify instances were DSS (or patient care information systems, PCIS, as they call it) foster errors rather than reducing them. They distinguish between

- Errors in the process of entering and retrieving information
- Errors in the communication and coordination process

They conclude that systems need to have a fast response time, have negligible downtime, be easily accessible and have interfaces that are easy to understand and navigate.

Two important papers deal with the application of DSS in two concrete cases. Galanter (2002)[89] recounts the experience of developing a decision support tool for **stroke prevention in auricular fibrillation** (deciding whether to take Warfarin). The development of the tool drew upon the views of patients and GPs in an iterative process. Initial application to a number of patients has shown that the tool is acceptable and can be applied in an older population, but that it requires time and expertise to use. A randomised controlled trial will shortly be undertaken to assess the efficacy of the tool.

Secondly, a clinical guidance programme for the **decision about prophylactic oophorectomy in women undergoing a hysterectomy**[90] was developed. This computerised clinical guidance programme (CGP) provides patient specific guidance on the decision whether or not to undergo a prophylactic oophorectomy in order to reduce the risk of subsequent ovarian cancer. The programme gives specific individualised evidence based health guidance which is adjusted to account for individual risk factors and a patient's own values and preferences concerning health outcomes.

A preliminary pilot was carried out, in which the participating women expressed overall satisfaction with the system. The authors conclude that future decision aids and support systems need to be developed and evaluated in a way which takes account of the variation in patients' preferences for inclusion in the decision making process.

Finally, DSS developers will need to become more aware of regulatory issues. Although DSS are currently exempt from regulation in UK, unlike the closed loop systems that measure pa-

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[87] Liu J, Wyatt JC, Altman DG (2006) Decision tools in health care: focus on the problem, not the solution. BMC Med Inform Decis Mak. 2006 Jan 20;6:4

[88] Ash et. al (2004) Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. Journal of the American Medical Informatics Ass. 11:104-112

[89] Galanter William L (2002) Preventing Exacerbation of an ADE with Automated Decision Support, in: Journal of Healthcare Information Management — Vol. 16, No. 4, p.44-49

[90] Pell et al. (2002): Development and preliminary evaluation of a clinical guidance programme for the decision about prophylactic oophorectomy in women undergoing a hysterectomy. in:Qual Saf Health Care 2002;11:32-39.

tient variables and automatically adjust a drug infusion device for example, this may change[91]. For example, the National Institute for Health and Clinical Excellence in England is currently piloting methods to test the clinical and cost effectiveness of DSS[92]. If this pilot becomes a permanent NICE work programme, it will act as a regulatory hurdle to the introduction of DSS into the UK National Health Service.

4.1.3 Computerised Physician Order Entry (CPOE)

Computer Physician Order Entry or CPOE can be defined as a **process whereby the instructions of physicians regarding the treatment of patients under their care are entered electronically and communicated directly to responsible individuals or services.** In the past such orders were hand written or verbally communicated which led to medical errors.[93] Clinical decision support systems (see above) are built into almost all CPOE systems to varying degrees, providing basic computerised advice regarding drug doses, routes and frequencies, as well as more sophisticated data such as drug allergy, drug-laboratory values, drug-drug interactions, checks and guidelines.[94] CPOE are applied in a variety of physical and technical environments using currently available vendor software but CPOE is also very resource-intensive, time consuming, and expensive. [95]

Proponents of CPOE systems argue that they have led to reductions in **transcription errors**, which in turn have led to demonstrable improvements in patient safety. Furthermore, CPOE systems that include data on patient diagnoses, current medications, and history of drug interactions or allergies can significantly reduce **prescribing errors**.[96] CPOE systems also improve the quality of care by increasing clinician **compliance with standard guidelines** of care, thereby reducing variations in care.

A 2001 debate of the American College of Medical Informatics[97] focused on the proposition that **national regulatory mandate** of computer-based provider order entry (CPOE) - to take effect by the end of 2005 - brings greater benefit than risk for health care delivery. Both sides accepted that provider order entry offers potential benefit. Those supporting the proposition emphasized public safety, noting that payers have little economic incentive to pay for quality and that a mandate would force vendors to improve the usability and value of their systems. Overhage[98] outlines the following concrete benefits of CPOE:

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[91] Donawa M. (2002) FDA final guidance on software validation. Medical Device Technology. 2002;**13**:20–24

[92] National Institute for Health and Clinical Excellence (2005) NICE to assess the feasibility of evaluating computerised decision support systems. http://www.nice.org.uk/page.aspx?o=265920

[93] For this definition see http://en.wikipedia.org/wiki/CPOE. Compare also FCG (2003):Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach and Bonnabry Pascal (2003) Information Technologies for the Prevention of Medication Errors. Business Briefing: European Pharmacotherapy 2003 1-5.

[94] Bonnabry Pascal (2003) Information Technologies for the Prevention of Medication Errors. Business Briefing: European Pharmacotherapy 2003 1-5.

[95] It is estimated that five percent of hospitals now have CPOE, but the implementation is costly; see FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach.

[96] Bates, D.W., L.L. Leape, D.J. Cullen, N. Laird, L.A. Petersen, J.M. Teich, E. Burdick, M. Hickey, S. Kleefield, B. Shea, M. Vander Vliet, and D.L. Seger (1998) Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. Journal of the American Medical Association 280(15): 1311–1316. Bates, D.W., J.M. Teich, J. Lee, D. Seger, G.J. Kuperman, N. Ma'Luf, D. Boyle, and L. Leape. 1999. The impact of computerized physician order entry on medication error prevention. Journal of the American Medical Informatics Association 6(4): 313–321. Leapfrog Group. 2000. Leapfrog Patient Safety Standards: The Potential Benefit of Universal Adoption. Available online at: http://www.leapfroggroup.org.

[97] Overhage et. al (2002) Does National Regulatory Mandate of Provider Order Entry Portend Greater Benefit Than Risk for Health Care Delivery? The 2001 ACMI debate. Journal of the American Medical Informatics Association Volume 9 Number 3 May / Jun 2002. 199-208.

[98] Overhage et. al (2002) Does National Regulatory Mandate of Provider Order Entry Portend Greater Benefit Than Risk for Health Care Delivery? The 2001 ACMI debate. Journal of the American Medical Informatics Association Volume 9 Number 3 May / Jun 2002. 201.

- Improvement of clinical processes, which decrease lost orders, transcription time, and cost.

- Reduction of ambiguity secondary to illegible handwriting and incompleteness of written orders.

- Support of cost-effective decision making, improving formulary compliance; cost-effective medication ordering; appropriateness of medication administration, route, dosage, duration, and interval

- Decrease in test redundancy; and improvement in consequent, contingent, and corollary orders.

From 4 studies on CPOE with DSS, analysed by Kaushal and Bates (2003)[99] (three of which were conducted at Brigham and Women's Hospital), the first study (from BWH) found a 55% decrease in serious medication errors. As a secondary outcome this study found a 17% decrease in preventable adverse drug events (ADE). The second study, a time series analysis, found marked reductions in all medication errors excluding missed dose errors and ion non-intercepted serious medication errors. Correcting for the number of opportunities for errors the total number of ADEs/100 patient days decreased from 14.7 to 9.6 (p=0.09). For the sub-category of preventable ADEs, the reduction from 5 to 2 achieved borderline statistical significance (p=0,05). Overage et al.'s study shows a greater than 100% improvement in the rate of corollary orders (p<0.0001). Teich et al demonstrated 5 prescribing improvements in types, doses and frequencies of drug usage.

All the systems analysed were developed in house and not bought from a commercial organisation on the market.

Drug prescribing is an important area for the use of decision support systems in medicine. Improvements in doctors prescribing decisions could avoid many errors, many of which result in patient harm, and save a considerable fraction of the drugs bill[100].Considering the impact of CPOE on medication administration processes **pharmacies** have been identified as important players and need to be involved in the decision on CPOE implementation. In a CPOE–pharmacy interfaced environment, the CPOE system's medication order contains data fields that must map clearly to the pharmacy data fields.[101] At **Wirral Hospital NHS Trust** the introduction of structured, ICT-supported medication handling pathways drastically reduced errors in the prescription of specific high risk drugs. For instance, an error rate of 82% in the prescription of low molecular weight heparin (identified by an audit) was eliminated. Similarly, in paediatrics structured pathways led to reductions of specific error rates from 26% to just 4% for paediatricians and from 76% to less than 7% for non-paediatric specialists. Furthermore, the introduction of an automated dispensing system reduced the risk of medication errors while electronic prescription improved the legibility and completeness of prescriptions. Moreover, the use of ICT applications supporting work processes freed staff for clinical activities at the bedside.

However, many physicians express concern that CPOE based ordering takes longer than paper based ordering. Features of CPOE that can reduce the time burden to physicians include the use of predefined collections of orders for complex conditions (for example, initial man-

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[99] Kaushal Rainu, Bates David W. (2003) Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs). Chapter 6 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.59-70

[100] see Fox John (2002): Designing safety into medical decisions and clinical processes Published in: U. Voges (Ed.): Computer Safety, Reliability and Security. Proceedings of 20th International Conference, SAFECOMP 2001, Budapest, Hungary, September 26-28 2001, Springer-Verlag, Berlin, 2002.

[101] groupPOE (10/2002): Landmines and Pitfalls of Computerized Prescriber Order Entry by groupPOE.

agement of the patient after bypass graft surgery), access to CPOE from locations other than the hospital or office, adequate training, easy access to patient and reference data, and progressive familiarity with the application. Continual system refinement can also improve efficiency over time. The presence of alerts and reminders that prevent errors and ordering in an information-rich environment may also make computerized ordering a satisfying experience.

The report "Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started (2001)"[102] provides a starter set of information for decision-makers in hospitals to help them organize their CPOE effort and launch the search for an appropriate CPOE solution. Sources of information include vendor demonstrations and conversations with vendor CPOE project managers, combined with the prior knowledge and experience of First Consulting Group (FCG). The specific CDS features of CPOE are identified from previous contacts and conversations with a number of CPOE pioneers.

The California HealthCare Foundation and First Consulting Group sponsored a research study to provide information about **CPOE implementation in a community hospital setting.**[103] The research focuses on how community hospitals can implement a CPOE system and work with a universal CPOE and how CPOE can best be incorporated in hospital order management. They conclude that careful planning including good technology management is necessary, including good communication. Similarly, in their analysis of CPOE implementations Sittig and Stead (1994)[104] point out that **key ingredients must be present for a system to work.** These include: the system must be fast and easy to use, the user interface must behave consistently in all situations, the institutions must have broad and committed involvement and directions by clinicians prior to implementation, the top leadership of the organisation must be committed to the project and a group of problem solvers and users must meet regularly to work out procedural issues.

Because implementing CPOEs is a complex undertaking Kuperman et al. (2003)[105] warn that it should not be the first computerized clinical system to be implemented by an organization. Implementing CPOE is a large enough project that the organization should be wary of doing other major administrative or clinical information system projects concurrently. Furthermore, vendor offerings are evolving rapidly and purchasers must take care to understand the details of the software. More research is needed to create and evaluate models of CPOE implementation and to understand the specific challenges that exist for institutions of different sizes and different staffing models. Generally, **return on investment for a CPOE project may be difficult to calculate because baseline costs of key processes are hard to determine;** several benefits are not easily amenable to measurement (for example, improved interdepartmental communication and strategic positioning); and many organizations do not currently measure rates of medication errors and adverse drug events. CPOE should be viewed as supportive technology for such organizational initiatives as quality improvement, patient safety, and cost reduction. In addition, it is important that CPOE be considered **part of an organizational strategy** to achieve the previously mentioned objectives rather than as an information technology initiative.

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[102] Metzger Jane and Turisco Fran, First Consulting Group (2001) Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started

[103] see chapter VI: "Keys to success with CPOE" in: Metzger Jane and Turisco Fran by FCG (2003): Computerized PhysicianOrder Entry in Community Hospitals. Lessons from the Field. The Quality initiative.

[104] Sittig and Stead (1994): Computer based physician Order Entry: the state of the art; in: Journal of the American Medical Informatics Association. 108-123.

[105] Kuperman et al. (2003) Computer Physician Order Entry: Benefits, Costs, and Issues, American College of Physicians 139:31-39.

Indeed, some authors have drawn attention to the **potential danger** of CPOE use. Studies in the US, UK and Australia have found that "commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management systems may generate new types of error because of user-interface design, but also because of events in the workplace such as distraction affecting the actions of system users."[106] Han et. al (2005)[107] found an unexpected increase in child mortality after the introduction of a commercially sold computerised physician order entry system. Univariate analysis revealed that the mortality rate increased from 2.80% (39 of 1394) before CPOE implementation to 6.57% (36 of 548) after CPOE implementation. As yet this phenomenon remains unexplained. Hence, institutions should remain vigilant in monitoring mortality effects. Koppel et al (2005)[108] add that while some emphasis has been put on medication error reduction through CPOE, less focus has been put on the existence or types of medication errors facilitated by CPOE. They found that **CPOE in fact facilitates 22 types of medication error,** for instance though fragmented CPOE displays that prevent a coherent view of patients' medication history. Similarly, Handler et al.[109] (2004) find that CPOE and DSS can reduce certain types of errors but may also slow down clinicians and increase other types of error. To ensure success **seamless integration of CPOE and DSS into systems and workflow is necessary**.

CPOE should be viewed as supportive technology for such organizational initiatives as quality improvement, patient safety, and cost reduction. More research is needed to create and evaluate models of CPOE implementation and to understand the specific challenges that exist for institutions of different sizes and different staffing models. In this context, human factor analysis, discussed below, can provide valuable input.

4.1.4 Adverse Event Systems and Alert Systems

Whereas CPOE systems aim to prevent errors, **computerized Adverse Event** Systems aim to monitor the occurrence of instances which could be adverse events and alerting a clinicians when certain indicators are present. The most common adverse events are nosocomial infections and adverse drug events (ADE) and consequently IT systems have been tested primarily in these areas.[110] Most institutions use spontaneous incident reporting (relies exclusively on voluntary reports from nurses, pharmacists and physicians focused on direct patient care) to detect ADEs; however, this method is generally regarded as rather ineffective and only identifies about one in 20 ADEs.[111]

Conversely, most IT trials have found a **significant increase in the number of ADEs reported** (see below). **Automatic alerts** can also **improve the time until treatment is ordered for patients with critical laboratory results**.[112] Tools such as event monitoring and natural language processing can inexpensively detect certain types of adverse events. These approaches already work well for some types of adverse vents, including adverse drug events and nosocomial infections and are in routine use in some hospitals. In addition**, these tech-**

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[106] FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach.

[107] Han, Yong et al. (2005): Unexpected increased mortality after implementation of a commercially sold computerized Physician order entry system in: Paediatrics Vol116 No.6 (12/2005) 1506-1512.

[108] Koppel Ross et al. (2005): Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors; in: JAMA 293:10.

[109] Handler et al.(2004):Computerized Physician Order Entry and Online Decision Support, in: ACAD EMERG MED d November 2004, Vol. 11, No. 11 1135-1141

[110] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 p. 119

[111] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 p. 116

[112] Kuperman et al. (1999) Improving Response to Critical Laboratory Results with Automation: Results of a Randomized Controlled Trial. JAMIA 6 512-22.

niques seem to be well adaptable for the detection of broad arrays of adverse events, in particular as more information becomes computerised.[113]

In their review Gandhi and Bates[114] report one study demonstrating significant decreases in adverse clinical outcome with alert systems, in particular regarding allergic reactions. Significant improvements in response times concerning lab values were reported by several studies, with another study reporting significant decrease in the risk of serious renal impairment. Furthermore, significant changes in physician behaviour and modification of therapy were reported base on alerts with recommended actions:[115]

Developing and maintaining a computerized screening system generally involve **several steps.** The first and most challenging step is to collect patient data in electronic form. The second step is to apply queries, rules, or algorithms to the data to find cases with data that are consistent with an adverse event. The third step is to determine the predictive value of the queries, usually by manual review. The data source most often applied to patient safety work is the administrative coding of diagnoses and procedures, usually in the form of ICD-9-CM ("International Classification of Diseases") and CPT codes. This coding represents one of the few ubiquitous sources of clinically relevant data.

Pharmacy data and clinical laboratory data represent two other common sources of coded data. With increasing frequency, hospitals and practices are installing workflow-based systems such as inpatient order entry systems and ambulatory care systems. Yet this information is rarely available in coded form, even with the growing popularity of workflow-based systems.[116]

Computerized **ADE alert monitors** use rule sets to search signals that suggest the presence of adverse drug events. The most frequently studied rule sets (or "triggers") are those that search for drug names (e.g. naloxone, kayexalate), drug-lab interactions (e.g. heparin and elevated PTT) or lab levels alone (e.g. elevated digoxin levels) that frequently reflect an ADE. Simple versions can be implemented with pharmacy and laboratory data alone, although the yield and positive predictive value of signals is higher when the 2 databases are linked.[117]

Kuperman et al. (1999)[118] evaluate the **effect of an automatic alerting system on the time until treatment is ordered for patients with critical laboratory results.** Their results indicate that the alert system did indeed reduce the time until appropriate treatment was ordered for such patients and confirm the potential for such technologies to improve quality of care. In detail they found that the intervention group had a 38% shorter median time interval until an appropriate treatment was ordered (1.0 hours vs. 1.6 hours P =0.003). The study was carried out a Brigham and Women's Hospital (BWH), a 720-bed tertiary care hospital in Boston, Mass.

With **inpatients**, hospital information systems can be used to identify adverse drug events (ADEs) by looking for signals that an ADE may have occurred and then alerting someone - usually a clinical pharmacist - who can investigate. A problem with the broader application of these methods has been that computer monitors use both drug and laboratory data and in many hospitals the drug and laboratory databases are not integrated. Nonetheless, this ap-

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[113] Bates et. Al (2003) Detecting Adverse Events Using Information Technology. J Am Med Inform Assoc 10. 122.

[114] Gandhi Teal K., Bates David W.:Computer Adverse Drug Event (ADE) Detection and Alerts (2001) .Chapter 8 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.81 http://www.ahrq.gov/CLINIC/PTSAFETY/index.html#toc

[115] Gandhi Tejal K., Bates David W.:Computer Adverse Drug Event (ADE) Detection and Alerts (2001) .Chapter 8 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.83 http://www.ahrq.gov/CLINIC/PTSAFETY/index.html#toc

[116] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10. 115-128

[117] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 115-128

[118] Kuperman et. al (1999) improving response to critical laboratory results with automation: results of a randomised control trial. Journal of the Amercian Medical Informatics Ass. 6: 512-522

proach can be successful in institutions with less sophisticated information systems by downloading information from both systems to create a separate database. Fewer data is available regarding ADE rates in the **outpatient setting**.[119,120] It has been suggested that electronic medical records may facilitate information gathering on outpatients, using similar methods as in an inpatient setting. The study "Decision Support System Design and Implementation for Outpatient Prescribing: The Safety in Prescribing Study" examined the effectiveness of decision support (i.e. alerts and reminder) for reducing potential medication errors for outpatients[121], with the following results:

- Clinicians prefer decision support alerts that are clear, concise, and easy to navigate, with minimal information in the alert text.

- Patient safety-related alerts were seen as more helpful than more routine health maintenance alerts. Alerts that appeared in an inappropriate place in the workflow were subject to override, whereas alerts during medication prescribing were generally viewed as more helpful.

- Prescribers prefer alerts related to drug interactions, appropriate medication dosing, and patient allergies

- Small differences in alert text could significantly improve the clarity, and possibly acceptance of alerts.

In an evaluation including one year's data of electronic medical records for 23,064 patients, including 15,665 patients that came for care, 864 ADEs were identified. Altogether, 91% of the ADEs were identified using text searching, 6% with allergy records, 3% with the computerized event monitor, and only 0.3% with ICD-9 coding. The dominance of text searching was a surprise and emphasizes the importance of having clinical information in the electronic medical record, even if it is not coded.

In conclusion it can be asserted that the current approach used by most organizations to detect adverse events - spontaneous reporting - is clearly insufficient. Computerized techniques for identifying adverse drug events and nosocomial infections are sufficiently developed for broad use. They are much more accurate than spontaneous reporting and more timely and cost - effective than manual chart review. Research will probably allow development of techniques that use tools such as natural language processing to mine electronic medical records for other types of adverse events. A key benefit of electronic medical records will be that they can be used to detect the frequency of adverse events and to develop methods to reduce the number of such events.[122]

However, computerized decision alerts can only be effective if they are relevant. If clinicians are over-alerted to the potential hazards of each drug, it is possible that excessive information could lead to 'alert blindness'. This can result in the recipient not identifying the most relevant and important details or, worse still, switching off the alerts altogether and putting patient lives

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[119] Gandhi Tejal K., Bates David W.:Computer Adverse Drug Event (ADE) Detection and Alerts (2001) .Chapter 8 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.79-86. http://www.ahrq.gov/CLINIC/PTSAFETY/index.html#toc

[120] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 115-128

[121] see Feldstein Adrianne C. : Decision Support System Design and Implementation for Outpatient Prescribing: The Safety in Prescribing Study, in: Advances in Patient Safety: Vol. 3, p. 35-51

[122] Bates et. al (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 115-128

at risk.[123] Studies thus far suggest, though, that **physicians view computerized alert systems favourably**. Forty-four percent of physician-respondents receiving alerts indicated that the alerts were helpful and 65% wished to continue receiving them (although these alerts went to many physicians because it was unclear who the responsible doctor was). In another study in which alerts were sent only to the responsible physician, 95% of physician-respondents were pleased to receive them.[124]

4.1.5 Incident reporting systems

On a larger scale, several countries have already implemented or are considering national or regional **incident or event reporting system** (a concept that is also used in a variety of non-health related areas). By accumulating patient data from a variety of local sources such systems can be used for biosurveillance, and fast alert and pattern tracking in case of a bioterrorism attack or an epidemic outbreak. The benefits from a **connected system** of healthcare information for **improved public health and security** are expected to be considerable:

- *Automated tracking for patterns and locations of patient diagnoses and treatment* could support medical research and medical practice, activities such as *bio surveillance*, quick response to outbreaks of disease or to chemical or biological attacks, and improved monitoring of adverse drug effects. An electronic health information exchange would provide more *thorough monitoring of adverse drug effects*, and citizens could be automatically notified if their medication was no longer safe to take.

- *Tracking research and disease incidence:* Without a connected system of healthcare information, there is no way to accurately track trends of disease and injury. Tracking how a disease spreads helps health officials understand the size of the threat. By looking at how quickly diseases spread through a particular area, officials can accurately determine the number of vaccinations needed to control the disease.

- *Better tools for first responders:* A connected system would also support individual responders. Emergency workers would be able to get the most up-to-date information on vaccines and treatment for biological threats. They could more efficiently coordinate with hospitals and clinics, and all healthcare providers could more easily find up-to-the-minute information to provide care and to help contain a health crisis or epidemic.

Several countries have already implemented or are considering **national or regional event reporting systems** that could gather the information about the *type, rate, frequency of medical errors and adverse events*.

In Australia, for instance, an incident reporting system (AIMS) was already set up in 1987, initially only in the field of **anaesthesia.[125]** Until 1992, **2000 incidents had been collected and reviewed,** leading to **significant changes** at the local and national level. One example given describes the case of a patient who remained fully aware but paralysed during his hip operation. In order to find out what had gone wrong local doctors consulted the AIMS-Anaesthesia database and the information contained therein led not only to the solution of the problem but also to a new guideline concerning the use of online volatile agent monitoring during anaesthesia. During the analysis of the 2000 incidents collected in the database it was recognised that there was no clinically useful **comprehensive information for "things that go wrong in**

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[123] First DataBank Europe (FDBE) argues that clinical IT systems with effectively implemented clinical decision support can help to reduce ADRs and improve patient safety.

[124] Gandhi Tejal K., Bates David W.:Computer Adverse Drug Event (ADE) Detection and Alerts (2001) .Chapter 8 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.79-86. http://www.ahrq.gov/CLINIC/PTSAFETY/index.html#toc

[125] Runciman W.B. (2002) Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system – is this the right model? Quality and Safety in Health Care 11/2002: 250

health care". It was thus decided to develop such a classification - that is to create a framework into which all iatrogenic events could be classified. In 2000, AIMS was replaced by a new system, AIMS-2 which was **designed to be used across the entire spectrum of a national healthcare system by staff, patients and relatives as well as being useful to specialists, accessible on the web and suitable on the national and local level.** Through the experience with AIMS in the past 15 years the following lessons have been learned:

- The need to put patient safety and reporting and surveillance systems in context
- The need for common tools and terminology
- The need to set priorities and to act on the local, national and international level
- The need for large repositories to collate information from many sources
- The need for a just system
- The need for separate processes for accountability and for "systems learning"
- The need for feedback and the evidence of action
- The need to involve and inform healthcare professionals, consumers and the public at large

In the UK the **National Reporting and Learning System** (NRLS) has been set up in the framework of the National Patients Safety Agency. The NRLS collects reports of patient safety incidents and their root causes, in order to learn from them and to develop solutions to enhance safety. The NRLS receives reports about patient safety incidents from NHS organisations throughout England and Wales (see also the section on international activities, UK). The report of the National Reporting and Learning System and the Patient Safety Observatory on July 2005 provides the first public analysis of national patient safety data in England and Wales.[126] The report found 493 instances of mismatching from 45 reporting trusts with two-thirds of these reports coming from medical, surgical and diagnostic specialties in acute hospitals. One in eight incidents was related to the issue of identification of patients via wristbands and half of these were due to a missing wristband. With a recent achievement of 70,000 reports/month in 2006, the NLRS is the most active reporting system in the world to date.

In the US, **NYPORTS** is the ***mandatory recording system*** of the State of New York and the oldest in the world (19 years old). Currently, 21 states have some kind of "safety event systems" project underway. The US government is pushing ahead the idea of a nationwide mandatory event reporting system. Under the legislation recently approved by the House, officials would voluntarily report medical errors to patient safety organizations, which would use a network of databases to analyse the data and make recommendations. Most hospital executives believe that state-mandated medical error-reporting systems that make data available to the public would do little to improve patient safety and would lead to more lawsuits, according to a survey of 200 hospital executives published in the Journal of the American Medical Association.

The ***Canadian Institute for Health Information (CIHI)*** and Statistics Canada are developing methods to routinely report on disease-specific hospital-based mortality rates for deaths following treatment for myocardial infarction and other interventions. Readmission rates for selected conditions have been used in Ontario as a quality measure, and this methodology should be further developed and utilized (Ontario Hospital Association 2000).

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[126] Scobie Sarah (2005) National Patient Agency: Building a memory: preventing harm, reducing risks and improving patient safety. The first report of the National Reporting and Learning System and the Patient Safety Observatory

The implementation of such systems raises many issues concerning the interfaces with existing hospital information systems as well as confidentially and legal issues. ***Data mining of existing and future databases*** of events reported could play a role in patient safety. One of the issues is to collect "near misses" and analyse them, as for the airline industry. Event reporting systems is therefore a field of ICT R&D to be considered in our study.

4.1.6 Sentinel systems

Javitt et al. (2005)[127] demonstrate the potential effect of deploying a sentinel system that scans administrative claims information and clinical data to detect and mitigate errors in care and deviations in medical practice. Results show that in the intervention group there were 19% fewer hospital admissions than in the control group (P<.001). When recommendations were communicated charges were 77.91$ lower per months and paid claims were 68.08$ lower than among the control group (P=0.03 for both). Paid claims for the entire intervention group (with or without recommendations) were still 8.07$ lower than for the control group. The intervention cost 1.00$, suggesting an eightfold return of investment. The authors thus conclude that ongoing use of sentinel systems resulted in a reduction in hospitalization, medical costs and morbidity.[128]

Brossette et al. (2006) showed that widely accepted nosocomial infection surveillance methods, however, are limited in scope, not sensitive, and applied inconsistently. In 907 inpatient admissions to Evanston Northwestern Healthcare hospitals (Evanston, IL), nosocomial infection identification by the Nosocomial Infection Marker (MedMined, Birmingham, AL), an electronic, laboratory-based marker, was compared with hospital-wide nosocomial infection detection by medical records review and established nosocomial infection detection methods. The sensitivity and specificity of marker analysis were 0.86 (95% confidence interval [CI 95], 0.76-0.96) and 0.984 (CI 95, 0.976, 0.992). Marker analysis also identified 11 intensive care unit-associated nosocomial infections (sensitivity, 1.0; specificity, 0.986). Nosocomial Infection Marker analysis had a comparable sensitivity (P>.3) to and lower specificity (P<.001) than medical records review.[129]

4.2 Towards user friendly and integrated systems

So far, this paper has, after some initial definitions, provided an overview about the major components underpinning the impact of Information and Communication technologies on Patient Safety and Risk Management. A variety of different possible applications such as Decision Support Systems, Computer Physician Order Entry, Sentinel systems, Alert Systems and Incident Reporting systems have been reviewed. **Multiple studies support the conclusion that these systems can induce considerable benefit in the Patient safety area.** In the case of sentinel systems, alert systems and incident reporting systems, for instance, it is clear that the approach currently used by most organisations – which does not rely on ICT – is insufficient and that ICT tools for identifying adverse drug events and nosocomial infections are sufficiently developed for broad usage. They are much more accurate than spontaneous reporting and more timely and cost-effective than manual chart review.[130]

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[127] Javitt J. (2005): Using a Claims Data–Based Sentinel System to Improve Compliance With Clinical Guidelines: Results of a Randomized Prospective Study. The American Journal of Managed Care 11:2 93-102

[128] Javitt J. (2005): Using a Claims Data–Based Sentinel System to Improve Compliance With Clinical Guidelines: Results of a Randomized Prospective Study. The American Journal of Managed Care 11:2 99

[129] A laboratory-based, hospital-wide, electronic marker for nosocomial infection: the future of infection control surveillance? - Am J Clin Pathol. 2006 Jan;125(1):34-9.

[130] Bates et al. (2003) Detecting Adverse Events Using Information Technology. JAMIA 10 115-128

However, **the research also emphasised that several factors need to be carefully considered when implementing ICT tools in order to truly accomplish increased patient safety.** For example, in the particular case of the Decision Support Systems, some cautionary elements emphasized in Garg et al's systematic review[131] include:

- Failure of clinicians to use the DSS e.g. because they did not understand what it was for, the prevailing clinical culture was against it, their patients or peer group objected to it, it was too slow, or was not linked to the electronic patient record (EPR).

- The DSS did not produce an effective output in time to influence their decision: e.g. the output was not available in time; clinicians could not understand the output.

- The output was not convincing enough to persuade the users to change their practice: e.g. the output showed poor accuracy, was badly worded, users had never before heard of this drug and required more details.

- The output was available and was convincing enough to influence user decisions, but the user was unable to change their practice: e.g. the drug was too expensive to prescribe, there was adverse peer or patient pressure, the user was missing some vital information, equipment or skill that they needed before being able to enact their decision.

- The performance of the clinicians was already optimal, given the circumstances and patient case mix.

Each of these potential reasons for failure needs to be considered carefully by DSS developers before they start work. This means that DSS developers need to start with the steps necessary to bring about the intended user actions or behaviour, not with the improvement of the quality of user decisions or the accuracy of the DSS itself. Liu et al. (2006) thus advocate that the development of decision support systems need to **shift from being technology led to problem led,** and that a new mindset is needed to encourage this.[132]

Indeed, a major lesson to be learned from the previous experiences with the implementation of ICT tools for increased patient safety is how important it is to design systems **with the end-user in mind.** In fact, it has been shown that **if applications like DSS, CPOE or alert systems are not properly designed they will be in the best case ineffective and in the worst case actually increase the error rate**. Furthermore, if systems are not fast and display all relevant information in a coherent and easy to use manner they will be rejected by the clinician. Furthermore, the organisational culture, including barriers to reporting errors, will play a key role in the acceptance of electronic tools such as incident reporting systems. This is discussed in more detail in chapter 6 below.

Additionally, optimal benefits from ICT tools will only be reaped if these tools do not merely operate next to each other but with each other, i.e. if they are implemented in an **integrated fashion.** Some systems, such as DSS and CPOE are already often used in combination. In the future such **fully integrated system will make use of automation in all stages,** as depicted in the figure below:[133]

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[131] Garg et al. (2005) Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA. 2005;293:1223–1238.

[132] Liu J, Wyatt JC, Altman DG (2006) Decision tools in health care: focus on the problem, not the solution. BMC Med Inform Decis Mak. 2006 Jan 20;6:4

[133] Bates David W.: Using information technology to reduce rates of medication errors in hospitals, in BMJ VOLUME 320 18 MARCH 2000 www.bmj.com, p. 788-791

FIGURE 15: EHEALTH AUTOMATION CHAIN

Prescribing
Physician order entry
Computerised design support

Transcription
Electronic order transcription

Dispensing
Robots
Bar coding
Automated dispensing devices

Administration ⟶ **Medication administration**
Bar coding   **record**
Automated dispensing devices   Computerised medication
                                                   administration record
                                                   Automated dispensing devices

Monitoring
Computerised monitoring of adverse drug events

Source: adapted from Bates (2000)

One example of such an already existing integrated system is the **Acute Cardiac Ischemia Time-Insensitive Predictive Instrument Information System** (ACI-TIPI-IS) Demonstration Project at Tufts–New England Medical Center[134], which used multiple IT applications for patient safety, combining real-time decision support, alerting, and retrospective feedback for performance improvement, all for the care of patients presenting to the emergency department (ED) with symptoms suggestive of ACS (acute coronary syndrome). This ACI-TIPI- and TIPI-IS-based project aimed at reducing errors in emergency cardiac care **illustrates the use of usual clinical IT (conventional computerized electrocardiographs with ACI-TIPI software) and existent hospital IT, along with conventional PC-based and interface IT.** The project successfully demonstrated that a patient safety system using a completely electronic data collection and feedback reporting system and offering real-time decision support, concurrent patient safety alerts, and retrospective physician level feedback reports could be implemented in a variety of hospital settings.

In conclusion, the literature review and analysis of some current experiences of eHealth applications in the area of Patient safety shows a potential benefit if the implementation conditions are carefully evaluated and planned. **The implementation must take into account not only the technical feasibility but also cultural, organisational, legal, ethical and quality assurance issues.** Future research is needed not only on the technological side but also on the human behaviour side as well as on the methodological aspects. Moreover, **the integration of the existing technologies appears as a promising field of research** in the area of Patient safety.

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[134] Daudelin Denise Hartnett et al. : Using Specialized Information Technology to Reduce Errors in Emergency Cardiac Care, in: Advances in Patient Safety: Vol. 3

4.3   Research issues – results from literature review

New and developing technologies have a significant patient safety component, either because they pose risk or because they may offer benefits in their application to patient safety – or both. In the following we discuss and explore some generic concepts and research challenges worth to pursue regarding new methods and emerging technologies. Their applications to increase patient safety across the whole health value system providing benefits for healthcare, education/training, clinical research, both in the foreseeable future and the longer-term are analysed.

4.3.1   Towards a culture of safety in eHealth RTD

Whereas eHealth tools and services are intended to have a beneficial impact on citizens' health, recent research has shown that **some of these tools and services may under certain circumstances also be potentially harmful to citizens' health.** New technologies inherently pose new risks. Health risk and patient safety aspects should therefore be taken into account by all health ICT RTD from EHR integration, home monitoring and assistive living to bio-medical informatics, nano-devices and grid computing. Identification and prevention of new risks requires both action to alert researchers in all relevant fields to known sources of risk and action to monitor for new risks. Appropriate support actions are proposed to prepare information on patient safety for use in a full range of ICT research fields and to monitor risks presented by the application of emerging ICT technologies to healthcare.

4.3.2   Data mining for improved patient safety

Data mining techniques can be **applied to emerging electronic health record and clinical research databases to push forward knowledge of risks associated with unique patient characteristics and treatment patterns**. Such tools need to be developed to discover, e.g., instances where patient safety has been endangered and identify the causes. Data mining techniques can also be applied to information not yet coded in a standard electronic format. In particular, using advanced language processing, information from unstructured notes taken by healthcare professionals should be made accessible to such mining tools.

4.3.3   Ontology of patient safety

It is proposed that a taxonomy and ontology covering healthcare risks and safety considerations be developed. This will facilitate the exchange of information on patient safety, and serve as a common framework for modelling threats to safety. It will also support communication between clinicians and others on patient safety issues. Research should cover techniques for coding knowledge to facilitate rapid integration of emerging understanding into decision support systems and predictive models. The taxonomy and ontology should be introduced into European / global standardisation procedures capable of achieving consensus and adoption by both systems developers and clinicians.

4.3.4   Mathematical modelling and simulation

Modelling and simulation tools are anticipated to have a significant impact on patient safety especially through advancing prediction, prevention and personalisation of healthcare. The European Information Society Technologies Advisory Group (ISTAG) proposed in 2004/2005

to stimulate research in the area of "*The Disease and Treatment Simulator*":[135] - a computational platform for simulating the function of a concrete disease. "This simulator will enable medicines to be tested without putting people at risk, and will accelerate research into damaging diseases such as heart disease and cancer." The Advisory Group also suggested that the disease and treatment model should interface directly with other projects of human benefit, such as the *Physiome* project[136] and the modelling of whole organs. In this context the European Commission (EC) is supporting research on the *Virtual Physiological Human*[137] (VPH) which is expected to accelerate knowledge discovery leading to improved disease prevention, early diagnosis and individuals' health risk management. To reduce risks to citizens participating in clinical research, to enable a radical expansion of the volume of research into clinical outcomes to the full range of treatments and to significantly accelerate production of results from clinical research it appears important to support research into tools to implement *virtual clinical trials*. According to the Academy of Medical Sciences[138] in the UK, "sophisticated modelling has great potential. It is possible to envisage a time when models could be used to test a greater range of possible situations than it is practical to address in affordable clinical trials." This also "permits the evaluation of heterogeneity and the active exploration of those who may be at risk." Simulation has already enabled pharmaceutical companies to eliminate four-fifths of a clinical trial, to reduce the total number of recruited patients by 60% and to shorten the trial's duration by 40%.[139] "Virtual patient" engines are helping researchers and physicians select the best among existing therapies, e.g., for breast cancer[140], and to develop optimal dosing regimes. So-called "computer-assisted trial design" systems - a field in which models have become so useful that the FDA itself is adopting them[141] - model and simulate clinical trials to determine the optimal number of patients, dose amounts, and dosing frequency. These results have for years mostly been obtained through time-consuming and costly trial and error.

4.3.5 Medical simulation and virtual reality

This is already being used as a training and feedback method in which learners practice tasks and processes in lifelike circumstances using models or virtual reality (VR), with feedback from observers, peers, actor-patients, and video cameras to assist improvement in skills. Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without harming patients. VR simulations are revolutionising surgical training[142] (e.g., for laparoscopic, gastrointestinal, plastic, ophthalmological, dermatological, and some laryngological procedures), and error reporting[143] in the healthcare field.

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[135] Information Society Technologies Advisory Group (ISTAG), Working Group "Grand Challenges in the Evolution of the Information Society", W. Wahlster (ed.), July 2004, p. 26-29

[136] IUPS Physiome Project Roadmap, 2005, www.physiome.org.nz/roadmap/roadmap-mar05

[137] Towards Virtual Physiological Human: Multilevel modelling and simulation of the human anatomy and physiology, White Paper 2005, http://europa.eu.int/information_society/activities/health/docs/events/barcelona2005/ec-draft-vph-white-paper-v2.8.pdf, p. 3

[138] Academy of Medical Sciences (2005) Safer Medicines. A report from the Academy's FORUM with industry, November 2005 http://www.acmedsci.ac.uk/p99puid61.html, p. 22

[139] Optimata, Entelos Win Simulation Patents, John Russell, Bio-IT World, January 26, 2006, http://www.bio-itworld.com/newsitems/2006/january/01-26-06-news-biosimulation

[140] Zvia Agur (2006) "Biomathematics in the development of personalized medicine in oncology" Future Oncology, Feb 2006, Vol. 2, No. 1, pp 39-42.

[141] Models that take drugs. Biosimulation: Designing drugs in computers is still some way off. But software is starting to change the way drugs are tested, The Economist, June 9th 2005

[142] Gorman PJ, Meier AH, Krummel TM (2000) Computer-assisted training and learning in surgery. Comput Aided Surg 2000;5:120–30.

[143] Fried M P et al. (2004): Identifying and reducing errors with surgical simulation, Qual Saf Health Care 2004;13(Suppl 1):i19–i26. doi: 10.1136/qshc.2004.009969, http://qhc.bmjjournals.com/cgi/content/full/13/suppl_1/i19

4.3.6 Healthcare system risk models

Healthcare provision is an ever more specialised, flexible and, at the same time, integrated service, delivered by a wide variety of collaborating actors. As interoperability between previously isolated ICT systems increases and as patients and staff become more mobile, healthcare systems are becoming so complex that the ultimate safety and risk implications of changes anywhere in the system are very difficult - if not impossible - to foresee. There is a need to build adequate systems models to cope with this new reality. Development and iterative improvement of health system risk analysis tools and models to enable identification of major clusters of risk at all levels of organisation from the doctor's practice or the individual hospital to an interoperating European health system should be a focus. Modelling techniques could include neural networks and usefully integrate approaches such as Failure Mode Effects Analysis (FMEA) - identifying the ways a given procedure can fail to provide desired performance such as due to late or incomplete information - or Hazard Analysis and Critical Control Points (HACCP). Specific, adaptive Systems Control Tools for continuous monitoring like Statistical Process Control (SPC) to ensure that care processes are operating within their prescribed limits need to be developed, thereby reducing errors and improving the use of resources. Furthermore, testing of approaches successfully applied in such disparate sectors as aviation or food production for substantially improving the safe delivery of healthcare is a new field in need of further study. This may include areas like Human Factor Research (HFR) focusing on integrating the human element into systems analysis, modelling and design.[144]

4.3.7 Pathways and health pathway risk models

Pathways are generally multidisciplinary by design and may incorporate the responsibilities of physicians and nurses with those of ancillary medical providers including pharmacists, physical therapists and social workers. They are regularly intercalated into the point-of-care and may incorporate or even replace traditional chart documentation. Pathways are often evidence-based and may even be integrated with locally or nationally developed clinical practice guidelines. Most pathways, however, are locally developed and are most frequently implemented at the level of the hospital or medical centre as part of a cost-containment or quality assurance initiative.[145]

In the future it may be possible to build health pathway models which encompass citizen / patient passage through clinical pathways, with predictive ability, focussing on the prior identification of potential risks to a citizen's future health. Early models would include mainly data from clinical phases, driven by health records, and output to clinicians only; later models are to provide appropriate output to both clinician and patient, enable patient input on life-style parameters, diet, physical activity and other events of potential clinical relevance. The health pathway model would draw on work to model human physiology, in order to enable predictive analysis of health-relevant characteristics in a health pathway. Thus a future in-silico physiological model could become a component of such a health pathway model.

4.3.8 Examples for applications

Below follow a few examples for illustration purposes only.

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[144] see also the discussion of these tools in the previous chapter

[145] See Trowbridge Robert and Weingarten Scott (2001) Critical Pathways. In: University of California at San Francisco (UCSF)-Stanford University Evidence-based Practice Center. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment Number 43. http://www.ahrq.gov/CLINIC/PTSAFETY/chap52.htm

a)   Bar Code and RFID

Bar Codes can help to eliminate the potential for administration errors. Advantages include real time updates allowing providers to alter medications and adjust delivery schedules with ease, simultaneous access to the system at multiple sites and the elimination of phone calls and paperwork. However, significant barriers remain, such as[146]:

- Only 8% of hospitals use bar coding and scanning technology
- No universal bar code symbology
- Expense of implementing
- Lack of industry prepared bar coded packages
- Cost of in house repackaging
- Bar coding of IV admixtures
- Non-bar coded doses such as ointments, partial dose meds, inhalers.

RFID (radio frequency identification) is generally regarded as the successor to bar code technology, doing away with the need to scan in every individual item by using radio signals from electronic chips attached to specific items. There is a wide variety of uses for RFID (radio frequency identification) applications in healthcare and its use in some areas is growing significantly.[147] Areas of applications include security (e.g. access control , anti-theft device), medication administration, authentication and stocking (tracking of drug origin and expiration data), hospital equipment, medical waste and supply tracking as well as patient tracking, blood banking (tagging blood transfusions) and medical alerts implants. For outpatient self-medication, e.g. for seniors, RFID is also an option. Some of these uses are currently handled through bar coding as RFID is currently at an early stage. However, feasibility studies, clinical pilots and advances in other vertical industries, such as retail, have jointly driven RFID to the forefront of healthcare. However, the cost of RFID tags must come down and the technology further customized for the healthcare vertical (e.g. to allow scanning through liquids) in order to become a widely-deployed technology.

b)   Neural networks

One of the original aims of artificial neural networks (ANN) was to understand and shape the functional characteristics and computational properties of the brain when it performs cognitive processes such as sensorial perception, concept categorization, concept association and learning.[148] A generic artificial neural network can be defined as a computational system consisting of a set of highly interconnected processing elements, called neurons, which process information as a response to external stimuli. Unlike traditional computing, ANNs have a structure and operation that resembles that of the mammal brain. In healthcare, neural networks are to some extent already used. Papnet, for instance, is a commercial neural network-based computer program for assisted screening of Pap (cervical) smears. A Pap smear test examines cells taken from the uterine cervix for signs of precancerous and cancerous changes. If properly taken and analysed, Pap smear can detect very early precancerous changes. These precancerous cells can then be eliminated, usually in a relatively simple office or outpatient procedure.

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[146] Ebertowski Sue (2001): Implementation of an Electronic Medication Administration Record using Bar Code Technology. A collaborative project between Pharmacy, Nursing, Respiratory Care and Information Systems (ppt presentation)

[147] See Eastwood G. et al (2005): ICT Opportunities in Healthcare, in: Business Insights, London, April 2005 and Fraunhofer Institut Software- und Systemtechnik: Business Opportunities für den Einsatz in RFID im Gesundheitswesen

[148] Sordo M. (2002): Introduction to Neural Networks in Healthcare. Open Clinical.

c)   eICU (e-Intensive Care Unit) and WIMS (Wireless Integrated MicroSystems)

eICU[149] is a project to redesign the intensive care unit (ICU), a complex clinical environment with high mortality and high daily costs as well as a high incidence of medical errors and particularly vulnerable patients. Several trends make ICU reform necessary: firstly, the number of ICU patients is increasing but at the same time the number of ICU nurses is decreasing and those still working in ICU have less experience. Furthermore, the number of doctors is also inadequate.

Thus, the eICU solution has been designed in order to improve patient safety and operating efficiency. It consists of two main features. First, technology is used to bridge the manpower gap by creating networks of ICUs and linking them to command centres (eICU facilities). Secondly, technology is used on site and remotely to help specialists; ICTs are used to identify problems and guide decision making. The goal is to make every (hospital) room an intensive care unit in the coming decades.

This can be achieved through the integration of micro-electromechanical systems (MEMS) with microelectronics and wireless interfaces in order to create **Wireless Integrated Micro-Systems (WIMS)**. These new devices could potentially provide continuous monitoring of critical functions. WIMS devices small enough to be worn comfortably and unobtrusively could communicate with a bedside receiver that communicates, in turn, with monitoring stations and a larger health care facility. WIMS for health care are expected to be technically feasible in the coming decade, but to reduce costs; they must be part of a complete *system*.

While the application of WIMS technologies in the hospital promises to significantly improve the quality and patient-centeredness of inpatient and ambulatory care the potential impact of WIMS on home care is even greater[150]. With properly integrated home-based WIMS systems, patients could be monitored on a continuous basis and care professionals alerted automatically when events merit attention.

WIMS systems are still scarce, and their performance is limited, but they are emerging. Blood oximeters, heart rate monitors, and temperature sensors could all be components of WIMS; orally administered capsules for viewing the digestive tract are already in use[151]. Wearable devices that monitor blood pressure (hypertension), breathing patterns (sleep apnea), and other variables will certainly be available in the near future. These kinds of capsules for internal viewing and measurements could significantly improve diagnoses of a variety of conditions and thus could improve the quality of health care.

Problems that still need to be solved include privacy issues as well as technical issues related to the development of reliable interfaces, educational issues and general resistance to change.

4.3.9   Socio-economic and behavioural aspects

Furthermore, a promising field of research concerns the change in the behaviour of health professionals, citizens and patients as eHealth applications lead to the re-engineering of healthcare processes and improve system safety and performance. This should also involve

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[149] Breslow, Michael J. (2005): The eICU Solution: A Technology-Enabled Care Paradigm for ICU Performance. In:

Proctor P. Reid, W. Dale Compton, Jerome H. Grossman, and Gary Fanjiang, Editors, (2005): Building a Better Delivery System: A New Engineering/Health Care Partnership Committee on Engineering and the Health Care System, National Academies Press. p.209-213

[150] Whitten et al. (2003) Telehospice : end of life care over the lines. Nursing Management 34 (11): 36-39

[151] Fireman, Z. (2004) The light from the beginning to the end of the tunnel. Gastroenerology 126 (3): 914-919 as well as Pelletier, F. (2004) Wireless tech allies with low power gear. EE Times, August 16, 2004 and Pennazio et al., (2004) Outcomes of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. Gastroenerology 126 (3): 643-653.

analysing the impact of medico-cultural, legal/regulatory and socio-economic factors. Assessing the risk and developing guidelines and certification procedures for Decision Support and Expert Systems and other tools need also to be mentioned here. In this context, systems engineering and design tools, including human factor research (as outlined above) can be highly useful.

4.3.10 Monitoring and risk management of large-scale events

Further to additionally existing incident reporting and alert systems (see the discussion in this deliverable) an important challenge concerns research into strategies and ICT support for preparedness for large-scale events like pandemics or bio-terrorism attacks (e.g. epidemiological modelling of regional events). It may allow a better response to threats through better information but also could play a key role in resource planning and management. ICT should also be exploited as a means to inform and reach professionals and the public on a large scale and help adapt responses. The use of Geographical Information Systems in healthcare appeared recently as a promising field and research should be conducted involving epidemiologists, managers of health resources and policy makers.

4.4 Methodological framework and key issues for a research roadmap

It should be stressed once again that within this study we take *a broader look* at the general contribution ICT tools can make to higher quality of care, increased patient safety and better risk management (and not just reduction of errors and adverse events). Thereby we apply a broad definition of risk management to optimise patient safety in a holistic fashion **across the whole health value system,** first of all through (better) *information and prevention*, and if this is not sufficient and *diagnosis and treatment* become necessary, *optimise* (often minimize) the number, processes and severity of interventions including surgical procedures, drugs etc., and the same applies to biomedical and clinical *research, training and education, and* the whole *public health* domain.

The study has reviewed the state of play in some key ICT areas for patient safety and risk management and has analysed the international activities in the field. Furthermore, it has taken a look at safety and risk management concerns in other domains in order to identify lessons to be learned. Conceptually, these issues are integrated in the model for patient and health system risk depicted below. This allows us not only to relate different types of risk and ICT applications relevant to patient safety to the corresponding meta categories but it may also direct the research towards other innovative fields which may prove to be of considerable importance.
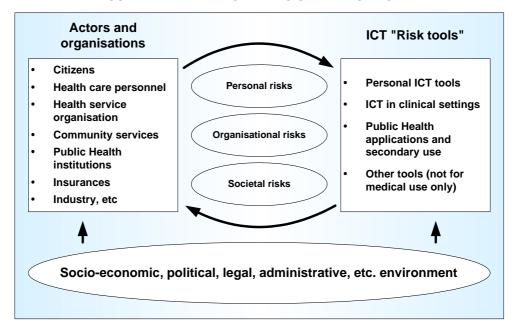
FIGURE 27: INITIAL MODELLING OF THE RISK DOMAIN

Source: © empirica, eHealth for Safety study, 2006

Of course, the issues vary according to the different applications outlined. It is for this reason that Chang et al (2005)[152] have developed a ***patient safety event taxonomy.*** Although they

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[152] Andrew Chang et al. (2005) The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. International Journal for Quality in Health Care (2005) Advance Access February 21, 2005. 10.1093/intqhc/mzi021. p.1-11.

focus on near misses and adverse events only, their classification is useful both for the evidence reviewed in this deliverable and for further research. Chang et al. categorized elements of existing models into five complementary primary classifications, which were divided into 21 sub classifications, which, in turn, depicted more than 200 coded categories. The following graph presents the primary classification, including some secondary items which were deemed to be of particular relevance:

FIGURE 28: PATIENT SAFETY EVENT TAXONOMY (AFTER CHANG ET. AL.)

Source: empirica, following Chang et al. (2005)

In its sub classifications (not depicted here) the **impact** node contains a classification of the degree of harm for the medical category, ranging from no harm to profound mental harm or death. Within the **type** classification, different communication problems and substandard patient management as well as clinical failures are addressed. Within the **domain** issue Chang et al. (2005)[153] group clinical settings such as the various departments in a hospital but also include the GP office, ambulatory clinics and nursing homes. They also include the different staff categories involved as well as patient characteristics, ranging from age, gender and education to duration of disease, socio-economic status and diagnosis. The systems subcategory within the primary category **cause**, deals with organisational aspects such as management, organisational culture, protocols and transfer of knowledge and technical aspects such as the quality of facilities. The human factor concerns primarily a discussion of different errors. **Prevention and mitigation,** finally, addresses, "universal" preventive and corrective measures that are designed for everyone in the eligible population, "selective" measures that are directed to a risk subgroup and "indicated" measures for specific high risk individuals. For the broad approach to patient safety applied in this study, this taxonomy provides valuable input, although it needs to be taken into account that it has been developed with adverse events and near misses in mind.

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[153] Andrew Chang et al. (2005): The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. International Journal for Quality in Health Care (2005) Advance Access February 21, 2005. 10.1093/intqhc/mzi021. p.3

It is noteworthy to mention that JCAHO is a partner of WHO in the "Patient Safety Alliance" and has contributed to establish the WHO taxonomy. The International Patient Safety Event Classification (IPSEC)[154] aims to define, harmonize and group patient safety concepts into an internationally agreed upon classification in a way that is conducive to learning and improving patient safety across systems. It is intended to be adaptable yet consistent across the entire spectrum of health care and across cultures and languages.

For a broader perspective it is therefore useful to recall the outcome of the extensive review of ICT applications undertaken in the first part of this report. The literature review and analysis indicated a potential benefit of ICT applications for patient safety if the implementation conditions are carefully evaluated and planned. It was demonstrated that not only the technical feasibility but also cultural, organisational, legal, ethical and quality assurance issues need to be taken into account. Consequently, future research is needed not only on the technical aspects but also on human behaviour. Moreover, the integration of the various existing ICT applications into a coherent system was singled out as an important aspect.

Drawing on these results the eHealth for Safety Study developed a multi-level approach to patient safety, which takes into account not only technical and RTD issues but also the organisational and the policy level. The following table gives an overview of the components of this multilevel approach.

FIGURE 29: COMPONENTS OF A MULTI-LEVEL APPROACH TO PATIENT SAFETY

Level	Component
Policy level (regional, national, European level)	• Patient safety policies • Implementation measures • Socio-economic and health policy framework conditions • Legal and ethical issues • Funding, clinical and economic evaluation
Organisational level	• Organisational structure and culture • Work processes • Change management • Training and learning
Technical & RTD level / applications	• Personal ICT tools, e.g., biomedical sensors • ICT in clinical settings, incl. EHR, DSS, CPOE • Public health applications & secondary use, e.g., event reporting, alert systems • Semantic aspects / ontologies • Emerging technologies

Source: © empirica, eHealth for Safety study, 2006

This framework and the issues outlined in this report constituted phase I of the eHealth for Safety study and provided input for the empirical work conducted in phase II, involving evidence based information gathering work. In the course of the study these issues have been further refined and provided important input to this report.

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[154] http://www.who.int/patientsafety/taxonomy/report_drafting_group_gva_dec06.pdf

5 Current and future research topics – results of empirical data gathering

Phase I of the eHealth for Safety study, baseline research, provided a first structure of the patient safety and risk management domain and identified current and emerging research topics based on a focused review of the literature and other sources. These were the input to phase II, the empirical work, which consists of several workshops and expert interviews validating and improving the desk research findings.

Importance was attached to the structure of the workshops and interviews in order to be wide and generic enough as to permit open discussions and the identification of new ideas and topics not yet covered by results available from desk research. The topics addressed have been chosen using a preliminary list developed within this study as illustrated in the following Figure focusing predominantly on innovative approaches and emerging technologies:
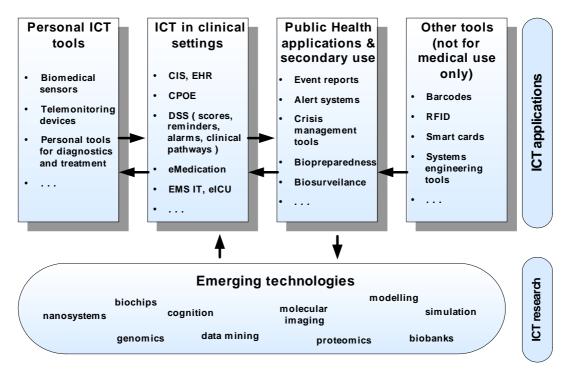
FIGURE 29: ICT IN SUPPORT OF PATIENT SAFETY AND RISK MANAGEMENT

Source: © empirica, eHealth for Safety study, 2006

This study did not intend to undertake a large scale survey, but concentrated on identifying and approaching key individual researchers and experts, (national) organisations involved in healthcare policies and implementation in general and/or institutions specialising in patient safety, as well as government units/offices and others. Key tools for the work and core of the second phase of the project were three workshops, which took place in Malaga, Brussels, and Geneva during 2006. They were explicitly designed to promote a two-way dialogue, increase the public awareness, and enable different experts to exchange views and ideas, learn from each other, and relate the topics and issues discussed to their own daily work and needs.

This chapter is structured along the three workshop locations and times, yet the content of the sections also includes observations and insights gained from the more informal discussion on the side of the formal events, as well as relevant interviews independent of time and location.

5.1 Workshop I, Malaga, May 2006: Benefits of ICT for patient safety

5.1.1 Organisation and speakers

The first workshop was organised by the consortium as a strategic seminar alongside the eHealth High Level Conference in Malaga, Spain. The event took place on Wednesday, 10th May 2006. It was chaired by the EU Commission services and proved the particular interest that is shown in the subject of patient safety. The intention was to gather a number of well known experts in the area.

The workshop was divided in two parts, the first one focusing on real life experience and evidence in the domain covered by eHealth for Safety, and the second one devoted to identifying emerging and required future research topics.

The chair of the first part of the session – Mr Octavian Purcarea – from the European Commission (DG Information Society and Media (INFSO), Unit ICT for Health) briefly introduced the topic of patient safety, its importance, and the particular interest of the Commission in listening to different user views. He also outlined the importance of the workshop in terms of orientation of the future research programme (7th EU Framework Programme of Research and Development). This part of the workshop consisted of four (from altogether nine) presentations, which all dealt with experience and evidence in the eHealth for Safety area and a discussion about some specific aspects addressed by the speakers.

The second part, dealing with "the research agenda", was opened by Ilias Iakovidis, Deputy Head of Unit "ICT for Health", DG INFSO, European Commission, who gave an overview of "20 years of ICT research for better health". Then there were five more presentations, followed by a global discussion on priority research needs and opportunities.

Speakers of the first part were:

1. John F. Ryan, Head of Unit Health Information, DG Health and Consumer Protection, European Commission

2. Jean-Pierre Thierry, *eHealth for Safety* study, Symbion, France

3. Kendall Ho, University of British Columbia, Canada

4. Alberto Sanna, Scientific Institute Hospital San Raffaele, Italy

Speakers of the second part were:

5. Scott Young, Agency for Health Research and Quality, USA

6. Michael J. Ackerman, National Library of Medicine (NLM), USA and James Goldberg, University of Nice, France

7. Veli Stroetmann, *eHealth for Safety* study, empirica Communication and Technology Research, Germany

8. Octavian Purcarea, Unit "ICT for Health", DG Information Society and Media, European Commission

9. Greg T. Mogel, MD, Deputy Director, TATRC

5.1.2 Content of the workshop

The issue of patient safety is playing an increasingly important role in all discussions on healthcare across the EU. All participants agreed that there are great expectations on what can be achieved in healthcare from both patients and health professionals. People across Europe expect the care they receive to be of high quality. There was a wide consensus among the speakers that action on patient safety is imperative at all levels, if people are to have a right to the same high level of care in all countries as they move freely across borders. A culture of safety needs to be built, based on human factors and technology factors. The ultimate safety and risk implications of changes anywhere in the system are already very difficult to foresee.

Presentations and discussions concentrated on the following topics and issues:

a)   Lack of methodological uniformity and interoperability

It became apparent that there is a lack of methodological uniformity in identification and measurement of adverse events, and that a comprehensive approach is essential to prevent, or at least manage the risk of such. There is still not enough awareness of the problem of adverse events and the best way to minimise their occurrence. It was pointed out that studies from around the world consistently suggest that about 10% of hospital admissions involve some kind of harm to patients and that 50% of these patient safety incidents could have been avoided, if only lessons from previous incidents had been learned.

Very little is known about the direct and indirect costs associated with healthcare delivery inefficiencies and failures. In the US, total national costs of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion, of which preventable healthcare costs represent over one-half. In the UK, patient safety incidents cost the NHS an estimated £2 billion a year in extra bed days. Hospital acquired infections add a further £1 billion to these costs.

Addressing this problem requires implementation of measures spread along a continuum figured in the following figure:

FIGURE 2: POINTS OF IMPACT OF PATIENT SAFETY MEASURES

Source: Jean Pierre Thierry 2006[155]

eHealth is one of many tools. One should observe the paramount role of non-ICT measures in order to ensure patient safety:

- Leadership and strategic priorities issues
- Safety culture

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[155] Thierry JP (2006) eHealth for Safety: Global Evidence and Challenges, presentation at the ehealth High Level Conference Malaga, figure based on IOM (2001) Crossing the Quality Chasm.

- Teamwork and communication among healthcare professionals
- Safety procedures
- Medical education
- Education and training.

The role of ICT for health is seen in various domains such as information, knowledge sharing and discovery, normal practice, all ancillary activities, organisation, management, event reporting, and epidemiology. The different relevant components of eHealth can be: the Electronic Health Record, the Personal Health Record, the Computer Physician Order Entry, the Computerised Decision Support Systems, the mobility tools, the simulation tools, the education programmes, applications for telemedicine and telehealth.

Interoperability among these tools, including semantic interoperability and methodological uniformity in identification and measurement, and adequate adverse event reporting schemes were identified as important in addressing the adverse event problem. Medical software should not be a risky solution and development, deployment and follow-up should benefit from a certification/accreditation process. From an economic perspective, the potential value of the interoperable exchange of health related data between healthcare institutions is expected to be substantial. To give an idea of the dimension in numbers, one speaker noted recent studies in the USA, which estimated that the national implementation of fully standardised interoperability between healthcare providers and five other types of organisations (such as specialists, laboratories, and insurance funds) may yield up to around $US 75 billion annually of savings, or about 5 percent of the projected $US 1.7 trillion spent on United States' healthcare in 2003.

b)   Collaboration and communication at the point of care

During the workshop it became clear that rather than continue with a "blame culture", all key players - health professionals, hospital managers, patients, their families, national authorities and policy makers - should consult and collaborate. Everyone has his or her own part in facing the challenge and in learning from near misses and adverse events.

The importance of communication between members of a medical team must not be underrated. But the priorities of patient care seem to differ between members of the healthcare team and it was highlighted that verbal communication between team members is not consistent yet. According to a survey performed in 2004[156], from the point of view of consumers, the lack of coordination among health professionals is a major problem (for 69% of the interviewed persons).

ICT, as part of the new patient safety paradigm, induces a major change in a secular professional culture. Doctors may feel the risk of loss of professional empowerment. This issue should be addressed appropriately and evaluated regularly with appropriate and defined criteria. The change will also affect the traditional patient-doctor relationship. ICT will foster inter-professional communication and patient's access to medical information. A proper decentralisation/centralisation balance affecting knowledge and data processing should take into account social reactions of the public as well as the professional confidence.

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[156] "National Survey on Consumers' Experiences with Patient Safety and Quality Information" Kaiser Family Foundation / AHRQ / Harvard (2004)

c)   Collaboration and communication on policy level

It was also noted that global distribution of IT advanced solutions that will affect Professional and Patient Safety and Quality of Care should be considered at the regional, national and international level.

Cooperation on European level has great potential to bring benefits, both to individual patients and to health systems overall. It is important to identify prior patient safety areas where European level collaboration and coordination of activities could bring added value.

The safety of medicinal products has been improved over the years through European Directives and Regulations, with better structured national Adverse Events Reporting systems and an increasingly strong co-ordination of responses via the European Medicines Agency. In December 2005 political agreement was reached on the Commission proposal for the Regulation on Medicinal Products for Paediatric Use, ensuring that medicines will be routinely tested for use with children.

Biological substances such as blood, tissues and organs, which are of high therapeutic value, may also carry risks for the recipients. Here the Community contributes to reducing such risks by adopting legislation on quality and safety of these substances. Similar improvements should progressively be applied to medical devices.

Nevertheless, the organisation of health services and the delivery of healthcare cannot be regulated at European level under the Public Health Article of the EU Treaty of Nice (Article 152). Therefore, most patient safety issues can only be addressed by non binding instruments such as European co-operation (Open method of co-ordination), joint projects, guidelines and recommendations.

Current efforts focus on reporting and learning systems of adverse events in healthcare by developing common approaches for reporting policies and strategies and by establishing a European-wide collation, analysis and sharing of information on patient safety problems; developing national patient safety policies and programmes; designing safer devices; and integrating patient safety more effectively in training and education programmes

To deal with the topic of patient safety and IT in a more concrete way the speakers outlined several applications, the pros and cons of implementing them and noted some ideas and challenges concerning respective issues.

d)   Prescribing and Electronic Medical Records (EHR)

The act of prescribing involves medical knowledge that is evidenced-based, and a continuous feedback on allergies and side effects. In this closed loop, the role of IT is seen as a facilitator of knowledge at the point of care in order to enable the best prescribing possible and also as monitoring facilitator.

Mr Kendall Ho explained in detail the case of the drug Rofecoxib, which was withdrawn by the FDA in 2005 from the US market. The role of IT was determinant in the study done by Kaiser Permanente. This study, performed between 1999 and 2001, showed that from 2,302,029 patients treated with Rofecoxib per year 8143 suffered cardiovascular problems, from which 2210 were fatal. The Kaiser Permanente study showed also that the odds ratio was superior for the patients treated with Rofecoxib and proposed a decrease in use of this drug internally in Kaiser Permanente. As a result in Kaiser Permanente the prescribing of Rofecoxib decreased to 4% for all anti-inflammatory drugs compared to 40 % in the rest of USA.

Lappe et al (2004)[157] have shown that important improvements in clinical outcomes of cardio-vascular patients are observed after one year after discharge with the use of an electronic pre-scription system, shown in the figure below. Overall, a 27% decrease in unadjusted absolute death rate is observed.
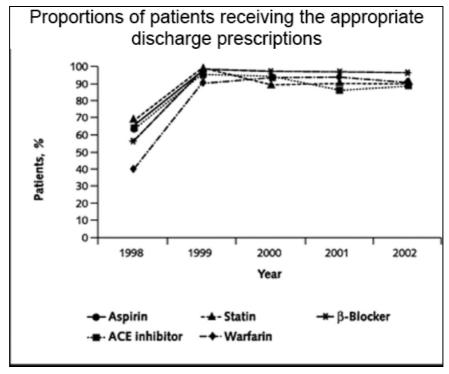
FIGURE 3: EFFECT OF EPRESCRIBING ON CLINICAL OUTCOMES

ePrescribing systems appear to improve work flow and contribute to evidence based medicine. They also proved to be an interim step towards seamless reporting integrated into a full Electronic Medical Record. However, the way to such integrated records is still long and difficult. In physician offices more then 85% of medical records are paper records. In hospitals the figure is 65%. [158] This is unfortunate, given the need for coordination of care in an increasingly complex health sector, especially in light of the observed increased prevalence of chronic conditions.

e)   Computer Physician Order Entry (CPOE)

In this context CPOEs are another application from which healthcare could benefit. CPOEs received considerable attention in the USA as a key technology to help realise the goal of reducing medical errors.

A CPOE allows a reorganisation of healthcare flow of information permitting multiple information exchange and validation feedback loops, as illustrated in the figure below. These feed-

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[157] Lappe et al (2004) "Improvements in 1 Year Cardiovascular Clinical Outcomes Associated with a Hospital -Based Discharge Medication Program" Ann Intern Med

[158] Mr Young quotes these numbers from the US in his presentation. Numbers in Europe are not expected to be significantly different.

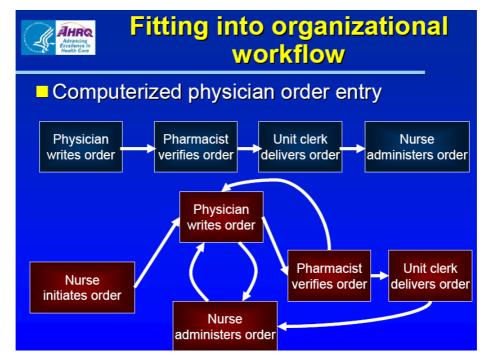back loops can significantly improve patient safety by detecting potential risks before they become threats.

FIGURE 4: CPOE ENABLING FEEDBACK LOOPS

Source: Scott Young 2006[159]

The importance of thorough assessment of users' needs was outlined as one of the success factors for implementation of CPOE. Workflow and healthcare process integration were stressed as important success factors; the quality of the technical implementation, the efficiency and quality of the management, the motivation of the staff, the leadership, the cost and the perceived value for the users are only some aspects concerning this topic.

There were positive and negative issues pointed out with regard to implementation of CPOEs. Proponents argue that CPOE systems that include data on patient diagnoses, current medications and history of drug interactions or allergies can significantly reduce prescribing errors which in turn leads to demonstrable improvements in patient safety. CPOEs also improve the quality of care by increasing clinician compliance with standard guidelines of care, thereby reducing variations in care.

However, some speakers also drew attention to the potential danger of CPOE use. Studies in the US, UK and Australia have found that "commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management systems may generate new types of error because of user-interface design, but also because of events in the workplace such as distraction affecting the actions of system users."[160]

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[159] Young S (2006) ICT Related Patient Safety Initiatives in the USA, Presentation at eHealth High Level Conference, Malaga, May 2006.

[160] Coiera E, Westbrook JI, Wyatt JC (2006) The Safety and Quality of Decision Support Systems, IMIA Yearbook 2006 1 1: 20-25.

Recent evidence (Koppel R et al – 2005)[161] suggests that there could be multiple medication errors associated with low quality CPOE systems or inappropriate use of CPOE:

- Fragmented CPOE displays that prevent a coherent view of patient;
- Pharmacy inventory displays mistaken for dosage guidelines
- Ignored antibiotic renewal notices placed on paper charts than in the CPOE system;
- Separation of functions that facilitate double dosing;
- Inflexible ordering formats generating wrong orders.

f)   Decision Support Systems (DSS)

There is a clear consensus that the use of Decision Support Systems (DSS) can improve patient outcomes and make clinical services more effective. Evidence indicates that they can indeed enhance clinical performance for drug dosing, preventive care and other aspects of care, yet less so for diagnoses.   Experience shows diverse results from using DSS. These reach from a significant improvement of clinical performance to no effect on physicians' adherence to care suggestions or negative comments about a DSS. The three main concerns voiced by clinicians are: timing of the guideline trigger, ease of use of the system, and helpfulness of the content.

The use of clinical decision support systems can improve the overall safety and quality of healthcare delivery, but may also introduce machine-related errors. Recent concerns about the potential for DSS to harm patients have generated much debate, but there is little research available to identify the nature of such errors, or quantify their frequency or clinical impact.

Nevertheless, research in the direction of diagnostic and treatment with the simulation of diseases, eLearning procedures, standards of care, and technology enabled knowledge translation seems promising. The latter is also expected to have a positive impact on prevention, surveillance and reporting systems, as well as evidence based policy making.

g)   Adverse Drug Events (ADEs) monitoring

A further topic of discussion at the workshop was the monitoring of adverse events, and in particular of Adverse Drug Events (ADEs). Whereas CPOE systems aim to prevent errors, Computerised Adverse Event systems aim to monitor the occurrence of instances that could be adverse events and alert the clinician when certain indicators are present. The most common adverse events are nosocomial infections and ADEs and consequently IT systems have been tested primarily in these areas. Most institutions use spontaneous incident reporting (relies exclusively on voluntary reports from nurses, pharmacists and physicians focused on direct patient care) to detect ADEs; however, this method is generally regarded as rather ineffective and only identifies about one in 20 ADEs.

Conversely, most IT trials have found a significant increase in the number of ADEs reported. Automatic alerts can also reduce the time until treatment is ordered for patients with critical laboratory results. This already works well for some types of adverse events, including adverse drug events and nosocomial infections, and are in routine use in some hospitals. In addition, these techniques seem to be well adaptable for the detection of broad arrays of adverse events, in particular as more information becomes computerised.

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[161] Koppel Ross et al. (2005): Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors; in: JAMA 293: 10

h)   Bar codes and RFID

These two tools help to reduce administration and logistics errors by allowing real time up-dates, in particular to medication delivery schedules. These technologies can offer simultane-ous access to the system at multiple sites, elimination of phone calls and paperwork, but more importantly elimination of time lags in information exchange. Radio Frequency Identification (RFID) tools are used for:

- security (e.g. access control)

- medication administration, authentication and stocking (tracking of drug origin)

- hospital equipment, supply tracking

- patient tracking, tagging blood transfusions and medical implants

- option for outpatient self-medication, e.g. for seniors

i)   Integration of different tools into systems

Mr Alberto Sanna, from Scientific Institute Hospital San Raffaele, Italy presented the benefits for patient safety along the continuum of care based on evidence from an Italian case. As part of a research project, coordinated by the Foundation San Rafaelle, named DRIVE, a proactive patient safety system was developed (see figure below).

The role of ICT in preventing errors is identified along the continuum of care and several spe-cific improvements are suggested at the level of diagnostic procedure, ordering and distribu-tion of drugs, therapy preparation and administration. The system was designed to be ex-tended to the public health authority in the process of registration and surveillance of drugs.
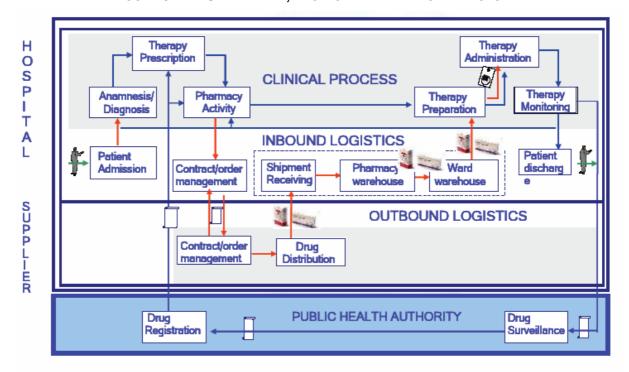
FIGURE 5: AN ICT ENABLED, PRO-ACTIVE PATIENT SAFETY SYSTEM

© Alberto Sanna - Scientific Institute H San Raffaele, eHealth for Safety - May 10, 2006 Malaga (ES)

The main component, the DRIVE Clinical module, allows the electronic prescription for doctors, the electronic ordering and administration for nurses and ePrescription validation for pharmacists.

5.1.3 Conclusions and major challenges

It was noted that integrated systems, e.g. a combination of DSS, CPOE and alerting, seem to be better accepted. Moreover, systems should be designed with, and not just for, the end-users, who are the busy or poorly resourced clinicians. The relevant information must be displayed fast and in a coherent and easy to use manner. Otherwise they will be rejected by the professionals and can even lead to more errors, not less. A deeper understanding of the "complex set of cognitive and socio-technical interactions" is essential. The organisational culture, including barriers to reporting errors, plays a key role in the acceptance of electronic tools such as incident reporting systems.

Last but not least some major challenges were noted during the workshop:

- The future of Medical Autonomy is still unclear, as professional ICT enters the new healthcare paradigm and induces a major change in a secular professional culture. It could render the practitioner more accountable for his or her practice and more prone to criticism. Doctors may feel a risk of losing professional empowerment. This issue should be addressed appropriately and evaluated regularly with appropriate and defined criteria. One must not forget that there are costs associated with the implementation of patient safety ICT, which are a perceived barrier for the adoption of ICT tools.

- For the centralisation and control of information, a centralised architecture of eHealth information models is needed for an improvement of patient safety. Monitoring of cost and behaviour/practice through a centralised collection of data could be scientifically justified. A proper decentralisation/centralisation balance affecting knowledge and data processing should take into account social reactions of the public as well as the professional confidence.

- Automation, explicit rationing and accountability could shift the responsibility from the individual "in charge" to the supervisor or the manager of the system.

- Improvement of quality and safety of IT: IT as a "risky" solution for fighting risks because of software failures. So there is a new threat because of inappropriate medical software, which could be prevented by a certification process for medical software comparable to pre-market approval of drugs or medical equipments. IT is a key component towards a safer environment for healthcare (but it's only a component and management and cultural issues deserve the same attention).

- Some additional issues were named, such as the role of IT in the evolution of underdeveloped healthcare systems or the role of IT in the management of pandemics at a global level (i.e. need for implementation of surveillance systems in underdeveloped countries where the outbreak has the greatest chance to erupt). A global distribution of an IT advanced solution that will affect Professional and Patient Safety and Quality of Care should be considered at the regional, national and international level.

5.2 Workshop II, Brussels, June 2006: Impact of Emerging Information and Communication Technologies on Patient Safety

5.2.1 Organisation and speakers

The second expert meeting was on the 30th of June and focused on the intersection of patient safety with the topics of the conference "ICT for Biomedical Sciences", i.e. not on patient safety in general and not on non-technological issues commonly associated with patient safety. The technologies under consideration were modelling and simulation, biomedical imaging, visualisation techniques, data mining and grid computing. Their contribution to improvements in healthcare delivery, training and research for the foreseeable future was discussed.

The workshop was chaired by Mr Gérard Comyn, Head of Unit "ICT for Health", DG Information Society and Media, European Commission and moderated by Mr Ilias Iakovidis, Deputy Head of Unit ICT for Health, and featured contributions by the following speakers:

1. Octavian Purcarea, Unit "ICT for Health", DG Information Society and Media, European Commission

2. Antoine Geissbuhler, MD, Professor and Director, Division of Medical Informatics, Geneva University Hospitals and School of Medicine

3. Peter Hunter, Professor of Engineering Science, Director, Bioengineering Institute, University of Auckland

4. Zvia Agur, Optimata Ltd. & President of the Institute for Medical BioMathematics (IMBM), Israel

5.2.2 Content of the workshop

The presentations and discussions focused on modelling and simulation, and the Virtual Physiological Human (VPH), as well as other emerging ICT solutions, in particular those relating to specific drug, implant and device safety aspects. Technology enables clinicians to pre-screen patients and indications for optimal regimens and the development of safer, personalised and cost effective therapeutics, minimise patient exposure to risks in clinical trials, and minimise toxicity in trials and treatments. The following issues were central outcomes of the workshop:

a)   Clinical trials, drug and therapy discovery
         Drug discovery

Simulation can help to predict, assess and monitor clinical trial outcomes (impact, efficacy, safety for individual patients) in drug discovery. Applying *modelling* at different levels of the human body and at every stage of the drug development process, from the modelling of cellular function, including molecular pathways, to modelling virtual patients and populations, and simulating all phases of the drug development process will improve safety, speed up and reduce the costs involved in new drug development. This will have strong impacts on the drug industry in the foreseeable future.

Special emphasis should be placed on safety in late stage clinical development and clinical testing through the coupling of disease models, population modelling research, sub-population simulations, top-down and bottom-up approaches. For instance, progress is to be expected from combining bottom-up simulation of physiological processes and simulation of situations

impossible or impractical to realise with real humans, with a top-down "inference modelling" approach based on the analysis of clinical-trial data linked with actual human outcomes data, using machine-learning and data-mining techniques (both to confirm known behaviour of biological systems, and to predict other, unknown behaviour). *Data mining* efforts that effectively protect the details of proprietary data from pharmaceutical industry would be useful in order to further develop predictive safety models.

Imaging technologies have the potential for providing earlier assurance of drug activity. E.g., molecular imaging tools in neuropsychiatric diseases or as measures of drug absorption and distribution may provide powerful insights into the distribution, binding, and other biological effects of pharmaceuticals.

Development and testing of medical devices and implants

New technical developments that rely on *in silico modelling* of devices and implants and their interactions with the human body allow for better performance and more durable devices and implants. These include prediction of the device or implant fatigue life through numerical analysis, coupling of multiple areas of computational mechanics and body motion simulations. The lack of accuracy, practicality (in many cases animal models don't work), and the expense of the in-vitro testing increase the importance of these novel techniques.

b) Personalised care
Drugs

ICT tools are needed to achieve further advances in PK/PD modelling, integration of data and knowledge from various fields crucial to personalising medicine, like pharmacogenetics, genomics, and toxicogenetic/ -genomic based knowledge underlying the aetiology of individual Adverse Drug Events (ADRs). For example, using powerful computational methods that can help identify genetic or other traits likely to affect an individual's drug reactions, helping to pinpoint combinations of genetic predispositions for serious ADRs with structural properties of the drug and risk factors, and integrate heterogeneous knowledge and data on ADRs, incl. pharmacovigilance data.

Care paths according to individual conditions and needs

Coupling images with models will enable quantitative & predictive medicine and tailored patient-specific image-guided therapy. For example, tumour growth modelling using imaging is used to analyse the tumour evolution, predict the actual frontier, i.e. personalised safety margins, which enables very precise treatment.

Part of an optimal, personalised care path will often include emphasis on care at home, outside the walls of healthcare organisations, thus reducing the risk of harm that inpatients are exposed to.

There is a general need for support and assistance towards developing a common, generic framework and tools to support the assessment of the potential impact on later clinical applications developing from basic research and emerging ICT technologies, and to develop strategies for accelerating the translation of basic research into clinical applications and full integration into care processes and clinical pathways, including communications with policy makers and stakeholders.

c) Integrating research into daily clinical practice
An emerging challenge is the integration of simulation into the management of care processes and clinical pathways – individual profiling of patients incorporated in *decision support systems*

(DSS). Meeting this challenge requires coordination across Europe, as it cannot be achieved at national level. The improvement of healthcare quality will in part be dependent on integrating a number of established and emerging tools and procedures, including:

- Simulation for predicting and monitoring the impact, efficacy, safety of drugs on patients

- Simulation for education and continuous training (not available from industry) further improving the skills and bringing up-to-date with state-of-the-art best practices the knowledge of medical doctors

- Ongoing professional assessment of skills, quality control, and also feedback of impact to medical doctors

- Tools for automatic monitoring of the outcome of clinical trials and drug-drug interactions based on EHRs.

The need for a framework for pre-assessment, impact evaluation, knowledge translation and monitoring of the process of adapting emerging ICT technologies to clinical settings, fostering industrial involvement to speed up innovation was highlighted. For instance, osteoporosis modelling and simulation can predict the risk of fracture; simulate related drug trials and their impact on short-term and long-term risk of fracture. Applying the results to better guide and improve the monitoring of clinical outcomes and, if needed, change guidelines will both improve the quality of clinical outcomes and reduce the risk to patients.

d)   Data presentation research

The presentation of data is a key aspect of successful integration of new technology in daily working practices. Specific issues include:

- The need for better solutions for "how to technically and logically present" new knowledge to medical doctors and patients at the point of care (like that generated from simulations) to support improved knowledge transfer and earlier acceptance into clinical routine

- Learning to cope with data overflow (e.g. from data capture from sensors and monitoring devices)

- Knowledge presentation interface - developing interface tools with diverse modalities for different types of users, adapted to their qualifications and needs.

- Collaborative tools are needed for: data capture, organisation of data flow, decision making, especially for chronic disease management (various medical professionals involved, multiple participants in decision making).

5.3 Workshop III, Geneva, October 2006: workshop and educational session

5.3.1 Organisation and speakers

The third and last event took place on 10th-12th of October and was split into a workshop and an educational session.

In order to increase public awareness, collect views and inputs on the future research topics in the area of Patient safety the consortium organised, a session of education and a workshop on the theme "Improving Patient Safety: Which ICT Contribution? - ICT in support of a holistic strategy to improve the quality of healthcare". The seminar and the education session were conceived as a satellite event during the "World of Health IT" Conference in Geneva.

The workshop, which gathered a number of well known experts, took place on the first day (10th of October) and was chaired by the EU Commission services and proved the particular interest that it is shown to this subject. The educational session took place on the 12th of October and was offered by the Standing Committee of European Doctors (CPME), the European Health Management Association (EHMA), and the European Hospital and Healthcare Federation (HOPE) with the support of the European eHealth for Safety study.

The workshop was chaired by Mr Ilias Iakovidis, EC Commission (Unit ICT for Health) and featured contributions by the following speakers:

1. Pr Christian Lovis, University Hospital of Geneva
2. Mr Leonard Fass ,GE Healthcare
3. Dr Octavian Purcarea, Unit ICT for Health (DG INFSO)
4. Mr Marc Peeters, F.Hoffmann-La Roche Ltd
5. Prof Ed Hammond, Duke University Medical Centre

The educational session included presentations form:

1. Dr. Markku Äärimaa, Former President of the Standing Committee of European Doctors (CPME), Member of the national Social and Health Affairs Committee, Finland
2. Céline Van Doosselaere Head from EHMA (European Health Management Association), Belgium
3. Dr. Veli Stroetmann, empirica Communication and Technology Research, Germany
4. Dr. Jean-Pierre Thierry, eHealth for Safety Study, France

5.3.2 Content of the workshop

The chair of the session – Mr Ilias Iakovidis – from EC Commission (Unit ICT for Health) introduced briefly the importance of the Patient safety field and the particular interest for the Commission in listening to the different user views. He also outlined the importance of the workshop in terms of orientation of the future research programme (7th EU Framework Programme of Research and Development). A round table allowed the participants to introduce themselves and their interests.

The speakers agreed that modern healthcare is evolving towards a citizen centred approach. Currently, workloads are high and projected to continue their upward trend but the healthcare professionals are forced to do more with much less, while the pool of patients grows. One important problem is that costs increase by 1-2% per annum due to the aging population and technology introduction, but budgets are contained. Productivity and efficiency decrease and also the satisfaction levels for both patients and the care givers are declining. An increased

workload, fewer care givers, long working hours etc. lead to more and more medical errors, the causes of which seem to be more dependent on the medical system and organisation then on clinical skills.

Dr. Purcarea shared some suggestions that have been included in the 2007-2008 research programme, based on the interim deliverables of the Patient safety study, such as:

- Data mining for improved patient safety
- Ontology of patient safety
- Healthcare system risk model
- Multilevel modelling and simulation of the human anatomy and physiology, the so-called Virtual Physiological Human (VPH)

The presentations and discussions focused the attention to the following topics.

a)   Integration and traceability of data

Speakers pointed out the importance of integration of multiple sources of data, especially in the area of bio-informatics, such as whiteboards, medical records, nursing observations, follow-up and planning, and medical orders. There is a need to integrate the knowledge from all along the life of a patient. The aim is to leverage the power to learn at every level to the benefit of clinical research as well as policy makers. This can be achieved when knowledge interoperability is guaranteed, which supposes information chain integrity along the supply chain up to the patient and then from individual patients to the whole population. Fields stressed in this context of integrating are epidemiology, physiology and pathology.

The future of clinical research is centred on the use of appropriate standards which will allow interoperability. Such standards are related to:
- Data elements:
- Structures built from data elements
- Structured Clinical Documents (CDA, CCD)
- Transport Standards (data, audio, images, waveforms)
- Communication Standards
- Security and Confidentiality Standards
- EHR Architecture and Functional Requirements
- Decision Support including Research protocols and guideline specifications

Current challenges, preventing technical as well as semantic interoperability, include multiple coding such as ICD, ICPC, SNOMED, LOINC, DRGs etc.

Traceability generally relates to the ability to recover the path leading to a certain outcome. In the healthcare context, this includes identification of where "the systems" has failed, thus learning how to change and prevent adverse events in the future, as well as tracing the origins of a particular health condition of a specific patient. Current applications in the field of traceability include features like:

- supporting clinical trial management in terms of compliance

- tracking high value re-usable assets

- reducing errors in logistics - a 'real time' picture of inventory

- Patient safety: reducing errors during drug prescription, dispensing and medication/administration, counterfeiting.

These by no means exhaust the potential of tracing solutions. Further research, especially on the medical side of traceability is required.

b)   Patient data and Electronic Health Records (EHR)

The possibility to re-use electronic health data from respective record systems was a topic given particular attention. There is number of arguments for using patient care data for clinical research:

- Costs: separated clinical research and EHR systems are redundant and are overly expensive.

- Interoperability: if data elements are consistent and precisely defined and thus semantically interoperable both patient care and research could benefit

- The volumetric point of view: all persons, with their permission, would be able to contribute to clinical trials and the extraction of knowledge for evidence-based medicine.

- Speed: research results would be available more quickly and the time frame from bench to bedside would be significantly reduced

- Accuracy: as a result of computer algorithms and an expanded use of information, the data collected for both patient care and research would be more accurate.

- Completeness: structured data, structured clinical statements, structured documents and structured EHRs could result in more complete and more meaningful documentation.

Not to be neglected is also the argument of patient safety – all of the above have a connection to the risks that patients are exposed to during treatment and during research trials. For example, a more accurate estimation of treatment effects allows identifying potential harmful side-effects. The speed of drug discovery can have an impact on the length of hospitalisation and thus on the probability of confronting patients with adverse events in the hospital setting.

Nonetheless, there are a number of concerns for using patient care data that must not be ignored. First, data collected for patient care is not the same as for clinical research (some experts estimate as little as 50% overlap). Moreover, the providers do not have time to collect additional data. The data collected for patient care will always be of lower quality because of lack of motivation, lack of time, and interruptions, it will be inconsistently collected and incomplete, unstructured, and uncontrolled.

Patient care data needs to be what actually is measured rather than an interpretation. For that purpose one should record actual temperature rather than elevated temperature, record actual cholesterol rather than elevated cholesterol and record actual dates of occurrence rather than sore throat within the last 6 months.

Despite the difficulties and challenges, the hopes associated with the increasing diffusion of EHRs (or EPRs) in the field of patient safety are significant. For example, in the Netherlands, research[162] carried out by TNS-NIPO, a market research organisation, shows that around 800,000 Dutch people over the age of 18 have been subject, in their own perception, to errors based on the inadequate transfer of medical information. Of the respondents interviewed, 86 percent expected that this type of error would be reduced once an electronic patient record has been introduced.

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[162] For relevant information, see http://www.npcf.nl/. Similar information is also available from WINAP and from the Dutch Association of Pharmacists.

c) Nanotechnology and wireless technology

A number of developments in current-age health systems, such as increased workload, significantly fewer care-givers, long work times, lower productivity and increased frustration, lead to more and more medical errors. The causes of errors appear to be more dependent on the medical system and organisation then on clinical skills, as illustrated in the figure below.
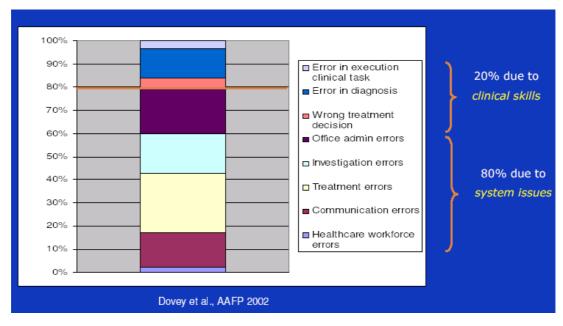
FIGURE 6: SOURCES OF MEDICAL ERRORS

Leonard Fass 2006[163]

Nanotechnology and wireless technology were named as key technology drivers able to help address the system related errors. Wireless networks are used to access patient records from central databases or to add observations to databases and to check on medications. Wireless technology allows tracking, therapy through real time data collection and simulation, with smart systems talking to central, learning engines. In terms of critical care, clinicians can have access to vital signs and alarm history events as the patient is transferred between hospital departments. Multiple vital parameters such as weight, oxygen saturation, blood pressure, blood glucose, heart rate, heart sounds, electrocardiogram breathing sounds and volumes, sleep apnoea, hydration etc., can be measured remotely.

The growing use of wireless networks by healthcare professionals presents tremendous challenges to healthcare IT managers. The actual challenge is to connect medical devices to medical informatics networks with common standards for data storage. There is a trade-off between access and security: easier access means greater security risks.

d) Computer aided prognostics

Wrong patient management is one of the largest factors adding costs and avoidable mortality instances in healthcare. A computer aided prognostics work station could help the physician make critical judgement on risk assessment, survival probability, drug response, rate of disease progression, therapy planning and monitoring, and clinical outcome. Close collaboration between industries will be necessary to develop such tools, which will be key to offering the best patient management at the lowest cost. These systems should be based on Evidenced

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[163] Fass L (2006) Patient Centric HealthcareOpportunities from technology convergence, Presentation at the eHealth for Safety Workshop in Geneva.

Based Medicine and give healthcare management the possibility to slow down the rate of overall cost increase in the healthcare system.

The project ePISODE was described as working towards development of computer aided prognostics systems. In particular, the project aims at redefining the screening process and developing a new generation of risk stratification that is truly preventive and specific. The expected outcomes of the project are: the definition of new risk indicators, lifestyle management guidelines for the patient and redesign of health policies towards increased lifestyle management and prevention.

e)   Addressing the continuum of care

The patient safety area could be seen as a continuum, as outlined in a workshop for health professionals on the use of ICT in patient safety risk management (2004), organised by the European Commission. This view is still valid and was confirmed by the workshop participants. Hence, the health risk management domain can address three levels, following the process of care:

- personal health, addressing prevention, life style and behaviour, and environmental factors
- care in professional settings, addressing decision support, intra-hospital monitoring, CPOE, alert systems etc.
- follow-up and rehabilitation phase, addressing disease management, further prevention and policy measures at a political level.

This is illustrated in the figure below.

FIGURE 7: ADDRESSING THE CONTINUUM OF CARE

EC - DG Information Society 2006[164]

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[164] Purcarea O (2006) Patient safety in eHealth Research and Development : the FP7 perspective, Presentation at the eHealth High Level Conference in Malaga, May.

5.3.3 Content of the educational session

The session took place tow days after the workshop and was opened by a welcome note by Dr. Markku Äärimaa, Former President of the Standing Committee of European Doctors (CPME), Member of the national Social and Health Affairs Committee, Finland and a short introduction by Céline Van Doosselaere Head from EHMA (European Health Management Association), Belgium.

Dr. Veli Stroetmann from empirica Communication and Technology Research, Germany presented the state of play of ICT in support of patient safety with foci on applications like decision support systems (DSS) and computerised physician order entry (CPOE); good practice examples, success and failure factors in ICT implementation, followed by a brief reflection on research needs and challenges.

Dr. Jean-Pierre Thierry from Symbion for the eHealth for Safety study, France, took a systemic approach considering public health needs: from hospital to public health information systems.

Special attention was given to the need for developing patient safety indicators and the opportunities from ICT enabled syndromic surveillance medicine. Hence, "Real-time" public health surveillance is using data that is routinely collected for other purposes. The conclusions of the speaker were that IT is a key component of the Patient Safety Movement and the rise of "surveillance medicine" is justified by the new epidemic threats and the quest of Quality in Healthcare and Patient Safety. Nevertheless, Public Health Informatics should be promoted to find the proper way to use IT efficiently. These new research areas should encompass several academic fields of expertise including bioInformatics and IT specialists. Interoperability issues for the creation of seamless Health Information Systems is a key issues that should complement current work done most notably for EHR interoperability.

The presentations were followed by a 20 min round table discussion with representatives of CPME, HOPE, EHMA, the speakers, and the audience.

The round table addressed and emphasised some of the following issues:

1) IT as an enabler and a key component of a safer healthcare environment (knowing that this is only a component, and management and cultural issues deserve the same attention), moreover, a comprehensive strategy is needed.

2) ICT induces a major change in professional culture. Doctors may feel the risk of loss of professional empowerment. This issue should be addressed appropriately and evaluated regularly with defined criteria.

3) Medical software should not be a risky solution: its development, deployment and diffusion should benefit from a certification/accreditation process.

4) Interoperability issues should be addressed properly, e.g., patient and HCP identification, authentication, semantics.

5) Research and Development must contribute to address these and other issues.

Dr. Markku Äärimaa concluded the session emphasizing the importance of research and proper implementation of ICT in the area of Patient Safety.

To sum up, the educational session emphasised a number of issues related to the proper implementation of ICT in healthcare such as the need of a comprehensive strategy in the area of Patient safety, including human, cultural and organisational factors, the need for interoperability and certification and accreditation processes as well as the need for a comprehensive policy of research and development in the area of ICT for Patient Safety.

6 Vision and recommendations for future research efforts

This final chapter provides a brief summary of main findings of the study, a vision of how ICT may impact patient safety in the future, and in what direction RTD efforts should be concentrated in order to optimise the positive effects on the quality of health and healthcare for citizens. Risk management and risk avoidance are an integral part of this perspective. A greater awareness of risks inherent in the healthcare domain is a necessary first step towards improved management of these risks and thus for providing an optimal level of patient safety.

6.1 A holistic view and vision

Complex care processes, missing information, regular interruptions of ongoing activities, and sometimes chaotic communications all contribute to medical errors and adverse events, and can have a corresponding, significant impact on patient safety and the quality of healthcare. eHealth or ICT-based solutions are becoming key tools to cope with these challenges. They can guide care processes and support work flows, provide pertinent patient information when and where needed, and improve diagnosis and treatment through decision support. Through the provision of timely health and lifestyle information, eHealth also contributes to improved information for citizens and thereby to better prevention. Through support for research it supports the discovery of better medical knowledge and the development of improved and new guidelines. eHealth will have a significant impact on better training, improved preparation for surgery or managing long-term conditions. All of these improve patient safety in a wider sense, and lead to improved health and quality of care.

In this study we analysed from a *holistic point of view newly emerging opportunities* to preserve health and improve the quality of acute and longer-term care, also reflecting on the expected contributions to such a holistic concept of patient safety by *biomedical and other fundamental research*, supported by ICT-based solutions.

> *In summary, our overall vision of patient safety is to optimise patient safety and improve the quality of care across the whole health value system including disease prevention, personalised care, best practice medical interventions, clinical research, risk assessment, training and education.*

The study identified the potential benefits induced by the use of ICT along the full continuum of care, and provided a perspective for advanced research in this area.

6.2 ICT in healthcare: Summary of state of play

This *"eHealth for Safety"* study reviewed a large amount of literature published since the famous USA report *"To Err Is Human: Building a Safer Health System"*[165], thereby underlining that the subject of patient safety and medical errors has gained wide international attention in health policy, healthcare and research environments. Several European Union Member States (MSs) have estimated the scale of patient safety problems, with findings similar to those in the USA. Information and communications technology has proven to contribute not only to reducing the rate of errors by providing more accurate and transparent information, thus preventing mistakes and avoiding adverse events, but also to facilitating a rapid response after an adverse event has occurred, and to tracking and providing feedback about such events. However, patient safety should not only focus on reducing medical errors. The literature review and expert consultations conducted have confirmed that ICT solutions supporting healthcare professionals can greatly contribute to improving the quality of care more generally.

It was shown that ICT applications can be useful in almost every aspect of healthcare, including facilitating information and communication within and among healthcare organisations, supporting diagnostic and therapeutic processes, allowing the delivery of care to remote locations, increasing the efficiency of delivery, and, last but most important, increasing the quality of care provided to citizens. Wachter believes that "it seems self-evident that many, perhaps most, of the solutions to medical mistakes will ultimately come through better information technology. We may finally be nearing the time when institutions and providers will not be seen as credible providers of safe, high-quality care if they lack a strong IT backbone." [166]

One of the most important developments in recent years in many MSs has been the planning and implementation of EHRs at the national, regional and local level. In England, an evaluation of the *National Care Record System* led to the conclusion that it has significant potential to improve safety as lost or poorly completed records are a major contributory factor to patient safety incidents. It is likely that these large scale deployments of eHealth infrastructures will lead also to the broader implementation of other ICT tools.

The IOM has advised that *moving from a paper to an electronic based patient record system would be the single step that would most improve patient safety*. In UK, the National Programme for Information Technology in the NHS being delivered by the Department's agency, *NHS Connecting for Health*, has begun to roll out its National Care Record system and expects it to have full functionality by 2010. An evaluation of the activities conducted so far in the UK states that "the *National Care Record has significant potential to improve safety as lost or poorly completed records are a major contributory factor to patient safety incidents."*[167]

A study found that 80 percent of medical errors began with miscommunication, missing or incorrect information about patients, or lack of access to patient records.[168] The following case study illustrates the benefits of a hospital-wide electronic patient record system demonstrating improvements in quality of care, access to care and even economic benefits:[169]

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[165] IOM Report (2000). To err is human: Building a safer health system. Institute of Medicine, 287 p. Available at: http://books.nap.edu/books/0309068371/html/index.html.

[166] Wachter, R (2004) The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human'. Health Affairs Web Exclusive. W4- 539.

[167] NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf, p.9

[168] A String of Mistakes: The Importance of Cascade Analysis in Describing, Counting, and Preventing Medical Errors, Annals of Family Medicine, 2004

[169] eHealth is Worth it. The economic benefits of implemented eHealth solutions at ten European sites. Karl A. Stroetmann, Tom Jones, Alexander Dobrev, Veli N. Stroetmann, Luxembourg: Office for Official Publications of the European Communities, 2006, http://europa.eu.int/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf

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Elios and Prométhée at Institut Curie, France

Elios – a comprehensive Electronic Patient Record, containing structured reports, free text, images, accessed by all doctors involved in a patient's treatment, and Prométhée – a biomedical informatics search meta-engine used for answering medical questions across research and clinical databases, across a large number of Curie's other hospital (patient and administrative) and clinical research databases, have fundamentally transformed healthcare processes at Institut Curie and have improved the quality of care through:

- faster, shared access to comprehensive, accurate, timely clinical data
- better preparation of consultation (the day before)
- real-time clinical audit studies to measure outcomes and control quality
- real-time organisational audit studies to streamline workflow
- faster compliance with new clinical guidelines and organisational protocols

The annual net economic benefit was estimated at over €3m per year

The estimated productivity gain, measured in eHealth cost per patient, was found to be 17%.

Source*: www.ehealth-impact.org

There is a wide consensus that the use of a **Decision Support System (DSS)** can improve patient outcomes. DSSs are broad solutions, which are often incorporated in a variety of eHealth applications. They go back as far as 1974, and evidence indicates that they can indeed enhance clinical performance for drug dosing, preventive and other aspects of care, but so far not really convincingly diagnoses. However, it is also known that they may occasionally foster errors in entering and retrieving information, and errors in the communication and coordination process, rather than reducing them. *Coiera* concluded that "the use of clinical decision support systems (CDSS) can improve the overall safety and quality of healthcare delivery, but may also introduce machine-related errors. Recent concerns about the potential for CDSS to harm patients have generated much debate, but there is little research available to identify the nature of such errors, or quantify their frequency or clinical impact." [170]

Computerised Physician Order Entry (CPOE) systems have received considerable attention as a key technology to reduce medical errors. CPOE systems support a process whereby instructions regarding diagnosis and treatment are entered electronically and communicated directly to responsible individuals or services. DSSs are built into almost all CPOE systems to varying degrees, providing basic computerised advice regarding drug doses, routes and frequencies, as well as more sophisticated data such as drug allergy, drug-laboratory values, drug-drug interactions, checks and guidelines.

The following case study illustrates the benefits of a CPOE system:

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ePharmacy at a London hospital, UK, is a combination of ePrescribing, eDispensing using a robot system, eStockmanagement and eProcurement, used for outpatients and discharged patients. The following benefits were reported:

- Fewer prescribing errors and discrepancies
- Fewer dispensing errors: down from 30 to 21 per 100,000 packs, with a 29% gain
- Shorter response time for urgent prescriptions: from 37% within one hour to 89%
- Most dispensary staff redeployed to wards

The annual net economic benefit was estimated at approximately €1.5m

Source*: www.ehealth-impact.org

However, there is also a potential danger involved. Studies in the US, UK and Australia found that "commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management sys-

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[170] E. Coiera, J.I. Westbrook, J.C. Wyatt (2006): The Safety and Quality of Decision Support Systems. In Haux R, Kulikowski C, editors. IMIA Yearbook of Medical Informatics 2006. Methods Inf Med 2006; 45 Suppl 1

tems may generate new types of error because of user-interface design, but also because of events in the workplace such as distraction affecting the actions of system users."[171]

Whereas CPOE systems aim to prevent errors, **computerized adverse event systems** monitor the occurrence of instances that could be adverse events and alert the clinician when certain indicators are present. The most common adverse events are nosocomial infections and Adverse *Drug* Events (ADE) and consequently IT supported reporting systems have been tested primarily in these areas. Up to now, most institutions use voluntary incident reporting to detect ADEs; however, this method is rather ineffective and identifies only about one in 20 ADEs. Conversely, most IT applications have found a significant increase in the number of ADEs reported. **Automatic alerts** can reduce the time until treatment is ordered for patients with critical laboratory results. These techniques seem to be well adaptable for the detection also of other adverse events, in particular as more information becomes computerised.

Research has shown how important it is to design systems with the end-user, the clinician, in mind. If systems do not respond fast and display all relevant information in a coherent, easy to use manner, they are rejected and can even lead to more errors, not fewer. Only a deeper understanding of the complex cognitive and socio-technical interactions which are so characteristic of healthcare processes will result in the design of systems which support safe outcomes in the hands of busy or poorly resourced clinicians. Furthermore, the organisational culture, including barriers to reporting errors, will play a key role in the acceptance of electronic tools such as incident reporting systems.

ICTs play also a very important role in **improving communication**, for instance, ePaging, where a system identifies and pages the professional on call (*role* based) which leads to a more rapid treatment (e.g., in case of critical lab results). Such a system requires physician-on-call schedules, known responsibilities, traceability, etc. The following case illustrates the benefits of a practical application of this:

DISPEC – ambulance emergency service, Romania, is a sophisticated, electronic emergency ambulance teletriage and dispatch system, introduced in 1996 by the City of Bucharest Ambulance Service. The nature and severity of an incident is identified by trained personnel based on information received from the caller, and the best matching ambulance equipment and team (4 types of ambulances equipped with GPS located across the city) is sent to the emergency site. The following benefits were reported:

- The incidence of death per emergency decreased by >25%
- Handling of increasing number of emergency calls with shrinking financial and staff resources
- Dramatic drop in call to dispatch time - decrease in average time by about 30%
- Dramatic drop in time till arrival at emergency site - decrease in average time by 35%

The annual net economic benefits were estimated at €1.4m per year

Source*: www.ehealth-impact.org

6.3 Advanced ICT for Risk Assessment and Patient Safety

The overall goal of patient safety and risk assessment is to improve disease prevention and minimize the potential of adverse effects on citizens caused by any research, clinical trials, diagnostic and treatment interventions, including environmental factors. A key aspect of further research for improved risk management is an enhanced evidence base which requires better integration of data from heterogeneous sources and information systems. Furthermore, knowledge representation and utilisation are prime tools for enabling optimised and safer care processes.

Several innovative, knowledge-based approaches to develop advanced ICT solutions for risk assessment and patient safety applications can be recommended as a result of this study. These solutions can be grouped by several categories introduced previously.

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[171] FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach

1. Innovative integrated systems for clinical settings

Evidence has shown that integrated, easy to use applications have better acceptance and benefits results. Further research into advanced tools for a better *integration* of decision support systems (DSS) and alerting, CPOE and intelligent medication delivery (e.g. RFID-based) systems, (adverse) event reporting and related application systems *with patient record systems* is urgently needed. Advanced computerised adverse event systems (beyond merely reporting nosocomial infections and/or Adverse Drug Events - ADE) aiming at identification of common patterns in *safety-relevant events and workflows* are another focus in need of research; such work must also take into account new tools for prediction, detection and monitoring the occurrence of the broad arrays of such instances that could be or develop into adverse events, incl. alerting and management support.

2. Tools for information retrieval

A longer-term research objective should focus on integrated clinical - EHR - and biomedical informatics *search meta-engines* to improve safety and thereby the quality of care, which - based on a wide variety of clinical and research data bases - would allow at the point of care access to and comprehensive answers to ad-hoc clinical and research questions, real-time adjustment and evaluation of clinical practices (professionals, devices) and guidelines, or real-time clinical audits and quality control.

3. New tools for data mining

New data mining applications like expanded predictive analytics and powerful language processing algorithms to analyse structured and unstructured data (e.g. the text of a physician's notes) for identifying factors in clinical settings associated with better medical outcomes or risk deserve special attention and support. Emerging technologies like semantic mining will enable researchers to find semantic meaning hidden in data and documents, and relate it to information available in other forms like images. Further research into the fusion of medical images (MRI, CT, PET, X-rays, ultra sound) and other multimedia data for multidimensional-multimodal image analysis and integrated mining together with qualitative information and quantitative data is strongly recommended. Utilising data mining techniques with these various structured and unstructured data from clinical databases about patient diagnoses, lab test results, images, medical treatment data, etc. is a great challenge and a virtually unexplored frontier which holds great promises for improving patient safety.

4. Advanced modelling and simulation techniques

For *technology-dependent high risk procedural areas* like the operating theatre, intensive care units, cardiac catheterisation or interventional radiology units *intelligent risk assessment and management tool development* should be supported. These may be tools for an intelligent surgical and anaesthetic pre-operative assessment, built on domain ontologies, using a combination of anaesthetic peri-operative data and surgical data for outcomes research and providing automatic risk scoring, alerts and clinical decision support. Another avenue would be bringing image-guided interventions into clinical practice. Advances in medical imaging (soon to include molecular imaging), image processing and display, surgical simulation, surgical navigation and robotics as well as surgery adapted PACS infrastructures are the driving forces for these developments. At the same time, such systems should be able to learn, to support collaboration, and allow for the traceability of care processes.

5. Integration of multi-disciplinary knowledge for simulation of pathophysiology and pharmacological trials

Simulating drug effects or the outcome of surgical interventions will allow safer, more individualised treatments. New approaches and tools are also needed for *coupling of* research *data* from, e.g., pathophysiological modelling with large empirical databases (from omics through EHR to public health /population data). Feedback and knowledge-coupling across such disparate domains will provide for a better understanding of disease development, personal risk and individualised treatment response. This will also support the empirical base for better simulating disease development and drug impact - *virtual clinical trials* - thus reducing risks to citizens participating in clinical research.

6. Personal Health systems

Personal ICT tools, e.g., biomedical sensors, home monitoring, compliance control and assistive living systems can equally improve safety and allow for better risk monitoring. There is a substantial research needed on advanced, user-friendly, interoperable Personal Health Systems (PHS),, complemented by implementation support for their wider diffusion. Such systems should become integrated with clinical applications of both hospitals and GPs for fostering better compliance by patients and avoiding errors of treatment (type of drug, administration, timing, dosage…) as well as for receiving at home or even on the move appropriate feedback from health professionals.

7. Public health applications

The increasing probability of *large scale* local, regional or even global adverse health *events* requires new surveillance, risk prediction, risk assessment and risk management tools for prevention, preparation, intervention, control and support. The developing regional and national healthcare ICT infrastructures should be used to capture relevant information as a by-product of care, particularly of emergency care. Secondary usage of medical and others routinely collected data for syndromic surveillance, preparedness planning and crisis management (in cases like a new SARS outbreak, Avian flu, other threats), will become an important priority at the national and European level.

Research into advanced tools for risk prediction and risk propagation modelling, probabilistic risk assessment algorithms based on data mining, simulation or event-fault tree data and models, semantic models to support surveillance analysis, or knowledge management and decision support for triage and intervention management require advanced ICT support. Research should also include a review and adaptation of experience gained in other industries with respect to assuring the safety of mission-critical functions during such events.

8. Validation and socio-economic assessment of ICT applications

Furthermore, it is necessary to facilitate research on the validation, socio-economic impact assessment and uptake of ICT applications which will improve the management of health risks and patient safety. Further research should be supported on appropriate formative and summative evaluation methodologies, including tools useable already during the research and development stages to guide research towards outcomes which have the highest probability to indeed become successfully implemented and diffused when taking into account their expected organisational, economic and socio-cultural impacts. Furthermore, a better understanding is needed of how to combine the investment in such patient safety-supporting ICT solutions with complementary investments in new working practices, human capital, and related organisational restructuring.

Further research is also needed on the organisational and cultural contexts in which people are most prone to commit errors, like what is the influence of teamwork on the likelihood of patient safety relevant incidents, how do resource pressures affect the behaviour of clinicians, and how can ICT applications contribute to mitigate such challenges?

Other important areas for further research concern the appropriate level of patient involvement in patient safety research and the development of reliable patient safety indicators, and last but not least the appropriate evaluation of patient safety interventions. So far, little reliable data exists on the effectiveness of routinely recommended interventions, including incident reporting and analysis.

6.4 Outlook

Overall, it would be beneficial to

- systematically collect and analyse information, data and clinical research results on patient safety for use in a full range of ICT research fields,

- monitor risks presented by the application to healthcare of emerging ICT technologies,

- support the transferability of approaches and improved models in systems analysis and control incorporating patient safety aspects,

- enable learning from applications in more advanced fields like aviation or food production,

- study the medico-cultural, legal/regulatory and socio-economic issues related to safety aspects.

Another key aspect is to assure that health risk and patient safety aspects are evaluated and taken into account by other relevant ICT RTD like on EHR/support for personalised care, grid computing, wearable systems, micro- and nano-devices, bio-medically based diagnostics, home-based and mobile telemedicine or assisted living systems.

All of this needs to be focused on aspects which are of particular relevance in the European context and with respect to Member States health system policy priorities.

The development, deployment and diffusion of eHealth systems would also benefit from a certification process put into place. Interoperability issues should also be addressed properly, e.g., patient and HCP identification, authentication, semantics. A key barrier to the wider diffusion of these systems is user acceptance. A deeper understanding of the complex cognitive and socio-technical interactions characteristic of healthcare processes will result in the design of even better systems to support safer outcomes in the hands of busy or poorly resourced physicians. Overall, ICT is an enabler that can revolutionise healthcare processes, and a key component of a safer healthcare environment. However, it is only one component, and management and cultural issues deserve the same attention. Moreover, a holistic vision and strategy taking into account also organisational factors is mandatory if safety is to be strengthened for all - be they healthy citizens or patients in need of service. Research and Development must contribute to address these issues.