eHealth for Safety
Impact of ICT on Patient Safety and Risk Management

eHealth for Safety Report

October 2007

European Commission
Information Society and Media

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eHEALTH FOR SAFETY

eHealth

eHealth for Safety
Impact of ICT on Patient Safety and Risk Management

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About this report

eHealth for Safety is a European study that addressed research and technology development (RTD) needs that arise from the potential contributions of information and communications technologies (ICT) applications to enhancing both patient safety and health systems' risk management.

The study had two overarching goals. These were:

- Identifying the key issues, topics and challenges where ICT applications can have a high impact on improved patient safety.
- Developing recommendations for RTD measures within the European Union (EU) 7th Framework Programme of research and other longer-term research activities.

Acknowledgements

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We are grateful to numerous speakers and experts at workshops and sessions organised in the course of the study for sharing their views and experience.

Foreword

Citizens are at the very centre of health services across the European Union. Enabling and supporting them to stay healthy is the optimal way to foster patient safety. Improving the access, quality, and effectiveness of healthcare provided is a second best, but equally crucial means, whether the care is chronic or acute, whether the patient is eight months, eight years, or eighty years old.

Towards the end of the last century, many years of seminal clinical research finally alerted the public to the deplorable state of patient safety, and the preventable harm and even death citizens experience when being treated. This triggered global attention to the potential risks that patients run when they have an encounter with their health system. In Europe, we have observed the development of this concern closely. Avoiding unnecessary suffering has become a high priority of health policies.

eHealth, the beneficial application of ICT-based systems and solutions, has been identified as potentially *the* key enabler to fundamentally improve patient safety in clinical contexts. This is why the European Commission launched the eHealth for Safety study at the beginning of 2006. It will help European policy-makers, and particularly research policy decision-makers, to understand more completely the potential role of information and communications technology (ICT) in making European patients' experiences more safe, sound, and secure. The study's contribution is to enrich the comprehensiveness of our knowledge of how ICT tools can help. More specifically, we need to know how European research support programmes can contribute to improve patient safety.

The study findings help put flesh on this challenge. Firstly, it shows us what ICT applications are being implemented today in practice. Policy-makers are always on the lookout for good practice. Leading examples in the field of eHealth for safety appear to be emerging across many, if not all Member States, albeit often only in specific settings and not across the entire healthcare domain. Such cases of good ICT practice are well worth further exploration, and examination of the transferability of their experiences to other regional and national settings.

"Citizens are at the very centre of health services across the European Union. Enabling and supporting them to stay healthy is the optimal way to foster patient safety."

Secondly, it reminds us that any field, however, must be well-grounded in empirical research, and this is equally true of eHealth for Safety. Specific examples of possible ICT applications for future exploration and assessment in terms of their impact on patient safety include electronic health and care record systems in support for personalised care, wearable systems, micro- and nano-devices, bio-medically based diagnostics, home-based or mobile telemedicine, and knowledge management and decision support systems.

Finally, these days groundbreaking knowledge development in any subject predominantly occurs in multi-disciplinary and interactive settings. The eHealth for Safety domain has especially benefited from the exchange of information among eminent international researchers and practitioners. Facilitated by European Union Research Support Programmes, we are pleased to see leading European researchers and practitioners come together with their counterparts internationally from countries like Australia, Canada, China, New Zealand or the United States of America to analyse and debate the successes and challenges of eHealth in patient safety research and implementation.

As a result of such dialogue, and the compilation of core research and implementation ideas, we hope very much to consider the further development of some of the visions developed in this report in the future directions to be taken by European research and development.

Gérard Comyn
Head of Unit
ICT for Health

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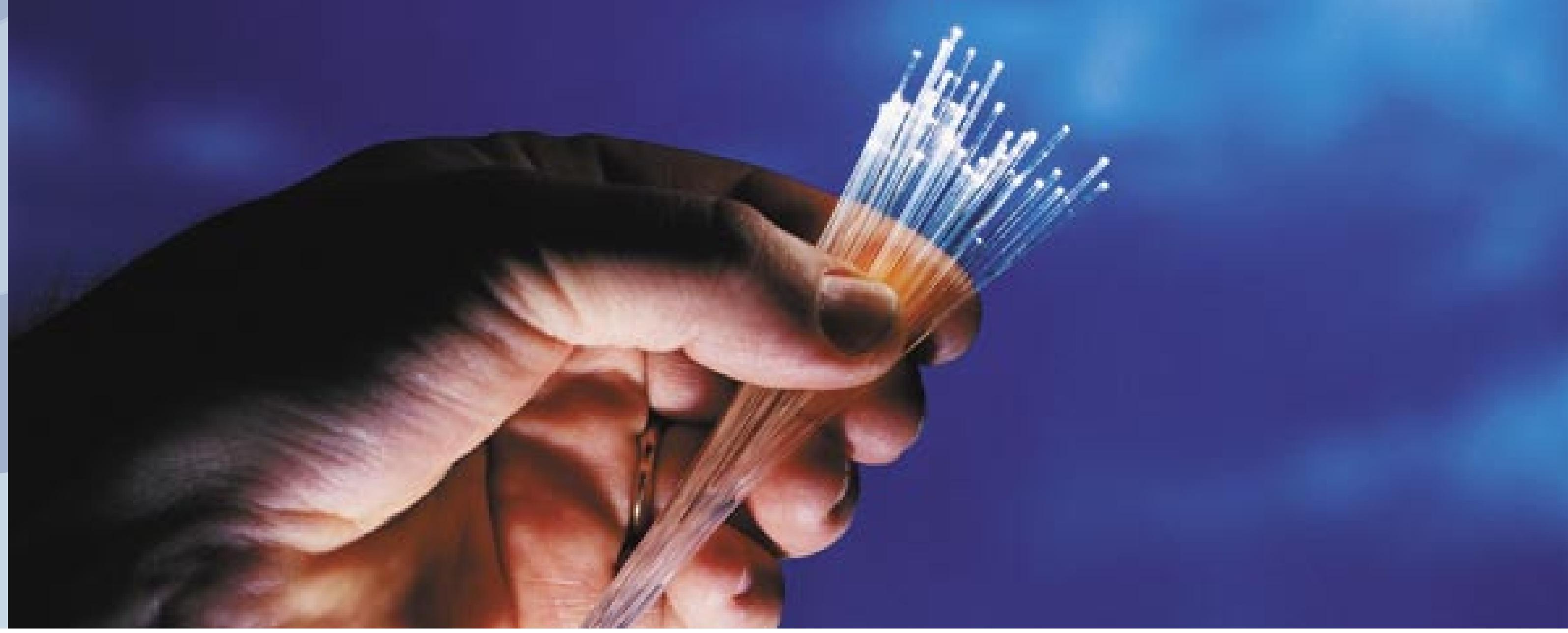
1 Executive summary



A holistic overview of the subject of patient safety can tell us a considerable amount about the organisation and management of health services, and the risks for citizens and patients implicit in such a system. **Our vision is to optimise patient safety and improve the quality of care across the whole health value system** including health promotion and disease prevention, personalised healthcare, good practice medical interventions, long-term care, clinical research, training and education.

The eHealth for Safety study takes a broad look at the information and communication technology (ICT) tools that can lead to higher quality of care, increased patient safety, and better risk management in health services and healthcare in Europe. It does so through a mix of desk research and provision of empirical evidence. It brings together into this mix the views of leading researchers and practitioners from around the globe from a series of high-level discussions and workshops.

As a result, this report outlines the whole field of ICT and patient safety as seen from our holistic vision. It includes appropriate definitions, gathers and analyses factual data, describes the main workshop outcomes, and then makes a definitive set of recommendations for future research on ICT and patient safety. Among the consistent roadmapping that is currently being undertaken in relation to European research, this report provides yet another vision of important, possible research directions.

The study examines the complementarities and overlap among patient safety, risk management, the study of medical errors, and quality assurance. It outlines the reality of patient risk and patient safety in practice. Based on a considerable stream of seminal clinical research, the twenty-first century began with the launch of two groundbreaking reports from **the United States Institute of Medicine alerting the public to the deplorable state of patient safety** and submitting recommendations for action. Internationally, these reports have formed the backbone of the rationale for global attention to the potential risks that patients run when they receive treatment in a country's health system or service. The influence of these reports has been substantial, and their figures and statistics are easily translatable into a European context.

The challenges to the patient undergoing clinical care are tremendous: travel - whether by air, rail, or car - or, e.g., chemical manufacturing are less dangerous to average citizens than are their encounters with a healthcare system. A 2005 report concluded that: "**medical errors are killing more people each year than breast cancer, AIDS, or motor vehicle accidents**."

Adverse drug events are among the most dangerous side-effects of medical treatment. In the Netherlands, over five per cent of all emergency admissions are related to adverse drug events, and four per cent of all the United Kingdom (UK)'s hospital beds are filled with patients who experience similar circumstances. The risk of such an adverse event occurring in a hospital seems to be higher, even considerably higher. The biggest risk of such an episode is death or severe long-term impairment. Figures, again from the Netherlands and the UK, can tell us the costs in terms of extra hospital bed days and compensation mechanisms. Are these human costs, and organisational costs, ones that we as Europeans are willing to bear?

How is Europe, on the one hand, to avoid such tragedies and, on the other, such obvious inefficiencies and waste of resources? Many of the answers are clearly systemic. This study therefore **covers a wide range of contemporary research and practice in the patient safety field** broadly defined. First, we need to understand the root cause of adverse medical events in order to avoid them or to deal with them; second, we also need to understand the methods that can be used to calculate their impacts and costs, in order to take the most targeted and specific of approaches to handling them; then, third, **we need to understand the role that ICT can play in this domain.**

This is the importance of this study: it shows us that ICT tools can enhance patient safety in three ways: they can help prevent medical errors and adverse events; they can initiate rapid responses to any event; and they can enable the tracking of events, if they occur, and provide feedback on them to learn from it. It is possible to use this approach both for the individual, and when wider public health trends, threats and challenges are at stake.

How to pursue and promote user-friendly, patient safety-enabling and risk-managing ICT systems, therefore? The particular fields of useful implications where implementation already appears to be taking place are many. In the case of clinical and organisational decision support systems, internationally, **there are over two decades of sound evidence** on their benefits. However, we should also explore the possibilities offered by: electronic healthcare records; computerised professional (physician) order entry systems; adverse event systems and alert systems; incident reporting systems; and so-called sentinel systems.

Yet, the theories and evidence show that patient safety does not just involve technical feasibility. Taking a wider, systemic view of patient safety is vital. It involves having a bird's eye view of the entire health system, its organisations, its legal and regulatory context, ethical challenges, and quality assurance methods. It is evident that a similar approach is becoming increasingly pertinent not only in the different regions and nations of Europe, but also at a European level. Illnesses and diseases do not necessarily stop at borders: the notion of a safe Europe without frontiers for its citizens and patients shows that both policy-makers and researchers need to think at a higher-level of granularity. In all European Union Member States **citizens are at the very centre of health services. Empowering, enabling and supporting them to stay healthy is surely the optimal way to foster patient safety.**

The study concludes that the **emphasis of research should be on topics like:**

- Patient safety-supporting ICT solutions coupled with profound process reengineering across health organisations
- Complementary new workflow, change management and human resource management tools
- Truly connected health information systems from the individual citizen/patient to organisational, public health and research levels
- New generation of advanced, user-friendly and ubiquitous tools for better integration of decision and work flow support systems with patient record and clinical information systems
- Integration of patient data across the continuum of care
- Knowledge representation and coupling across disparate knowledge domains
- Advanced terminology-driven eHealth tools for data entry and retrieval, including voice recognition and adaptable user interfaces
- Personalised simulation models of patients and diseases, leading to individual health risk analyses and early diagnosis, as well as personalised treatment
- Technology Assessment of eHealth systems, clinical and socio-economic validation of ICT applications
- Integration of clinical care with clinical trial and research records.

The efficiency of such research and the benefits to be derived can be leveraged through international cooperation. This includes cross-Member State collaboration on EU level as well as global partnerships. This was underlined by the various eHealth workshop organised by the project team or co-organised with the European Commission and the U.S. Department of Health & Human Services.

In summarising the main trends of this report, we want to emphasise one main set of facilitating elements, one main barrier, and a single overarching view.

Facilitating patient safety and enhancing risk management would benefit from a certification process for systems and applications being put into place, the interoperability issues of electronic health systems being addressed, and more applied research being done on patient and healthcare professional identification, authentication, and semantics.

A key barrier to the wider diffusion of patient safety ICT tools is user acceptance. Understanding better the sophisticated cognitive and socio-technical characteristics implicit in healthcare processes would result in designing safer work flows and healthcare systems for a wide range of healthcare professionals that would support improved clinical and organisational outcomes. ICT tools are enablers. As a fundamental component of a safer healthcare environment, they can support transforming healthcare processes.

However, **Europe also needs a holistic vision**. A strategy is required that can take into account the complex, organisational elements of Europe's health systems. **Safety for all is an imperative, whether we apply it to healthy citizens or to patients undergoing treatment**. Research and development in ICT can contribute fundamentally to finding solutions to these demanding questions that challenge the safety of our people.

"

People save people. Information technology can only improve the chances of doing that better.

"

Ilias Iakovidis, Deputy Head of Unit ICT for Health, European Commission

2 Introduction

In this report, we take **a broader look at the contribution that ICT tools can make to higher quality of care, increased patient safety and better risk management in healthcare**, and do not just concentrate on the reduction of medical errors and adverse medical events. We apply a broad definition of risk management with the intention of **optimising patient safety in a holistic fashion across the whole health value system**. This optimisation process occurs, first of all, through the provision of better information and prevention. Later, if this is not sufficient, and diagnosis and treatment become necessary, the process involves optimising the number and severity of clinical interventions in any course of treatment. A similar approach can also, mutatis mutandis, be applied to biomedical and clinical research, training and education and, indeed, to the whole of the public health information domain.

After briefly outlining relevant definitions, we present evidence on the various dimensions of patient risk and safety. Next, we lay out the most important findings from our desk research and follow with the findings from the empirical information gathering consisting of several workshops and expert interviews which validated, improved and complemented the desk research conclusions. The majority of the activities focused predominantly on innovative approaches and new and emerging technologies in order to provide a long-term perspective for advanced research.

In addition to technology oriented issues, a number of organisational, ethical, and economic aspects are highlighted as well as the value added of international cooperation and the establishment of a reference framework of good practices in implementation of ICT systems and solutions. Like in other industrial sectors, strong evidence suggests that it is not ICT in isolation that leads to benefits like improved quality of care, reduced errors and, at the same time, significant cost savings, but rather the "right" combination with complementary investment in working practices, human capital, and healthcare process restructuring. Integrative research into the combination of these factors would strongly contribute towards alleviating key barriers to successful implementation and diffusion of RTD results and lead to faster benefits realisation.

The result of the analysis of the empirical work of the study team is a vision and a set of recommendations for future research efforts on ICT and patient safety. These recommendations have already found their place in the preparations for the first call of the EU's 7th Framework Programme. They will continue to guide the EC in further calls related to the field of patient safety and risk management in ICT-related healthcare.

"

ICT systems that provide timely information can save live, improve the quality and efficiency of the health delivery system and contain the cost.

"

Viviane Reding, European Commissioner for Information Society and Media

3 Relevant **definitions**

Because *eHealth for Safety* addresses the research and technology development (RTD) needs that arise from the potential contributions of information and communication technologies (ICT) applications to enhancing both patient safety and health systems' risk management, we decided first to concentrate on an understanding of a number of important areas of research that underpin the notions of patient safety and risk management. This chapter therefore reviews the key terms that are referred to and used throughout this report.

The four issues of patient safety, risk management, medical error, and quality assurance may all overlap considerably. Therefore each of these categories is discussed in this report. Nevertheless, special emphasis is placed on patient safety and on risk management, as the focus of the study and current international research. Hence, we concentrate first on the two domains of patient safety and risk management.

Defining patient safety

There is, according to Baker and Norton[1], **no standard listing of the topics and areas included under "patient safety"**. Indeed, patient safety can be defined narrowly to include only issues specifically related to adverse events and their prevention. Or, it can be defined more broadly to include any aspect of healthcare and health services that may lead to patient injury, and any interventions, including clinical, organisational and policy changes that aim 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 been galvanised in recent years in many developed countries. This has also occurred globally also through the initiative led by the World Health Organisation[2] known as the "World Alliance for Patient Safety". The rate of development of patient safety programmes and initiatives has increased to the point that patient safety is now one of the most important issues in healthcare internationally. While many less tangible quality issues are open to debate, the need to improve patient safety through reduction in the incidence of potentially preventable harm, now appears to be difficult to argue against. Purely as an example, an internet search for "patient safety" in February 2004 revealed just over half a million results. The same search in March 2005 revealed 2,680,000 results - a five-fold increase in a little over a year's time.

The **five elements of patient safety** that most developed countries identify in their strategies for improving patient safety are:

- A 'just' or 'fair' culture that encourages a reporting and questioning culture that is complemented by systems for reporting and analysing incidents both locally and nationally.
- A good indepth analysis process to establish root causes for selected individual incidents and aggregate incident reviews which enables learning.
- A process to ensure that actions are implemented, and corresponding improvements in patient safety and quality of care can be demonstrated.
- Effective processes for sharing information at various levels - nationally, organisationally and clinically - for learning and improvement.
- A redefinition of both punitive and non-punitive compensation systems in the healthcare environment, and an assessment of their impact on the patient safety culture and its achievements.

To improve the understanding of the extent and impact of patient safety incidents, research projects have been carried out in various countries. As a result of these, several patterns and trends are emerging.

Information collated on international studies that involved retrospective reviews of patient records for in-patients, to determine the incidence of patient safety incidents. The data shows that the average incidence is 8.9 per cent and the average incidence of potentially avoidable adverse events is 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 the organisational learning needed to facilitate 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 healthcare provision can exist within individual countries, this information does, however, need to be interpreted with some caution.

In his article "The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human'", Wachter[4] points out that **improving safety requires a multidimensional approach**. He identified five major areas of activities and initiatives that marked the five-year period between 1999 and 2004. Although some of the efforts made may be seen as cross-cutting, they fall into the five broad categories:

- regulation
- error-reporting systems
- information and communication technologies
- the malpractice system and other vehicles for accountability; and
- workforce and training issues

On reviewing the key patient safety initiatives in several countries during the same time-period, other authors 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"** (Baker and Norton[5]). These authors highlight that each of these countries has established a high-profile committee with a mandate to examine patient safety, improve reporting, and develop recommendations to address system deficiencies. These efforts include strong support from the federal governments (and state governments in Australia). A wide variety of professional groups, employers, regulators, and healthcare providers have also initiated a wide range of efforts to address patient safety.

Defining risk management

There is a range of definitions for risk management which are derived from both the commercial work environment and from healthcare. Each reflects 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"**.[6] When applied to healthcare, this definition dispels certain misconceptions. These three main messages are that risk management:

- is not primarily about avoiding or mitigating claims; rather, risk management is a tool for improving the quality of care
- is more than simply about reporting patient safety incidents. Risks also have to be analysed, treated and monitored
- is not only the business of service managers, risk management is also the concern of working clinicians

Risk management therefore addresses four basic questions that are outlined in the figure below. Each question is complemented by an explanation of the contribution of each of the questions to risk management improvement[7]:

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)

We can differentiate between **four different levels of risk**, according to Reid and colleagues[8]. These are **individual risks, care member risks, healthcare organisation risks, and risk at the socio-economic level**. We explain these risks in greater detail:

- **Individual or patient risks**: these are potential compromises to the health of an individual caused by some action of the system.
- **Care team member risks**: these are occupational risks, such as exposure to disease, physical stress or difficulties, and workplace hazards such as exposure to toxic substances, radiation, or equipment malfunctions.
- **Healthcare organisation risks**[9]:
  - 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, reduced payment for services, or the risk of significant financial liability.
  - environmental risk, such as the risk of damage by forces external to the organisation.
  - 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, the lack of adaptability of organisation, and the misalignment of objectives.
- Risk management involves the analysis and assessment of risks, as well as the development of strategies to reduce risk, protect against losses, and ensure that the risks that are transferred from one agent to another are compensated fairly.

Managing risk in a healthcare organisation is therefore more about corporate design, and the improvement or changing of systems of work rather than being simply a staff function that is assigned to an office or to an individual whose post is labelled "risk management", as Knox (2002) points out. Integrating an awareness of risk into organisational and managerial culture and making it an explicit step in the organisational decision-making process is critical to the future successful management of corporate healthcare risk.[10] As an example, Figure 2 below suggests a list of triggers for incident reporting in maternity care.[11]

One way of identifying prospective risks in healthcare organisations is through a tool called Failure Mode and Effects Analysis (FEMA). For a good 'after the fact' approach to identifying what could have gone wrong in practice, the so called London Protocol has proved a useful tool. It outlines seven clear, key steps to risk assessment[12]:

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

How risk is communicated to patients is also of considerable importance. One study[13] found that patients preferred health risks to be framed in absolute terms, using bar graphs, and to be calculated over their expected lifetime. There was no clear preference by patients for presenting a treatment's effect on multiple outcomes.[14]

At the European level, the European Commission's Directorate-General (DG) Health and Consumer Affairs (known as SANCO) is working to identify, encourage and support both post-graduate trainees and scientists working in the public risk assessment area.[15]

We 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 and we review in somewhat more detail the FEMA analysis method as a key tool in systems engineering and human factor research.

SUGGESTED TRIGGER LIST FOR INCIDENT REPORTING IN MATERNITY

Suggested trigger list for incident reporting in maternity

Maternal incident	Fetal/neonatal incident	Organisational incident
• Maternal death	• Stillbirth > 500 g	• Unavailability of health record
• Undiagnosed breech	• Neonatal death	• Delay in responding to call for assistance
• Shoulder dystocia	• Apgar score < 7 at 5 minutes	• Unplanned home birth
• Blood loss > 1500 ml	• Birth trauma	• Faulty equipment
• Return to theatre	• Fetal laceration at caesarean section	• Conflict over case management
• Eclampsia	• Cord pH < 7,05 arterial or < 7,1 venous	• Potential service user complaint
• Hysterectomy/laparotomy	• Neonatal seizures	• Medication error
• Anaesthetic complications	• Term baby admitted to neonatal unit	• Retained swab or instrument
• ITU admission	• Undiagnosed fetal anomaly	• Hospital-acquired infection
• Venous Thromboembolism	• European Congenital Anomalies and Twins (Eurocat)	• Violation of local protocol
• Pulmonary embolism		
• Third/fourth degree tears		
• Unsuccessful forceps or ventouse		
• Uterine rupture		
• Readmission of mother		

Source: Royal College of Obstetricians and Gynaecologists (2005)

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**.[16] Medical error reduction is an international issue, as is the implementation of patient care information systems as a potential means to achieve medical error reduction.[17] The serious problem of medical error is not new. However, in the past, the challenges it poses were perhaps not as widely exposed and, certainly, did not get the attention they deserve.

The available data suggest that errors in medicine are frequent, and they result in substantial harm being done to patients.

Errors occur, however, not only in hospitals but also in other healthcare 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 there too. One area that has been paid a great deal of attention is that of the prescribing of medicines. For example, in a study of the work of the state's pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the Massachusetts alone.[18]

Nine basic, very general recommendations exist for a reduction of the frequency and consequences of errors in medical care[19]. They are to:

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

Of course, a certain number of these recommendations, such as the development of communicating systems and using systems in new or alternative ways, may in turn have side-effects that could affect the level of medical errors, if they are not well and thoroughly tested in their own right. It goes without saying that the highest level of judiciousness and caution should be used in all cases.

As a result of this wider analysis, three very **specific recommendations to reduce medical error** are to:

- implement provider order entry systems, especially computerised prescribing,
- implement bar-coding for medications, blood, devices, and patients, and
- use modern electronic systems to communicate key elements of asynchronous data such as markedly abnormal laboratory values.[20]

The importance of these recommendations for areas of potential patient safety development in Europe, such as ePrescribing, are paramount.

Defining quality assurance and improvement

The underlying rationale of quality assurance is that the health system must deliver the best possible outcomes for patients within the constraints of available resources. Citizens and patients expect the best possible healthcare. Quality and safety in patient care is a fundamental and primary obligation of all Europe's health services. Healthcare provision is complex, and it does carry risk of patient harm. Improving the quality and safety of care for Europe's citizens, and enhancing the clinical governance systems, are essential for a healthcare organisation that wishes to reduce harm and waste[21]. Care cannot be considered to be of high quality unless it is safe.[22]

Appropriate collection analysis and feedback of health information are essential to the building of a safer, better health system. The development of electronic health records is a complicated process, but it is an essential resource for safe, knowledge-based healthcare[23]. The exploration, piloting, and testing, of a possible unique electronic health record for Europe would be even more sophisticated a task. Quality and safety for patients therefore depends on a robust:

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

Let us take a single example of a country which places considerable focus on quality assurance in healthcare for its people. Quality improvement and assurance is an important feature of healthcare in Australia. Accreditation by the Australian Council on Health Care Standards was developed in 1974, with the intention of improving the structures, processes and out-comes of the country's health system. The evolution through quality assurance to continuous quality improvement led to the notion of clinical governance that emerged in the 1990s. Its fundamental purpose is the improving the quality and safety of care in the health system.

This is a key priority for healthcare in Australia locally and nationally, and even in its international relations. 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 MacArthur Health Service Investigation report found that the effectiveness of crucial quality and safety systems, such as incident reporting and complaints management, had been limited and made ineffective by a considerable 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 healthcare 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, and
- inadequate resourcing of key quality and safety systems and personnel[24]

The effectiveness of many **quality improvement interventions** has been studied. Research suggests that most interventions **have highly variable effects which depend heavily on the context in which they are used and the way they are implemented**. This finding 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 a single technique carefully, and then persevere to make it work.

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

Thirdly, **some element of evaluation should be incorporated into every quality improvement programme** so that their effectiveness can be monitored and the information can be used to improve the systems for improvement.[25]

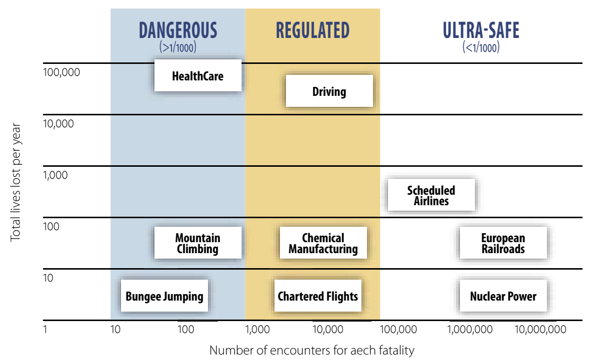
> *Focusing on patient safety may give different orientation/ priorities to software development from the 'productivity/logistics' approaches currently dominating, but it is not necessarily in competition with those.*
>
> *Ilias Iakovidis,* Deputy Head of Unit ICT for Health European Commission

4 Patient risk and safety in **practice**

Since the publication in the United States of America of two Institute of Medicine reports at the beginning of this century, To Err Is Human[26] (2000) and Crossing the Quality Chasm[27] (2001), patient safety issues have received considerable attention internationally. The first report includes an estimate that **systems' failures in healthcare delivery** (i.e. poorly designed or "broken" care processes) **are responsible for between 44,000 and 90,000 deaths in the US each year**. The second report reveals **a wide chasm between the quality of care that the US health system should be capable of delivering**, given the astounding advances in medical science and technology in the last fifty years of the twentieth century, **and the quality of care that most Americans actually receive**.

The risks that people are exposed to when they enter a healthcare system are underestimated intuitively. Research compares contacts with the healthcare system with other potentially risky activities. Travel by rail in Europe and commercial air travel are 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 car accidents. It is no surprise that, statistically, mountain climbing and bungee jumping are among the most dangerous physical activities. The most striking result of all is that there are more deaths per encounter with a healthcare system than for most of the other activities.[28]

RISK OF FATALITY IN DIFFERENT DOMAINS



Source: AHRQ, 2005 / Commission on Systemic Interoperability, 2005

Most of the available evidence on patient safety comes from the US. In Europe, the Institute of Medicine study (2000) often serves as a benchmark to allow the extrapolation from micro-level results in order to arrive at an estimate of the overall incidence of adverse events at the various national levels.

The size of the challenge

The incidence of adverse events that result in injuries or other types of harm is widespread. In the US more than one million patients experience injuries each year as a result of these 'broken' healthcare processes and system failures.[29,30] In the United Kingdom (UK), the Department of Health estimates that one in ten patients admitted to national health service hospitals are unintentionally harmed[31] **Patient surveys also reveal a worryingly large incidence of medical errors**. In a recent international survey released by The Commonwealth Fund[32], patients were asked whether they believed they had experienced a medical mistake in treatment or care, were given the wrong medication or dose, were given incorrect test results, or had experienced delays in receiving abnormal test results. Thirty-four percent of US respondents reported at least one error. Thirty percent of the Canadians who responded also claimed at least one such error. Twenty percent of Australians, 25 percent of New Zealanders, 23 percent of Germans, and 22 percent of people in the UK made similar allegations.

Although these numbers are striking, they 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 are more likely to be smaller. The effect of extensive inclusion criteria on international patient safety statistics is illustrated in 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 Feasability Study	23	1974	20.864	4.65*
Harvard Medical Practice Study (HMPS)	51	1984	30.195	3.7
Utah-Colorado Study (UTCOS)	28	1992	14.052	2.9
Quality in Australian Health Care Study (QAHCS)	28	1992	14.179	16.6
United Kingdom	2	1999	1.014	10.8
Denmark	17	1998	1.097	9.0
New Zealand	13	1998	6.579	11.2
France**	7	2002	778	14.5
Canada	20	2000	3.745	7.5

* The California study assesed "potentially compensable events"

Source: Vincent (2006), p. 42

Here, the Australian data are surprisingly high. This anomaly can be accounted for by the wider range of adverse events included in the study: since adverse events occurring outside the hospital were also included, and the overall focus of the study was on the quality of care delivered rather than negligence. Thus, minor complications such as wound infections, skin injury or urinary tract infections were included; these were, however, elements which were discarded by the American studies.[33] It has been also said that the better information that was gathered from the Australian medical records could explain the differences.

The challenge of measuring adverse drug events

Adverse drug events and adverse drug reactions are the subject of many international studies. Many of the studies date from the period between 2003-2006. They represent a major sub-group of patient safety issues.

These studies are distinguished from the larger category of medication error studies, since the latter may or may not lead to an adverse drug event. Medication error studies assess whether a drug was prescribed and administered correctly with or without actual or potential harm to the patient. Adverse drug event studies, on the other hand, focus on the harm that may or may not be caused by an error.[34] Assessing the real extent of adverse drug events is difficult. There are several reasons for this. The first reason concerns the overemphasis on in-patients in hospitals in most studies. A second reason is concerned with the differences in the types of incidents reported: they either focus on adverse drug events that take place while in hospital care, or include the adverse drug events that led specifically to hospital admission. Further difficulties arise when the focus of a study is on a particular age group of patients, for example the over-65 years old.

A literature review study from 2003 on hospital adverse drug events that combines data from ten studies found that the median incidence of preventable adverse drug events is 1.8% with a range from 1.3% to 7.8%.[35] This figure is in line with estimates from the Netherlands where the number of hospitalisations for adverse drug reactions was analysed in a 2001 study. Lithe study found that 1.83% of all hospitalisations are related to adverse drug reactions.[36] A later study from 2006 called the HARM study, which covers 21 out of around 100 Dutch hospitals over a 40-day period, found that medication-related admissions amounted to 2.4% of all admissions and 5.6% of emergency admissions.[37]

A study of hospital admissions in the UK, published in 2004, shows that 6.5% of people admitted to hospital experience an adverse drug event. In 80% of cases, the adverse drug event is the direct cause of the admission. Patients with adverse drug events occupy 4% of the UK's national health service hospital bed capacity.[38] Preliminary data from an ongoing study at the Royal Liverpool University Hospital indicate that about 16% of patients experience an adverse drug reaction as hospital in-patients. In line with these preliminary UK data, a small US study finds that around 25% of out-patients experience an adverse drug reaction; in many instances these are either preventable or ameliorable.[39] Many adverse drug events are also experienced by patients when they are being treated in either primary care or as out-patients. It is difficult to quantify the actual prevalence of adverse drug reactions. **There has also been little research undertaken into the incidence of adverse drug reactions in patients treated in primary care.**

The overall rate of preventable adverse drug events **in the US** is estimated at 1.5 million preventable adverse drug events each year. In hospitals, **figures vary between 380,000 and 450,000 preventable adverse drug events a year, based on conservative estimates.**[40] In ambulatory care 530,000 preventable adverse drug events have been projected for out-patient Medicare alone.[41] A meta-analysis of adverse drug reactions in hospitalised patients in the US found that the overall incidence on admission and experienced while in hospital to be 6.7%. Fatal adverse drug reactions constitute 0.32%.[42]

In Spain, a National Study of Adverse Events related to Healthcare in Hospitals (ENEAS) estimates that **medication-related adverse events accounts for 37.4% of all adverse events.**[43] In both the Dutch and Spanish studies, the vulnerability of older patients to adverse events. in general, and adverse drug-related events, in particular, is highlighted. The HARM study indicates that **patients who are older than 65, have a twice-higher frequency of drug-related hospitalisations than younger patients**. The Healthcare Quality Report for **the Netherlands found that one in five of independently-living elderly persons is prescribed at least one potentially hazardous medication a year**. This finding may concern medicines that are unsuitable for elderly persons or that should be prescribed in a smaller dosage for them.[44] The particular vulnerability of Dutch patients aged 65+, who were two times more likely to be subject to an adverse event, is confirmed in the ENEAS study.[45] However, these findings should not come as a surprise, given that many older peoples' medication regimes often involve taking more than one form of medication, and combination of drugs can be difficult to manage.

In summary, the available evidence suggests that **adverse drug events should be a cause for serious concern**. Although there are important methodological difficulties, the evidence suggests that between 2% and 8% of hospitalised patients experience an adverse drug event. **Elderly people older than 65 years old have a risk which is twice as high as people from younger age groups**. It is, on the other hand, difficult at this stage of data collection in Europe to get a clear idea of the differences between adverse drug events during patients' hospitalisation as opposed to adverse drug events that occur prior to the hospitalisation. Since hospitalisation may be directly dependent on an adverse drug event that has occurred in the home or through primary care treatment, there should be a clear distinction made in future data collection between adverse drug events that happen:

- during patient stay at the hospital due to in prescription
- as a cause of hospitalisation due to errors of prescription or administration

Estimating the costs of adverse events

Measuring the cost of patient safety-related incidents is extremely difficult. Costs affect not only healthcare providers, in terms of prolonged hospital stays or increased re-admission rates, but they also affect society as a whole through, for example, earnings lost due to prolonged illness. In US terms, if patient safety-related incidents are conceptualised as one indication of bad care processes, resource waste, and poor communication, then an estimated thirty to forty cents of every US dollar spent on healthcare, or more than half a billion dollars a year, is spent on system failures, unnecessary repetition, poor communication, and inefficiency"[46]. Costs for hospital adverse drug event errors are estimated at between $US 2.3 billion (1993 value) and US$ 3.5 billion (2006 value), and at US$ 887 million for ambulatory care-related adverse drug events. However, these calculations do not take important cost factors like costs of morbidity and mortality, or lost earnings and compensation payments, into account. Thus, they are likely to be underestimates.[47]

In the UK, **patient safety incidents cost the national health service an estimated £2 billion a year in extra bed days**, and 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 at end of that year were in excess of £2 billion. Adverse drug reactions in the UK national health service create an annual cost to the service of £466 million.

In the Netherlands, a study carried out by WINAP (a scientific institution of pharmacists) shows that the costs arising from over 90,000 hospital cases of errors in medication amounted to €300 million each year[48]. **Extrapolated cost estimates for adverse drug events in the Netherlands puts the costs at €76 million a year.**[49]

Preventable adverse events

There are relatively few discussions about "whether errors are by definition preventable or whether every preventable adverse event is necessarily associated with an error" (Kanjanarat and his colleagues).[50] Most studies assume that a distinction can be made between adverse events which are the result of an error, and are thus preventable, and events which "cannot be prevented given the current state of knowledge."[51] Given both the high costs and the high incidence of adverse events, it is startling to note the preventability ratios of adverse events. For example, **in the UK, the Department of Health estimates that one in ten patients admitted to its hospitals will be unintentionally harmed**[52], a rate similar to other developed countries. Around 50 per cent of these patient safety incidents could be avoided, if only lessons from previous incidents were taken into account.[53] A small study in the US found that around 25 per cent of out-patients experience an adverse drug event and that, in many instances, these were preventable or ameliorable.[54] **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.**[55] Of these hospitalisations, 46% are assessed as being potentially preventable. If the results of this study are extrapolated to all Dutch hospitals, 41,000 of hospitalisations annually are drug related; and 16,000 drug-related admissions are preventable. A retrospective study of patient records in two English hospitals found that 10.8% of patients experience an adverse incident, of which around half are judged to be preventable.[56]

Estimating the number of deaths caused by adverse events

The most extreme effect of adverse events in healthcare is death. In its 2005 report entitled "*Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*"[57], the US Commission on Systemic Interoperability points out that **medical errors are killing more people each year than breast cancer, AIDS, or motor vehicle accidents altogether**.[58] In its groundbreaking, turn-of-the-century, report "To Err is Human", the US Institute of Medicine estimated that systems failures in healthcare delivery were responsible for some 44,000 to 90,000 deaths each year.[59] 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 UK, an analysis of hospital trust surveys found that **169 trusts can provide data on the number of deaths that result from patient safety incidents**. Between 2004 and 2005, there were 2,181 deaths recorded, even though it is acknowledged that there is a significant under-reporting of deaths and serious incidents.[60] The available evidence on deaths related to adverse drug events in the UK indicates that over 2% of those patients who were admitted to hospital with an adverse drug event died.[61] 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%.[62]

Causes of adverse events, and their solutions

If we want to arrive at a complete explanation of the causes of adverse events, the role of incomplete or missing information, and organisational factors, has to be taken into account. Most research on the causes of adverse events places a **high responsibility on systemic failures: that is, deficiencies in system design, organisation and operation, rather than on errors made by individuals**. Institutional factors of which we should be aware include an organisation's strategy, its quality management tools, and its capacity to learn and adapt.[63] The critical role of information is highlighted when it comes to medication-related adverse events. According to the US Institute of Medicine, over half a million people are injured each year because of adverse drug events. Many of these could be avoided if healthcare providers had more complete information about which drugs their patients are taking and why.[64] Similar observations are made in the Dutch Healthcare Performance Report of 2006. Out-of-hour pharmacies, the report notes, lack access to patients' complete medical history. As a consequence, the level of care delivered is substandard, and increases the risks of adverse drug reactions.[65]

In a 2002 survey, two reasons for medical errors were given by both US physicians and the US public: shortage of nurses (commented on by 53% of physicians, and 65% of the public) and overworked, stressed and fatigued healthcare providers (mentioned by 50% of clinicians, as opposed to 70% of the public). The public also cited that too little time was spent with physicians (72%), and the fact that clinicians do not work as a team or communicate insufficiently (67%).[66]

The Institute of Medicine study (2000) suggests that **several ICT possibilities exist in order to reduce the adverse drug event rate**. In a hospital setting, these solutions include Computerised Physician (Professional) Order Entry, Decision Support Systems, and bar coding applications. In particular, electronic prescribing and monitoring for errors in all care settings is seen as essential. In addition to these technical components, improved provider-patient communication is a key component.[67] A consensus is also emerging on possible solutions to improve patient safety. **Hospital executives in Australia, Canada, New Zealand, the UK and the US outline several suggestions for improved quality of care, many of which feature prominently ICT tools**[68]: Bar coding medications is considered a very effective measure by a considerable majority of respondents, ranging from 62% in the US to 36% in Australia. Standard treatment guidelines finds the highest support among respondents. Between 43% and 59% of respondents consider this a very effective measure. Similar high levels of support are found for the 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**: firstly, by preventing errors and adverse events; secondly, by facilitating rapid responses after an adverse event; and, thirdly, by tracking and providing feedback about adverse events.[69] As an example, in a controlled trial, Computerised Physician Order Entry Systems are found to reduce serious medication errors by 55%.[70] On a more fundamental level, **ICT tools help to compensate for and address failures in communication, which are the most common factor that contribute to adverse events.**[71]

Although these insights are now entering the mainstream, a status report on patient safety efforts undertaken five years after the publication of the Institute of Medicine "To Err is Human" report[72] found that Computerised Physician Order Entry Systems are only fully implemented by 34.2% of the survey's hospitals. A substantial number of hospitals had, however, 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.

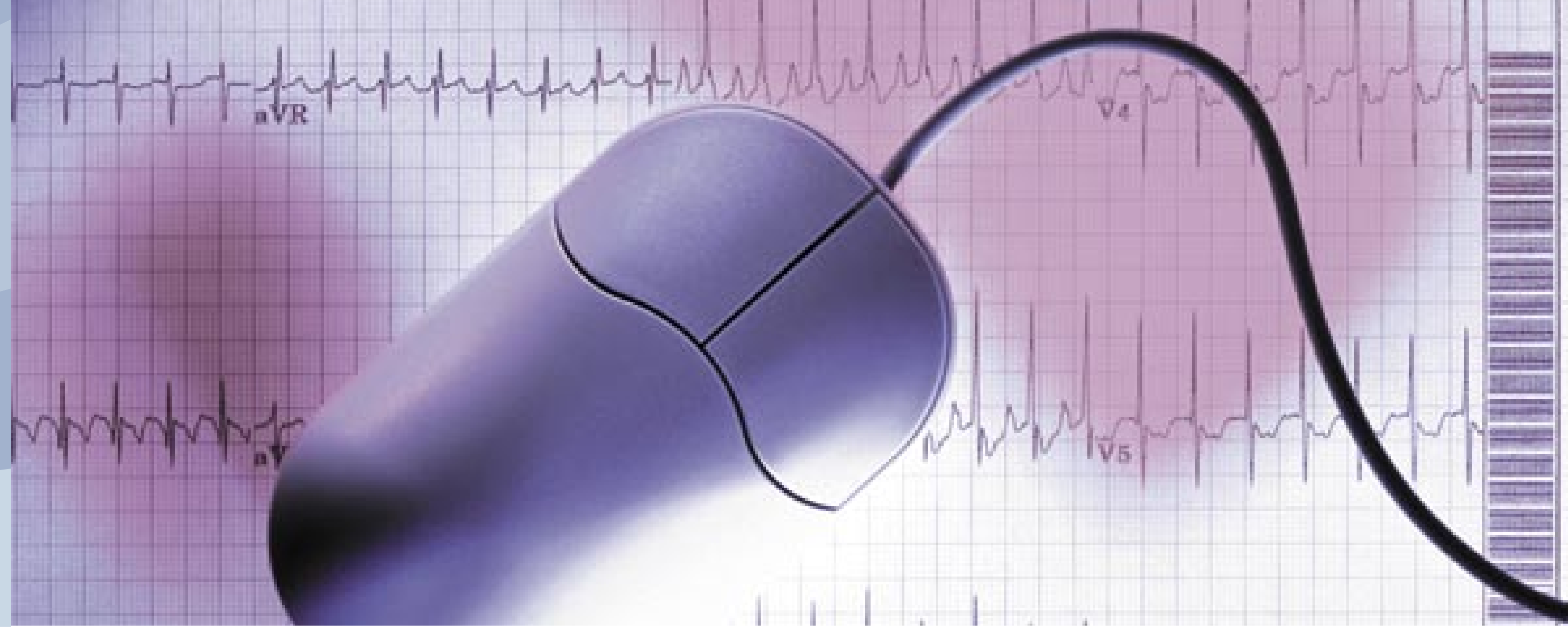
"*Avoiding unnecessary suffering has become a high priority of health policies*"

Gérard Comyn, Head of Unit ICT for Health, European

"*Knowledge and technology in healthcare evolve faster than our work culture, processes and systems. We need to explore the human, environmental and cultural factors, and better understand these complex processes.*"

Zoi Kolitsi, Ministry of Health and Social Solidarity, Greece

5 ICT applications in healthcare



This chapter gives an overview of those ICT applications that are currently or could potentially in the future be used in healthcare and that could either enhance the level of patient safety or could improve the degree of risk management in healthcare. The chapter later examines what these findings mean for the field of patient safety research, and discusses implications for the future.

ICT in healthcare: a review of the evidence

Many ICT applications are currently available in healthcare; here we review a set of five applications. In the following sub-sections, we offer a detailed review of literature on important ICT applications. We start with the implementation of electronic health records, and progress through the range of decision support systems, computer physician order entry, adverse drug event and alert systems, and incident reporting systems, and sentinel systems. As a result, we concentrate on the aspects of those systems, and the analysis of their findings, that can **enable future pursuit of user-friendly, patient safety-enabling and risk-managing ICT systems.**

What appears to emerge is that eHealth applications in the area of patient safety show a potential benefit if the implementation conditions are carefully evaluated and planned. **While implementation needs to take into account the technical feasibility, it must also maintain awareness of all those issues that are related to the culture, organisation, legal and regulatory conditions, ethical issues, and quality assurance**. Future research is also needed into the ICT themselves, behavioural aspects of ICT use, and the use of appropriate evaluation and monitoring methodologies. Moreover, **the coordination and integration of already existing technologies also seems to be a promising field of research** for the area of patient safety and risk management.

Electronic health record implementation

In many European countries, **one of the most important developments in eHealth in recent years has been the spread of implementation of electronic health records** at all three, national, regional and local levels.

In the UK, the National Programme for Information Technology (NPfIT) in the national health service is delivered by the Department of Health's agency, the national health service's Connecting for Health. The roll-out of the national care record system is expected to be fully functional by 2010. Most UK hospital trusts foresee that this roll-out will help them to ensure **that patient records are not lost** and that there are **better controls over the prescribing of medicines**. In the UK, these two issues have in the past led to significant numbers of patient safety incidents. The UK National Audit Office underlines the **key role that information technologies should play in improving patient safety** by helping not only to avoid medication errors, to support retrospective audits, but also to provide information to healthcare professionals. The National Audit Office notes that Connecting for Health, the agency tasked with delivering the NPfIT, has asked the UK National Patient Safety Agency to assure the programme's specifications. It would like to ensure that **patient safety is an inherent feature of the system. In the UK, therefore, ICT is seen as an important facilitator of patient safety**. In its evaluation of the activities conducted so far in the country, 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."[73]

On the US side, the Institute of Medicine advises that **moving from a paper to an electronic based patient record system would be the single step that would most improve patient safety**. The US national health information infrastructure (NHII) was created to overcome the ICT deficit in healthcare. The goal of the national health information infrastructure is to be a secure, reliable, and adaptable national infrastructure. It must be capable of connecting and supporting highly distributed, varied, independently-managed, multi-tiered, intra-institutional, clinical information or communications technology systems and applications.

While the implementation of comprehensive electronic healthcare record systems has lagged behind in the US, considerable progress has been made in certain areas, such as computerised reporting of laboratory results. Two cases of the use of electronic healthcare records have been documented by Reid et al.[74] The Veterans Health Information Systems and Technology Architecture supports a continuum of care, from intensive care units and other in-patient areas, to out-patient care settings, long-term care settings, and homecare environments. The Veterans Health Administration Computerised Patient Record System provides **a single interface where healthcare providers can review and update patients' medical records**, and place orders for medications, special procedures, x-rays, imaging, nursing care, dietary requirements, and laboratory tests. The Automation of the Clinical Practice Project at the Mayo Clinic in Jacksonville, Florida in the US, which was initiated in 1993. It had as its objective to switch to the **paperless practice of medicine** in order to improve patient safe, enhance physician effectiveness, and reduce expenses. The clinic's last paper-based record was circulated in the clinic three years later in 1996. By only 2002, 445,000 patient visits were conducted using a computer-based patient record.

Decision support systems

Decision support systems are wide-ranging solutions which **incorporate a variety of eHealth applications.** In particular, decision support systems and Computer Physician Order Entry (which are dealt with separately in the next section) are highly complementary to each other, and should ideally be incorporated in a single solution. Due to the broadness of the field of decision support, several definitions of decision support system are available. At a general level, decision support systems can be described as a "**computer based support for management decision makers who are dealing with semi-structured problems**."[75] There are, however, two types of decision support systems: business and clinical. These two types of systems differ significantly in intent and content but, at the same time, they share many common elements. Potentially, these enable useful synergies to be established through the integration of clinical decision support with business decision support.[76]

According to Liu et al (2006), a '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."[77] This definition is an updated and more general version of Wyatt and Spiegelhalter's 1991 definition of computer decision aids that are "active knowledge systems which use two or more items of patient data to generate case-specific advice".[78]

Safety in the clinical environment is based on three issues. Firstly, it is 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 while **protocols** that incorporate more complex rules reduce the clinical decision error rate. When explicit computerised protocols are driven by patient data, the protocol output or instructions is patient-specific. Thus, it provides individualised treatment while it standardises clinical decisions. The expected decrease in variation and increase in compliance with evidence-based recommendations is intended to decrease the error rate and enhance patient safety.[79]

Since decision support systems date back as far as 1974, **many different reviews of the evidence collected** of the use of decision support systems in clinical contexts have taken place in the thirty-year period since its first developments. The most important of these are highlighted in Annex 1.

Most recently, it has been noted that **decision support systems' developers need to become more aware of regulatory issues**. For example, although decision support systems are currently exempt from regulation in the UK, unlike the closed-loop systems that measure patient variables and adjust a drug infusion device automatically, this may change[80]. The National Institute for Health and Clinical Excellence in **England is currently piloting methods to test the clinical and cost effectiveness of decision support systems**[81]. If this pilot becomes a permanent element of the National Institute for Clinical Excellence work programme, it will act as a regulatory addition to the introduction of decision support systems into the UK national health service.

Computerised physician order entry

Computer Physician Order Entry (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, these orders were either hand-written or communicated verbally, which led to medical errors.[82] Clinical decision support systems are built to varying degrees into almost all CPOE systems, and they provide basic computerised advice regarding drug doses, routes and frequencies, and on more sophisticated data such as drug allergy, drug-laboratory values, drug-drug interactions, checks and guidelines.[83] CPOE can be applied in a variety of physical and technical environments that use currently available vendor software. However, CPOE can also be very resource-intensive, time consuming, and expensive.[84]

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 the history of drug interactions or allergies can **reduce prescribing errors significantly**.[85] CPOE systems also improve the quality of care by **increasing clinician compliance with standard guidelines** of care, and thereby reducing variations in care.

A 2001 debate which took place at the American College of Medical Informatics[86] focused on the proposition that a **US national regulatory mandate** of computer-based provider order entry - to take effect by the end of 2005 - would bring greater benefit than risk for healthcare delivery. Both sides accepted that provider order entry offers potential benefits. Those supporting the proposition emphasised the benefits to public safety, and noted that payers have little economic incentive to pay for quality whereas such a mandate would force vendors to improve the usability and value of their systems.

Four studies on CPOE combined with decision support systems were analysed by Kaushal and Bates[87]. Of these, a first study found a 55% decrease in serious medication errors. As a secondary outcome, this study found a 17% decrease in preventable adverse drug events. The second study, a time series analysis, found marked reductions in all medication errors excluding missed dose errors and non-intercepted serious medication errors. Correcting for the number of opportunities for errors, the total number of adverse drug events/100 patient days decreased from 14.7 to 9.6 ($p=0.09$). For the sub-category of preventable adverse drug events, the reduction from 5 to 2 achieved borderline statistical significance ($p=0,05$).

Overage et al's study, on the other hand, shows a greater than 100% improvement in the rate of corollary orders ($p<0.0001$). Four concrete benefits of CPOE are outlined by Overhage and his colleagues[88]:

- Improvement of clinical processes which decrease lost orders, transcription time, and cost.
- Reduction of ambiguity due 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 intervals.
- Decrease in test redundancy; and improvement in consequent, contingent, and corollary orders.

Five prescribing improvements in types, doses and frequencies of drug use were demonstrated by Teich and colleagues[89]. All the systems analysed were developed in-house and were 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 by doctors when prescribing decisions could avoid many errors which result in patient harm, and could save a considerable percentage of a country's drugs' bill[90]. Considering the impact of CPOE on medication administration processes, pharmacies have been identified as important players in this field. Certainly, pharmacies 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's data fields.[91] At the Wirral Hospital NHS Trust in the UK, the introduction of structured, ICT-supported medication-handling pathways reduced drastically errors in the prescription of specific high-risk drugs. For instance, an error rate of 82% in the prescription of low molecular weight heparin (that was 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 patients' bedsides**.

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 management 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 technical 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 computerised ordering a more satisfying experience.

The report "*Computerized Physician Order Entry: A Look at the Vendor Marketplace and Getting Started*" (2001)[92] provides a starter set of information for decision-makers in hospitals to help them to organise their CPOE effort, and to 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 the First Consulting Group. Specific clinical decision support features of CPOE are identified from previous contacts and conversations with a number of CPOE pioneers.

The California HealthCare Foundation and First Consulting Group also sponsored a research study to provide information about **CPOE implementation in a community hospital setting**.[93] The research focuses on how community hospitals can implement a CPOE system, work with a universal CPOE, and how CPOE can best be incorporated in hospital order management. They conclude that careful planning that includes good technology management is necessary, and should also include good communication. Similarly, in their analysis of CPOE implementations, Sittig and Stead (1994)[94] 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 CPOE systems is a complex undertaking, Kuperman *et al* (2003)[95] warn that it should not be the first computerised clinical system to be implemented by an organisation. Implementing CPOE is a large enough project in its own right; so, organisations should be wary of undertaking other major administrative or clinical information system projects concurrently. Furthermore, vendor offerings are evolving rapidly, so purchasers must take care to understand the details of the particular software involved. 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 organisations do not currently measure rates of medication errors and adverse drug events. CPOE should be viewed as **supportive technology for such organisational initiatives as quality improvement, patient safety, and cost reduction**. CPOE system should additionally be considered **part of an organisational strategy** to achieve such objectives rather than purely as an information technology initiative.

Indeed, some authors have drawn attention to the potential dangers of CPOE systems' use. Studies in Australia, the US, and UK 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."[96] Han *et al* (2005)[97] found an unexpected increase in child mortality after the introduction of a commercially-sold CPOE 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)[98] add that, while emphasis has been placed on medication error reduction through CPOE, less focus has been put on the existence of types of medication errors facilitated by CPOE. They found that **CPOE actually facilitates 22 types of medication error**, for instance, through fragmented CPOE displays that prevent a coherent view of patients' medication history. Similarly, Handler and colleagues[99] (2004) find that, while CPOE and decision support systems can reduce certain types of errors, they may also slow down clinicians and increase other types of error. To ensure success, **seamless integration of**

CPOE and decision support systems into systems and workflows is necessary.

More research is certainly 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 can provide valuable research input.

Adverse event systems and alert systems

Whereas CPOE systems aim to prevent errors, **computerised adverse event systems aim to monitor the occurrence of instances which could be adverse events** and to alert clinicians when certain indicators are present. The most common adverse events are nosocomial infections and adverse drug events; consequently, ICT systems have been tested primarily in these areas.[100] Most institutions use spontaneous incident reporting (which relies exclusively on voluntary reports from the nurses, pharmacists and physicians who are focused on direct patient care) to detect adverse drug events; however, this method is generally regarded as ineffective since it only identifies about one in 20 events.[101]

Conversely, most ICT trials have found a **significant increase in the number of adverse drug events that are reported. Automatic alerts** can also **improve the time until treatment is ordered for patients with critical laboratory results**.[102] Tools such as event monitoring and natural language processing can detect inexpensively certain types of adverse events. These approaches already work well for some types of adverse events, including adverse drug events and nosocomial infections, and are in routine use in some hospitals. **These techniques seem to be well adapted to the detection of broad arrays of adverse events, in particular, as more information becomes computerised**.[103]

In a review article, Gandhi and Bates[104] report on one study that demonstrates **significant decreases in adverse clinical outcome with alert systems**, particularly regarding allergic reactions. Significant improvements in response times concerning laboratory values were reported by several studies. Another study reports significant decreases in the risks related to serious renal impairment. Furthermore, significant changes in physician behaviour and modification of therapy were reported based on alerts with recommended actions:[105]
Developing and maintaining a computerised screening system generally involves at least three 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 International Classification of Diseases (ICD)-9-CM and Current Procedural Terminology (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 in-patient order entry systems and ambulatory care systems. However, this information is rarely available in coded form even with the growing popularity of workflow-based systems.[106]

Computerised **adverse drug event 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 Partial Thromboplastin Time - PTT) or laboratory levels alone (e.g. elevated digoxin levels) that frequently reflect an adverse drug event. Simple versions can be implemented with pharmacy and laboratory data alone, although the yield and positive predictive value of signals is higher when the two databases are linked.[107]

Kuperman *et al* (1999)[108] 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 they confirm the potential for such technologies to improve quality of care. 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, a 720-bed tertiary care hospital in Boston, Massachusetts in the US.

With **in-patients**, hospital information systems can be used to identify adverse drug events by looking for signals that an event may have occurred and then alerting someone – usually a clinical pharmacist – to investigate. A problem with the broader application of these methods is that computer monitors use both drug and laboratory data and, in many hospitals, the drug and laboratory databases are not integrated. Nonetheless, this approach can be successful in institutions with less sophisticated information systems by downloading information from both systems to create a separate database. Fewer data are available regarding adverse drug event rates in **out-patient settings**.[109,110] It has been suggested that electronic medical records may facilitate information gathering on out-patients, using similar methods as in an in-patient setting. The Decision Support System Design and Implementation for Outpatient Prescribing: The Safety in Prescribing Study examines the effectiveness of decision support (i.e. alerts and reminders) for reducing potential medication errors for out-patients[111], with these 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 are seen as more helpful than more routine health maintenance alerts. Alerts that appear in an inappropriate place in the workflow are subject to override, whereas alerts during medication prescribing are generally viewed as more helpful.
- Prescribers prefer alerts related to drug interactions, appropriate medication dosing, and patient allergies.
- Small differences in alert text could improve the clarity significantly, and possibly the acceptance of alerts.

In an evaluation that included one year's data from electronic medical records for 23,064 patients, including 15,665 patients that came for care, 864 annual drug events were identified[112]. Altogether, 91% of the events were identified using text searching, 6% with allergy records, 3% with the computerised event monitor, and only 0.3% with ICD-9 coding. The dominance of text searching was a surprising result, and it emphasises the importance of having clinical information available in an electronic medical record even if the data are not coded.

The current approach used by most organisations to detect adverse events – spontaneous reporting – is clearly insufficient. Computerised 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 enable the 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** is that they **can be used to detect the frequency of adverse events, and to develop methods to reduce the number of such events**.[113]

However, computerised 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 them to 'alert blindness'. Hence, the clinician may not identify the most relevant and important details or, worse still, might switch off the alerts altogether and put patients' lives further at risk.[114] However, studies thus far suggest that **physicians view computerised alert systems favourably**. In one study, 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.[115]

Incident reporting systems

On a larger scale, several countries have already implemented or are considering national or regional **incident or event reporting systems** – 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 bio-surveillance, and fast alert and pattern-tracking in case of a bioterrorism attack or an epidemic outbreak. The benefits of 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**: these systems 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 notified automatically 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 track trends of disease and injury accurately. 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 determine accurately 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 get the most up-to-date information on vaccines and treatment for biological threats. They could coordinate their work more efficiently with hospitals and clinics, and all healthcare providers could find more easily 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 (called AIMS) was set up in 1987, initially only in the field of anaesthesia.[116] In the five years of operation until 1992, **2,000 incidents had been collected and reviewed**, which had **led to significant changes** at the local and national levels. One example 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. The information contained in the database 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. In the analysis of the 2,000 incidents collected in the database, it was recognised that there was no clinically useful **comprehensive information for "things that go wrong in health care"**. It was thus decided to develop such a classification; a framework was created into which all iatrogenic events could be classified. In the year 2,000, 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, to be useful to specialists, to be accessible on the web, and to be suitable at both the national and local levels. Through their experience with AIMS over the past twenty years, Australians have learned a number of lessons, and have identified certain needs, that can be classified briefly into a list of **eight issues**:

- Put patient safety and reporting and surveillance systems in context
- Create common tools and terminology
- Set priorities and to act on the local, national and international levels
- Create large repositories to collate information from many sources
- Build a just system
- Create separate processes for accountability and for "systems learning"
- Ensure feedback and the evidence of action
- Involve and inform healthcare professionals, consumers and the public at large.

In the UK, the **National Reporting and Learning System** has been set up in the framework of the National Patients Safety Agency. The National Reporting and Learning System collects **reports of patient safety incidents and their root causes**, in order to learn from them and to develop solutions to enhance safety. The system receives reports about patient safety incidents from national health service organisations throughout England and Wales. 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.[117] 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 the achievement of 70,000 reports each month in 2006, the system 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 is the oldest in the world. Currently, 21 US states have some kind of safety event systems' project underway. The US government is pushing ahead with the idea of a nationwide mandatory event reporting system. Under legislation approved by the House, healthcare officials would report medical errors voluntarily to patient safety organisations, which would use a network of databases to analyse the data and make recommendations. According to a survey of 200 hospital executives published in the Journal of the American Medical Association, however, 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.

The **Canadian Institute for Health Information and Statistics Canada** are together developing methods to report routinely 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, according to a report from the province, this methodology should be further developed and used (Ontario Hospital Association, 2000).

For Europe, 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 reported events could play an important role in patient safety. One of the main challenges is, as with the airline industry as an analogy, to collect "near misses" and analyse them. Event reporting systems is therefore a field of ICT RTD that is considered to be important.

> *Growing evidence indicates that errors in communication (in healthcare) give rise to substantial clinical morbidity and mortality ... Understanding the dynamics of communication between human beings can also improve the way we design information systems in healthcare.*
>
> *Enrico Coiera*, University of New South Wales, Australia

> *Safer systems for a safer NHS - recent developments:*
> - *appointment of Chief Clinical Officer*
> - *development of new Health IT Standard*
> - *development of patient safety policy*
> - *description of safety management approach*
> - *refinement of safety incident management process and procedure*
>
> *Michael Thick*, NHS Connecting for Health, United Kingdom

Towards user-friendly and integrated systems

Multiple studies support the conclusions that ICT systems can lead to considerable benefits in patient safety. In the case of alert systems, incident reporting systems, and sentinel systems, for instance, it is clear that the approach currently used by most organisations – which does not rely on ICT - is inadequate. Instead, ICT tools for identifying adverse drug events and nosocomial infections are sufficiently developed for broader use than at present. They are much more accurate than spontaneous reporting and more timely and cost-effective than manual chart review.[121]

However, **the research literature also emphasises that several factors need to be carefully considered when implementing ICT tools in order to accomplish fully increased patient safety**. For example, in the particular case of decision support systems, five cautionary elements were emphasised in Garg *et al*'s systematic review[122]. They show that:

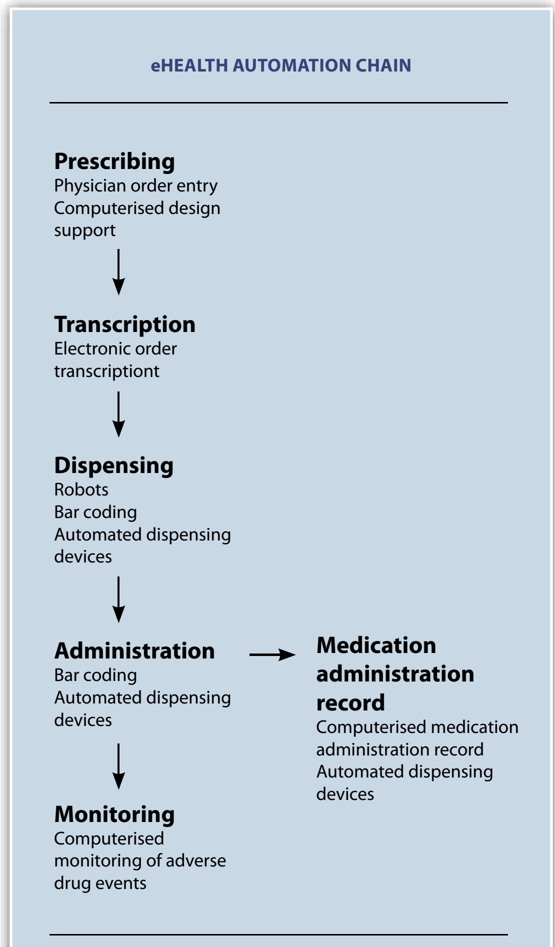
- Clinicians do not use the decision support system for several reasons: for example, because they did not understand what it was for, the prevailing clinical culture was against it, their patients or peer group objected to it, it was too slow, or it was not linked to the electronic patient record.
- The decision support system itself did not produce an effective output in time to influence their decision: e.g. the output was not available in time, and the clinicians could not understand the output.
- The output was not convincing enough to persuade the clinicians to change their practice: e.g. the output showed poor accuracy, was badly worded, the clinicians had never before heard of the particular drug and perhaps required more details.
- The output was available and was convincing enough to influence user decisions, but the users were 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, or they did not have the 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 decision support system developers before they start work. This means that decision support system 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 needs to **shift from being technology-led to being problem-led**, and that a new mindset on the part of developers is needed to encourage this.[123]

Indeed, a major lesson to be learned from the experiences that are reported with the implementation of ICT tools for increased patient safety is **how important it is to design systems with the end-user in mind**. Indeed, **if applications like decision support systems, CPOE systems, or alert systems are not properly designed they will, in the best case be ineffective and, in the worst case, actually increase error rates**. Furthermore, if systems are not fast and display all the relevant information in a coherent and easy-to-use manner, they will be rejected by clinicians.

Furthermore, organisational culture, including any barriers to reporting errors, will play a key role in the acceptance of electronic tools such as incident reporting systems.

Additionally, optimal benefits from ICT tools will only be reaped if these tools do not merely operate alongside each other but actually with each other, i.e. if they are implemented in an **integrated fashion**. Some systems, such as decision support systems and CPOE, are already often successfully used in combination. In the future, such **fully integrated system will make use of automation in all stages**, as depicted in the Figure below where prescribing, transcription, dispensing, administration and the use of an electronic medical record, and eventual monitoring are all coordinated:



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 used at Tufts–New England Medical Center[125]. This system uses multiple IT applications for patient safety, and combines real-time decision support, alerting, and retrospective feed-back for performance improvement. All are applied to the care of patients who present to the emergency department with symptoms suggestive of acute coronary syndrome. This package illustrates the benefits of a combined approach: **that is, the use of combined, usual clinical ICT (that is, conventional, computerised electrocardiographs with ACI-TIPI software) and existent hospital ICT, alongside conventional personal computer-based and interface ICT**. The initiative demonstrated successfully that a patient safety system that uses a completely electronic data collection and feedback reporting system and offers real-time decision support, concurrent patient safety alerts, and retrospective physician-level feedback reports could be implemented not only in emergency settings relevant to cardiac arrests but also in a variety of hospital settings.

In conclusion, the literature review of some of the recent and current experiences of eHealth applications in the area of patient safety, and its analysis, shows a considerable potential benefit for ICT if the implementation conditions are carefully evaluated and planned. **The implementation must take into account not only the technical feasibility but also issues related to the cultural, organisational, legal, ethical and quality assurance contexts**. Future research is needed not only on the technological side but also in terms of behavioural aspects, and the use of appropriate methodologies. Moreover, **the co-ordination and integration of already existing technologies (which could have offshoots and emerging aspects from their combination) also appears to be a promising field of research** for the area of patient safety. We therefore progress to examining ten possible future areas of research into patient safety with ICT at their base.

Research challenges

These new and developing ICT that we have explored previously are embedded with significant patient safety aspects, either because they pose a direct risk or because they may offer benefits in their application to patient safety, or both. In this report, we have only explored potential risks implicitly. Rather, **we are concentrating on the positive aspects of the ICT for patient safety and risk management**. Future research may be advocated that explores some of these potentially risky issues in more detail.

Following the previous, more general assessment of research possibilities, we now discuss and explore some more specific concepts and research challenges that are worthwhile pursuing in relation to new methods and emerging technologies. **Ten key research areas are highlighted**. An analysis is undertaken of these applications' possibilities to increase patient safety across the whole health value system, and thus to provide benefits for healthcare, education and training, and clinical research, both in the foreseeable and in the longer-term futures.

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 electronic health record 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 the relevant fields to known sources of risk, and action to monitor the 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 to healthcare.

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 to identify the causes. Data mining techniques can also be applied to information that is not yet coded in a standard electronic format. In particular, by using advanced language processing, information from unstructured notes taken by healthcare professionals could be made accessible to such data mining tools.

An ontology of patient safety

It is proposed that a taxonomy and ontology that covers healthcare risks and safety considerations should be developed. Such an ontology would 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 the rapid integration of emerging understanding into decision support systems and predictive models. The taxonomy and ontology should be introduced into European and/or global standardisation processes and procedures that are capable of achieving consensus and adoption both by systems developers and clinicians.

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. In 2004/5, the European Information Society Technologies Advisory Group (ISTAG) proposed to stimulate research in the area of "*The Disease and Treatment Simulator*":[126] which would develop into a computational platform for simulating the function of concrete diseases: "**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 Group also suggested that disease and treatment models developed should interface directly with other projects for human benefit, such as the Physiome project[127] and the modelling of whole, human organs. In this context the EC currently supports research on the **Virtual Physiological Human**[128], which is expected to accelerate knowledge discovery that leads to improved disease prevention, early diagnosis of disease, and individuals' health risk management. This concept is at the heart of the Second Call in relation to eHealth of the 7th Framework Programme.

The Virtual Physiological Human concept aims to reduce risks to citizens who participate in clinical research and to enable a radical expansion of the volume of research into clinical out-comes to the full range of treatments. To accelerate significantly the production of results from clinical research, it appears to be important to support research into ICT tools that can implement **virtual clinical trials**. According to the Academy of Medical Sciences[129] 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 the work of clinical trials, to reduce the total number of recruited patients by 60%, and to shorten trials' duration by on average 40%.[130] **Virtual patient software engines** are today helping researchers and physicians to select the best among existing therapies, for example, for breast cancer[131], and to develop optimal drug dosing regimes. So-called **computer-assisted trial design systems** is a field in which computer models have become so useful that the US Federal Drugs Agency is adopting them[132]. These systems help to model and simulate clinical trials to determine the optimal number of patients needed to be involved, dose amounts, and dosing frequency. Previously, for many years, these results have mostly been obtained only through time-consuming trials based on costly trial and error.

Medical simulation and virtual reality

Medical simulation and virtual reality is already being used as **a training and feedback method** in which learners practice tasks and processes in life-like circumstances that use models or virtual reality, and with feedback from observers, peers, actor-patients, and video cameras that assist an improvement in skills. Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without harming patients. Virtual reality simulations are revolutionising surgical training[133] (e.g., for laparoscopic, gastro-intestinal, plastic, ophthalmological, dermatological, and some laryngological procedures), and involve error reporting[134] in the healthcare field.

Healthcare system risk models

Healthcare provision is an increasingly specialised, flexible and, at the same time, integrated service, that is 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, to the individual hospital, to an interoperating and inter-connected European health system should become a focus of future research. Modelling techniques could include neural networks and could integrate usefully such approaches as Failure Mode Effects Analysis (FMEA) or Hazard Analysis and Critical Control Points (HACCP). The first of these approaches identifies ways in which a given procedure can fail to provide its desired performance due to late or incomplete information, for example. Specific, adaptive Systems Control Tools for continuous monitoring like Statistical Process Control (SPC) that ensure that care processes are operating within their prescribed limits need to be developed. Such tools would thereby reduce errors and improve the use of resources. Furthermore, the testing of approaches that are today applied successfully in such disparate, but analogical, sectors as aviation or food production is a new field in need of further study that could improve substantially the safe delivery of healthcare. This may include areas like Human Factor Research that focuses on integrating the human element into systems analysis, modelling and design.[135]

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 incorporated into the point-of-care and may include or even replace traditional chart documentation. Pathways are often evidence-based and may even be integrated with locally or nationally developed clinical practice guide-lines. **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**.[136]

In the future it may be possible to build **health pathway models which encompass citizen/patient passage through clinical pathways, with predictive ability**, that focus 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, with 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.

Examples of ICT applications that can facilitate patient safety

Below follow three examples for illustration purposes only of ICT that facilitate patient safety. These are the use of bar codes and radio-frequency identification neural networks, electronic intensive care units, and wireless integrated mechanisms.

Bar codes and-radio-frequency identification

Bar codes can help to eliminate the potential for administration errors. Advantages include real-time updates that enable providers to alter medications and adjust delivery schedules with ease, provide simultaneous access to the system at multiple sites and the elimination of phone calls and paperwork. However, significant barriers remain, such as[137]:

- Only 8% of hospitals use bar coding and scanning technologies.
- There is no universal bar code symbology.
- Expense of implementation.
- Lack of industry-prepared bar coded packages.
- Cost of in-house repackaging.
- Bar coding of intravenous admixtures.
- Non-bar coded doses such as ointments, partial dose meds, and inhalers.

Radio-frequency identification (RFID) is generally regarded as the successor to bar code technology, since it does 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 applications in healthcare and its use in some areas is growing significantly.[138] Areas of applications include security (e.g. access control; anti-theft devices), 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 out-patient self-medication, e.g. for use with elderly persons, RFID is also an option. Some of these uses are currently handled through bar coding, as RFID is currently at an early stage of development. However, **feasibility studies, clinical pilots and advances in other vertical industries, such as retail, have together driven RFID to the forefront of healthcare**. However, the cost of RFID tags must come down and the technology must be further customised for the healthcare industry (e.g. to allow scanning through liquids) in order to become a widely-deployed technology.

e-Intensive Care Unit and Wireless Integrated MicroSystems

e-Intensive Care Unit (eICU)[140] is a project intended 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 insufficient.

Thus, **the eICU solution is 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 both on-site and remotely to help specialists; ICT are used to identify problems and to guide decision-making. The goal is to make every hospital)room an intensive care unit in the coming decades.

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

While the application of WIMS technologies in the hospital promises to improve significantly the quality and patient-centredness of in-patient and ambulatory care, the potential impact of WIMS on homecare is even greater[141]. With properly integrated home-based WIMS systems, patients could be monitored on a continuous basis and healthcare professionals alerted automatically when adverse 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[142]. Wearable devices that monitor blood pressure (hypertension), breathing patterns (sleep apnea), and other characteristics will certainly be available in the near future. These kinds of capsules for internal viewing and measurements could improve substantially the diagnoses of a variety of conditions and could thus improve the quality of healthcare.
Problems with WIMS that still need to be solved include privacy issues, technical issues related to the development of reliable interfaces, educational issues and, more generally, the classic challenge in organisational behaviour which is classified as resistance to change.

Socio-economic and behavioural aspects

A particularly promising field of research concerns the potential psychological and behavioural changes necessary in the comportment of health professionals, citizens and patients as eHealth applications lead to a re-engineering of healthcare processes and improve system safety and performance. This field of research should also involve analysing the impact of medico-cultural, legal/regulatory and socio-economic factors. Assessing the risk and developing guidelines and certification procedures for decision support systems and expert systems and other tools also require further enquiry. In this context, systems engineering and design tools, including human factor research can be highly useful.

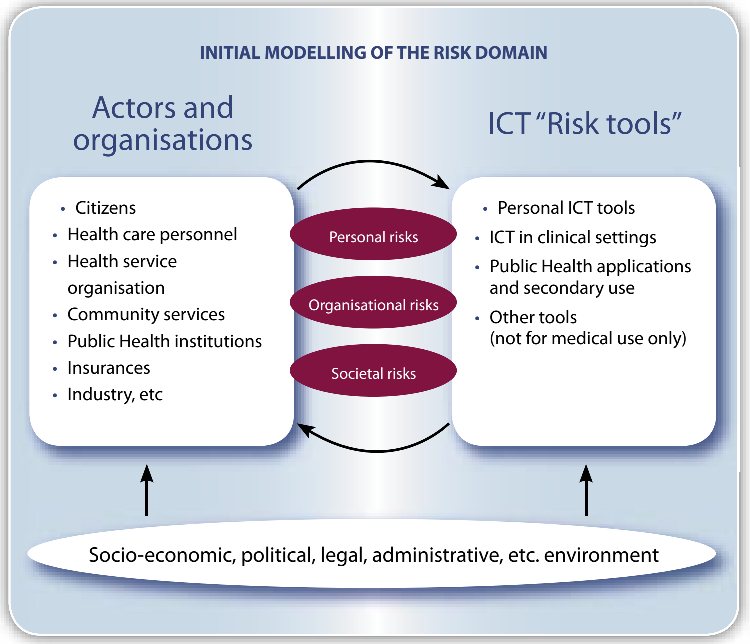
Monitoring and risk management of large-scale events

Further to the already existing incident reporting and alert systems, an important challenge to patient safety concerns further 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). While such larger-scale research may enable a more effective response to threats through the acquisition and analysis of better information, it could also play a key role in resource planning and management. ICT should also be exploited as a means to inform and reach healthcare and other professionals and the public on a large-scale and help to adapt adequate responses. The use of geographical information systems in healthcare has appeared recently as a very promising field, and research should be conducted that involves such cross-disciplinary occupations as epidemiologists, managers of health resources, and policy-makers.

Methodological framework and key issues for research

Within this study, it should be emphasised once again that we take **a broad look at the general contribution that ICT tools can make to higher quality of care, increased patient safety, and better risk management**. Therefore, 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, this occurs through better information and prevention and, if this is not sufficient, and diagnosis and treatment become necessary, it means the need to optimise and often even to minimise the number, processes and severity of interventions including surgical procedures and drugs. The same applies to biomedical and clinical research, training and education, and the whole public health domain.

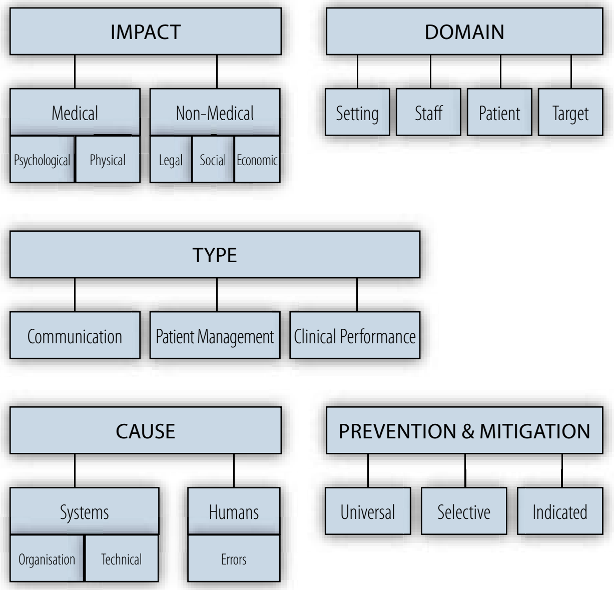
The study has reviewed the state of play in some key ICT areas for patient safety and risk management and has analysed the international activities that are taking place in the field. Furthermore, it has taken a look at safety and risk management concerns in other domains in order to identify lessons to be learned. Conceptually, these issues are integrated in the model for patient and health system risk depicted below. This allows us to relate different types of risk and ICT applications relevant to patient safety to the corresponding meta-categories, and it also directs the research towards other innovative fields which may prove to be of considerable importance.



Source: adapted from Bates (2000)

Of course, the issues vary according to the different ICT applications outlined. It is for this reason that Chang *et al* (2005)[143] have developed a **patient safety event taxonomy**. Although the authors focus on near-misses and adverse events only, the classification is useful both for the evidence reviewed in this study and for consideration of further research. Chang and colleagues categorised elements of existing models into **five complementary primary classifications**, which were divided into 21 sub classifications. These, 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:

PATIENT SAFETY EVENT TAXONOMY (AFTER CHANG *ET AL*)



Source: empirica, following Chang et al (2005)

In its sub-classifications (which are not depicted here), Chang *et al*'s (2005)[144] **impact** node contains a classification of the degree of harm for the medical category, which ranges 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 and colleagues' group together clinical settings, such as the various departments in a hospital, a general practitioner's office, ambulatory clinics and nursing homes. They also include the different staff categories involved and patient characteristics, ranging from age, gender and education to duration of disease, socio-economic status and diagnosis. The system's sub-category 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 sub-group and "indicated" measures for specific high risk individuals. For the broad approach to patient safety applied in this study, Chang *et al*'s taxonomy provides extremely valuable input, even though it needs to be borne mind that it was developed with adverse events and near-misses in mind.

It is noteworthy to mention that JCAHO, about which Chang writes, is a partner of the World Health Organisation (WHO) in the "Patient Safety Alliance", and it has contributed to establish the WHO taxonomy. The International Patient Safety Event Classification (IPSEC)[145] aims to define, harmonise and group patient safety concepts into an internationally-agreed classification in a way that is conducive to learning and to improving patient safety across systems. It is intended to be adaptable yet consistent across the entire spectrum of healthcare 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 from eHealth for Safety Study. 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 of a system but also on human behaviour. Moreover, the integration of the various existing ICT applications into a coherent system was singled out as a crucially 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 issues at the organisational and the policy levels. The following table gives an overview of the components of this multilevel approach which draws on three levels and their components.

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

The formulation of this framework, and the issues outlined to this point in this report, constituted the first phase of the eHealth for Safety study and provided input for the empirical work conducted in the second phase that involved evidence-based information gathering work. In the course of the study, these issues have been further refined and have provided important input to this final report.

"*The ultimate goal of European eHealth interoperability is to enable access to a patient's summary and emergency data from any place in Europe, respecting data privacy and security.*"

Octavian Purcarea, Unit ICT for Health, European Commission

"*A grand challenge is to build semantically consistent information networks spanning the wide spectrum of stakeholders and healthcare situations: from the hospital to the patient's home, from individuals to populations, from regions to a global reach.*"

Antoine Geissbuehler, Geneva University Hospitals, Switzerland

6 Priority research fields from the **expert workshops**

Overview

The previous chapter identified ten current and potential future research topics as a result of literature review and empirical data gathering. These were the input to the second phase, the empirical work which consisted of several workshops and expert interviews that validated and improved the desk research findings.

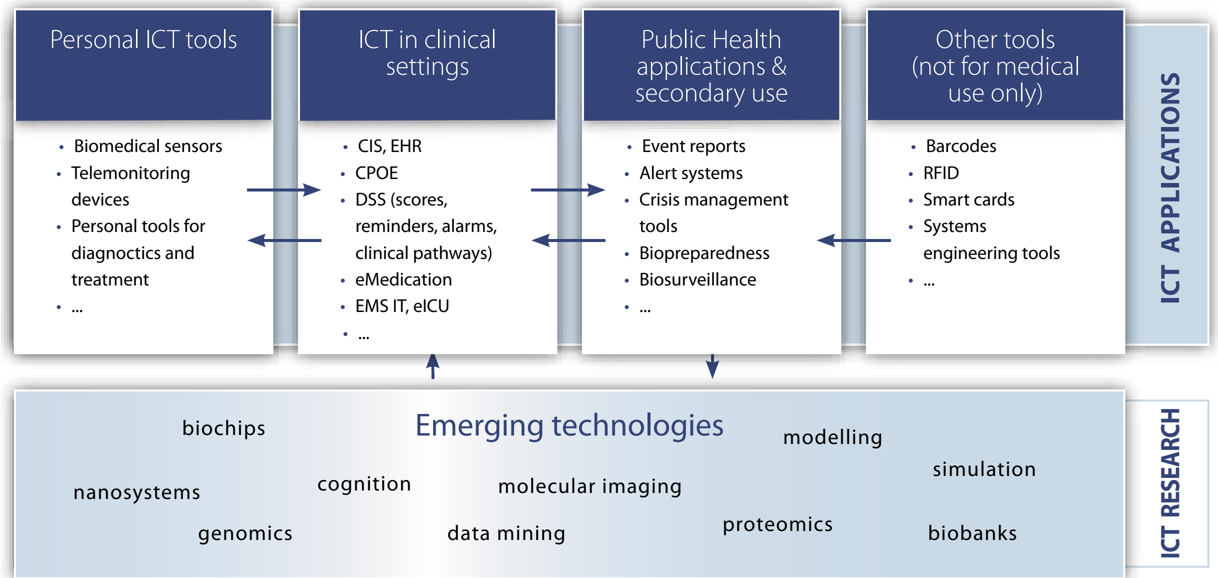
Importance was attached to both the content and the structure of the workshops and interviews in order to be as potentially broad and sufficiently generic so as to permit open discussions and the identification of new ideas and topics not yet covered by results available from desk research. The topics addressed were chosen using a preliminary list developed within the study. These topics are illustrated in the Figure below that focuses predominantly on innovative approaches and emerging technologies:

This second phase concentrated on identifying and approaching key researchers and experts, national organisations involved in healthcare policies and general eHealth implementation, or institutions that specialise in patient safety.

The key basis for this were three workshops, which took place in Malaga, Brussels, and Geneva during 2006. They were explicitly designed to promote a two-way dialogue, increase public awareness, and enable different experts to exchange views and ideas, learn from each other, and relate patient safety and risk management challenges to their own daily work and needs.

The very concrete discussions that took place, and which in many cases led to the provision of empirical information used throughout this final report, are laid out in Annex 2. While the feed-back from the three workshops is structured in the Annex along the three workshop locations and times, the brief discussion of the content which follows 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.

ICT IN SUPPORT OF PATIENT SAFETY AND RISK MANAGEMENT



Source: © empirica, eHealth for Safety study, 2006

While all workshops focused on patient safety and risk management, and the positive role that ICT can play in enhancing these aspects of modern healthcare, they covered a range of more detailed topics and specific perspectives.

For example, the first workshop on patient safety and risk management discussed widely the lack of methodological uniformity and interoperability of various ICT tools in the patient safety field, the need for additional collaboration among healthcare professionals at the point of care so as to reduce the risks patients are exposed to, and the more challenging need for collaboration and communication at the policy level on what the needs of patient safety in relation to ICT are. The specific ICT applications covered have added to the richness of this report, and reflect interest in concrete solutions like ePrescribing and electronic healthcare records, CPOE, decision support systems, adverse drug events reporting and information schemes, bar codes, RFID and, finally, the integration of a total package of ICT tools into daily work process support.

The second workshop focused on ICT for patient safety in a more bio-medical context, and hence concentrated on ICT use in clinical trials, drug discovery and therapy improvement, personalised healthcare, and data representation research.

The third workshop included discussions on the integration and traceability of health data, improving safety along the medication lifecycle, the role of nanotechnologies, advanced imaging technologies, computer-aided prognostics, and the need to focus on ICT-enabled, real time team work and collaboration at the very point of patient care.

The empirical findings were wide-ranging in both quantity and scope. The following are the key areas for research efforts in coming years, as identified by this empirical work. The following topics recurrently entered the discussions of the workshops, as well as the numerous formal and informal interviews and face-to-face discussion with experts and stakeholders.

Integration and traceability of data

Patient safety will tremendously benefit from integration of data from multiple sources, especially also personalised biomedical information, data from whiteboards, medical records, nursing observations, planning of interventions and follow-up, medical orders, and other contextual data. There is a need to integrate the knowledge from all sources 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 health organisations and public policy makers. This can be achieved when knowledge interoperability and translation into the appropriate semantic context is guaranteed, which supposes information chain integrity along the supply chain up to the patient, and from individual patients to the whole population. Fields stressed in this context are epidemiology, physiology, and pathology.

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 system" 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 tracking high value reusable assets, reducing errors in logistics - a 'real time' picture of inventory, and tracking drug prescriptions and medication records, identifying potential risks stemming from the medication portfolio.

Integration and tractability of data is dependent on the existence and adherence to appropriate standards that will allow technical, as well as semantic interoperability.

Re-use of electronic health record (EHR) data

The possibility to re-use electronic health data from respective record systems, e.g. from hospitals or GP offices, was a topic given particular attention. There is a 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 would 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.

All of these have a connection to the risks that patients are exposed to during treatment as well as 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 about 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 incentives and motivation, lack of time, and interruptions. It will be inconsistently collected and incomplete, partially unstructured, and not quality uncontrolled. Addressing this challenge should be a priority research topic if the expected significant benefits from data re-use are ever to materialise.

International cooperation

The potential benefits from use of ICT for improving patient safety standards are multiplied through international cooperation. This includes cross-Member State collaboration on EU level, as well as global partnerships. This was underlined by the eHealth policy workshop co-organised by the European Commission and the U.S. Department of Health & Human Services, in conjunction with the European-American Business Council, which devoted a whole session to «Improving Patient Safety through IT». The event, actively supported by the eHealth for Safety study team, took place in Brussels, on May 10th 2007.

A number of implementation challenges as well as research issues were discussed. For example, the current projects of the NHS Connecting for Health safety team in the areas of ePrescribing, patient ID management, and cross-professional and cross-institutional handover of patients were addressed. Some areas of future research identified as important include:

- Federating clinical data repositories / EHR systems of hospitals for secondary use, creating new opportunities for Patient Safety research
- Improving prediction and detection of adverse drug events with the help of IT
- International interoperability of medication history data and adverse drug events (ADE) data
- Clinical and socio-economic impact assessment of available health IT solutions, such as CPOE
- Optimising decision support, e.g. defining priority lists of alerts
- Defining functionalities of CPOE and clinical decision support systems (CDSS) critical for improving patient safety
- Standards and certification:
  - More detailed standards for medication decision support
  - Criteria and strategies for certification of CPOE and/or CDS systems
- Integration of knowledge into patient workflows
- Types and causes of unexpected adverse events caused by CPOE and CDSS
- Combining CPOE and CDSS with RFID-based patient identification systems
- Financial return on investment and cost effectiveness analyses for Health IT and health information exchange (HIE).

Transatlantic efforts could help to establish a reference framework of best practices and mistakes, as well as organisational, ethical, and economic aspects. It would be useful to establish a priority list starting with applications that have demonstrated, in a known and detailed context, their ability to increase patient safety. Incremental implementation of solutions might be recommended, taking into account the need to establish an appropriate learning curve.

“

EU-US collaborative efforts can accelerate our progress in addressing the Health IT challenges. By working together we can
• draw on experience, success from all participants
• solve problems together
• increase momentum ‘back home’
• drive solutions
• disseminate results

”

William B Munier, Agency for Healthcare Research and Quality, USA

“

Success factors for implementation of innovative IT identified:
• Hospital administration is aware of the problem and its relevance
• Interprofessional team has analysed the medication process for uncontrolled risks
• Physician leadership of the project group
• Software is compatible with clinical workflow and continuously optimized
• Continuous scientific analysis of the effects of the systems on patient safety, user acceptance and treatment costs

”

Daniel Grandt, Klinikum Saarbrücken, Germany

“

Information technology is a power-tool - it holds great promise but can cause great harm

”

J. Marc Overhage, Regenstrief Institute, Inc., USA

7 Vision and recommendations

This final chapter outlines a vision of how ICT may impact patient safety in the future, and in what direction RTD efforts should be concentrated so as to optimise 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 the risks inherent in the healthcare domain is a necessary first step towards improving the management of these risks and, thus, for providing an optimal level of patient safety.

> *"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 health promotion, disease prevention, personalised healthcare, good practice medical interventions, long-term care, clinical research, risk assessment, training and education."*

A holistic view of patient safety

Healthcare is so complex a system that it is viewed most effectively from a holistic perspective. Complex care processes, missing information, regular interruptions of ongoing activities, and at times chaotic communications, all contribute to medical errors and adverse events. These features can have a corresponding, significant impact on patient safety and the quality of healthcare. eHealth or ICT-based solutions are now key tools to cope with these challenges. ICT applications can guide care processes and support workflows, provide pertinent patient information when and where needed, and improve diagnosis and treatment through relevant decision support. Through the provision of timely health and lifestyle information, eHealth contributes to improved information for citizens and, therefore, to more effective prevention. Through support for research, ICT solutions support 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, and the management of long-term or chronic disease conditions. All of these effects 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, some newly emerging opportunities that can enhance health and improve the quality of acute and longer-term care. We also reflected on the expected contributions to such a holistic concept of patient safety through the undertaking of biomedical and other fundamental research, supported by ICT-based solutions.

The study identified the potential benefits created by the use of ICT along the full continuum of healthcare, and provided a sound and wide-ranging perspective for advanced research in this area.

ICT in healthcare

This chapter summarises the current state of play in ICT in healthcare. The eHealth for Safety study reviewed the very large amount of literature that has been published since the famous US report "*To Err Is Human: Building a Safer Health System*"[144]. The wealth of available literature underlines the sense that the twin subjects of patient safety and risk management have gained wide international attention in health policy, healthcare and research environments. Several EU Member States have estimated the scale of patient safety problems, with results that are similar to those in the US.

ICT has been shown to contribute not only to reducing the rate of errors in healthcare by providing more accurate and transparent information, but also by facilitating a rapid response after an adverse event has occurred, and tracking and providing feedback about such events. However, patient safety should go further than merely reducing medical errors. The literature review and expert consultations confirmed that ICT solutions that support healthcare professionals in their work can contribute greatly to improving more generally the quality of care.

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, enabling the delivery of care to remote locations, and increasing the efficiency of delivery. Last but perhaps most importantly, it can increase the quality of care provided to citizens. It has been said 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."[147]

One of the most important developments in recent years in many Member States is the planning and implementation of electronic health records at the national, regional and local levels. In England, an evaluation of the National Care Record System led to the conclusion that the system has significant potential to improve safety since lost or poorly completed records are a major contributory factor to patient safety incidents. Such large-scale deployments of eHealth infrastructures can lead also to the broader implementation of other ICT tools.

The US Institute of Medicine 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 NPfIT for the national health service which is 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 achieve 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**."[148]

One study found that 80 percent of medical errors began with miscommunication, missing or incorrect information about patients, or lack of access to patient records.[149] Another case study illustrates the benefits of a hospital-wide electronic patient record system to demonstrate improvements in quality of care, access to care, and economic benefits:[150]

Elios and Prométhée at the Institut Curie, Paris, France

Elios - a comprehensive electronic patient record, that contains structured reports, free text, images, and is accessed by all the doctors involved in a patient's treatment, and Prométhée - a biomedical informatics search meta-engine used for answering medical questions across research and clinical data-bases across a large number of the Curie Institute's hospital, patient, administrative, and clinical research databases, have transformed healthcare processes fundamentally at the Institut Curie in Paris, France. They have improved the quality of care through:

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

The annual net economic benefit to the Curie Institute has been estimated at over €3m a 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** can improve patient outcomes in treatment. Decision support systems are broad solutions which are often incorporated in a variety of eHealth applications. They date back as far as 1974. Evidence indicates that they can indeed enhance clinical performance for drug dosing, preventive and other aspects of care, but so far not really convincingly for diagnoses. However, a word of caution: decision support systems may occasionally foster errors in entering and retrieving information, and errors in the communication and coordination process rather than reducing them. One researcher eventually 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."[151]

Computerised Physician Order Entry systems have received considerable attention as a core technology in the reduction of medical errors. CPOE systems support a process whereby instructions regarding diagnosis and treatment are entered electronically, and then communicated directly to responsible individuals or services. Decision support systems are built to varying degrees into almost all CPOE systems. They provide 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:

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

- Fewer prescribing errors and discrepancies
- Fewer dispensing errors: down from 30 to 21 for each 100,000 prescription 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 in CPOE. 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."[152]

Whereas CPOE systems aim to prevent errors, **computerised adverse event systems** monitor the occurrence of instances that could potentially lead to adverse events and alert the clinician when certain indicators are present. The most common adverse events are nosocomial infections and adverse drug events. Consequently, ICT-supported reporting systems have been tested primarily in these areas. Up to now, most institutions use voluntary incident reporting to detect adverse drug events; however, this method is rather ineffective and identifies only about one in 20 events. Conversely, most ICT applications have found a significant increase in the number of events reported. **Automatic alerts** can reduce the time until treatment is ordered for patients with critical laboratory results. These techniques seem to be well adapted to the detection 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, for example, the clinician, in mind. If systems do not respond fast and display all the relevant information in a coherent, easy-to-use manner, they will be rejected. This 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.

ICT play also a very important role in **improving communication**. ePaging, where a system identifies and pages the healthcare professional on call can lead to more rapid treatment (e.g., in the case of critical laboratory results). Such a system requires physician-on-call schedules, known responsibilities, traceability, and so on. The following case illustrates the benefits of a practical application of enhanced communication:

DISPEC – ambulance emergency service, Romania, is a sophisticated, electronic emergency ambulance teletriage and dispatch system, which was 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 (there are four types of ambulances equipped with global positioning systems 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 drops in call to dispatch time on average by about 30%
- Dramatic drop in time until arrival at emergency site - a decrease in average time by 35%.

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

Source: www.ehealth-impact.org

Advanced ICT for risk assessment and patient safety: eight research directions

The overall goal of patient safety and risk assessment is to improve disease prevention and minimise the potential of adverse effects on citizens that can be caused by any research, clinical trials, diagnostic and treatment interventions, including environmental factors. A key aspect of further research for improved risk management is to create an enhanced evidence base which requires better integration of data from heterogeneous sources and information systems. Furthermore, knowledge representation and use 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 are grouped into the following categories.

Innovative integrated systems for clinical settings

Evidence has shown that integrated, easy-to-use applications are accepted better and have more beneficial results. Further research into advanced tools for a better **integration of decision support systems with** alerting, CPOE or intelligent medication delivery such as RFID-based systems, adverse event reporting, and related application systems with **patient record systems** is urgently needed. Advanced computerised adverse event systems that go beyond merely reporting nosocomial infections and/or adverse drug events and aim instead at identification of common patterns in **safety-relevant events and workflows** are another area in need of further research. Such work must also take into account new tools for prediction, detection and monitoring the occurrence of the broad arrays of instances that could be or could develop into adverse events, including alerting and management support.

Information retrieval tools

A longer-term research objective should focus on integrated clinical - electronic health record - and biomedical informatics **search meta-engines** to improve safety and quality of care. Based on a wide variety of clinical and research data bases, this research would allow questions at the point of care access, and comprehensive answers to ad hoc clinical and research questions, real-time adjustment and evaluation of clinical practices for both healthcare professionals and medical devices and guidelines, real-time clinical audits, and quality control.

New tools for data mining

New data mining applications like expanded predictive analytics and powerful language processing algorithms to analyse structured and unstructured data (such as the text of a physician's notes) for identifying factors in clinical settings associated with better medical out-comes or risk deserve special attention and support. Emerging technologies like semantic mining will enable researchers to find semantic meanings hidden in data and documents, and relate them to information available in other formats such as images. Further research into the fusion of medical images (MRI, CT, PET, x-rays, and ultra sound) and other multimedia data for multidimensional-multimodal image analysis and integrated mining, together with both qualitative information and quantitative data, is strongly recommended. Using data mining techniques alongside these various structured and unstructured data from clinical databases about patient diagnoses, laboratory test results, images, and medical treatment data offers a considerable challenge. This is a virtually unexplored frontier which holds great promise for improvements in patient safety.

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. Examples of these could be tools for intelligent surgical and anaesthetic pre-operative assessments, that are built on domain ontologies, and use a combination of anaesthetic peri-operative data and surgical data for out-comes research while providing automatic risk scoring, alerts and clinical decision support. Another potential research avenue would be to bring image-guided interventions into clinical practice. Advances in medical imaging (which will soon include molecular imaging), image processing and display, surgical simulation, surgical navigation, robotics, and surgery-adapted Picture Archiving and Communication System (PACS) infrastructures, are the driving forces behind these developments. At the same time, such systems should be able to learn, support collaboration, and enable the traceability of care processes.

Integration of multidisciplinary knowledge

Research in the integration of multi-disciplinary knowledge for the simulation of pathophysiology and pharmacological trials would be invaluable. Simulating either drug effects or the outcome of surgical interventions will allow for safer, more individualised treatments. New approaches and tools are also needed for **the coupling of research data** from, e.g., pathophysiological modelling with large empirical databases (from omics, through electronic health records, to public health and/or population data). Feedback and knowledge coupling across such disparate domains will provide a better understanding of disease development, personal risk, and individualised treatment response. Such research will also support the empirical base for simulating more effectively disease development and drug impact – such as in **virtual clinical trials**. This could thus reduce the risks to citizens who participate in clinical research.

Personal health systems

Personal ICT tools, such as biomedical sensors, home monitoring, compliance control and assistive living systems, can also improve safety and enable better risk monitoring. There is a substantial amount of research needed on advanced, user-friendly, interoperable personal health system, that is complemented by implementation support for their wider diffusion. Such systems should become integrated with clinical applications of both hospitals and general practitioners so to foster more effective compliance on the part of patients, to avoid errors of treatment (type of drug, administration, timing, and dosage), and to enable appropriate feed-back from health professionals to be received either at home or even on the move.

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. Developing regional and national healthcare ICT infrastructures should be used to capture relevant information as a by-product of care, particularly of emergency care. The secondary use of medical and other routinely-collected data for syndromic surveillance, preparedness planning and crisis management could become an important priority at the national and European levels. Disease outbreak examples could include SARS outbreaks, avian flu, or other health threats.

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 all 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.

Validation and socio-economic assessment of ICT applications

It is absolutely 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. This should include tools that are already usable during the research and development stages of research. They should guide research towards outcomes which have the highest probability to be implemented and diffused successfully when their expected organisational, economic and socio-cultural impacts are taken into account. Furthermore, more effective understanding is needed of how to combine 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. Examples could include 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. Last but not least, the appropriate evaluation of patient safety interventions needs to be included in future research directions. So far, little reliable data exists on the effectiveness of routinely recommended interventions, including incident reporting and analysis.

Concluding outlook for research

Overall, the emphasis of research should be on topics like:

- Patient safety-supporting ICT solutions coupled with profound process reengineering across health organisations
- Complementary new workflow, change management and human resource management tools
- Truly connected health information systems from the individual citizen/patient to organisational, public health and research levels
- New generation of advanced, user-friendly and ubiquitous tools for better integration of decision and work flow support systems with patient record and clinical information systems
- Integration of patient data across the continuum of care
- Knowledge representation and coupling across disparate knowledge domains
- Advanced terminology-driven eHealth tools for data entry and retrieval, including voice recognition and adaptable user interfaces
- Personalised simulation models of patients and diseases, leading to individual health risk analyses and early diagnosis, as well as personalised treatment
- Technology Assessment of eHealth systems, clinical and socio-economic validation of ICT applications
- Integration of clinical care with clinical trial and research records.

The efficiency of such research and the benefits to be derived can be leveraged through international cooperation. To facilitate patient safety and to enhance risk management, the development, deployment and diffusion of eHealth systems would also benefit from a certification process to be put into place. Interoperability issues of electronic health systems should also be addressed properly, and could involve more applied research into, for example, patient and healthcare professional identification, authentication, and 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 would result in the design of even more effective systems that would support safer out-comes in the hands of busy or poorly resourced physicians.

Overall, ICT is an enabler that can revolutionise healthcare processes, and a core component of a safer healthcare environment. However, it is only one component, and management and cultural issues deserve the same attention. Therefore a holistic vision and strategy that also takes into account the considerable organisational factors at play in Europe's health systems is mandatory if safety for all is to be strengthened whether for healthy citizens or patients in need of support. Research and development in ICT must continue to contribute to addressing these crucial issues.

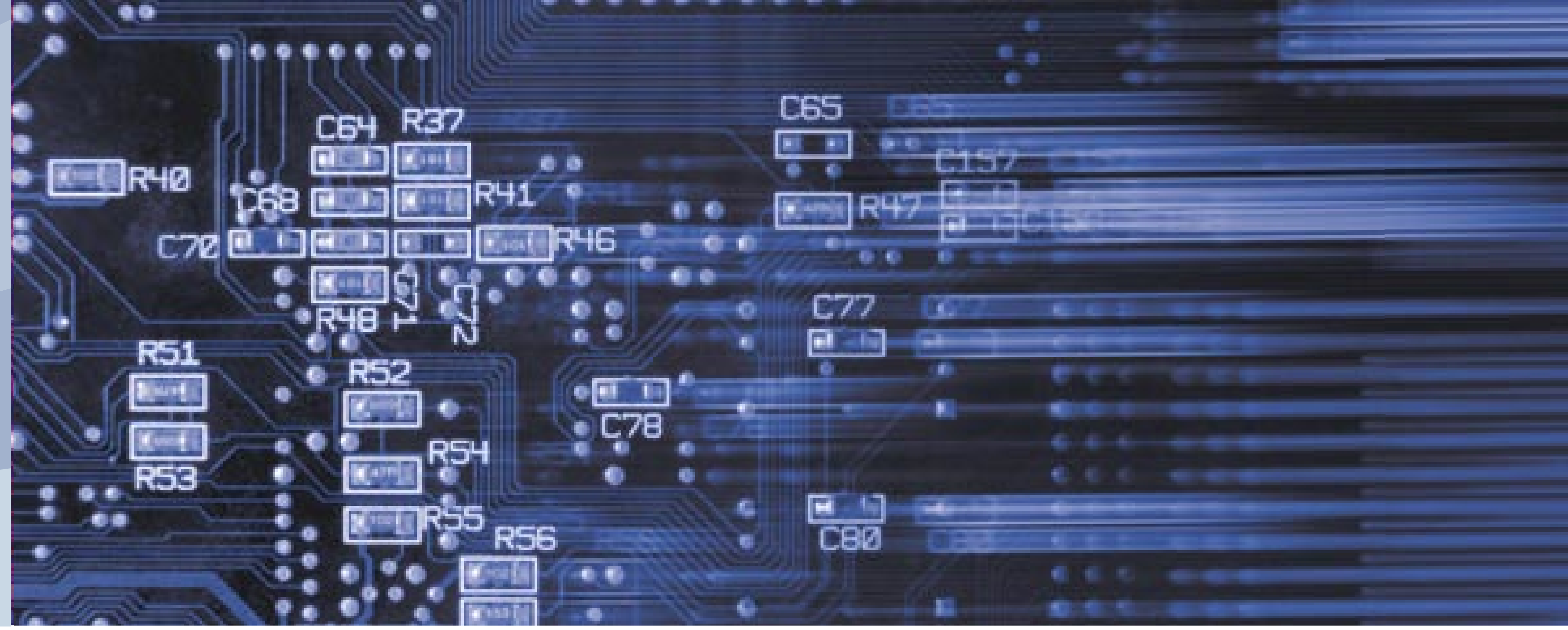
> *Solving the 'traceability issue' will significantly increase patient safety in hospitals. It is a vision developed around an electronic health record which allows for real-time workflow monitoring while covering actors, objects, locations, actions (e.g., each single treatment), time, and is based on unique shared semantic*

Christian Lovis, Geneva University Hospitals, Switzerland

> *Providing clinicians with simultaneous access to accurate patient records, quality-assured knowledge and details of local care pathways is key to ensuring safe and effective healthcare in the future. With changes in patterns of work and increased patient mobility ... the Electronic Health Record has much to offer patients in a healthcare system in which they may be the only constant..*

Department of Health, UK

Annex 1: Two decades of evidence on decision support systems



This annex outlines the main highlights of over two decades of evaluation work undertaken on decision support systems in clinical settings. The main observations can be described as:

- Hunt *et al's* 1998 review[153] concludes that **clinical decision support systems can enhance clinical performance** for drug dosing, preventive care and other aspects of care but are not convincing for diagnosis. In this review, 68 controlled trials in a 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; six found improvements with the use of decision support systems. Four trials also evaluated patient outcomes, and only one found a significant benefit when it compared decision support systems with usual clinical practice. Nineteen Studies of clinical decision support systems providing preventive care were also analysed by Hunt and his colleagues. 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[154] lists several evaluation studies of decision support systems The most important of these are described in detail in separate bullets below.
- Sintchenko et al[155] (2004) note that the use of decision support systems used in conjunction with microbiology reports 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 **improve decision quality significantly**.
- In their assessment of computer-based cardiac care suggestions, Tierney *et al* (2003)[156] found that the intervention had **no effect on physicians' adherence to care suggestions**. Physicians viewed guidelines as providing helpful information but as setting limits to their practice. The study authors suggest that future studies must weigh the costs and benefits of different, perhaps more draconian, methods of influencing clinician behaviour.
- Van Wijk *et al* (2002)[157] determined the compliance of general practitioners with recommendations made for blood test orders. A guideline-based decision support system, Blood Link, was integrated into the electronic medical record of 31 general practitioners in 23 clinical practices. **71% of practitioners used the decision support software rather than the paper-order forms**. The most frequent type of non-compliance was the addition of further tests. The authors conclude that, this could be the case because practitioners are already applying new clinical insights that have yet to be included in the official guidelines.
- Rousseau *et al* (2003)[158] report **primarily negative comments about a decision support system**. The three main concerns voiced by clinicians were: the timing of the guideline trigger, lack of ease of use of the system, and lack of helpfulness of the system's content.
- Similarly, Kawamoto *et al* (2005)[159] 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%).

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 system**. 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 (the rate difference ranges from 26%, from 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 analysis, 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 that lacked any of the four features improved clinical practice in only 18 out of 39 cases (46% (30% to 62%)) analysis. [160]

- In Garg *et al's* systematic review of controlled trials of decision support systems, **about two-thirds of these are effective** at narrowing knowledge gaps, improving decisions, clinical practice or patient outcomes[161], but many are not.[162] Why did one-third of the computerised decision support systems that were sufficiently mature to be exposed to a randomised trial fail to influence clinical actions in this systematic review? Five possible reasons are offered as to why this might have happened include the failure of clinicians to use the decision support system. These relate to: lack of understanding on the part of the clinicians; outputs produced in insufficient time to influence decisions; unconvincing outputs; outputs that were available but showed that drugs were too expensive; and, finally, that the clinicians' behaviour was already optimal given the context and the case mix. Each of these potential reasons for failure needs to be considered carefully by decision support system developers before they start work: they 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 decision support system itself. Designers who wish to improve clinical practice and patient outcomes need to analyse the steps necessary to bring about the intended change. They need to accept that, quite often, a decision support system will not be the solution, as the long list of issues above demonstrates.
- Liu *et al* (2006) advocate that the development of decision support systems needs to shift from being technologyled to problemled. A new mindset is needed to encourage this.[163]
- Complementary to this information, Ash and colleagues (2004)[164] identify instances where decision support systems (or patient care information systems, as they call them) foster errors rather than reducing them. They distinguish between errors in the process of entering and retrieving information and 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)[165] recounts the experience of developing a decision support tool for **stroke prevention in auricular fibrillation** (on deciding whether to take Warfarin). The development of the tool drew on the views of both patients and general practitioners 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.

A clinical guidance programme for the decision about prophylactic oophorectomy in women undergoing a

hysterectomy[166] was developed. This computerised clinical guidance programme 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 women participating 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.

Annex 2: eHealth for safety workshops

Workshop 1, Malaga, May 2006: Benefits of ICT for patient safety

Organisation and speakers

The first of the workshops was organised by the consortium as a strategic seminar alongside the eHealth High-Level Conference in Malaga, Spain. The event took place on 10th May 2006. It was chaired by the EU Commission Services and showed clearly 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 part focused on real-life experience and evidence in the domain covered by eHealth for Safety, and the second part was 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 introduced briefly the topic of patient safety, its importance, and the particular interest of the EC 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 dealt with experiences and evidence in the eHealth for Safety area, and a discussion on some specific aspects addressed by the speakers.
The second part, dealing with the research agenda in patient safety, was opened by Ilias Iakovidis, Deputy Head of Unit of the DG INFSO, EC ICT for Health Unit, who gave an overview of "20 years of ICT research for better health". Five more presentations followed, and were completed by a comprehensive discussion on priority research needs and opportunities.

Speakers in the first part of workshop were:
1. John F. Ryan, Head of Unit Health Information, DG Health and Consumer Protection, EC
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 in the second part of the workshop were:
1. Scott Young, Agency for Health Research and Quality, USA
2. Michael J. Ackerman, National Library of Medicine, USA, and James Goldberg, University of Nice, France
3. Veli Stroetmann, eHealth for Safety study, empirica Communication and Technology Research, Germany
4. Octavian Purcarea, Unit ICT for Health, DG Information Society and Media, EC
5. Greg T. Mogel, MD, Deputy Director, TATRC, USA

Content of the workshop

Patient safety is playing an increasingly important role in all discussions on healthcare across the EU. All the 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.

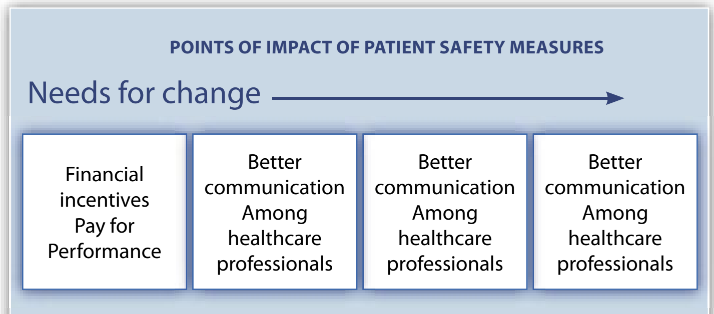
Presentations and discussions concentrated on the following topics and issues:

- **Lack of methodological uniformity and interoperability**

There is a lack of methodological uniformity in identification and measurement of adverse events. A comprehensive approach is essential to prevent, or at least manage, the risk arising this lack of uniformity. 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 national health service 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 the implementation of measures spread along a continuum figured in the following figure:



Source: Jean Pierre Thierry 2006[167]

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

- Leadership and strategic priorities issues
- Safety culture
- 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 include the Electronic Health Record, the Personal Health Record, the Computer Physician Order Entry, 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 US, 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**.

- **Collaboration and communication at the point of care**

During the workshop, it was clear that rather than continue with a "blame culture", all the 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 patient safety challenge and in learning from near-misses and adverse events**.

The importance of communication among members of a medical team must not be underrated. But the priorities of patient care seem to differ between members of the healthcare team. It was highlighted that verbal communication between team members is not yet consistent According to a survey performed in 2004[168], 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.

- **Collaboration and communication on policy level**

It was also noted that new, global distribution of ICT advanced solutions that will affect professional and patient safety. The quality of care provided should therefore be considered at the regional, national and international level.

Co-operation on the 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 EC proposal for the Regulation on Medicinal Products for Paediatric Use, thus 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 their recipients. Here the Community contributes to reducing such risks by adopting legislation on quality and safety of these substances. Similar improvements should be applied progressively 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 (called the open method of co-ordination), joint initiatives and 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.

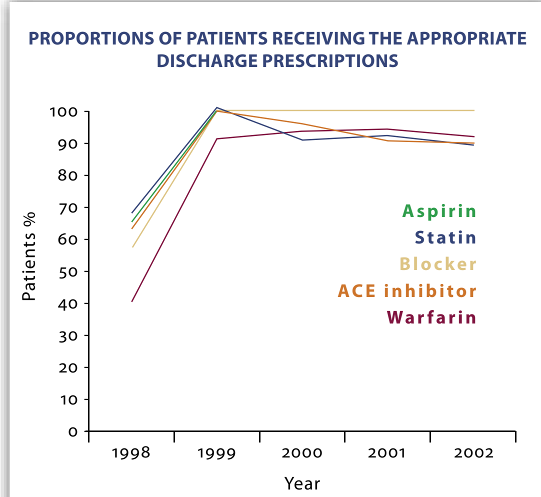
To deal with the topic of patient safety and ICT in a more concrete way, the speakers outlined several applications, the advantages and disadvantages of implementing them and noted some ideas and challenges concerning the respective issues.

- **Prescribing and Electronic Medical Records**

The act of prescribing involves medical knowledge that is evidenced-based, and provides a continuous feedback on allergies and side-effects. In this closed loop, the role of ICT 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 federal Drugs Agency in 2005 from the US market. The role of ICT 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, of which 2210 were fatal. The Kaiser Permanente study showed also that the odds ratio was superior for the patients treated with Rofecoxib and therefore 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 the US.

Lappe *et al* (2004)[169] 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 prescription system, shown in the figure below. Overall, a 27% decrease in unadjusted absolute death rate is observed.



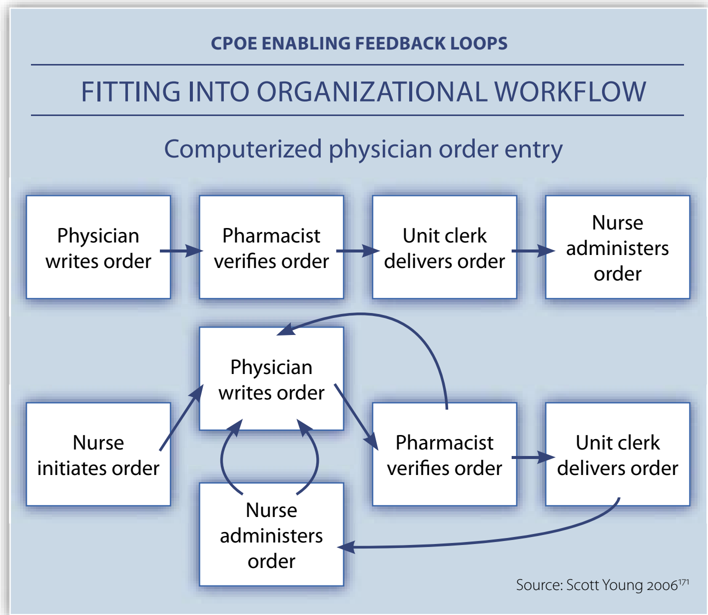
Source: Lappé *et al.* 2004

ePrescribing systems appear to improve workflow and contribute to evidence-based medicine. They also proved to be a sound, interim step towards seamless reporting integrated into a full Electronic Medical Record. However, the journey towards the introduction of such integrated records is still long and difficult. In physicians' offices more then 85% of medical records are paper records. In hospitals, the figure is 65%.[170] This is unfortunate, given the need for the co-ordination of care in an increasingly complex health sector, especially in light of the observed increased prevalence of chronic conditions.

- **Computer Physician Order Entry**

In this context, computerised physician order entry (CPOE) are another application from which healthcare could benefit. CPOE have already received considerable attention in the USA as a key technology to help achieve the goal of reducing medical errors.

A CPOE enables a reorganisation of healthcare flow of information which permits multiple information exchange and validation feedback loops, as illustrated in the figure below. These feedback loops can improve patient safety significantly by detecting potential risks before they become threats.



Source: Scott Young 2006[171]

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 CPOE. Proponents argue that CPOE systems that include data on patient diagnoses, current medications and history of drug interactions or allergies can reduce substantially prescribing errors which in turn leads to demonstrable improvements in patient safety. CPOE 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 Australia, the US, and the UK 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."[172]

Recent evidence (Koppel et al, 2005)[173] 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.

- **Decision support systems**

In this workshop, there was a clear consensus that the use of decision support systems 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 decision support systems. These reach from a significant improvement of clinical performance to no effect on physicians' adherence to care suggestions or negative comments about a decision support system. 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 decision support systems 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.

- **Adverse drug events monitoring**

A further topic of discussion at the workshop was the monitoring of adverse events, and in particular of adverse drug events. 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 adverse event systems, and consequently ICT systems have been tested primarily in these areas. Most institutions use spontaneous incident reporting (which relies exclusively on voluntary reports from nurses, pharmacists and physicians focused on direct patient care) to detect such events; however, this method is generally regarded as rather ineffective and only identifies about one in 20 adverse drug events. Conversely, most ICT trials have found a significant increase in the number of adverse drug events 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.

- **Bar codes and radio-frequency identification**

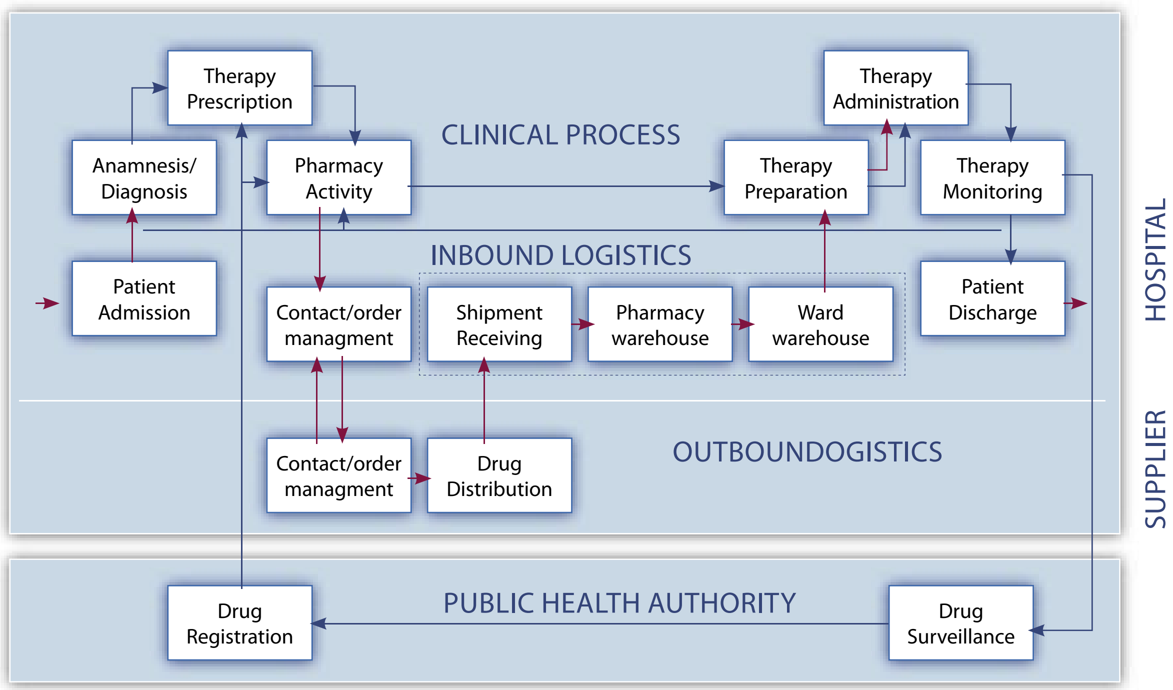
These two tools help to reduce administration and logistics errors by allowing real-time updates, in particular to medication delivery schedules. These technologies can offer simultaneous access to the system at multiple sites, elimination of phone calls and paperwork, but more importantly elimination 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 elderly persons

- **Integration of different tools into systems**

Mr Alberto Sanna, from the 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 the figure below).

The role of ICT in preventing errors is identified along the continuum of care and several specific improvements are suggested at the level of diagnostic procedure, ordering and distribution of drugs, therapy preparation and administration. The system was designed to be extended to the public health authority in the process of registration and surveillance of drugs.

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 of the project, the DRIVE clinical module, allows the electronic prescription for doctors, the electronic ordering and administration for nurses and ePrescription validation for pharmacists.

Conclusions and major challenges

The workshop concluded that the concept off integrated systems, e.g. that combine DSS, CPOE and alerting, seem to be better accepted. Moreover, systems should be designed with, and not just for, the end-users, who are either 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 healthcare professionals involved 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 for patient safety were discussed 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. 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 ICT: ICT 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. ICT is a key component towards a safer environment for healthcare (but it is only a component, and it was felt that management and cultural issues deserve the same attention).
- Some additional issues were named, such as the role of ICT in the evolution of underdeveloped healthcare systems or the role of ICT 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 ICT advanced solution that will affect professional and patient safety and the quality of care should be considered at the regional, national and international levels.

•••

Workshop 2, Brussels, June 2006: Impact of Emerging Information and Communication Technologies on Patient Safety

Organisation and speakers

The second expert meeting was held on 30th June 2006, and focused on the intersection of patient safety with the topics of the conference "ICT for Biomedical Sciences". Hence, it was not concerned with patient safety in general nor with the 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 of these ICT-related applications 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, EC, and was moderated by Mr Ilias Iakovidis, Deputy Head of Unit ICT for Health, and featured contributions from the following speakers:

1. Octavian Purcarea, Unit "ICT for Health", DG Information Society and Media, EC
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, New Zealand
4. Zvia Agur, Optimata Ltd. & President of the Institute for Medical BioMathematics (IMBM), Israel

Content of the workshop

The presentations and discussions focused on modelling and simulation, and the Virtual Physiological Human, as well as other emerging ICT solutions, in particular those relating to specific drug, implant and device safety aspects. ICT 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 ICT applications and issues were central outcomes of the workshop:

- **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 do not work or work well), and the expense of the in vitro testing increase the importance of these novel techniques.

- **Personalised care**
  Drugs

ICT tools are needed to achieve further advances in Pharmacokinetics and Pharmacodynamics (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. 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 adverse drug reactions with structural properties of the drug and risk factors, and integrate heterogeneous knowledge and data on adverse drug reactions, including pharmacovigilance data.

Care paths according to individual conditions and needs Coupling images with models will enable quantitative and 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 to which in-patients are exposed.

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.

- **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. 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 electronic healthcare records.

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.

- **Data presentation research**

The presentation of data is a key aspect of successful integration of ICT 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 (when various medical professionals involved, and there are multiple participants in decision-making as is more and more common in multi-disciplinary clinical teams).

Workshop 3, Geneva, October 2006: workshop and educational session

Organisation and speakers

The third and last workshop event took place on 10th-12th of October, 2006 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 an educational session 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 to the "World of Health IT" Conference held in Geneva at the same time-period.

The workshop, which gathered a number of well-known experts, took place on the first day of the World of health IT conference (10th of October) and was chaired by the EU Commission Services. Once again, it illustrated the keen interest that it is shown to patient safety. The educational session took place on the 12th of October and was offered collectively 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. Professor Christian Lovis, University Hospital of Geneva, Switzerland
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. Professor Ed Hammond, Duke University Medical Centre, US

The educational session included presentations from:

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 of the EHMA Brussels office (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

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 of the EC 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 all the participants to introduce themselves and their interests.

The speakers agreed that modern healthcare is evolving towards a citizen-centred approach. Currently, healthcare professional workloads are high, and are projected to continue their up-ward 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, and long working hours 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 DG INFSO 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.

The presentations and discussions focused the attention to the following topics: integration and traceability of data, semantic interoperability, nanotechnology and wireless technologies, computer-aided prognostics, addressing the continuum of care, etc.

- **Integration and traceability of data**

The various 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 lifecycle 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 of research emphasised in this context of integrating included 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
- Electronic health record Architecture and Functional Requirements
- Decision Support including research protocols and guideline specifications

Current challenges, preventing technical as well as semantic interoperability, include multiple forms of coding such as ICD, ICPC, SNOMED, LOINC, and DRG.

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 have 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
- reducing errors during drug prescription, dispensing and medication/administration, counterfeiting.
- These applications by no means exhaust the potential of tracing solutions. Further research, especially on the medical side of traceability, is certainly required.

- **Patient data and Electronic Health Records**

The possibility to re-use electronic health data from respective record systems was a topic that was given particular attention. There was a number of arguments for using patient care data for clinical research that were included. These were comprised of costs, interoperability, volume, speed, accuracy, and completeness:

- 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 electronic healthcare records could result in more complete and more meaningful documentation.

The patient safety argument should also not be neglected. All of the six points listed above have a connection to the risks to which patients are exposed 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.

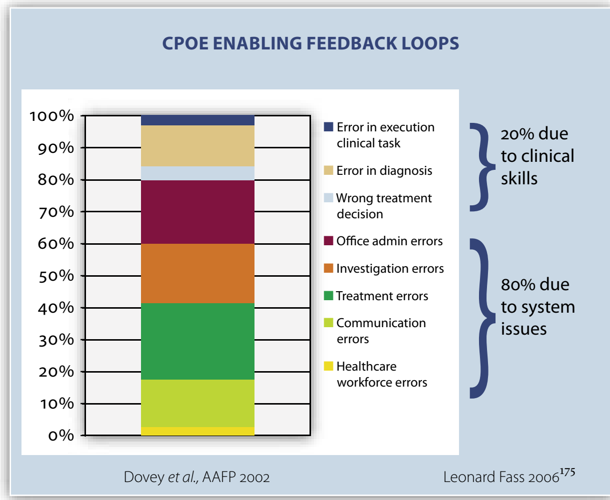
Nonetheless, there are a number of concerns for using patient care data that must not be ignored. First, data collected for patient care is not the same as for clinical research (some experts estimate that there is as little as a 50% overlap). Moreover, the providers do not have time to collect additional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

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

Despite the difficulties and challenges, the hopes associated with the increasing diffusion of electronic health (or patient) records in the field of patient safety are significant. For example, in the Netherlands, research[174] carried out by TNS-NIPO, a market research organisation, shows that around 800,000 Dutch people over the age of 18 have according to their own perceptions been subject 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.

- **Nanotechnology and wireless technologies**

A number of developments in the health systems currently operating in European Member States, such as increased workload, significantly fewer care-givers, long work times, lower productivity and increased frustration, are leading 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 is illustrated in the figure below.



Nanotechnology and wireless technology were named as key technology drivers that are able to help address these system-related errors. Wireless networks can be 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, and through smart systems that can talk 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, and hydration 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.

- **Computer-aided prognostics**

Incorrect patient management is one of the largest factors that adds costs and avoidable mortality instances to healthcare. A computer-aided prognostics work station could help physicians make critical judgements on risk assessment, survival probability, drug response, rate of disease progression, therapy planning and monitoring, and clinical outcomes. 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 evidence-based medicine and give healthcare management the possibility to slow down the rate of overall cost increase in the healthcare system.

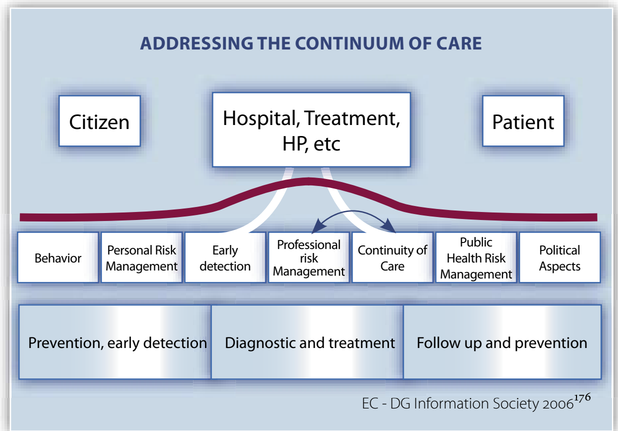
The project ePISODE was described as working towards development of computer-aided prognostics systems. In particular, the project aims at redefining the screening process and developing a new generation of risk stratification that is truly preventive and specific. The expected out-comes of the project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

- **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 EC. This view is still valid and was confirmed by the workshop participants. Hence, the health risk management domain can address three levels, that follow the process of care:

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

This is illustrated in the figure below.



Content of the educational session

The session took place two 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 by a short introduction by Céline Van Doosselaere, Head of the EHMA Brussels office (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 a focus on applications like decision support systems and CPOE; good practice examples, success and failure factors in ICT implementation. She followed this information with 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 uses data that is routinely collected for other purposes. The conclusions of the speaker were that ICT 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 for quality in healthcare and patient safety. Nevertheless, public health informatics should be promoted to find the proper way to use ICT efficiently. These new research areas should encompass several academic fields of expertise including bio-informatics and ICT specialists. Interoperability issues for the creation of seamless health information systems is a key complement to the current work done most notably for electronic healthcare record interoperability.
The presentations were followed by a 20-minute round table with discussion from representatives of CPME, HOPE, EHMA, the speakers, and the audience.

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

1. ICT 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 healthcare professional identification, authentication, and semantics.
5. Research and development must contribute to address these and other issues.

Dr. Markku Äärimaa concluded the session by emphasising the importance of research into the proper implementation of ICT in the area of patient safety.

To sum up, the educational session emphasised a number of issues that are 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, and the need for a comprehensive policy of research and development in the area of ICT for patient safety.

EU-US eHealth policy workshop, Brussels, May 2007: Session on patient safety

This eHealth policy workshop, co-organised by the European Commission and the U.S. Department of Health & Human Services, in conjunction with the European-American Business Council, took place after the official closure of the study. Nevertheless the main outcomes of the session «Improving Patient Safety through IT», supported by the eHealth for Safety study team, are briefly reflected here because of the international relevance of the topics addressed and opportunities for global cooperation identified in this field. The approach towards a cooperative eHealth for Safety work that evolved from the discussion can be summarised as follows:

It would be useful to document and manage the risks associated with IT implementation by working with Patient Safety specialists and Risk Managers. A proper cooperation between IT specialists and safety/quality organisations has not yet been realised, and the two communities should meet and discuss the topic in greater depth. Simultaneously, successful implementation of actual and future IT tools for Patient Safety (including risk assessment and "IT adverse events reporting"), requires effective management of social and organisational dimensions.

Transatlantic efforts could help to establish a reference framework of best practices and mistakes, as well as organisational, ethical, and economic aspects. It might be useful to establish a priority list starting with applications that have demonstrated, in a known and detailed context, their ability to increase Patient Safety. Incremental implementation of solutions might be recommended, taking into account the need to establish an appropriate learning curve.

Some specific areas of future research addressed by the discussion include:

- Federating clinical data repositories / EHR systems of hospitals for secondary use, creating new opportunities for Patient Safety research
- Improving prediction and detection of adverse drug events with the help of IT
- International interoperability of medication history data and adverse drug events (ADE) data
- Assessment of available health IT solutions, such as CPOE
- Optimising decision support, e.g. defining priority lists of alerts
- Defining functionalities of CPOE and clinical decision support systems (CDSS) critical for improving patient safety
- Standards and certification
  - More detailed standards for medication decision support
  - Criteria and strategies for certification of CPOE and/or CDSS
- Integration of knowledge into patient workflows
- Types and causes of unexpected adverse events caused by CPOE and CDSS
- Combining CPOE and CDSS with RFID-based patient identification systems
- Financial return on investment and cost effectiveness analyses for Health IT and health information exchange (HIE).

The following are brief summaries of individual participants' contributions in the overall discussion:
Antoine Geissbuehler, Medical CIO, University Hospital Geneva, Switzerland

Antoine demonstrated that Patient Safety issues are related to Knowledge Management and need to be addressed as part of the process of care. Alerts, clinical decision support and quality loops should be implemented considering patient workflow and should be compliant with clinical pathways. The creation and use of knowledge, in this context, is a challenge. Even in academic institutions at the leading edge of HIT, cultural, ethical, and economic issues are difficult to address. These, however, are critical to the transformation into a "learning organisation". Long term issues concern the extension of the learning organisation across the process and actors of care including health professionals outside hospitals such as GPs, the home care environment, and the patient. Antoine's presentation was appropriate to remind us that Patient Safety issues are justifying R&D efforts in IT.

Rainu Kaushal, Associate Professor of Public Health and Pediatrics, Cornell University; Director, Pediatric Quality and Safety, KCCH at NYPH, USA

Rainu laid out the important experience gained in the US with issues regarding the prevention of Adverse Events, such as medication errors, one of the leading types of medical errors. CDSS should be integrated in CPOE, but the frequent overwriting of medication suggestions shows that additional effort should be made (Human Computer Interface, CPOE system for routine use). Like Antoine, Rainu stressed the fact that CDSS should be integrated in the process (i.e. nurse workflow), in the organisation, and across boundaries. Another issue discussed was the need for an industrialisation of CPOE beyond the home-grown systems used by academic institutions. The rapid change of knowledge could also be considered. The economic impact of an achievable error reduction rate is documented, yet not easily understood by key players, since it relies mainly on models rather than on primary data. A robust business model should be established to be shared and understood by decision makers and the industry.

Maureen Baker, National Clinical Lead for Patient Safety, NHS, UK

Maureen explained that Connecting for Health (CfH), the National Program for IT of the National Health Service (NHS) in England, has evolved in order to take into account the Patient Safety issue. At the beginning, it was assumed that the users (healthcare professionals) will address instinctively Patient Safety. A collaboration of the National Patient Safety Agency (NPSA) to the program has been established and it was stated that the project was not using Patient Safety as an explicit primary goal within the general objectives of modernisation of the NHS. As one of the results, a more robust structured proactive manner was designed that led to the implementation of a generic standard for safety applied to the supplier of IT solutions to the CfH project. Introduction of safety incident monitoring process is mandatory to fix the safety-related problems.

Daniel Grandt, Head of Department of Internal Medicine, Klinikum Saarbruecken, Germany

Daniel stressed the fact that medication errors are not only an IT problem. The workplace specificity should be taken into account and difficulties met are more often on the social and organisational sides than on the pure technical side. Part of the solution is the research towards a comprehensive approach to Patient Safety, including participation by healthcare professionals as well as managers and policy makers. He agrees with Maureen that unattended possible consequences after IT/CPOE implementation should be collected and managed. Acceptance is a key factor and is a prerequisite to realising net economic benefits and Return on Investment.

Marc Overhage, Director of Medical Informatics, Regenstrief Institute, Inc.; USA

Marc began his presentation by reminding us that part of the medical errors are due to underutilisation of care (omission) and not only overuse (commission). Focusing on CPOE, he confirms that CDSS is needed, but very difficult to implement. One issue is the way knowledge should be managed at the workplace. Adaptation of alerts, as an example, should be made if the system is to be used effectively. With CPOE, it is possible to state that IT could be a "power tool" that could bring more harm than good if not designed and used appropriately. CPOE at the present stage of diffusion still needs careful assessment.

"

What are we learning:

- *successful health IT implementation requires vision, leadership, & stamina from clinicians & top management*
- *changes in workflow and culture are inevitable and desirable*
- *off-the-shelve solutions may require selective customization – caution!*
- *integrated systems are often preferred to best-of-breed, especially in small hospitals*
- *technology placed in the patient's home needs to be simple*

"

William B Munier, Agency for Healthcare Research and Quality, USA

Annex 3: Endnotes

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