



## eHealth for patient safety: towards a European research roadmap

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**Summary:** This paper analyses key issues towards a research roadmap for eHealth-supported patient safety. The *raison d'être* for research in this area is the high number of adverse patient events and deaths that could be avoided if better safety and risk management mechanisms were in place. The benefits that ICT applications can bring for increased patient safety are briefly reviewed, complemented by an analysis of key ICT tools in this domain. The paper outlines the impact of decision support tools, CPOE, as well as incident reporting systems.

Some key research trends and foci like data mining, ontologies, modelling and simulation, virtual clinical trials, risk models, health pathways, bar codes and RFID, preparedness for large-scale events are touched upon.

Finally, the synthesis points to the fact that only a multilevel analysis of ICT in patient safety will be able to address this complex issue adequately. The *eHealth for Safety study* will give insights into the structure of such an analysis in its lifetime and arrive at a vision and roadmap for more detailed research on increasing patient safety through ICT.

### Healthcare as a risky endeavour

Reflecting on more than a decade of global research, two, by now famous, USA Institute of Medicine (IOM) reports, *To Err Is Human*<sup>1</sup> (2000) and *Crossing the Quality Chasm*<sup>2</sup> (2001) highlighted the risks of modern healthcare. The first report included an estimate that organisational systems failures in healthcare delivery (i.e., poorly designed or “broken” care processes) were responsible for at least 90,000 deaths each year in the USA. The second report revealed a wide “chasm” between the quality of care the health system should be capable of delivering today (given the astounding advances in medical science and technology in the past half century) and the quality of care most Americans received. In its recent report *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*<sup>3</sup> the *US Commission on Systemic Interoperability* pointed out that *medical errors are killing more people each year than breast cancer, AIDS, or motor vehicle accidents*.<sup>4</sup>

It is widely believed that the situation in many, if not all European health delivery contexts is characterised by similar, if not the same deficiencies. Of activities seen as potentially risky, travel by rail in Europe or commercial air travel are actually among the safest activities, with fewer than one in 100,000 fatalities per personal encounter or trip. Driving is far more dangerous as Figure 1 shows. It is no surprise that statistically, mountain climbing and bungee jumping are among the most dangerous

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<sup>1</sup> IOM Report (2000). *To err is human: Building a safer health system*. Institute of Medicine, 287 p. Available at: <http://books.nap.edu/books/0309068371/html/index.html>.

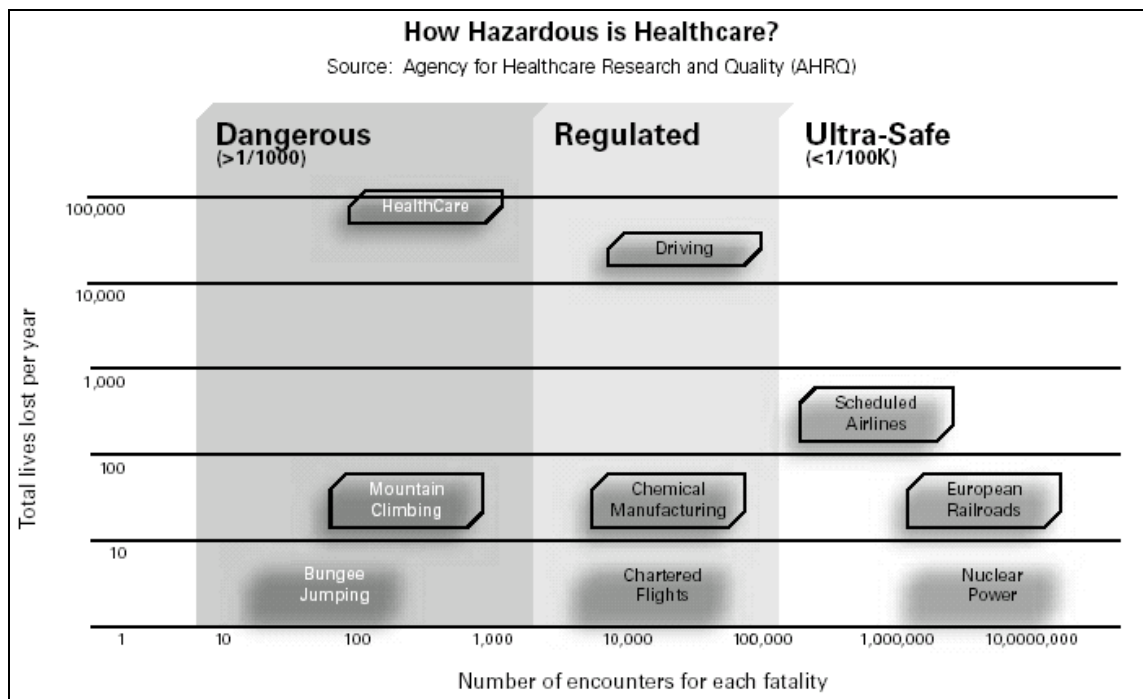
<sup>2</sup> IOM Report (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*, Committee on Quality of Health Care in America, Institute of Medicine, 364 p., <http://books.nap.edu/catalog/10027.html>

<sup>3</sup> Commission on Systemic Interoperability (2005): *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology*, U.S. Government Printing Office (GPO), Washington, October 2005, 249 p., <http://endingthedocumentgame.gov/PDFs/entireReport.pdf>

<sup>4</sup> Institute of Medicine, Centers for Disease Control and Prevention; National Center for Health Statistics: *Preliminary Data for 1998 and 1999*, 2000.

activities. But a great surprise is that *there are more deaths per encounter with the healthcare system than for any of these other activities.*<sup>5</sup>

**FIGURE 1: RISK OF FATALITY IN DIFFERENT DOMAINS**



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

### ICT in healthcare: current state of play

The benefits that information and communications technologies (ICT) can bring for improved quality of care and increased patient safety are briefly reviewed in this section, complemented by a short analysis of the state of play in the implementation of some key ICT tools.

ICT applications can be useful in almost every aspect of healthcare, including the delivery of care to remote locations, reducing costs, increasing the efficiency of delivery, facilitating information and communication within and among healthcare organisations, simplifying diagnostic and therapeutic processes and, last but not most important, increasing the quality of care provided to patient, including improvements in patient safety.<sup>6</sup> ICTs are expected to help relieve the strain that healthcare systems experience: the pressure to increase the quality of care and decrease costs simultaneously.<sup>7</sup> The recent IOM/NAE report<sup>8</sup>, *Building a Better Delivery System: A New Engineering/Health Care Partnership* underscores the *importance of information and communications technologies* for meeting multidimensional performance challenges. It also identified proven, fundamental engineering concepts, such as designing for safety, mass customisation, continuous flow, and production planning, that could be brought to bear immediately to redesign and improve care processes to facilitate risk management, deliver greater patient safety and better quality.

Furthermore, Wachter<sup>9</sup> indicates 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

<sup>5</sup> Scott Young. The Role of Health IT in Reducing Medical Errors and Improving Healthcare Quality & Patient Safety. Agency for Healthcare Research and Quality. August 2005. [http://www.ehealthinitiative.org/assets/documents/Capitol\\_Hill\\_Briefings/Young9-22-04.PPT](http://www.ehealthinitiative.org/assets/documents/Capitol_Hill_Briefings/Young9-22-04.PPT)

<sup>6</sup> JRC/IPTS (2004) eHealth in the Context of a European Ageing Society. A Prospective Study. P.17.

<sup>7</sup> European Commission: The Social Situation in the European Union 2003. Luxembourg: Office for Official Publications. P. 69.

<sup>8</sup> Proctor P. Reid, W. Dale Compton, Jerome H. Grossman, and Gary Fanjiang, Editors, (2005): *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Committee on Engineering and the Health Care System, National Academies Press, 276 p., <http://www.nap.edu/catalog/11378.html>

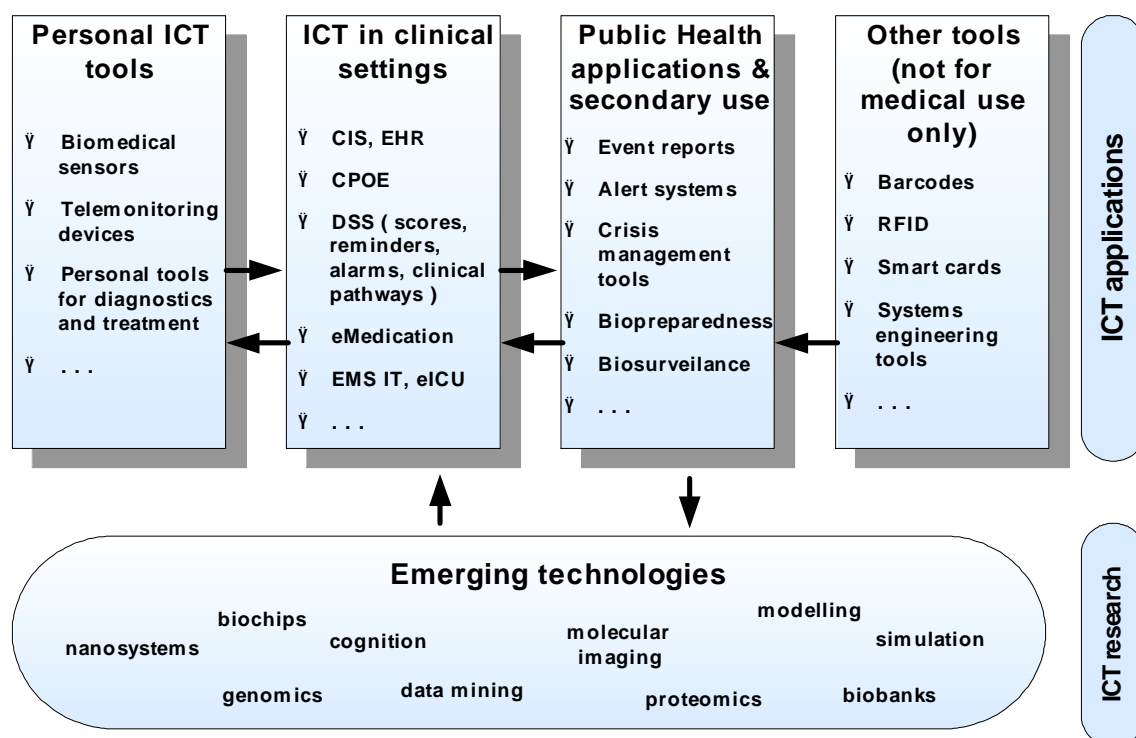
<sup>9</sup> Wachter, R (2004) The End Of The Beginning: Patient Safety Five Years After 'To Err Is Human'. Health Affairs Web Exclusive. W4- 539.

if they lack a strong IT backbone.” This development, he adds, is fuelled by the activities of the *Leapfrog Group*, a business coalition that promotes patient safety through public reporting and pay for performance initiatives.<sup>10</sup> The National Audit Office in the UK also sees the preventing of errors by the appropriate use of information technology as a well established fact.<sup>11</sup>

A report on a workshop about the use of ICT for patient safety and risk management<sup>12</sup> (2004), organised by the European Commission, outlines as a key finding that *information society technology can reduce the rate of errors in three ways: by preventing errors and adverse events, by facilitating a rapid response after an adverse event has occurred, and by tracking and providing feedback about adverse events*. However, one should also mention some concerning reports of multiple errors actually introduced by IT systems themselves.<sup>13</sup> For risk and safety management, ICT applications have a certain "Janus" characteristic: On the one hand, they develop into the key tool to improve safety in health systems. On the other hand, they themselves may become the cause of pertinent risks.

Figure 2 provides an overview of the areas where ICT can support patient safety and risk management. The *eHealth for Safety* study is currently reviewing the state of the art in some of these application fields, and will outline major opportunities and challenges as well as to identify in a next step important research aspects and innovative approaches to address patient safety issues. In many of the fields in the Figure below, only experimental or pilot systems and applications are as-of-yet available. In this paper we briefly review only a few well known ICT tools and some emerging technologies.

**FIGURE 2: ICT IN SUPPORT OF PATIENT SAFETY AND RISK MANAGEMENT IN HEALTHCARE**



Source: © empirica, *eHealth for Safety* study, 2005

One of the most important developments in eHealth in recent years in many countries has been the ongoing spread of activities concerned with the implementation of Electronic Health Records (EHR) on

<sup>10</sup> Milstein A. et al., "Improving the Safety of Health Care: The Leapfrog Initiative," *Effective Clinical Practice* 3, no. 6 (2000): 313–316; and N. Versel, "Performance Driving Investment Up," *Modern Physician* (November 2003): 15, 23.

<sup>11</sup> NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., [http://www.nao.org.uk/publications/nao\\_reports/05-06/0506456.pdf](http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf)

<sup>12</sup> Veronique Lessens (Deloitte) and David Lloyd-Williams (Silicon Bridge Research) (2004): *Workshop on Risk Management for Health Professionals. Use of ICT, Workshop Report*, p. 14. Workshop organised by the European Commission, DG Information Society and the Media.

<sup>13</sup> Ash, J.S., M. Berg, and E. Coiera, "Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-related Errors," *Journal of the American Informatics Association*, 11, no. 2 (2004): 104–112.

the national, regional and local level. The IOM has advised that *moving from a paper to an electronic based patient record system would be the single step that would most improve patient safety*. In UK, the National Programme for Information Technology in the NHS being delivered by the Department's agency, *NHS Connecting for Health*, has begun to roll out its National Care Record system and expects it to have full functionality by 2010. An evaluation of the activities conducted so far in the UK states that "the *National Care Record has significant potential to improve safety as lost or poorly completed records are a major contributory factor to patient safety incidents.*"<sup>14</sup> It is likely that these large scale development of eHealth infrastructure in many countries will lead to broader implementation of other well known ICT tools, like the ones addressed below.

According to Coiera et al<sup>15</sup> there is a clear consensus that the use of **Decision Support Systems (DSS)** can improve patient outcomes and make clinical services more effective. DSS are broad solutions, which are often incorporated in a variety of eHealth applications. They go back as far as 1974, and evidence indicates that they can indeed enhance clinical performance for drug dosing, preventive care and other aspects of care, but so far not really convincingly for diagnoses. This is the main finding of Hunt et al's review (1998)<sup>16</sup>. Several other reviews of the evidence collected so far have taken place. A study by Sintchenko et. al<sup>17</sup> (2004) notes that the use of DSS plus microbiology report improved the agreement of decisions by clinicians with those of an expert panel from 65% to 97% ( $p=0.0002$ ) or to 67% ( $p=0.02$ ) when only antibiotic guidelines were accessed.

In their assessment of computer-based cardiac care suggestions Tierney et al (2003)<sup>18</sup> found that the intervention had *no effect* on physicians' adherence to care suggestions. Physicians viewed guidelines as providing helpful information but containing their practice. They suggest that future studies must weigh the costs and benefits of different (perhaps more Draconian) methods of affecting clinician behaviour. Rousseau et. al (2003)<sup>19</sup> report primarily negative comments about a DSS. The three main concerns voiced by clinicians were: timing of the guideline trigger, ease of use of the system and helpfulness of the content.

In Garg et al's systematic review of controlled trials of DSSs, about two thirds of these are effective at narrowing knowledge gaps, improving decisions, clinical practice or patient outcomes<sup>20</sup>, but many are not (e.g. computer-based guidelines on the management of angina and asthma<sup>21</sup>). Ash et al (2004)<sup>22</sup> identify instances where DSS (or patient care information systems, PCIS, as they call it) foster errors rather than reducing them. They distinguish between errors in the process of entering and retrieving information, and errors in the communication and coordination process.

A recent report by Kawamoto et al (2005)<sup>23</sup> reviewed seventy studies and concluded that decision support systems significantly improved clinical practice in 68% of trials. Most notably, 75% of interventions succeeded when the decision support was provided to clinicians automatically, whereas none succeeded when clinicians were required to seek out the advice of the DSS. Similarly, systems that were provided as an integrated component of charting, or order entry systems, were significantly more likely to succeed than stand alone systems.

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<sup>14</sup> NAO (National Audit Office) (2005) "A Safer Place for Patients: Learning to improve patient safety", November 3, 2005, Department of Health, 86 p., [http://www.nao.org.uk/publications/nao\\_reports/05-06/0506456.pdf](http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf), p.9

<sup>15</sup> E. Coiera, J.I. Westbrook, J.C. Wyatt (2006): The Safety and Quality of Decision Support Systems. In Haux R, Kulikowski C, editors. IMIA Yearbook of Medical Informatics 2006. Methods Inf Med 2006; 45 Suppl 1 (in print)

<sup>16</sup> Hunt et al. (1998): Effects of computer-based clinical decision support system on physicians performance and patient outcomes: a systematic review. JAMA 280: 1339-1346

<sup>17</sup> Sintchenko et. Al (2004) Comparative impact of guidelines, clinical data and decision support on prescribing decision: an interactive web experiment with simulated cases. J Am Med Inform Assoc 11 (1) 71-7.

<sup>18</sup> Tierney et. Al (2003) Effects of computerized guidelines for managing heart disease in primary care. J Gen Intern Med 18 (12): 967-76.

<sup>19</sup> Rousseau et. al (2003) Practice based, longitudinal, qualitative interview study of computerised evidence based guidelines in primary care. BMJ. 2003 Feb 8;326(7384):314.

<sup>20</sup> Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene S, Sam J, Haynes RB. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA. 2005;293:1223-1238.

<sup>21</sup> Eccles M, McColl E, Steen N, Rousseau N, Grimshaw J, Parkin D, Purves I. Effect of computerised evidence based guidelines on management of asthma and angina in adults in primary care: cluster randomised controlled trial. BMJ. 2002;325:941-944. doi: 10.1136/bmj.325.7370.941.

<sup>22</sup> Ash et. al (2004) Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. Journal of the American Medical Informatics Ass. 11:104-112

<sup>23</sup> Kawamoto et al. (2005): Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ, April 2, 2005; 330(7494): 765.

Coiera et al conclude 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.

**Computerized Physician Order Entry systems (CPOE)** have received considerable attention in the USA as a key technology to help realize the goal of reducing medical errors. CPOEs are 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.<sup>24</sup> Clinical decision support systems are built into almost all CPOE systems to varying degrees, providing basic computerised advice regarding drug doses, routes and frequencies, as well as more sophisticated data such as drug allergy, drug-laboratory values, drug-drug interactions, checks and guidelines.<sup>25</sup> CPOE are applied in a variety of physical and technical environments using currently available vendor software but CPOE is also very resource-intensive, time consuming, and expensive.<sup>26</sup>

Proponents of CPOE systems argue that they have led to reductions in transcription errors, which in turn have led to demonstrable improvements in patient safety. Furthermore, CPOE systems that include data on patient diagnoses, current medications, and history of drug interactions or allergies can significantly reduce prescribing errors.<sup>27</sup> CPOE systems also improve the quality of care by increasing clinician compliance with standard guidelines of care, thereby reducing variations in care.

From four studies on CPOE with DSS, analysed by Kaushal and Bates (2003)<sup>28</sup> - three of which were conducted at Brigham and Women’s Hospital (BWH) - the first study (from BWH) found a 55% decrease in serious medication error. As a secondary outcome this study found a 17% decrease in preventable Adverse Drug Events (ADE). In their analysis of CPOE implementations Sittig and Stead (1994)<sup>29</sup> 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. The following case study illustrates a practical application of CPOE:

#### **Improving medication handling through structured prescribing pathways - Wirral Hospital NHS Trust, UK**

At Wirral Hospital NHS Trust the introduction of structured, ICT-supported medication handling pathways drastically reduced errors in the prescription of specific high risk drugs. For instance, an error rate of 82% in the prescription of low molecular weight heparin (identified by an audit) was eliminated. Similarly, in paediatrics structured pathways led to reductions of specific error rates from 26% to just 4% for paediatricians and from 76% to less than 7% for non-paediatric specialists. Furthermore, the introduction of an automated dispensing system reduced the risk of medication errors while electronic prescription improved the legibility and completeness of prescriptions. Moreover, the use of ICT applications supporting work processes freed staff for clinical activities at the bedside.

Source: Case study originally prepared for the *eHealth Impact study*: [www.ehealth-impact.org](http://www.ehealth-impact.org)

<sup>24</sup> FCG (2003): Computerized Physician Order Entry: Costs, Benefits and Challenges. A Case Study Approach

<sup>25</sup> Bonnabry Pascal (2003) Information Technologies for the Prevention of Medication Errors. Business Briefing: European Pharmacotherapy 2003 1-5.

<sup>26</sup> It is estimated that five percent of hospitals in the US now have CPOE, but the implementation is costly; see FCG (2003)

<sup>27</sup> Bates, D.W., L.L. Leape, D.J. Cullen, N. Laird, L.A. Petersen, J.M. Teich, E. Burdick, M. Hickey, S. Kleefield, B. Shea, M. Vander Vliet, and D.L. Seger. 1998. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. *Journal of the American Medical Association* 280(15): 1311–1316. Bates, D.W., J.M. Teich, J. Lee, D. Seger, G.J. Kuperman, N. Ma’Luf, D. Boyle, and L. Leape. 1999. The impact of computerized physician order entry on medication error prevention. *Journal of the American Medical Informatics Association* 6(4): 313–321. Leapfrog Group. 2000. Leapfrog Patient Safety Standards: The Potential Benefit of Universal Adoption. Available online at: <http://www.leapfroggroup.org>.

<sup>28</sup> Kaushal Rainu, Bates David W. (2003) Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs). Chapter 6 in: *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Evidence Report/Technology Assessment: Number 43. AHRQ Publication No. 01-E058, July 2001. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/ptsafety/>, p.59-70

<sup>29</sup> Sittig and Stead (1994): Computer based physician Order Entry: the state of the art; in: *Journal of the American Medical Informatics Association*. 108-123.

However, some authors have also drawn attention to the potential danger of CPOE use. Studies in the US, UK and Australia have found that “commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management systems may generate new types of error because of user-interface design, but also because of events in the workplace such as distraction affecting the actions of system users.”<sup>30</sup> Han et al<sup>31</sup> recently reported about an unexpected increase in child mortality coincident with CPOE implementation. While the exact reason for this correlation remains unclear, it underlines that institutions should evaluate mortality effects, in addition to medication error rates, for patients who are dependent on time-sensitive therapies.

Whereas CPOE systems aim to prevent errors, **computerized 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 Drug Events (ADE) and consequently IT systems have been tested primarily in these areas.<sup>32</sup> Most institutions use spontaneous incident reporting (relies exclusively on voluntary reports from nurses, pharmacists and physicians focused on direct patient care) to detect ADEs; however, this method is generally regarded as rather ineffective and only identifies about one in 20 ADEs.<sup>33</sup>

Conversely, most IT trials have found a significant increase in the number of ADEs reported. **Automatic alerts** can also reduce the time until treatment is ordered for patients with critical laboratory results.<sup>34</sup> 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.<sup>35</sup>

In their review Gandhi and Bates<sup>36</sup> report one study demonstrating significant decreases in adverse clinical outcome with alert systems, in particular regarding allergic reactions. Significant improvements in response times concerning lab values were reported by several studies, and one study reported significant decrease in the risk of serious renal impairment. Furthermore, noteworthy changes in physician behaviour and modification of therapy based on alerts with recommended actions were reported.<sup>37</sup>

On a larger scale, several countries have already implemented or are considering **national or regional incident or event reporting system** (a concept that is also used in a variety of non-health related areas). By accumulating patient data from a variety of local sources such systems can be used for biosurveillance, such fast alert and pattern tracking as in case of a bioterrorism attack or an epidemic outbreak. In Australia, for instance, an incident reporting system – *AIMS* – was already set up in 1987, initially only in the field of anaesthesia.<sup>38</sup> Until 1992, 2000 incidents had been collected and reviewed, leading to significant changes at the local and national level.

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<sup>30</sup> see footnote 24

<sup>31</sup> Han, Yong et al. (2005): Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system in: *Pediatrics* Vol116 No.6 (12/2005) 1506-1512.

<sup>32</sup> Bates et. al (2003) Detecting Adverse Events Using Information Technology. *JAMIA* 10 p. 119

<sup>33</sup> *ibid*, p. 116

<sup>34</sup> Kuperman et.al (1999) Improving Response to Critical Laboratory Results with Automation: Results of a Randomized Controlled Trial. *JAMIA* 6 512-22.

<sup>35</sup> See Bates et. al (2003) p. 122.

<sup>36</sup> Gandhi Tejal K., Bates David W.: Computer Adverse Drug Event (ADE) Detection and Alerts .Chapter 8 in: University of California at San Francisco – Stanford University Evidence based Practice Center Making Health Care Safer: A Critical Analysis of Patient Safety Practices. p.81

<sup>37</sup> *ibid*, p.83

<sup>38</sup> Runciman W.B. (2002) Lessons from the Australian Patient Safety Foundation: setting up a national patient safety surveillance system – is this the right model? *Quality and Safety in Health Care* 11/2002: 250

### **Case Study: Incident Reporting in Australia**

Advanced Incident Management System (AIMS) is a computerised system for collecting, classifying, managing and learning about “things that go wrong in healthcare”. AIMS is designed as a single point of entry for information from a variety of health related sources including incident notification, occupational health records and coroner reports. AIMS was first set up in 1987, initially only in the field of anaesthesia. Until 1992, 2000 incidents had been collected and reviewed, leading to significant changes at the local and national level. During the analysis of the 2000 incidents collected in the database it was recognised that there was no clinically useful comprehensive information for “things that go wrong in healthcare”. It was thus decided to develop such a classification - that is to create a framework into which all iatrogenic events could be classified. In 2000, AIMS was replaced by a new system, AIMS-2, which was designed to be used across the entire spectrum of a national healthcare system by staff, patients and relatives as well as being useful to specialists, accessible on the web and suitable on the national and local level.

Additionally to the voluntary AIMS approach the Quality in Australia Health Care Study (QAHCS) was established. It involves the non-voluntary retrospective analysis of medical records of hospital admissions.

Sources: Malpass et. al (1999), PSI (2005), Runciman (2002)

Ideally, these and other applications will become part of an integrated system, for instance a combination of DSS, CPOE and alerting. Actually, in some cases such integration has already been achieved.

Research has also shown how important it is to design systems with the end-user, the clinician in mind. If systems are not fast and do not display all relevant information in a coherent and easy to use manner they will be rejected by the professionals and can even lead to more errors, not less. As Coiera et al<sup>39</sup> conclude, a deeper understanding of the “complex set of cognitive and socio-technical interactions” can result in the “design of systems which are not just intrinsically ‘safe’ but which also result in 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.

### **Some research trends and emerging technologies**

New and developing technologies also have a significant patient safety component, either because they pose risks or because they may offer benefits in their application to patient safety – or both. In this section we provide an overview of such emerging technologies and their (potential) application to patient safety and risk management in healthcare.

#### ***Towards a culture of safety in eHealth RTD***

Whereas eHealth tools and services are intended to have a beneficial impact on citizens' health, recent research has shown that some of these tools and services may under certain circumstances also be potentially harmful to citizens' health. New technologies inherently pose new risks. Health risk and patient safety aspects should therefore be taken into account by all health ICT RTD from EHR integration, home monitoring and assistive living, to bio-medical informatics, nano-devices and grid computing.

#### ***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, for example, instances where patient safety has been endangered, and identify the causes.

#### ***Ontology of patient safety***

For exchanging information on patient safety, as a common framework for modelling threats to safety and to support communication between clinicians and others on patient safety issues, a taxonomy and ontology covering healthcare risks and safety considerations should be developed.

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<sup>39</sup> see footnote 24

### **Mathematical modelling and simulation**

Modelling and simulation tools are anticipated to have significant impact on patient safety especially through advancing prediction, prevention and personalisation of healthcare. The European Information Society Technologies Advisory Group (ISTAG) proposed in 2004/2005 to stimulate research in the area of "*The Disease and Treatment Simulator*":<sup>40</sup> - a computational platform for simulating the function of a concrete disease. "This simulator will enable medicines to be tested without putting people at risk, and will accelerate research into damaging diseases such as heart disease and cancer." The Advisory Group also suggested that the disease and treatment model should interface directly with other projects of human benefit, such as the *Physiome* project<sup>41</sup> and the modelling of whole organs. In this context the European Commission (EC) is supporting research on the *Virtual Physiological Human*<sup>42</sup> (VPH) which is expected to accelerate knowledge discovery leading to improved disease prevention, early diagnosis and individuals' health risk management. To reduce risks to citizens participating in clinical research, to enable a radical expansion of the volume of research into clinical outcomes to the full range of treatments and to significantly accelerate production of results from clinical research it appears important to support research into tools to implement *virtual clinical trials*. According to the Academy of Medical Sciences<sup>43</sup> in UK, "sophisticated modelling has great potential and 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" which also "permits the evaluation of heterogeneity and the active exploration of those who may be at risk." Using simulation has already enabled pharmaceutical companies to eliminate four-fifths of a clinical trial, reducing the total number of recruited patients by 60% and shortening the trial's duration by 40%.<sup>44</sup> "Virtual patient" engines are helping researchers and physicians select the best among existing therapies, e.g., for breast cancer<sup>45</sup>, and to develop optimal dosing regimes. So-called "computer-assisted trial design" systems - a field in which models have become so useful that the FDA itself is adopting them<sup>46</sup> - model and simulate clinical trials to determine the optimal number of patients, dose amounts, and dosing frequency, all of which have for years mostly been determined through time-consuming and costly trial and error.

### **Medical simulation and virtual reality**

This is already being used as a training and feedback method in which learners practice tasks and processes in lifelike circumstances using models or *virtual reality* (VR), with feedback from observers, peers, actor-patients, and video cameras to assist improvement in skills. Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without harming patients. VR simulations are revolutionising surgical training<sup>47</sup> (e.g., for laparoscopic, gastrointestinal, plastic, ophthalmological, dermatological, and some laryngological procedures), and error reporting<sup>48</sup> in the healthcare field.

### **Healthcare system risk models**

Healthcare provision is an ever more specialised, flexible and, at the same time, integrated service, delivered by a wide variety of collaborating actors. As interoperability is increasingly achieved between previously isolated ICT systems 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. Modelling techniques could include neural networks and usefully integrate approaches such as Failure Mode Effects Analysis (FMEA) - identifying the ways a given procedure can

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<sup>40</sup> Information Society Technologies Advisory Group (ISTAG), Working Group "Grand Challenges in the Evolution of the Information Society", W. Wahlster (ed.), July 2004, p. 26-29

<sup>41</sup> IUPS Physiome Project Roadmap, 2005, [www.physiome.org.nz/roadmap/roadmap-mar05](http://www.physiome.org.nz/roadmap/roadmap-mar05)

<sup>42</sup> Towards Virtual Physiological Human: Multilevel modelling and simulation of the human anatomy and physiology, White Paper 2005, [http://europa.eu.int/information\\_society/activities/health/docs/events/barcelona2005/ec-draft-vph-white-paper-v2.8.pdf](http://europa.eu.int/information_society/activities/health/docs/events/barcelona2005/ec-draft-vph-white-paper-v2.8.pdf), p. 3

<sup>43</sup> Safer Medicines, Academy of Medical Sciences. A report from the Academy's FORUM with industry, November 2005 <http://www.acmedsci.ac.uk/p99puid61.html>, p. 22

<sup>44</sup> Optimata, Entelos Win Simulation Patents, John Russell, Bio-IT World, January 26, 2006, <http://www.bio-itworld.com/newsitems/2006/january/01-26-06-news-biosimulation>

<sup>45</sup> Zvia Agur: "Biomathematics in the development of personalized medicine in oncology" Future Oncology, Feb 2006, Vol. 2, No. 1, pp 39-42.

<sup>46</sup> Models that take drugs. Biosimulation: Designing drugs in computers is still some way off. But software is starting to change the way drugs are tested, The Economist, June 9th 2005

<sup>47</sup> Gorman PJ, Meier AH, Krummel TM. Computer-assisted training and learning in surgery. *Comput Aided Surg* 2000;5:120-30.

<sup>48</sup> Fried M P et al. (2004): Identifying and reducing errors with surgical simulation, *Qual Saf Health Care* 2004;13(Suppl 1):i19-i26. doi: 10.1136/qshc.2004.009969, [http://qhc.bmjournals.com/cgi/content/full/13/suppl\\_1/i19](http://qhc.bmjournals.com/cgi/content/full/13/suppl_1/i19)

fail to provide desired performance such as due to late or incomplete information - or Hazard Analysis and Critical Control Points (HACCP).

### ***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. In the future, it may be possible to build health pathway models which encompass citizen / patient passage through clinical pathways, with predictive ability, focussing on the prior identification of potential risks to a citizen's future health.

### ***Bar Code and RFID***

Bar Codes can help to reduce administration and logistics errors. Advantages include real time updates allowing providers to alter medications and adjust delivery schedules with ease, simultaneous access to the system at multiple sites and the elimination of phone calls and paperwork. RFID (radio frequency identification) is generally regarded as the successor to bar code technology, doing away with the need to scan in every individual item by using radio signals from electronic chips attached to specific items. There is a wide variety of uses for RFID applications in healthcare and its use in some specific areas has the potential for significant growth.<sup>49</sup> Areas of applications include security (e.g. access control, anti-theft device), medication administration, authentication and stocking (tracking of drug origin and expiration data), hospital equipment, medical waste and supply tracking as well as patient tracking, blood banking (tagging blood transfusions) and medical alert implants. It is also an option for outpatient self-medication, e.g. for seniors.

### ***Socio-economic and behavioural aspects***

Research into how eHealth applications and the concomitant re-engineering of healthcare processes may change the behaviour of health professionals, care personnel, citizens and patients to improve system safety and performance is a promising field. This 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 and Expert Systems and other tools need also to be mentioned here.

### ***Monitoring and risk management of large-scale events***

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

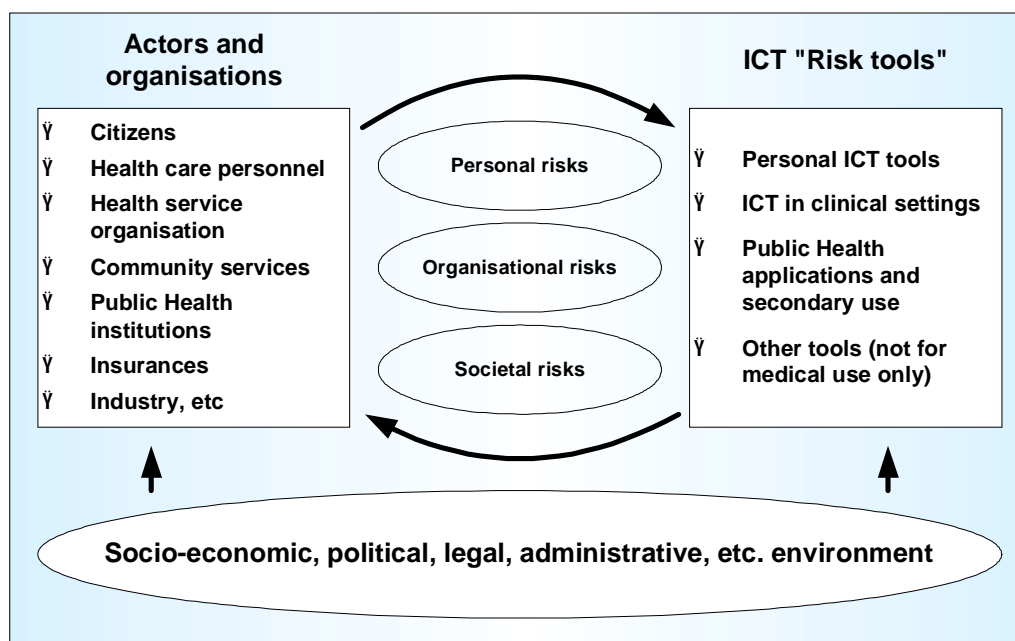
### **Summary - key issues for a research roadmap**

To summarise our initial discussions, Figure 3 illustrates and delimits an initial model for the patient and health system risk domain. This model will not only allow for different types of risks and ICT applications relevant to improve safety management to be related to the corresponding meta categories, but it may also direct the research towards other innovative fields which may be critical and important.

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<sup>49</sup> See Eastwood G. et al (2005): ICT Opportunities in Healthcare, in: Business Insights, London, April 2005 and Fraunhofer Institut Software- und Systemtechnik: Business Opportunities für den Einsatz in RFID im Gesundheitswesen

FIGURE 3: INITIAL MODELLING OF THE RISK DOMAIN



Source: © empirica, *eHealth for Safety* study, 2005

Our recent research showed that it is vital not only to look at the issues from their technical point of view but also to take organisational and political factors into account, which will play a key role if patient safety is to be strengthened. The following table gives an overview of the components of each level:

Table 1: Components in a multi-level approach to patient safety

Level	Component
Policy level (regional, national, European level)	<ul style="list-style-type: none"> <li>• Patient safety policies</li> <li>• Implementation measures</li> <li>• Socio-economic and health policy framework conditions</li> <li>• Legal and ethical issues</li> <li>• Funding, clinical and economic evaluation</li> </ul>
Organisational level	<ul style="list-style-type: none"> <li>• Organisational structure and culture</li> <li>• Work processes</li> <li>• Change management</li> <li>• Training and learning</li> </ul>
Technical & RTD level / applications	<ul style="list-style-type: none"> <li>• Personal ICT tools, e.g., biomedical sensors</li> <li>• ICT in clinical settings, incl. EHR, DSS, CPOE</li> <li>• Public health applications &amp; secondary use, e.g., event reporting, alert systems</li> <li>• Semantic aspects / ontologies</li> <li>• Emerging technologies</li> </ul>

In its work the *eHealth for Safety* study will apply this multilevel analysis of ICT in patient safety in order to arrive at a vision and roadmap for future research which will ultimately benefit European citizens and healthcare providers.

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