



TAKING STOCK: REPORT OF A EUROPEAN WORKSHOP ON

PRIORITIES IN RISK MANAGEMENT FOR PATIENT SAFETY

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SAFER, SMARTER, GREENER

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INTRODUCTION

SAFETY CHALLENGES OF MODERN HEALTHCARE

Many health outcomes continue to improve rapidly through new and more effective treatments. At the same time harm to patients remains an issue in all healthcare systems.

Healthcare carries an inherent risk of harm which must be continually reduced but cannot be eradicated (Berwick 2013). Approaches to optimising safety must include measures to detect adverse occurrences and to mitigate the harm they may cause. The task of developing new and more effective treatments must be complemented by an understanding of how to improve healthcare continuously and to build safer systems.

The risks of healthcare have now been extensively mapped and we have a much better understanding

of the vulnerabilities of healthcare systems and the factors that lead to patient harm. A considerable number of interventions of different kinds have shown that errors can be reduced and processes made more reliable. Interventions such as computer order entry, standardisation and simplification of processes, systematic handover have all been shown to improve reliability, and in some cases reduce harm, in specific contexts. We have however relatively few examples of large scale interventions which have made a demonstrable impact on patient safety. There is also an urgent need to build capacity within healthcare for education and training on safety and for delivery of operational improvement programmes.

THE WORKSHOP

PURPOSE AND STRUCTURE

The workshop took place on 26th November 2013 and with an invited expert group from across Europe. Representatives included: national and international patient safety policy makers and thought leaders; national patient safety experts; leaders in the field of patient safety research.

The aims of the workshop were

- To assess developments in policy and practice in patient safety across Europe.
- To review recent research on the impact of patient safety initiatives in Europe

- To identify potential future priorities for patient safety research and practice in Europe
- To further develop the specific contribution of DNV GL to patient safety knowledge and practice.

In this report we first provide brief summaries of the main presentations and the principal points from the discussions that followed. We then draw out the principal patient safety challenges that emerged during the workshop and consider future priorities.

WORKSHOP PRESENTATIONS



EUROPEAN PATIENT SAFETY POLICY AND INITIATIVES

(Mrs Katja Neubauer)

Governments across the European Union and around the world have developed patient safety strategies and implementation programmes. The World Health Organisation has had a major impact by developing capacity, providing guidelines and addressing major safety challenges.

The European Commission Patient Safety Council Recommendation (2009) called on EU Member states to: develop national policies on patient safety; inform and empower patients; establish reporting and learning systems on adverse events; promote education and training for health workers and to adopt and implement a strategy to prevent and control healthcare associated infections.

The most recent report of the Commission (November 2012) found that patient safety is now widely embedded in public health policies in almost all member states. A number of new initiatives on healthcare associated infections have been triggered by the Recommendation. Reporting and learning systems have been widely implemented though there is little information on their use of effectiveness.

The main gaps identified as requiring further development were:

- Developing the role of the patient and citizen in patient safety
- The education and training of health workers in patient safety
- Safety initiatives in the community and in primary care
- Development of a common terminology for patient safety

Considerable progress has been made by supporting exchanges of good practices between member states. However the implementation of known solutions to safety problems has been variable across different member states and, as the DUQUE project shows, highly variable within member states.



SAFETY AND QUALITY MANAGEMENT IN EUROPE: DUQUE

(Professor Rosa Sunol)

The “Deepening our understanding of quality improvement in Europe” (DUQuE) project studied the effectiveness of safety and quality improvement systems in European hospitals.

This major study assessed the relationship of organisational safety and quality improvement systems and culture, professionals’ involvement, and patient empowerment with the quality of hospital care. The role of external influences and governance on quality improvement strategies was a particular focus. Data has been collected at different levels (hospital, departmental, professional and patient) using survey methods organizational and clinical audit, administrative data and patient surveys. Over 200 hospitals and over 10,000 patients have been involved in the study. Highly sophisticated analyses have allowed conclusions to be drawn both across and within countries and at different levels of the healthcare system.

Some of the key emerging findings are as follows:

→ Patient involvement in safety and quality management remains weak. Even when hospitals have succeeded in engaging patients this has

seldom led to improvements in the care actually provided to patients. This may be because these initiatives are relatively new and have not yet had their full impact or it may be that, while patient engagement may have other benefits, it is not a major driver of improvement on the frontline.

- Implementation of known safety strategies (such as those recommended by the WHO Patient’s safety Alliance, and Patient safety agencies) is highly variable. Countries have progressed at different rates but variation within countries is much larger than between countries
- The most encouraging finding is that the introduction of quality management systems is associated with improved patient outcomes. The effect is strongest for quality management systems at the clinical level which is to say that well-developed systems of measurement, review and improvement are associated with better clinical outcomes. However the effect is much weaker for hospital level systems which are only weakly associated with better outcomes.



LESSONS FROM A TRAGEDY: THE FRANCIS INQUIRY

(Professor Charles Vincent)

Patient safety policy has often been driven by serious incidents and major failures. In the UK the tragic events at Mid Staffordshire hospital, in which many patients died or were seriously harmed over a period of years, have led to a series of major reports with widespread implications for the UK National Health Service and potentially for other healthcare systems. The report by Robert Francis contained 290 recommendations for change, almost all of which have been accepted by the UK government (Francis 2013). These included a much more active regulatory regime, much greater attention to the monitoring of safety, a renewed plea for person centred care, much stronger focus on patient evaluation of care and, above all, a call for a culture of compassion and respect within the NHS. In a further forward looking review, commissioned by the UK Government, Don Berwick and his expert group made a number of recommendations for the achievement of a safe healthcare system.

The Berwick report contains a number of recommendations to amplify these themes. These include the importance of developing strategic aims in safety, the establishment of safety as a priority for Boards, leaders and staff at all levels in the organisation, the creation of capacity and knowledge

about safety in the system, and the encouragement of learning through collaborative improvement networks.

The core philosophy of the report was summarised as:

The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end. Place the quality of patient care, especially patient safety, above all other aims. Engage, empower, and hear patients and carers at all times. Foster whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work. Embrace transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

(Howard, Avery et al. 2003, Berwick 2013)

DNV GL HEALTHCARE RESEARCH

(Dr. Morten Pytte)

Building on the global experience and expertise from other safety critical industries, DNV GL contributes to improving performance and reducing harm in healthcare organisations worldwide. The Healthcare Research group is currently adapting best practices from other safety critical industries to the healthcare context to improve patient safety. This work is designed to support the development of safer, smarter and sustainable healthcare organisations and will contribute to the broader understanding of safety in healthcare. The main research priorities are:

- Safety Culture for patient safety with the objective to develop, pilot and refine methods to assess safety culture and to use the results for organisational development and improvement.
- Safety Cases for patient safety with objectives to adapt the safety case approach for healthcare organisations and to evaluate its applicability with the aim of developing a “best practice” for healthcare.
- System knowledge from a risk perspective with the objective to develop and test solutions for real time monitoring and management of hazards in healthcare.
- Person-centred care with the objective to capture and distil new and developing solutions and technologies for safer, smarter, person-centred healthcare and drive their scale and spread in ways that will enable healthcare providers to envision and implement sustainable high quality health services. We will distil the learning from these examples and to build them into DNV GL services.
- Standard development with the objective of drawing on experience and best practice from healthcare and other safety critical industries to create the next generation of knowledge based, consensus driven DNV GL standards for healthcare organisations and, through this, to continue to drive improvement in performance and reduce patient harm



PRIORITIES FOR THE FUTURE





SAFETY ALONG THE PATIENT PATHWAY

Patient safety has been driven by studies of specific incidents in which patients have been harmed by healthcare. Eliminating these distressing, sometimes tragic events, remains a priority for patient safety but we require a broader vision of safety when we examine the risks of care given outside hospital. Patients face risks from failures in the healthcare system of many different kinds, some specific to each setting and others from the poor coordination of care across many settings.

Use of medication is the most common medical intervention in community settings; two thirds of patients will receive at least one prescription in a

given year from their family doctor. However, 5% of admissions to NHS hospitals are due to medication-related harm, half of which are preventable (Howard, Avery et al. 2003), and 1-2% of inpatients suffer harm due to medication error. With earlier discharge and a drive to provide more care outside hospital patients may face increased risks at home. People who are both old and ill are already more vulnerable to accidental injury and studies have found that 25% report an additional healthcare related adverse event in the past three months (Sorensen, Stokes et al. 2006). A significant number of these adverse events are due to the failure of hospitals to explain properly to the patient how to take drugs at home.

SAFETY CULTURE IN ORGANISATIONS

Safety culture is about the ways in which people in organisations create or degrade safety. Such cultures thus can range between the pathological to generative (Westrum 1997). In a pathological culture safety is ignored and information about error and harm is hidden. At the other extreme a generative culture is constantly seeking to monitor and improve; safety is everybody's business and it is an integral part of everything the organisation does. Although the importance of having a safe culture in healthcare is well-known, it is evident that healthcare still struggles to create and maintain a safe culture consistently in all organisations (Francis, 2013).

Improving safety culture means changing the way healthcare functions into becoming one more favourable for patient safety. Dixon-Woods et al. (Dixon-Woods, Baker et al. 2013) suggest several crucial points for healthcare to prioritise if safety culture is to be improved:

- To create clear and explicit goals coherent within organisations,
- To have an organisational intelligence to know where the organisations stand regarding safety and what to improve,
- To continue reviewing and improving the systems for patient safety.

Knowledge of problems and priorities for action, although essential, are not sufficient to change a culture. Changing culture needs a good understanding of the local cultures and innovative, committed leaders to motivate organisational members to internalise new norms more favourable for patient safety. The WHO surgical safety checklist provides a good example. There is strong evidence that the use of checklists significantly reduces surgical complications and mortality (de Vries, Dijkstra et al. 2010) and the catheter-related bloodstream infections in ICUs (Pronovost, Needham et al. 2006). These success stories, however, will easily fail in other contexts or settings if the sociocultural conditions in which the success was built on are disregarded (Dixon-Woods, Bosk et al. 2011).



SAFETY MEASUREMENT AND MONITORING

Patients, clinicians, managers all want to be reassured that their healthcare organisation is safe. But there is no consensus about what we mean when we ask whether a healthcare organisation is safe or how is this achieved. The Berwick review found that most UK health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information. A recent report (Vincent 2013) has proposed a framework which can guide clinical teams and healthcare organisations in the measurement and monitoring of safety and in reviewing progress against safety objectives.

The framework has a number of immediate practical implications. A critical recommendation is to prioritise safety monitoring as an activity. Time to walk, talk and watch is critical to monitoring and maintaining safety as are handovers, debriefing and other methods of team reflection. Patients, carers and others play a particularly critical role in this regard both in monitoring their own safety and that of the wider safety of the healthcare system. While

regulators struggle with intermittent visits and a lack of timely data, patients have immediate experience of poor or dangerous care.

A further critical task for many healthcare organisations is to develop an effective safety information reporting system, which should really be seen as an 'information, analysis, learning, feedback and action' system. Only a very few healthcare organisations have achieved this. There are examples of high performing teams who regularly reviewed a variety of sources of safety information combining quantitative measures of harm and reliability combined with the softer intelligence of observation and conversation. For instance Intermountain healthcare system has created an online reporting portal for quality and patient safety. The portal incorporates 80 patient safety metrics housed in a dimensional database that allows web-enabled reporting and has the capacity to produce statistical process control charts on demand.

FIVE

DIMENSIONS ARE PROPOSED

1.
PAST HARM

2.
RELIABILITY

3.
SENSITIVITY TO
OPERATIONS

4.
ANTICIPATION
AND
PREPAREDNESS

5.
INTERGRATION
AND
LEARNING

PATIENT ENGAGEMENT

High quality care must be, by definition, person-centred and person-centred care has to engage patients as active partners (Rasmussen, Jørgensen and Leyshon 2014).

Active patient engagement is a continual attempt to ensure that the healthcare system genuinely takes account of patient needs and preferences and remains focused on the patient at all times.

Patient engagement has many facets and is critical in disease prevention, diagnosis, decisions on treatment, safety during care and in management of long term conditions (Vincent and Coulter 2002).

Some of the most important current developments and directions are:

→ **Shared decision making.** Treatment decisions are particularly critical. Decisions about treatment depend not only on clinical evidence but on patient preferences, values and circumstances. A chosen course of treatment for a mother with young children may be entirely wrong for an older person near the end of life with no dependents. Patients tend to be more conservative than their doctors, often ready to watch, wait and monitor (Barry and Edgman-Levitan 2012). When patient preferences are

ignored interventions may be clinically reasonable but at a later date deeply regretted by both patients and staff.

- **Patient perspective on safety.** Clinicians are constantly on the alert for signs of deterioration in their patients and also for problems and failings in the healthcare system. Patients can, and should, do the same particularly in the home and community when they are in charge of their care. Patients see flaws in healthcare systems that are invisible to clinicians.
- **Guiding the organisation.** As well as engaging in their own healthcare patients have a major role to play in supporting the care of other patients and in supporting healthcare organisations. Healthcare providers leading the way in this area have patients on all important hospital committees, there to highlight and communicate the patient experience, to be the critical friend to the clinicians and to link the hospital with the wider community. Patients support each other in countless societies, discussion groups and forums and in providing advocacy for better care and safer systems.
- **Policy and practice.** Healthcare, as every other industry, lives under financial constraints. There are choices to be made in every area about how to allocate resource and what to prioritise. Engagement also means drawing people into public debate whether it concerns hospital closures, clinical research priorities or funding of services.



REFLECTIONS AND CONCLUSIONS

Patient safety has become a priority for almost all major healthcare systems in Europe. The field has matured considerably in the last decade both in terms of the scientific understanding of safety and in knowledge of the challenges of implementing practical safety programmes. We now have a good understanding of the nature and scale of harm, the causes of error and harm and, to a lesser extent, the solutions to these problems.

There are two particular challenges in the coming years: The first will be to extend our safety knowledge and practice into care in the home and in the community. The second major challenge is to move from evidence of the effectiveness of specific

projects to large scale implementation and sustained improvements of safety.

Patient engagement and empowerment will be fundamental to safety programmes in the home and community as will an understanding of how safety can be managed along the entire patient pathway. Safety measurement and monitoring will be key to assessing safety across an entire health economy and to assessing the long term impact and sustainability of programmes and policies. Finally, all this change will need to be underpinned by the embedding of safety as a core value in all healthcare systems: creating generative cultures with a continuous focus on safety and improvement.



APPENDIX 1: WORKSHOP PARTICIPATION

Individuals from the following organisations took part in the workshop:

Health First Europe, EPPOSI, Standing Committee of European Doctors (CPME), European Union of Medical Specialists - UEMS, European Health Management Association - EHMA, European Patients' Forum - EPF, DG Connect, Mission of Norway to the EU, DG SANCO, Imperial College London, Universitat Autònoma de Barcelona

Please note: The views expressed in this report are those of the authors and do not necessarily reflect the position or policy of any individual participant or organisation.

APPENDIX 2: WORKSHOP AGENDA

12.00	Registration & buffet lunch
12.30-12.40	Opening welcome and introduction (Stephen Leyshon, DNV GL)
12.40-1300	Opening remarks: An overview of European Commission's work on Patient Safety and Chronic Care (Katja Neubauer, DG SANCO)
13.05-13.25	Keynote: Patient Safety today and challenges still ahead (Charles Vincent, Imperial College)
13.30-13.50	Keynote: Lessons learned from DUQuE project (Rosa Sunol, Avedis Donabedian Research Institute)
13.50-14.00	Overview of DNV GL Research work on Patient Safety and plans for next year (Morten Pytte, DNV GL)
14.00-14.10	Q&A
14.10-15.25	Workshop session: Envisioning the future: priorities in risk management for patient safety (Stephen McAdam, DNV GL)
15.25-15.40	Summary of the Round Table discussions (Charles Vincent, Imperial College)
15.40-15.45	Closing address (Stephen McAdam, DNV GL)

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ABOUT THE AUTHORS

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Charles Vincent trained as a Clinical Psychologist and worked in the British NHS for several years. Since 1985 he has carried out research on the causes of harm to patients, the consequences for patients and staff and methods of improving the safety of healthcare. He established the Clinical Risk Unit at University College in 1995 where he was Professor of Psychology before moving to the Department of Surgery and Cancer at Imperial College in 2002. He is the editor of Clinical Risk Management (BMJ Publications, 2nd edition, 2001), author of Patient Safety (2nd edition 2010) and author of many papers on medical error, risk and patient safety. From 1999 to 2003 he was a Commissioner on the UK Commission for Health Improvement and has advised on patient safety in many inquiries and committees including the recent Berwick Review. In 2007 he was appointed Director of the National Institute of Health Research Centre for Patient Safety & Service Quality at Imperial College Healthcare Trust. He is a Fellow of the Academy of Social Sciences and was recently reappointed as a National Institute of Health Research Senior Investigator. In 2014 he has taken up a new post as Health Foundation professorial fellow in the Department of Psychology, University of Oxford where he will continue his work on safety in healthcare. Professor Vincent is also an independent consultant and acted as rapporteur for the Workshop.

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Eva Turk joined the DNV GL Research and Innovation, Healthcare programme in Oslo, Norway in January 2012. Recently she joined the Joint Action on Patient Safety, where she is working on implementation of safe clinical practices in the EU. Prior to joining DNV GL, Eva was working at the National Institute of Public Health in Slovenia, where she was responsible for implementation and development of Health Technology Assessment (HTA) in Slovenia. She has been involved in EC DG RTD Frameworks 6 and 7. Her PhD studies were on Patient Reported Outcomes in elderly diabetic patients.

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Morten Pytte joined DNV GL Research and Innovation in 2011 where he is now the Programme Director for the Healthcare programme. Morten is a physician by training specialised in anaesthesia and intensive care medicine with more than ten years of clinical experience. Besides anaesthesia and intensive care Morten's clinical expertise is on sudden cardiac arrest and resuscitation. Between 2005 and 2009 Morten did clinical and experimental research on cardiopulmonary resuscitation and finished a one year fellowship at the Weil Institute of Critical Care Medicine in California in 2007-2008.

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Senior Researcher, Healthcare, DNV GL Strategic Research and Innovation

Tita joined DNV GL Research and Innovation in Norway in November 2011. She has backgrounds in Psychology and Human Factors in healthcare. Her focus area now is to develop a global service on safety culture assessment and improvement in healthcare organizations.

Stephen McAdam DPhil (Oxon)stephen.mcadam@dnvgl.com

Global Technical Director, Healthcare, DNV GL Business Assurance

An immunologist by training, Stephen McAdam spent a decade working in laboratories working with pathogens such as HIV and HCV in hospitals in the US, Africa and Europe. Following a post-doctoral period at the National University Hospital in Oslo he spent 10 years in DNV's Department Research and Innovation exploring systems based approaches to management and risk assessment in areas where the principal hazard is a biological agent (biorisk). Stephen has collaborated with many of the world's leading organizations in the area of laboratory biorisk management, including the WHO, ECDC, Canadian Science Centre, and the UK Health Protection Agency. Stephen spent two years establishing a research programme focused on patient safety before switching roles within DNV to take on responsibility for developing DNV's standards in healthcare.

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Stephen Leyshon joined DNV GL in 2011, where his responsibilities include managing applied research into person-centred care and risk management. Prior to this, he was the Clinical Lead for Primary Care and Ambulance Services at the UK's NHS National Patient Safety Agency, working nationally and internationally to develop practice and policy to manage risk and improve the safety of care outside of hospital. A Registered Nurse, Stephen has over 20 years of experience in healthcare and his previous roles include Health Services Manager, Lecturer in Health Policy and Ethics at King's College London, Research Fellow in Primary Care at King's College London (a shared appointment with University College London), and Lecturer-Practitioner.



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DNV GL

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Our healthcare research programme is multidisciplinary with a commitment to contribute to patient safety through its research and evaluation activities.

Building on our additional extensive expertise in biorisk, we aim to have a significant impact on the patient safety and productivity of healthcare organisations. This we seek to achieve through mitigation of risk and identification of effective ideas for the improvement of practice.