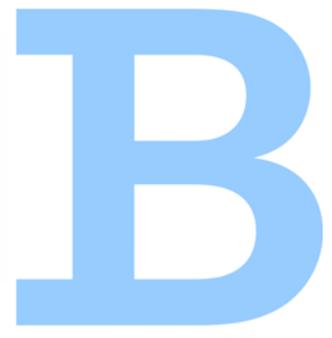




Briefing Paper



Principal Investigator: Professor John Clarkson

Should the NHS adopt a new system for predicting possible risks to patient safety?

Introduction:

Patient safety is a high priority in healthcare and much time, effort and money is being invested into studying how it can be improved upon. Around 10% of patients admitted to NHS hospitals every year experience some kind of health care related harm. Estimates show that half of these incidents could be prevented. The Department of Health's **Patient Safety Research Portfolio** (PSRP) is a national drive to study errors made in healthcare, measure them and find ways of preventing them in the future.

This briefing paper is based on work undertaken by a team of researchers from the University of Cambridge, University of Surrey and Greenstreet Berman Limited and was led by Professor John Clarkson, Director of the Cambridge Engineering Design Centre at the university. For the study, first published in 2010, the researchers developed a toolkit of prospective hazard analysis (PHA) methods. The toolkit was specifically tailored for use in healthcare, and then evaluated with NHS clinicians and managers in a range of health service settings, focusing on current NHS topics of interest. The toolkit provides a proactive, systemic and structured process that supports the identification of sources of harm, their potential consequences and hence risk. The study is being highlighted now as part of a drive to promote the many pieces of research into patient safety carried out by the PSRP.

This briefing paper is aimed at healthcare professionals working in the UK and abroad, patients and carers using NHS services, academics and health service managers.

Key Messages:

- The NHS is sometimes an unsafe system and suffers from a lack of proactive, systematic and system-wide risk assessment
- There is a lack of guidance to help NHS staff to perform prospective hazard analysis (PHA), so the researchers developed and evaluated a PHA toolkit for use in the NHS
- By drawing pictures of the system to be analysed, the toolkit encourages its users to set appropriate boundaries and aims for proactive risk assessment, and introduces the PHA process in an adaptable two-stage approach
- The toolkit was designed for use by NHS staff, including clinicians and managers
- NHS staff tested the toolkit and found it to be both usable and effective, but further evaluation will be needed to strengthen this evidence base
- Using PHA in the NHS could help identify potential risks to patient safety and a range of other types of risk including cost effectiveness
- A major cultural change may be necessary to change the NHS's attitude to patient safety from a reactive one to a prospective, preventative one, and such a change will need to be properly resourced if it is to be effective.

Background:

There is a growing trend for greater scrutiny of healthcare, NHS organisations and the staff who work in them. Patient safety, preventing medical errors and reporting of adverse events are all a high priority for the Government.

A drive to tackle these issues began shortly after the publication of a report by the former Chief Medical Officer Sir Liam Donaldson in 2000 that looked into adverse events in the NHS. It found that 400 people die or are seriously injured every year because of an adverse event involving a medical device and 10,000 people a year have a serious adverse reaction to drugs.

Other estimates say there are around 850,000 adverse events a year in NHS hospitals with a resulting cost of £2billion in additional hospital stays. This also leads to clinical negligence claims that cost the NHS around £400million a year.

As well as setting up the NPSA in 2001, the Government launched a large-scale research programme to:

- explore the size and nature of the problem
- understand the factors causing harm
- develop interventions to reduce errors
- assess how effective the attempts to reduce errors have been
- implement ways of guaranteeing change in people and organisations.

The method known as prospective hazard analysis (PHA) is little known or used in the NHS, but elsewhere it is standard practice in several high risk industries such as aerospace and nuclear power. The PHA process includes a range of approaches and tools, which can be used to thoroughly evaluate conceivable risks to workers or the public as well as disruption to work processes and the environment. As well as identifying possible sources of harm, it can also assess their potential consequences and considers how likely these risks are to actually happen. In particular, it is proactive, systemic (it takes account of the interaction of the part of the system being examined and the wider system within which it sits) and structured (being methodical and logical, which in turn supports a comprehensive risk assessment).

Currently, the NHS tends to have a reactive approach to patient safety, learning from past mistakes, which is in contrast to the PHA approach, which is proactive and predictive.

Aims of the Study:

The overall aim of the study was to investigate the potential for using PHA in the NHS with a focus on patient safety, and to research the benefits of doing so.

The study's specific aims were to:

- understand current practice in the NHS over risk assessment and how the PHA approach fits in
- determine a set of needs for a practical set of tools to support the application of PHA in the NHS

- identify a set of appropriate PHA methods for inclusion in a toolkit for the NHS
- develop and test a toolkit of PHA methods for the NHS.

About the Study:

The researchers' work was organised in different phases. To begin with, they carried out literature reviews and research with healthcare and risk experts so they could define the healthcare requirements for PHA guidance for the NHS.

Workshops were then held with risk experts to identify, choose and tailor the right PHA methods for a healthcare context. By analysing the data obtained from the previous two steps and speaking to healthcare domain experts, the researchers then created a toolkit of PHA methods and a tool selection framework.

Several workshops were held in different healthcare settings to try out the toolkit and refine it. These workshops dealt with current NHS topics of interest including risks in surgery, risk assessing mental health patients, and assessing risk in cancer screening services.

Practical findings:

Initial research

Using various sources, the researchers began by looking at existing relevant research that dealt with PHA practice outside of healthcare. This revealed that other industries have successfully applied a wide range of PHA methods and techniques to address various different risk assessment needs and they use process descriptions as a starting point for risk assessment.

This led the researchers to conclude that it would be crucial for any PHA toolkit being used in healthcare to be supported by the development of appropriate process descriptions. It would also require guidance on how to use the methods within the context of risk assessment, in addition to providing guidance on the use of individual methods.

A total of 30 documents produced by the Department of Health and its arm's length bodies such as the National Patient Safety Agency (NPSA) and the NHS Institute for Innovation and Improvement, were then analysed to identify the extent to which formal policy discussed the use of PHA methods.

From this work it emerged that awareness of PHA methods is growing slowly and is seen as positive by many stakeholders, but knowledge is very limited. An additional review of documents at a local level showed how risks are managed across NHS trusts, but very little advice seemed to be given on how to identify risks.

No mention was made in these documents of PHA methods to help with risk assessment, which suggested that trusts do not take a systems-based approach to risk management and current use of PHA is very limited in the NHS. In a further review of national and international

healthcare journals, the researchers found that this literature reported on the use of only a few PHA methods in healthcare – structured what-if technique (SWIFT); barrier analysis; event tree analysis (ETA); fault tree analysis (FTA); influence diagrams; failure mode and effect analysis (FMEA); and risk matrices.

Informal semi-structured interviews took place with seven NHS staff members to help plan part of this project and to understand more about current risk management practice in the health service. These interviews revealed problems with both reactive and proactive risk assessment although some elements of good practice were seen. Concerns were raised about potential limitations in applying PHA, such as a lack of necessary resources.

Finally in this phase of the study, the researchers carried out a small scale evaluation of healthcare guidance to see the types of guidance available and what makes different guidance types more effective.

This showed that a range of presentational factors had a bearing on how effective guidance was, such as use of colour, pictures, columns and spacing, use of graphics, language, length and highlighting of key points and quotes.

Toolkit requirements

The researchers set out to create a toolkit for the NHS, starting with defining its requirements.

They wanted to obtain a clear picture of the potential users of the toolkit, their knowledge and understanding of risk issues, the users' needs, the context in which the toolkit might be used, and what results would be needed from the toolkit.

The work done in the first phase of their study in analysing existing research and policy guidance influenced the development of the toolkit's requirements.

To add to this, the researchers had gathered information from their informal interviews with NHS staff members and also sought views from a range of potential users and stakeholders.

One of these efforts involved members of the research team attending a three-monthly forum for risk managers from a strategic health authority.

Around 70 clinical risk managers and health and safety managers from a wide range of NHS sectors were invited to attend each session, talking about various subjects including compliance with risk management standards; responses to NPSA alerts and guidance; reports on major incidents and sharing of lessons learned; quality inspections; and staff competencies in dealing with violent patients.

Semi-structured interviews were also carried out with 18 people who were a mixture of PHA experts, novice PHA

users, potential users, and stakeholders and NHS management. Analysis of these interviews came up with 54 requirements for a PHA toolkit suitable for the NHS. Some themes that emerged included the needs for:

- PHA to have a clear description of its aims and how it should be done
- an emphasis on the benefits of such a method but also the need to spell out the limitations
- explanations to dispel common misconceptions
- weighing up the costs and benefits of this kind of work
- an explanation of its purpose and uses
- engagement of clinicians
- explanation of how users will be trained, giving illustrative examples
- defining the boundaries of analysis
- clear definitions and language
- ensuring the guidance is interesting and engaging.

Developing and creating the toolkit

To develop the toolkit, the researchers regularly sought input from NHS staff through informal interviews, discussions and testing of case studies.

An expert user group was formed to identify a shortlist of potential risk assessment methods. Four experts in risk assessment and human factors in the UK took part in a workshop that helped to identify, choose and tailor suitable PHA methods for a healthcare context.

At the workshop, the experts and researchers considered four healthcare scenarios – analysis of a paediatric fracture case, Intensive Care Unit lines, GP repeat prescribing, and a handover case – and 17 possible PHA methods of dealing with them. From this exercise, a shortlist of PHA methods was agreed and developed further by the researchers.

It was decided that the toolkit should be split into two parts involving a 'preliminary risk review' as a brief analysis to determine whether or not the second part of the toolkit called 'comprehensive risk assessment' was needed.

Ultimately, the researchers decided on 10 PHA methods for inclusion in the toolkit. Main characteristics of the toolkit were agreed to be:

- a systems-based approach
- a 'triage'-based approach, whereby the user is helped to undertake a preliminary risk review to ensure there is a sufficient understanding of the risk issues and what is needed to assess them with appropriate resources
- a repetitive approach that allows risk assessment to remain focused and appropriate
- user-focused so that it supports a range of different users, including risk specialists and clinicians with less experience of risk assessment
- modular, so that the toolkit can be expanded and developed
- output-focused, so that results of the assessment can be communicated to end- users in a practical and useful way.

Testing the toolkit

The toolkit was evaluated in several ways internally within the PHA team and externally with NHS staff. Evaluations with staff were carried out in a review with a forum of risk managers and two separate informal reviews with a risk manager and a patient champion.

In addition, five case studies took place with more than 20 NHS staff, across a range of NHS settings and scenarios. Prior to these, an initial case study was carried out at a GP practice, focused on the process behind repeat prescribing of medicines at the practice.

Three PHA methods were tested – FMEA (failure mode and effect analysis), FTA (fault tree analysis) and SHERPA (systematic human error reduction and prediction approach). The three participating groups said all three methods were easy to use, and generally agreed that the hazards identified were realistic. This showed that all these methods could be used in a primary care setting.

One of the many evaluation efforts involved an evaluation workshop using an early draft of the toolkit with 11 risk managers taking part. These managers came from various backgrounds including acute and primary care and the ambulance sector.

Participants raised several issues that could improve the toolkit including prioritising and communicating risks to the chief executive of an organisation; using prompts and aids; providing descriptions of risk related terminology; including a generic PHA method to simplify the process; highlighting the need to train users; that the toolkit would be easier to use in electronic form; and that it should have accessible language and be simple to use.

Five case studies were conducted with five sets of NHS staff to assess the usability and usefulness of the PHA toolkit.

These workshops dealt with various scenarios including assessment of an acute trust's patient discharge process, a risk assessment of mental health trust's patient risk assessment procedures at patient admission to a secure unit, and risks in surgery.

Observations made from all five case studies indicated an unsafe healthcare system with little systematic and system-wide investigation of risk related issues.

The participants had not seen anything similar to the toolkit before but their responses to it were positive. They stated that some strengths of the toolkit were that it was able to tackle systems-related issues, it was easy to understand, it improved the participants' understanding of the system and that using it would lead to improvements in safety.

The researchers said that PHA was not a "magic bullet" and still relied on the knowledge and skills of the participants and the facilitator.

A real need was also apparent to train expert facilitators if the toolkit was to be rolled out into the NHS.

Summary of main findings:

- Case studies conducted during this project suggested that the NHS is sometimes an unsafe system with little systematic and system-wide investigation of risk related issues
- There is a failure in the NHS to perform good quality, proactive risk assessment
- Little guidance exists to help NHS staff identify or control risks proactively
- Use of PHA methods in the NHS is currently extremely limited and in its infancy
- NHS staff who tested the toolkit said it was easy to grasp, improved their understanding of the system and that using it would lead to improvements in safety
- Staff testing the PHA toolkit were cautiously positive but sceptical about adopting it into practice because of resource and time pressures.

Recommendations for potential research and further work:

- There is significant scope for the PHA toolkit to help NHS staff in using different methods to take a systems-based approach to managing risks before they result in harm to patients
- It is important that a number of people are trained to become expert facilitators of the toolkit initially
- The NHS should use the PHA toolkit but whether it will depends on convincing the right people in the NHS of the potential benefits of the toolkit versus the costs of not using it
- Whilst initial evaluations demonstrated the potential benefit of the toolkit, further evaluation is needed to build up a strong evidence base of the effectiveness of the toolkit. These could involve examining whether recommendations from using the toolkit lead to savings in the long term.

Further information:

The full report, this research summary and details of other Patient Safety Research Portfolio work can be seen at <http://www.haps.bham.ac.uk/publichealth/psrp/commissioned.shtml>

About the Patient Safety Research Portfolio:

The Patient Safety Research Portfolio (PSRP) was created in 2001 as a programme to promote research into patient safety. It followed a report published by chief medical officer Sir Liam Donaldson in 2000 that looked at learning from adverse events in the NHS. The PSRP is funded by the Policy Research Programme at the Department of Health and reports directly to the CMO. The programme has also commissioned research on behalf of the National Patient Safety Agency (NPSA).

It funds research aimed at reducing errors that lead to bad outcomes for patients by:

- measuring the types and frequency of error
- analysing root causes to identify problems and how lessons can be learned
- specifying and testing interventions
- making sure that useful findings from research are distributed widely across the country

The programme is based at the University of Birmingham's Department of Public Health and Epidemiology and is directed by Professor Richard Lilford. The PSRP team has a history of building capacity in the area of patient safety and is currently involved in evaluating The Health Foundation's *Safer Patients Initiative* and has recently published a series of papers on methods for patient safety research. The views expressed in this publication are those of the authors and not necessarily those of the PSRP, the Department of Health or the NPSA.

For further information about the PSRP visit our website at <http://www.pcpoh.bham.ac.uk/publichealth/psrp/> or contact:

Patient Safety Research Portfolio
School of Health and Population Sciences
Unit of Public Health, Epidemiology & Biostatistics
University of Birmingham
90 Vincent Drive
Edgbaston
Birmingham B15 2SP
Tel: +44 (0) 121 414 2226
Fax: +44 (0) 121 414 6805
Email: l.priest.1@bham.ac.uk