

From information to action:
Improving implementation of patient
safety guidance in the NHS

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Abstract

Patient safety is a high priority for everyone working within healthcare (Vincent 2006, Walshe and Boaden 2006). However, while over the last decade or so there has been an outpouring of information to improve the safety of patient care, unfortunately, putting the recommended changes into practice has fallen short of their envisioned potential (Mulrow 1994, Berwick 2003, Elwyn et al. 2007). The project context was the NHS in England and Wales with the scope of the project limited to the acute care hospital setting in England and Wales. The project sought to identify how the NPSA could support improvement in implementation. It sought to explore the factors that help or hinder successful implementation, through a collective effort, using my personal experience and expertise, that of NPSA colleagues, external experts and the views of staff in acute care hospitals across England and Wales together with the literature.

The findings led to the design and development of an implementation toolkit, initially targeted at NPSA staff and other national bodies responsible for issuing guidance and safer practices. The project output therefore comprises a product in the form of an implementation toolkit supported by a critical commentary on the development of the product. These will provide an original contribution to my own knowledge and understanding, as well as that of my work place, the NPSA, my professional areas, nursing and patient safety, and the knowledge base of the Middlesex University. Post-doctoral activity will involve the promotion, use and evaluation of the toolkit in 2009.

Chapter 1: Introduction

“We need to redouble our efforts to implement systems and interventions that actively and continuously reduce risk to patients”

Sir Liam Donaldson, Chief Medical Officer
Safety First
Department of Health 2006b

1.0 Introduction

Patient safety is a high priority for everyone working within healthcare (Vincent 2006, Walshe and Boaden 2006). While, it is not a new idea, even as early as 1863, Florence Nightingale wrote that it may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm, knowledge and understanding of this complex subject has only really increased over the last two decades. There is now compelling evidence to show that on average there is a 10% error rate in healthcare which results in thousands of individual tragedies every year, with both patients and those that provide their care suffering the consequences (Brennan et al. 1991, Institute of Medicine 1999, Wilson et al. 1995, Department of Health 2000b, Vincent et al. 2001).

The speciality of patient safety is difficult to grasp, difficult to solve, seldom clearly defined and is still the subject of much debate (Vincent 2006, Pronovost 2006). It is widely acknowledged that there can never be a completely safe health service; by its very nature healthcare is inherently risky, medicine isn't a perfect science and knowledge is constantly changing (Esmail 2006). Patient safety is about trying to achieve the safest and best possible care for patients while balancing the risks with the need to innovate, learn and improve (Department of Health 2005, Department of Health 2006a, Esmail 2006, Department of Health 2007). Vincent (2006) defines patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries

stemming from the process of healthcare. Examples of adverse outcomes include the wrong diagnosis or the harmful effects of incorrect prescribing. It is related to quality and improvement, and adds to these disciplines by seeking to understand why things go wrong and to address the potential error and harm with preventative solutions that focus on the system as well as the individual (Reason 2000, Department of Health 2000b, National Patient Safety Agency 2004). Over the last decade or so there has been an outpouring of information to improve the safety of patient care, unfortunately, putting the recommended changes into practice has fallen short of their envisioned potential (Mulrow 1994, Berwick 2003, Stelfox 2006, Elwyn et al. 2007). Thus it is clear we need to understand why effective strategies to improve patient safety are not implemented (Leape et al. 2006).

1.1 My personal journey

I have worked in the NHS for nearly 30 years. My career started as a nurse, specialising in paediatric intensive care. Being a nurse has shaped the person I am today. From my first day as a student nurse until this day I have never been bored, constantly challenged and carried responsibility for peoples lives within a complex team of multi-professionals. I saw life begin and life end. As a nurse you step into peoples lives and try to make a difference, whether that is to help them to be well again or to support them to have a dignified and pain free end. This desire to make a difference led me to this doctorate programme and my final doctorate project.

My passion for improving the safety of patient care was triggered by my own experience of error. Small things go wrong all the time in healthcare, you learn to live with it and it becomes a part of the job. However, I was woken up from this state of acceptance with a jump following an incident where I calculated a drug dose wrongly. I made an error with the decimal point and administered ten times the prescribed dose to a young child in my care. While the child survived this mistake I was devastated. I

knew then something needed to change. I also knew I was not alone and that if I was going to make a difference I would need to figure out why mistakes happen and how I could improve things. I sought knowledge to back up this experience and undertook an MSc in Clinical Risk Management. I then progressed to leadership positions with a focus on quality of care, clinical risk and patient safety.

This journey led me to the National Patient Safety Agency (NPSA). I joined the NPSA in 2003, following a 2 year period as clinical risk advisor in the Department of Health. The NPSA provides leadership and national policy direction for patient safety improvement in the NHS in England and Wales. It was established as a Special Health Authority in 2001 following the seminal publication, *An Organisation with a Memory* (Department of Health 2000b). Over the last 5 years my remit has grown and I was promoted to the Director of the Strategy Unit at the NPSA in November 2007. From 1 May 2008 I will also be working as a special advisor to Sir Bruce Keogh, the medical director for the NHS.

In 2003 I wrote, with a number of key experts, national patient safety guidance for the NHS, titled *Seven Steps to Patient Safety* [to be referred to as *Seven Steps* throughout this document], (National Patient Safety Agency 2003, 2004 and 2005). A significant effort went into producing the guidance which was based on a combination of a systematic review of the research, assimilation of the international and national patient safety knowledge and understanding, my own personal experience, expertise and judgement. It was launched at the NPSA's annual conference in 2004 and disseminated throughout the NHS by NPSA staff. *Seven Steps* was used to train over 8000 NHS staff in patient safety. In 2007, the NPSA conducted two reputational polls which found that *Seven Steps* had been successfully communicated (Ipsos MORI 2007), and that *Seven Steps* was the most thoroughly read publication, with 65% of those who received it having read it all (IFF Research Ltd 2007).

'I love the [Seven Steps] and I'm being perfectly honest, I really do. You may sit down and think really heavy reading, but that to me is more like reading a novel, because it's the stuff that you love, and I think it's written in a way that is easy to read. For me it just provides me with great ideas, initiatives, to implement locally really. So I do really love it'

Risk Manager (interviewee), 2007

Over 100,000 copies have been downloaded from the web. Seven Steps has also been adopted internationally including, Denmark, Spain, the Netherlands, Australia, Saudi Arabia and Singapore. However, despite this successful dissemination, effective implementation in England and Wales has not occurred (National Audit Office 2005, Department of Health 2006b).

In 2005, I applied to undertake the doctorate in professional studies at the Institute for Work Based Learning, Middlesex University. I sought and gained accreditation of previous research and my work in writing the Seven Steps. This project builds on that accreditation and is submitted as the final stage of my professional doctorate programme. The title of the award sought is Doctor in Professional Studies (Improving Implementation of Patient Safety Guidance). This title reflects the overall structure and focus of the programme of:

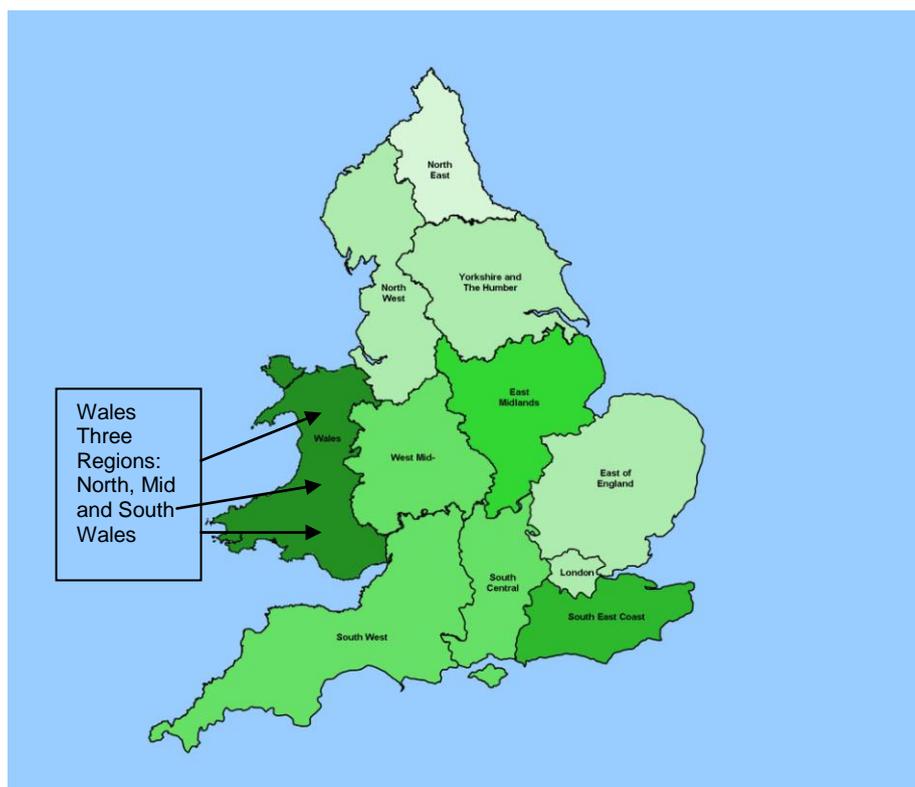
- Review of Learning (20 credit points)
- Recognition and Accreditation of Learning (RAL) at Level 4 (100 credit points)
- Recognition and Accreditation of Learning (RAL) at level 5 (160 credit points)
- Programme Planning and Rationale (DPS 4541) at level 4 (40 credit points)
- Professional Studies Research methods (DPS 4825) at level 4 (20 credit points)
- Final project (DPS 5200) - From information to action: Improving implementation of Patient Safety in the NHS – at level 5 (200 credit points)

1.2 Context: The NHS in England and Wales

The project context is the NHS in England and Wales which, having been launched in 1948, celebrates its 60th birthday this year. In England it is led by the Department of Health and in Wales it is led by the Welsh Assembly Government. The NHS employs over 1.3 million staff who provide for more than a million patients on a daily basis with: 1.9 million prescriptions, 124,000 outpatient consultations, 50,000 accident and emergency attendances and nearly one million general practitioner appointments (Department of Health 2006a). The NHS comprised at the time of the project; 173 acute care hospitals, 152 primary care trusts (PCTs), 13 ambulance trusts, 55 mental health trusts and 10 care trusts (National Patient Safety Agency 2008). Acute care hospitals manage over 12 million admissions each year and provide a multiplicity of care. They are staffed by Chief Executives, Chairs, and Trust Boards, managers (directors and enablers responsible for the operational activity), frontline clinical staff e.g. doctors, nurses, professions allied to medicine physiotherapists (implementers), and support staff e.g. porters, administrative staff. A new type of hospital has emerged over the last few years known as foundation trusts. These are a key part of the reform programme in the NHS, as they are autonomous organisations, free from central Government control. They decide how to improve their services and can retain any excess money they generate or borrow to support these investments. They are regulated by Monitor. There were 92 foundation trusts at the time of writing. Hospitals provide care which is commissioned by PCTs who are in charge of primary care and control 80% of the NHS budget, overseeing 29,000 GPs and 18,000 NHS dentists (NHS Choices 2008).

An intermediate tier between the Department of Health and local NHS services are regional offices, known as strategic health authorities (SHAs) in England and regional boards in Wales (figure 1). These implement central government policies, impose targets and measure performance of local organisations (Mooney 2008).

Figure 1 A map of the regional NHS in England and Wales



To support, regulate, inspect, set standards for and monitor organisations in the NHS there are a collection of umbrella national organisations. One of these is the NPSA. A stakeholder exercise was undertaken in February 2007, by me in partnership with the Healthcare Commission. The methodology of this approach is described in appendix 1. Stakeholder mapping was conducted to identify all relevant organisations in the NHS in England and Wales (shown in the appendix) that had either been engaged by the NPSA or were actively and demonstrably working to improve patient safety. The subsequent list found below therefore reflects a snapshot in time of those stakeholders. This is not to say that other organisations were not engaged in patient safety but what this showed was that they were not working with the NPSA and were not demonstrating their approach. Also, it did not reflect the total number of stakeholders who should be involved in patient safety as all NHS organisations have a role to play in patient safety. The mapping exercise highlighted the gaps in stakeholder engagement such as the Royal Colleges.

Table 1 National organisations which were found to have an influence on patient safety in the NHS in England and Wales (at the time of the analysis)

Org	Nature of Patient Safety Activity	Key roles
NHS Institute for Innovation and Improvement (NHSII) (England)	The NHSII provides a patient safety programme of activity which includes a patient safety training course and the development of an expert clinical faculty. It also aims to develop a quality and safety academy for senior leadership teams. The NHSII provides advice and expertise in their knowledge in adoption, spread and sustainability. It is a partner for the patient safety campaign for England.	<ul style="list-style-type: none"> ▪ Expertise ▪ Issuer of guidance ▪ Supporter role ▪ Opinion Leaders ▪ Training and education
Medicines and Healthcare Products Regulatory Agency (MHRA)	The MHRA issue alerts and recommendations. The implementation of these is vital for the success of their organisation.	<ul style="list-style-type: none"> ▪ Issuer of alerts and guidance
NHS Confederation	The NHS Confederation works together with NHS managers and NHS Employers to support patient safety activities.	<ul style="list-style-type: none"> ▪ Networks ▪ Issuer of guidance ▪ Supporter role ▪ Opinion Leaders
National Institute for Health and Clinical Excellence (NICE)	NICE has an ongoing programme of guidance development. NICE has developed a renowned approach to implementation and has developed guidance for implementers which has been a source of information for the development of the implementation toolkit.	<ul style="list-style-type: none"> ▪ Expertise ▪ Issuer of guidance ▪ Standard setting ▪ Supporter role
Healthcare Commission	The Healthcare Commission assesses compliance by NHS organisations with core and developmental standards and targets - safety is a central feature of each. These assessments focus on patients and public attention on the safety of patients.	<ul style="list-style-type: none"> ▪ Regulation and inspection ▪ Assessment and assurance ▪ Supporter role
Nursing and Midwifery Council (NMC)	Ensuring regulation of nurses and midwives to ensure safety of patients.	<ul style="list-style-type: none"> ▪ Regulation and inspection ▪ Supporter role
General Medical Council (GMC)	The GMC's work includes licences to practise and revalidation, implementing the civil standard of proof and core standards guidance, Good Medical Practice	<ul style="list-style-type: none"> ▪ Regulation and inspection ▪ Supporter role ▪ Issuer of guidance
NHS Litigation Authority (NHSLA)	The NHSLA assesses NHS organisations against the NHSLA risk management standards to determine their level of compliance, supported by a programme of education. The standards are designed to provide a framework to support NHS organisations in developing, implementing, and monitoring the effectiveness of systems and processes to ensure the safety of patients and well being of staff with their own organisations.	<ul style="list-style-type: none"> ▪ Regulation and inspection ▪ Assessment and assurance
NHS Connecting for Health (NHS CFH)	NHS CFH is involved in the development of international standards and the Clinical Safety Management System to maximise the benefits of patient safety from new technology and, at the same time, minimise risks.	<ul style="list-style-type: none"> ▪ Specialist expertise ▪ Issuer of guidance ▪ Standard setting ▪ Supporter role
Royal College of Nursing (RCN)	The RCN represents and supports nurses and nursing at all levels. Patient safety is a core component to the College's Learning and Development strategy ensuring that patient safety is included in all nursing competencies.	<ul style="list-style-type: none"> ▪ Networks ▪ Issuer of guidance and resources ▪ Supporter role ▪ Opinion Leaders ▪ Training and education

Org	Nature of Patient Safety Activity	Key roles
Action Against Medical Accidents (AvMA)	AvMA in partnership with NPSA supports the involvement of lay people in patient safety.	<ul style="list-style-type: none"> ▪ Networks ▪ Issuer of guidance and resources ▪ Supporter role ▪ Opinion Leaders ▪ Training and education
The Health Foundation	Charitable Foundation which runs the Safer Patients Initiative and other programmes of work to improve the safety of patient care. They are a partner for the patient safety campaign for England	<ul style="list-style-type: none"> ▪ Lobbying ▪ Guidance ▪ Training and Education ▪ Opinion Leaders
Patients Association	The Patients Association's workstreams include lobbying and working with government and others on issues of safety.	<ul style="list-style-type: none"> ▪ Lobbying
NHS Purchasing and Supply Agency (PASA)	Activity by PASA includes purchasing for safety.	<ul style="list-style-type: none"> ▪ Purchasing ▪ Assessment and assurance
Health Protection Agency (HPA)	Patent safety activity includes action around reducing infections.	<ul style="list-style-type: none"> ▪ Issuer of guidance and resources ▪ Supporter role ▪ Opinion Leaders ▪ Training and education
Health and Safety Executive (HSE)	The HSE selects patient safety incidents for investigation in line with their incident selection criteria and the HSE's Enforcement Policy Statement	<ul style="list-style-type: none"> ▪ Investigation ▪ Guidance issuer ▪ Supporter role
Healthcare Inspectorate Wales (HIW)	Assessments against the Healthcare Standards for Wales.	<ul style="list-style-type: none"> ▪ Regulation and inspection ▪ Assessment and assurance
Wales Centre for Health	Improvement organisation for quality and safety.	<ul style="list-style-type: none"> ▪ Supporter role ▪ Opinion Leaders
National Leadership and Innovations Agency for Healthcare (NLIAH)	NLIAH provides initiatives to improve patient empowerment, and quality and safety of care.	<ul style="list-style-type: none"> ▪ Supporter role ▪ Opinion Leaders ▪ Training and education

With regard to patient safety and quality improvement there has been a significant amount of change within the NHS over the last decade (Department of Health 2000a, Department of Health 2000b, Department of Health 2004a, Department of Health 2006b). Enabling strategies for improvement include; the operating framework for the NHS in England, targets, commissioned care, patient choice, system management and payment by results (Department of Health 2007). From 2008, the NHS in England will be undergoing further changes; a review, led by Lord Darzi aims to provide a new vision and strategy for the next 10 years of the NHS, and new processes of licensing and registration of NHS organisations will be consulted on and assessed by the Care

Quality Commission [formerly the Healthcare Commission]. The Darzi review will focus on improving equity, personalisation, effectiveness, local accountability and quality and safety of care. In Wales, there has also been an increased focus on quality and safety with their strategy set out in *Designed for Life; 10 year Strategy for Health and Social Care* (Welsh Assembly Government 2005a), the *Healthcare Standards for Wales* (Welsh Assembly Government 2005b) and the *Healthcare Quality Improvement Plan; Designed to Deliver* (Welsh Assembly Government 2006).

1.3 Rationale

An essential step in achieving patient safety within healthcare organisations is implementing practices that have been shown to reduce errors (Leape et al. 2006). Effective implementation of evidence into clinical practice is of paramount importance to ensure that patients benefit from research (Bradley et al. 2006). There has been an increased debate in implementing research findings into clinical practice because of the growing awareness of the gap that exists between what we know works and the practice being provided (Grimshaw and Russell 1993, Davis and Taylor-Vaisey 1997, Bero et al. 1998, Thomas et al. 1998, Balas and Boren 2000, Morris 2002, Black and Hutchings 2002, Berwick 2003, Grol and Grimshaw 2003, van Bokhoven et al. 2003). Studies suggest that it takes on average, 17 years to turn 14% of original research findings into practice (Lenfant 2003), and that there is a failure rate of up to 70% of organisational change (Elwyn et al. 2007). Improved understanding of the reasons for the lack of uptake of research findings and guidance and the facilitating and hindering factors for implementation requires insights from a range of disciplines (Haines and Donald 1998).

Safety First (Department of Health 2006b), called for a need to redouble the efforts to implement systems and interventions that actively and continuously reduce risks to patients. It also called for more collaboration at a national level to ensure that this

doubling of effort is not hampered by the complexity and multi-faceted nature of the NHS (Department of Health 2006b). The NPSA therefore should play a significant role in creating conditions to stimulate and guide the NHS to improve implementation. The current approach mainly used is to rely on passive diffusion of information to inform health professionals' about safer practices, this is doomed to failure in a global environment in which well over 2 million articles on medical issues are published annually (Haines and Donald 1998, Hunter 2002). The NPSA should in fact spend more time on ensuring guidance gets implemented and evaluated than it does on producing its solutions and guidance.

This project therefore, sought to identify how the NPSA could support improvement in implementation. It sought to explore the factors that help or hinder successful implementation, using my own personal expertise, other experts, the views of staff in acute care hospitals across England and Wales and the literature. Following the initial interpretation and analysis of the literature and the data collected from the participants, a solution emerged. This was to design and develop an implementation toolkit, primarily aimed for NPSA staff, but also of use for other developers of guidance and safer practices and those responsible for implementation (Frush et al. 2006, Fracica et al. 2006, Leape et al. 2006). This project therefore comprises a product in the form of an implementation toolkit supported by a critical commentary on the development of the product. These will provide an original contribution to my own knowledge and understanding, as well as that of my work place, the NPSA, my professional areas, nursing and patient safety, and the knowledge base of the Middlesex University.

This document is the critical commentary which provides the written critique, methodological and contextual information, together with a description of the development and content of the toolkit. It is set out in 8 chapters. This chapter, chapter 1, introduces the reader to the main theme of patient safety, my own personal journey, the NHS context and the broad rationale for pursuing the project. Chapter 2

presents the pertinent literature on which the methodology draws and describes the terms of reference. Chapter 3 provides a description of the planned methodology. Chapter 4 details how the project was conducted and any variance from plan. Chapter 5 reveals the project findings. Chapter 6 describes the development of the toolkit based on the project findings and a further literature review. Chapter 7 presents reflections about work based research, how the project has enhanced my knowledge and understanding and impacted on my professional and personal development. Chapter 8 ends the commentary with the project conclusions and recommendations.

Chapter 2: Terms of Reference

'It started with a call to better inform the public about what research is being done in the private sector and public sector – and ended with a plea for the NHS to become more effective at implementing what we already know'

Alexis Nolan
Health Service Journal
27 March 2008

2.0 Introduction

In this chapter I present the initial literature review used to inform the aims and objectives and methodology of the project. This also includes the terms used throughout the commentary.

2.1 Literature review

The following literature describes the relevant research published over the last 15 years. The methodology used for the literature review is shown in appendix 2. The literature which informed the design and development of the implementation toolkit is presented in Chapter 6.

The overarching finding in the literature from a range of disciplines is that effective implementation of knowledge, research and information into practice remains an unconquered challenge (Grimshaw and Russell 1993, Bero et al. 1998, Freemantle et al. 2000, Grol and Grimshaw 2003). Several perspectives on this challenge exist. They have largely concentrated, in healthcare, on evidence based guidelines and their effectiveness (Grimshaw and Russell 1993). Other disciplines that have studied this challenge relate to innovation, improvement, quality management and change management (Iles and Sutherland 2001).

A systematic review by Grimshaw and Russell (1993) suggested that while change in clinical practice had been effected by guidelines, the level of success had varied considerably. They indicated that there were various factors which increased levels of compliance, for example they cited one study which had increased compliance by involving clinicians in developing the guidelines (Putman and Curry 1985). Other factors cited were the receptive context and the methods used to develop, disseminate and implement the guidance. The most effective strategy found in their review was when education was used to disseminate the guidance. The least effective was found to be simply mailing the guidance or the guidance disseminated through journal publications.

Four years later a systematic review carried out in Canada found similar results (Davis and Taylor-Vaisey 1997). This review again found that dissemination and implementation strategies had varied results. The factors which affected the success of adoption included the quality of the guideline, the receptive context, incentives used and patient factors. The most effective strategies found were reminder systems and a combined approach using a number of the strategies together. Those found to be moderately effective were audit and feedback, and targeted guidelines reinforced by peers or opinion leaders. The least effective was found to be didactic education and mailing.

One year following the Canadian study, an overview of systematic reviews of interventions to promote the implementation of research findings was published (Bero et al. 1998). Bero and colleagues (1998) found it hard to separate out the effects of the intervention from the influence of contextual factors. They found that the strategies which were consistently effective were educational outreach visits, reminders, multifaceted interventions and interactive educational meetings. They described audit and feedback, the use of local opinion leaders, local consensus processes and patient mediated interventions as variably effective. The least effective were passive

dissemination of educational materials such as guidelines and didactic educational meetings such as lectures. In fact, mass dissemination of guidance, is cited as the least effective in a large number of studies (Grimshaw and Russell 1993, Davis and Taylor-Vaisey 1997, Bero et al. 1998, Thomas et al. 1998, Morris 2002, Black and Hutchings 2002, Grol and Grimshaw 2003, van Bokhoven et al. 2003, Grzybicki 2004).

Bero and colleagues (1998), highlighted the limitations of the research they reviewed, i.e. the limited study of behavioural change, the lack of research comparing one strategy against another and the difficulties with generalisability because the studies were carried out in one care setting or with one profession. The authors recommended that policymakers pay attention to implementation research, that greater attention should be paid locally to actively ensuring research findings were implemented, and there needed to be a greater emphasis on evaluation of the success of implementation (Bero et al. 1998).

In 2000 there was an increased focus in healthcare on change management and organisational change, partly due to the new emphasis in the NHS on improvement (Department of Health 2000a, Iles and Sutherland 2001, Bate et al. 2004).

Organisational change management literature is vast and complex and provides important insights to help address the challenges of implementation and can be used when developing an implementation strategy (Iles and Sutherland 2001). One of the challenges related to change programmes is that they are viewed as top down initiatives, isolated from the front line and ignorant of reality (Øvretveit and Gustafson 2003, Hulscher et al. 2003, Gaba et al. 2003, Bate et al. 2004). Researchers who have studied change management found that implementation needed to be thought about when planning and designing an initiative; if not then there was a high likelihood of failure (Iles and Sutherland 2001).

Implementation of policy also came under scrutiny (Hunter 2002). Hunter (2002) describes how since 1970's studies of policy implementation have tried to explain the 'implementation gap' (Dunsire 1978), and that the ability to get policies implemented was becoming increasingly rare. The principal messages similar to that in change management were that; policy formulation and implementation are interdependent, they should be considered in combination and if implementation is to be successful then those that have responsibility for it should be involved in the design (Hunter 2002).

To seek further clarity and address the limitations of previous systematic reviews, Grimshaw et al. (2004) conducted a further review of guideline dissemination and implementation strategies. The authors found that the evidence base to support decisions about which implementation strategy is more effective than another was inadequate. Their review provided some contradictory findings from previous reviews. They found that even though improvements were small, simple reminders were the most effective intervention observed, educational outreach programmes only led to modest effects on implementation, dissemination of educational materials led to some effective change and multifaceted interventions were not necessarily more effective than single interventions. The authors acknowledged the limitations of poor methodological quality of the studies reviewed and the fact that the scope of their review was limited to experimental study designs such as randomised control trials and before and after studies in medicine. While these limitations should be noted, this review introduced a note of caution for those that feel high intensity and high cost multiple strategies is the approach to take based on earlier findings (Grimshaw et al. 2004).

The literature review informed the project methodology by indicating the need to explore, in the real world, perceptions of implementation. The focus, steered by these early studies, was to identify the different factors which would either help or hinder implementation, and to understand the strategies that worked better than others. It

also indicated the need to explore the role that a national organisation could play in helping local implementation.

2.2 Limitations of the literature

Literature on the implementation of patient safety was particularly sparse. There were many articles related to the field of patient safety but only a few related to the implementation of patient safety guidance (Leape et al. 2002). As stated, many of the researchers who conducted systematic reviews cited the poor methodological quality of the studies reviewed and the lack of cause and effect, i.e. being able to separate out and understand the variables related to the outcome (Grol and Grimshaw 2003, Lanier et al. 2003, Grimshaw et al. 2004). Also, the description of implementation was inconsistent, terminology was used interchangeably and there was little clear evidence provided of successful implementation or even what the researchers were expecting. The research rarely demonstrated the measures used to describe levels of success or failure of implementation. The majority of studies related to single settings, or single professions, presenting concerns of generalisability. The beneficial effect on performance of taking part in research, i.e. the Hawthorne effect, was rarely described (Cohen et al. 2000). Therefore any conclusions drawn must be considered with an amount of caution.

2.3 Terms

Throughout this commentary I refer to patient safety guidance or safer practices to sum up the outputs of the NPSA that seek to change behaviour and practice to improve the safety of patient care. The outputs, which this project seeks to improve implementation of, are therefore the multiple communications, including alerts, notices, guidelines, solutions, initiatives, research and advice that the NPSA issues.

There are also a number of different terms which describe various components for successful implementation referred to throughout this project commentary. These are used interchangeably by different individuals and disciplines for the diverse concepts surrounding the uptake and use of guidance. The following were adapted from the literature (Rogers 1983, Fraser 2002a, Gustafson 2003, Greenhalgh et al. 2005, NHS Institute for Innovation and Improvement 2006):

- Director is a person that directs, the person who is responsible for the interpretive aspects of a procedure, who then supervises the integration of all the elements
- Diffusion and dissemination are the processes by which the guidance or safer practice is communicated
- Guidance is something that guides
- Safer practice is the habitual practice, habit or custom which makes things safer
- Adoption is the decision by others to adopt the guidance
- Implement is to carry out an action or put into effect a plan or procedure
- Implementer is someone who carries out that action
- Implementation is when new ways of working are acted upon and changes are made to behaviour and or practice
- Embedding is when the new ideas or practice are spread within organisations or between organisations to enable sustainable change i.e. the new ways of working and improved outcomes become the norm, and part of everyday practice

2.4 Boundaries and constraints

The boundaries and constraints were related to budget, time, politics and scope.

- Budget: The project had a finite amount of funding, totalling £30,000 over the two year period. The project needed to adhere to the conduct rules associated with the use of public money, i.e. financial, procurement and governance constraints and regulations.

- **Time:** The project spanned a two year period from March 2006 until May 2008. The project needed to be completed by early 2008 so that the toolkit was ready for the launch of the patient safety campaign in July 2008. It needed to fit in with the other objectives that I was expected to achieve in my role.
- **Politics:** Working for a national organisation that reports to the Department of Health and which focuses on the complex and sensitive subject of patient safety there were many political considerations that needed to be taken into account as the project progressed. These were essentially around managing the publicity, the communications and turning the findings and output into opportunities rather than threats.
- **Scope:** The scope was limited to the acute sector of the NHS and did not include primary care, mental health or ambulance care settings. The reason for this was multifactorial; the primary care sector in England has recently been significantly reconfigured, the level of understanding of patient safety in primary care is at an early stage and the unique challenges of these diverse areas (primary care, mental health and ambulance care) require a separate focused project.

2.5 Aim and Objectives

The project aim was to improve the implementation of national patient safety guidance.

The initial objectives set out in the project proposal were to:

1. Critically examine the literature in relation to the factors that help or hinder the implementation of national guidance at a local level
2. Undertake a stakeholder analysis and identify the contextual and environmental factors in relation to patient safety in the NHS
3. Explore the factors that help or hinder implementation in acute hospitals
4. Explore any differences between the acute hospitals

5. Triangulate and critically analyse the literature and theory, the stakeholder analysis, and content gained from acute hospitals
6. Draw connections between all information to identify the factors for implementation in acute hospitals and the interrelationships between those factors
7. Draw conclusions from the findings in order to provide recommendations on future implementation of guidance with respect to patient safety
8. Extrapolate the findings in order to provide recommendations on future implementation of guidance throughout healthcare

The emerging findings from the initial literature review, backed up by the interviews and questionnaire results led to the addition of a ninth objective:

9. Design and develop an implementation toolkit, a combination of advice, tools and techniques for the developers of guidance to support local NHS organisations to implement patient safety guidance.

Chapter 3: Methodology

'For much real world research, it is valuable to have what I will call a 'scientific attitude'.

By this I mean that the research is carried out systematically, sceptically and ethically'

Colin Robson
Real World Research, 2002

3.0 Introduction

In order to advance knowledge and understanding in relation to implementation of patient safety guidance, and to address the aim and objectives within the boundaries and constraints of this project, a qualitative approach was chosen to study practice in acute hospitals. This was because it enabled me to collect qualitative data through a range of interviews from four acute care hospitals and a questionnaire sent to every risk manager in the 173 acute hospitals in England and Wales.

3.1 Research theory

The research was based in the research theories of constructionism and interpretivism (Crotty 1998). Constructionism challenges the objectivist stance of positivism (Cohen et al. 2000). The view is that all knowledge, and therefore all meaningful reality, is dependent upon human practices being constructed in and out of interaction between human beings and their world (Crotty, 1998). This project aimed to view the problem of implementation within the real world of acute care hospitals as perceived by the people who worked within those hospitals. This approach lent itself to in depth interviews in each site and open ended answers to questions in the questionnaire to make sense and meaning out of the real world (Robson 2002, Karatas and Murphy 2003). It accepted, as does constructionism, multiple interpretations of an issue with none of them as the objective truth (Cohen et al. 2000).

Interpretivism uses explanatory research to explain and analyse experiential evidence (Weick 2002). The interpretive approach also views that people actively construct their social world and that the researcher should study the social world without intervention of or manipulation by the researcher (Cohen et al. 2000). In depth interviews which require the participant to provide their experience and understanding of their everyday world were chosen to generate new knowledge (Cohen et al. 2000). By interpreting and analysing the participant views, at interview and in response to the questionnaire, this would help construct meaning and understanding from that knowledge. Key characteristics of interpretivism are that; the research gathers or portrays participant's accounts of a phenomenon in order to understand how it is experienced and understood by those directly affected, the researcher distinguishes themes and common elements of experience and differences between groups and reflects on the relationship of the research findings with theories and constructs in the literature (Weick 2002).

Self-reflexivity is important within interpretive approaches. This involves the idea that the research reflects the identity of both the researcher and the research subjects. In the name of self-reflexivity, I describe my own personal motives, background and relationship to the project within this commentary. I was acutely aware of the fact that my background, occupation, values and opinions, together with my actions, selectivity and perceptions would shape my understanding and knowledge and therefore affect the research (Cohen Manion and Morrison 2000).

3.2 Research approaches considered

The following describes the journey towards the eventual choice of research approach and starts with two potential research approaches that could have been used and explains why they were not chosen.

An ethnographic approach: Ethnography or participant observation could have been used to observe and gain an in-depth view of the behaviour of a group of individuals within acute care hospitals over an extended period of time (Wilkinson 2000, Robson 2002). This was not chosen because it is time consuming, takes time for the researcher to be accepted and then ignored and can introduce research bias. It would not have fitted within my own capacity and the time constraints of the project. Also, pragmatically, it was felt that I would collect enough information through the in depth interviews and questionnaire.

Nonetheless, an ethnographic component of the case study approach was considered and initially proposed (Robson 2002, Silverman 2004). This would have involved the 31 patient safety managers (the remote workforce of the NPSA) undertaking a short period of ethnographic observation within a sample of acute hospitals. However this could not be taken forward, because in December 2006 a recommendation was made by the Department of Health to transfer the remote workforce from the NPSA to Strategic Health Authorities (Department of Health 2006b). Consequently, the staff were coping with significant personal changes. It was therefore felt inappropriate to ask them to undertake the ethnographic component.

Action research: Action research would have enabled me to use an iterative inquiry process to discover the problem with implementation and the potential solutions, take action, apply changes, test and evaluate those changes (Iles and Sutherland 2001, Robson 2002). This is similar to the small step change approach in patient safety and soft systems methodology (Berwick 1998, Iles and Sutherland 2001). The strengths of this approach would have been that it would have provided a non-threatening method of learning, well suited to the real world and would have been useful to create collaborates. Again the reasons for not choosing this approach were to do with its time

consuming nature and the difficulty of getting time with busy local staff on an ongoing basis for a period of months (Iles and Sutherland 2001).

3.3 Research approach chosen

The objective of the research was to explore, interpret and obtain a deeper meaning and understanding of implementation factors for patient safety guidance. The qualitative approach lent itself well to this objective. I was not trying to determine the incidence or prevalence of those factors or to test one method or piece of guidance with another which would have lent itself to a quantitative methodology.

Case Study Strategy

A case study strategy (Yin cited in Robson 2002) for doing research, involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence was appropriate. I chose to use the principles that form the basis of case study methodology to help me explore the perceptions of healthcare staff in acute care settings (the real life context) of implementation factors (the particular contemporary phenomenon) (Yin 1994, Cohen et al. 2000, Wisker 2001, Iles and Sutherland 2001, Robson 2002, Kumar 2005). The multiple sources of evidence would be provided by the 19 interviews across the sites, policies and procedures from each site reviewed, feedback in relation to each site from the relevant national patient safety manager, the literature relating to implementation, experience of the NPSA, and the responses found in the questionnaires.

This method was adaptive and enabled me to choose a number of research techniques to help problem solve. It also helped to bring together all the intellectual sources to identify a solution to the problem (Phillips and Pugh 2000). However, the project did not intend to provide a detailed account of a case or cases (Robson 2002). While I

proposed to analyse the contextual factors, perceptions and attitudes of individuals within each case study I did not propose to create a detailed account of all aspects related to each hospital site. Additional data which may have been useful to explore and compare would have been the leadership style, the decision making processes, the infrastructure provided for patient safety and the patient safety culture of each site. Pragmatically, given the capacity and time constraints I felt that I needed to focus on achieving my objective of identifying the factors which help or hinder implementation from the perceptions of the individuals rather. I did propose to access their policies and procedures related to patient safety. I also proposed to discuss each site with the relevant patient safety manager for each organisation to provide insight from their perspective.

In order to identify the sites that I would visit, I chose to divide the acute care hospitals into the four 'regions' covered at the time of the study by the NPSA. These were North England, South England, London and the East of England, West of England and Wales. The names of the hospitals were to be placed in four different boxes for and one was to be picked out from each box. Out of the 173 acute care hospitals, 4 organisations would represent 2.3% of the total number in England and Wales. Hospitals which cared for the mentally ill, community based hospitals, ambulance and primary care organisations were excluded.

The qualitative collection and analysis of data was through a mixture of both deskwork and fieldwork. A summary of the research approach and techniques chosen and why is shown in the following table (Taylor and Bogdan 1998, Cohen et al. 2000, Wisker 2001, Robson 2002).

Table 2 Research approach and techniques chosen

	Objectives	Research approach chosen	Research techniques chosen
1	Critically examine the literature in relation to the factors that help or hinder the implementation of national guidance at a local level	Explanatory research approach was chosen to structure and define the problem. Initially through a review of the available literature.	The deskwork would include searches and critical analysis of documentation, literature and internet material.
2	Undertake a stakeholder analysis and identify the international and national contextual and environmental factors in relation to patient safety in the NHS	Explanatory approach.	This would be a mixture of fieldwork (meeting the stakeholders) and deskwork with stakeholder mapping and analysis techniques to describe the macro context in relation to acute care hospitals in the NHS.
3	Explore the factors that help or hinder implementation in acute hospitals	A case study approach was chosen to explore local practice within its real life context in acute care hospitals. Qualitative analysis with some quantitative analysis using descriptive statistics.	The fieldwork would be a mixed approach of face to face in-depth interviews at the hospital sites together with an electronic questionnaire.
4	Explore any differences between the acute hospitals	Qualitative analysis of the interviews from each hospital site. Interpretation of documentation provided from each site.	Deskwork following interviews using analysis of the interview findings and information provided by the sites together with insight from patient safety managers.
5	Triangulate and critically analyse the literature and theory, the stakeholder analysis, and content gained from acute hospitals	Qualitative review of all data collected.	Deskwork by the researcher to review the interviews, the literature and the questionnaire together and identify themes which were consistent in all the different sources.
6	Draw connections between all information to identify the factors for implementation in acute hospitals and the interrelationships between those factors	Qualitative review of all data collected.	Deskwork using the triangulation to identify the factors which help and hinder implementation in acute hospitals and identify themes.
7	Draw conclusions from the findings in order to provide recommendations on future implementation of guidance with respect to patient safety	Qualitative review of all data collected.	Deskwork by the researcher to review triangulation, connections and themes to identify conclusions and recommendations for patient safety.
8	Extrapolate the findings in order to provide recommendations on future implementation of guidance throughout healthcare	Qualitative review of all data collected.	Deskwork by the researcher to review triangulation, connections and themes to identify conclusions and recommendations for other fields.
9	Learn from the findings to develop an implementation toolkit – a combination of tools and techniques for the developers of guidance to support local NHS organisations to implement patient safety guidance	Collaborative approach to construct the implementation toolkit content and design.	Further literature search. Drawing from all deskwork and field work and interactions in the workplace to identify draft content and design. Share draft with internal and external colleagues to construct final toolkit.

3.4 Research techniques

3.4.1 In depth interviews

To build on the literature review, in depth interviews were chosen as a flexible and adaptable technique for collecting rich data from and about the acute care setting in the NHS (Taylor and Bogdan 1998). The unstructured or in depth approach was chosen because it would enable a conversation in an informal way (Taylor and Bogdan 1998, Robson 2002). The information would be gained with a minimum of prompting (Robson 2002). Appendix 3 shows the prompts that would have been used if required.

I proposed to use the interview to gain individual perceptions about the participants level of patient safety knowledge and their perceptions about the factors that help or hinder implementation locally in their organisations. I planned to interview six individuals who represented staff groups within each of the four sites (a total of 24). I proposed to interview two types of staff, individuals that lead and direct, [to be referred to throughout the commentary as 'the directors'] and individuals who are directed to implement, [to be referred to throughout the commentary as 'the implementers']. The directors were the chief executive the medical director and the nursing director. The implementers were the risk manager, a frontline nurse and a frontline doctor.

The interviews would be used to develop an understanding of the overall issues and then the similarities and differences between the different groups (Robson 2002). They were proposed to be one to one, and face to face to enable me to pick up on the subtle cues, expressions and body language of the interviewee and follow up any interesting responses. Each interview was planned to take place within the interviewee's own place of work enabling them to be more at ease and to easily recall their own practice and the issues they deal with in their everyday work. Each interview would be for one hour; less than 30 minutes was unlikely to be of value, over 60 minutes may have caused unreasonable demands on the busy participants (Robson 2002). This

approach would use my skills and experience honed over 25 years observing and communicating with patients and healthcare staff. The sample size was felt to be a sufficient sample size in each site to provide perceptions of local implementation factors. At the end of the interviews I would assess as to whether I needed to undertake some more interviews, this would have been appropriate if an individual within a group had not been represented at all, e.g. no doctors or no chief executives turned up.

A weakness of the unstructured interview is that it raises concern about reliability and bias. To mitigate the bias I would use a consistent approach by doing all the interviews myself and using the suggested interview sequence by Robson (2002) shown in appendix 3. Bias was also addressed by taping and word for word transcription of each interview (Robson 2002). Another weakness is the time consuming nature of interviewing as it involves preparation, site visits and complex analysis (Robson 2002). However, this is balanced by the fascinating insights provided and the joy of working with others to construct knowledge and understanding.

3.4.2 Questionnaire

The interviews were used in combination with a questionnaire to gain a larger amount of information to triangulate with the literature (Cohen et al. 2000). The questionnaire was targeted at each risk manager in every acute care hospital in England and Wales (n=173). It was assumed that they have the relevant knowledge to answer the questions posed as they have a key role in implementation of all relevant standards and guidance to improve clinical risk and patient safety (Department of Health 2004b).

The questionnaire was proposed for self completion by each risk manager, as an individual and not as a representative of their organisation. This type of questionnaire was chosen because of its advantages in terms of low cost and its ability to gain

perceptions from a large sample of risk managers (Robson 2002). I intended to keep it short to maximise response and reduce burden for busy staff (Robson 2002). The wording needed to be neutral so as not to lead the respondent (Robson 2002). A copy of the questionnaire is found in appendix 4.

The disadvantages of this type of survey are that; response rate is likely to be low, the respondents can answer the questions in any order, there is a medium chance of response bias and the quality of the data received is out of the researcher's control, for example the questionnaire could have been completed by anyone (Robson 2002). Additionally, there is no interaction with the researcher so the respondent can only answer the questions posed; there is no way of expanding points or clarifying points.

Questionnaires usually rely on closed questions; however I chose to use open-ended questions to enable a freedom of thought and a richness of information (Robson 2002). The descriptive text rather than categorised answers meant that the eventual analysis would take longer.

The questionnaire would be sent electronically via email. The NPSA had (at the beginning of the project) 31 Patient Safety Managers (PSMs) who worked around the country in the four regions. Their role was to support every organisation in their patch and their key contact was the risk manager in each organisation. The PSMs would be asked to send the questionnaire to the risk managers, or equivalent, in their patch. The questionnaires respondents were asked to return their questionnaires to their PSM who anonymised them before sending them to me. The risk managers were given 4 weeks to complete with a gentle reminder from their PSM at the end of the 4 weeks for any that had not returned it.

3.5 Data Analysis

The data collected from the interviews and questionnaire were to be analysed and interpreted using colour coding and thematic analysis. I chose not use a word processing package, rather I chose to conduct an analysis of the content of the interviews and questionnaires myself. I planned to undertake the systematic process of sifting, highlighting and sorting the information into the different issues and themes in order to identify the different comments and factors. Each comment would be highlighted and colour coded and thematically organised.

The approach used would be an interpretive and iterative one, with colour codes based on interpretation of the meanings within the texts. This would use my own insight, expertise and experience. At the outset no predetermined themes had been created for the interview comments to fit into, i.e. the themes would be created by interpreting the phrases and comments not the other way round. My expertise and understanding in the subject would be used to understand the differences and similarities between the different groups, the directors and the implementers in the different hospital sites. Not using content analysis software meant that the data analysis had the potential to be quite time consuming, however, my belief was, and still is, that this process required someone who had an intimate knowledge of patient safety and had undertaken the interviews. By doing it myself I felt my understanding of the local views would be markedly increased and it would help me to identify the issues and potential solutions to the challenges raised. The advantage of me doing the analysis would mean that I could pick up the subtle meanings that are often crucial elements missed by using generic tools. This is as much an art as a science, learnt from experience and over time.

Quantitative analysis would be undertaken by ranking the themed responses in order. Descriptive statistical and inferential statistical analysis using Microsoft Excel data

analysis tools would be undertaken. The data would then be triangulated to identify connections between theory, literature, stakeholder analysis, questionnaire responses and interview comments. The data findings and themes would be compared with the literature findings to identify patterns and validate the views of the participants.

3.6 Trustworthiness

The traditional positivist criteria of objectivity, reliability and validity are inappropriate for qualitative research (Guba and Lincoln 1994, Taylor and Bogdan 1998, Wisker 2001, Robson 2002, Peräkylä 2004). Qualitative research requires the demonstration that it is both trustworthy and applicable (Yin 1994, Guba and Lincoln 1994, Cohen et al. 2000). The methodology, design and conduct of this project would provide the foundation for the credibility and trustworthiness of the findings and the contribution to knowledge. The project was planned to be conducted using a systematic, transparent, consistent and neutral approach to collection and analysis of the data. The use of taping, transcription and triangulation would add to this foundation and support the ability to generalise the findings (Greenhalgh 1997, Cohen et al. 2000, Kumar 2005). The credibility of the study would also be built on by the credibility of the researcher. My own personal credibility was demonstrated at the beginning of the doctorate programme and re-iterated in the project proposal, where I described my authority, autonomy and ability to influence. The triangulated findings from the literature and data collected would be used to demonstrate that the output of the project is both a valid and valuable approach to improving implementation. A robust evaluation will be undertaken to assess that it is doing what it was expected to do, i.e. whether it is fit for purpose and fit of purpose.

3.7 Ethics and confidentiality

The conduct of the project would be undertaken in accordance with ethical principles to ensure that the knowledge and understanding was gained without abusing the power base of the researcher (Wisker 2001, Robson 2002). The project would demonstrate that it met the key criterion that it was a worthy area to study through the rationale and evidence collected. The project was planned to meet the relevant ethical guidelines for the Middlesex University and the NHS. The study proposal was submitted to the Middlesex University on two occasions; firstly for approval of the chosen project and secondly to update the University on changes to the output of the project. It was also submitted for assessment by the Central Office of Research Committees (now the National Research Ethics Service) to identify if it required a Local Research Ethics Committee (LREC) approval for each participant site. It was classed as an audit of a service and did not need to go through each LREC. Each organisation could log it as an audit. Voluntary, informed consent to participate would be obtained from each participant (Behi 1995). Like any research my presence may interfere in some way with the behaviour of the participants producing respondent bias, ranging from obstruction or withholding information to wanting to please or provide answers I was seeking or perceived to be seeking. This was particularly pertinent because I represented a national organisation, with its perceived power. This was a potential threat to the participants openness. I would need to be consistent, considerate, and sensitive to the potential biases and needs of the participants. All data storage would be in accordance with the data protection act and research governance principles. No harm or detriment would be incurred by any individuals or participant organisations;

- the interviews would be kept to one hour to minimise the burden in time
- no assessment of performance by any organisation or individual would be made in such a way that blame could be attributed
- no patients or minors would be recruited as participants
- no patients' records or any patient related information would be accessed

Also, there was no financial gain by the participants or the researcher. I would be travelling to the four study sites by train with the subsequent minor effect on the environment that this caused.

3.8 Work-based research

Work based research is where the research is carried out by someone who holds down a job in a particular area and at the same time undertakes a period of research which is relevant to that job (Robson 2002). The doctorate in professional studies (DProf) is a post graduate work based area of study equal in level and rigor to other doctorate programmes, designed to fit in with full time work and at the same time based on that work (Costley 2007). The work based researcher is someone whose learning is attained through collective effort and dedicated application but highly opportunistic (Portwood 2000).

This project would be achieved through a collective effort and the social interaction with colleagues within the NPSA and colleagues within the specialist field of patient safety. Collaboration is commonly known as a process where two or more people work together toward a common goal, typically an intellectual endeavour, since the second world war the term collaboration has acquired a very negative meaning, referring to persons and groups which help a foreign occupier of their country (Wikipedia 2008). Collaborationism is the more specific term for collaboration with an occupying army (Wikipedia 2008). For this project, the more appropriate description is collaborative learning. This describes the interaction between myself and my colleagues to create shared meaning and knowledge, which involved the structuring and restructuring of knowledge (Smith and MacGregor 1992). The collaborative approach links back to the research theory that underpins this project, that of constructionism (Robson 2002). Collaboration in terms of this project therefore, involved listening, skilled relationship

management and political astuteness. I encouraged people to participate and continued to do so while at the same being flexible. The following tables describe my own strengths and weaknesses in relation to my role as a work based researcher.

Table 3 Strengths of myself as a work-based researcher

Critical Reflection	Effect at the start of the project
My position and role as Director at the NPSA provide me with opportunities.	I have the seniority, authority and autonomy to carry out the project which is central to my work. Opportunities provided by seniority – self directed workload and objectives. Ability to set my own objectives and fit the doctorate around my other activities. I can ensure the project and the organisation have mutual aims.
My background is a source of 'data' for the project. With over 10 years of expertise in risk management and patient safety; in-depth knowledge and understanding of subject	Pre-understanding of subject. Foundation for developing knowledge further.
My work place contributes to the research and provides additional sources of data with access to experts both international and national	I will maximise the use of my workplace, and experts while at the same time not taking advantage of them or their goodwill.
Pre-existing knowledge and experience e.g. masters level academic qualifications in risk management	I will use this knowledge as a basis for the research methodology and conduct of the research.
Opportunities provided by working in a national organisation	I have access to international experts in patient safety and the ability to go to international conferences; this can also increase credibility locally.
Nearly 30 years in the NHS a significant part of which was working as a nurse; realistic view of what can be achieved with NHS research. In work based research, there is an interaction of researchers with their world.	Understanding of environmental context. The research participants will be helping me to construct the reality of what is happening locally. I will need to be reflexive i.e. self critical and objective. Flexible designs require flexible researchers (Robson 2002). Listening skills and sensitivity will be important for the interviews. Ability to be flexible and an open and enquiring mind; my experience as a nurse has honed my listening skills and ability to be sensitive.

Table 4 Weaknesses of myself as a work-based researcher

Critical Reflection	Effect at the start of the project
Literature Search Stage: Too much	Difficulty to précis down for the commentary document.
Time – trying to fit in the Doctorate project while carrying out the ‘day job’ – because it is expected as part of the ‘day job’.	Need good preparation and planning, good time management and constant reflection. Work with the Senior Management to ensure they understand the project plans, timetable and accept these – if changes are expected earlier – then write this up as part of the project and describe the impact – use as a learning exercise. Pressure by organisation to complete the project earlier because it may be needed for the next stage of the organisation’s objectives.
Lack of expertise – self direction may mean I am not aware of what I don’t know.	I need to work through the user guide activities and ensuring I regularly review the suggested research books. Access experts; constantly review the knowledge and horizon scan the environment.
Preconceptions about issues in relation to any aspect of the project	I may make assumptions based on my own experience or knowledge – so need to ensure I take into account my own bias or hindsight knowledge.
Ability to be reflective and objective.	This means I will need to be acutely aware of the ways in which my values, attitudes, opinions, actions, feelings, selectivity, perception, and background shape the research.
Power – perceived in relation to working for a national organisation; Hierarchy – abuse of power and authority	Especially with subordinates and participants – I need to ensure that I do not abuse the power and authority and only ask what would be reasonable and agreed – and thank them.
High expectations of peers/team	I may expect people to put in time or expect peers to provide advice when they are not able to – I need to make sure that I do not abuse people’s good will, access them when they have the capacity and thank them

In work based research the concept of bounded rationality is particularly pertinent, i.e. that the world is large and complex, we have limited time to make decisions and we are limited by our minds and resources, therefore, perfectly rational decisions are not always feasible (Simon 1982). The work based researcher’s response is to pause and reflect and decide whether the rational decision is also an adequate decision. To, where necessary and because of external demands or constraints, replace the optimum with the sufficient. Bounded rationality affected this project in the choices

made. First, limiting the scope to focus on one care setting in the NHS for reasons described earlier. Secondly, the boundaries placed on the literature review. For example, initial searches found a vast amount of literature across a variety of disciplines, a decision was therefore made to concentrate the scope to literature relating to evidence based guidance and implementation, the transfer of guidance or knowledge into action. Primarily health care articles were searched. Thirdly the project activity was limited to 2 years to fit in with my own time and the external agenda, it was also limited to research approaches and techniques that would be completed within this time.

3.9 Limitations in the range of care settings

The focus on acute care hospitals means that there is still research required to understand the influencing factors across the different care settings e.g. mental health and primary care.

The focus on the specific participants means that there are certain staff groups who were not represented. These would be useful to tap into in the future e.g. pharmacists and other allied health professionals.

Chapter 4: Project Activity

“We have the science of discovery, but [what we need] is the science of implementation. One thing we are not short of in this country is guidelines or standards. We probably have the best engine producing this through NICE and others, but not necessarily the best system in which we can implement these.”

Lord Darzi
Health Service Journal
27 March 2008

4.0 Introduction

Project activity is divided into two parts. The first part is the activity undertaken to plan the project, collect the data and analyse the data including initial triangulation. The second part is the activity undertaken to develop the implementation toolkit. This chapter therefore describes the first part of the activity of the project and shows where relevant how it varied from what I planned to do. The following figure describes the project activity from March 2006 until July 2007.

Table 5 Action plan March 2006 to July 2007

Stage	Activity	Date and length
1	Project proposal Literature search Project proposal developed and approved	March 2006 to July 2006
2	Project Planning Ongoing literature review Recruit interview sites and design questionnaire	August 2006 to December 2006
3	Data Collection Interviews conducted Questionnaire sent and returned	January to April 2007
4	Data Analysis and Triangulation Information analysis Formal analysis of coding, analysis and interpretation Triangulation of literature, interviews and questionnaire	May to July 2007

4.1 Project proposal and project planning

The first phase of the project was to develop knowledge and understanding of the theory and research drawn from the literature. This validated and enhanced my understanding of the challenges of implementation. I developed a heightened awareness of the problems with implementation and used this wherever I went. I attended conferences and chose to steer my way to presentations which discussed any aspect of implementation. I read journals, newspapers and viewed web-sites through the lens of implementation. Every week I would check the literature published in the research databases, journals and specialist web sites.

In the autumn of 2006 I invited the 4 chief executives (CEs) of the hospital sites to take part. I explained the details about myself, the project and the reason they were selected i.e. 'out of a hat'. I did not want them to feel that they had been chosen for any other reason e.g. that I thought they were unsafe. All chose to accept the invitation. I informed the chief executive that I wanted to interview themselves together with 5 other staff. These were their medical director, nursing director, risk manager, one frontline doctor and one frontline nurse. This meant that it was at the discretion of the organisation as to who they put forward as the frontline doctor and nurse, the others were dictated by their job title. The potential weakness of this approach was that they would choose a doctor and nurse who would be picked to show their organisation in a good light. However, this would not have affected the project as the study was not about assessing whether the organisation was good or bad, it was about gaining local perceptions of implementation factors.

Each organisation provided a contact name who would then provide me with the names of the people to be interviewed. We created an interview schedule which involved interviewing 3 people on one day and 3 people on the second day. This gave

me time in between each interview and time to walk around each site to gain a sense of the environment.

The contact person was provided with copies of the project proposal and consent form to give to each participant in advance. The project was locally approved and participation at each site was voluntary, although one could argue that if asked by a senior person within your organisation to be an interviewee it would be hard to say no. The letter of invite clarified the voluntary nature of the interview and that the project was not about judging individual or organisational performance and that no one would be identified in any report or publication. The consent form, invite letter and prompt interview questions are found in appendix 3.

During this time, in December 2006, Safety First, a review of patient safety in the NHS was published (Department of Health 2006b). This report had 14 recommendations for the NHS including the NPSA. The recommendations for the NPSA were to refocus and restructure in order to increase the momentum of patient safety improvement for the NHS. Importantly, Sir Liam Donaldson, the Chief Medical Officer in his foreword, called for a redoubling of efforts to implement systems and interventions that actively and continuously reduce the risks to patients (Department of Health 2006b).

4.2 Data collection

In January 2007 I commenced the visits to the hospital sites, with the first site used to test the interview process. A breakdown of the participants is shown in Chapter 5. Consent to the interview was undertaken. All agreed to be taped after being informed of the use of the tape recorder and as agreed beforehand, the recordings would be transcribed (by a transcriber) and the tapes destroyed at the end of the project. I used a small and discrete tape recorder in order to minimise the inhibitory factor that being taped can sometimes bring. They had a choice at any stage to say no to the interview,

to halt the interview process and to stop the taping. They were informed again that their contribution would be anonymised.

The interview process went very smoothly. All organisation and interviewees were delightful and welcoming. They were keen to share their knowledge. They were also keen to talk about the recent publication, Safety First (Department of Health 2006), which was a slight distraction. Unfortunately, five interviewees could not attend on the day due to workload and other commitments, 3 of these were the chief executives of the organisation.

The only issue of concern was by the front line doctors and nurses, all of whom had either limited or no knowledge of the NPSA. They felt they were letting me down by not knowing. Two of these had not heard of the NPSA until the day of the interview, as the interview itself triggered them to look the agency up on its website. They felt embarrassed about this. I reassured them by stating that not knowing about the NPSA was important because it told me that our communications and outputs were not reaching the right people.

I reviewed the first site interviews to see if the process had elicited enough of the type of information I was seeking. The first site interviews clearly demonstrated this. The qualitative approach to sampling and data collection is fluid and flexible, i.e. stop collecting when further data collection would appear to add little or nothing to what has already been learned. The appropriateness of the sample size was determined by:

- The scope of the study: in this case clearly limiting it to implementation factors in acute care settings. Also, the sites were not meant to be representative of all acute care hospitals but provide insights that can apply to all acute care hospitals.
- The nature of the topic: the subject matter was easy and clear to talk about and gather information on

- Quality of the data: the study produced a rich amount of data therefore requiring fewer participants
- Study design and research method to gain the appropriate level of data: the unstructured interview approach produced rich data, therefore the number of interviewees provided an appropriate amount of data. Semi-structured interviews would have required around 30-60 interviewees (Robson 2002). The open ended questions in a questionnaire also gained a rich amount of data

In March 2007 the questionnaire survey was emailed from the NPSA patient safety managers. A total of 173 surveys were sent out, with 58 returned. The questionnaire was sent out a very busy time for the risk managers who were undertaking their self assessments for the Healthcare Commission at the time. I decided therefore not to push them for a response, so they were only sent one gentle reminder.

4.3 Data analysis

The analysis and interpretation started almost immediately after its collection. This initial informal analysis included a read through of the interviews, recall of the interview discussions and a review of the questionnaire responses.

The formal analysis was conducted as described in chapter 3, and the interview methodology is found in appendix 4. I used a systematic approach to content analysis, sifting, colour coding, and drawing up a list of categories and themes. I did not make a judgement on the amount of comments provided by each individual - although it was useful to place the comments into a hierarchy, e.g. the order of the amount of comments made for each theme. At the outset no predetermined themes had been created for the interview comments to fit into, i.e. the themes would be created by interpreting the phrases and comments not the other way round

The potential weaknesses were:

- A) Not using content analysis software: This meant that the data analysis was quite time consuming, however, I felt able to do this as I had experience of content analysis, an intimate knowledge of patient safety and had undertaken the interviews. I used my own insight, expertise and experience to understand the differences and similarities between the different groups, the directors and the implementers in the different hospital sites. By doing it myself I felt my understanding of the local views was markedly increased and it helped me to identify the issues and potential solutions to the challenges raised. The advantage of me doing the analysis meant that I could pick up the subtle meanings that are often crucial elements missed by using generic tools.
- B) No independent analysis: The interpretation of the themes were down to me. However, the validation is through the triangulation of the data, the similarity of the interviewees perceptions to the survey respondents, and similarities with the literature as well as the views of experts consulted.

A variation from the intended plan related to the questionnaire themes. While there were no pre-determined themes for the interview comments, a different approach was taken for the questionnaires. Once the themes had been created for the interviews the questionnaire responses were purposefully themed against them so that I could compare across the interviews and questionnaires.

4.4 Triangulation

All the data collected by the end of April 2007 from the interviews and questionnaire were triangulated with the earlier findings from the literature. Triangulation also included testing the findings and the potential options with my colleagues, within and external to the NPSA. In fact every meeting, reception and conference I attended provided me with an opportunity to debate the findings, the issues and the challenges

relating to implementation. I attended a number of national and international meetings and met with experts in patient safety across the globe. Particular meetings that enhanced my thinking on different solutions for the implementation challenge were; a meeting with the Implementation Team at NICE, the International Forum for Quality and Safety in Prague, meetings with the National Institute for Innovation and Improvement (NHSIII) and the Health Foundation to discuss the design of the patient safety campaign and a meeting at the World Health Organisation in Geneva to discuss safer surgery. Other highlights were discussions with individuals involved in the social transformation and social movement work, innovation and improvement experts from the NHSIII, implementation experts, and experts in the systems approach to patient safety and change management.

The emerging findings demonstrated that:

- the developers of guidance or safer practices in national organisations, including the NPSA, were not providing the right support and help to local organisations in relation to implementation. An exception was NICE. NICE was seen as credible, authoritative and supportive with an excellent approach to implementation.
- the NPSA was not as effective as it could be, clearly frontline doctors and nurses, the very people we want to help, knew very little about what we did.
- doctors were overloaded with information at induction with the consequential lack of time for patient safety.
- there is a need for learning sets for chief executives.
- the NPSA needed to review the inclusion of patient safety in basic nurse training and medical school training.
- the NPSA was continuing to produce guidance for the NHS in the same way, however, it was clear that the effectiveness of implementation was a serious problem.

- the NPSA needed to champion patient empowerment in relation to patient safety.

I attended to these concerns during the project by:

- a) presenting the findings to over 20 national organisations at a collaborative event in July 2007
- b) influencing discussions at the National Patient Safety Forum (the overarching Board for patient safety in the NHS)
- c) influencing and supporting the patient safety campaign in England, which starts in 2008, to align all outputs relating to patient safety
- d) exploring the findings with my work colleagues at our weekly team meetings. There was a resounding agreement that this the NPSA's role in implementation was a significant problem and a challenge that should be addressed as a matter of urgency
- e) using my position to discuss the initial findings with the chief executive and medical director of the NPSA – we agreed to discuss with the teams responsible for outputs which were the patient safety division and the communication team
- f) meeting with colleagues from NICE to understand and learn from their implementation processes

This meant that even as the project progressed different ways in which we could improve implementation of guidance and implementation of safety programmes were being considered. An emerging conclusion from these interactions and the early triangulation led to the extra objective:

- to design and develop an implementation toolkit, a combination of advice, tools and techniques for the developers of guidance to support local NHS organisations to implement patient safety guidance.

Chapter 5 demonstrates the findings which form the basis of this conclusion and describes in further detail the summary conclusion from the triangulation.

4.5 Finances

The project was a component of a wider programme of embedding patient safety. A total budget of £30,000 for the 2 years was set aside. Financial expenditure in the NHS is assessed from April to end March each year. The following figure describes the costs incurred for the two years of the project.

Table 6 Costs incurred for the two years of the project

Expenditure	Financial year April 06 to March 07	Financial year April 07 to March 08	Total project costs
Travel and accommodation for the interviews	£5,000	-	-
Transcription of interviews	£3,500	-	-
Design work	-	£6,000	-
Print for 300 toolkits	-	£4,168	-
Total	£8,500	£10,168	£18,668

These are specific costs only. My time and other NPSA staff time was provided 'in kind' and was not an additional cost to the project. Meetings, collaborative workshops were seen as part of the work of the agency and not costed to the project.

Resource implications for the service from the use of the toolkit are estimated to be minimal. The toolkit is designed to be used without any additional training.

Additionally, it is seen as a resource that will support improvement, reducing variance in care, error and harm. There is also an assumption that it will have potentially long term cost savings locally. All these will be determined as part of the evaluation.

4.6 Reflection on the process, tools and techniques

Collaboration: A virtual project team consisted of; patient safety experts at the NPSA, the Chief Executive, the Director of Safer Practice and Deputy Chief Executive, the Director of Epidemiology and Research, the Head of Knowledge Management and communication specialists. Their contributions to the project were advisory and they helped to test the findings from the literature and other data collections. Additionally my team, the NPSA patient safety managers, provided feedback on the project findings as it progressed during our monthly meetings. They also contributed significantly by disseminating the questionnaire to their risk manager contacts, receiving the responses, anonymising them and sending them on to me electronically.

Interviews: While the number of interviewees was relatively small, the time taken in interviewing was 8 days in total to interview with triple that for the analysis. Getting external transcription helped to cut down the amount of work involved. The quality of the data collected via the interviews and questionnaire were dependent upon the participants' ability and willingness to engage. Each interviewee appeared not to be significantly affected by the fact that I was from a national organisation. If I sensed this I made a conscious effort to put them at their ease and be as considerate and sensitive as I could. I did not feel the interviewee want to please me or held back information which may have put their organisation into a bad light. Unstructured interviews can get side tracked and this occasionally happened as stated with interviewees wanting to discuss Safety First (Department of Health 2006). I don't feel that I influenced the interviewees; however, on reflection the only way of telling would have been to evaluate the interview through a post-interview survey.

Questionnaire: The questionnaire lacked definitions of the terms. I did not define implementation, solutions, interventions and guidance. I assumed a level of understanding of the risk managers that they would know what these were. From the

responses received, there is no evidence that this reduced the quality of response but it clearly would have been a good idea. The question wording is crucially important (Robson 2002). In hindsight, the questions were not simple, or in fact three single questions as intended. There were multiple questions. This could have confused but does not appear to have done so. I should have separated out the components. For example for question 1 asked, 'What do you think are the factors which help uptake, implementation and sustainability of patient safety solutions, interventions and guidance?' This should have been split into:

- What do you think are the factors which help uptake?
- What do you think are the factors which help implementation?
- What do you think are the factors which help sustainability?

Analysis: On reflection, it would have been useful to have had someone check the analysis and coding of the interview and questionnaire findings. However, the interaction with my supervisors helped to question the analysis and findings, and constantly revisit them to ensure they accurately reflected what was said.

Chapter 5: Project Findings

'Making sure documents get used is a part of the organisation's work as much as preparing them. Implementing NICE guidance is fundamentally about improving patient care and patient safety.....if you are following NICE guidance, patients should be getting optimal care'

Dr Gillian Leng
Implementation Director, NICE
Health Service Journal Supplement
6 December 2007

5.0 Introduction

This chapter presents the participant details and findings from the hospital site participant interviews and the questionnaire responses. I also present a summary of the findings following the triangulation of all of the data sources.

5.1 Interviews

In order to identify what people think, feel or perceive about implementation in their organisation, interviews were an appropriate way of collecting this information, within the constraints of the available time and resources. The unstructured approach to the interviews was successful in its purpose of gaining a rich amount of descriptive data.

5.2 Interview participants

The interviews were undertaken from January to April 2007. Twenty four participants were invited, 19 were interviewed, 9 representing directors and 11 representing implementers. Five were unable to attend on the day of the interview due to work commitments. The participants did not represent all healthcare staff but represented core groups in acute care hospitals. The interviewees are shown in table 4. Only one Chief Executive out of the four was interviewed. This could be seen as a reflection of the priority that Chief Executive's place on patient safety. The NPSA has often found it difficult to engage with this important group of NHS staff. The barriers have been cited as a lack of time, lack of resources, delegation of responsibility for patient safety to an executive director in their team and a lack of awareness of their role in patient safety (Leape et al. 2006). In the one organisation that the Chief Executive was available, the value added by that particular individual was demonstrated in the whole organisation's approach to patient safety. This visible leadership at the top is clearly demonstrated in the literature (National Patient Safety Agency 2004). A constant was the risk manager (or equivalent) the person who is responsible for patient safety in each hospital.

Table 7 Participants interviewed

Site	1	2	3	4	Totals
Chief Executive	1	0	0	0	1
Medical Director	1	1	1	0	3
Nursing Director	0	1	1	1	3
Deputy Nurse Director	1	0	1	0	2
Risk manager	1 nurse	1 nurse	1 nurse	1 nurse	4
Front line doctor	1 registrar	0	1 consultant	1 registrar	3
Front line nurse	1 matron	1 staff nurse	0	1 sister	3
Totals	6	4	5	4	19

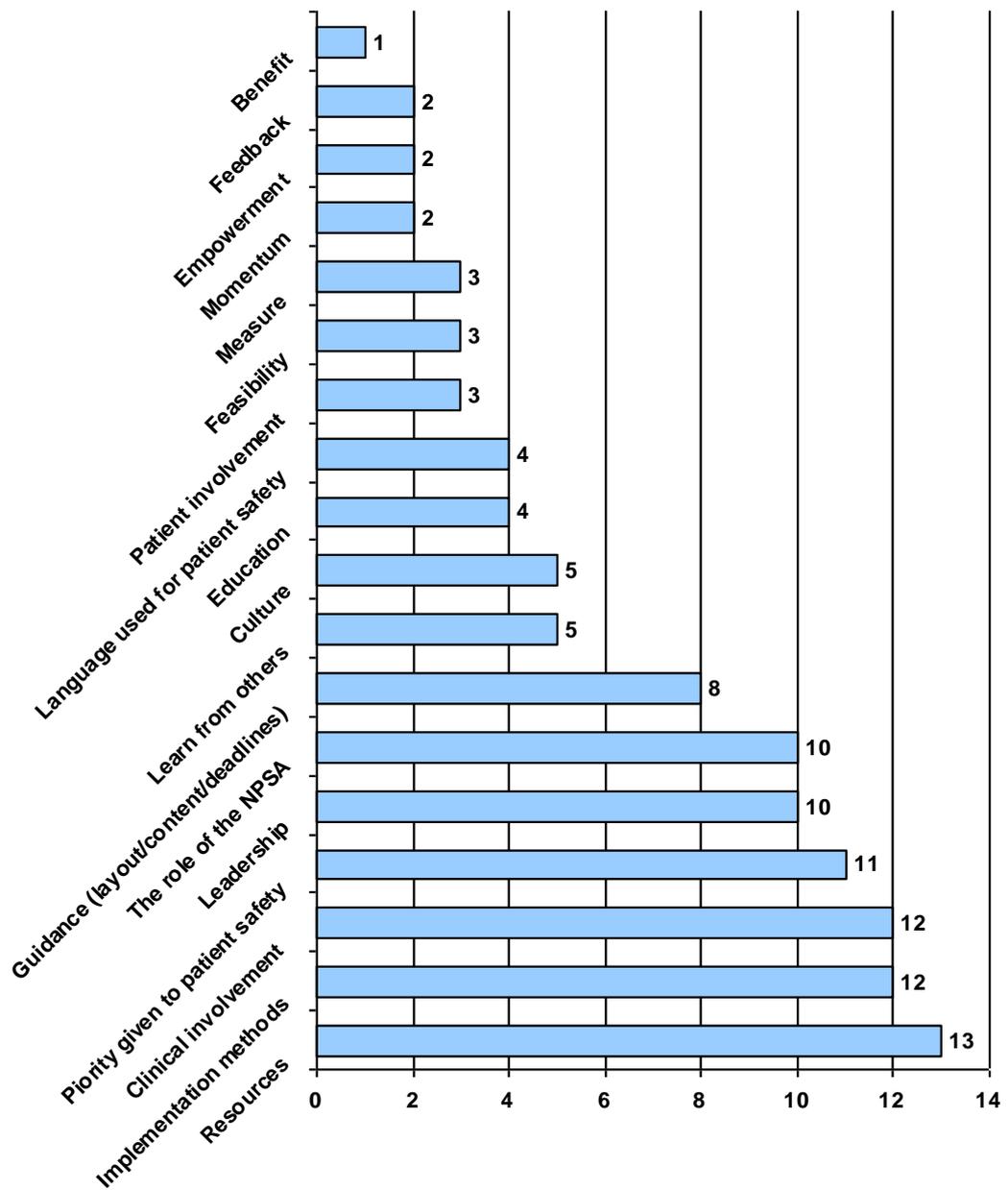
5.2 Interview findings

The interviews explored the participants views about the factors that help or hinder implementation of patient safety guidance and ascertained the level of knowledge in patient safety and that of the NPSA. The participants interviewed fell into two main categories, those that direct implementation and enable it to happen (directors) and those that are expected to implement the change or guidance (implementers). I therefore divided the analysis up between these two groups to see if there were any similarities or differences for these two groups. The findings from the synthesis of the interviews are shown in the following section.

5.2.1 Directors

These represented chief executives, medical directors or directors of nursing. A total of 110 comments were elicited from the transcribed interviews of this group and clustered into themes.

Figure 2 Themed comments from directors



The most number of comments related to resources (n=13). These were to do with having enough time, money or people for patient safety activity.

Table 8 Factors related to resources cited (directors)

Factor type	Summary of comments
Facilitating factors	Invest in patient safety (considered worthy and potentially cost effective over time)
	Infrastructure to spend time on this is crucial
	Fund staff to take time out to be involved in patient safety as well as changing practice
Hindering factors	Not enough time
	Take people away from the day job (to do patient safety)

Initial analysis identified a large number of comments which were coded as **implementation methods**. Further analysis led to the identification of a number of clusters within the theme which were then picked out to create additional themes.

Table 9 Factors related to implementation methods cited (directors)

Factor type	Summary of comments
Facilitating factors	The use of systems that embed things into everyday practice and support implementation
	Integrate processes and systems to effect implementation
	Integration with other national or local guidance thereby reducing the burden locally
	NICE system is a good example of implementation support
	Use of improvement science to change practice e.g. small step changes
Hindering factors	Simple dissemination of guidelines does not change individual practice
	Lack of knowledge and understanding of how to change behaviour
	Frustration - Inability to embed changes with lack of implementation support
	Difficulty in getting staff to comply [with guidance or changes]

'you can write as many guidelines as you want it still doesn't change people's individual practice' Director, 2007

Clinical Involvement (n=12) was viewed as ensuring that clinicians were involved, engaged and listened to.

Table 10 Factors related to clinical involvement cited (directors)

Factor type	Summary of comments
Facilitating factors	Picking interventions that clinicians would relate to because its part of what they are doing every day.
	Support for doctors to lead improvements
	Ensure clinicians can relate to the guidance
	Provide support to engage and empower
	Listen to clinicians
Hindering factors	Resistance to change by clinicians
	Targets switch doctors off
	Lack of skills and understanding (by clinicians) of what patient safety is
	Making the change a governance issue
	Lack of responsibility (taken by clinicians)

'there is a risk that once you make it part of your governance arrangements, the doctors suddenly flood away' Director, 2007

Giving priority to patient safety (n=11) was through demonstrating to staff its importance. Hindering factors cited were; the competing priorities for patient safety, the complexity of healthcare, externally set targets and a focus in the NHS on finance and performance. All of which steered organisations away from a focus on patient safety.

'The board here is all about finance, it's about activity and performance ..there's very, very little in there about patient safety' Director, 2007

The role of the NPSA (n=10) and to **the role of leadership** (n=10) had equal number of comments. With regard to the role of the NPSA, the facilitating factors cited were: its ability to be supportive, its role in identifying best practice and its ability to standardise across the NHS and influence manufacturers. The hindering factors cited were; its inability to force change, a lack of practical support provided locally and the view that the NPSA had created burden by issuing guidance which did not appear to consider the local context. The participants were very vocal about the role of national organisations and their relationship with each other. The view was that there were too

many national organisations, they all seemed to be working in silos and it was about time that they collaborated with one another to reduce the confusion and burden locally. Collaboration was not seen as a threat but as an opportunity.

Participants cited the approach taken by NICE [National Institute for health and Clinical Excellence] as good practice by a national organisation, providing clear guidance, support and tools to support implementation. They explained that in coping with the external demands made by national organisations, priority was given to those that were required by regulatory bodies or standard setters such as the Healthcare Commission, or NICE. The NPSA guidance was not considered a priority because it did not have the same level of authority.

'NICE guidance that was published last year, we've fully implemented it we build it into the plan and that becomes the norm, so to me it's about embedding things into everyday practice and not being an add-on or the must do, but people see it as a value as well really'

Director, 2007

The role of leadership (n=10) was key to demonstrating the importance of patient safety through role modeling and going out, listening and helping staff to sort out a problem.

Table 11 Factors related to leadership cited (directors)

Factor type	Summary of comments
Facilitating factors	Leadership to drive patient safety
	Demonstrate the leadership commitment
	Provide visible support
	Leaders desire to make a difference and to demonstrate the difference made
	Act as a filter when disseminating key messages to the staff
	Role modeling
	Demonstrate the importance of reflection
	Leaders to go out and about listening to staff (leadership walkabouts)
	Help implementers to sort out a problem
Hindering factors	Lack of ability to influence (by leaders at Board level)
	Lack of support by leaders
	Lack of visibility of leaders

Other themes identified were guidance (layout, content, deadlines) (n=8), which was essentially a plea for them to be simple, short and printable. The lack of a summary format was considered a hindering factor. Learning from others (n=5), described the desire to hear about what others had done and good practice examples as well as stories which described the problem in patient safety to raise awareness. Culture (n=5), related to (facilitating) pride, wanting to do well, energy and joy at work, and (hindering) lack of discipline and blame culture. Comments which were less than 5 included, education (n=4), language (n=4), patient involvement (n=3), feasibility (n=3), measure (n=3), momentum (n=2), empowerment (n=2), feedback (n=2) and demonstrating the benefit (n=1).

The facilitating factors cited from this group were:

- Learning sets for chief executives

- Patient safety a component in basic nurse training and medical school training
- Training programmes for all staff
- Patient empowerment – to be able to question the doctors and healthcare professionals more
- Working in partnership with patients and patient empowerment
- Benchmarking and measuring to demonstrate effectiveness of the change

The hindering factors cited were:

- Not sharing lessons and wasting time coming up with the same conclusions in isolation
- Clinical governance – a term which turned people off patient safety
- Language of risk assessment turn off doctors
- Terms which were ‘almost swearwords’, ‘integrated care pathway’, ‘modernisation’
- Using data to simply admire the problem rather than solve it

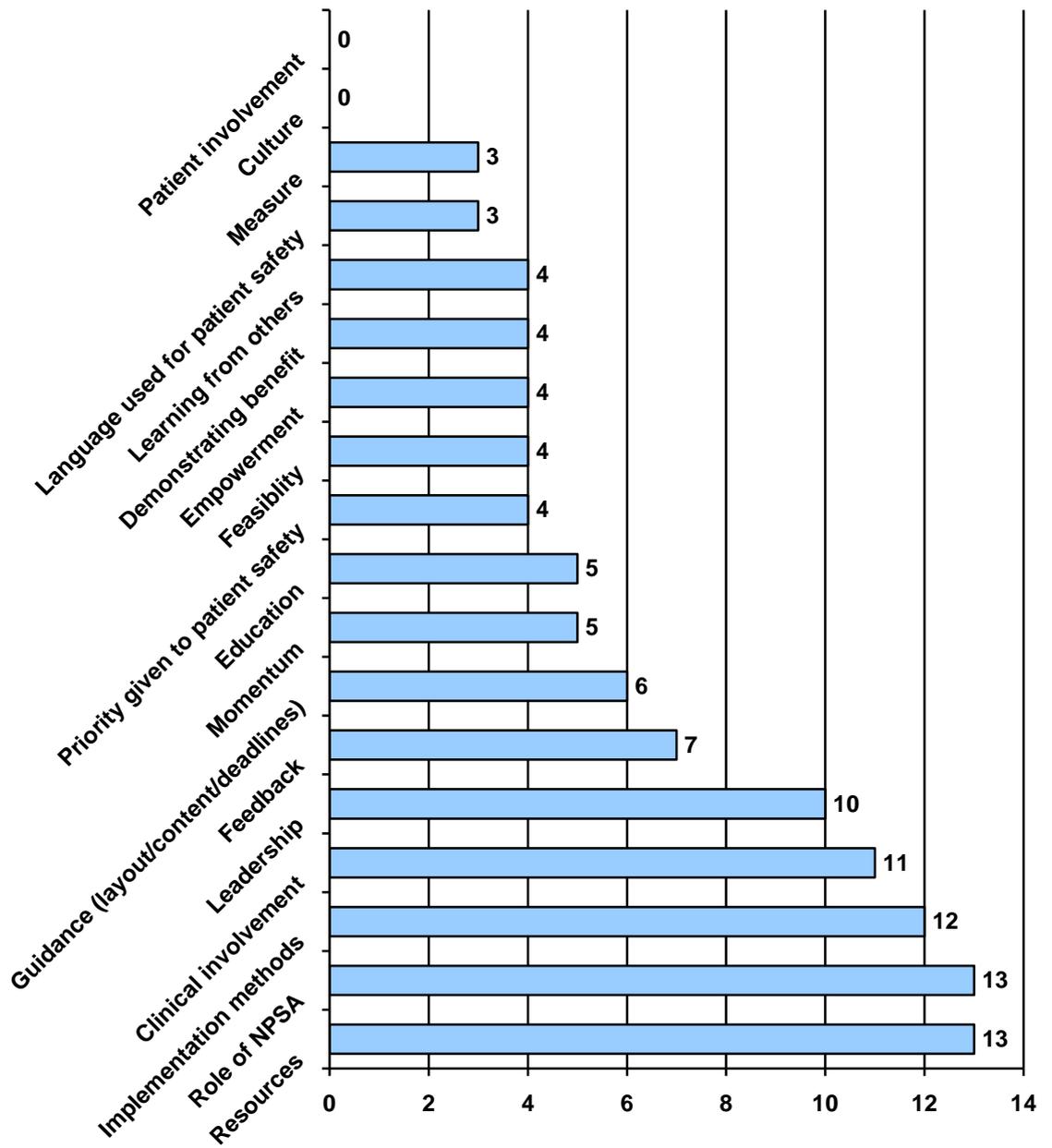
"benchmark, we need to know are we doing well and can we improve, or are we doing really badly and there's something really wrong with the organisation"

Director, 2007

5.2.2 Implementers

A total of 108 comments were made by the implementers group. This group represented risk managers and nurses and doctors who work 'at the frontline' (i.e. working directly with patients). As with the directors group, initially there were a large number of comments which fitted within the implementation methods theme. As with the other group this theme was reassessed and a number of sub-themes were identified. The resulting analysis is shown in the following.

Figure 3 Themed comments from implementers



Most comments were made in relation to **resources** (n=13) and **the role of the NPSA** (n=13), followed by **implementation methods** (n=12). Comments in relation to resources were made about money and time.

Table 12 Factors related to resources cited (implementers)

Factor type	Summary of comments
Facilitating factors	Resources to enable change to happen
	The resources are targeted like NICE guidance
	Simple information for busy staff
	Provide staff with protected time
	Make it easier for staff who don't have time to implement
Hindering factors	No new resources for quality and patient safety
	There are not enough resources to do everything that is needed
	Staff feel harried and pressured
	Staff are stressed and stretched
	Copious amounts of paper is not always the answer

'There's never any resources for the nurse to be able to give that quality, it's always your resources aren't going to change but we want you to do this, this, this and this as well and to find the time in your day to do it' Implementer, 2007

Those that had heard of the NPSA stated they liked some of the NPSA outputs because they were a useful focus. However, they commented that the NPSA 'lacked teeth', as 'it doesn't carry a big stick', and was perceived as not as important as other external bodies. Organisations cited were NICE, the Healthcare Commission and the NHS Litigation authority as having more power and authority than the NPSA.

Table 13 Factors related to the NPSA role (implementers)

Factor type	Summary of comments
Facilitating factors	Explain reasons for change from a national organisation
	Reflect the local context.
Hindering factors	National initiatives added burden to local work
	National initiatives lacked practical support
	National initiatives were a waste of time

'I think there is a lack of credibility around the NPSA, I know there is a lot of work that the NPSA do around a solid evidence base, but there's a big difference between evidence base and providing some practical help'

Implementers, 2007

Implementation methods (n=12) included the following:

Table 14 Factors related to implementation methods cited (implementers)

Factor type	Summary of comments
Facilitating factors	Use role models
	Provide reward; congratulate and celebrate
	Use patient safety champions
	Make the new guidance or policies or practices available on the intranet of an organisation and make access to computers easy
	Involve people at the grass roots
	Make it relevant and applicable to the local need
	Target the audience about what they need to do
Hindering factors	Don't just come up with the paperwork and say this is what we want you to do; ask people what they think and would they be able to use it [guidance etc]
	Not showing the reason behind the change
	Letting people take short cuts
	The change and approach divorced from reality
	Lack of evidence of testing
	Lack of evidence base
	Distraction with other initiatives
	Challenge of size of organisation
	There is no magic bullet
Repetition of guidance	

Nurses were felt to be far more engaged and involved than doctors. Doctors saw it as 'a session to attend' rather than an every day activity. Clinical involvement (n=11) included:

Table 15 Factors related to clinical involvement cited (implementers)

Factor type	Summary of comments
Facilitating factors	Clinicians taking ownership
	Recognise the champions and give them a high profile
	Provide the clinical evidence it works
	Make it relevant to the doctors
Hindering factors	Turnover of junior staff
	Clinicians don't feel they have to listen to other clinicians as they don't have perceived levers or sticks to influence them
	Skeptical staff led to compliance plummeting
	If they don't think it is necessary they wont do it
	Lack of involvement of doctors at patient safety events
	Doctors are asked to do so many things without any real evidence and peer review
	Ability to transmit the enthusiasm back to colleagues who have been carrying on with their day to day work [when returning from a conference or training event]

'The other doctors were very skeptical [of the new safer practices] and therefore the compliance plummeted' Implementer, 2007

'As part of all of the medical or surgical training, we would all have some sessions in terms of our training days that would be allocated maybe once every two years, depending on who wanted to take it up, depending on who has an interest in areas like risk' Implementer, 2007

"Unless it's something that you interface with... you're not going to come upon it [patient safety] - you're going to chance upon it really in quite a haphazard kind of a way" Implementer, 2007

With regard to the role of leadership (n=10), the facilitating factors cited all involved the role of the chief executive as a key factor for pushing change. It was felt chief

executives needed to provide visible leadership. Some of the clinical staff did not know who the chief executive was or who the lead director was for patient safety. If they did know who they were they did not feel that they could approach them or that they would listen. In some cases they felt that the leaders were distanced from the front line.

Feedback (n=7) related to providing feedback on incident reports or safety issues, with participants considering their reports not being addressed. Comments related to guidance (layout, content, deadlines) (n=6) were; keep the language simple, make it short, to the point and practical, make the guidance personal to the audience don't just send out on a big distribution list and have realistic deadlines.

Education (n= 5) comments were around the lack of training the participant had had on patient safety, overload at induction, lack of training in medical and nursing school, the lack of emphasis on training on why patient safety is important. Momentum (n=5) related to spreading the change and getting people to keep on track, the need to drive the change because other things took priority. Safety briefings were cited as keeping the profile up as well as the drive of individuals.

Comments which were less than 5 included priority given to patient safety (n=4), feasibility (n=4) which related to lack of testing before being disseminated, the importance of empowerment (n=4), demonstrating the benefit (n=4), learning from others (n=4), language which turned people off patient safety (n=3) such as 'risk' and 'risk assessment' and the need to measure (n=3) as a way of motivating and demonstrating success.

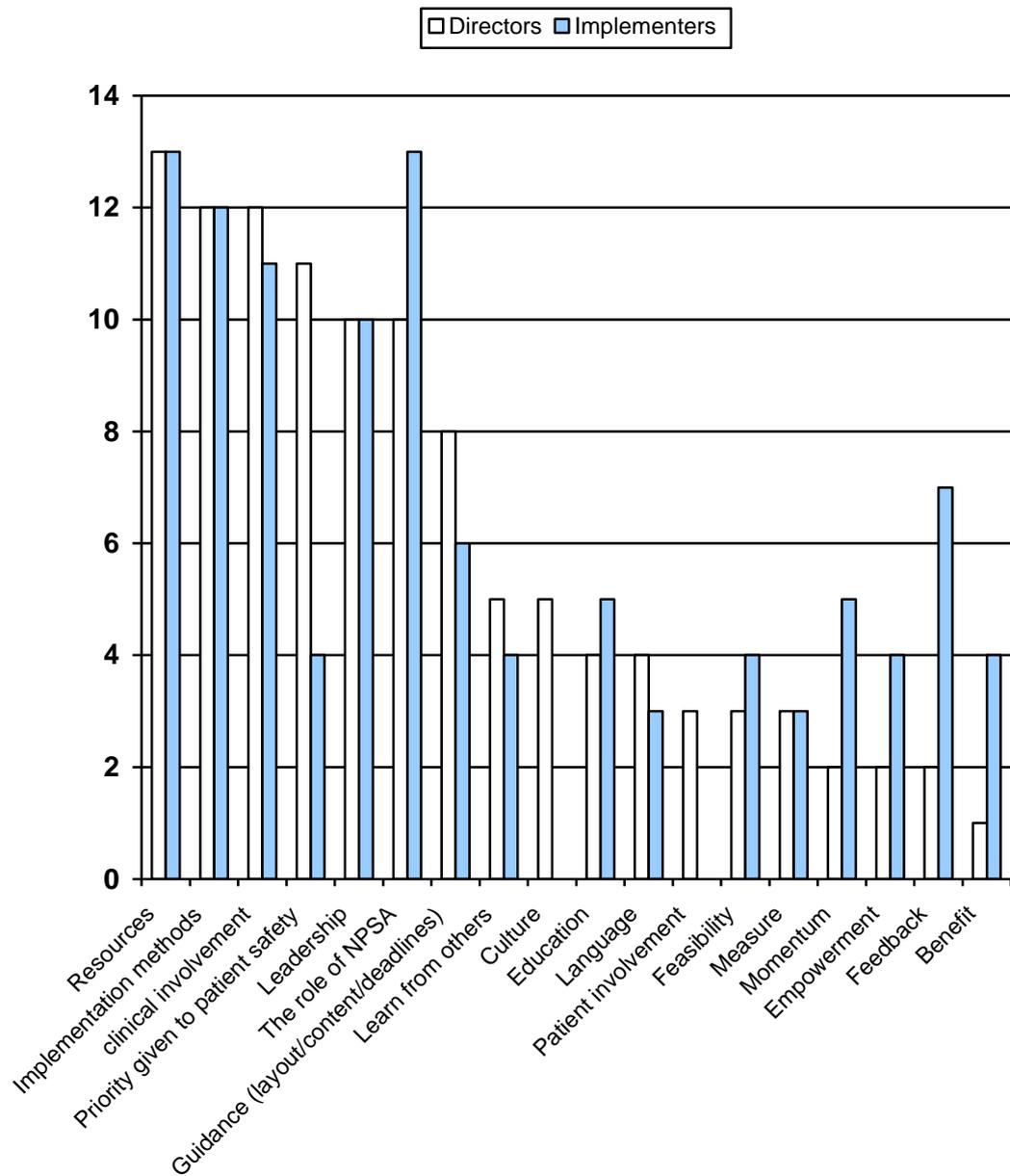
5.3 The similarities and differences between the groups

There was no statistically significant difference in the factors identified by the different groups. Both groups had a very similar number of comments (directors n=110; implementers n=108). The groups provided the same number of comments for:

- Resources
- Implementation methods
- Leadership
- Measures

The following shows the comments from each group together in the one figure

Figure 4 Number of comments per group compared



Both groups provided the same number of comments with regard to resources, both citing the importance of having resources in terms of money and people and time to undertake improvement work. Both groups cited NICE as a good example of a national organisation that had both authority and had succeeded in helping with local implementation.

The directors mentioned integration at a national and organisational level to improve implementation. The directors cited the difficulty in getting clinicians to change their practice, and cited a number of facilitating factors which were validated by the implementers themselves, such as address their needs, ensure they can relate to the guidance, and provide support to engage. Both groups agreed that leadership was important, and in particular the chief executive, to drive patient safety and this needed to be visible to all staff.

The interviews also generated comments in relation to the level of knowledge and expertise in patient safety. This was particularly patchy. Many of the clinicians had not heard of the NPSA before being invited to interview. They also, even after being informed of what the NPSA did, did not view the NPSA as relevant to their day to day activity. This was not reflected by the directors, all of whom stated they had heard of the NPSA, stating how important they thought it was. However, when exploring their level of understanding, most thought that infection control and falls made up most of what the NPSA covered. The only individuals who knew who the NPSA was and what it did were the risk managers.

In the main, local awareness of the NPSA and patient safety was poor. Concern was raised about the number of national bodies generating work for local organisations, with comments that there were too many of them and 'too many administrators'. The factors cited indicated that much of the national guidance from the NPSA had not addressed the needs of the participants and had not considered the hindering factors or barriers, equally, the NPSA had not maximised its impact by making effective use of the facilitating factors. These are particularly useful to consider for the content design of the toolkit.

5.4 The similarities and differences between the hospitals

An overview of the management processes and infrastructure of each organisation in relation to patient safety was also carried out. The following is as assessed by myself and the relevant patient safety manager for each site. The policies in each organisation were different and bespoke. There were different approaches to incident reporting, risk assessment and investigation and ways in which organisations had set up structures and systems for patient safety. There was also no common language, with inconsistent use of terms such as clinical governance, quality, clinical risk and patient safety. This variation at all levels of the organisation from the chief executive's involvement through to the participation of front line implementers is similar to other reviews of the NHS (National Audit Office 2005).

All four sites were of similar size delivering services to a mainly urban community. There was evidence of a leadership that was committed to patient safety, however, this was demonstrated more effectively in two of the sites. Two of the sites quite clearly had champions for patient safety at either chief executive or director level. These two sites were also foundation trusts and felt that they had achieved financial balance so therefore could 'afford to concentrate on quality and safety'. The other two sites differed in that they felt that finances and targets were still the key issues for the board to consider and worry about. The non-foundation trusts were keener to develop the business case for patient safety to prove that it was important. This difference was reflected in the comments made and in the way the frontline staff felt that patient safety was prioritised in the hospital. Those that felt that patient safety was a high priority at leadership level were also more committed to it at front line level. This reflected previous research that it is important for leaders to drive implementation and to be seen as doing so. The evidence of the most awareness and understanding of patient safety was in the one hospital where the chief executive was also available for interview for the project.

5.5 Questionnaire findings

The questionnaire was purposefully simple with questions that were open ended to generate descriptive answers:

Q1. What do you think are the factors which help uptake, implementation and sustainability of patient safety solutions, interventions and guidance?

Q2. What do you think are the factors which hinder uptake, implementation and sustainability of patient safety solutions, interventions and guidance?

Q3. How do you think the NPSA could help you implement patient safety solutions, interventions and guidance?

The design of the questions was a weakness of the design;

- the lack of defined terms meant that different interpretation could be placed on the questions
- the questions were poorly worded and were in fact multiple questions within questions

There is evidence of 'reliability' as the answers from all respondents were very similar and were in concordance with the interviews and literature.

A total of 173 questionnaires were sent out to all risk managers in acute care hospitals in England and Wales, of which 58 (33.5%) were returned. The following describes the comments provided in answer to these questions.

5.5.1 Responses to question one

There were a total of 143 comments related to facilitating factors cited within 10 themes.

Figure 5 Themed responses from risk managers (facilitating factors)

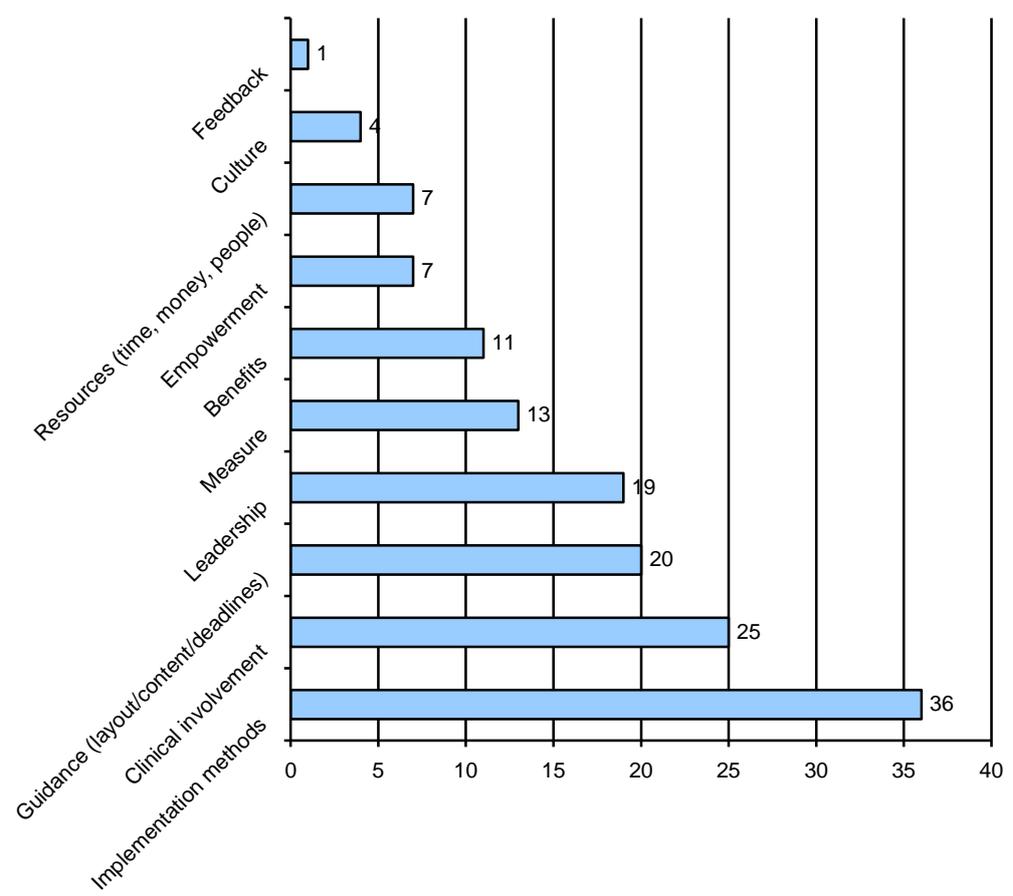


Table 16 Facilitating factors; comments per theme (risk managers)

Theme	Examples of comments
Implementation methods	<ul style="list-style-type: none"> ▪ Prompts and reminders ▪ Must do approach ▪ Education with formal training events for all staff ▪ Positive feedback ▪ Visual aids ▪ Easy to implement ▪ Availability of resources and templates ▪ The developers providing the evidence base for change ▪ Solutions are achievable and realistic
Clinical involvement	<ul style="list-style-type: none"> ▪ Guidance must be deemed important to implementers ▪ Strong clinical leadership ▪ Clinical practicality ▪ Clinical forum/collaborates to coordinate implementation locally ▪ Frontline clinicians to be patient safety champions
Guidance format	<ul style="list-style-type: none"> ▪ Clear rationale and recommendations ▪ Simple instructions with clear deadlines
Leadership	<ul style="list-style-type: none"> ▪ Lead roles in implementation ▪ Charismatic leadership ▪ Need for leadership to effect change
Measures	<ul style="list-style-type: none"> ▪ Ensuring there were monitoring and measurement processes
Demonstrating benefits	<ul style="list-style-type: none"> ▪ That the guidance or solution demonstrated the benefits
Empowerment	<ul style="list-style-type: none"> ▪ The change needed to be owned by the staff
Resources	<ul style="list-style-type: none"> ▪ Enough time and money to make the change
Culture	<ul style="list-style-type: none"> ▪ The developers considering the receptive context for the guidance
Feedback	<ul style="list-style-type: none"> ▪ Positive feedback

“Deliver the message in person – written communication on its own is ineffective”

Risk Manager, 2007

5.5.2 Responses to question two

There were a total of 116 comments related to hindering factors cited.

Figure 6 Themed responses from risk managers (hindering factors)

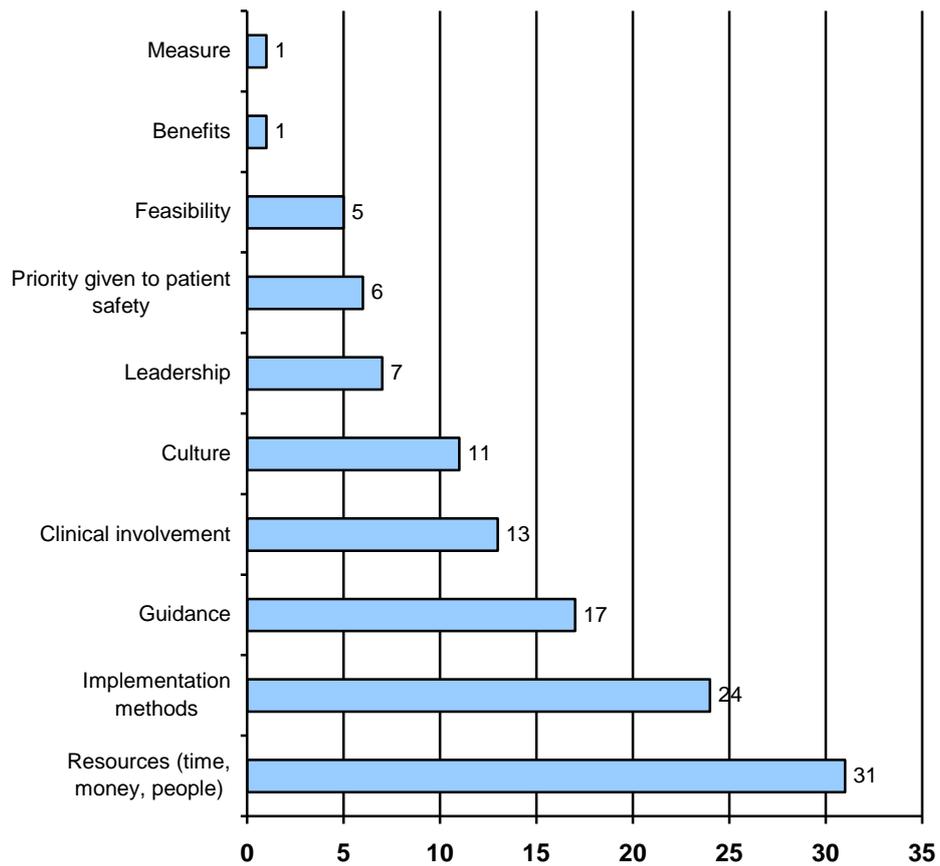
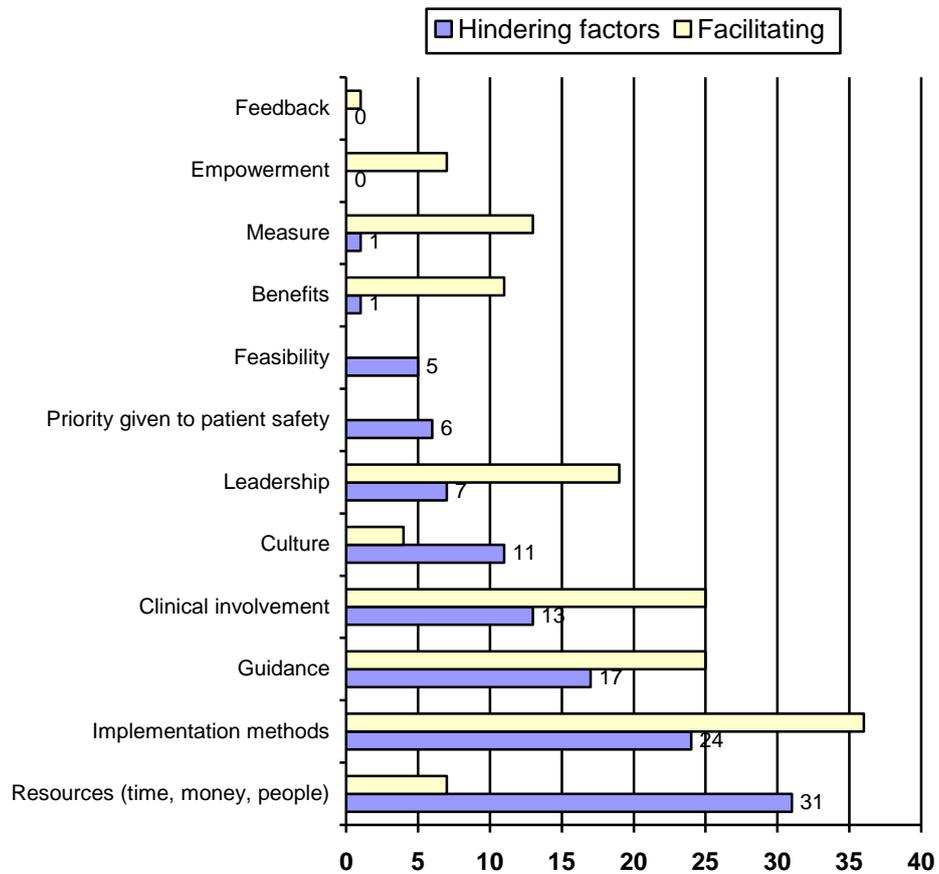


Table 17 Hindering factors; comments per theme

Theme	Examples of comments
Resources	<ul style="list-style-type: none"> ▪ Lack of resources ▪ Lack of finances ▪ Lack of time to implement ▪ Need dedicated staff time ▪ Low staffing levels ▪ Lack of equipment/supplies ▪ Without dedicated support to encourage uptake, implementation and sustainability there can be little certainty that messages are being acted upon ▪ Current financial situation/cut backs in relation to training etc ▪ Poor local resource to support implement
Implementation methods	<ul style="list-style-type: none"> ▪ Random dissemination with no support or follow up ▪ Not knowing what guidance is coming in the near future so unable to prepare ▪ They appear to come in blocks rather than at regular interval which makes managing some of them difficult ▪ The pace of safety notices, there was a time when so much was coming out that local safety managers were sagging under the weight ▪ Too much / too many pieces of new evidence together ▪ Excessive amounts of must-do requests ▪ Exasperated, exhausted, de-moralised staff who see the guidance as yet another demand that they will not be able to fulfil ▪ In large complex organisations this is very difficult ▪ There is no reward for those who take leadership in this area ▪ Environmental factors not considered ▪ Forced initiatives ▪ Problem of getting the right message to the right people hinders the process
Guidance (layout/content/deadlines)	<ul style="list-style-type: none"> ▪ Unrealistic expectations, targets and deadlines – behavioural change takes years to change – to unlearn old behaviour and relearn new takes time ▪ Deadline dates are not long enough, this makes it difficult to implement by the deadline date, and / or may lead to the work hitting the deadline, but not as robustly as work would be if longer time and though could have been given ▪ Woolly guidance that generally say 'here's the problem' with no suggested solutions, which means that all trusts come up with different actions and solutions - with no guidance as to what's good or bad ▪ Lengthy documentation ▪ Complex recommendations ▪ Volume of paper / guidance to wade through before getting to what needs to be done and why ▪ Out of date

	<ul style="list-style-type: none"> ▪ Too technical ▪ Inconsistency and poor direction in implementation expectations ▪ Too much theory ▪ Rationale – this is often not clear from the alert document and shroud waving that n patients have died from x procedure with no data on the denominator is very unhelpful as far as providing an evidence base for the need to change
Clinical involvement	<ul style="list-style-type: none"> ▪ Lack of involvement, acknowledgment, validation [of front line staff] ▪ Resistance to change ▪ Lack of 'Buy in' and understanding ▪ Relevance/impact to clinical practice ▪ Staff not willing to change ▪ The greatest hindrance is that the consultants do not feel that they are part of the solution ▪ No evidence of clinical staff involvement ▪ Lack of will, lack of energy, self-interest, arrogance, ignorance, egotism, tiredness ▪ Fear of change and drivers to change
Culture	<ul style="list-style-type: none"> ▪ Overcoming the blame culture ▪ Cultural change takes time ▪ Cultural resistance ▪ Culture of routine violations ▪ Culture of the team; people fearing blame, fearing failure, or ridicule
Leadership	<ul style="list-style-type: none"> ▪ Poor / weak leadership ▪ capacity and capability of leaders ▪ Top-level commitment (lack of)
Priority given to patient safety	<ul style="list-style-type: none"> ▪ Conflicting priorities [within the organisation] ▪ Low priority to patient safety (targets and finance superseding this) ▪ Competing directions e.g. no time other than finance or performance issues ▪ Too many external assessments taking too much time
Feasibility	<ul style="list-style-type: none"> ▪ Too much is required in one go - it is very difficult to implement ▪ Complex initiatives which cover more than one area
Benefits	<ul style="list-style-type: none"> ▪ Minimal tangible benefits balanced against effort to do
Measure	<ul style="list-style-type: none"> ▪ Failure to monitor properly

Figure 7 Comments related to facilitating and hindering factors compared



'If too much is required in one go it is very difficult to implement'

Risk Manager, 2007

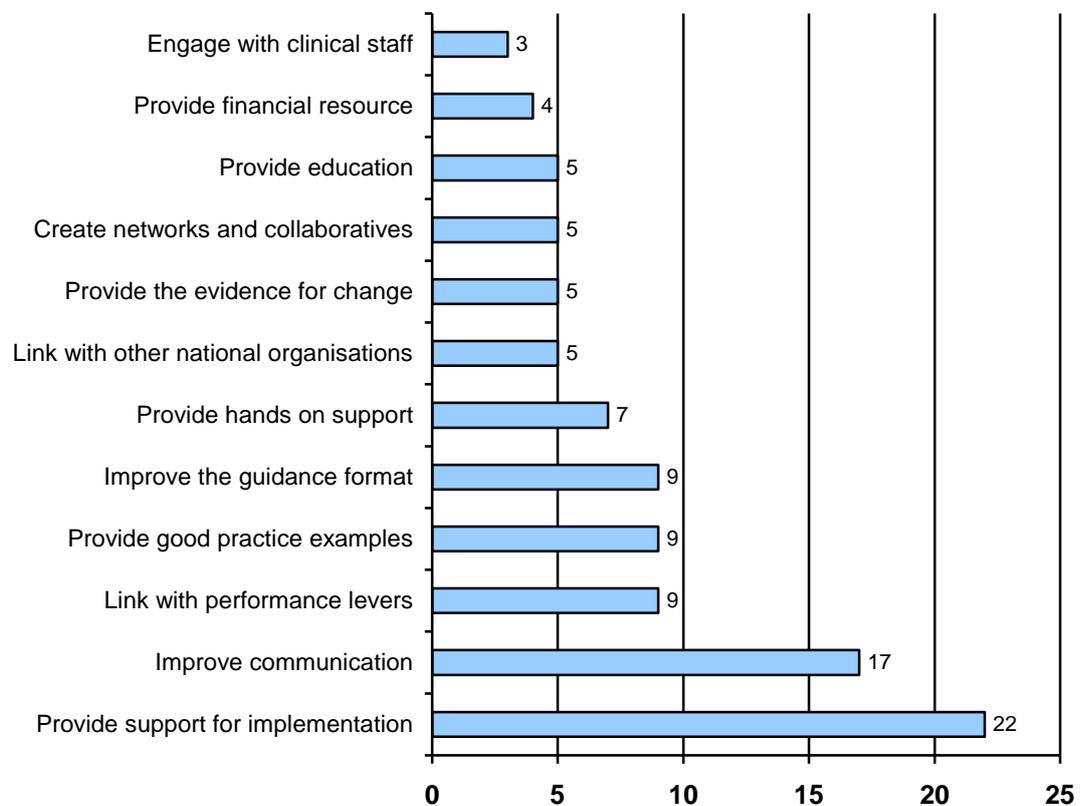
'behavioural change takes years to change – to unlearn old behaviour and relearn new takes time'

Risk Manager, 2007

5.5.3 Responses to question three

The final question asked the risk managers what they thought the NPSA could do to help them implement patient safety solutions, interventions and guidance. There were 100 comments made with regard to the role of the NPSA. With the largest number (22%) related to support for implementation.

Figure 8 The role of the NPSA to help implementation



“If Seven Steps to Patient Safety had been mandatory for all Trusts by named date, then it would have been done - if not mandatory, then it will compete with other non urgent directives”

Risk Manager

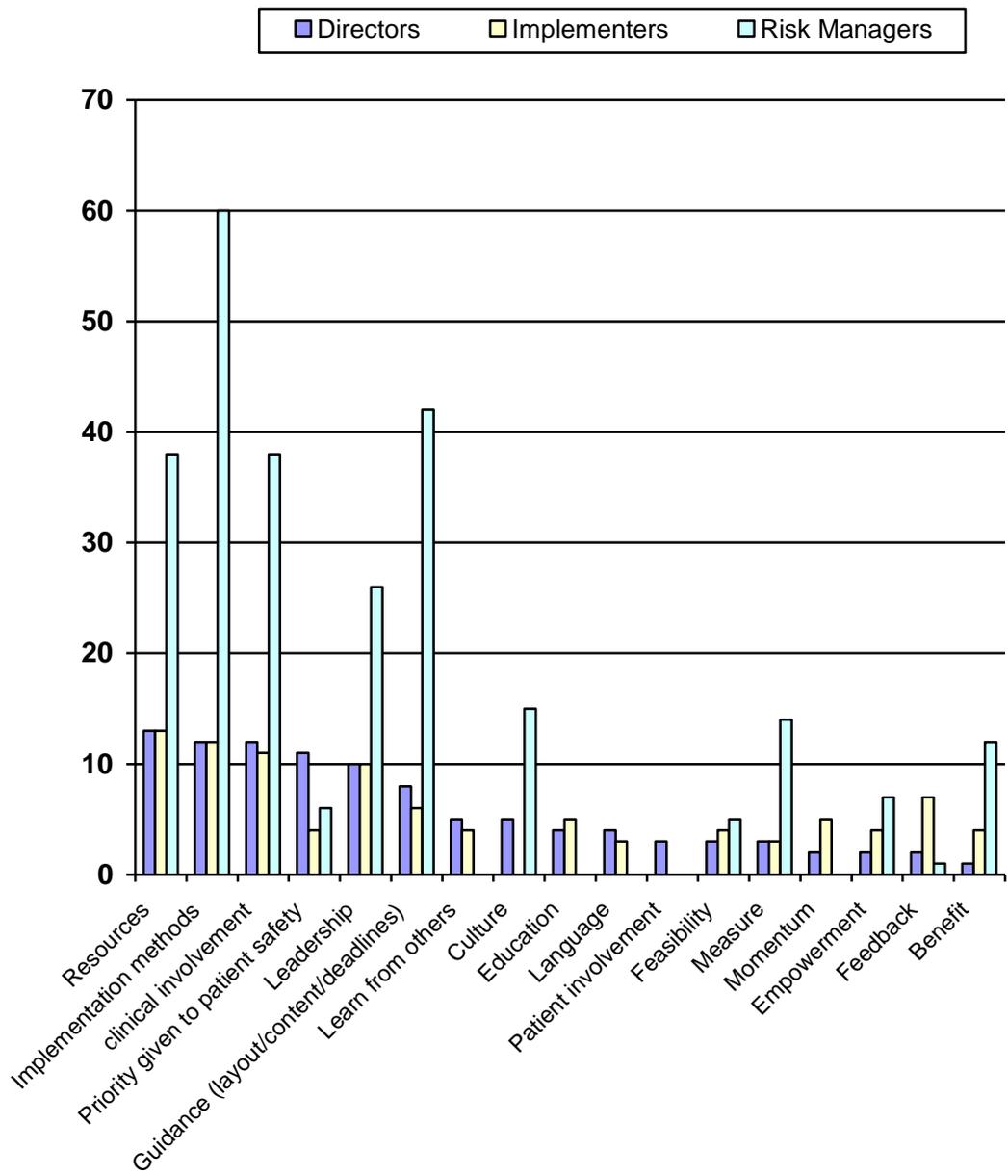
Table 18 How can the NPSA help local organisations per theme

Theme	The NPSA should.....
Support for implementation	Get experts in the field to think the solutions through first, and then test them to ensure they work before sending out
	Provide a step by step approach using the “best way to implement” so that more processes are standardised across the NHS
	Make it easier to implement and sustain the change than to continue with the old practice
	Think more about behavioural theory when planning change and implementing solutions
	Set up national project teams to look at the implementation of the guidelines before sending them out
Communication	Provide quarterly newsletters
	Use multiple methods of raising awareness, promotion and dissemination e.g. workshops, leaflets, paper guidance, computer-assisted guidance, posters, using a stand in the main atrium of a hospital
	Provide a forward planner so that organisations were aware of what the NPSA was working on and what was coming out and when (n=8),
	Use patient safety champions
	Target Chief Executives and Senior Clinicians providing key points and knowledge
Performance levers	Ensure greater clarity
	Influence change
	Create an environment where organisations are answerable to the NPSA (as with the Healthcare commission)
	Make recognised patient safety guidance mandatory
Best practice examples	Use organisations to learn from each other
	Use real case studies
	Use testimonials
	Use good examples of implementation from other healthcare providers
Improving guidance format	Provide clear unambiguous guidance
	Make it short
	Provide realistic and achievable recommendations
Other	Provide hands on support
	Link with other national organisations
	Provide the evidence for change
	Create networks and collaboratives
	Provide financial support
	Provide education
	Engage with clinical staff

5.6 Similarities and differences across all three groups

The following figure compares the number of comments cited by all groups. Clearly caution should be used when reviewing this graph, as the sizes of the groups were different (risk managers n=58), directors (n=9) and implementers (n=11) and the types of data collection were different (focused questionnaire –v- unstructured interviews). For example, the role of the NPSA was a specific question asked of the risk managers therefore much higher than the other groups (n=100), directors (n=10) and implementers (n=13). This theme is excluded from the chart.

Figure 9 Comparison of comments per group (across all three)



5.7 Summary conclusions

The findings are a glimpse of the views of the participants held in a moment in time. What the information did do was provide another piece of the jigsaw, supporting the emerging ideas and thoughts first triggered by the literature and my own knowledge.

The stakeholder mapping provided a clear reflection of the effectiveness of the stakeholder engagement strategy of the NPSA at that time and where the agencies efforts should be focused in the future. For example, the analysis provided a clear indication that the Agency had not effectively engaged clinical stakeholders and in particular the medical profession and their Royal Colleges.

The findings from the interviews and survey were consistent in terms of factors cited by all three groups and the similarities with those found in the literature.

Building on the previous chapter, the conclusions from the triangulation of the literature, interviews and questionnaire findings were:

- The assumption that there is a gap between what we know improves patient safety and what is actually done in practice was validated
- There are strategies that work when used in the appropriate context, however it is difficult to draw definitive conclusions on which are the most effective implementation strategies
- There appears to be no one strategy for implementation that works for all
- There are a considerable number of implementation factors, both those that help and those that hinder, which need to be considered when developing the guidance (or intervention or safer practices) and the implementation strategies
- NICE was cited as a good practice organisation with regard to implementation (they have support guidance and tools for implementation)

- Other national organisations, such as the NPSA, are seen as increasing the burden by; forcing top down initiatives, creating poorly worded guidance, simply disseminating guidelines to try to change individual practice, not providing implementation support.
- However, national organisations can help and have a part to play to support local organisations to implement by; making it easier for staff who don't have time to implement, targeting like NICE guidance, providing resources to enable change to happen, reflecting on the local context, creating resources and templates and providing dedicated support to encourage uptake, implementation and sustainability.
- Also the participants provided ideas such as; create lead roles in implementation, get experts in the field to think the solutions through first, and then test them to ensure they work before sending them out, make it easier to implement and sustain the change than to continue with the old practice , think more about behavioural theory when planning change and implementing solutions.
- More specifically, they suggested a step by step approach using the "best way to implement" so that more processes are standardised across the NHS, national project teams to look at the implementation of the guidelines before sending them out and multiple methods of raising awareness, promotion and dissemination.

"Safety is the hardest to implement"

Implementers, 2007

"We like the guidance but actually implementing it is a lot more difficult"

Implementers, 2007

5.9 Action post findings

These conclusions confirmed the idea of creating an implementation toolkit to help local organisations implement guidance and safer practices. This period of introspection, exploration and collaboration culminated in a meeting at the beginning of May 2007 with my specialist supervisor, Prof D Portwood. We met to review the progress of the project and discussed the potential for developing a toolkit as part of the project. My project proposal had planned for an output of a single commentary. Prof Portwood provided some excellent advice and agreed with the need for a change to the proposed project from a single document to two documents. We agreed that the project should culminate in an implementation toolkit, the other a commentary to support the development of that toolkit. The initial view was that the toolkit would be developed by myself on behalf of the NPSA to disseminate to staff within the NHS. On 29 March I had a telephone meeting with my Middlesex University Supervisor, Dr Pauline Armsby. Our discussion confirmed that I was on the right track. I subsequently informed her of the proposed changes. An addendum to the project proposal was completed, submitted and approved by the Middlesex University at the end of May 2007.

Therefore, the next key stage in the project was to design and develop an implementation toolkit to support local organisations with improving patient safety by sustainable implementation of practices that we know will make patient care safer (Department of Health 2006b). This recommendation led to a re-visit of the literature to identify any further research in relation to implementation and to detect and learn from other implementation toolkits, in order to inform the content of the toolkit. The design and development of the content and format of the implementation toolkit is presented in chapter 6.

Chapter 6: Toolkit development

'Provide a step by step approach using the best way to implement so that more processes are standardised across the NHS'

Risk Manager,
Questionnaire respondent, 2007

6.0 Introduction

The second phase of the project activity was to design and develop the implementation toolkit. The draft toolkit was constructed from the data found in the literature, the interviews and the questionnaire responses. The following iterations were then developed and improved through the collective activity of sharing and feedback. The following figure describes the activity from August 2007 until May 2008.

Table 19 Action plan August 2007 to May 2008

	Activity	Date
1	Scoping the toolkit Identify the literature related to toolkits Triangulate with the literature to date, the interviews and questionnaire findings Discuss with internal and external experts Submit ideas and draft toolkit for experts to comment Design of the toolkit	August 2007 to February 2008
2	Finalise Print final toolkit Finish project and negotiate submission date Complete write up and submit by 1 May 2008	March to May 2008
3	Post doctorate activity Create an implementation strategy for the toolkit Create a communication strategy for the toolkit Create an evaluation strategy for the toolkit Promulgate doctorate findings	May onwards

6.1 Development of the toolkit

'Making it easier for staff who don't have time to implement'

Implementer, 2007

From August 2007 to May 2008 I set about the design and development of the implementation toolkit. Monitoring of the literature had been an ongoing and continuous process up until this stage, but in order to inform the development of the toolkit, I needed to conduct a second key literature search and review. This second review was carried out to discover other implementation toolkits, any research that I may have missed in the first search and any research that had been published since.

6.1.1 Literature review summary

The highly diverse literature on implementation draws mainly from the disciplines of evidence based medicine and guidance implementation, together with the diffusion of innovations, change management, organisational development and behavioural theories. An emerging science is that of implementation science. This is the study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice (Eccles and Mittman 2006). The literature search focused mainly on literature related to getting evidence into practice. These are studies which have explored ways to address the knowledge gap through mass media or education, the motivation gap using the social influence of opinion leaders and on methods to change clinical behaviour and practice (Grol and Grimshaw 2003, Grimshaw et al. 2004, Gravel et al. 2006, Gagnon et al. 2006, MacDermid et al 2006, Sladek et al 2006, McAlister et al, 2006, Hysong et al. 2006, Grimshaw et al. 2006).

I added a search term of 'implementation toolkit' and sourced a number of examples which indicated that resources, such as toolkits are useful in developing understanding

and providing support for implementation (Iles and Sutherland 2001, Registered Nurses Association of Ontario 2002, The National Center for the Dissemination of Disability Research 2004, Dobbins et al. 2005, National Institute for Health and Clinical Excellence 2005, Agency for Healthcare and Research Quality 2005, Canadian Collaborative Mental Health Initiative 2006, Frush et al. 2006, Health Canada 2006, Leape et al. 2006, The National Institute for Health and Clinical Excellence 2007, Ploeg et al. 2007, Nursing Times 2007).

A second triangulation of the data, involved reviewing the original literature again (Grimshaw and Russell 1993, Davis and Taylor-Vaisey 1997, Bero et al. 1998, Iles and Sutherland 2001, Grol and Grimshaw 2003, Grimshaw et al. 2004). The consistent finding was that the implementation of good practice, guidance and research findings is a slow and haphazard process and continues to be a complex challenge for many individuals and organisations (Greenhalgh et al. 2005, Dobbins et al. 2005, Gagnon et al. 2006, Wensing et al. 2006, Bhattacharyya et al. 2006, Eccles and Mittman 2006, Grimshaw et al. 2006, Ploeg et al. 2007). In addition, national organisations should take account of the helping and hindering factors at multiple levels as they have the great potential to improve success in implementation (Leape et al. 2006).

The limitations of the research reviewed related mainly to methodological quality and the lack of robust long term evaluation. The subsequent findings should therefore be regarded as an indication of the issues to consider when designing an implementation strategy.

6.1.2 Development of the content

The literature was compared with the interview and questionnaire responses to develop the content and design of the toolkit. A draft toolkit emerged which I tested with colleagues and experts. This was a continuous cycle of activity. Each draft was

shared with NPSA colleagues, in particular the heads of the patient safety teams (n=8), the director and associate director of the patient safety division and the communication team at the NPSA. I consulted with external contacts, experts in patient safety and implementation together with representatives from other national organisations. The communication specialists at the NPSA provided content, editing and design expertise. Experts who provided content advice included; the Head of the London office of World Health Organisation, the Director of Implementation at NICE, and the staff at the NHS Institute for Innovation and Improvement. Each draft was returned with tracked changes, annotations and comments. For example, suggestions about providing completed examples and templates rather than blank ones were felt to be more helpful. Each iteration was developed from this feedback.

The build up of the toolkit was a very effective process to ensure that it was as evidence based as possible. However, it can sometimes be difficult to meet different individual's needs. For example, when one influential individual provided feedback on the toolkit after it had gone to print I had to make a decision on whether to ignore the comments or to pull the print run. The comments were of sufficient value to pull the print run and make changes. This had implications for the costs of the project with a small additional design cost. An initial draft was submitted to the on-site designer in February 2008 and a final draft in March 2008.

6.1.3 The target audience

The audience for the toolkit was subject to some debate. While there was an overwhelming support for a toolkit, there were differing views as to whether it should be targeted at national organisations or targeted at local organisations or both. At a macro level there are the overarching organisations who direct, such as the Department of Health, NICE and the NPSA who develop guidance and solutions. There is the intermediate level of SHAs who enable change to happen through monitoring and

targeting. Then there are the local organisations that are required to implement these changes. At a micro level, within the local organisations there are the directors, the enablers and the implementers. Research has to date focused on the role of the implementers at the sharp end with some attention paid to the enablers and little attention paid to the directors and developers.

Colleagues at NICE reinforced the importance of concentrating on the implementation strategy at a national level. The interview and questionnaire responses demonstrated the need for support from national organisations in implementation. The risk managers in particular suggested a step by step approach using the “best way to implement” so that more processes are standardised across the NHS. They also suggested national project teams to look at the implementation of the guidelines before sending them out and multiple methods of raising awareness, promotion and dissemination. The literature re-enforced the fact that national organisations need to play their part in supporting local organisations and the use of a toolkit appeared to work (Leape et al 2006). The principles within the toolkit are also appropriate for the dissemination and implementation of the toolkit itself. Therefore, the toolkit would need to be tested for its applicability and effectiveness in a planned and systematic way.

For these reasons the staff at the NPSA and other national organisations responsible for creating guidance and interventions were chosen as the target audiences for the toolkit in its first year. How this will be taken forward is described in the post doctoral activity of this commentary in chapter 8.

6.2 The Toolkit

The toolkit is titled ‘Closing the Gap: toolkit for improving implementation of safer practice’. The toolkit is structured into seven sections described in the following figure. There are tips and help points and links to references or other work along the way.

Table 20 The toolkit content

Part	Description
Introduction	The introduction sets the scene and explains implementation, why we need to improve it and how the toolkit aims to address the gap between what we know improves patient safety and what is actually done in practice. It explains who the toolkit is for and where the evidence was derived.
1: Before you start	This section outlines the key steps the developer needs to take to create an implementation strategy and plan. Methods for developing safer practices and interventions are outside the scope of the publication, however, this section provides a checklist to ensure that the developer has a strong safer practice on which to build the implementation strategy. It helps developers justify the safer practice, create the evidence base, undertake a cost benefit analysis, be creative when generating new approaches to improving patient safety and conduct a risk assessment.
2: Getting to know your audience	This section stresses the importance of understanding the people and organisations who will be affected by the safer practice, those that can help and support, those that may challenge it. It invites the developer to identify their stakeholders, categorise and prioritise the stakeholders with an example grid and provides some theory related to understanding why some people rush to adopt and others wait.
3: Understanding the receptive context for implementation	The section suggests the developer understands the context over and above a stakeholder analysis. The tools recommended include the PESTLE, SWOT, and readiness factors.
4: Identifying the right implementation approach	This section explains the complexity of implementation and prompts the developer to think about the barriers and facilitating factors for implementation and how to mitigate them. It helps them choose the implementation method or methods (based on the research evidence) for their particular safer practice and test and develop the approach.
5: Communicating	The section shows the importance of communicating effectively, describes the different communication methods and explains some key principles to use when creating the written outputs.
6: Spread and sustainability	This section recommends and points the reader to the sustainability model developed by the NHS Institute for Innovation and Improvement. It also helps the developer consider the different measures for sustained success and how to evaluate their progress.
7: Templates	This section provides the developer with templates to download.

The following describes the sections in detail and the references to literature sources and findings that inform the content. The section heads mirror the section headings in the toolkit.

6.2.1 Introduction: 'About this toolkit'

The introduction describes the central principle of the toolkit to provide practical support and resources to support the implementation process and to address the knowledge practice gap. It explains the step by step approach to helping the reader develop an implementation strategy. It explains the need to improve implementation and how the toolkit will address this gap. It explains who the toolkit is for and where the evidence was derived.

6.2.2 Part 1: Before you start

The first part of the toolkit is titled 'before you start' because it is about ensuring that the developer has got the right solution for the particular problem being addressed, prior to creating the implementation strategy. It helps the developer think through:

- Justifying the safer practice
- Creating the evidence base
- How to undertake a cost benefit analysis
- Being creative
- Risk assessment

Justifying the safer practice and creating the evidence base are about having the evidence with which to convince others to change (McFadden et al. 2006, Leape et al. 2006). In the interviews, those that direct others to implement commented on the need to ensure that clinicians can relate to the guidance and those tasked with the implementation cited hindering factors as; asking doctors to change without any real

evidence or peer review, lack of evidence of testing, lack of evidence base and not showing the reason behind the change.

The questionnaire responses from the risk managers cited a facilitating factor as the developers providing the evidence base for change, and the role of the NPSA to provide the evidence for change, case studies and testimonials to demonstrate best practice examples. They stated that the rationale for change was often not clear from the guidance and that incident data did not provide the basis of the evidence base for the need to change.

The literature cited facilitating factors as; providing unequivocal and high quality (preferably from randomised control trials) evidence that the change is better than the current practice and a belief that the change will work (Walshe and Boaden 2006, Sladek et al. 2006, Bhattacharyya et al. 2006, Ploeg et al. 2007).

The term safer practice is used throughout the toolkit. Leape et al. (2006) defined a safer practice as a collection of many individual practices which involved decisions and process changes to implement. The authors also identified criteria for selection (Leape et al. 2006);

- a) importance of the problem
- b) availability and proven efficacy of the practice
- c) feasibility of implementation
- d) potential impact on safety

Help to undertake a cost benefit analysis is provided is often overlooked by developers of guidance leaving local organisations to have to re-prioritise their resources. The interviewees and questionnaire respondents all commented on the importance of having the right resources, (time, money, people and infrastructure) to enable change to happen.

In the interviews, those that direct others to implement commented on the importance of investing in patient safety and having the right infrastructure to spend time on it e.g. funding staff to take time out. Those tasked with the implementation cited [the right] resources as facilitating factors, including protected time for staff as well as demonstrating the benefit of the change. They cited hindering factors as not enough resources for quality and patient safety.

The questionnaire responses from the risk managers cited enough time and money to make the changes as a facilitating factor and a lack of resources, finances, staffing, equipment/supplies and time as hindering factors. They also cited the need for the guidance or solution to demonstrate the benefits.

This section also reminds the developer to be creative and provides them with key links to the work of NICE and the NHSIII (NHS Institute for Innovation and Improvement 2007, National Institute for Health and Clinical Excellence 2007). The section finishes with a 'how to guide' for risk assessment, a key tool to ensure the suggested safer practice does not create further risks for patients.

6.2.3 Part 2: Getting to know your audience

Part 2 helps the developer:

- Identify their stakeholders
- Categorise and prioritise their stakeholders
- Understand their audience

The interview and questionnaire findings cited the importance of understanding the people who were being expected to change their practice and behaviour. All groups

interviewed felt that they lacked knowledge and understanding of how to change behaviour.

Much of the literature found that the likelihood of success in implementation increases when a systematic process is used to identify and engage stakeholders appropriately (Registered Nurses Association of Ontario 2002, Leape et al. 2006, Ploeg et al. 2007). Effective diffusion and dissemination is helped by undertaking the detailed stakeholder analysis and mapping exercise to identify who the audience is, analyse their interest and address the different communication strategies to engage them (Registered Nurses Association of Ontario 2002).

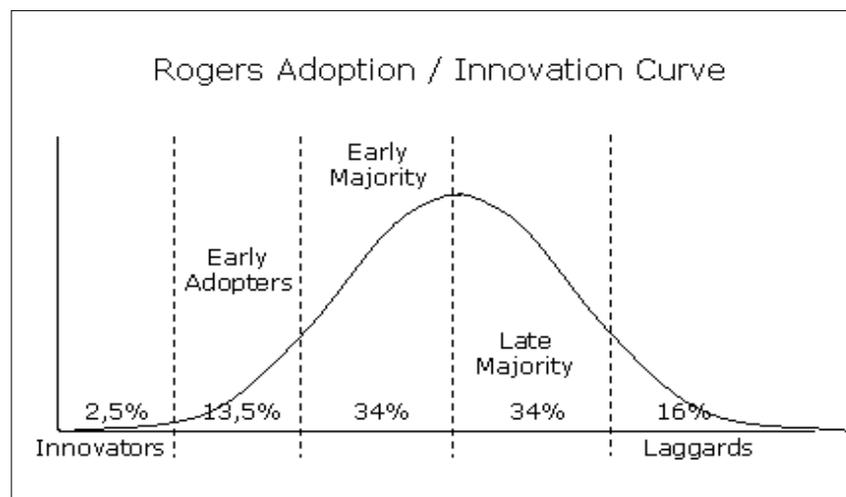
'Seek "Buy in" from all stakeholders including patients in identifying what the problem is that lead to harm, the root causes and then implementing solutions'

Risk Manager, 2007

Once the stakeholders have been identified then the developer needs to categorise and prioritise activity for each stakeholder (Cook et al. 2004, Cabinet Office 2007).

The developer is encouraged to understand why some people change and others wait a while by reviewing knowledge and understanding developed in industry (Rogers 1995). This views and categorises adopters of any innovation or new idea from innovators to laggards (Rogers 1983). These groups are plotted on a distribution curve to demonstrate the percentage of each group within a wider population, as shown in the following figure.

Figure 10 Rogers (1983) adoption and innovation curve



The toolkit provides the developer with an example of these characteristics when viewed through the lens of patient safety as shown in the following figure. It helps provide an understanding of the potential barriers to address in order to increase adoption of guidance.

Table 21 Innovation adoption model adapted in relation to patient safety

Category	Definiton	Characteristics relating to patient safety	Potential barriers
Innovators	Brave, pulling change, very important communicators.	Already undertaking significant activities to address patient safety issues and achieving significant improvements. Potentially could be one of the Safer Patients Initiative or other similar initiative participants. Could be positioned as a role model and a mentor.	Already ahead of the game, what benefit to them? Risks associated with putting yourself forward as an example. Too busy doing existing work.
Early adopters	Respectable, opinion leaders, try out new ideas in a careful way.	Already undertaking activity to address patient safety issues and seeing some improvement. Likely to benefit from tools and resources but also potential to provide mentoring and / or learning to other trusts.	May think existing work is better than anything offered. Wants to do it on their own.

Category	Definiton	Characteristics relating to patient safety	Potential barriers
Early majority	Thoughtful, careful but accept change more quickly than the average.	May already be undertaking activity (or about to) to address patient safety issues. May have seen some improvement but perhaps not widespread or sustained. Will gain significant benefit from the tools and resources.	May not feel ready to take on the challenge. May want to do it on their own.
Late majority	Sceptics, will use new ideas or products only when the majority is using them.	May be undertaking some activity but hesitant to make large scale changes, not convinced about some interventions and/or improvement processes. May be wanting to commence activity but don't know where or how to start.	May not feel ready or want to take on the challenge. Need convincing of worth, gain and significant benefit.
Late starters or laggards	Traditional, care for the 'old ways', are critical to new ideas and will only accept if the new idea has become mainstream or even tradition.	Not convinced about interventions and / or improvement processes, doesn't see reason to change, focused on other priorities.	Under fire on many levels, hard to find time to focus on another new initiative. Lack of staffing and funding. Lack of knowledge and ability across majority of staff. Low morale.

The developer is also shown another form of categorising their stakeholders; pre-contemplative (can't see the need for change, low awareness of change), to contemplative (thinks some change is needed, requires information and evidence) to active (wants to change now) (Fraser 2002b).

The toolkit helps the developer think though the decision making stages to adoption; raising awareness, persuasion, decisions leading to action (Fraser 2002a, Grol and Grimshaw 2003, Cook et al. 2004, Michie et al. 2005, Greenhalgh et al 2005, Fracica et al. 2006, Newton et al. 2007). The developer needs to understand the behavioural factors which affect adopters' (and clinicians') willingness include enthusiasm,

professional judgement, decision making, group and peer support and alignment with personal beliefs, values and goals (Janis and Mann 1977, Triandis 1979, Stocking 1985, Cook et al. 2004, Greenhalgh et al. 2005, Gagnon et al. 2006, National Institute for Health and Clinical Excellence 2007, Newton et al. 2007, Nolan 2007). It is equally important to understand why people are reluctant to adopt. For example, Leape et al. (2006) interviewed leaders who did not participate in their study to try to understand why they were not keen to be involved. They found that limited resources, lack of staff, financial constraints and competing priorities influenced their decision to participate.

The following list describes the actions that developers of guidance can take to boost adoption. This is summarised from the interview and questionnaire findings and backed up by the following literature (Gustafson et al. 2003, Lankshear et al. 2005, Francois et al. 2005, Michie and Lester 2005, Grimshaw et al. 2006, NHS Institute for Innovation and Improvement 2006, MacDermid et al. 2006, Leape et al. 2006, Frush et al. 2006, Gravel et al. 2006, McAlister et al. 2006, Hysong et al. 2006, Massoud et al. 2006, Schutz et al. 2007, Michie et al. 2007, Dobbins et al. 2007):

- Provide clear expectations for adoption and participation, particularly in relation to dedicated staff time and administrative need
- Provide a forward plan, explaining when and who are likely to be affected and what it will involve so they can create a local action plan
- Undertake an active, tailored process of communication, persuading users to adopt the guidance or intervention explaining that the current situation can be improved, so that adopters actively seek the change
- Engage with the leaders of the organisation and align with their goals, demonstrating their role in providing funding, support and resources
- Engage with clinical staff, more specifically, doctors at the beginning
- Engage with opinion leaders (from topic or specialty specific fields, as there are different leaders for different issues) to develop the guidance and support the

guidance when it is ready to be disseminated rather than impose it in a top down way

- Provide high quality materials i.e. the safer practice needs to be disseminated with supportive tools
- Monitor, measure and feedback - to provide valid performance data and useful feedback to motivate

6.2.4 Part 3: Understanding the receptive context for implementation

Part 3 helps the developer assess the receptive context for implementation through the use of various tools. This is so that the implementation strategy considers the role of the organisation and the organisational factors for implementation. The interview participants and questionnaire respondents all commented on the need to reflect the local context.

The interviews with those responsible for directing implementation cited hindering factors as; the competing priorities for patient safety, the complexity of healthcare, externally set targets and a focus in the NHS on finance and performance. The interviews with those responsible for implementation cited distraction from other initiatives and the size of the organisation as hindering factors. The risk managers' responses in the questionnaire cited environmental factors not being considered as a hindering factor and the problems of complexity and size of organisation. All of which steers organisations away from a focus on patient safety.

External and organisational factors play a crucial role in influencing the effectiveness of implementation (Greenhalgh et al. 2005, Marchionni and Ritchie 2008). To ensure smooth implementation it is essential to assess the receptive context, i.e. the environment in which the guidance will be implemented (Registered Nurses Association of Ontario 2002). The toolkit helps the developer build up an

understanding of the receptive context by using tools such as PESTLE (political, economic, socio-cultural, technical, legal and environmental factors), SWOT (strengths, weaknesses, opportunities and threats) and readiness factors (Pettigrew et al. 1992, Kitson et al. 1998, Iles and Sutherland 2001, Registered Nurses Association of Ontario 2002, Black and Hutchings 2002, Bate et al. 2004, Grol and Grimshaw 2003, Greenhalgh et al. 2005, Cook et al. 2004, Snooks et al. 2005, NHS Institute for Innovation and Improvement 2006, Leape et al. 2006). The following is an example of an assessment of the readiness factors, picking out the key findings from the interviews, questionnaires and literature sources above, which are presented in the toolkit.

Table 22 Assessment of readiness factors

Element	Question	Facilitating factors	Hindering factors
Structure; staffing practices, physical facilities and available resources	Are there enough staff to support the change process	Multidisciplinary team approach	Lack of time to attend meetings
Workplace culture; values, beliefs, and how they are expressed in day to day activities;	To what extent is the intervention consistent with the values, attitudes and beliefs of those required to implement the change?	Use of opinion leaders	Lack of evidence or benefits not clearly demonstrated
Communication; both formal and informal processes for information exchange, the interdisciplinary relationships especially between managers and implementers;	Are there adequate formal and informal communication systems?	Email updates, regular bulletins, newsletters, meetings, events	Limited opportunity to communicate
The influencers – the presence of influential champions or opinion leaders within the organisation	Who are the influences for this particular subject?	Use to front up the work – influences others to change	One opinion leader to one person is not necessarily the right opinion leader for someone else

Knowledge, skills and attitudes of target group; those that will be required to implement the change in practice recommended, their motivation towards adoption of new idea and practices, whether they have the skills required	Do the staff have the necessary knowledge and skills?	Faculty Training Simplicity	Complexity creating resistance
Leadership; the extent to which the leaders and managers at all levels will influence and enable the changes recommended	To what extent to the leaders support the change?	Chief Executive support clearly evident	Change not shown as a priority
Available resources; financial or human requirements necessary to achieve the changes	Are there necessary human, financial resources available?	Dedicated time Lead roles for implementation Business case development	Competing priorities Limited resources

6.2.5 Part 4: Identifying the right implementation approach

Part 4 is probably the heart of the toolkit. It helps the developer:

- Identify the facilitating factors and barriers
- Choose the right implementation method
- Test and develop their approach

The interview participants and the questionnaire respondents all cited the need for appropriate implementation strategies, but no one approach came across as the magic bullet. The right choice of method of implementation is vital (Greenhalgh et al. 2005).

This section of the toolkit starts by suggesting the developer takes an active approach to understand the psychology of change and the social and behavioural factors that need to be addressed.

'Think more about behavioural theory when planning change and implementing solutions'

Risk manager, 2007

Michie et al. (2005) suggested that successful implementation would be improved if interventions were informed by human behaviour theories including motivational theories, social learning theory, action theories and organisational theories (Michie et al. 2005). They also suggested addressing issues such as reward, incentives, goals, feedback, local context, organisational and team culture, individual motivation and attitudes to change behaviour.

The interview participants and the questionnaire respondents also commented on the need to ensure that clinicians, and in particular doctors are involved from the start and that the potential resistance to change by clinical staff is addressed.

The developer is then advised to undertake an assessment of the facilitating factors and barriers for the particular change they want to make. There were many factors which help and hinder implementation identified from the interview comments and questionnaire responses. The risk managers were asked to specifically identify these factors. These are demonstrated in the previous chapter. The toolkit provides a summary of the following findings identified in the interviews and questionnaire responses and from the following literature (Bero et al. 1998, Thomas et al. 1999, Grimshaw and Russell 1993, Grimshaw et al. 2001, Fraser 2002a, Hunter 2002, Grol and Grimshaw 2003, Øvretveit et al. 2002., Øvretveit 2003, Øvretveit and Gustafson 2003, Wilson et al. 2003, Grimshaw et al. 2004, Greenhalgh et al. 2005, Lankshear et al. 2005, NHS Institute for Innovation and Improvement 2006, Wensing et al. 2006, Leape et al. 2006, National Institute for Health and Clinical Excellence 2007, Ploeg et al. 2007).

Figure 11 Facilitating factors

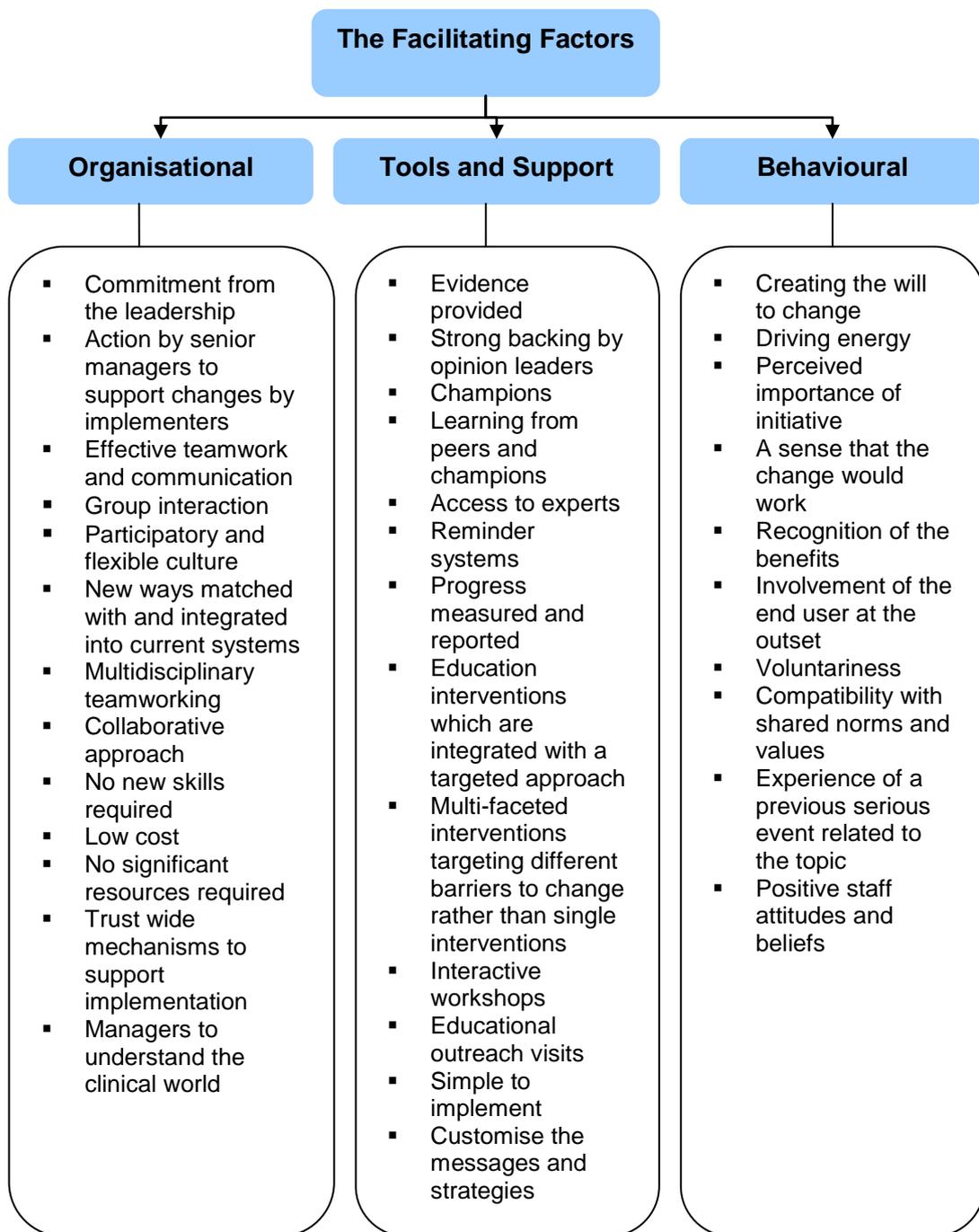
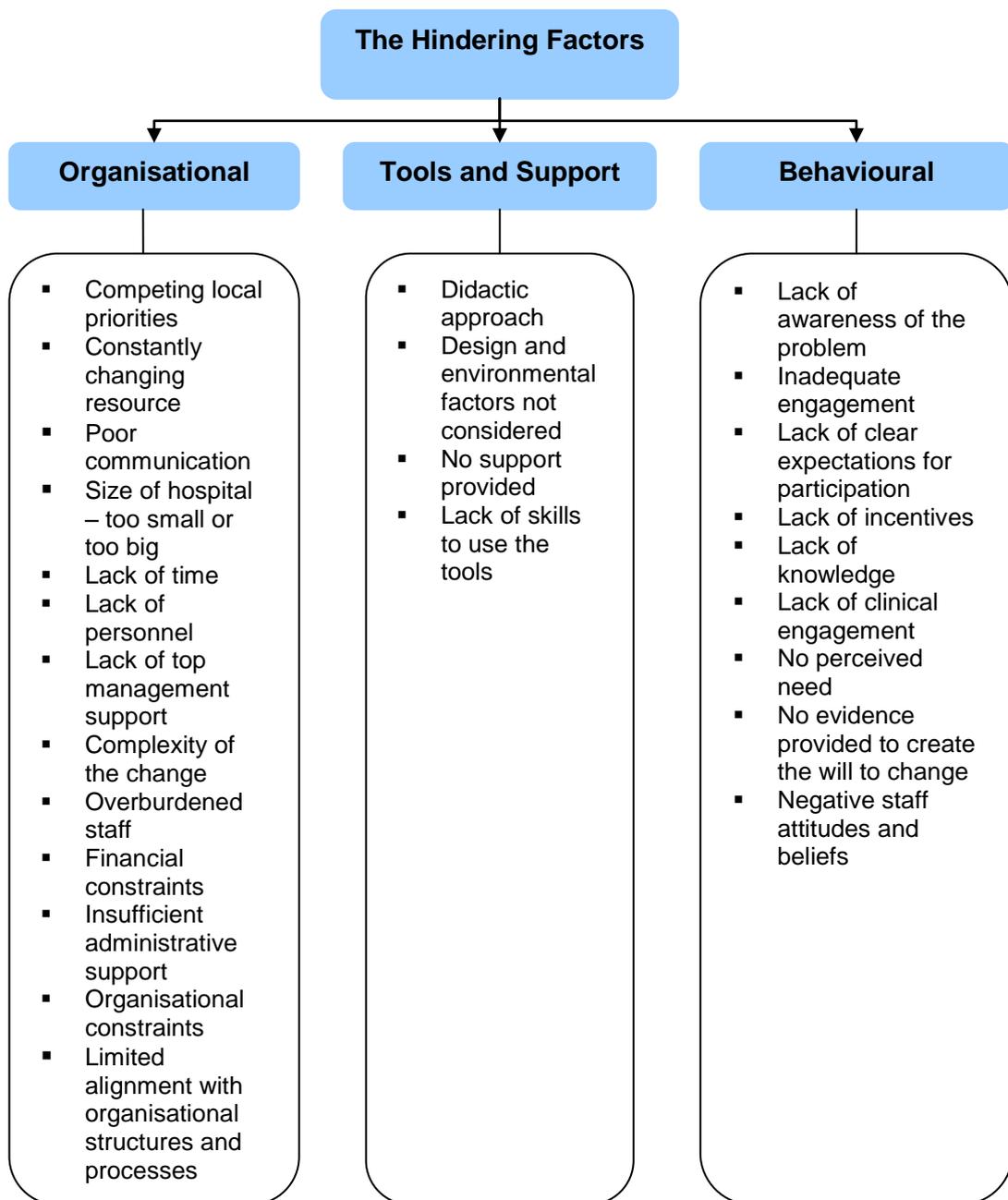


Figure 12 The hindering factors



The 'list of factors that help' in the toolkit describe the need for a participatory and flexible culture. The term culture is used in many different ways, it is the norms, values, beliefs and behaviours of individuals, teams and organisations (National Patient Safety Agency 2004, Francois et al. 2005, Leape et al. 2006, NHS Institute for Innovation and Improvement 2006, Singer et al. 2007, Newton et al. 2007). Patient safety is reliant on a safety culture which is open and fair within healthcare organisations (Reason 1990, 1997 and 2000, Department of Health 2000b, National Patient Safety Agency 2004, Westrum 2004, Lewis and Fletcher 2005, Stryer and Clancy 2005, Leape et al. 2006). It is also a culture where everyone contributes to ensuring that care is delivered as safely as possible and that safety is taken seriously at every level of the organisation (Vincent 2006). Translating evidence based knowledge and guidelines is one of the components of a safety culture, helping achieve both reliability and resilience (Stryer and Clancy 2005, Frush et al. 2006, Fracica et al. 2006, Kirk et al. 2006, Department of Health 2006b, Vincent 2006).

The list also describes the need for a committed leadership. The interview participants and the questionnaire respondents commented on the importance of leadership to demonstrate the importance of patient safety. Leadership is crucially important for implementation, spread and sustainability, i.e. to drive change through an organisation (Mills and Weeks 2004, Weingart and Page 2004, Massoud et al. 2006, Nolan 2007, Newton et al. 2007). Leaders impact on safety in many ways, they make decisions higher up the organisation which can affect those at the front line (Reason 2000, Vincent 2006).

With regard to implementation, help should be targeted at leaders both managerial and clinical, so that they can provide the right support to their staff such as time, resources, training and funding (Francois et al. 2005, Lewis and Fletcher 2005, Gravel et al. 2006, Leape et al. 2006, NHS Institute for Innovation and Improvement 2006, McCarthy and Blumenthal 2006, Newton et al. 2007). Hindering factors in relation to leaders have

been identified as; lack of top management support, lack of resources, incentives and knowledge (McFadden et al. 2006).

The different approaches to implementation has been subject to much debate and is central to this project together with the implementation toolkit (Grimshaw and Russell 1993, Davis and Taylor-Vaisey 1997, Bero et al. 1998, Thomson et al 2000, Iles and Sutherland 2001, Registered Nurses Association of Ontario 2002, Grol and Grimshaw 2003, Grimshaw et al. 2004, Grimshaw et al. 2006, Wensing et al. 2006, Thompson et al 2007). When testing the content of the toolkit a number of colleagues suggested that it should prescribe an implementation approach rather than providing difference approaches to choose from. However, a clear finding in the literature, the interview comments and the questionnaire responses, is that there is no one approach or strategy which applies in every situation or that is considered the most affective (Registered Nurses Association of Ontario 2002). Implementation is a complex process and the local context is equally complex. Therefore, the notion of a single approach must be rejected.

Consequently, a key aim of this section of the toolkit was to explain that the method chosen should be the best method that fits the proposed practice ensuring a flexible approach (Registered Nurses Association of Ontario 2002, Greenhalgh et al 2005). It should be based on the assessment of the type of practice, the type of change expected, the stakeholders involved, the receptive context including local capacity and the resources available (Parcel et al. 1990, Rycroft-Malone et al. 2002, Registered Nurses Association of Ontario 2002). This section therefore provides the developer with the selection of approaches for them to decide which one fits their safer practice as evidenced by the literature sourced.

The traditional approach to dissemination has been the publication of findings and safer practices on the internet and in journals together with mass mailing to all

organisations (Grilli et al. 2000, Bate et al. 2004, Bate and Robert 2006, Dinsdale 2006, Grimshaw et al. 2006). This is the main approach to implementation used by the NPSA. There is a belief that the audience will read and change their practice. However, the recognition of the failure of this model has led to the greater awareness of the role of other factors which influence implementation (Hunter 2002, Bate et al. 2004, Lewis and Fletcher 2005, Grimshaw et al. 2006, Neale et al. 2007).

Top down directives seem to only work if a simple message is combined with other strategies (Lankshear et al. 2005). These include an irrefutable solution which has clear advantages for patients and staff. It is facilitated by senior management endorsement, has strong backing by peers and opinion leaders and offers (in this case nurses) staff with a solution to a worrying problem, thereby providing 'peace of mind' (Lankshear et al. 2005). In fact, research has shown that some healthcare staff would like a top-down drive for improving clinical standards to balance the focus on targets and waiting times (West 2006).

An implementation strategy that appears to be a favoured approach for patient safety and improvement is the collaborative process (Leape et al. 2006, Jain et al. 2006). Leape and colleagues (2006) led a project which directed organisations to change their practices in key areas. They used a collaborative model to implement chosen practices supported by a toolkit containing safer practice recommendations, a change package and implementation strategies (Leape et al. 2006). The change package consisted of the evidence base, a description of the roles for each participant, development of measures, data collection methods, implementation tips, reference material and a set of sample tools such as flow charts and policies. Ploeg and colleagues (2007) identified the factors which influenced best practice guideline implementation. Facilitating factors included group interaction, positive attitudes, leadership support, champions, and collaboration. Barriers included limited integration of guideline recommendations into organisational structures and processes, time and

resource constraints. The factors which supported the collaborative approach were engagement with the implementers in deciding what those practices would be, the stakeholders chose the subject focus. Teams are also motivated by events and toolkits, external facilitation, interactive education, measurement, preparation and multifaceted interventions (Leape et al. 2006, Pronovost et al. 2006, Stetler et al. 2006, Newton et al. 2007).

A collaborative approach which has led to some compelling success was demonstrated by Pronovost and colleagues (2006). They invited intensive care units in all hospitals in Michigan to participate in a collaborative project which was to implement a number of interventions to reduce catheter related (central line) bloodstream infections. This study demonstrated a reduction of infections to zero within 3 months of implementation. Collaboratives are not easy to evaluate because, as is similar with quite a bit of research related to implementation, it is difficult to separate out the impact of the collaborative from other interventions (Leape et al. 2006).

Various implementation methods were cited by all three groups interviewed and surveyed. The interviewees responsible for directing implementation felt that the following implementation methods were effective:

- systems that embed things into everyday practice and support implementation
- role modeling

Simple dissemination of guidelines was not thought to be effective. The interviewees responsible for implementation stated that telling people what to do was also not the answer. They felt that national initiatives added burden to local work, lacked practical support and were a waste of time. They cited effective implementation methods as:

- Role models
- Reward; congratulate and celebrate
- Patient safety champions

- Involve people at the grass roots
- Make it relevant and applicable to the local need
- Target the audience about what they need to do

Risk managers surveyed cited effective implementation methods as:

- Prompts and reminders
- Education with formal training events for all staff
- Positive feedback
- Visual aids
- Availability of resources and templates
- Clinical forum/collaborates to coordinate implementation locally

Ineffective methods were:

- Top down directives
- Too many all at once

The toolkit provides a list of the strategies and their relative effectiveness as shown in the following figures. These are sourced from the interview findings and questionnaire responses together with the following literature (Registered Nurses Association of Ontario 2002, Greenhalgh et al. 2005, Bekkering et al. 2005, NHS Institute for Innovation and Improvement 2006, Leape et al. 2006, McCarthy and Blumenthal 2006, Gravel et al. 2006, Gagnon et al. 2006, Sladek et al. 2006, McAlister et al. 2006, Hysong et al. 2006, Bhattacharyya et al. 2006, Stetler et al. 2006, Wensing et al. 2006, Newton et al. 2007).

Table 23 Examples of approaches that have been shown to support change

Implementation Method	Description	Why choose this method
Building local consensus	Inclusion of local staff in the development of the guidance or intervention.	<p>This approach will help you target your audience; generate ideas for the solution and guidance. It engages all levels of staff from board to ward.</p> <p>Note: It can be time consuming</p>
Educational outreach visits	Trained individuals and experts visit healthcare staff in their workplace to offer information, support and instruction to explain the desired change.	<p>This approach is effective in tackling certain types of change, such as practice changes. It increases in effectiveness if there are more than one visit. It is more effective when combined with reminders and or interventions aimed at patients and when tailored to individual barriers and situations.</p> <p>Note: The identity of the outreach visitor may have an impact on its effectiveness (positively or negatively). It is not proven to be effective for complex change. Time and resources are needed.</p>
Reminders	Manual and computerised reminders to prompt behaviour change; reminder notes on medical notes; computer aided decision support.	<p>This approach is effective for reminding individuals of best practice. They remind healthcare staff to take or avoid a certain action. They are effective in changing behaviour if given at the point of decision making. Increasing the frequency can increase effectiveness – although too many alerts mean result in the alert being ignored and over ridden</p>
Interactive educational meetings	<p>Facilitated meetings involving learners in discussion and active participation.</p> <p>Provide training modules, define the competencies required</p>	<p>This approach works for small scale meetings such as workshops and training courses where the participants take a more active role in learning. It stimulates problem based learning for change. The more interactive a meeting, the more effective it is to changing behaviour and practice.</p> <p>Note: It is reliant on interaction – which requires specific skills from the facilitator.</p>
Multifaceted interventions integrating audit and feedback, reminders and marketing principles	Assessment of clinical performance charted over time. Combined with feedback in the form of outcomes of care, costs, trend analysis, promoting achievement.	<p>Audit can be a positive way of generating change. The quality and type of data are important – it needs to be clinically rich in order to be interesting to implementers. This approach is more effective if staff buy-in to the process, and they have an active role to play.</p> <p>Feedback needs to be delivered by those</p>

		<p>who are respected. It needs to be timely, and combined with educational materials and meetings.</p> <p>Marketing processes help you to target the guidance and intervention using marketing principles in development, planning, design, advertising, promotion, dissemination and evaluation.</p>
Opinion leaders	Respected individuals or peers who can influence others to change behaviour and practice.	<p>This approach is an effective way of disseminating information and works if the right well respected opinion leaders are used – these need to be either peers, role models or recognised experts who can make a positive difference by adding signature, delivering speeches, writing articles in influential journals and undertaking outreach visits.</p> <p>Note: It is difficult to identify the appropriate opinion leaders – an opinion leader for some is not necessarily an opinion leader for all.</p>
Collaboratives	Providing structured networks to bring organisations and individuals together to learn and share from each other.	<p>This approach is effective for encouraging a partnership approach to the implementation of your safer practice. It creates a network and supportive system for implementation.</p> <p>Note: works best when there is leadership support and regular and repeated attendance</p>
Patient-mediated strategies	By giving information to patients and the wider public we can help change the behaviour of healthcare staff.	This approach uses patients as influencers. For example communicating with patients and informing them of the latest evidence based practice through mass media campaigns. This works best if the campaigns are aimed at informing and educating professionals and patients together.

Table 24 Approaches that have been found to be less successful at creating sustained change

Implementation Strategy	Description	Why choose this method
Educational / printed materials on their own	Books, leaflets, journal supplements, CDs, videos, DVDs, online tools.	<p>This approach raises awareness of the change. It is a low cost choice. It is most effective when combined with other methods.</p> <p>Note: While it disseminates and shares information it does not usually change practice. It is a passive approach and therefore reliant on healthcare staff to read. It is therefore considered only appropriate for raising awareness and short term change only.</p>
Didactic educational meetings	Conferences, workshops, training courses, lectures or presentations with healthcare staff; usually passive.	<p>This approach raises awareness about the desired change on a large scale. There is little or no interaction</p> <p>Note: Similar to the printed material dissemination it is less effective at making change happen and achieves short term change only.</p>

An approach not presented in the toolkit is the methodology for large scale change developed from social movement theory (Bate et al. 2004). Social movement theory supports change by producing a compelling case for change with a focus on spreading energy from the grass roots up. It is similar to the concepts of social epidemics described by Gladwell in the Tipping Point (2000). While this approach can support the transfer of research into practice there are challenges in the NHS is its size and complexity, as most movements begin either in a specific locality or with a particular profession. This approach forms the foundations of the patient safety campaign for England and will be evaluated over the next 2 years. A description together with help for the developer will be inserted following this evaluation.

The final section of part 4 reminds the developer that any safer practice and implementation approach chosen must be tested in relation to process, uptake, resource requirements and outcome.

'Get experts in the field to think the solutions through first, and then test them to ensure they work before sending them out' Risk Manager, 2007

6.2.6 Part 5: Communicating

Part 5 helps the developer to communicate the safer practice and write up their approach. Following the creation of the guidance and implementation approach, the developer needs to consider the different aspects of diffusion, dissemination and communication. Ensuring that the guidance is clearer and effectively communicated was a key finding from the interviews and questionnaire responses.

The interview and questionnaire findings supported the need for improved guidance format. For example, the interviewees of those who direct implementation wanted the guidance to be simple, short and printable. They also wanted to hear about what others had done and good practice examples as well as stories. The lack of a summary format was considered a hindering factor. The implementers interviewed wanted to keep the language simple, make it short, to the point and practical, and for the guidance to target the audience. They wanted clear rationale and recommendations and simple instructions with clear deadlines.

There were a large number of comments from the risk managers in relation to deadlines and expectations. It was felt that national guidance was consistently issued with unrealistic expectations, targets, actions deadlines. In particular the risk managers suggested:

- Quarterly newsletters
- Multiple methods of raising awareness, promotion and dissemination e.g. workshops, leaflets, paper guidance, computer-assisted guidance, posters, using a stand in the main atrium of a hospital

- A forward planner so that organisations were aware of what the NPSA was working on and what was coming out and when
- Targeting Chief Executives and Senior Clinicians providing key points and knowledge

Telling people what is happening, when and why are key principles (Fracica et al. 2006). Fracica et al (2006) recommended 10 key steps to support communication and implementation of patient safety;

- conduct an initial culture and communication assessment
- continue to assess over time
- build buy in
- develop robust reporting tools
- develop educational tools
- use investigatory processes
- develop robust feedback mechanisms
- foster a system focused, non-punitive culture
- reinforce safe behaviours and refuse to tolerate unsafe behaviours
- develop effective communication techniques.

Barriers to communication in healthcare include the hierarchical nature of hospitals and healthcare teams, the structure of an organisation, the social networks, the dispersal of responsibility and the silo working of each profession (West 2006).

'I can't remember whether they were explained fully but I still to this day don't know fully why they were changed' Implementer, 2007

Different approaches to diffusion and dissemination include mass diffusion, spread through social networks, delivery through social influencers such as opinion leaders, peers and champions and targeted dissemination (Rogers 1995, Gladwell 2000,

Greenhalgh et al. 2005, Bekkering et al. 2005, NHS Institute for Innovation and Improvement 2006, Wensing et al. 2006). Targeted dissemination usually involves an active, tailored process of communication, with a goal of persuading users to adopt an innovation (Rogers 1995).

6.2.7 Part 6: Spread and sustainability

'Make it easier to implement and sustain the change than to continue with the old practice' Risk Manager, 2007

The sixth part describes ways in which to enhance spread and sustainability of new ideas and practices and helps the developer:

- Measure for sustained success
- Evaluate to know who well they are implementing

Spread and sustainability requires closing the gap between best practice and common practice and is dependent upon the ability of organisations to mainstream and embed these new ideas (Massoud et al. 2006, NHS Institute for Innovation and Improvement 2006). It is reliant upon effective leadership at both managerial and clinical level together with clinical engagement (Bates et al. 2004, Gollop 2004, Leape et al. 2006, Pronovost et al. 2006). The toolkit promotes the sustainability tool for assessing and scoring the potential level of sustainability of the chosen approach (NHS Institute for Innovation and Improvement 2005). For example, to garner clinical support, they should be involved in the design of the safer practice and the guidance needs to apply to their relevant patient groups, specialty or clinical situations and enhance their personal aims (Grimshaw et al. 2001, Hunter 2002, Lankshear et al. 2005, NHS Institute for Innovation and Improvement 2006, Gravel et al. 2006).

Measurement for sustained success is vital (Registered Nurses Association of Ontario 2002). The interviewees of those responsible for directing implementation suggested the need for benchmarking and measuring to demonstrate effectiveness of the change. The implementers interviewed talked about creating momentum i.e. spreading the change and getting people to keep on track, the need to drive the change because other things took priority. Safety briefings were cited as keeping the profile up as well as the drive of individuals. The risk managers surveyed cited the need for monitoring and measurement processes.

To know if a safer practice has spread and is a sustained practice, evaluation must be undertaken over time in order to assess the level of implementation achieved (Registered Nurses Association of Ontario 2002). The sixth part of the toolkit also describes the importance of evaluation. Leape et al. (2006) described a five point rating scale for evaluating implementation;

- planning stage only
- testing changes
- partial implementation
- fully implemented in some areas
- fully implemented throughout the institution

The study undertaken by Leape et al. (2006) found a wide variety of success with few participants progressing further than partial implementation. However, participants reported that especially helpful were hearing from national leaders, learning from peers and the implementation toolkit.

6.2.8 Templates

Part 7 provides the developer with templates to use and references. It also acknowledges the key individuals who provided significant feedback and comments.

6.3 Next steps

The implementation toolkit was printed in March 2008. Since then it has been distributed to the relevant staff within the NPSA, to the implementation team at NICE the safer programme team at the NHSIII and the Royal College of Nursing. By adopting the principles and guidance suggested in the toolkit these national organisations will support others to implement (Dobbins et al. 2005, Leape et al. 2006, National Institute for Health and Clinical Excellence 2007). Each received a copy with a view to testing the toolkit over the next 6 months. It is vital to evaluate its effectiveness and impact before it is developed for the rest of the NHS. Post doctorate activity described in chapter 8 describes how this will be taken forward.

In order to raise awareness at the highest level, it has also been sent to key individuals within the Department of Health which include the patient safety team, the hospital acquired infections team, the NHS Medical Director, the NHS Chief Executive and the Director General of Commissioning and Systems Management.

Chapter 7: Critique and reflection

“Humility need not be mistaken for confusion....learning depends far more on recognising what we do not yet know than on displaying what we do”

Donald M Berwick
Foreword
Organizing for Quality; the improvement journeys of leading hospitals in Europe and the United States
September 2007

7.0 Introduction

The following chapter provides a reflection of the project, including whether the aim and objectives were achieved, its contribution to knowledge, its impact on myself and a re-visit of the strengths and weaknesses of work based research.

7.1 The aim revisited

The project aim was to improve the implementation of national patient safety guidance. It is hoped that this will be achieved through the use of the implementation toolkit. Through its effective use nationally, local organisations will be supported with implementing guidance, safer practices and interventions that have been developed by using the principles described in the toolkit. The toolkit will be tested first at a national level and benefit the NPSA. Once tested and evaluated it will be made available to the wider NHS, the specialist field of patient safety internationally, and all other bodies responsible for developing and disseminating interventions. It will also be available for staff locally to develop their own implementation strategies. The consequences of improved implementation will ultimately help improve the safety of care for patients.

7.2 The objectives revisited

Objective: Critically examine the literature in relation to the factors that help or hinder the implementation of national guidance at a local level.

How met: The literature provided a foundation from which to understand the challenges of successful implementation, the factors that help or hinder, and the potential ways in which they can be dealt with.

Objective: Undertake a stakeholder analysis and identify the contextual and environmental factors in relation to patient safety in the NHS.

How met: A stakeholder mapping exercise was undertaken and shared with all national organisations bringing them together in a national collaborative for patient safety. Following a mapping exercise, stakeholders are then usually analysed in order to categorise them. This can be done by using a grid or matrix, such as the one shown below, using various identifiers. For example the stakeholders can be classified according to influence and support. A stakeholder analysis to categorise the stakeholders was not carried out. This is usually done for a particular activity. For example it can be used as part of an implementation strategy for each individual output to decide who to collaborate with, who to keep informed, who to build relationships with and so on.

Objective: Explore the factors that help or hinder implementation in acute hospitals.

How met: The interview participants within the case study sites in acute care hospitals provided their views of the factors which helped and hindered them locally when trying to implement national guidance. The risk managers who responded to the questionnaire provided responses to the questions about factors that help, factors that hinder and the role of a national organisation to support this process.

Objective: Explore any differences between the acute hospitals.

How met: The differences [and similarities] of the groups and acute hospitals were explored and presented.

Objective: Triangulate and critically analyse the literature and theory, the stakeholder analysis, and content gained from acute hospitals.

How met: All data collected were reviewed together at various stages of the project.

Objective: Draw connections between all information to identify the factors for implementation in acute hospitals and the interrelationships between those factors.

How met: The triangulation provided the method to draw connections from all the data.

Objective: Draw conclusions from the findings in order to provide recommendations on future implementation of guidance with respect to patient safety.

How met: The early conclusion and recommendation was to design and develop and implementation toolkit, a combination of advice, tools and techniques for the developers of guidance, to support local NHS organisations to implement patient safety guidance. Further conclusions are identified in chapter 7.

Objective: Extrapolate the findings in order to provide recommendations on future implementation of guidance throughout healthcare.

How met: The study findings will be shared widely with the NHS. While the study examined a specific issue and does not claim to represent generic and common practice found across the NHS or in other domains, the findings nonetheless have a degree of transferability to other national organisations responsible for creating guidance and interventions for implementation by others.

Objective: Design and develop an implementation toolkit, a combination of advice, tools and techniques for the developers of guidance, to support local NHS organisations to implement patient safety guidance.

How met: The implementation toolkit has been designed and developed and is ready to be launched for the NHS as part of the patient safety campaign.

7.3 Research approaches revisited

7.3.1 Strengths

The research design was based on appropriate research strategies and methods to address the problem identified. The rationale, aim and objectives were clearly stated, the approach and techniques were explained as fit for purpose and the appropriate literature was accessed. The rigour of conduct was established by demonstrating each stage of the process, the decisions made and how the findings were arrived at. The credibility of the study was enhanced by the constant comparison and triangulation of the interview and questionnaire findings with the prior research found in the literature.

Case study approach: The application of the principles of the case study approach was well suited to the constructivist view and iterative process of data collection and enrichment of knowledge within the study. This iterative process provided a continuous method to develop emergent ideas and solutions which in turn allowed for

interpretation and sense making in parallel with the evolving nature of both my organisation and the field of patient safety. A more accurate description of the project methodology would be to call it an exploratory project using case study principles rather than a case study.

Interviews: The series of interviews provided me with the ability to view local practice; they were an economical and focused way of providing me with a large amount of rich data. The quality of the information collected rested on the ability of the participants to be able to describe their practice. I felt that, from my perspective, I quickly developed a rapport with each participant which was both crucial and rewarding. During the interview process, seen more as a conversation rather than a one sided interview, the participants commented on how the process provided them with an opportunity to reflect and to improve their understanding of the subject.

Questionnaire: The questionnaire, despite the weak design of the questions as discussed earlier, enabled me to gain a larger amount of information focused on the influencing factors, from risk managers within acute care hospitals.

7.3.2 Weaknesses

The body of this commentary contains both a reflection on the process together with the weaknesses in relation to the interviews and the questionnaire. A final potential weakness is that the project has not yet 'solved the problem' by producing a tried and tested solution. It has however produced a solution which will be tried and tested. The implementation toolkit will be robustly evaluated and tested for its effectiveness over the next year as it is used.

7.4 Work-based research revisited

The following analysis of my own strengths and weaknesses demonstrates how I have enhanced my strengths and made improvements of the areas of weakness during the progress of the project.

Table 25 Strengths of myself as a work-based researcher revisited

Critical Reflection	Statement at the start of the project	Review at end of project
My position and role as Director at the NPSA provide me with opportunities.	I have the seniority, authority and autonomy to carry out the project which is central to my work. Opportunities provided by seniority – self directed workload and objectives. Ability to set my own objectives and fit the doctorate around my other activities. I can ensure the project and the organisation have mutual aims.	My current level of seniority will add weight to the findings and help me promote them widely.
My background is a source of 'data' for the project. With over 10 years of expertise in risk management and patient safety; in-depth knowledge and understanding of subject	Pre-understanding of subject. Foundation for developing knowledge further.	The level of pre-understanding helped in assessing the literature and in analysing the interviews and questionnaires. The project has enhanced my knowledge and understanding.
My work place contributes to the research and provides additional sources of data with access to experts both international and national	I will maximise the use of my workplace, and experts while at the same time not taking advantage of them or their goodwill.	I had access to numerous national and international experts who helped validate the findings and the output. Informal and formal conversations provided day to day testing / validity of the findings and material for the toolkit. I will continue to use this expertise to help promote the findings and increase their level of knowledge and understanding.
Masters level academic qualifications in risk management	I will use this knowledge as a basis for the research methodology and conduct of the research.	Experience of literature review, data analysis and interpretation and statistics helped me progress through the project.
Opportunities provided by working in a national organisation	I have access to international experts in patient safety and the ability to go to international conferences; this can also increase credibility locally.	I attended a number of key international conferences and symposiums. This provides me with a platform from which to promote and share the knowledge and understanding gained including the implementation toolkit.
Nearly 30 years in the NHS a significant part of which was working as a nurse; realistic view of what can be achieved with NHS research. In work based research, there is an interaction of researchers with their world.	Understanding of environmental context. The research participants will be helping me to construct the reality of what is happening locally. I will need to be reflexive i.e. self critical and objective. Flexible designs require flexible researchers (Robson 2002). Listening skills and sensitivity will be important for the interviews. Ability to be flexible and an open and enquiring mind; my experience as a nurse has honed my listening skills and ability to be sensitive.	Understanding of the NHS and having worked I the NHS for nearly 30 years gave me a pre-understanding of the context, helped me to build on this during the data collection, helped me understand any terminology used and benefited from my listening skills.

Table 26 Weaknesses of myself as a work-based researcher revisited

Critical Reflection	Statement at the start of the project	Review at end of project
Literature Search Stage: Too much information	Difficulty to précis down for the commentary document.	I accessed much more literature than I needed to despite trying to focus the literature search scope; the project has helped me conduct literature searches in a focused way and has helped me become more succinct.
Time – trying to fit in the Doctorate project while carrying out the 'day job' – because it is expected as part of the 'day job'.	Need good preparation and planning. Good time management and constant reflection. Work with the Senior Management to ensure they understand the project plans, timetable and accept these – if changes are expected earlier – then write this up as part of the project and describe the impact – use as a learning exercise. Pressure by organisation to complete the project earlier because it may be needed for the next stage of the organisation's objectives.	This undoubtedly was the hardest part of the project. Mainly because it was undertaken at a time of immense change both within the NPSA and externally. The changes at the NPSA meant that at times the project had to be put on hold while addressing the amount of workload created by change. I was also promoted which while great, came with it added responsibility and significant competing priorities. The project has helped me appreciate others who are undertaking work place research and how I can support others through my own experience.
Lack of expertise – self direction may mean I am not aware of what I don't know.	I need to work through the user guide activities and ensuring I regularly review the suggested research books. Access experts; constantly review the knowledge and horizon scan the environment.	I read and re-read the user guide on an ongoing basis – this became a reassuring guide to keep me on track and provide me with a framework. I ensured anything I didn't understand was researched so that I felt comfortable with the detail. A key area of challenge for me related to research theory. The project has further helped me understand how to undertake self directed learning and to plan for unexpected events, which in turn helps me in my own work as well as when studying.
Preconceptions about issues in relation to any aspect of the project	I may make assumptions based on my own experience or knowledge – so need to ensure I take into account my own bias or hindsight knowledge.	I made an assumption that I would find some key factors that would identify a clear and simple solution. This was quickly dispelled by the literature search at the beginning. The project has helped me to understand that prior assumptions should be put to one side.
Ability to be reflective and objective.	This means I will need to be acutely aware of the ways in which my values, attitudes, opinions, actions, feelings, selectivity, perception, and background shape the research.	The project helped me to approach the data collection and data analysis with as much of a neutral mindset as possible.
Power – perceived in relation to working for a national organisation; Hierarchy – abuse of power and authority	Especially with subordinates and participants – I need to ensure that I do not abuse the power and authority and only ask what would be reasonable and agreed – and thank them. This is particular pertinent in practitioner research where there is a particular relationship between the researcher and the setting.	The project made me understand the perceived privileged position I am in and how not to abuse that. My conduct needed to be sensitive of this.
High expectations of	I may expect people to put in time or	While, people were more than happy

peers/team	expect peers to provide advice when they are not able to – I need to make sure that I do not abuse people’s good will, access them when they have the capacity and thank them	to provide their expertise. The project helped me value anyone’s input or advice. I kept requests to a minimum and always thanked people for their help.
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7.5 Boundaries and constraints revisited

The project was carried out within the boundaries and constraints described in chapter

2. The boundaries and constraints were related to budget, time, politics and scope.

- Budget: The project had a total budget of £30,000. The actual cost was £18,668.
- Time: The project was completed in May 2008 before the deadline of July 2008.
- Politics: The findings are considered of value and will help the Department of Health and the NPSA. The output and findings will also help achieve some of the expectations in Safety First in relation to improving implementation (Department of Health 2006b).
- Scope: The scope remained limited to the acute sector of the NHS. While the findings and output will be of use for other care settings, a recommendation has been made for further research in these areas.

7.6 Contribution to knowledge

A work based project is a unique approach to facilitating research and learning at work (Armsby 2000). The advantages of this work-based project was its synergy with all the other projects and programmes of work I was involved in throughout the length of the project. The project was influenced by and interacted with a number of other areas of work within the NPSA. The project has generated an increase in my knowledge and understanding throughout. This knowledge has been used in my day to day work and has not only enhanced my work, it has enhanced the work of the NPSA and advanced the progress of improving patient safety in the NHS. The project has helped my thinking and my thought processes. The rigour of undertaking systematic review has

helped provide rigour to other aspects of my work. My enhanced research skills have improved the way I review documents and provide constructive critical comments.

I started with an in depth understanding and level of expertise in patient safety with both tacit and explicit knowledge to draw from, and gained an in depth understanding of implementation. When I wrote the Seven Steps I was naïve in thinking that people would read it and take action to implement the changes suggested. The improved understanding of implementation has helped me understand the principles behind getting people to change practice and the importance of stakeholder analysis and mapping.

I have used this knowledge to help the NPSA improve its approach to patient safety. I have used this knowledge at numerous external meetings as well. For example, in early 2008 I attended a global meeting at the World Health Organisation to improve the safety of surgery across the world. During that meeting I discussed the issues of implementation that may or may not help implement a surgical checklist, clearly acknowledging that there would be some unique factors relating to developing countries that I did not have knowledge of. A follow up meeting with all the relevant royal colleges representing doctors, anaesthetics, nurses and peri-operative practitioners in the UK was held in April 2008 where I presented the findings from my doctorate project. This knowledge and the resources in the toolkit will be used to create the implementation strategy for the surgical checklist in the UK.

7.7 Personal impact

The doctoral project was conducted in parallel with conflicting personal, career and occupational demands. I did not have a lengthy time of reflection, or the ability to solely concentrate on the project. Shortly after the start of the project, in July 2006, the leadership of the NPSA suddenly changed and my original line manager was appointed

as Deputy Chief Executive. I was subsequently promoted on an interim basis to the Director role. With increased responsibility and decreased numbers of staff, my time was devoted to helping the NPSA continue while meeting internal and external demands and business objectives. I had attempted to have a day each week to work on my Doctorate project; this quickly reduced to weekends only and at one point none at all with day to day work impinging on my weekend time. In fact, if I had not had the interviews booked during January to March 2007 I know external pressures would have coerced me to delay booking them, finding it hard to justify the use of the precious time. Yet, this was at the same time, an incredibly valuable activity enabling me to take time out from the stress and lift my head above the parapet.

In general, the changes at the NPSA led to a lengthy period of uncertainty and anxiety for the staff, a reduction in morale, motivation and production together with an increased staff turnover. This impacted in a number of ways on the project. Positively, the project provided me with a key motivator during the times of uncertainty. Also the focus on implementation had coincidentally become a heightened area of concern across the NHS and therefore provided me with a personal validation that it was the right project to concentrate on. My confidence and authority has increased with my ability to contribute to the debate on changing practice and behaviour.

As described earlier, from July 2006 until December 2006 a review of patient safety within the NHS was conducted by the Department of Health. At the start of the project therefore, the outcome of the review was unknown with various options rumoured, such as the NPSA no longer existing or having a different remit with the potential that the project became redundant. The project was undertaken knowing that there may be a need to adapt to any of these options and any unanticipated situations. Fortunately, when the review was published the project became even more important for the NPSA's agenda. As stated earlier, the report, Safety First, which was launched on 15 December 2006 called for a renewed impetus and focus on implementation. However,

the report also recommended a significant number of changes to the NPSA which in turn led to an increase in my workload. I was asked to lead on two of the recommendations, both of which had key links to the output of this study:

- To lead the design of a strategy for a National Patient Safety Campaign for England to make patient safety everyone's priority
- To lead the employment transfer of the 28 patient safety managers in England to regional level as part of the Patient Safety Action Teams within Strategic health Authorities

Since early 2007 therefore my role at the NPSA has significantly evolved. I am now the Director of the Strategy Unit responsible for a small team of very senior staff who provide strategic leadership for a number of major, complex outward facing projects with the main aim of improving patient safety in the NHS. I am also about to embark on a new role, in conjunction with my present role, as a Special Advisor to Sir Bruce Keogh, the NHS Medical Director. The output and the increased knowledge from this project will change the way the NPSA design and develop safer practice guidance and solutions and this has made me feel that my contribution to patient safety will be long lasting. An aspect of personal impact has also been the wonderful relationships I have developed with people who are equally passionate about this subject. Their help and support has truly been invaluable. With comments such as:

"Huge congratulations for the excellent toolkit you have developed.

The finished product barely does justice to the scope of the work that went into producing it.- It is always the way of course. People see something and they don't appreciate the hours of effort, the worry, the research, the writing, the checking, the referencing and everything else required to produce something that meets the need"

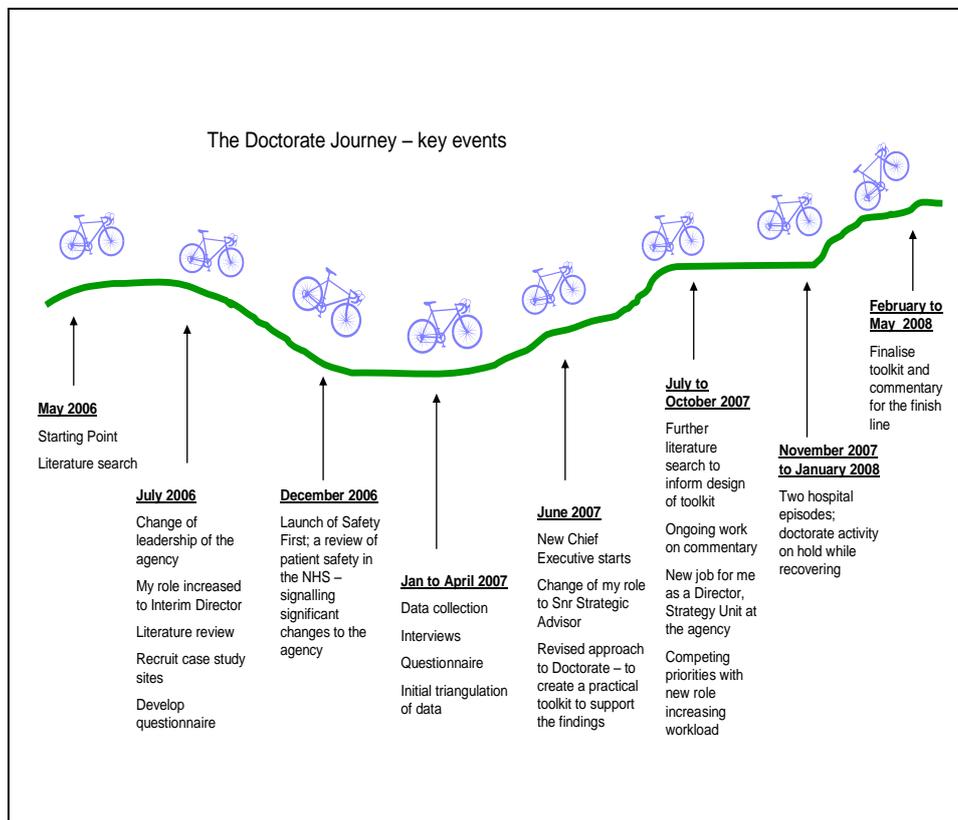
Patient Safety Colleague, 2008

“Have had a read through this and think it has lots of really useful information so well done- it looks great!”

Patient Safety Colleague, 2008

The doctorate has therefore been both life enhancing and life changing, and at times taken over my life completely. Also, any project that is undertaken over a longer period of time, in this case from May 2006 to May 2008, is inevitably affected by events in the researchers personal life. A lesson I learnt when undertaking my MSc was to always factor in extra time to take account of the unexpected. It is important that the researcher notes these events, even if for own private reflection, as they inevitably change you, change the person you are and the way that you view your work as they can test your priorities, values and beliefs. The following describes some of the key moments within this journey.

Figure 14 The doctorate journey – key events



Chapter 8: Conclusions and recommendations

“The fact that all of us, and our families and friends, may also be patients at some point also provides an imperative for improving patient safety in our own spheres of influence. Patient safety is not only about patients – it is about us”

Kieran Walshe and Ruth Boaden
(2005)
Preface, Patient safety: Research into practice

8.0 Introduction

The concluding thoughts for this project are that implementing safe patient care should be every health professional's top priority. However, despite the wealth of research and information available, putting recommended changes into practice often falls short of their envisioned potential. Effective and timely implementation of research into practice remains fragmented and inconsistent. This is the unconquered challenge. Unsafe care results in far too many individual tragedies every year, with both patients and those that provide their care suffering as a consequence. More energy is needed to implement safer practices and reduce the harm and error. Closing the implementation gap in a way that successfully achieves a greater priority for patient safety is urgently required.

Chapter 7 provides a reflection on whether the aim and objectives were met. In summary, I have achieved the project aim by addressing the objectives of the study. I have identified the factors that help or hinder the implementation of national guidance at a local level, critically examined the literature, explored the factors that help or hinder implementation in acute hospitals and explored any differences between the acute hospitals. I have also analysed the contextual factors through a stakeholder analysis. I

then triangulated the information and developed my knowledge and understanding. An understanding of the barriers and facilitators influencing implementation has demonstrated that these are complex and challenging. One of the key factors demonstrated by the literature and data collected, which has yet to be addressed, is the role of national organisations in implementation. They can be a hindering factor, (increasing burden, providing a lack of clarity, making recommendations while having a limited understanding of the receptive context or targeted stakeholders' needs). They can be a facilitating factor, (by acting as a role model and opinion leader for implementation, for demonstrating leadership and providing support, resources and tools).

In conclusion, it is hoped that the implementation toolkit will achieve the project aim and improve implementation of national patient safety guidance. The toolkit aims to address the factors that both hinder and help effective implementation which have been identified in the literature and backed up by the findings from the interviews and questionnaire. By supporting staff locally by developing national guidance using the principles and tools within the toolkit, it is hoped that it will go a long way towards closing the gap between evidence and practice so that organisations are more effective in reducing risk and harm to patients.

8.1 Post doctoral activity

8.1.1 Sharing the knowledge

The new knowledge and understanding will be used post doctorate to inform, raise awareness and increase understanding of the complex process of implementation of patient safety guidance. I will adapt the content and findings of this commentary for different audiences:

- a summary will be provided for the NPSA patient safety bulletin distributed on the npsa web-site and to all NHS organisations
- an article will be written for submission to the peer reviewed journal, Quality and Safety in Healthcare in relation to the lessons for patient safety and a separately focused article for the online journal, Implementation Science in relation to the lessons for implementation
- an executive summary for use as a separate short document
- a press release for any media requests will be made available
- a variety of speeches and powerpoint presentations to be delivered to my peers, to the regional network of patient safety action teams and for other national and international meetings and conferences

In addition, I will also be hosting an international symposium on implementation.

8.1.2 Testing the toolkit

The evaluation plan will be designed to assess process, uptake, resources and impact. Evaluation measures and methods will be created. Consideration will be given to the use of action research or small step changes to assess its use, effectiveness and refine.

At a national level:

The toolkit will be made available in both electronic and hard copy. The hard copy in the form of a handbook has been printed. The next steps are to test it and ensure the toolkit itself is implementable. I have already negotiated with the clinical teams at the NPSA to use it and evaluate its effectiveness. The clinical teams will test it with local organisations throughout 2008, which has been designated, as a direct result of this doctorate project, 'implementation year' for the NPSA. Activity planned is as follows:

- a) the resources within the toolkit will be used to create an implementation strategy for the toolkit itself
- b) measures will be developed to evaluate use and impact
- c) the toolkit will be used to reflect on past guidance and its effectiveness
- d) implementation strategies will be developed for all new guidance using the toolkit – implementation will then be tested in local organisations
- e) to complete the cycle of the doctorate programme, the toolkit will be used to implement the 2008 version of the Seven Steps to Patient Safety which will be written by myself over the summer and launched in the autumn of 2008
- f) a cost benefit analysis will be undertaken to assess cost burden against the benefits achieved

Other national organisations have been asked to consider its use within their own fields of work. To date NICE, the NHSIII and the Infection Control teams at the Department of Health have all asked for copies to test. These will all be disseminated and actioned in a planned way. Yet more guidance being disseminated without support will just perpetuate and add to the problem.

With risk managers:

This project has also reminded me of the complex role of the risk manager and their key role in implementation. Therefore, I will create a project plan to work with a number of risk managers (who have already volunteered), who will help review and test it locally. They are most likely to find it useful as it will support them with their day to day activities creating structure rather than additional work to their role in implementation. It will also improve their understanding of implementation and may raise their expectations from developers and empower them to demand more support. This process will involve the patient safety action teams in SHAs to help them understand how to use the toolkit. Lessons will be used for all other risk managers when it comes to rolling out the toolkit. Activity with risk managers will involve the creation of a test version which will be placed on the NPSA website in the community zone to be reviewed online. The toolkit will be divided into the different sections with the tools in test mode to evaluate the sections as stand alone and then as a whole. The risk managers will test the sections and use an online survey which has an analysis component.

Once tested and refined the toolkit will be made available in hard copy and on the NPSA web-site so that it is freely and universally accessible online, for anyone at no cost. This will assure the dissemination to the widest possible audience, in the most cost effective way. The final web version will be designed by myself in collaboration with others. It will be e-friendly, so that it is easy to download and print, i.e. not dependent upon colour printing and uses as little paper as possible.

8.1.3 Marketing and communication of the toolkit

Initial discussions with the communication team have created an interim communication strategy. The first stage is to raise awareness that the NPSA is reviewing its approach to implementation and of the testing and development phase of the toolkit. Once the toolkit has been refined strategies will be developed for communication, dissemination and distribution. Post doctoral activity will include a marketing and a segmentation strategy. This will support the development of a matrix that will enable messages to be targeted appropriately to different groups of staff within the NHS depending on what category they are in. In England the principles within the toolkit will be promoted as part of the National Patient Safety Campaign. This is because the campaign is about implementing practices that are known to make patient care safer. In Wales the principles will be promoted through the patient safety team.

8.2 Conclusions and Recommendations

The implementation toolkit is one step in the journey to improve implementation. The findings also pointed to some additional conclusions and recommendations to support the toolkit and address the project aim. The seven conclusions and recommendations are set out below and it will be my responsibility to ensure that these are actioned as appropriate.

1 Conclusion

The NHS is looking to the NPSA to help them implement safer practices. The toolkit requires appropriate and targeted communication and promotion at national and local level at various stages over the next year commencing with an awareness raising strategy.

Recommendation: A communication and dissemination strategy will be developed by the Director of Strategy at the NPSA with the communication team. This will also include working with other national organisations, the NPSA, the patient safety action teams and the patient safety campaign team.

2 Conclusion

The project findings from the literature, interviews and questionnaire responses are that national organisations are a vital component for supporting local organisations to improve implementation. As much time should be spent on ensuring guidance gets implemented at a national level as it does on producing the advice.

Recommendation: It is recommended that the NPSA uses the toolkit when creating guidance and safer practices and uses the toolkit to develop implementation strategies to support others to implement. It is recommended that this is through the clinical teams at the NPSA working with a number of local organisations to test the toolkit as part of a robust evaluation strategy.

3 Conclusion

The literature and data collection identified that understanding and knowledge of implementation of patient safety guidance needs improving.

Recommendation: The NPSA should set up an awareness and education programme to ensure that knowledge and understanding of implementation is spread

throughout the patient safety division of the agency and is continuously built upon. The knowledge and understanding from this doctorate project and the subsequent evaluation of the toolkit should be published and presented in peer reviewed journals, national and international conferences and any other relevant forums to share the learning. All patient safety guidance produced by the NPSA must be evaluated, in particular the level of implementation needs to be explored. This knowledge should then be shared in journals and other methods of dissemination.

4 Conclusion

The data collection demonstrated that knowledge of what the NPSA is working on and will be producing for the service needs improving.

Recommendation: The NPSA should involve the service in developing guidance and safer practices and in the implementation approach chosen. It also should provide a forward planner each year so that the NHS can plan for the implementation of the various outputs

5 Conclusion

The findings have demonstrated the importance of national and international collaboration. Currently national organisations and the national approach to implementation are disjointed with efforts being undertaken independently.

Collaboration at a national and international level would maximise the knowledge and understanding in this complex and challenging area. By working together there is the potential to making a significant difference across multiple fields by working together.

Recommendation: It is therefore recommended that the NPSA collaborates with other national agencies and organisations in the UK and internationally. This should commence with the holding of an international symposium, with a view to bringing together the key international experts from across the world in the field of implementation. This will pool learning, share ideas and identify areas of joint working.

6 Conclusion

The scope of the project as identified at the outset was acute care hospitals and with three staff groups. Understanding and knowledge of implementation in other care settings needs exploring.

Recommendation: It is therefore recommended that the NPSA conducts similar (but taking into account the unique individual aspects) in primary care, mental health and ambulance trusts, together with exploring the perceptions of different staff groups.

7 Conclusion

The literature reviews found that specific research with regard to implementation of patient safety guidance, practices and interventions was sparse. More research is required to understand diffusion, adoption and implementation of patient safety guidance.

Recommendation: It is therefore recommended that the NPSA should publish any evaluations of their work together with considering further research on:

- the relationship between guidance, the process or implementation approach chosen and the uptake and impact of that guidance
- to identify lessons for patient safety from the change management and organisational learning theories for adoption, implementation and sustainability

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## Appendices

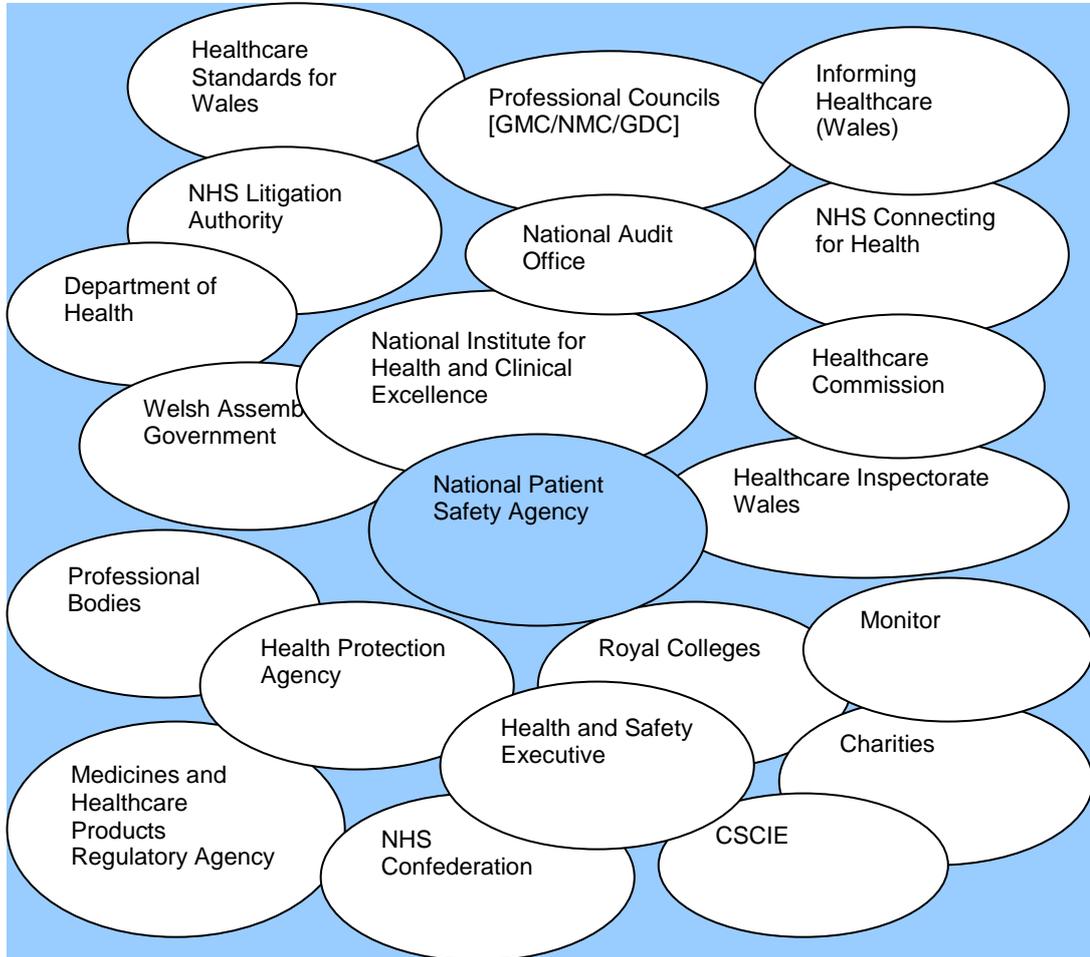
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### Appendix 1 Stakeholder analysis methodology

In February 2007 I conducted a stakeholder analysis jointly with the Healthcare Commission. Over 20 national organisations in England were invited by the NPSA and the Healthcare Commission to sign a charter to show their commitment to patient safety. This collective then met in the summer of 2007. I and my equivalent at the Healthcare Commission asked them to provide a description of their role and activity in patient safety and to define that role in the form of a function e.g. opinion leader, supporter, lobbying. They were asked to provide details to be discussed at a follow up meeting in July 2007.

This stakeholder analysis was used to map out the multiple activities across the NHS in England. These were themed according to their different roles and the relevant Welsh organisations were added. Some of these had more than one role identified. The following figures show the organisations as they described themselves, as standard setters, regulators, inspectors and performance assessors and supporters.

**Figure i** Key standard setters in England and Wales



**Figure ii Regulators, inspectors and performance assessors (England and Wales)**



**Figure iii Supporters in England and Wales**



When developing guidance or interventions a stakeholder analysis of these organisations should be undertaken to determine the level of stakeholder influence and support, and the appropriate strategies for stakeholder engagement to maximise successful implementation. This should be undertaken every time guidance or interventions are developed as different strategies may need to be employed depending on the changes in stakeholder support and influence. Areas for

consideration when developing the stakeholder analysis should include assessing the interest in the guidance or intervention, the involvement and impact of the guidance or intervention on the stakeholder. The analysis should include dividing organisations into high and low influence, high and low support (figure 1.4).

**Table I Matrix for high and low influence and support**

|                              |                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>High Influence</b></p> | <p>Those who have high influence and are low in support need the greatest amount of attention in order to get them on board.</p> <p>Strategies:<br/>Collaborate<br/>Involve at some level<br/>Encourage participation<br/>Encourage feedback<br/>Empower</p>   | <p>Those who have high influence and are highly supportive can be counted on to most positively influence dissemination, adoption and implementation.</p> <p>Need information and attention to maintain level of support.</p> <p>Strategies:<br/>Collaborate<br/>Involve and or provide opportunities for support<br/>Nurture<br/>Encourage feedback<br/>Empower</p> |
| <p><b>Low influence</b></p>  | <p>Those who have low influence and low support are lowest on the priority list but still require engagement to ensure at least a neutral position.</p> <p>Strategies:<br/>Build relationships and consensus<br/>Recognise needs<br/>Involve at some level</p> | <p>Those that have low influence but are highly supportive need great amount of attention to prevent them from becoming neutral or negative towards the change.</p> <p>Can negatively affect dissemination and adoption</p> <p>Strategies:<br/>Build relationships and consensus<br/>Recognise needs<br/>Involve at some level<br/>Show the evidence</p>             |
|                              | <p><b>Low Support</b></p>                                                                                                                                                                                                                                      | <p><b>High Support</b></p>                                                                                                                                                                                                                                                                                                                                           |

At an international level there are a number of key stakeholders which were identified as important for patient safety in England and Wales. These are:

- World Health Organisation (WHO); within the WHO there is the World Alliance for Patient Safety who set global challenges for all WHO Member States.
- The Institute of Healthcare Improvement (IHI) in the United States. The IHI have had a significant influence on patient safety and improvement within the UK with guidance and training as part of programmes of work set up by the NHS Institute for Innovation and Improvement and The Health Foundation.
- Other international and national agencies or foundations for or influencing patient safety which include:
  - Danish Patient Safety Agency – DPSA - Denmark
  - Australian Patient Safety Foundation – APSF – Australia
  - Australian Commission on Safety and Quality in Healthcare
  - Canadian Patient Safety Institute – CPSI – Canada
  - Agency for Healthcare Research and Quality – AHRQ – US
  - Consumers Advancing Patient Safety (CAPS)
  - Plan de Calidad del Sistema Nacional de Salud (Spain)
  - Health Information and Quality Authority (Ireland)
  - The Joint Commission (US)
  - National Patient Safety Foundation (US)
  - The Commonwealth Fund
  - International Alliance of Patient’s Organisations
  - International Council of Nurses
  - International Federation of Infection Control
  - International Federation of Red Cross and Red Crescent Societies
  - International Society for Quality in health Care Inc (ISQua)

## **Appendix 2 Literature review methodology**

The literature was assessed to ensure it met the appropriate quality (Greenhalgh 1997). The search covered systematic reviews, peer reviewed journals and all other relevant databases; National Library for Health, Pubmed, Medline, CINAHL, (nursing and allied health database), Biomed Central, Dialog Datastar, Proquest, Cochrane Library, PsycLIT (psychology, psychiatry and related subjects). It also included the Kings Fund database, government and health web-sites, international and national patient safety and quality improvement websites.

I accessed literature from a variety of areas including change management, organisational development, knowledge management, social transformation, social marketing and quality improvement, patient safety, evidence based practice, clinical guidance, behavioural and implementation science. Journals searched covered healthcare, health services research, quality and patient safety, the main ones being the Quality and Safety in Health Care, the British Medical Journal and Implementation Science. Other material included conference material, Google and Google scholar searches. Additionally, I searched the references sections in articles sources. Grey literature was also accessed. This included unpublished literature from within the NPSA and other documents provided to me from colleagues in other national organisations and articles awaiting publication often sent for comment to the NPSA.

### **Search strategy:**

The searches on the databases were undertaken using key words and combined:

- (1) MeSH terms "patients" and "safety"
- (2) MeSH term "risk management" and keyword "safe"
- (3) MeSH term "change management, health care" and keyword "safe"
- (4) keywords "patient" and "safety"
- (5) keywords "implementation" and "guidance"

(6) MeSH terms "implementation", "guidance", "patient" , "safety" and "safety management"

The following peer-reviewed journals were searched for relevant articles:

American Journal of Epidemiology

American Journal of Health-System Pharmacy

Anaesthesia

British Journal of General Practice

British Medical Journal

Canadian Medical Association Journal

Drug Safety

Ergonomics

International Journal of Health Services

International Journal of Health Care Quality Assurance

International Journal of Medical Informatics

International Journal of Nursing Studies

International Journal of Pharmacy Practice

International Nursing Review

Joint Commission Perspectives on Patient Safety

Joint Commission Journal on Quality and Patient Safety

Journal for Healthcare Quality

Journal of Advanced Nursing

Journal of Hospital Infection

Journal of Nursing Care Quality

Journal of Nursing Management

Journal of Laboratory Clinical Medicine

Journal of The American Medical Association

New England Journal of Medicine

Pharmaceutical Journal

Quality Management in Health Care

Quality & Safety in Health Care

The Lancet

**Inclusion criteria:**

Criteria was used to decide which articles would be downloaded or printed for further study and relevance to this project and its aim and objectives of the project. Literature before 1994 and not in English was excluded. It therefore concentrated on studies which provided evidence of implementation of national guidance/interventions and patient safety guidance/interventions and the factors that helped or hindered their implementation at a local level.

The criteria for inclusion into the project evidence were:

- those that related to implementation in patient safety, which included therefore quality improvement and innovations, rather than general healthcare guidance or guidelines
- those which impacted on national approaches or strategies rather than in a particular specialty area
- focused on acute care hospitals

**Data extraction and analysis:**

Each relevant source was critically appraised for study design, methodology, validity and reliability of design and findings. A checklist was used to compare the relevant literature. This process was adapted from the systematic review by Greenhalgh and colleagues (Greenhalgh et al. 2005) and used the principles identified in Greenhalgh's 'How to read a paper' (1997).

**Table ii      Example of the literature analysis table using one reference**

| Reference                                                                                                                                                                                                                                                                                                                        | Factors reported to influence implementation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Leape, L., Rogers, G., Hanna, D., Griswold, P., Federico, F., Fenn, C.A., Bates, D.W., Kirle, L., &amp; Clarridge, B.R. (2006). 'Developing and implementing new safe practices: voluntary adoption through statewide collaboratives', <u>Quality and Safety in Health Care</u>, 15, pp. 289-95</p> <p><b>Context: US</b></p> | <p><b>Facilitating Factors Cited:</b><br/> Commitment from the hospital leadership<br/> Senior leadership responsible to CE for the success of the project<br/> Progress reports submitted to CE<br/> Regular standardised measures<br/> Commitment to use the 'model of improvement [PDSA]'<br/> Success is dependent on effective teamwork and communication<br/> Meet frequently with frequent data collection (?motivation)<br/> Check implementation period is long enough<br/> Active engagement of a senior administrator<br/> Engagement of nurses<br/> Increased frequency of data collection<br/> Small steps (PDSA)<br/> Leadership engagement<br/> Regular meetings<br/> Review of progress by CE<br/> Leadership direction and support</p> <p><b>Post study survey factors identified:</b><br/> To participate need an interest in the topic among clinical leaders<br/> Sense that recommendations are likely to work<br/> Costs of participating were low<br/> Access to experts<br/> Learning from peers<br/> Set of implementation strategies<br/> Least facilitating factor: sentinel event experienced</p> <p><b>Hindering Factors Cited:</b><br/> Identifying and specifying all the steps for the change is laborious involving all stakeholders.<br/> 'Push back'.<br/> Resources and lack of personnel<br/> Size – small hospital<br/> Financial constraints<br/> Overburdened quality staff<br/> Vacant positions<br/> Competing priorities such as accreditations<br/> Complexity of project<br/> Inability to achieve clinician buy<br/> Implementation costs<br/> No perceived need<br/> Getting people to change the way they work<br/> Staffing time required<br/> Other competing priorities<br/> Time taken to put together a toolkit or resource pack of tools and templates;<br/> type of resource – requires financial resources, dedicated time and expertise.</p> | <p>Key comment for a National Organisation – prepare in advance resource toolkits to help with implementation which build on the facilitating factors.</p> <p>Primary Research. Experimental - before and after interventional study – mixed quantitative and qualitative study. Aimed to implement 2 safer practice solutions across one state in the US. The 2 practices were chosen through a process which included a multi-stakeholder committee and based on literature and databases of serious reportable events. The two practices were 'reconciling medications' and 'communicating critical test results'.</p> <p>The study does not state its hypothesis or aim and there is little evidence to back up the author's statement that an essential step in achieving a safe culture within healthcare organisations is implementing practices that have been shown to reduce errors and that identifying which safe practices are effective is a challenge. However, the importance of the subject is clear and the researchers state at the outset that the lessons they have learned could be used to support future voluntary collaborative efforts. They aim to describe how they chose the two practices, how they enlisted participating hospitals and how they facilitated implementation. Using collaborative model and 'group change theory'.</p> <p>They enrolled hospitals through writing to the CEs and inviting them to participate. Of the 8 that did not sign up to the project they were interviewed as to why not - reasons given were:</p> <ul style="list-style-type: none"> <li>– Size – small hospitals</li> <li>– Geographically distant from collaborative sites and meetings.</li> <li>– Resources and lack of personnel to do the project.</li> <li>– Financial constraints</li> <li>– Overburdened quality staff</li> <li>– Vacant positions</li> <li>– Competing priorities such as accreditations</li> </ul> <p>Those that participated (58 acute care institutions – 88% of total acute care institutions in state) went through a resource intensive process of implementation (facilitation factors).<br/> Rating used for success:<br/> 1 planning only<br/> 2 testing changes<br/> 3 partial implementation<br/> 4 fully implemented in some areas<br/> 5 fully implemented throughout organisation –</p> <p>To create the long list of patient safety topics they triangulated data from incident reporting systems, experts, local chief executives and</p> |

| Reference | Factors reported to influence implementation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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|           | <p>'Failure to develop and communicate the infrastructure [toolkit], may be a major reason why many hospitals have been slow or have failed in implementing required safe practices. Lack of clear expectations for participation (adoption) – particularly dedicated staff time and active engagement of administrative leadership. Clinician participation is required and if not involved hinders success. Lack of reporting or monitoring processes. Inadequate engagement of organisational leadership. Need to actively support their teams – may need coaching. Lack of comparative data to stimulate improved performance. Insufficient emphasis on use of measures. Failure to provide baseline data and therefore motivation from seeing the data improve. Using complex statistical tools to measure success. Insufficient administrative support. Changes suggested requiring changes to clinician's daily work.</p> <p><b>Note:</b></p> <p>A key factor to implementation may be related to the decision to participate in the first place and the level of external support provided.</p> <p>Chief executives were asked to sign a pledge of participation and were followed up by email, telephone, visits, presentations and newsletters. The chief executives were asked to form multidisciplinary teams of clinical staff and a quality specialist and to provide support and commitment. The teams were provided advice for enlisting doctors and for dealing with 'pushback' i.e. rejection. They were advised to have frequent meetings, described as 'huddles' and to report monthly to their chief executive. A web-based community (listserv) was set up for exchange of information and questions and answers. A project director was available for telephone support. The subsequent three meetings were for reporting progress and sharing problems and solutions.</p> <p><b>Conclusion:</b></p> <ul style="list-style-type: none"> <li>– Implementation of new safe practices is a difficult and complex task for hospitals</li> <li>– The collaborate process is a powerful way to motivate and support change</li> </ul> | <p>directors and the literature. A list of 10 was further reduced to two through an advisory committee of front line clinical staff, managers, researchers, professional associations and insurers. The criteria used to prioritise the two were; importance of the problem, availability and efficacy of the practice, feasibility of implementation and potential impact on safety. A stakeholder group of experts for each practice defined what changes need to take place, the steps necessary and created guidance.</p> <p>An extensive effort was made to enrol as many hospitals in the state as possible. This started by sending an invitation to each chief executive. The Massachusetts Hospital Association (MHA) Board voted to make implementation of the two practices 'flagship initiatives' and called on all hospitals to participate. It is not quite clear the role of the MHA or whether all hospitals in the state were part of this association. Also, it does not say if there were sanctions if the hospitals did not participate but the US healthcare system is reliant on insurance based funding and competition for referrals. The role of the MHA was found to have played a role in choosing to sign up. The MHA publicised the progress in its communications to hospital leaders and provided a comparative list of performance for each participating hospital at its annual meeting in 2004.</p> <p>Evaluation of implementation used a five stage assessment scale previously developed by the IHI; 1 = planning only, 2 = testing changes, 3= partial implementation, 4 = fully implementation in some areas, 5 = fully implemented throughout the organisation. Each safe practice had success measures which were quantifiable. They also evaluated 'various factors responsible for hospital team success', through surveys of chief executives and leaders. These factors were; the decision to participate, organisational and administrative factors that facilitated implementation, the role of the collaborative, data collection methods and the PDSA improvement model, implementation and measurement for each practice and barriers to implementation.</p> <p>Bivariate cross tabulations to test the effect of these factors on reaching implementation stage 3, 4 or 5 was used with no statistically significant findings for the critical results safe practice. Reconciling medications outcomes were associated with active engagement of management, engagement of nurses, increased frequency of data collection (all at <math>p &lt; 0.05</math>) and use of PDSA cycles (at <math>p &lt; 0.001</math>).</p> <p>The 22 references to support the article included seminal texts from the US and related peer reviewed articles ranging from 1998 to 2006. The references also included supportive documentation of further detail</p> |

| Reference | Factors reported to influence implementation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | <ul style="list-style-type: none"> <li>- Small changes fuel excitement and enthusiasm for larger changes – pilots work well</li> <li>- Sharing innovations are valued</li> <li>- Support from leadership – front line staff can develop creative methods for improving patient care and patient safety</li> <li>- Separate strategies are required for all the sub-practices of each change – multiple changes are needed for implementation of the whole</li> <li>- Lack of sufficient development and understanding of these sub-practices may be one of the reasons many hospitals have found it difficult to implement new safe practices [from national organisation]</li> <li>- Sufficient resources needed for success. Even when toolkits available, complex organisational change requires dedicated staff time to test the changes, measure the impact, refine the approach and spread the changes through the organisation.</li> </ul> | <p>from the study published elsewhere.</p> <p>The mixed methods approach chosen for measuring success through both qualitative and quantitative approaches was appropriate. The length of the project over time with four collaborative meetings over around 18 months gave the participants time to make the changes suggested.</p> <p>The first meeting described the evidence base and methodology using an action research approach of 'plan do study act (PDSA)' developed by W Edwards Deming and championed by the Institute for Healthcare Improvement (IHI) in the US. Participants were provided with a toolkit containing a change package and implementation strategies. The change package provided an explanation, rationale and recommendations including roles for each participant, development of measures, data collection of baseline data and ongoing, forms, flow charts, policies, implementation tips and reference material.</p> <p>Resource intensive – ?generalisability – needs significant commitment and time. Daunting with the collection of data – frequent meetings (which they failed to do) – reports to the CE on a monthly basis – reliant on real buy in not token approval from the CE. Could argue that any change with this much effort would be a 'success'. Good idea to follow up those that didn't take part as much as those that did. The study does not talk about the wider political environment – the competition that this project created and the competition naturally in US healthcare.</p> <p>The results section described the implementation of the safe practices. This was less clearly demonstrated. The results were broken down for each safe practice. The table showed that for reconciliation of medicines, 8 reached stage 1, 17 reached stage 2, 16 reached stage 3. So 41 out of 50 organisations had not progressed to fully implemented in some areas or across all areas. However, the text is misleading stated that 50% of this group had implemented this practice partially or fully (stages 3-5). This was similarly described for the other safe practice. This is confirmed later in the results section when the authors state that the surveys showed that the teams found implementing the recommended practices difficult.</p> <p>The table appeared to show that the majority of organisations had achieved stages 2-3 i.e. testing changes and partial implementation. The text is not as clear stating that 50% of those implementing the medicines safe practice and 65% of those implementing the test results safe practice had achieved stages 3-5. Recommendation for national organisation:</p> <ul style="list-style-type: none"> <li>o Before mandating change – develop</li> </ul> |

| Reference | Factors reported to influence implementation | Comments                                 |
|-----------|----------------------------------------------|------------------------------------------|
|           |                                              | recommendations, test different elements |

### **Appendix 3 Interview methodology and documents**

The sequence for interview was as suggested by Robson (2002):

Introduction – I introduced myself, explained the purpose of the interview, assured the interviewee with regard to confidentiality and identification, asked permission to tap and explained what I would do with the tape and transcript.

Warm-up – I started with gentle conversation to settle both of us down.

Many body of the interview – I covered the issues of patient safety, implementation – the progress and conversation generated by the interviewee with occasional prompts from myself.

Cool off – a few quick easy questions at the end to lead to the closing of the interview.

Closure – a thank you and goodbye – prompted by turning the tape off, thanking them for giving up an hour of their time and wishing them well for the rest of the day.

## **a) Copy of consent document**

### **Project Proposal**

#### **Improving Implementation of National Patient Safety Interventions**

#### **Informed Consent Form**

### **Introduction**

The purpose of this document, in accordance with the requirements of the Middlesex University's Code of Research Ethics is to make explicit the nature of the proposed involvement between the researcher and the person or organisation agreeing to supply information (the participants) and to record that the research subjects understand and are happy with the proposed arrangements.

### **Study**

The researcher in charge of this project is Suzette Woodward, Deputy Director of Safer Practice of the National Patient Safety Agency, 4-8 Maple Street, London W1T 5HD. The study is part of a Professional Doctorate as well as the National Patient Safety Agency's objectives. The project title is: '*Improving Implementation of National Patient Safety Guidance*'. The project aim is to improve the implementation of national patient safety guidance.

The objectives are to:

1. Critically examine the literature in relation to the factors that help or hinder the implementation of national guidance at a local level
2. Undertake a stakeholder analysis and identify the contextual and environmental factors in relation to patient safety in the NHS
3. Explore the factors that help or hinder implementation in acute hospitals
4. Explore any differences between the acute hospitals
5. Triangulate and critically analyse the literature and theory, the stakeholder analysis, and content gained from acute hospitals
6. Draw connections between all information to identify the factors for implementation in acute hospitals and the interrelationships between those factors
7. Draw conclusions from the findings in order to provide recommendations on future implementation of guidance with respect to patient safety
8. Extrapolate the findings in order to provide recommendations on future implementation of guidance throughout healthcare

### **Participant involvement**

Participants will be requested to be interviewed for up to one hour. The interviews will be recorded on audiotape. The interviewee is free to decline to answer any question, to terminate the interview at any time and to require any section or the whole of the recording to be deleted.

All information provided by the participants will be treated as confidential. Unless specifically agreed otherwise, references in any documents will be anonymised and any information which may make identification possible will be removed.

### **Use of the information**

The aim will be to eventually present the project data along with other data collected in other parts of the study in appropriate contexts, academic and professional through final project report, journal publications, conference presentations, teach and so on. The researcher will not use data that can identify any participants or participant sites or that is considered sensitive. The participants will be given copies of the findings.

Declaration by the participant.

I have read and am happy with the proposal and arrangements as set out in this document.

Date ...../...../2007

Signature of participant

Name of participant (printed)

Researcher Signature

**Suzette Woodward**  
Deputy Director of Safer Practice  
National Patient Safety Agency

**B) Copy of invite letter**



**National Patient Safety Agency**

Suzette Woodward  
4-8 Maple Street  
London  
W1T 5HD

[insert date]

Tel: 020 7927 9500  
Fax: 020 7927 9501

[name]  
[address]

Dear [name]

I am writing to invite you and your organisation to be participants in research being undertaken by the National Patient Safety Agency on identifying factors that help or hinder local implementation of national patient safety guidance. This research is both part of the NPSA's objectives and part of a Doctorate I am undertaking with the Middlesex University, London. I understand that your NPSA Patient Safety Manager, [x] has discussed this with you.

My proposal is to visit 4 case study sites, which are acute hospitals in England and Wales. Within the 4 sites I, the researcher, propose to interview 6 staff for one hour; 3 representing the management side and 3 representing front-line staff.

I would be delighted if you would consider your organisation as one of those case study sites. The information will be used to recommend ways in which we can improve the implementation of national patient safety guidance. It will not be used to performance manage any of the organisations or individuals and any output will not name or identify the sites or individuals involved. I will share the findings with yourselves to help you consider ways in which your organisation can improve implementation.

If you are happy to volunteer as a participant organisation I would be grateful for a single contact point from your organisation so that I can discuss the arrangements for the interviews at your convenience between now and the end of March 2007. It is important to stress that your organisation can back out at any stage of this process. Each individual will be consented prior to the interview which will be un-structured in format and will be taped and transcribed. A copy of the transcription will be sent to each interviewee. A copy of my research proposal is attached. I would be delighted if you would consider this and I look forward to hearing from you.

Yours sincerely

Suzette Woodward, Deputy Director of Safer Practice



## **C) Interview notes**

Start by introducing yourself and reminding the interviewee of what the project is about, why you are doing it and what is expected of them. Explain clearly about the content process and their choice to stop at any stage. Explain the taping and transcription process.

Start with asking them about themselves, what they know of patient safety and the national patient safety agency. Then lead on to a discussion around implementation. If the discussion dries up or gets completely off track the following can be used as prompt questions:

Could you let me know of any patient safety interventions that you have noticed have been disseminated within your organisation? If the interviewee does not recall any then you could remind them of projects such as cleanyourhands campaign, the 2222 arrest number changes, potassium chloride alert, and seven steps to patient safety.

Who do you think is responsible for dissemination?

Who do you think is responsible for implementation?

What do you think are the factors that hinder implementation?

What do you think are the factors that facilitate or help implementation?

What do you think a national organisation could do to help?

## **Appendix 4 Data analysis methodology**

### **Interviews**

I firstly read through each interview and reminded myself of the interviewee and the non-verbal cues and made notes in the margins of each transcription. Notes in the margins were also made to describe the type of comment made, e.g. guidance format, leadership and so on. I then went through electronically and using different coloured highlighting started to pick out the consistent comments using similar phrases and words. These comments were then, as they grew, clustered into themes with titles for each theme. For example a comment such as 'support for doctors to lead improvements' was placed in the theme titled 'clinical involvement', and the comment such as 'I think we just sometimes have to say, lets just spend the money because, at the end of the day, if it stops us making one error a month, it was worth it' was placed in the theme titled 'resources (time, money, people). This was done for all of the interviews. A review of the small clusters (1 or 2 comments) was undertaken again to consider whether they could be included in any of the other themes.

In an effort to be able to compare the groups I undertook a second assessment to see if the themes could be the same for each group. This led to a slight change to some of the themes and titles. For example 'guidance (layout , content, deadlines)' was originally described as 'guidance length' for the directors group and 'realistic deadlines' for the implementers.

The third stage was to identify the facilitating and hindering factors. Not all of the comments were classified as these factors. Some were simply comments in relation to the theme, for example, 'if you don't get clinicians involved, particular Consultants, your organisation is going to be dysfunctional' is a general comment about clinical involvement in the NHS which may also be a facilitating factor for implementation but

that is not what the interviewee related it to. So within each theme I colour coded comments which described a factor which facilitated e.g. The Chief Executive has got to be on board and passionate, and comments which were hindering e.g. lack of time [to implement].

## **Questionnaire**

All the responses were placed in a table with three columns for each question. All comments within each column were then themed in the same way as the interviews.

## Appendix 5 Questionnaire

Dear Colleague

I am conducting a project as part of a professional doctorate in patient safety which also feeds into the objectives of the National Patient Safety Agency. This is to identify the certain conditions and factors that can help and hinder uptake, implementation and sustainability of patient safety solutions, interventions and guidance. I would be most grateful if you would take the time to answer the three following questions, your expertise and knowledge will really help us to make a difference in the future.

However, if you do not wish to take part that is absolutely fine.

Regarding confidentiality, I would also like to assure you that while you will reply to your local patient safety manager, who will then send onto myself, neither your name nor the name of your organisation will be retained and you will not be identified or attributed to in any reports or output which follows this survey.

Q1: What do you think are the factors which help uptake, implementation and sustainability of patient safety solutions, interventions and guidance?

Q2: What do you think are the factors which hinder uptake, implementation and sustainability of patient safety solutions, interventions and guidance?

Q3: How do you think the NPSA could help you implement patient safety solutions, interventions and guidance locally?

Any other comments you would like to add?