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PATIENT SAFETY RESEARCH PORTFOLIO

A Multi-Method Study of the Uptake of Advice, Directives and Guidelines to the NHS Concerning Patient Safety by the Safety Alert Broadcast System

Final Report

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AUGUST 2007

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Acknowledgements

We are grateful to all the Trusts who generously gave their time to assist in this study.

We would also like to thank the members of the Steering Group who gave us helpful suggestions and commented on numerous interim reports.

We are also grateful to Karen Fritz, Sue Ford, Fiona McInnes, Sarah O'Reilly, Gill Punton and Lyn Rowark, from the Department of Health Sciences at the University of York, for helping with the project, in particular the site visits.

Finally our thanks to the Patient Safety Research Programme (now Patient Safety Research Portfolio) for funding this study.

SECTION A

Design and Methodology

Section 1: Introduction and Overview

1.1 INTRODUCTION TO STUDY

A team of researchers from the York Health Economics Consortium at the University of York, and from the School of Nursing and Midwifery at Cardiff University was commissioned by the Patient Safety Research Programme (PSRP, now the Patient Safety Research Portfolio) to carry out a study with the following aims:

- To determine how SABS directives are disseminated and acted upon in trusts;
- To identify the ways in which the SABS system could be improved;
- To determine whether, and how quickly, a range of alerts were implemented;
- To identify, in cases of non-compliance, the factors impeding implementation of the requirements of the alert.

The study commenced in April 2006, and was completed at the end of July 2007. The project was steered by a Steering Group, which was chaired by a representative from the PSRP and comprised individuals from a range of organisations including:

- The Patient Safety Team from the Department of Health;
- Estates Division from the Department of Health;
- NPSA;
- MHRA;
- Senior representatives of NHS Trusts;
- Public Health Department of North East Regional Office;
- Healthcare Commission.

Appendix 1 of this Report lists the members of the Steering Group**.**

The study was deemed to be audit by the chair of Northern and Yorkshire Multi-Centre Research Ethics Committee.

1.2 BACKGROUND TO THE STUDY

In 2001, the Department of Health (DH) estimated that adverse events featured in around of 10% of admissions to hospital, affecting 850,000 people a year (Department of Health, 2001). More recent data show that of the 13 million patients that were admitted to NHS hospitals in 2005, the NPSA reported that it had received 484,441 reports of adverse events of which 1,804 (0.4%) had resulted in the death of a patient (Patient Safety Observatory, 2005). However, this figure may significantly

underestimate the problem, specifically in relation to certain categories of incidents (such as medical devices) and to non-acute trusts and GP surgeries with relatively underdeveloped reporting structures.

The costs to the NHS alone are estimated to be in the region of £2billion (Department of Health 2001) and this figure must be viewed in addition, to the human cost in terms of pain and suffering and the loss to the economy through days lost from work. Some of these events will result in legislation, the estimated costs of medical negligence claims for 2001/02 totalling £446 (CMO 2003)

In the United States (US), the safety of healthcare is a high priority as evidenced by several seminal reports on, for example, anaesthesia mishaps and adverse drug events, which have stressed the importance of systems rather than people as causes of medical errors (Cooper 2001). Publication of the report by the Institute of Medicine in the US, *To Err is Human: Building a Safer Health System* (Institute of Medicine 1999) dramatically raised the profile of medical error and patient safety (Stelfox, Palmisani et al. 2006) in the US, and proved equally influential in the UK. This study demonstrated that errors are shaped and provoked by 'upstream' systemic factors, which included an organisation's strategy, its culture and the approach of management towards risk and uncertainty.

An Expert Group, set up by the Chief Medical Officer to promote learning from adverse events in the NHS, reviewed the literature and findings from international studies, as well as studying extant processes and procedures within the NHS. In their report, *An Organisation with a Memory*, (Department of Health 2000) they identified barriers that can prevent active learning from taking place, and highlighted two areas in particular. If organisational cultures can be characterised as having a 'safety' or 'blame culture' the NHS errs towards the latter. The second potential barrier related to the existence and use of reporting systems. They noted the limitations of the many systems extant in the NHS at the time. In particular, they identified the lack of a single focal point for information on adverse events and concluded that the information available is under-exploited as a learning resource. Finally, the Expert Group highlighted four key requirements:

- Unified mechanisms for reporting and analysis when things go wrong;
- A more open culture, in which errors or service failures can be reported and discussed;
- Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;
- A wider appreciation of the value of the system approach in preventing, analysing and learning from errors.

In the above review of current research on patient safety in the US conducted by Cooper (2001)the author also sought to understand issues in respect of behaviour towards and funding for initiatives and research on patient safety in organisations. Two questions that are of relevance here are:

1. How does patient safety fit within the organisation's mission? and
2. What is the organisation's attitude towards funding patient safety projects now and in the future?

He found that most organisations viewed patient safety and the reduction of medical error as integral parts of their strategy to improve the quality of care; stating that "patient safety and quality improvement are complementary activities with great potential for synergy" (p22). He also investigated the existence of processes to enable organisations to track links between, for example, research findings or information disseminated, and changes in practice. Finally, he identified barriers to developing research and implementing findings across organisations. These included the complexity and fragmentation of Healthcare systems, a culture of blame, the lack of clear definitions and nomenclature, and the lack of priority of patient safety.

The Department of Health Report, *Building a safer NHS for patients* (Department of Health 2001) detailed the implementation of the earlier report. Six key steps, *inter alia*, were identified:

- Establishing agreed definitions of adverse events and near misses for the logging and reporting within the NHS, with the issuing of detailed guidance;
- Formalising a minimum data set;
- Producing a standardised format of reporting;
- Building expertise within the NHS in root cause analysis;
- Ensuring that information from all other adverse event reporting systems are fed into the new system;
- Promoting a culture of reporting and patient safety with NHS organisations, building on the clinical governance initiative.

One important initiative coming out of the implementation plan was the establishment of the safety alert broadcast system (SABS), a process for:

- Bringing together the alerts identified by the NPSA, NHS Estates and the MHRA;
- Compiling alerts that are focused, clear to understand and prioritised;
- Issuing alerts through a single mechanism;
- Receiving alerts across the NHS through a structured and common process;
- Ensuring that organisations across the NHS have received the alerts and have a plan for dissemination and implementation, using electronic feedback;
- Ongoing feedback from individuals and organisations on the content and usefulness of alerts;
- Monitoring the implementation of alerts.

The structures put in place for the implementation of the alerts by the SABS notification process and the response and monitoring process by trusts themselves and SHAs, in part ensure that many of the features identified are (in theory) in place, and that compliance levels should be improved. However, factors influencing likelihood of implementation, as identified in interviews at trusts, included the trust culture, locality decisions such as who has responsibility and whether this is seen as a priority, the systems in place, funding, and most importantly, clinician buy-in. It is likely that these factors will also exist in the adoption and implementation of alerts.

1.3 BACKGROUND TO SABS

The safety alert broadcast system (SABS) is an electronic system developed by the UK Department of Health to disseminate four distinct types of risk alerts to the NHS: alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) which issues notices about actual and possible risks in medical and scientific equipment; from the National Patient Safety Agency (NPSA), which requires organizations to reduce risks to patients and staff by the design and introduction of safer ways of working; from the Department of Health's Estates and Facilities Division (DHEF), which warns of defective non-medical equipment and the risks inherent in the physical environment, and from the Department of Health which has issued two alerts.. Each alert is categorized into for information only, for action and for urgent action. On the front piece of each alert, dates are given for trusts to:

- Initiate action;
- Complete action.

Trusts have to respond to the SABS system by acknowledging receipt of the alert and hence indicating action has commenced, and that action has been completed. Trusts can also indicate that an alert is not relevant for their organization, in which case action is not required.

The aim of the SABS system is to bring the different types of alert together into one electronic system and to streamline the way in which the alerts are issued. For the first time, the system would also require Trusts to provide feedback to the Patient Safety Team in the Department of Health about the relevance of the alert to the organization, the action taken and the date of the completion of action. SABS was launched in April 2004.

1.4 OVERVIEW OF SABS PROCESS

1.4.1 Summary of Process

Diagrams 1.1 and 1.2 give an overview of the:

- Process for drawing up an alert within the originating bodies;

- Process for disseminating the alerts.

These are discussed in more detail overleaf.

Diagram 1.1: From incident report to safety alert (Diagram from DH)

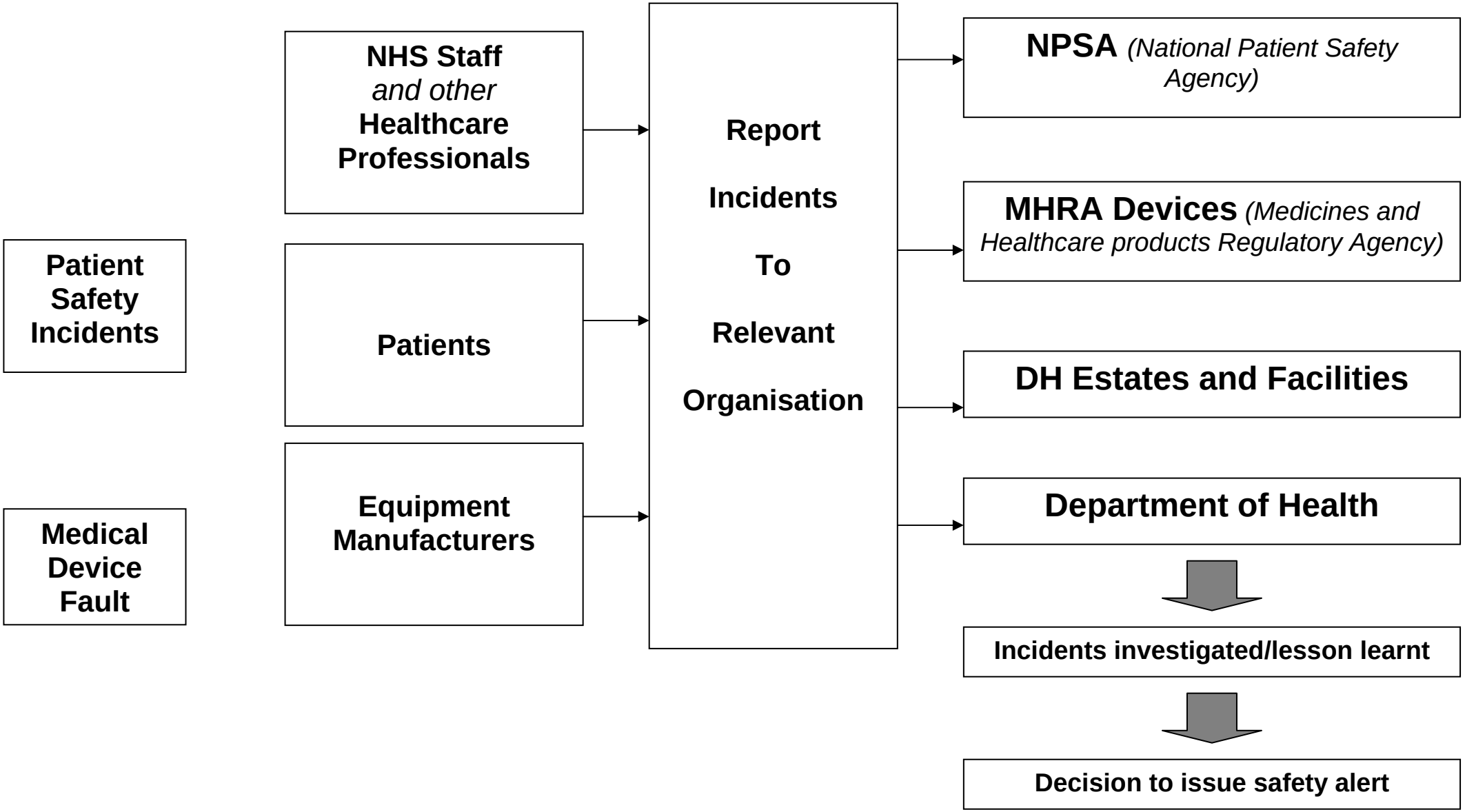
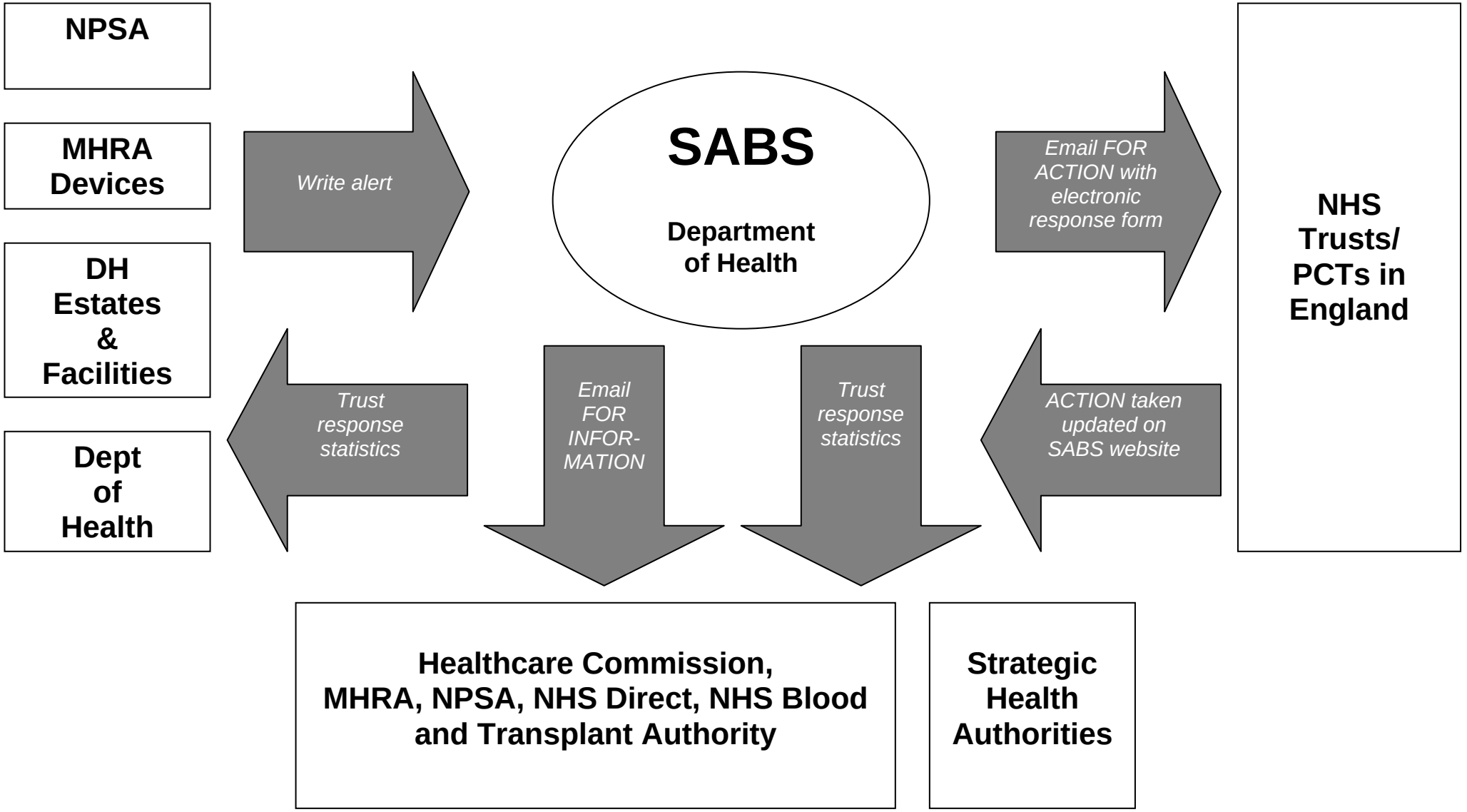


Diagram 1.2: Issuing a safety alert – gathering feedback on action (Diagram from DH)



1.4.2 Drawing Up an Alert within an Originating Body

The approaches adopted by the three main originating bodies (namely, DHEF, MHRA and NPSA) are broadly similar, although the identification of areas of concern for which an investigation is carried and thence an alert issued may vary. All originating bodies receive information from manufacturers, and also from trusts in the NHS. Trusts may report problems through their local risk systems and via the National Reporting and Learning System . Calls are also made to the NHS requesting information about problems. Other data sources include the NHS Litigation Authority, medical defence organisations, the Healthcare Commission and the general public. The originating bodies themselves are moving to sharing information and working closer together on standardising approaches and ensuring that the most appropriate body is undertaking the investigation. For example, many incidents are investigated by the MHRA which could equally be investigated by the DHEF, for example equipment, furniture and fittings.

The decision as to whether a problem area warrants further investigation is based on algorithms taking into account, for example, the level of risk, the likely extent of the risk, whether the problem is urgent, and whether information is available. Manufacturers may be asked to investigate problems, and the originating bodies have their own teams of investigators who will also undertake investigations, which may be rapid response or in-depth. The originating bodies in the UK share information with other similar bodies on an international basis. Solutions to problems may take time to develop as they are likely to involve front line staff, patients and carers, as well as the manufacturer.

Table 1.1, taken from the MHRA Devices Bulletin of Adverse Incident Reports for 2005 gives an indication of the nature of incidents and problems, their frequency and the responses.

Table 1.1: MHRA adverse incidents

Description of reports or action taken	**Number of reports**	**Number of reports %**
Were reported as involving a fatality	222	2.8%
Were reported as involving a serious injury (including implant or pacemaker revision)	1,331	16.9
Prompted in-depth MHRA investigations	2,075	26.4
Were investigated by manufacturers under MHRA supervision	2,255	28.7
Did not require immediate MHRA action, but were entered onto a database enabling trend monitoring and pattern detection	1,931	24.6
Were reports of incidents similar to those already known to the Agency	933	11.9
Were from secondary report sources, duplicating existing reports	410	5.2
Did not relate to medical devices	167	2.1
Were investigated by other organizations and their conclusion made available to the MHRA	42	0.5

Taken from MHRA (2006) Device Bulletin Adverse Incident Reports 2005 DB2006(02) London :MHRA

Action taken, as indicated in the report, included:

- 72 safety warnings were issued;
- 77 notifications were shared with authorities in EU member states;
- 589 manufacturer's field safety corrective actions;
- 232 other manufacturer's field actions;
- 455 cases requiring the provision of advice on safer device use or improved staff training;
- 635 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

Thus, originating bodies may issue a number of responses of which patient safety alerts which are disseminated through the SABS system are only a proportion. Conversely, at the time at which this study was undertaken, the NPSA issued three distinct colour-coded types of publication all of which were distributed to the NHS via SABS: safer practice notices, patient safety information and safety alerts.

1.4.3 Process for Disseminating Alerts

All originating bodies send their alerts to the Patient Safety Team (PST) at the DH for onward issue through SABS. Apart from the NPSA with whom the PST may jointly sponsor alerts, originating bodies will entirely decide on the content of a proposed alert. Therefore, the PST may comment on the completed alert submitted to them in respect of, for example, length, presentation and content. The DH Gateway process ensures that the alert is appropriate for dissemination to the NHS, and that messages in the alerts are in no way contradicting current or planned guidance. Alerts are thence issued through the SABS system to the SLOs in trusts, who initially acknowledge receipt, and then initiate action within their trusts for relevant alerts. Action commenced and action completed is communicated to the PST for recording on the electronic SABS database. SABS allows trusts to record the action they are taking in response to alerts through filling in an electronic response form and, if relevant, updating its status until action is completed. This feedback is intended as a means by which Trusts can track their progress, and that SHAs and bodies such as the Healthcare Commission can check that they are complying with safety guidance.

1.4.4 Summary

Although we have interviewed individuals in the originating bodies in order to inform the research study, the focus of our study is on the effectiveness and impact of the SABS system as a method of disseminating patient alerts. Nonetheless during our study, we have collected information about the views of individuals in trusts on the alerts themselves, and we have commented on ways in which improvements to the alerts may lead to an improvement in the processes and hence impact of the alerts.

1.5 STRUCTURE OF THIS REPORT

We have structured this report to reflect the process of collecting and analysing the resulting data. We have therefore broken down the final report into four main sections:

- Section A, which comprises the introductory sections of which this is part, and a section on research design and methodology for the study;
- Section B, which comprises three parts and describes the analysis of the high-level data collected nationally
- Section C, which presents the evidence from site visits to forty one participating organisations on the implementation and outcomes for the tracker alerts
- Section D, in which we present a discussion of our findings with a series of recommendations.

This report also contains two short appendices, the first giving the membership of the Project Steering Group, the second providing a summary of the tracker alerts. We have also provided as a separate document, a technical appendix comprising all research tools, questionnaires and interview schedules

Section 2: Study Design and Methodology

2.1 OVERVIEW

The study design and methodology has been informed by two previous national studies carried out by the present research team. One evaluated the implementation of NICE guidance (Sheldon et al, 2004) and one the implementation of the NPSA guidance on potassium chloride solution (Lankshear et al, 2005).

There are four steps in the process to be studied:

- Receipt of the alert;
- Dissemination;
- Implementation;
- Monitoring.

The research comprises a two-phase study:

- A high level study;
- An in-depth study of up to eleven alerts.

2.2 HIGH LEVEL STUDY

The high level study investigates the dissemination and monitoring processes adopted by trusts and monitoring processes undertaken by Strategic Health Authorities. It comprised three elements:

- Interviews with key stakeholders from the issuing bodies and from the Patient Safety Team at the DH. The purpose of the interviews was to inform the research and the research tools;
- A survey of SABS Liaison Officers in Trusts and PCTs;
- Telephone interviews with those in SHAs responsible for actioning and monitoring the performance of Trusts in respect of SABS.

We also examined data derived from the SABS reporting system itself.

2.3 IN DEPTH STUDY

2.3.1 Site Visits

The research team made site visits to twenty acute trusts and fifteen PCTs both selected by randomised samples and stratified by geographic location, and by size (beds for acute trusts and population for PCTs) and to a random sample of four ambulance and two mental health trusts Within the trusts we interviewed key staff about the management, reception, dissemination and implementation of alerts, and we examined evidence of the implementation of eleven tracker alerts, not all of which were relevant to every organisation. We also undertook an audit of staff awareness and sought evidence of implementation.

2.3.2 Selection of Alerts

We selected the alerts using a typology that ensured that alerts covered all originating bodies, categories of product (e.g. drugs and devices), and applied to a variety of organisations. Following piloting, an additional alert was included as being more relevant to the ambulance trusts, and a second that was more relevant to mental health trusts. The alerts chosen are shown in Table 2.1.

Table 2.1 Alerts selected for in depth study

Alert	Originating Body	Action	Date of issue	Reference number
Needle free intravascular connectors	MHRA medical device alert	Action	17th May 2005	MDA/2005/030
Protecting people with allergy associated with latex	NPSA	Action	26th May 2005	NPSA/2005/8
Reducing the harm caused by oral methotrexate	NPSA	Action	29th July 2004	Patient Safety Alert 03
Safe delivery of radiotherapy	DH	Action	23rd December 2004	None
Reduction of risks associated with mobile food trolleys	DH Estates and Facilities	Action	17th August 2005	DH (2005) 11
Reduction of risk associated with problems with implantable cardioverter defibrillators (ICDs)	MHRA medical device alert	Action and updates	Multiple in 2005 & 2006	Numerous (10)
Reduction of harm caused by misplaced nasogastric feeding tubes	NPSA	Immediate action	21st February 2005	Patient Safety Alert 05
Alcohol based hand rub	DH Estates and Facilities	Action	16th June 2005	NHSE (2005) 07
Universal hospital supplies of Guedel airways	MHRA medical device alert	Immediate action	3rd May 2006	MDA/2006/026
Electrically operated beds	MHRA Medical device alert	Action	23rd August 2004	MDA/2004/042
Shower heads	DH Estates and Facilities	Immediate action	25th July 2006	DH (2006) 05

2.3.3 Selection of Trusts

2.3.3.1 Selection of acute trusts

We drew a stratified sample of 40 acute trusts, the criteria being size (small, medium and large according to bed numbers), and geographical location. After follow-up by letter to non-responding trusts, we drew a further sample of 10 trusts. This second sample was purposive in that we selected randomly from trusts that undertook specific procedures under-represented in the initial group of participating trusts. We successfully recruited 20 trusts And table 2.2 shows their number by criteria for selection.

Table 2.2 Selection of acute trusts

Size: no of beds	No of trusts	%	No in sample	
			Planned	Actual
<500 beds	43	24.9%	5	7
500-999 beds	74	42.8%	9	8
1000+ beds	56	32.4%	6	5
Total	**173**	**100.0%**	**20**	**20**

2.3.3.2 Selection of PCTs

A stratified sample of 30 PCTs was drawn, the criteria being size (small, medium, large and very large according to population), and geographical location. After follow-up by letter to non-responding trusts, we drew a further random sample of 10 PCTs. We successfully recruited 15 PCTs which reflected the criteria selected, including one care trust and one provider PCT, in an area in which the commissioning is being undertaken by another separate organisation. However, due to the re-organisations and mergers of PCTs taking place during the course of the study, the criterion of size of PCT became redundant. Additionally, in some PCTs, due to management re-organisations, we could only access information from one locality (the original PCT selected), whilst in others, we were able to gain a picture of the whole PCT. Table 2.3 shows the number of trusts by original criteria for selection.

Table 2.3 Selection of PCTs

Size: population	No of trusts	% of PCTs by population	No in sample	
			Planned	Actual
<100k	42	14.1%	2	4
100-149k	99	33.2%	5	2
150-199k	84	28.2%	4	3
200+	73	24.5%	4	8
Total	**298**	**100%**	**15**	**15**

2.3.3.3 Selection of ambulance and mental health trusts

We selected ambulance and mental health trusts by random sample only. We wrote to six ambulance trusts, of which four indicated their willingness to participate, and to four mental health trusts, of which two indicated their willingness to participate.

2.3.4 Recruitment of Trusts

We approached all organisations by means of a letter to the chief executive enclosing a one page briefing sheet describing the study. We asked the chief executive to return a form indicating approval in principle and giving us the name of a contact person with whom further arrangements would be made.

Trusts that agreed to participate did so with enthusiasm. Most were quietly confident about their procedures and welcomed the audit opportunity. We pay tribute to the significant investment of time and effort required to organise and facilitate the visits.

2.3.5 Organisation of the Visit

On receipt of a positive response from the chief executive, researchers contacted the person named as a contact, and sent them the briefing sheet and the MREC letter giving the view that the study was classified as audit. Trusts used the documentation that we provided for research governance purposes.

The process of arranging a PCT visit was more time-consuming than was the case for acute trusts, as all PCTs required the research team to make contact with the individual responsible for research governance, frequently located in another organisation. All gave clearance for the study to proceed without further processes, but identifying and making contact with these individuals was the cause of some delay. Two of the original ten acute trusts and one of the PCT respondents withdrew after research governance clearance was given and we began to discuss the visit in detail.

The site visits were either arranged by telephone or via a pre-site visit in conjunction with the named contact. A typical visit to an acute trust, dependent on size of trust, range of services and number of sites took between 2-3 days for two researchers, a PCT visit and a mental health trust visit took 1-2 days for one researcher, and an ambulance trust visit normally took one researcher one day. Occasionally, we had to undertake telephone interviews if key individuals were not available for interview on the day of the site visit.

Additionally, in each PCT, we interviewed by telephone up to eight practice managers from a stratified sample of GP practices, selected according to practice population, or in the event that this data was not available, by number of GPs working in a practice. We wrote to the practice manager of each selected GP practice, inviting them to participate in a short telephone interview. We also provided information about the study. Telephone contact was made shortly afterwards. In the event of a practice not wishing to participate we wrote to a reserve practice. We also ceased follow up after three failed attempts to arrange an interview with the practice manager or nominated deputy, and selected a reserve practice.

2.3.6 Data Collection

All interviews were undertaken using structured questionnaires. Questionnaires allowed for the ticking of boxes and free text comments, the intention being to acquire specific recordable and quantifiable information but also to allow respondents to explain their particular context, structure and views. The recording instruments allowed for the recording of responses to open questions and volunteered information. All data from questionnaires were input to linked access databases designed for the study, with a database for each category of interview, and were exported to SPSS (version 15) for statistical analysis.

2.3.7 Acute Site Visits

Table 2.4 shows whom we interviewed in acute trusts (where relevant) about the management of alerts in general and the implementation of our tracker alerts. 393 interviews were undertaken in total across all of our acute trust site visits.

For specified alerts we collected evidence of compliance by visiting up to 10 relevant wards to conduct brief (15-20 minute) structured on-site interviews with one front-line member of staff in each area (usually the ward sister or nurse in charge). We also audited the availability of policy documents and obtained evidence of implementation of alerts from an audit of equipment and documentation.

Table 2.4 Interviews undertaken in acute trusts

Staff Group	No of interviews
SABS Liaison officers	20
Senior managers	50
Chief pharmacist	19
Consultant rheumatologist/nurse specialist	12
Superintendent in charge of radiotherapy/departmental or radiotherapy services manager	5
Consultant cardiologist/senior cardiac physiologist/cardiac specialist nurse or technician	10
Director of facilities	18
Purchasing manager	20
Senior electrician	9
Porters	19
Ward managers	170
Generic interviews, e.g. infection control team members	41
Total interviews undertaken in acute trusts	393

170 ward interviews and audits were undertaken across the acute trusts. A wide variety of clinical areas were visited including acute medicine, A&E, cardiology, care of the elderly, burns, children's, day case units, orthopaedic, gynaecology, obstetrics, SCBU, haematology, renal, intensive care and theatres. Although trust contacts were given guidance regarding the range of areas that the researchers wished to visit for the interviews and audits, trusts chose the areas themselves ensuring that there was a broad range. The number of areas

visited in any one trust varied from 4 to 12. Not every interview was fully completed, for example due to problems with accessing the ward, the intervention of clinical issues, and insufficient time. We also conducted audits in pharmacies, cardiology departments and rheumatology out-patient departments.

2.3.8 PCT Site Visits

2.3.8.1 Context

The ongoing restructuring of PCTs delayed this phase of the study. All but two of the PCTs visited had been involved in merger and all but one was currently engaged in internal re-structuring. This resulted in the need for considerable negotiation around the people to whom we should speak. We were frequently asked if we wanted to speak to the person who was the nurse adviser/risk manager on the previous week or the one who was taking up post in the week in which the conversation took place. As the study was retrospective, we tried to speak to the individual with a memory of how the alerts had been handled, but corporate memory in many PCTs was limited.

2.3.8.2 Overview of site visits

We undertook site visits at 15 PCTs. Table 2.5 shows the total number of people interviewed by staff grouping. It should be noted that we took the decision at the outset not to interview staff from any PCT community hospitals, but to concentrate on community nursing staff.

Table 2.5 Interviews undertaken in PCTs

Staff group	No of interviews undertaken
SABS liaison officer	13
Senior managers	30
PEC Chair/ medical director	19
Community nurse managers	29
PCT pharmacy advisers	14
Community nurses	63
PCT IT advisers	3
Total face to face interviews undertaken in PCTs	171

Additionally, we undertook 15 equipment audits, and 95 practice manager telephone interviews giving a total of 171 face to face interviews and 95 telephone interviews.

2.3.9 Ambulance and Mental Health Trusts

2.3.9.1 Mental health trusts

Table 2.6 shows whom we interviewed in the two mental trusts

Table 2.6 Interviews undertaken in mental health trusts

Staff group	No of interviews undertaken
SABS liaison officer	2
Senior managers	7
Chief pharmacist	1
Purchasing Manager	2
Director of Facilities	2
Senior electrician	1
Porters	1
Ward managers	11
Generic interviews	2
Total interviews undertaken in mental health trusts	29

2.3.9.2 Ambulance trusts

Table 2.7 shows whom we interviewed in the four ambulance trusts.

Table 2.7 Interviews undertaken in ambulance trusts

Staff group	No of interviews undertaken
SABS Liaison Officer	4
Senior manager	4
Purchasing manager	2
Ambulance staff, including team leaders or PMTs in up to 6 ambulance stations	22
Total interviews undertaken in ambulance trusts	32

We visited 22 separate ambulance stations, at all times accompanied by a member of the trust staff. On arrival at many ambulance stations, no staff were present as the ambulances and crews were out on a journey. In these cases, it was not possible to interview staff, but it was possible to examine policies and procedures and documentation at the stations and examine stock rooms for equipment and supplies. We also examined the inside of a few ambulances, which were deemed representative of the whole of the ambulance fleet for a particular trust. The number of stations per trust visited is shown in Table 2.8.

Table 2.8 Number of stations visited per trust

Ambulance trust	Number of stations visited
Trust A	5
Trust B	8
Trust C	3
Trust D	6

2.3.10 Audits

2.3.10.1 Overview

We audited availability of policy documents and obtained evidence of implementation of alerts from audits of equipment.

2.3.10.2 Latex products

We undertook audits of latex products on acute wards, in health centres and clinics and in ambulance stations. We had asked for copies of policy documents from senior managers, but on wards and in clinics and health centres also asked to see policies. This was to determine:

- Whether the ward had access to a copy of the policy;
- Whether the policy accessed by the ward was the same as that offered by managers.

We noted the date of the policy and took a copy of the latex allergy policy and of the nasogastric tube policy from each trust.

In respect of the latex allergy alert, we asked to see latex-free versions of the following equipment on each of the ten wards visited. Box 2.1 shows the extent of the audits.

Box 2.1: Audits of latex products

Respiratory Equipment: Airways; O_2 masks
IV and Feeding Tubes: Nasogastric tubes; IV lines; Dextrose 5% IV fluid;
Monitoring and Observation Equipment: Gloves; BP cuffs; Resuscitation equipment;
Other Equipment: Adhesives; Mattresses.

2.3.10.3 Nasogastric tubes

We undertook audits on acute wards and in health centres and clinics. Nasogastric tubes were not used in any of the ambulance trusts visited and therefore no audits were undertaken in these organisations. We also asked to see pH paper, and determined whether the pH result was recorded on patient notes before feeds took place.

2.3.10.4 Needle-free intravascular connectors

We undertook audits on acute wards and in health centres and clinics. We asked to view the instructions for use, and determined whether the date and time of insertion was recorded on the tube or on patient charts..

2.3.10.5 Methotrexate

We asked to view the methotrexate 2.5 and 10 mg tablets within pharmacies.

2.3.10.6 ICDs

We examined ICD recall processes in acute trusts where relevant.

2.3.10.7 Mobile food trolleys

We examined any mobile food trolleys that we observed on wards or in corridors in acute or mental health trusts.

2.3.10.8 Alcohol based hand rubs

We reviewed the availability of alcohol based hand rubs in all acute wards, in ambulance stations and on a sample of ambulances, and on wards in mental health trusts. We also assessed the volume and the location of dispensers.

2.3.10.9 Shower heads

We examined shower heads which could act as ligature points in one mental health trust.

2.3.10.10 Guedel airways

We reviewed the usage of Guedel Airways in ambulance station equipment storage rooms.

2.4 2.4 LIMITATIONS OF THE STUDY

Despite undertaking a robust study, we recognise that by the nature of the methodology employed, the study has a number of limitations.

Firstly, all of the trusts agreed to participate and represented about one third of the organisations approached. It would be reasonable to assume that there was some degree of self-selection, which might imply that our results were biased. However, we do not believe that this was the case since the evidence that we collected indicated variable quality of process and outcomes both in and across all trusts including those that believed they had good systems. Some Trusts explicitly chose to participate in our study precisely because they did not feel that their systems and processes were very good, and believed our study would help to highlight inadequacies and the need for improved processes. We also

discovered that other organisations that believed that their systems were very good had misplaced confidence in them.

Secondly, all of the trusts knew that we were visiting and on which alerts we were focusing. In a few trusts there was evidence of senior managers having been briefed in advance of our visit. Occasionally too, respondents told us that they had just received an alert within the weeks preceding the visit, despite these being published years before. We believe that our routine request for policies, memos and minutes gave us some insight into these events, even where staff did not tell us openly. The number of alerts involved precluded a full audit trail of all the alerts, which we have undertaken in other, less complex, studies

Thirdly, the briefing sheet sent to trusts prior to the visit listed the people we wished to interview, but also requested that we interview others who were instrumental in the implementation of the alert. These lists were inevitably passed to secretaries/administrative staff charged with setting up the interviews and few respondents other than those named had been identified. Wherever possible, we tried to arrange an interview during the visit, when the identity of key individuals became clear, but this could not always be arranged at short notice. One alert with which we had some problems in acute trusts was that relating to mobile heated food trolleys, where we asked to speak to porters or catering staff responsible for moving food trolleys and frequently met with one group only to find that they had no responsibility in this respect. The problem was found to be greater in PCTs, where the preliminary pre-visit discussions with key people were less likely to identify the person who had led the implementation of the alert. In some cases the person who took the lead was no longer employed within the organisation, having moved to another organisation during the recent PCT mergers.

Finally, due to the inevitable time lag between receiving funding for this study, commencing the study and undertaking site visits, the alerts aged, and memories became weaker. In the last months of the study, we were interviewing staff about alerts issued two years before.

Despite these limitations, we believe that the extensive and comprehensive nature of the data collected, plus the emergence of common themes across the range of methodologies adopted, points to a robust set of evidence collected and conclusions drawn.

SECTION B

Dissemination and Performance Management

Section 3: Processes for Dissemination of Alerts

3.1 OVERVIEW

We focused on the processes around the dissemination of alerts, both from the issuing body and within the trusts themselves. There are four aspects to this part of the study:

- We reviewed the numbers, types and processes for selection of topics, design of alerts and dissemination by the SABS process. We also interviewed key stakeholders from the originating bodies;
- We examined the SABS system from the perspective of providing information to trusts and SHAs as to their performance against dissemination and actioning of trusts;
- We undertook a survey of safety alert broadcast system liaison officers;
- We asked interviewees during our site visits about the process for dissemination of alerts.

Each of these aspects of the research is discussed below.

3.2 ALERTS FROM ORIGINATING BODIES

This section seeks to offer a contemporary picture of the pattern of publication of alerts through SABS and of Trust completion records. The alerts analysed are not those studied during the site visits and which are reported on in later sections. We analysed the alerts issued from October 2006 to June 2007 using the SABS database. Table 3.1 shows the analysis of these alerts.

Table 3.1 Alerts by issuing body

Issuing body	No issued	%
Department of Health: Estates and Facilities	12	12.5%
MHRA	73	76.0%
NPSA	10	10.4%
Department of Health	1	1.0%
Total	**96**	**100%**

Of the 10 issued by the NPSA, six were about safer medication practices, one about actioning radiological reports, and the remaining three were about colour coding cleaning materials, bed rails, and identification of blood. Of the 12 issued by the Department of Health: Estates and Facilities, four were about fixtures, fittings and design, three were about electrical fittings and design, three about engineering features, and the remaining two were

about helicopter landing areas and the process for dissemination of alerts and notification of problems by the DHEF. The majority of those issued by the MHRA are in respect of medical equipment, although alerts are also issued about beds, stretchers, bed rails and grabs, condoms and contact lens solutions. They also issued an alert describing the process dissemination of alerts and notification of problems. The one alert issued by the Department of Health was on security in medium secure psychiatric units. 94 alerts were for action, of which four were for information and three were updates, and 32 were for immediate action, of which one was for information and four were updates.

We also examined the date of issue as interviewees frequently made reference to several alerts arriving together. We found that on eight occasions during the first six months of 2007, between 3-5 alerts had been sent out together. Table 3.2 shows the frequency of date of issue indicating that alerts are rarely sent out on a Friday, and in fact none had been sent out on a Friday since early January 2007.

Table 3.2 Analysis of date of issue of alerts

Day of week	No issued	% of those issued
Monday	25	26.0%
Tuesday	15	15.6%
Wednesday	30	31.3%
Thursday	22	22.9%
Friday	4	4.2%
Total	**96**	**100%**

3.3 SABS AS A PROVIDER OF INFORMATION

Trusts and SHAs can view progress against implementation of alerts using the SABS system. Information is provided for each trust, linked by SHA, which gives information as to how many alerts are awaiting acknowledgement, how many alerts have issues not yet completed, and how many alerts are completed or have no action required.

We analysed data on the SABS system as at the 22nd June, 2007 at which time there was information available for 95 alerts. Below is the analysis of data on trust performance. We noted that the SABS system did not contain the names of all trusts, and also there were some extreme values being reported. For these values we do not know whether trusts are truly having delays in reporting and implementing alerts, or whether the SABS system is reporting an incorrect value. Whilst we have received favourable reports about the system as a mechanism for dissemination of alerts, we are aware of problems in the system on reporting, for example, whether the system correctly reflects the trusts electronic reporting and whether different parts of the system are showing different data. Trusts and SHAs have identified problems in the accuracy and timeliness of reflecting actions and updates actually undertaken by trusts within the system.

Table 3.3 shows the analysis that we undertook about the action on the 95 alerts issued between October 2006 and June 2007. This table indicates by each category of trust, the

total number of alerts across the categories of action, the average, shown as ( ), and the range for the categories of alerts.

Table 3.3 Action on alerts, by type of trust

Type of trust	Number of alerts by type of trust			
	Awaiting Acknowledgment	**Issues Not Yet Complete**	**Complete or No Action**	**Total alerts issued**
Acute & foundation	86 (0.87) range : 0-33	2748 (27.76) range: 7-69	6655 (67.22) range :26-88	95
PCT	96 (1.01) range: 0-24	2976 (31.33) range:1-92	6049 (63.67) Range:3-94	95
Mental health	43 (0.96) range 1-7	938 (20.84) range 3-43:	3335 (74.11) range:52-92	95
Ambulance	3 (0.6) range : 0-1)	55 (11) range: 1-21	420 (84) range 74-94	95

Even with some concerns around the data, the above analysis shows that there are significant variations across trusts in their responses to the SABS system, and also between categories of trusts where it appears that PCTs have the greatest problems in implementing alerts.

We recognise that the timescales for action complete on the patient alerts issued since October 2006 vary from between one month to one year, and therefore legitimately, many trusts have not completed action on alerts in advance of the completion date. Therefore, we analysed the actions on all alerts issued from October 2006 to the end of March 2007, excluding those with a timescale for completion later than the end of July 2007: 52 alerts were analysed. We would expect actions to be completed for these alerts, and yet, as shown in table 3.4, this is not the case.

Table 3.4 Action on alerts, for which action should be completed

Analysis	**Action completed or not required**	**Action on-going**	**Action not yet started**	**Total trusts**
Average (% of total issued)	360 (91.3%)	10 (2.6%)	24 (6.0%)	394
Range	257-364	0-97	7-57	

Our analysis indicates that on average only 91.3% of trusts have either completed action or declared that action is not required. On average for each of these alerts, 10 trusts still have action on-going, with a maximum number of 97, and an average of 24 trusts have not started action, with a maximum number of 57.

The alert for which 97 trusts still have action on-going (and 40 have declared action not yet started) is that issued by the NPSA in November 2006, entitled *Right Patient, Right Blood*,

for which action was to be completed by 1st May, 2007. The alert for which 57 trusts still had not started action (and 40 have declared action ongoing) is that issued by the DHEF, also in November 2006, entitled *Electrical Distribution Switchgear, 160a And 200/250a FCS Switches/Fuse Switches* , for which action was to be completed by 1st March, 2007. This latter alert was deemed to be for immediate action.

3.4 SURVEY OF SAFETY ALERT BROADCAST SYSTEM LIAISON OFFICERS

3.4.1 Overview

The Department of Health requires that there is one named person in each Trust, the SABS Liaison officer (SLO) who receives the alerts electronically, is responsible for disseminating them to the most appropriate people and who notifies the DH when the required action is taken. This aspect of the research investigates the roles and responsibilities of these key individuals, how they interpret their responsibilities and how they view the system. This section reports on a survey of SLOs in the NHS that we undertook between June and September 2006.

3.4.2 Methodology

A draft questionnaire was devised after careful consideration of the stated aims of the SABS system and a discussion with key individuals during the early face-to-face interviews being carried out at the time of its development. The survey tool was then piloted in an acute trust and a primary care trust (PCT) after which alterations were made. The resulting electronic questionnaire was sent to every trust SLO (n=561) using the DH Patient Safety Team database in June 2006. Subsequently, two reminders were issued to non-respondents and finally 343 completed questionnaires were returned, a response rate of 61%. Data from these questionnaires were entered into an access database, and analysis was undertaken in SPSS. Table 3.5 shows the breakdown by trust type.

Table 3.5: Responses by trust type

Trust type	Number sent	Number of returns	% of returns	Response rate
Acute	168	111	32.4%	66.1%
Ambulance	30	20	5.8%	66.7%
Mental health	67	36	10.5%	53.7%
Primary care trust	296	176	51.3%	59.5%
Total	**561**	**343**	**100%**	**61.1%**

3.4.2.1 SLO roles and responsibilities

SLO respondents reported 216 different job titles, most of which were in the field of risk management (59.5%), clinical governance (28%) or health and safety (25%). Titles of "others" included that of Director of Public Health (1), estates and facilities managers and clinical roles such as physiotherapist (1). 35% had a clinical background (including nursing and medical) whilst 34% reported being in administration or career management. 55% were also the trusts medical devices officer. The remainder included estates, scientific and

technical and education and training staff. In a question designed to indicate the level of seniority of the respondent, 48% stated that they or their line manager was on the Trust Board.

When asked about the proportion of time spent on this aspect of their role, 61% indicated that this was between 2 and 10%, 23% between 11 and 25%, with 7% reporting that they spent over 25% of their time on SABS. 26 respondents made comments in response to the open questions on their role and workload. Many of these suggested that the growth of the system had been unanticipated and that as a group they felt overworked, and some unsupported in what was a demanding role. One even suggested that an otherwise excellent system was being let down at Trust level because of lack of resources:

"This is an additional role added to an already fully utilised role and difficulty is experienced keeping pace with the system."

"(SABS is an) excellent system it is a lack of human resources at local level that make follow up and audit not possible."

Linked to the comments that the role was not a discrete one, there was some concern about the extent of its responsibilities. Some stressed the need for individual judgement in dissemination and felt that the responsibility assumed was not commensurate with their position in the organisation. It was evident that others clearly felt they should be doing more than merely administering the system. Two mentioned raising awareness amongst colleagues, and others discussed the need to audit implementation:

"Have some concerns as to the level of responsibility/authority I have as an individual in making decisions on behalf of the Trust."

3.4.3 Dissemination of Alerts

Six questions requested information about the dissemination of the alerts in the organisation. In response, 223 (65%) respondents stated that their organisation had a formal policy or procedure for the dissemination of patient alerts, whilst 41 (12%) indicated that this was in draft format and 75 (22%) had no formal policy to which to work.

The majority of SLOs who responded distributed the alerts according to combinations of personal knowledge of the organisation (199 - 58%) and either local lists (117 - 34%) or according to the alert (99 - 29%). In response to the question on independent scrutiny of the SLOs' decisions regarding the relevance of the alert, or the distribution list, 75 (22%) indicated that there was independent scrutiny via a manager, 69 (20%) via a committee, and 144 (42%) indicated there was no independent scrutiny. The 'other' means, indicated by 51 (15%) mostly included variants on cross checking with specific others.

244 (71%) respondents indicated that they disseminated only those alerts deemed relevant to their organisation, whilst 96 (28%) disseminated all alerts. From the open text responses it

was clear that those with a clinical background felt that they had an advantage in judging where to send the alerts:

"As a clinician … disseminating the SABS information is easier for me than it would be for the non-clinician as I am able to judge who to send each alert to."

"My clinical nursing background enables me to determine target areas for distribution of alert in the Trust especially when it comes to actioning."

110 (32%) indicated that alerts were distributed electronically and 123 (36%) using a mixture of electronic and hard copy. Only 7 (2%) used hard copy only. Explanations and comments included need for faxes and hard copy for those on dispersed premises such as District Nurses, GPs, dentists and pharmacists. The majority indicated a preference for electronic circulation. Of those 183 (53%) respondents circulating hard copies, 159 (87%) indicated that they always photocopied the alert in its entirety.

3.4.4 Management and Audit of Alerts

Six questions requested information about auditing the implementation of alerts. 32% of respondents indicated that their organisation had never undertaken an audit, and 11% only once. As a result of addressing the same questions in interviews in a total of 40 NHS Trusts we later identified the potential for misinterpretation of this question. For some interview respondents, carrying out an audit of action meant auditing the receipt of responses on action from managers – i.e. an examination of the paper trail. It is likely then that the figure given overestimates the extent of audit of action taken.

9% of respondents (29) indicated that some alerts, although relevant to the organisation, had not been actioned. Reasons given for non compliance included disagreement with the stated risk or the proposed solution and costs of implementation:

"Wrist bands within mental health are a contentious issue. The need for better means for identification is recognised but alternative ways e.g. photographs are being considered. But agreement to bring in new practice takes time".

"Some of the early SABS alerts pertaining to estates are still open".

In response to a question asking about the required steps to be taken if no response was received, 76% stated that they would report this to a line manager (35%) or committee (41%). In the case of PCTs, one issue was the source of most of the comments:

"We do not chase independent contractors, due to capacity issues".

Finally, we asked how those responsible for implementation notify the SLO when action is complete. 192 (56%) respondents expected to be notified by email and 175 (51%) had designed a form (paper or electronic) which was to be completed by managers responsible for implementation.

3.5 ANALYSIS OF SABS POLICIES AND PROCEDURES

3.5.1 Methodology

SLOs were also asked to attach copies of their Trusts SABS policies and procedures when returning completed survey questionnaires. 110 (32%) trusts sent to us copies of their Trusts policies or procedures, which we analysed. From one trust we received a power point presentation on their Trust policy. Seven Trusts sent medical device policies of which 6 had no mention of the SABS system within them and two sent photocopies of a guide explaining how to use the SABS computer system.

Out of the 110 policies and procedures returned, 62 (56%) were sent from PCTS 40 (36%) from acute hospitals, and 8 from other trusts

3.5.2 Findings

70 (64%) of the 110 policies received were found to contain detailed background information that gave a general description of SABS, as well as an explanation of the process and a description of the role of the SABS liaison officer and a brief summary of the person or team responsible. Five trusts only sent single page flow charts, which appeared to be from power point presentations.

Only a small proportion of these policies identified the Executive Director with the lead for SABS, of which 10 were medical directors, eight directors of nursing, five directors of public health and eleven who had titles indicating responsibility for governance and standards, risk management, corporate development, performance or operations. A majority of the policies (59) identified the SLO as either clinical governance or risk managers. Nineteen of the remainder contained no further information or used the name of the individual without title.

63 policies (57%) included clear, well presented flow charts showing how information was to be cascaded that demonstrated the process from the receipt of an alert to the acknowledgement and action.

The policies received varied in both content and style. 36% of the policies included a well informed distribution list for cascading all alerts and some included this within their flow charts. Detailed policies explained how distribution would occur and identified who was responsible for taking action.

60 out of the 110 (55%) policies highlighted that monitoring SABS is an integral part of their system to ensure people respond as required. Reports are prepared and presented to specific committees, as shown in Table 3.6

Table 3.6: How the trusts monitor/audit SABS

No of Trusts	Method for monitoring or auditing SABS
25 (23%)	Report to the Clinical Governance Committee
24 (22%)	Report to the Risk Management Committee
2 (25)	Report to the Health and Safety Group
1 (1%)	Bi annual reporting to Risk and Environmental Management Committee
8 (7%)	Monitor via Internal and External Audits

However, we believe that not all committees review in depth the implementation of patient safety alerts as we have many examples of very brief reports or notes in minutes of meetings to say that the report was merely noted with little or no discussion

Finally, only, nine policies included their Strategic Health Authority as part of their monitoring process.

3.5.3 Discussion

Policies received vary in terms of style and content. Overall the majority of well written policies give brief descriptions of the SABS system and identify SABS liaison officer within their Trusts.

These policies tend to also explain the role of the SABS liaison officer and give easy to follow instruction regarding the process which also includes a written flow chart with simplistic information of how the process works and who is involved at various stages. Often dissemination lists were included and an explanation of the importance regarding acknowledging receipt of the alert is highlighted within the guidance.

Only a small proportion of the 49 Acute Trust policies and 25 out of the 62 Primary Care Trusts have written systems to nominate a deputy in the absence of the SABS liaison officer.

One of the primary care trusts used an incident decision tree to aid the process of deciding the most appropriate course of action re SABS whilst an other highlights what to do in the case of IT system failure. One of the PCTs discusses the need to acknowledge that not all PCT contractors have access to email or fax and therefore are unable to provide rapid feedback on action taken on alerts.

Only ten primary care trusts include a subsection regarding alerts sent to independent contractors within their policies of which one includes a report showing by contractor group the number of alerts sent out and highlight the contractors who have not responded.

3.5.4 Good Practice

The SABS website, accessed by trusts and SHAs with password protection, provides examples in the help and advice section, of policies, spreadsheets for management of alert dissemination and responses, and internal trust feedback mechanisms. This section also

provides guidance to trusts in implementing SABS at a local level, including a description of the roles and responsibilities of the SLO.

The two example policies included as good practice include sections on what is the SABS system with the name and contact details of their SLO, what is the process for disseminating an alert in a trust, and for feeding back responses and who are the responsible individuals at, for example, directorate or departmental levels for ensuring implementation of an alert, as well as a flowchart of the local process. We regard these as minimum standards for a local trust SABS policy, and would expect policies to also include the contact details of the SLO deputy, who in a trust has executive responsibility, and the processes for monitoring both dissemination and implementation of the alert. Policies for PCTs would normally also contain details of the notification of independent contracts.

3.5.5 Summary of Analysis of SABS Policies

The policies and procedures that we received varied in both style and content. The best were thorough and contained easy to follow guidance of the SABS process which often included a flowchart and a distribution list with contact details for the SLO. These also highlighted who would deputise in their SABS liaison officers' absence. Often their executive director was highlighted as taking the overall lead and responsibility of ensuring the adequate running of this process and the monitoring and audit of the system was also an important aspect of their policies. These trusts would report their SABS to their Clinical Governance Committees or Risk Management Committees. A small proportion of policies highlight the need for SLOs to be trained in SABS whilst some PCTs stated that SABS training is part of their Trusts induction of new staff. A minority of policies sent did not mention SABS at all. Out of the 62 PCT policies read, only 10 included a subsection regarding alerts sent to independent contractors and of these only one discussed the problem of PCT contractors who did not have access to email or fax. Thus, whilst most of the policies adhered to good practice, a significant minority did not. This should be of concern given that SABS as a process had been in place for more than two years at the time of our research, and a robust policy for the management of SABS at a local level in our view is a basic requirement.

3.6 EVIDENCE FROM SENIOR MANAGER AND SLO INTERVIEWS

3.6.1 Background

In total, we interviewed 91 senior managers (50 from acute trusts, 30 from PCTs, seven from mental health trusts and four from ambulance trusts) and 33 SABS liaison officers (20 from the acute settings and 13 from PCTs). The information in this section comes mainly from directors of nursing, medical directors, clinical governance directors and SLOs.

In describing their organisations, the respondents from acute trusts tended to present established roles and procedures for the management of SABS. However, many were planning changes to their clinical governance structure or to the identity of their clinical governance leads in the near future. It was clear that many clinical governance and risk departments had been the subject of financial pruning in the recent past. One example was in a 500 bed District General Hospital with a budget of £100m recovering successfully from a 10% deficit. The risk manager had recently lost secretarial support for operating the SABS process, administrative support for inputting data from adverse incident forms and a medical devices training officer – 50% of the staff of the department. Morale was predictably low.

All but two of the PCTs had been involved in merger and all but one was currently engaged in internal re-structuring. We found that we were only able to obtain information about that part of the PCT whose SLO or director of nursing (for example) had been appointed to the new organisation – any information about others having been apparently lost in the changes, especially where a previous SLO had left the organisation and whose files had been deleted. This resulted in inconsistent accounts from staff interviewed in the new PCTs. It was also difficult to discuss the committee structure around the management of alerts, again for the reason that these were in the process of development or revision. One respondent, an associate director of clinical governance and the clinical governance lead for the organisation, commented:

"*Quality is an early casualty of instability*."

The mental health trusts visited were complex organisations, covering large geographical areas (whole counties) and with buildings, in one case, spread over 61 sites. In one of these trusts, facilities management, procurement, maintenance, payroll and IT were all provided by a shared services organisation which also provided services to 3 PCTs (recently merged).

Ambulance trusts had particularly slim clinical governance and risk departments, typically consisting of one person and a PA/administrator.

3.6.2 Management of the SABS System

Designated SLOs are identified in all organisations, although we found that the SLO designation is used in an interesting variety of ways. Most SABS liaisons officers were also risk managers, clinical governance directors or health and safety managers. In some acute trusts the SLO is a senior member of the organisation – frequently a clinical governance or risk manager who has a secretary or administrator to manage the system but who is intimately involved in decisions about the designation of leads and dissemination. In others the administrator will be the named SLO yet key decisions are actually taken by a line manager. In still other trusts, the SLO, who may be an administrator, health and safety officer or a senior EBME staff member, works in a fairly isolated way, seeking advice from whoever he or she feels to be appropriate. In acute trusts 50% (10) of interviewees and 23% (3) of PCTs said that they or their line managers were on the Trust board. Two trusts (one acute and one mental health) reported on the use of the trust risk register for patient safety issues, including the alert on the replacement of bed curtain rails with collapsible versions.

Of the SLOs themselves, 60% (12) in the acute trusts and 54% (7) from the PCT trusts were also the medical devices liaison officers (MDLO) and some that were not the MDLO nonetheless sat on the medical devices group. In acute trusts, most were experienced in the role, only 15% (3) having recently take it over. In the PCTs, 23% (3) had only recently taken over this role. No interviewee was found to be in acting up capacity but 23% (3) had only recently taken over this role. As in the survey, the majority of SLOs interviewed [65% (13) of those from the acute trusts and 54% (7) from PCTs] were found to spend between 2 and 10% of their jobs on SABS. 15% (2) said they spent 51-75% of their time on SABS.

77% (10) of PCTs and 85% (17) of acute trusts were found to have a formal policy, procedure or protocol for the management of SABS alerts although most PCT policies predated the mergers. Some copies were seen and obtained during the interviews and some were found to be in draft form and copies later forwarded on. Those that did not have policies had rolled the system over from the old medical devices system, and these trusts tended to have more isolated and specialist SLOs.

We noted more of a 'hands-off' approach to alerts by senior managers in PCTs than was the case in most (but not all) acute Trusts. In one, it was felt to be the professional responsibility of community nurses to ensure that they complied with safety alerts and the view was expressed in one that managerial responsibility did not extend beyond dissemination. In another PCT, of the three senior people interviewed (clinical governance manager, inpatient services manager, PEC chair), none was aware of any of our 'tracker' safety alerts. These respondents were entirely confident in 'the system' in place in the PCT and felt that the strategic nature of their role was such that it was entirely inappropriate for them to be involved in the management of alerts. Where the clinical governance lead was a PEC chair, there was a consensus that they had no responsibility for the implementation of safety alerts, which were perceived to be the responsibility of the nursing staff. The only exception to this lack of ownership of alerts amongst PEC chairs was in relation to those alerts that dealt with medicines, such as the methotrexate alert, which most did remember featuring in committee discussions.. In five PCTs there appeared to be no one with a clinical background within the risk department. In most of the PCTs a decision on relevance to the PCT is taken by the SLO and if that person is unsure, others are consulted. In only two PCTs was there a systematic means of determining relevance, with named persons representing a wide spectrum of expertise being consulted on each occasion.

SLOs in PCTs were more likely than their acute trust counterparts to report problems in establishing a lead for the more complex alerts, latex allergy being quoted as one which lay dormant for some time and required a different lead to be appointed.

Neither of the mental health trusts visited had a policy although one did have a Medical Devices Management Policy to which the MHRA document *Reporting adverse incidents and disseminating medical device alerts* was appended. This document did not include any reference to alerts from the NPSA or DH Estates and Facilities.

All the ambulance trusts visited had clear processes for the receipt and dissemination of alerts, although one related to medical devices only. All ambulance trusts had clear lines of accountability through committees, and strict procedures for checking and withdrawing equipment.

3.6.3 3.6.3 Reception and Assessment of Relevance

Decisions about the relevance of an alert to acute trusts and PCTs are usually made by SLOs in discussion with selected available individuals. Medical directors, nurse directors, facilities managers, purchasing managers, pharmacists, health and safety officers and clinical governance leads were all mentioned as assisting in this initial screening process in acute trusts. For alerts involving the isolation, maintenance or withdrawal of equipment, it would be usual to involve the purchasing or supplies manager alone. In two acute trusts the alert was automatically replicated in the inboxes of a small group, comprising a senior nurse, pharmacist, EBME manager and estates manager, who together decide on relevance and one of whom identifies him or herself as the most appropriate person to action the alert.

Some PCT SLOs felt that if any doubt they would send out the alert for information only and others explained how matrons or locality managers would receive alerts and distribute them accordingly if relevant to their areas.

In both mental health trusts, the SLO was a risk systems administrator or manager, who also dealt with data from the National Reporting and Learning System (NRLS). If unsure about the relevance of an alert, one SLO in a mental health trust reported that she would check with someone else but because she had been in the organisation for a long time she felt she knew the organisation well.

The ambulance trusts have mechanisms in place to ensure that the relevance is cross checked with a number of individuals before stating that they are not relevant. One ambulance trust had responsibility for out- of- hour's services, and therefore had to take account of alerts that would be relevant to GPs.

Again, in all organisations, whether the SLO had filtered the alert for relevance or not, middle managers pared down the numbers passed on to ward managers and team leaders. The latter then decided which of the alerts that had reached them were relevant to the team and distributed those to staff. Thus, alerts were subject to several levels of filtering through the organisation.

3.6.4 Dissemination

19 of 33 SLO respondents interviewed distributed alerts according to a pre-determined list as directed by trust protocol, policy or procedure. Nine said that they distribute to all named on the alert. 13 were found to distribute to selected people based on their own knowledge of the organisation and nine said they would distribute in the first instance to one lead person for a particular issuing agency. A majority have argued that alerts for directly managed services are best targeted to as few people as possible consistent with full implementation.

For alerts with a wide application, the alerts are passed to directorate or divisional managers, ambulance station managers or lead paramedics who are required to acknowledge receipt and respond with an account of action to be taken.

Electronic dissemination worked well at managerial level. 45 (90%) senior managers interviewed in acute trusts were satisfied that they were receiving all relevant patient safety alerts, and only one was not, although many said they did not know, or had to presume that they were receiving all relevant alerts. Three did state that they were aware of not having received an alert that they should have received. One specifically mentioned an alert on hip replacements:

"In December, the trust reported the fracture of two total hip replacements which had been put in by an overseas team of doctors who had used a prosthesis not normally used in the trust, but with which they were familiar. MHRA had not sent alert to trust (issued in the April) as they believed them to be non-users of the prosthesis."

16 (32%) senior managers told us that they received an alert within hours of publication, 17 (34%) within 2 days, 6 (12%) within a week, one within more than a week and four did not know. Qualifications to their responses included:

"Delay due to only checking the system weekly, not because the SLO is not sending it."

"So many that I don't open them - seems pretty quick."

"Would receive it in hours if it was flagged as being urgent. Sometimes it comes directly anyway, e.g. [alert on] methotrexate."

38 interviewees (76%) said that they did not believe there were ever delays of more than a week, although one believed there was, and four did not know. Reasons for delays were mostly attributed to annual leave.

At ward manager level however, only 34% received their alerts directly from the SLO, with 62% receiving them from other sources. 70 ward managers offered more information about the other routes and these included receiving them from named individuals in their trust, such as nursing administration, health and safety or infection control officers, notification in local nurses' or team leaders' meetings, trust briefings, or by reading alerts that are placed in folders on the wards. 68% of these respondents received their safety alert in electronic form and 31% in paper form. The remainder received alerts by fax or explained that they did not personally receive alerts but were told of them in meetings or saw details about them in other communications.

In PCTs, 25 (83%) senior managers reported that they regularly received alerts though the SABS system and only four did not. Four also received alerts from other external sources such as the CEO bulletin, from the PCT internal intranet system and from a colleague in risk management. 20 (67%) reported receiving their alert within 24 hours of publication and 2 (7%) within a week, others commented that it could be a week before seeing alerts since

they were frequently out of the office. 24 respondents (80%) believed that they were receiving all relevant alerts, whilst only two did not. Explanations included having a filtering process before or after they reach the senior manager. Only three were aware of not having received an alert that they should have received and one did not know. We were able to audit our tracker alerts in all but one PCT. In this, the system in use was only a year old and was pre-dated by a paper system in which no record of the tracker alerts was available.

PCTs use a variety of methods to distribute alerts as independent contractors are not all able to access electronic copies. Most 77% (10) distribute alerts electronically, 46% (6) used hard copies and 8% (1) reported using fax and post. In one area the interviewee explained that "*where recipients can't email back they respond in hard copy*". The named lead person and the locality managers were the key people within the delivery side of the organisation, who the SABS liaison officer expects to notify them that all action is complete.

As was found in acute trusts, the electronic system for dissemination in PCTs is only successful through the managerial grades of the organisation. There is a major problem with IT provision in community clinics, with eight staff sometimes sharing one computer. In fact, in one PCT, we found 22 staff in two clinics without any access to an operational computer at all. Most staff interviewed had not noted the time taken for the alerts to reach them, but two who had, reported that it took "a week or two." Booting times for PCs in clinics were very slow in the instances observed and one person reported that it had taken 30 minutes to print out one alert published recently. For this reason some community staff preferred the old paper system where alerts were received by fax. Those alerts that were deemed to be relevant to district nursing staff were usually mentioned at team meetings and staff asked to read the alert, which they were then expected to initial. It was reported by one team leader that work pressure made this unlikely.

In the mental health trusts visited the alerts are disseminated to relevant people only. For broad spectrum alerts such a ligature point removal will send to senior managers (clinical directors, director of nursing, general managers) for information and to team leaders for action. We were informed that Clinical Directors do complain about receiving alerts, which they believe have nothing to do with them. In one trust, the director of nursing, new in post, was unaware of the safety alert system and was not receiving alerts, including that on latex allergy. Most ward staff in mental health trusts were aware of relevant alerts although in one, the alert had been circulated in advance of the visit. In the other, there was evidence of contemporaneous action.

The clear and relatively simple hierarchies in ambulance trusts made dissemination simple although in some, the lack of IT infrastructure necessitated dissemination in paper form. Different ambulance trusts had different methods of disseminating alerts to their front line staff. One used an entirely paper system for disseminating the alert with an attached form for return to the SLO. Another issued the information contained in the alerts in the form of clinical practice circulars, which were held in blue folders at the ambulance stations. The folders, kept in obvious places, such as on the table in a staff rest room, were regularly updated. Ambulance crews knew of the system and were expected to review the information held in the folders on a regular basis. In other trusts and stations, the notices were pinned on

notice boards, or were issued via email. A total of 5 (23%) front line staff interviewed claimed never to have seen an alert at all.

3.6.5

3.6.5 Scrutiny of Decisions

72% of acute trust senior managers told us that there was a clear committee structure, involving clinical governance and clinical or risk management committees, through which the alerts for which they were responsible would be processed. However, interviewees told us:

"SABS has gone astray with restructuring but will be reviewed in January 2007."

"(SABS) has organised committee structure – starts at the Trust Board and is disseminated down to appropriate committee."

"Integrated governance group about to start to combine governance and risk management."

68% of these interviewees said that the relevant committee would consider all alerts, others that some alerts would go to specific committees, such as medicines management, or that committees would only consider those alerts that were relevant to the trust. 78% of respondents also said that they had an integrated risk committee, such as the clinical governance committee, a healthcare governance committee or a risk committee. Two interviewees told us that they were setting up such a committee.

On the other hand, only 37% of PCT senior managers and 52.6% of PEC chairs told us that relevant alerts were discussed at meetings they attended. Comments included:

"Occasionally at clinical governance meetings."

"They are received in general terms and not by specific alert, usually in report form quarterly."

"Discussed at Executive Board in old PCT – new structure being set up."

90% of PEC chairs and 77% of PCT senior managers told us that their PCT had an integrated risk committee, although many also qualified this by stating that their PCT is being restructured. One commented:

"Domination of financial risk puts discussion of clinical risk further down the agenda, squeezing the clinical aspects."

SLOs in eight trusts, informed us that someone other than their managers did independently scrutinise the decisions made regarding SABS. Some trusts highlighted the risk department or clinical governance or the audit department as the people who scrutinised this. One trust explained how alerts are taken to specific committees for scrutiny; 18 Trusts said that no independent scrutiny took place and felt that this was due to either lack of resources, or

simply that this was not seen as a priority. One comment made was "*It is not for the SABS Liaison officer to police."*

Whether committees are an effective means of ensuring that alerts are implemented is questionable. In one PCT, we obtained the minutes of the integrated healthcare governance subcommittee at which a list of the alerts issued during the period 1 May – 31 August 2005 was received. This list included four of the tracker alerts used in the present study: *protecting people with allergy associated with latex*, *correct placement of nasogastric feeding tubes, needle-free intra-vascular connectors* and the NHSE alert relating to *fire risk from alcohol based hand rub*. The entire record in the minutes is as follows:

"*A copy of the report showing the number of alerts received was circulated with the agenda. This was noted*."

There was no evidence of any discussion or of any identification of alerts relevant to the organisation or of any action intended or taken.

3.6.6 Action Complete

In both acute trusts and PCTs, SLOs had either developed electronic forms, which were sent out with the alerts and which recipients had to complete, or relied on responses to emails detailing action taken. A few SLOs had developed quite sophisticated databases which were completed by managers on line. 65% of interviewees told us that the process for notifying the SLO that action had been completed was via managers emailing the SLO, four that individual wards or department informed the SLO, three that they had another system and four did not know.

Action is normally understood to be complete when all managers to whom the alert was sent have responded stating either that the alert was irrelevant or that action has been taken, or alternatively, when corporate action such as the development of a policy is required, when that is developed. We were also told of processes within directorates or departments, or managed by the SLOs, for recording actions or monitoring responses.

However, in some PCTs, the action reported was intended action, rather than action complete. In one, in a process agreed with the SHA, notification of action taken was not required on all alerts. Instead, only a risk-assessed sample of alerts was followed up. Those alerts that were not to be audited were closed without notification of completion whilst those that were audited were followed up, managers being asked to confirm that the necessary action had been taken.

3.6.7 Audit of Alerts

Most SLOs interpreted questions on audit as the examination of a paper trail of responses. We came across just one example of an audit of action taken (i.e. evidence of change in processes or staff behaviour) in one acute trust.

One PCT had carried out an audit of action as part of their annual health check, the action being defined as a locality manager relaying the alert message to staff. In another we found two community nurse managers who had undertaken an audit of alert implementation in community nursing teams. However, the normal procedure was for managers to indicate that they had implemented the alert and no further checking was undertaken. Comments included the following:

"Not sure loop is closed and can't evidence it."

"We do have to respond saying what action has been taken."

"We have to send an action plan and send a report once you have actioned it."

One trust had an internal audit system which relied on cross checking the CEO bulletin against the work of the SLO. On receipt of the bulletin, the Director of Nursing's personal assistant would list the alerts that were listed and email the SLO to ensure that no alerts had been missed. This individual kept her own records of action taken by the risk department.

3.6.8 Performance Management

From the interviews with acute trust personnel, there was little evidence of SHA follow up but this may be due to prompt action by the trusts. We have encountered some evidence of monitoring and follow up by the DH (Deputy CMO) and NPSA where trusts have failed to close off alerts. Such contact was cited as an important element in alerting trusts to problems in the case of both the methotrexate and latex allergy alerts.

3.6.9 Summary

The profile of SLO roles appeared to suggest that our interview sample was broadly similar to the surveyed population. SLOs in acute trusts are more likely to be senior managers or be managed by a senior manager than is the case in PCTs, and there was evidence of more direct close involvement of senior managers in decision making and actioning in acute trusts.

Processes for making decisions on the relevance of alerts to the organisation are not always well set out and we have some concerns that these decisions and those on dissemination are not always adequately scrutinised. Most organisations had good systems for the distribution of SABS alerts to managers and to one lead person at ward and clinic level. The systems for sharing alerts amongst all ward and clinic staff, however, appear to be less well

developed. IT facilities and level of training in some PCTs and ambulance trusts are inadequate for this purpose.

The good distribution systems are matched by good response systems, but it should be noted that the level of management at which these responses are made is quite high. It is not unusual for a directorate manager to respond on behalf of many wards, without any systematic schedule of responses below this. Whilst audits of responses are not uncommon (ensuring that all who should respond have done so) we found little evidence of any audit of implementation of the more complex alerts at the level at which patient care is given. Occasional personal interventions by the CMO and NPSA to Chief Executives had resulted in prompt action on stalled alerts.

Section 4: Independent Contractors

4.1 INTRODUCTION

Evidence underpinning this section came from a number of sources. Firstly, SLOs were asked about the systems for disseminating alerts to PCTs. Secondly, we asked PEC chairs, medical directors, clinical governance managers and directors of nursing in PCTs about the responsibilities of the PCT in relation to independent contractors. Thirdly, in the course of their interviews, we also asked PEC chairs to respond to some questions from their perspective as GPs. Finally we carried out telephone interviews with practice managers.

4.2 DISSEMINATION OF ALERTS TO INDEPENDENT CONTRACTORS

Two of the SLOs interviewed played no part in the distribution of alerts to independent contractors, as this was the responsibility of a Primary Care Support Agency (PCSA), which typically provides services to a number of PCTs. The PCSA, not being a statutory body, does not receive SABS alerts directly but has them automatically forwarded from the box of the SLO in one of the PCTs. The PCSA is then responsible for forwarding the alerts to GP practices and other independent contractors (Pharmacists, opticians, dentists) in the area. Where this system was in place, we found no instance of a PCT asking for feedback from the PCSA about responses received from independent contractors. We also found other examples of similar arrangements where a support service arrangement would be in place in a PCT, but which was almost seen as independent from the main body of the PCT. In these instances we were not confident of the relatonship between the SLO and the management of the SABS process, and the dissemination and any follow up of action on alerts to independent contractors. Indeed, due to the management re-organisations ongoing during the period of our research, it was often problematic to ascertain relationships between different sections of a PCT or a merging PCT. Subsequent investigation of the number of PCSAs or similar organisations has proved difficult since there is no agreed list, nor is there a model for a PCSA in terms of the services provided or the location of the organisation.

Whether the responsibility for distribution lies with the PCT or a PCSA, alerts maybe distributed to GP surgeries by email, usually to practice managers although in some areas they are sent to GPs directly by email. Alerts may also be sent using hard copy or by fax to independent contractors. In only one PCT visited are alerts to GPs sent by fax and this will continue until the PCT receives the email addresses of three clinicians in each surgery, at which point the system of dissemination will change. In two other organisations visited, the Practice Nurse Development manager also sends out selected alerts to practice nurses for information. Dissemination to community pharmacists is by fax and three SLOs reported receiving regular complaints from pharmacists complaining that their fax machine had run out of paper due to the receipt of 10 page faxes. Alerts are sent to opticians and dentists by post. There is no receipt system.

An interview with one PCSA revealed that alerts are usually distributed to all recipients named on the alert named and if a risk assessment is required this is carried out by the PCT. Alerts are sent out by email to GPs who have been asked to access this email once a day. GPs are supposed to respond saying they have read the alert and that they have taken or will take action. However, we were told that despite the availability of this data, no one in any of the PCTs served by the PCSA had ever requested it.

Box 4.1: Case study: management of alerts in one PCSA

The PCSA uses a database to keep track of responses, recording: The alert number/CMO or SMS Reference; To whom it was sent; How it was sent; The date it was sent; Action underway deadline date; Action completed deadline date/two weeks response time for CMOs or SMS.
For each contractor response the PCSA recorded the following: The alert has been read and understood; The alert has been cascaded to relevant staff/contractors; If action is required, whether action has been or will be taken.

In a few areas, some GP practices were said to respond to alerts – 80% in one area, "a few" of whom would give action that would be taken. Several PCTs believe, based on anecdotal evidence, that many GPs automatically delete alerts without reading them.

4.3 PCT RESPONSIBILITIES

We asked senior managers and PEC Chairs/medical directors a series of questions about PCTs' responsibilities towards GP practices in respect of alerts. Tables 4.1 and 4.2 show the results of the analysis of their responses.

Table 4.1: The responsibilities of PCTs towards GP practices re SABS alerts

Responsibility	**Positive responses**	
	Senior managers	**PEC chairs /medical directors**
	No (%)	**No (%)**
Dissemination	19 (63.3%)	13 (68.4%)
Dissemination and signing off	7 (23.3%)	3 (15.8%)
Ensuring alerts are actioned	3 (10.0%)	3 (15.8%)
Unclear	0 (0.0%)	1 (5.3%)
Other	3 (10.0%)	3 (15.8%)
None	1 (3.3%)	0 (0.0%)

The responses shown in table 4.1 indicate that 63% of senior managers and 68% PEC chairs believe that their PCT has a responsibility for disseminating alerts, but only between 16-23% believe that the PCT has any responsibility for signing off the alert on behalf of practices, and only 16% or less that the PCT has any role in ensuring that alerts are actioned. Comments included:

"Not sure about responsibility re action for PCTs"

""With independent contractors it is more challenging. I am confident SABS liaison officer would disseminate them. PEC chair would have this in hand."

"We have to remind and encourage, but practices have their own responsibility. But if something untoward occurred we would have to take action – it would have to be after the event. QOF framework could be expanded to cover this. [It] may be clear, may not be understood"

Comments from senior managers included a few references to negative attitudes by GPs in respect of alerts, pointing out that *GPs 'feel bombarded by amount of stuff we send to them.'* 40% of senior managers and 32%PEC chairs interviewed in the PCTs told us that the attitude of practices is varied, some being less engaged than others. One commented:

"The PCT sends out lots of information. [The alerts are] part of a bundle of paperwork – it won't have such a high profile as the latest bunch of Trust results. If they get documents with attachments and pictures, they clog up their system".

Others thought that there was a lack of clarity and direction between SHAs and PCT in delivering messages as to their respective responsibilities. Comments from PEC chairs/medical directors reflect similar concerns, for example, one pointing out that:

"Most PCTs don't take this seriously because they are so busy working towards targets. My responsibility is to screen for relevance"

Less than 50% of senior managers and PEC chairs believe that the PCT has any responsibility to follow up GP practices, as shown in table 4.2, and between 16-27% do not know.

Table 4.2: Responsibilities of PCTs if GP practices fail to notify that SABS alerts implemented

Responsibility	**No of positive responses**	
	Senior managers	**PEC chairs /medical directors**
	No (%)	**No (%)**
Follow-up	12 (40.0%)	9 (47.4%)
None	2 (6.7%)	1 (5.3%)
Don't know	8 (26.7%)	3 (15.8%)

Senior managers confirmed that there is no check on whether implementation has happened or not, and one expressed some caution about the possibility of misinterpreting the returns from practices that did respond:

"Don't fully check if implemented. Trying to resolve via contract monitoring. Expect GPs to act on information given but realise that it is not good enough."

"No legal obligation but do request. One of the failings of the system as no mandatory response from them."

"Unsure if GPs just acknowledging as politeness or actually actioning."

One PEC chair, whilst acknowledging that it was difficult to enforce, claimed the PCT did make an effort through the clinical governance lead for the practice. Another stated that evidence of non-compliance would go on the risk register; whilst a third pointed out that the PCT took no interest in GP responses, to the extent of making no attempt to retrieve the information from the primary care support agency, which held it.

We did not specifically ask PCTs about the sending of alerts to private sector contractors such as Independent Sector Treatment Centres, but several volunteered the information that they do not communicate with contractors in this way.

4.4 RECEIPT OF ALERTS IN GP PRACTICES

Our interviews with practice managers gave us insights into how GP practices received and actioned alerts. 83% of those interviewed told us that they received their alerts from the PCT SLO, and only 9% received their alerts from other sources such as their professional organisation. 86% told us that they received their alert by email, 20% received them in paper form and 11% also said they received them in other forms including fax, hand-delivered 'blue bags' containing paper copies and by post.

42% of practice managers told us that they notify other staff in practices about safety alerts through email, but 58% notified them through paper distribution of alerts, and 16% notified staff verbally. Some of the managers who sent out copies of the alerts in paper form explained that within their practices "*GPs don't open emails so we photocopy alerts and put them into their pigeon holes*". Some of the practices had delegated the responsibility of filtering the alerts to a clinical member of staff, usually a nurse. One interviewee stated that only the nurses received alerts and had to action them. Only one practice explained that they operated a formal protocol in relation to SABS which included two delegated people filtering, one for clinical alerts and one for drug alerts. Often practice mangers highlighted that GPs did not read their emails and therefore safeguards were implemented such as nurses taking the responsibility of identifying whether alerts were relevant and if so addressing the issues.

Often alerts were found to be copied and placed in staff's pigeonholes or on the staff notice boards and in some areas communication books. In some practices alerts were circulated to all and then staff had to sign and date the copies once they had read the information regarding the alert. In this way the practice manager could ensure the information was being circulated to all the appropriate staff.

79% of practice managers used their own knowledge of the practice when to disseminating the information to appropriate staff but four felt it was not their responsibility to disseminate alerts to other staff in the practice. One respondent explained that if they were unsure if the alert was relevant then they would circulate it to all as a precaution. 7% sent alerts to all senior partners and one interviewee said that they only send those marked for GP attention. The majority of respondents were found to be filtering out alerts by passing alerts on to their clinical staff to identify if relevant to their practice before disseminating to others as the majority of practice managers did not have a clinical background.

86% of respondents stated that GPs were sent all the relevant alerts. Two interviewees did not send the alerts out to GPs but instead raised them at the practice meetings and four did not send out alerts to their GPs and again highlighted that not all GPs read their emails. One stated:

"They wouldn't look at them, if it is relevant we ask them".

One interviewee also left the alerts for the duty doctor to decide what action to take.

4.5 IMPLEMENTATION OF ALERTS IN GP PRACTICES

91% of practice managers had not experienced any problems with the implementation of any of the alerts. Out of the two respondents who had experienced problems with an alert on light fittings explained their light fittings were old and they did their best to make them safe.

Only 47% of practice managers told us that they notified the PCT or PCSA when all action is complete, and 40% told us they did not. Two comments indicated clearly that respondents were not aware that they should respond to the PCT:

"I didn't know we had to."

"*Are we supposed to?*"

In one PCT, half the interviewees claimed that they did respond and half said they did not. This PCT was later identified as one that had been created from the merger of two PCTs and therefore was still operating two systems. Some interviewees stated that they had not routinely responded in the past in the past but had recently been asked to do so. Other practice managers told us they always faxed a response whilst some explained that they only responded if the alert had been relevant to their practice. 62% of those who did notify the PCT did so by email, and 33% used other methods such as fax, post and telephone.

One manager explained that her PCT had asked her to but she never does and another said that there were too many to reply to them all.

4.6 4.6 ATTITUDES OF GP PRACTICES TOWARDS SABS

We asked both practice managers in their telephone interviews and PEC chairs in their face-to-face interviews about the attitudes of GP practices towards the receipt and implementation of alerts. Senior managers also volunteered their opinions during the course of our interviews with them.

Table 4.3 shows the analysis of the views of the practice managers on alerts.

Table 4.3: What is the view of the practice on alerts?

View of practice re alerts	No of Practice Managers	Percentage*
Vital	5	5.3%
Mostly helpful	21	22.1%
Too many	31	32.6%
Most not relevant	54	56.8%
Complete waste of time	2	2.1%
Other	12	12.6%
Don't know	1	1.1%
Total number of respondents	95	100%

* NB Percentages add up to more than 100% as respondents could give more than one response.

Only 22% believed that their practices thought that the alerts were mostly helpful, and 2% thought their practices saw them as a complete waste of time. Generally most practice managers felt that many of the alerts being sent to them were hospital based and thought that these should be filtered out prior to sending them in to general practice. One interviewee highlighted that when they were not relevant they were a complete waste of time but then explained that in those cases where alerts are relevant then they become vital. Some said 95% of alerts received are not relevant to their practice and another practice felt only 1 in 100 was applicable to them.

The practice manager interviewees were asked if they had experienced any difficulties in implementing any of these alerts, 5 (5.3%) said yes. Time was found to be one of the main problems experienced as alerts can be time consuming. One practice manager said that emails that were only sent to her were left in her email box until she returned back to work after any holiday or time off. This practice manager would prefer to receive faxed copies to ensure that alerts were not missed in her absence. This concern was raised by other managers interviewed. Some respondents felt that alerts should be sent to clinical staff and one concern raised was that due to the volume of inappropriate alerts received, relevant alerts can be missed and therefore alerts should be filtered.

21% of PEC chairs and 13% of PCT senior managers also told us that they believed GPs want better targeting of alerts. Examples of comments from senior managers included:

"GPs feel inundated and so many alerts are irrelevant to their practice"

"[they] *want alerts to be streamlined, e.g. pacemakers not relevant for general practice, but is relevant for information only and not always identified"*.

PEC chairs had the same views with one telling us:

"Many feel that risk management has become overly burdensome to point of idiocy, then specific alerts get ignored. Decontamination of chiropody equipment put up cost by 100%".

Two suggested that the subject line of an alert email be improved so that it is easier to identify the relevance and also the content be more focused. One commented that there was:

"Still an issue of cultural change to go though re patient safety especially in GP practices"

Section 5: Performance Management by Strategic Health Authorities

5.1 METHODOLOGY

In this section, we discuss the evidence collected from interviews undertaken with those who were deemed as having responsibility for SABS in all Strategic Health Authorities (SHAs).

We contacted all SHAs in England. A briefing note explaining the project with was sent out to all SHA Chief Executives. We asked each authority if they would like to participate in this research and if so to nominate the organisation's SABS lead person with their contact details. All interviews were then arranged and conducted via telephone at times suitable to the individual SABS leads.

Prior to each interview, a full explanation of the purpose of this research was given and the interviewees were informed that all information obtained would be anonymous. Each interview took on average 30 minutes to ask all of the questions and each interviewee was given the opportunity to add any additional comments regarding any aspect of the SABS system.

The interviews were semi structured, and all information collected was in the form of free text to specific questions. One interviewer undertook all interviews. The interview schedule is given at Appendix 3.

Fifteen people were interviewed by telephone from 9 out of the 10 SHAs contacted. Unfortunately despite considerable chasing up, we were unable to interview a further two individuals in two SHAs., and therefore were unable to collect information from this tenth SHA.. 21 questions were devised to obtain information on how the SHAs implement safety alerts and monitor the Trusts and PCT performance in relation to these alerts

5.2 INFORMATION ABOUT THE SABS LEADS

The findings have demonstrated that the majority of SABS leads are also the clinical governance managers or linked to public health. 13 out of the 15 people interviewed came from clinical backgrounds with the majority being nurses, although pharmacy, medicine, allied health professions and clinical scientists were also represented.

The majority of SABS leads are located in the public health directorate with the exception of two which sit under the nursing directorate. Out of the 15 people interviewed 13 said they spent 5% or less of their time on SABS and 2 said that they had delegated this work to their personal assistants.

Two interviewees did not see SABS as an important part of their role. One interviewee said that SABS "*was not on their radar*" and another said that they "*only look at SABS when it is time to prepare the Healthcare Commission Annual Health Check report*".

5.3 RECEIPT OF ALERTS

Eight out of the 15 people interviewed said that they did receive copies of the alerts. These were received in various ways such as from the chief executive bulletins or via the auto box alerts to prompts when the organisations have not acknowledged the alerts. However, it was noted that from the responses that copies of the alerts were only sent out to the SHA if the Trusts do not respond. Half of the interviewees stated that they had actually requested to receive copies of all alerts but this had never actually happened.

We understand that consultation carried out during the piloting of the SABs system in 2003 revealed that SHAs did not wish to receive alerts, and they would only copied into notifactions of failure to acknowledge alerts within 48 hours. This arrangement was reviewed in December 2006 and four of the then SLOs in the SHAs requested receipt of alerts. However, due to changes in staffing, it is likely that requirements have changed in SHAs.

12 people said they received alerts via email but one stated that they received theirs via fax from an NHS Direct office so alerts are obtained via the SABS website on a weekly basis in this area. One respondent did not know as the SABS lead was off on long term leave and had not realised that the role had been given to them until their chief executive had nominated them to take part in this research. They therefore had not done any work associated with SABS and did not feel able to comment sufficiently on many of the questions asked.

5.4 PERFORMANCE MONITORING OF TRUSTS

13 people said that they monitored the performance of the trusts and PCTs against the alerts and one reported they had in the past but due to *"inappropriate and inaccurate out of date information on the website"* had stopped. One believed it was not one of the present top indicators regarding performance so also did not.

Eleven were found to monitor against deadlines of action underway and action completed. One monitored just the action completed but did not feel that this was useful due to what they perceived to be unrealistic deadlines. One did not know and one stated that monitoring only occurs when making the Healthcare Commission annual health check commentary. One only monitored against risk and stated that it would have to affect the trust or a service that the Trust provided.

13 people said that the SHAs currently had processes in place to assist in monitoring the trusts' performance. Nine of these monitored the outstanding alerts and this varied from

daily, weekly, monthly, quarterly to annually. Two monitored non responders and one had implemented a process for acknowledging alerts within seven days. If trusts did not acknowledge these alerts within the set time frame, then the SHA contacted that specific trust to identify why they had not responded. One area had implemented the traffic light system and another had utilised the information off the website and had produced a spreadsheet. The trusts names had been removed to enable trusts to see anonymously how they ranked with others. One area checked non respondents daily and one monitored outstanding alerts. Two said that that they monitored progress only for the Healthcare Commission Annual Health Check.

Four out of the 15 produced reports which were submitted to the SHA Board, nine said that they did not and one stated that they only produced the report as part of the annual health check.

Copies of the reports submitted were requested. One agreed to send a copy of an old report prior to the SHA re structure on the 1st July 2006. Another agreed to send a copy via Email and two said they were unable to forward copies of the reports at this time but the information could be obtained via the board minutes on the internet.

Reports were found to be produced annually for one area, quarterly for another, and one said prior to the SHA re structure they reported 3-monthly but this had now stopped as requested by the board and one reported 2-monthly to their manager and 6-monthly to the SHA board.

When asked if they identify poor performing trusts and if so how, 11 responded that they used the SABS system to identify non responders. Two people did not see this as part of their role and one claimed the SHA do not check unless required as there are too many alerts that are not applicable. One respondent felt that the data was not reliable enough to use as the information on the system is often out of date and not showing accurate real time data so could not be used as a tool to monitor performance.

The interviewees were asked to give their definitions of a poor performing trust. The majority of responses included repetitive failings to meet deadlines and acknowledgements of the alerts sent out. Two people stated any trust with 5 or more alerts passed the deadlines set would be classed as poor performers.

When asked what action they would take against trusts that are poor performers, 13 stated they would contact the trusts direct to ascertain what the problems were and liaise to resolve any issues. One felt that it was not relevant as a bad result in terms of meeting deadlines does not necessarily mean that the trust is a poor performer and one stated they would make reference to the known deficiency in the annual health check commentary.

5.5 VIEWS ON THE SABS SYSTEM

Eleven people said that they used the reports available through the SABS system. One had reported a problem with accessing the website so had been unable to use the reports. Two did not use the reports personally but explained that their personal assistants did and one stated that the reports were then used annually for the healthcare checks or occasionally if a concern arose.

When asked what the beneficial feature of the SABS reports or systems were, the replies included: useful information, a good monitoring tool; helpful to allow trusts to see how they rank themselves; help improve performance and saving time as no need to search for the information; easy to use the summary reports; a national system; helps facilitate the audit process, and allows trusts to be alerted rapidly to a problem.

Duplication of alerts from different sources was highlighted as one of the problems regarding SABS. Nine respondents gave inaccurate out of date information on the system as key areas that they have encountered. When asked to be more specific, data that the SHA see on the website does not match to what the Trusts have inputted. The SHAs interviewed believe that the information they see does not always reflect what is actually happening and therefore can result in conflict if the SHA chase up Trusts that have responded to the alerts. Inappropriate deadlines were also a key factor that SHAs feel is a problem with the system as not all Trusts have 24 hour cover 7 days a week.

SECTION C

Analysis of Evidence Collected On the Tracker Alerts

Section 6: Analysis of Implementation of Alert on Methotrexate

6.1 SUMMARY OF ALERT

Reducing the harm caused by oral methotrexate	NPSA	Ref No patient safety alert 03 Action 29 July 2004
To reduce the risks associated with inappropriate dosage levels and monitoring of methotrexate		
• Agree appropriate local risk reduction actions through the Drugs/Medicines and Therapeutic Committee; • Provide patient information before and during treatment, including leaflets and patient-held monitoring and dosage record; • Update prescribing and dispensing software programmes to include alerts and prompts • Review purchasing to ensure tablets are visually distinguishable by shape and that packaging contains cautionary wording.		

6.2 INTRODUCTION

The actions required by the acute trusts and PCTs differed. We investigated whether acute trusts had withdrawn 10mg tablets and whether they had developed patient information leaflets. We explored the prescribing and dispensing of the tablets in PCTs and the role of the pharmacy adviser in relation to prescribing and dispensing by independent contractors. For both organisations, we investigated the processes for dissemination of the alert.

6.3 EVIDENCE FROM ACUTE TRUSTS

In 19 acute trusts interviews were undertaken with a chief pharmacist, directorate pharmacist or pharmacist responsible for medicines management or procurement. We also interviewed one consultant rheumatologist and five rheumatology specialist nurses.

All 19 pharmacy respondents reported receiving the alert on methotrexate issued in July 2004, and 15 (78.9%) said that the alert was discussed at a multi-disciplinary committee. Examples of committees included drugs and therapeutic, risk management, safe medication, pharmacy clinical governance and clinical governance. Because this alert was led by pharmacists in every trust, we did not receive the conflicting reports that were a feature of other alerts and therefore the quantitative data are presented. Table 6.1 shows the action taken.

Table 6.1: Action taken in response to methotrexate alert

Action taken	No	%
No action	0	0.0
Preparation/revision of pre-treatment patient information leaflet	13	68.4
Preparation/revision of patient information leaflet during treatment	10	52.6
Change to purchasing strategy	8	42.1
Other	5	26.3
Total	**19**	**100%**

One respondent reported having experience of eight separate incidents with methotrexate in the past, as a result of which the Trust had implemented a strict policy which only allowed Consultants to prescribe this drug. No stock of this drug is kept on any of the wards and if a patient is prescribed methotrexate then it has to be picked up on an individual patient basis from pharmacy. It is treated as a controlled drug and needs two signatures to dispense and administer it. 15 pharmacy respondents stated that they no longer stock 10mg tablets. One respondent who had retained both stated that the 10mg tablets were only kept for cancer patients and were stored separately. Tablets in one of the three trusts that still used 10mg tablets were slightly different either in shade of yellow or shape (torpedo/round).

In addition, to the actions reported in Table 6.1, respondents made reference to the need for negotiation both with clinicians and user groups in primary and secondary care regarding the drawing up of new patient leaflets. Another respondent reported preparing an annual update to all staff which highlights risk issues. An on-screen warning was also inserted on dispensing software.

16 respondents (84.2%) stated that patients received pre-treatment information, and 14 (73.7%) that it was necessary to draw up new patient information sheets in light of the guidance. 15 respondents gave information about who was responsible for drawing up the sheets: examples included the chief pharmacists, clinic staff, rheumatologists, dermatologists and working groups. Many described joint working between departments and professions and one described adopting the Arthritis and Rheumatism Council's (ARC) booklet. 15 respondents (78.9%) also stated that patients held a monitoring and dosage record, and two did not know, since the staff of the rheumatology clinics managed this aspect of care.

All pharmacist respondents had received the alert on methotrexate issued in June 2006 but three of the rheumatology nurses had not (one of these was interviewed only seven days after the publication of the alert). Ten pharmacists (52.6%) stated that their trust had adopted the NPSA patient information leaflet, 4 (21.1%) stated they had not, and three did not know. One respondent believed that the leaflet was too long and not helpful, and another that it was long and complicated and hence they are still reviewing it. A third explained how they used the ARC leaflet to produce small 'Barclaycard' size information cards.

Ten respondents (52.6%) believed that when dispensing methotrexate, pharmacy staff routine check the patient's monitoring booklet, although a further seven (36.8%) said they

did not, and two did not know or did not respond. Qualifications to these responses included the checking of blood results online, reviewing evidence on a compliance sheet, only checking inpatients but not outpatients, and having new guidance.

The arrangements for shared care were more complex, several respondents explaining that they were still under discussion or being finalised, that the trust does not have shared care or that leaflets were different across the departments. Evidence from the 12 rheumatology consultants and specialist nurses interviewed was used to ascertain the scope of the shared care arrangements and this is presented in Table 6.2.

Table 6.2: Issues under shared care

	No	**%**
Clarity of prescribing and monitoring responsibilities	8	66.7
How often blood tests will be conducted and in which location	10	83.3
Which clinician will be responsible for receipt and review of the results	8	66.7
Who will communicate any necessary dosage changes to the patient and the GP	8	66.7
Who will record test results on the patient-held monitoring booklet	5	41.7
Total	**12**	**100%**

The majority of these interviewees also gave further explanations and clarifications. Some sent all information sent to GPs in letter form. Others had put a paperless system in place. One consultant rheumatologist reported that there was a difference between what the trusts would like to do and what they are able to do, reporting that PCTs wanted these patients to make fewer visits to the rheumatology clinic in favour of GP care. Whilst there was pressure to get patients out into the community, in some areas patients were not, in the opinion of the consultant rheumatologist, being properly monitored. He put this down to the fact that prescribing and monitoring methotrexate was not in the QOF framework, adding that there was no financial incentive for anything in rheumatology. Others commented:

"There was difficulty in getting GPs to get involved with the shared care with the hospital. Difficulties when dealing with more than one PCT."

"Patients are provided with copies of the letters that are sent to the GP. Some of the GPs are not very good at using the blood monitoring records."

"Monitoring of results and dosage are shared between the hospital and the GP."

6.4 THE IMPLEMENTATION OF THE NPSA ALERTS ON METHOTREXATE IN PCTS

Senior managers and PEC chairs/medical directors were asked how the PCT managed the alert issued in June 2006. 15 (50%) of senior managers and 4 (21%) of PEC chairs did not know. One PEC chair who was able to respond stated that the 2004 alert had not been responded to although the Medicines Management Committee had worked on prescribing incentives and there had been attempts to limit use of 10mg tablets. The incentive came with the new GMS contract which provided an enhanced service element and feeling of increased responsibility. Other comments from PEC chairs are included in the section on primary care.

Of the 14 PCT pharmacy advisers we interviewed, 12 (85.7%) stated that they had received the alert, one commenting *"several times".* 13 (92.9%) also said that the alert was discussed at a multi-disciplinary committee. Examples of these committees included an Area Prescribing Committees, Clinical Governance Groups and Medicines Management Groups. One had set up a joint prescribing working group between the acute trust and PCT. 13 (92.9%) respondents stated that GPs sat on this committee. Table 6.4 shows the responses to the question in respect of action taken by the PCT in respect of the GPs.

Table 6.4: Action taken by PCT

Action taken	No of positive responses	%
No action	0	0%
Distribution of alert only	4	28.6%
Prepared revision of shared care arrangements	8	57.1%
Prepared revision of pre-treatment patient information leaflet	8	57.1%
Prepared revision of patient information leaflet during treatment	5	35.7%
Visits to practices	5	35.7%
None	0	0%
Other	2	14.3%

Six interviewees (42.9%) stated that both 2.5mg and 10mg were still being dispensed, whilst seven (50%) stated that 10mg tablets were no longer used. There was welcome evidence of audit of compliance of this aspect of the alert by PCT pharmacy advisers. Respondents commented:

"Low levels of practices still giving 10mg tablets as patients sometimes would rather take 2x10mg than 8x2.5mg tablets"

"Not supposed to be, but 10mg are still being prescribed and dispensed"

"Only seven prescriptions for 10mg tablets in last quarter."

Other respondents reported that they had sent newsletter to GPs and that one member of staff had worked with PCT provider units and one with GPs. Another reported that pharmacy

staff had searched GP records for patients on methotrexate to find out who had initiated prescribing and put a system in place to send out letters to all patients for monitoring. This PCT had also had a meeting with rheumatologists to discuss a new shared care protocol.

In a few PCT areas, pharmacists had visited GP surgeries, and, where permitted, had altered the system so that the prescribing of 10mg tablets was rendered impossible. One area had also reported writing the terms of the methotrexate alert into the GMS contract to ensure compliance, monitoring it via prescribing data. Ensuring GP implementation was, however, felt to be an uphill struggle, or, as one respondent put it, like going round in circles. No sooner had one round of compliance visits taken place than the prescribing data revealed that an already compliant surgery had prescribed 10mg tablets. Mergers had given PCT Pharmacy leads whole new populations of GPs of whom they had no knowledge, necessitating the re-introduction of all systems.

PCT pharmacy leads were also asked what action taken was taken in respect of local pharmacies. Table 6.3 shows the analysis.

Table 6.3: Action taken by local pharmacists

Action taken	No of positive responses	%
No action	1	7.1%
Distribution of alert only	6	42.9%
Discussion of alert at professional meetings	3	21.4%
Letter to local pharmacies	8	57.1%
Prepared revision of patient information leaflet	1	7.1%
Visits to practices	1	7.1%
Other	2	14.3%
None	0	0%

In one area the PCT reported having to carry the costs of “broken bulk” to recompense pharmacists for the withdrawal of the 10 mg tablets and another two areas reported conducting audits of community pharmacies under the terms of the contract with the PCT.

Six pharmacists stated that they were involved in the discussions about the need for changes to GP prescribing and dispensing software, and seven were not. Four interviewees stated that all systems were revised by the manufacturer. None of the IT advisers had been involved in the discussions about the need for changes to GP prescribing and dispensing software, and they believed that all changes would be directly through the software suppliers. Two told us that no audit had been undertaken of methotrexate flags on GP prescribing and dispensing software and one did not know.

Additional comments from pharmacists included being involved in the development of a policy, and putting into the QOF a requirement for an audit of patient dosage records. Dispensing practices were also reported to be undertaking pharmacy audits. Six interviewees reported that an audit had been undertaken of methotrexate flags on GP prescribing and dispensing software and six said an audit had not been undertaken. One respondent stated that the PCT had written to GPs asking for confirmation of compliance

with the alert. Only one interviewee confirmed that community pharmacists ask to see the patient monitoring booklet, explaining that GPs felt they were not sufficiently reliable up-to-date.

13 PCT interviewees (92.9%) had received the alert issued on June 2006. As a result, nine (64.3%) confirmed that the NPSA patient information sheet had been adopted locally, whilst two said it had not. Some had used the NPSA publication as a basis but had amended it for local use. Others commented that the local version had only just been amended by the time the 2006 alert was issued and those involved "*were disinclined to change it."*

6.5 EVIDENCE FROM GP PRACTICES

PEC chairs were asked how their practice responded to this alert. Table 6.5 summarises their responses.

Table 6.5: Action taken by practice

Action taken	No of positive responses	%
Flag on computer	14	73.7%
Cease use of 10mg tablets	9	47.4%
Revised shared care arrangements	10	52.6%
Did nothing	0	0.0%
Don't know/don't remember	0	0.0%
Other	0	0.0%

One reported that the practice had had a practice policy for the management of methotrexate, although there were 'gaps' in it. He reported having never used 10mg tablets. Two others explained their actions:

"This alert had most dramatic effect. Practice based pharmacist stopped us using 10mg and it was taken off computer so we were unable to prescribe 10mg"

"We had a sophisticated prescribing group between primary and secondary care. Methotrexate is something you have to be interested in. Decided to discontinue use of 10mg tablets. When we authorise methotrexate we get a large screen with an exclamation mark…flag has come up since 2006"

Two practice manager respondents told us that they had audited shared care arrangements, one that they worked with their local hospital re shared care, and another commented:

"[We] alerted the NPSA to safety issues re methotrexate as a result of concerns from within their practice. As a result the practice had a belt and braces review of all issues concerning this drug and they now have an extremely robust system in place. This included a lead nurse responsible for monitoring all patients who also have re-call dates."

A total of 25 practice managers reported changes to the IT system as a result of the 2004 alert and 37 did not know. A small proportion of interviewees was not in post at the time of this alert and therefore could not comment. Some areas highlighted that changes were made to the software but this was implemented directly by the software company and not the practices. The interviewees were asked if the IT system currently has a flag on Methotrexate, 64 said yes, 4 said no and 22 did not know. Some did not know but checked their computers during the interview to find out.

Out of the sample selected only 13 were dispensing practices. Two out of the eight stated that they stocked both the 2.5mg and 10mg tablets, 4 explained that they only stocked 2.5mg tablet and 4 interviewees did not know.

6.6 PROBLEMS ASSOCIATED WITH THE ALERT AND ITS IMPLEMENTATION

One acute trust respondent specifically mentioned a perceived problem with the NPSA leaflet, in that the example inside that shows how the form can be filled in does not state that this is only an example and hence could be taken as an actual patient record. Another respondent described trying to engage with dermatology and rheumatology department but "*hit a brick wall".*

Three respondents believed that there were difficulties with implementation due to problems associated with dispensing by community pharmacists. One acute trust respondent stated that he was aware of one recent incident where, despite the PCT issuing edicts regarding the withdrawal of 10mg tablets, a patient was dispensed 10mg tablets instead of 2.5mg tablets by a community pharmacist and had taken seven tablets weekly over a period. PCT pharmacy leads reported that community pharmacists had complained that they had bought 10mg tablets and asked who was going to pay for them if they could not use them.

Five reported that rheumatologists had disagreed with the original patient guidance and one that there were difficulties with pharmacists having to access blood tests before dispensing methotrexate. Two (4%) respondents reported that consultants, including dermatologists, had concerns about the transcription of results into a book, which might lead to error. As a result, the alert was flagged as red on the trust risk register. Four (8%) reported other problems including harmonisation of patient information, problems with junior doctors prescribing, and the short timescale for implementation. Other comments included compliance of consultants, the time for consultation and problems with the local pharmaceutical committee not supporting the withdrawal of 10mg tablets. Seven stated that there were no problems.

In GP surgeries, there were difficulties associated with the implementation of this alert including difficulties in identifying patients. Pharmacists found that they could track volumes of prescribing, but not individual patients. Another found that some patients were being prescribed Methotrexate by the hospital and so did not appear on the GP prescribing system.

Finally, several respondents commented that the alert was difficult to sign off because there were so many big issues. Many patients did not like changing to 2.5mg even though pharmacists believed it necessary. Another pharmacist reported the following:

"Trying to get agreement between consultants in rheumatology and dermatology; finding money to publish booklets, and software companies lagging behind".

6.7 COSTS OF IMPLEMENTATION

12 (63.3%) acute trust respondents said there were additional costs associated with the implementation of this alert including costs of printing or buying leaflets and staff time in developing or consulting on the leaflets.

Six PCT interviewees also believed that there were costs associated with the implementation of the alert, whilst eight believed that there were none. Costs cited included hand held records (estimated by one as £1000), hidden time costs, e.g. attending meetings, publications of booklets and reimbursement of broken bulk to community pharmacists (one PCT).

6.8 SUMMARY

This alert was well implemented, the action having been taken by chief pharmacists or their designated deputies. 17 of the acute Trusts reported having taken action to discontinue the use of 10mg tablets. Those that had retained the use of the larger tablets specified that they were either for the use of chemotherapy patients who were prescribed higher doses than patients with either rheumatoid arthritis or dermatological conditions or for children who refused to take the large number of tablets required by the use of 2.5 mg tablets only

Some trusts did report that although the trust had ceased the use of 10 mg tablets these were still in the system, having been supplied either by dispensing GPs or community pharmacists. The PCTs reported notifying both groups of a policy of using only 2.5mg tablets, but stated that this was difficult to enforce. Attempts were made by five to enforce this. Strategies employed included:

- Carrying the costs of "broken bulk" to recompense pharmacists for the withdrawal of the 10 mg tablets;
- conducting audits of community pharmacies;
- Altering GP systems (where permitted) so that the prescribing of 10mg tablets was rendered impossible;
- Writing the terms of the methotrexate alert into the GMS contract to ensure compliance, monitoring it via prescribing data.

Ensuring GP implementation was, however, felt to be an uphill struggle. One respondent reported that no sooner had one round of compliance visits taken place than the prescribing data revealed that a previously compliant surgery had prescribed 10mg tablets. Mergers had

given PCT Pharmacy leads whole new populations of GPs of whom they had no knowledge, necessitating the re-launching of all strategies to promote adherence to the policy.

There was reported disagreement about the first (2004) generation of patient information leaflets published by the NPSA. However, it did stimulate discussion, either within the trust or in the wider health community and where a new leaflet was not developed, the content of the existing leaflet was at least discussed. In those areas where new information leaflets were developed following the 2004 alert, frequently in discussion with GPs, there was little appetite for re-opening these discussions when the 2006 alert was distributed. However, from the interviews in acute trusts and PCTs it emerged that nineteen areas in total have adopted the NPSA patient leaflet and others had adopted it with slight modifications. The remainder were satisfied that their patient information contained all the necessary information required by the 2006 alert.

Section 7: Needle Free Intra Vascular Connectors

7.1 SUMMARY OF ALERT

Needle free intra-vascular connectors	MHRA Medical device alert	Ref No: MDA/2005/030 Action 17th May 2005
The instructions for use of many brands of needle-free connectors have undergone significant change, in particular to the maximum period of use of the device		
• Ensure that up to date instructions for use are available to users: if in doubt contact manufacturers; • Review local policies to ensure consistency with the current instructions for use, incorporate changes and modify training if required; • Previous editions of instructions should be disregarded and destroyed.		

7.2 INTRODUCTION

In both acute trusts and PCTs we questioned senior managers about the management of this alert, and then explored ward managers' and district nurses' awareness of the alert and its provisions. We also audited the availability of disinfecting solutions and, if there were patients on wards with one of these devices in situ, sought to determine how records were kept of dates and number of uses.

7.3 MANAGEMENT OF THE ALERT

Only three (6%) senior managers in acute trusts were able to state how this alert had been handled within trusts. In most acute trusts the subject of the alert had not been recognised as a device used by nurses in almost every ward, and the alert had therefore been erroneously classified as irrelevant. In one of the organisations that had actioned it, one of the purchasing managers to whom the alert was sent had a nursing background and had contacted the SLO to say that the alert should be widely circulated. In a second, the alert was handled by the Head of Medical Equipment who copied the instruction sheets that came with the connectors (1 per box of 50) and had them laminated and displayed in ward treatment and IV rooms. The instructions, however, did not give guidance regarding the number of uses or longevity of the connectors. In another trust there was a medical devices training officer in post, who had instigated training for ward staff. This person was subsequently made redundant for financial reasons.

Community nurse managers were asked whether community nurses gave IV drugs. 13 (44.8%) said they did, whilst 12 (41.4%) said they did not and one did not know.

Respondents also referred to community nurses flushing lines, which appeared to be relatively frequent. Six respondents (20.7%) from this group also stated that they distributed the alert, three (10.4) did not and eight (34%) did not know. They were also asked how their PCT responded to the alert. Table 7.1 shows the analysis of the responses.

Table 7.1: PCT response to the alert

Response to alert	No of positive responses	%
Developed a policy	2	6.9%
Offered training	2	6.9%
Distributed alert or other warning	3	10.3%
Distributed instructions	1	3.4%
Don't know	15	51.7%
Other	4	13.8%

The majority said they could not remember, although one stated:

"We looked at it and said it was not relevant. District nurses are now going to [local acute trust] for training. District nurses are cautious."

7.4 EVIDENCE FROM ACUTE TRUST WARD MANAGERS

63% of ward managers interviewed used needle free intravascular connectors (NFIVCs), and 84% of this group stated they only used one make. At ward level few respondents recognised the term used in the alert, referring to the devices as bungs, venflons or bionectors. A series of questions were asked about the use of NFIVCs. We are unable to give "correct" answers to these questions as the advice from different manufacturers varied. (Ryder, Fisher et al. 2007) In response to the question "Is there a prescribed time period after which you have to change NFIVCs?", 19% believed this was 24 hours or less, 46% between 24-72 hours, and 18% 3-7 days. Others commented on the specific arrangements in their department, such as ITU or theatre, or with their patient groups, such as children. A further 12% did not know or did not believe that there was a fixed time period.

In response to the question, "How do you keep track of how often a connector has been used or how long it has been in use?" 33% marked this on the patient's care plan, 15% marked it on the chart at the foot of the bed, 7% marked it on the medicine chart, and 21% said it was not an issue since they only used a connector for a short time. A further 17% gave other explanations such as having a connection record which is kept with the patient notes at the foot of the bed, marking on dressings or fluid charts or on the connectors, or having a fixed regime of changing them.

In response to the question, "Which disinfectant do you use before attaching a syringe or giving set to a valve connector", 94% said they used an alcohol wipe. In response to the question "Are you aware of any particular instructions regarding contact time with disinfectant", 9% said not less than 2 seconds, 15% between 3-5 seconds, 12% between 6-10 seconds and 58% said they just wiped the connector only. 7% said they did not use

anything. Nine commented that they did not know, or were not aware of any guidance. There were also a variety of views on the length of time that the disinfectant has to dry before use, with 18% saying there was no guidance, 5% not less than 2 seconds, 21% stating from 3-10 seconds, 10% from 11-20 seconds, 15% from 21-30 seconds and 30% over 30 seconds. Some said they would wait until the disinfectant just dried, or would wait up to 2 minutes. 62% said they did not have a policy on the management of NFIVCs, and 38% said they did although the researchers did not see two-thirds of these.

The ward audit investigated which manufacturers' NFIVCs and disinfection agents were currently used on the ward. We also attempted, and failed in all but one case, to locate instructions for use, as suggested by the alert. This is attributable to the fact that these small devices are delivered to the wards by means of a supply top-up system, which deliver the required number into plastic containers. The instructions are, presumably, thrown out with the empty box at the end of the supply round. The one ward in which we did find instructions had specifically ordered a full box as they were using many of these devices. Sadly, staff in this ward were unaware of the alert. Tables 7.2 and 7.3 show the results of the audit.

Table 7.2: Availability of NFIVCs on the wards

Manufacturer	**No**	**%**
Vigon	44	25.9%
Bionector	35	20.6%
Other	15	8.9%
Alaris	10	5.9%
Becton-Dickinson (BD)	8	4.7%
Smartsite	8	4.7%
Baxter	6	3.5%
Don't know	2	1.2%
Not stocked on ward	21	12.4%
No response	21	12.4%
Total	**170**	**100%**

Table 7.3: Availability of disinfection agents on the wards

Manufacturer	**No**	**%**
Steriswab	111	65.3%
Chlorhexidine	29	17.1%
Povidone-iodine	15	8.8%
Other	6	3.5%

7.5 EVIDENCE FROM COMMUNITY NURSE INTERVIEWS

22 (34.9%) interviewees told us that they gave intravenous medication and 19 (30.1%) did not. 24 (38.1%) told us they used NFIVCs, and only seven did not. We asked the interviewees whether there was a prescribed time period after which they had to change the NFIVCs. Two said 24 hours or less, three said between 24-72 hours and nine (14.3%) said between 3-7 days. Only one said there was not a time period, only two said they did not know, and eight (12.7%) gave another response. Qualifications to their responses included changing weekly, for example when a line is flushed, or changing fortnightly or monthly, or following the manufacturers' recommendations or after a given number of uses, varying from 6, 30 or 100. Some also referred to their PCT policy.

23 (36.5%) interviewees said that they kept track of how often, or for how long, a connector had been used by marking this on the patient care plan, others stated that there were changed and flushed weekly, on the same day of the week. 11 (17.5%) always used an alcohol wipe when attaching a syringe or giving set to a valve connector and six (9.5%) used non-alcohol wipes, many specifically mentioning chlorhexidine wipes and sprays and others hibitane or mediswabs. Few interviewees were aware of particular instructions regarding contact time with disinfectant, with one saying 3-5 seconds, six saying 6-10 seconds and 10 (15.9%) telling us they 'just wiped it.' Others suggested 30 seconds or even three minutes. Many commented that they just let the disinfectant dry or that they were not aware of a time factor.

7.6 SUMMARY

This clinically focussed alert appeared to have largely bypassed nursing staff. This may be because it was issued by the MHRA rather than the NPSA and therefore was not handled as a clinically focussed alert. The alert stated that the manufacturers' instructions for use of these devices had recently changed and that staff "should read the instructions." Because of the NHS Logistics top-up system, wards generally have no access to the instructions, which are supplied, in the stock boxes. Although the alert was marked 'for action by' infection control staff, there was no clear indication in the body of the alert that the devices, if not correctly used, were an infection risk.

We have identified only three trusts in which this alert was actioned. As the majority of nurses interviewed did not recognise the term 'needle free intravascular connector' used in the alert, it is unsurprising that SLOs failed to distribute this appropriately.

Section 8: Nasogastric Tubes

8.1 SUMMARY OF ALERT

Reduction of harm caused by misplaced nasogastric feeding tubes	NPSA	Ref No: patient safety alert 05
		Immediate Action
		21 February 2005
Reduction of likelihood of placing nasogastric tube into lungs, or moving out of stomach		
Provide staff, carers and patients in the community, with information on correct and incorrect testing methods: • Measuring the pH of aspirate using strips/paper; • Use of radiography for specific groups of patients, though not routinely; • Ceasing of use of 'whoosh test'; • Ceasing of use of blue litmus paper; • Ceasing of interpretation of lack of respiratory distress as positive indicator; • Carry out individual risk assessment prior to nasogastric feeding; • Review and agree local action; • Report misplacement incidents via local risk management systems.		

8.2 INTRODUCTION

Senior managers in both acute trusts and PCTs were asked about the management of this alert, and we then explored ward managers' and district nurses' awareness of the alert and its provisions. We also audited the availability of pH paper and sought to determine whether litmus paper was still available. If there were patients on wards at the time of the visit we asked to see whether a record of testing was kept before each feed was given.

8.3 IMPLEMENTATION IN ACUTE TRUSTS

It was claimed that this had been actioned in all acute trusts. Senior managers reported how the alert had been handled. 10 (20%) stated that implementation had been managed by a committee such as those responsible for clinical governance, nutrition or patient care. 15 (30%) reported that the trust had had to develop a new policy, revise an existing policy and or develop a new policy for children. Three others were dependent on *The Royal Marsden Hospital Manual of Clinical Nursing Procedures*. The ten interviewees who knew who had taken the lead, named specialist nurses, neonatologists, gastroenterologists, and senior nurses or modern matrons. 10 (20%) reported that the alert had been disseminated to staff via email and hard copy and 12 (24%) had instigated discussion on clinical governance days or had developed training materials such as the development of flow charts.

Only one purchasing manager believed that there were any costs associated with the implementation, five (25.0%) that there were none, whilst 10 (50%) did not know. Costs appeared to be associated with the withdrawal of litmus papers and the introduction of pH strips, and one respondent described problems with sourcing pH papers from a bulk

supplier. One purchasing manager explained how the implementation was a joint venture between risk management, nursing and supplies, whereby litmus paper was phased out and replaced by pH papers.

One medical respondent stated that they were awaiting guidelines from British Association of Perinatal Medicine and 6 (12%) others reported some level of disagreement from staff , including the number of times tubes should be checked, and staff reluctance to cease use of the 'whoosh' test which was seen as a tried and tested method.

8.4 IMPLEMENTATION IN PCTS

PCTs reported that these are seldom used in the general patient population since patients requiring enteral feeding at home are more likely to have a percutaneous enteral feeding tube in situ. One senior manager claimed that the PCT was already compliant, 7 (33%) had revised a policy, one had instigated staff training and one had made a change to the purchasing strategy. Six senior managers did not know how the alert had been handled.

Comments from senior managers included:

"A few patients have NG tubes. We have been using pH testing. We have no policy but are aware of the guidance around it."

"Looked at all standards of practice and purchased the 'Marsden' procedure Manual. NG feeding is mostly in Learning Disability homes, in paediatrics and for the Community Team"

In around half of the PCTs this alert was deemed to be irrelevant and had not been disseminated to district nursing staff. Community nurse managers commented:

"They normally assist patients, and only in extreme cases may they feed."

"Rarely: concerns about displacement are now referred to the secondary care specialist nurse."

"Usually use PEG feeds: it would be exceptional to have an NG tube."

"Usually fed by relatives."

8.5 POLICY DEVELOPMENT

We obtained 11 policies in total, seven from the twenty acute trusts and four from the fifteen PCTs and all but two faithfully followed the advice given in the NPSA alert. In one acute trust we were told throughout the visit that the lead had been taken by a practice development nurse who had introduced pH paper to the trust in 1999. She was said to be "well ahead of the game" and when interviewed stated that the trust guidelines had only had to be 'tweaked'

in the light of the NPSA alert. When we eventually obtained the policy we were concerned to find that it recommended the use of the "whoosh" test. There also appears to be a typographical error in the guidelines that states *"the whoosh test should be used in isolation to confirm placement."* The word not appears to be missing from the sentence. This policy was proudly displayed on every ward in a marked "nutrition folder." In one PCT that had developed a new policy this had not (as of March 2007) been circulated to staff, but it was said that the previous policy recommended the use of pH paper. The policy stated that the pH paper: *"should turn from blue to red.*"

8.6 EVIDENCE FROM WARD MANAGER/ DISTRICT NURSE INTERVIEWS AND AUDITS

67% (114) of interviewees in acute trusts stated that they checked that a nasogastric tube was in the stomach rather than in the lungs at the time of insertion by the use of pH indicator paper on aspirate, with 8% (13) using the whoosh test, 9% (15) stating they used litmus paper (which may really be pH paper) and 41%(69) using x-ray. Several respondents qualified their responses by stating that they may x-ray if no aspirate is obtainable, if there is any doubt, or for certain patient groups. The percentages for checking before each feed were 49% (84) using pH paper, 4% (7) using the whoosh test, 8% (14) using litmus paper and 4% (7) using x-ray. 17% (28) said they did not test before feeds. Interviewees were also asked to state the accepted range for pH paper to allow a feed to commence. The NPSA recommend proceeding provided the pH is 5.5 or below. Of the 130 respondents who replied to this question, 16% (21) said they had never used it, 17% (22) said the range was between 1-3, 32% (42) gave the range as between 4-6 and 4% (5) from 7-9, which is clearly in the alkaline range, and therefore unsafe. 31% (40) said they did not know. Again some qualified their response by stating that anything under 5 was acceptable, that they look for a change in colour or would follow the instructions on the pack. Others also stated that they used nasogastric tubes rarely and hence would seek guidance or read the manufacturers' instructions.

During the observation of records on the wards visited, 43 patients with NG tube feeds were found at the time of the audits, and 29 care plans recorded the testing of NG feeding tubes. 33 (77%) of relevant care plans had the pH method of testing recorded in the care plans. Other methods of recording included documentation on the HDU chart, on the electronic record or on the Kardex nursing record. It was noted that pH papers were only available on 36% of wards while litmus papers were seen by the research team on 16 (9%) of wards visited.

Amongst the district nurses interviewed, 26 (41.3%) interviewees told us that they had received the alert on the correct placement of nasogastric tubes issued in February 2005. Three (4.8%) were told about it, eight (12.7%) did not receive it, and nine (14.3%) did not know. However, only ten (15.9%) told us that they carried out nasogastric tube feeds, whilst 42 (66.7%) told us they did not. Some commented that gastrostomy devices or PEGs are more commonly used in the community although a few may support families with this procedure.

Ten (4.8%) district nurse interviewees told us that they would check that a nasogastric tube is in the stomach rather than the lungs at the time of insertion by the whoosh test, 21 (33.3%) would use litmus on aspirate, 20 (31.7%) would use pH indicator paper on aspirate and 18 (28.6%) would use x-ray. Only 3 said they did not know. Two commented that they were probably not up to date, and others said that the family would check using pH papers. 28 (44.4%) said they had used pH paper, but 21 (33.3%) said they had not. Nine (14.3%) interviewees said that the pH range was between 1-3, 12 (19.0%) between 4-6, three that it was 7-9 and 22 (34.9%) did not know. Many said they could not remember however, or have not done this for some time, and others said they would check the box.

8.7 SUMMARY OF FINDINGS

Fifteen acute trusts and five PCTs claimed to have written or revised a policy to reflect the NPSA guidance. One acute trust policy specifically advocated the use of the auscultation method and three other such organisations were dependent on The Royal Marsden Hospital Manual of Clinical Nursing Procedures, whose 6th edition predates the NPSA Safety alert. We are concerned about the advice in one PCT policy which appeared to ascribe to pH paper the properties of litmus paper. Five of the fifteen PCTs did not circulate the alert to district nursing staff as few or no such feeds are carried out in the community.

Although pH paper is to be found in the majority of wards in all trusts, researchers observed 16 instances where litmus paper is still available for use. Without direct observation, the picture would have been complicated by nurses using the term litmus paper for pH paper. The auscultation method is still in use and a minority of respondents in acute areas do not test placement before each feed. Almost 20% of acute nurses interviewed did not know the correct acidity range to allow a feed to continue or suggested a range of 7-9. (It may be that respondents are using colour cues checked against the information on the container.) This number rose to 40% amongst district nurses, although a majority of them did not undertake such feeds.

Section 9: Latex Allergy

9.1 SUMMARY OF ALERT

Protecting people with allergy associated with latex	NPSA	Ref no: NPSA/2005/08
		Action
		26th May 2005
To reduce the risk associated with the use of latex products by those with allergy		
Trusts should develop a comprehensive policy or review their existing policy, which should include measures to: • Substitute, control and eliminate latex where appropriate and possible; • Ensure staff are aware of and have access to safe and effective latex-free alternatives; • Limit latex to its most valuable uses; • Identify and protect sensitised patients; • Raise awareness about latex sensitivity amongst patients and staff; • Ensure that latex-free alternatives do not replace the risk of reaction to latex with another risk; • The policy should be backed up by efficient management arrangements and be audited.		

9.2 INTRODUCTION

We interviewed senior managers in acute trusts, PCTs, ambulance trusts and mental health trusts about the management of the alert and also interviewed purchasing managers about comparative costs. We then questioned ward managers, district nurses and paramedics to determine their awareness of its provisions and asked whether they had immediate ready access to latex-free versions of a range of common equipment. We audited stocks of the same equipment in clinical and storage rooms to determine the availability of latex free equipment.

9.3 IMPLEMENTATION OF THE ALERT

9.3.1 Overview

All Trusts reported that they had begun to tackle the issue of latex allergy under pressure from the Health and Safety Executive some time before the NPSA alert was published. We found that in some trusts this earlier advice, focussing on the risk to staff from latex gloves, gave rise to confusion at both senior management and ward level. In four organisations visited between July 2006 and June 2007 (one acute, one ambulance trust and two PCTs) revised policies were still in draft form and had not yet been ratified and distributed.

9.3.2 Implementation in Acute Trusts

We asked senior managers how the patient safety information bulletin published by the NPSA had been managed within the trust. Clinical Governance managers in acute trusts were the group most likely to know how it had been managed and medical directors least likely. 13 (26%) respondents reported that implementation was managed by a standing committee such as clinical governance, risk management, health and safety or infection control; or a specific group set up for the purpose. Five medical directors queried the need for the alert, questioning the prevalence of serious latex allergy in the community.

In four acute trusts the alert was reported to have had a false start, respondents reporting that it was only after telephone calls from the NPSA in response to failure to close the alert that they successfully took action. A respondent in one of the trusts in which action did not get under way smoothly reported that this was attributable to the alert being disseminated without clear identification of someone to take the lead. This respondent noted:

"Everyone thought someone else was doing something."

In the other organisations in which problems were experienced, lead nurses had been named but it later transpired that no action had been taken. In all of these cases it fell by default to the clinical governance or risk manager to lead on implementation.

In other acute trusts, the lead for this alert was taken by Directors of Nursing, infection control nurses, matrons, occupational health staff or clinical governance staff. Quantitative data are not useful on this point as in some trusts different answers were given by senior managers. For example in one trust, the Director of Nursing stated that the lead for the NPSA alert on latex allergy was taken by occupational health staff; the medical director thought the lead person was the Director of Nursing and the clinical governance manager stated that it was the infection control nurse. Comments included:

"A can of worms, no one wanted to touch it because it was 'more than gloves.'"

"There were issues of internal ownership of the alert and policy development."

9.3.3 Policies in Acute Trusts

18 (36%) acute trust respondents reported that they had developed new policies, or made amendments to existing policies. The development and ratification of policies appeared to be a lengthy process. In one acute trust visited in February 2007 the policy was still in draft form and had not yet been ratified and distributed although it did have clinical policies for theatres and A&E and both of these departments had latex free trolleys. We were able to access policies from seventeen acute trusts. These were enormously variable in length, the longest being 32 pages including 8 appendices. Some were sound, concise and practical documents which gave staff precisely the information that they needed to know and were accompanied by flow charts and clinical documentation. Two appeared to be a clumsy amalgamation of a previous glove policy and the NPSA alert. Most relegated to an appendix a list of equipment containing latex yet this is arguably the precise information needed by staff to offer

protection to a latex-sensitive patient. In the nursing records, latex is specifically listed under the allergies increase the likelihood that patients are asked about this.

Seven (35%) of the purchasing managers interviewed in the acute trusts stated that there was comprehensive working policy in their trust on the purchasing of latex-free products 'whenever possible', eight (40%) believed there was not, and three did not know.

9.3.4 Implementation in PCTs

PCTs presented some difficulties in determining action taken, and this may have been attributable to two factors – mergers and the fact that PCTs were interviewed later than acute trusts – in some cases almost two years after the NPSA latex alert had been published. If anyone in the organisation knew who had led on the alert it tended to be the SLO, but this information was not always recorded on the system. Senior managers and PEC chairs/medical directors were asked how the PCT managed the alert issued in June 2006. Table 9.1 shows the analysis of the responses.

Table 9.1: PCT management of alert

Management of response	**Positive responses**	
	Senior managers	**PEC chair/medical director**
	No (%)	**No (%)**
Considered and already compliant	6 (20.0%)	2 (10.5%)
Developed/revised policy	12 (40.0%)	3 (15.8%)
Change to purchasing	4 (13.3%)	2 (10.5%)
Created a box of latex free equipment	2 (6.7%)	1 (5.3%)
No action	0 (0.0%)	1 (5.3%)
Not relevant	0 (0.0%)	0 (0.0%)
Don't know	11 (36.7%)	8 (42.1%)
Other	3 (10.0%)	4 (21.1%)

Comments from senior managers included:

"Latex allergy policy has been around for a while and is currently being reviewed. Gloves and catheters are the main areas … Occupational Health leading - they started with staff, but are now concerned about risk to patients."

"Purchased latex free gloves for all practices."

"Downloaded posters for district nurses in clinics, Spoke to head locality nurses re awareness."

One manager with a purchasing responsibility had attempted to order specific latex-free equipment but did not find it easy to obtain information. It was said to be difficult, having identified a specific latex free product in the catalogue, to then identify the same product on the purchasing database.

9.3.5 Policies in PCTs

PCTs were less likely than acute trusts to have a ratified policy that was issued or formally revised after the publication of the NPSA policy. We were able to access nine PCT policies, five of which incorporated specific advice about protecting patients with latex allergy. The remaining four, put together by occupational health, health and safety committees and infection control teams, dealt almost exclusively with the risk to staff posed by gloves. In one PCT, both senior and middle managers reported reinforcing the messages to staff in the wake of the NPSA alert. They stated that before the alert had been issued, there had been awareness training, a training DVD had been issued to each team and each team also had a latex trainer. However, the audit highlighted the fact that the training materials and DVD related only to gloves and that the policy was dated December 2004. Another PCT, with an appropriate policy, had decided not to make a box of latex-free equipment available but said that they could delay transfer of a patient with a serious allergy for 24 hours until they could ensure that non-latex equipment was available.

The confusion found in acute trusts was also found amongst community nurse managers and district nurses. Whilst 19 (65%) of the managers claimed to have received the alert, the same percentage also claimed that the response by the PCT was the provision of latex-free gloves with only 3 (10%) stating that a policy had been developed. Comments included:

"A lot of girls tend to order latex free gloves."

"There is no policy, but we had a discussion about good practice and adopted gloves."

"Checked team managers on what latex was being used and checked a policy was in place for PCT. Not sure what policy is currently being used."

"PCT has had a latex policy for some time and we ensure staff have had recent updated latex training."

9.3.6 Implementation in Ambulance Trusts

Two ambulance trusts had taken the decision to purchase only latex free equipment and having taken this step had not circulated the alert to staff nor had they warned staff about the issue. One senior manager of an ambulance trust pointed out that no alerts were circulated until all appropriate action had been taken at management level. It was said that warning crews of a danger without supplying a solution at the same time was likely to result in highly unionised crews refusing to attend a scene. Recent mergers of ambulance trusts led to a disparity in the data between manager accounts and the understanding of front line staff, raising the spectre of the need to re-visit all closed SABS alerts in the wake of a merger. Box 9.1 provides a case study of how one ambulance trust implemented the latex free policy.

Box 9.1: Case study of implementation of a latex policy in an ambulance trust

Implementation: Head of integrated governance took the lead Purchasing manager identified all equipment that contained latex Trust gradually moved to non-latex for everything except gloves Policy developed from model policy on HSE website Although there is no specific latex free purchasing policy, purchasing manager purchases latex free products whenever possible
Problems identified: Temp-a-dot gloves was a new product supplied by NHS logistics but which contained latex, therefore a new product had to be identified Gloves are used extensively (an estimated 360,000 per annum), and cost differential estimated to be around £5,000 Many items of equipment are not marked as latex free, therefore it is unclear whether they do or do not contain latex. Examples include oxygen masks and nebulisers, some sizes of cannulae (although others are marked latex free), guedel airways, BP cuffs and trolley mattresses

9.3.7 Implementation in Mental Health Trusts

Both mental health trusts were found to have a glove policy which dealt with the care of affected members of staff. It was pointed out that gloves are used more frequently in this setting for non clinical procedures such as searching.

9.4 AVAILABILITY OF LATEX FREE PRODUCTS

Eighteen (90%) purchasing managers interviewed in acute trusts believed that the availability of latex free products had improved; whilst two did not believe this to be the case and one thought that manufacturers were exploiting the current concern about latex allergy. Respondents commented:

"The situation is quietly improving."

"Prices have come down."

"There is more on the market and more choice."

"Suppliers see latex free as a niche in the market which they can exploit."

There were significant differences of opinion around the costs of purchasing latex free equipment amongst senior managers in different organisations. One claimed that latex free gloves were around £3 per pair as opposed to 50p for latex gloves. In another trust, latex free gloves were kept locked in sister's office and required a medical certificate to release them to staff, whilst one ambulance trust had gone completely latex-free and reported that the difference in cost could be measured in pence. 40% of purchasing managers believed that latex free equipment was higher cost, 5% that it was lower cost, 10% that it was variable

and 30% about the same with 15% who did not know. The comments below, all from purchasing managers, reflected these differing opinions:

"Don't think it has added to cost of bread and butter products. Some super sensitive theatre gloves are very expensive."

"Prices are more. Latex free about 50% more expensive."

Ordinary latex free gloves are now as cheap."

"Not a huge difference but higher."

Eleven (55%) respondents said there were no difficulties associated with the implementation of this alert, three (15.0%) said there were difficulties and four did not know. Examples of difficulties included resistance from some departments and variation in clinical practice.

"This problem has been around for a while. A lot of work has been done by, e.g., NHS Supplies working with suppliers and making them aware of latex in products and using latex. But it is still difficult to find in a catalogue what products don't contain latex, and a lot of duplication of effort in identifying latex." (Purchasing Manager).

In PCTs, community managers pointed out that because they could not obtain a list of equipment that contained latex they were unable to put together a box of latex-free equipment, and several suggested that PASA should provide such a box for the use of community staff. One pointed out that there was a mismatch between the catalogue list and the procurement database and stated that it was difficult to obtain reliable information on equipment. Even contacting manufacturers did not resolve the issue as they themselves did not have the information.

9.5 AUDIT AND EVIDENCE FROM FRONT LINE STAFF

9.5.1 Evidence from Acute Trusts

It was difficult to obtain a clear picture of the awareness of the alert as some respondents claimed to have received it, but when questioned about the availability of latex free products immediately claimed that they only knew about gloves. Several claimed that they had never considered a patient having an allergy. It should be noted that in many trusts the alert itself was not distributed to staff as it was decided that a policy was required so it was unsurprising that some nursing staff had not seen the alert. All were aware of the existence of a trust policy dealing with some aspect of the management of latex allergy but only 43% could access it, either on the internet or as a paper copy.

All nurse respondents were aware that the policy addressed the problems of staff in relation to latex-containing gloves, but rather fewer knew of the possibility of patient reactions and of the range of equipment that could potentially contain latex. The groups of staff interviewed

who had a higher-than average awareness of latex allergy and its management worked in theatres, ITU and children's wards, where 'champions' had frequently carried out significant amounts of work to identify latex-containing equipment and to source alternatives. In addition to asking staff about the availability of latex free alternatives, researchers noted actual audit findings. Whereas only 45% of respondents thought that they had access to latex free Oxygen masks and IV lines, the reality was that over 70% of wards actually had access to latex free versions of this equipment. On the other hand the audit demonstrated that only 48% of ward areas had access to an ambu-bag that was marked latex free.

In a number of acute trusts, we were informed that, in the event of a patient with an allergy being admitted, staff had access to a latex free box of equipment, placed either on the unit or in a central point such as theatres. However, the researchers sometimes received conflicting information, being told by managers that latex –free boxes were available, but being unable to find these when visiting the ward and finding that some staff were unaware of such provision. In one trust, whilst managers informed us that a box had been made available in theatre, staff there denied that such a box existed:

"There was supposed to be a non latex box for months but we have not yet received it so we have to do a blue peter make-up, gathering stuff despite asking."

One trust claimed to have issued wards with a green box of latex free equipment yet on one of the areas visited we found a staff member who had a serious allergy to latex yet, despite requests, this ward did not have such a box. In another trust the boxes, which had been lying in a storeroom, were distributed on the day prior to the researchers' visit.

A small number of interviewees gave information on how a patient with known latex allergies would be managed, including wearing a red identity bracelet and having notices on their door. One patient with a latex allergy was identified during an audit visit and this was highlighted and observed in the nursing notes and Kardex. The patient was not available to check the red allergy bracelet that the nurse interviewed told the researcher she was wearing.

9.5.2 Evidence from District Nurse Interviews

In PCTs, 35 (55.6%) district nurse interviewees told us that they had received the alert on latex allergy, but it again transpired that many were thinking of other documents that contained warnings about the dangers to latex-sensitive staff and a majority had not considered that equipment other than gloves might contain latex. Both the following quotations are from district nursing staff:

"You assume equipment is safe for use."

"You just use what you've got, don't you?"

Many subsequently commented that equipment could be ordered on an individual basis for the patient if required; whilst others stated that the equipment was likely to be in place in the

home when they start visiting the patient. Notwithstanding the lack of awareness of staff, in the PCT clinic store rooms visited, 89% of the syringes and gloves observed were either all latex free or such alternatives were available. District nurses stated that oxygen masks were supplied by the company providing the gas. Most respondents (67%) stated that they had access to non-latex catheters, which were in any case usually ordered for each patient on an FP10 prescription form. One clinic had no latex free gloves and another no latex free adhesive available at the time of the visit, but the others did. BP cuffs were mainly rubber and unmarked.

9.5.3 Evidence from Paramedic Interviews

In ambulance trusts, 9 (41%) front line staff interviewed stated that their trust had a policy on latex allergy. Others reported that they had become aware of the issues in another way, for example via the hospitals they visited, but had not seen the NPSA notice nor had they seen a local policy. In the two ambulance trusts that explicitly stated that they were entirely latex free, front line staff were aware of neither problem nor solution – only managers knew what action had been taken. One interviewee in a latex-free ambulance trust stated that latex free gloves could only be obtained with a GP letter which prompts their manager to place an order. Others stated that there was a response bag available, which contained latex free products. We assume, although this was not recorded, that these were from another organisation prior to merger where different procedures applied.

Ambulance staff were asked about their access to latex free products. The analysis is shown in Table 9.2.

Table 9.2: Access to latex-free products in ambulance stations

Equipment	Yes	No	Don't know	Don't use	No response
Respiratory equipment					
Airways	11 (50%)	1 (5%)	8 (36%)	1 (5%)	1 (5%)
Oxygen masks	11 (50%)	1 (5%)	9 (41%)		1 (5%)
IV tubes					
NG tubes		1 (5%)	1 (5%)	11 (50%)	9 (41%)
IV lines		7 (32%)		6 (27%)	
Dextrose 5% IV fluid		9 (41%)		6 (27%)	
Monitoring and Observation equipment					
Gloves	16 (73%)	1 (5%)			5 (23%)
BP cuffs	7 (32%)	1 (5%)	8 (36%)		6 (27%)
Resuscitation equipment	10 (46%)		4 (18%)	1 (5%)	7 (32%)
Other equipment					
Adhesives	11 (50%)		8 (36%)		
Trolley mattresses	6 (27%)		7 (32%)	1 (5%)	

9.5.4 Evidence from Mental Health Trusts

Both of the mental health trusts visited had a glove policy which dealt with the care of affected members of staff. One (in which the Director of Nursing had not been receiving alerts) was developing a more extensive policy, although two of the ward staff interviewed stated that they had only become aware of this for the first time two days prior to the visit of the researcher. In the other mental health trust visited, all 6 ward managers interviewed were aware of the existence of the glove policy and could locate it either in hard copy or on the intranet. Ward staff (with one exception) were surprised to know that other equipment might pose a risk to patients. When prompted they assumed that the trust had already taken action and believed that, provided equipment had been procured in the normal fashion, it would be safe for use. Three ward managers across the two trusts thought their trust had a latex-free policy so would assume that all equipment was latex free. The audit in the mental health trusts revealed that, with three exceptions, ward areas all had immediate access to latex free gloves but that the availability of other equipment was varied. Sterile packs for wound care contained gloves and these packs were not MARKED latex free. Syringes were a mixture and not all areas had immediate access to latex free adhesives. Mattresses were unmarked. Most BP cuffs contained rubber latex, although some of the newer ones did not.

9.5.5 Evidence from Practice Manager Interviews

Practice managers were asked whether staff had immediate ready access to non-latex versions of the following equipment: syringes, gloves, BP cuffs and adhesives. The results can be found in Table 9.3.

Table 9.3: Availability of latex-free equipment in GP practices

Equipment	Yes	No	Other	Don't Know
Syringes	9.5%	14.7%	1.1%	68.4%
Gloves	82.1%	4.2%	0	7.4%
BP Cuffs	28.4%	14.7%	1.1%	49.5%
Adhesives	42.1%	12.6%	0	38.9%

The majority of respondents did not know if the staff within their practice had immediate ready access to syringes, BP cuffs and adhesives yet 78 (82.1%) said they did have immediate access to non-latex gloves. One area had access to all non-latex equipment due to one of their GP's having a severe allergy to latex. A large proportion of the interviewees stated that they did not know what clinical equipment they stocked as nurses order this.

9.6 DEALING WITH CONFUSED AND UNCONSCIOUS PATIENTS

Acute trust interviewees were asked what assumptions they would make if working with a newly referred, confused or unconscious patient. During the audit period, 6 wards (3.5%) had patients with latex allergies, and 18 wards had care plans in which allergies were marked. 72% of respondents stated that they would use latex products unless advised to the

contrary. Other approaches included asking relatives, and reviewing notes. Many respondents said this question was not applicable to their ward since they did not admit confused or unconscious patient, or pointed out that if on a surgical ward, the patient would have been assessed prior to surgery and this information would be included in the notes or with a wristband.

13 (20.6%) district nurses interviewed told us that they would use latex products unless told otherwise, 16 (25.4%) would use latex products with care, and 8 (12.7%) would avoid latex products. Eight (9.5%) did not know. District Nurses reported that they would also ask carers or referrers for information, check medical records, obtain information from the GP or carry out a patch test before using a catheter.

When asked the same question, front line ambulance staff were asked what assumptions they made when dealing with a patient who is unconscious or confused. Table 9.4 shows the analysis of responses.

Table 9.4: Assumptions when dealing with unconscious and confused patients

Assumption	Number (%)
Use latex products unless told otherwise	9 (41%)
Use latex products if no Medic-alert bracelet or other sign	1 (5%)
Use latex products with care	0 (0%)
Avoid latex products	6 (27%)
Don't know	1 (5%)
Other	1 (5%)
No response recorded	4 (18%)

In one of the latex free trusts, four of the respondents also commented that the paramedics should check for a medic-alert bracelet anyway. One interviewee commented that they did not feel that they had the full range of latex free products and would have to use the equipment they had *"I feel this is not sufficient"*. Another commented that because the equipment is not labelled, they would also have to use the equipment they had.

Nurses in both acute trusts and PCTs claimed that they would determine the latex status of patients in discussion with patients or relatives, with district nurses checking with GPs if necessary. In one trust latex sensitivity was specifically listed in the allergy section of the admission document to prompt nurses to ask.

All staff in all organisations were asked whether they asked new staff (including agency or locum staff) if they were sensitive to latex. Only 27 (15%) of acute trust respondents and 11 (17.5%) of PCT respondents reported that they would whilst all others felt that it was the duty of new staff to raise the issue if it was a problem, many pointing out that this would be determined by the occupational health department on appointment. Five respondents from a latex-free ambulance trust commented that this was not an issue in their organisation.

9.7 LATEX FREE MARKINGS

On many occasions the research team found the latex status of products difficult to determine. At best, equipment is poorly marked, with a variety of devices to indicate whether items are latex-free. This was sometimes as text within several lines of information in small font on a clear plastic container and sometimes so tiny that the symbol could hardly be read even with the help of a magnifying glass (see Figure 9.1). Latex-containing bed and trolley mattresses are indistinguishable from their latex- free counterparts. We have found no dextrose 5% or any other IV fluid marked latex free.

Figure 9.1: Example of latex free markings on a 5ml syringe

It should be noted that in some organisations emergency equipment is already removed from wrappings for speed and no information on latex content is available to these front line staff at the point of care.

9.8 SUMMARY

A majority of trusts had taken action following the NPSA alert issued in 2005, appointing leads and revising policies. Earlier warnings on the subject of latex allergy appeared to have caused ‘interference’ in the management of the alert, some senior managers relating the story of the management of earlier action on gloves. In some trusts the leads for this alert

were appointed from occupational health and infection control departments. The confusion was evidenced in some policies. In one acute trust and four PCTs, despite senior manager assurances that the alert had been incorporated into the trust policy, the audit found this to deal specifically with gloves as a threat to the wellbeing of staff.

Only two ambulance trusts had opted to become entirely latex free, although four acute trusts reported having a policy of purchasing latex free goods whenever possible, and a high proportion of syringes (87%) and a majority of BP cuffs (60%) were in fact free from latex. Estimates of the costs of latex free equipment varied wildly, with some claiming that the cost was highly significant whilst others believed it to be marginal. A number of trusts claimed to have made boxes of latex free equipment available but not all staff knew of these or the boxes had not yet been acquired (or in one case had been supplied the day before our visit). No PCT had taken the step of making latex free boxes available to community staff although it should be noted that we did not investigate community hospitals.

At ward and clinic level a high proportion of staff who said they had received the NPSA alert reconsidered their response when asked about their access to latex-free version of common equipment such as syringes, BP cuffs and Oxygen masks, saying that they had not thought of any equipment other than gloves being implicated. In all trusts only half the staff who knew there was a trust policy could access it on the intranet. Computer access in community clinics was particularly poor and many staff there preferred the previous system of distributing hard copies to the newer electronic distribution system. In any case, once printed at ward and clinic level, the alerts were placed in a folder for all to read which means that any colour coding of alerts is lost. Areas in which there was a higher degree of knowledge about equipment containing latex were theatres, paediatrics and A&E, many of whom boasted a “champion” who had become highly knowledgeable about the subject.

We found latex free markings on equipment to be an unsatisfactory source of information for practitioners, either because such markings did not exist (on mattresses) or because the information was given in small print amongst many lines of other information, or was just too small to read. Therefore, even if warned that a patient is highly allergic to latex, then staff may have no way of double-checking that an item is safe to use with that patient.

Section 10: Alcohol Based Hand Rub – Danger of Fire

10.1 SUMMARY OF ALERT

Alcohol based hand rub	DH F&E (NHS Estates)	Ref no: NHSE (2005) 07
		Action
		16th June 2005
Reduction of potential fire risk associated with alcohol based hand rub		
• Ensure that quantities of all flammable liquids, including alcohol based hand rub in the workplace does not exceed 50 litres; • Reserve stock of alcohol based hand rub and other flammable liquids in the workplace is kept in a lockable metal cupboard; • The hand rub is kept away from naked flames and ignition sources. Dispensers should not be sited directly above or adjacent to electrical sockets or switches; Where hand rub is sited in corridors and accessible to visitors: • Corridor width should be 2m or greater; • Dispensers should be a minimum of 1.2m apart; • Maximum container size should be 1 litre; • Dispensers should not be in public areas that are carpeted; • Ideally implement minimum stock levels via ward-based materials management approach; • Bulk storage is in fire resisting cabinets, whether in pharmacy or main stores.		

10.2 INTRODUCTION

Alcohol based hand rub dispensers were widely installed across hospitals, health centres and ambulance stations as part of the implementation of the Cleaner Hands Campaign. The patient safety alert advised trusts on the risks associated with the location of dispensers and the quantities stored. The alert applied to all organisations, and we therefore interviewed staff and conducted audits in acute trusts, PCTs, mental health trusts and in ambulance stations.

10.3 IMPLEMENTATION OF ALERT

Responsibility for this alert appeared to lie with different groups of people. It was reported that Directors of Nursing and infection control teams had taken responsibility for the implementation of the Cleaner Hands Campaign, of which the optimum location of the dispensers were a critical part. Therefore, although the alert focusing on the danger of fire with respect to ABHRs was issued by the DHEF, the lead for the implementation of this alert did not necessarily lie with the Estates and Facilities Directorates and normally involved combinations of Facilities, Infection Control, and occasionally fire officers or health and safety personnel. Additionally, in trusts with PFI buildings where services were provided by external contractors, such alerts necessitated complex negotiations involving up to four

organisations – the NHS Trust, the managing agent and the companies responsible for hard and soft facilities.

In our interviews with Directors of Facilities, three of the 18 respondents believed that their trust's chief nurse was responsible for the implementation of this alert, two that it was the risk manager, one that it was the clinical governance lead, three that it was the director of facilities, four cited others (including infection control, fire or health and safety and domestics) and three did not know. One commented:

"This was a contentious alert…it was discussed with fire officers. Fire officers had been to meetings about the increases in fire risk, but [we] believed that the impact of infection was greater than the risk of fire, and there are greater fire risks."

In PCTs, only four senior managers interviewed had a memory of action taken, two deciding that the PCT was already compliant and two reporting an audit of stocks and container sites. Another reported installing fire-proof cupboards. Two more told us who led on it, or who they thought would have led on it:

"Health and Safety Team would have dealt with this."

"Infection control led on it."

By contrast, eleven (38%) community nurse managers stated that they had received the alert but 16 (55.2%) had no memory of how the PCT had dealt with it. Others confirmed the above mentioned action taken. In two there had been discussion about the safety aspects of carrying alcohol-based hand rub in cars, especially in hot weather or its use in homes where patients were smoking.

10.4 LOCATION OF DISPENSERS

Only one of our facilities' interviewees confirmed they had a chart of the location of every hand rub dispenser, eleven (61.1%) stated they had not, and two did not know. One suggested that the infection control teams might have charts, or that they were mostly in given places such as one fixed outside every 6-bedded bay or are fixed at every bedside locker, at every ward entrance and every sink. One respondent believed that the site was too complex for such a chart. Only one respondent believed they had had to remove or re-site dispensers from carpeted areas in response to the alert. Only one had had to remove carpets from areas where dispensers were situated and two commented that all carpets had been removed in any case to reduce risks of infection.

10.5 PURCHASING OF ABHR

Six (30%) purchasing managers interviewed stated that the flash point is not taken into account when purchasing ABHR, and four (20%) stated that it was considered. Seven stated that they did not know, most commenting that they presumed PASA had reviewed this since the ABHRs were in their catalogues

10.6 STORAGE OF ABHR

10.6.1 Evidence from Interviews

In response to the question on how to ascertain the total quantity of flammable materials stored on a ward or in a department, 22% of facilities interviewees told us that they had undertaken an audit, 22% restricted ward supplies and 22% stated the trust had a top up system to the wards. Examples of how the total quantity was ascertained included:

"*It was all done through infection control…didn't get involved."*

"Fire officers undertook an audit of a sample of dispensers."

"It is the ward manager's responsibility."

The majority of respondents believed storage of ABHR was not an issue since the ward top up system precluded large quantities form being stored. Sometimes stocks are held in the loading bays, and small quantities may be kept in central stores.

Four Directors of facilities did tell us that they had specific stores where they were kept, three of whom stated they were in metal fireproof cupboards, or in another flammable storage area. A particular issue identified was the installation of the dispensers by a number of firms who appeared not always to adhere to the guidance.

10.6.2 Evidence from Audits

During the ward audits, researchers collected information about the quantity of ABHR stored on the wards. On 97 (57.1%) wards there were small quantities (Less than 10 litres) either in the form of boxes of bottles in ward cupboards or sluice rooms, stored individual refills for the ward dispensers (normally stored in locked cupboards). Additionally, on many wards, staff carried their own individual pouches or dispensers of 50-60ml. On 23 of the wards it was not possible to assess the quantities, and on 48 of the wards no data was recorded.

Researchers also noted the location of hand rub dispensers, and recorded examples of non-compliance in a total of 60 wards. Small numbers of non compliant dispensers were noted, for example, in corridors less than 2m wide (9 examples noted), closer than 1.2m to another dispenser (where on 35 occasions differing numbers of containers were noted, varying from 2 to 8), in carpeted areas (6 examples noted), located above or next to electrical sockets (45

examples noted including many next to light switches, one ward where all cubicle dispensers were next to light switches, and many examples where individual dispensers are above sockets and without drip trays). One was sited immediately above an extension socket lying o the floor, servicing an electric fan. We also noted that in 22 instances larger quantities were stored in total but there were no individual containers of more than one litre, and in all instances many smaller containers were stored together.

Very small stocks were carried in PCTs, and district nurses carried their personal supplies to patients. Mental Health Trusts are relatively low users but are more likely to have carpeted areas. We found that drip trays had been provided in this setting. Also stocks are locked away due to the risk of patients drinking it and also using it to set fires.

In ambulance trusts the gel was stored in fire proof cupboards. Most alcohol based hand rubs were found in dispensers over wash basins in ambulance stations, in small amounts. Ambulances also held small quantities in dispensers, and increasingly ambulance staff had their own small pouches which they carried around in their pockets for use in patients' houses.

10.7 SUMMARY

This alert was remembered and action taken in acute trusts and ambulance trusts although respondents in some Trusts felt that this alert had overstated the fire risk. We did find 60 cases in which the location of dispensers breached the guidelines in the alert. We found 45 dispensers situated above or close to electric sockets. Some ward entrance areas have a number of dispensers sited close together and one recently refurbished ward had a carpeted entrance with gel containers sited on the wall. Low volumes of stock were normally held in wards and clinics and as most trusts operated a just in time ordering system there was no large stock held in stores. Where stocks were held, they were normally kept in fire-proof cupboards. The only exception was immediately after delivery when a large quantity of stock (400 litres) might lie in stores overnight. Action in PCTs was difficult to determine as memory of this alert was limited. In one PCT an audit had been conducted at the time of the alert to determine the stocks carried in clinics, but all were below the stated level.

Section 11: Mobile Food Trolleys

11.1 SUMMARY OF ALERT

Reduction of risks associated with mobile food trolleys	DH Estates and Facilities Alert	Ref no: DH (2005)11
		Action
		17th August 2005
To reduce the likelihood of damage to the electrical power plug with consequential electric shock injury		
• Ensure plug is disconnected from power source and correctly located in trolley plug holder before moving the trolley; • Ensure cable stowage devices are properly used when trolley is in motion; • Carry out regular and frequent visual inspections of the plug and cable; • Arrange for the device to undergo Portable Appliance Testing (PAT) more frequently than 6 monthly intervals; • Consider appropriate training for operators under first three points.		

11.2 INTRODUCTION

We only investigated this alert in acute trusts, and the alert only applied to heated food trolleys, transporting food from kitchens to wards. We investigated two aspects to the alert: the safe movement of the food trolley and the maintenance of the food trolley. Trolleys may be moved by catering staff, porters or by generic ward staff and maintenance may be undertaken in-house. We also discovered that in trusts with PFI schemes, catering may be provided by an external company, and maintenance of food trolleys may be provided by the same or a different company. Additionally, many trusts have moved to cook-chill arrangements on different sites and therefore no longer have mobile heated food trolleys across the whole trust. Therefore, this alert often proved difficult to track through organisations. Although the letter setting up the visit asked to interview “porters or catering staff involved in moving mobile heated food trolleys” we were frequently scheduled to interview the wrong group of staff. In trusts with PFI schemes, we also often had to interview the Trust contracts manager as we were unable to gain access to the external companies providing services.

11.3 MAINTENANCE

11% of Directors of Facilities interviewed stated that their trust was already compliant when the alert was issued 28% that the maintenance strategy for the trolleys was changed, 33% that a memo or warning was issued and 33% that other action was taken. Several clarified their response, for example trusts were compliant with some aspects, but not the maintenance schedule, which had to be amended. One interviewee believed that it was unnecessary and too expensive to follow the required maintenance schedule, and hence their sites were adhering to the existing PAT maintenance schedule. One respondent told us

that their trust did not use this type of trolley at all, and hence the alert did not apply. From two respondents we received the following information:

"The wire is currently long and is wound round handle….in future a visual inspection of the plug will be carried out."

"No follow up action from the trust has occurred to check what they have done about compliance. Quite weak in ensuring that sub-contractors are complying with the guidelines and alerts as they don't see them."

In one trust, the hotel services manager did not receive alert until February 2007, in preparation for the visit.

In response to the question on ensuring that electrical devices are regularly serviced, six referred to their annual PAT check, whilst others described their planned preventive maintenance schedules. Others also informed us that their PFI partners were responsible for the maintenance of the trolleys.

We interviewed nine electricians regarding this alert on mobile food trolleys. All nine knew about the warning of the danger of electrocution from mobile food trolleys. The service intervals varied from less than three monthly to more than 6 monthly, and three did not know. One stated that it was the PFI contractor's responsibility, and hence did not know. Difficulties in ensuring the regular service is carried out included:

"There are different ways of working across the sites" and;

"When alert came out we had a sourcing contract in place. This was cancelled for financial reasons and we have had difficulties picking this up."

One respondent stated that there was now a weekly visual inspection, and if any problems were identified:

"It would be picked up by the audit trail and help desk."

Another believed the safety of equipment to lie in the hands of the user, stating:

"The user – all users of electrical equipment have a responsibility to ensure the safety of themselves and their colleagues while at work.'"

Five electricians stated that there were service logs for the trolleys, although two also said that service logs would be held by the PFI contactors. Maximum time between services varied between daily check at one hospital site, through three and six monthly to a maximum of 11 monthly.

11.4 USING MOBILE FOOD TROLLEYS

Most facilities interviewees told us that the manager of catering services (if in house), or the equivalent person in the PFI Company, would ensure that their staff were aware of this alert. Some systems included staff signing to indicate they had seen notices sent to them, others that a re-training programme was implemented, ensuring everyone had access to the food trolley training manual, and attaching laminated notices onto the trolleys themselves.

Only two electricians stated that there was any written guidance or instruction on the moving of mobile food trolleys, one commented that there were notices on the trolleys, and a second that they are on the catering belts in one of the kitchens. In response to the question, as to whose responsibility it is to monitor whether cables are being correctly stowed, 2 (11.1%) said head porter, 10 (55.6%) said other, and one (5.6%) said there was no monitoring. Examples of others included the catering services manager, the private company running catering services and domestic supervisors.

Nineteen interviews were undertaken with porters or catering staff about their knowledge of this alert: in some interviews a group were interviewed together. Of the 19 interviews, 9 (47.4%) interviewees or groups of interviewees were aware of the alert and in 10 (52.6%), they did not. One interviewee was aware of the risk assessment process undergone; two porters stated that the kitchen staff unplugged the trolleys (adding that they were given the alert two days prior to this interview) and porters in one interview stated that training had been given to them. The majority of interviewees (in 10 of the interviews) did not know how often the trolleys were serviced, and in only 4 interviews were they able to tell the interviewer of the service intervals. Comments from two respondents in one PFI trust were:

"Been here two years and never seen this. [Name of company] won't pay to get these serviced. Currently doors are unsafe and are being held together by webbing straps…[name of company] are being replaced in August due to not replacing these."

"Been here a year and not seen any [Name of company] are not bothered as they have lost the contract. Training is poor."

63% of facilities interviewees told us that there is an alert system (e.g. stickers or labels) on the trolley notifying of the last/next service, and 68% told us that the porters were able to stow away cables when the trolleys are moved. We were told of many versions of 'stowing away' including:

"Gets tied over handle."

"Has plug socket on back and plug them in when moved."

"trolley cable winds itself back into the trolley."

"Kitchen staff do that and they put through handle. A lot are going to break down soon."

Finally in 16 interviews (84.2%), porters told us that they were expected to take action if cables or plugs were fraying. Most stated that they would not use the trolley and would inform their manager, report it to the relevant member of the kitchen staff, or inform Estates or the PFI contractor via a help desk.

11.5 EVIDENCE FROM THE AUDITS

We were only able to see the PAT testing schedules in seven trusts. In four, these were up to date and complied with the alert. The remainder were not, with a gap of eight to fifteen months. Audit revealed fascinating complications in PFI trusts where responsibilities for this equipment were unclear and up to four organisations were involved in contract negotiations (NHS trust, managing agent, catering company and facilities support company). In another trust the maintenance of these trolleys had been contracted out at the time that the alert arrived. This contract had since been cancelled for financial reasons and the estates department respondent acknowledged that they were still struggling to incorporate this added work into their PAT scheme. In this trust there was a 10-month gap between the previous test and a recorded test in September 2006.

11.6 SUMMARY

Only one of our trusts did not use mobile heated food trolleys at all, having moved to cook chill systems, and several used cook chill on one or more sites, in which case we collected information about those sites where mobile food trolleys were used. Only two trusts reported having written guidance or instruction on the moving of mobile food trolleys. It was difficult to determine, until we reached the facilities directorates, who should have taken action on this alert and we were frequently scheduled to speak to inappropriate people. The alert was even more complex in PFI trusts. Memory of the alert was minimal amongst portering/catering staff, although it was clear in a most trusts that some action had been taken. Good storage facilities for flexes were seldom seen, most being wound around handles. About half of the PAT testing schedules seen were up to date, the others not. However, we saw no sign of any worn flexes on the trolleys we saw in use.

Section 12: Implantable Cardioverter Defibrillators

12.1 SUMMARY OF ALERT

<table>
<tr><td rowspan="3">Reduction of risk associated with problems with implantable cardioverter defibrillators (ICDs) Series of ten alerts issued for several manufacturers' makes and models of ICDs</td><td>MHRA Medical device alerts</td><td rowspan="3">Ref Nos:
MDA/2005/015
MDA/2005/018
MDA/2005/037
MDA/2005/038
MDA/2005/039
MDA/2005/041
MDA/2005/045
MDA/2005/046
MDA/2005/048
MDA/2006/006</td></tr>
<tr><td>Action and updates</td></tr>
<tr><td>2nd & 17th March 2005
27th (3) & 30th June 2005
25th & 26th July 2005
11th August 2005
6th February 2006</td></tr>
<tr><td colspan="3">Problems include premature battery depletion or failure, and other manufacturing and component faults. All problem ICDS are identified by manufacturer</td></tr>
<tr><td colspan="3">• Be aware that premature battery depletion and prolonged charge time may occur during three-month follow up period;
• Be aware that there may be other problems with the ICD, e.g. inadequate insulation within the device, random memory error, sticking of magnetic switch, high rate pacing due to out of specification component, seal failures;
• Identify patient affected by alerts;
• Ensure patients affected followed at intervals no longer than three monthly;
• Advice affected patients to contact their ICD centre if experiencing problems;
• Report all instances of unexpected battery depletion;
• Return unused ICDs to manufacturer.</td></tr>
</table>

12.2 INTRODUCTION

Ten alerts were issued in respect of numerous problems that emerged with ICDs. We collected evidence about the processes of identification of patients with ICDs affected by the problems, and the actions undertaken by the trusts thereafter.

12.3 RECEIPT OF ALERTS

We interviewed people at 10 trusts about the management of ICDs and we undertook an audit at six trusts that implant these devices, four of which implanted between 11-50 ICDs, and two more than 100 per annum. Four more trusts manage patients whose implants are done elsewhere. Respondents reported having received the alert from a number of sources – directly from the MHRA, the manufacturers, the consultant and the SLO. Trusts normally use only one or two makes and models although they do of course inherit patients who have moved into their area. Two of the centres used one make of ICD but with several models, and four used several makes and models. Two of the centres flag on their computer

database receipt of an alert of notification about a malfunctioning ICD, and five have other methods.

12.4 IDENTIFICATION AND MANAGEMENT OF PATIENTS

12.4.1 Identification of Patients

Methods used to identify which patients affected by the alerts are an electronic database (four centres), paper systems (four centres) and receipt of information from manufacturers and implanting centres. One centre knows that all patients have the same make or model.

Methods employed for matching serial numbers against their patients include electronic databases used by four, paper system used by four, patient notes used by one and patient ICD files in another. In trusts with electronic databases, on receipt of the alert they have to check each patient individually on the database, which is a time-consuming process as the serial numbers of affected devices are not in series. One trust was dependent on the HR UK computer database, which was reported to be out of order at the time of the publication of the alerts. As the department had been unable to finance a trust system, they were working with a paper-based system both at the point at which the alerts were issued and at the time of the visit. Some respondents reported that some manufacturers were happy to supply the department with serial numbers of machines for tracking purposes.

In no centre did we find a policy or procedure for the management of recalled patients. Five centres had patients affected by the ICD alerts: the numbers of patients affected ranged from one in one centre, to more than 100 (almost half of all transplants) in another.

12.4.2 Notification of Patients

Once patients had been identified a letter was sent out in four trusts, and the patient was contacted by mail or telephone and asked to attend an appointment. Three trusts also telephoned their patients. Trusts with large numbers of patients affected ran extra clinics or longer clinics to cope with the extra numbers. One trust assured us that if the patient failed to attend then the department would phone them again and if still no contact would ring the next of kin or the GP.

In one small trust, on receipt of the alert, the clinical investigation department checked the batch numbers against patients and identified that around 30 patients were affected. The clinical governance manager spoke to the cardiologist and offered to contact patients and arrange the recall. Patients were contacted by means of a letter and asked to confirm receipt. They letter gave the recipients the contact number for the Patient Advisory Liaison Service (PALS) and also offered the presence of the clinical governance manager at the interview as a supporter for the patient. The trust then provided taxis to bring recalled patients, all of whom were seen within a month, to and from the clinic.

During our audits of departments, in two trusts we saw documentary or other evidence that a search was carried out following an alert. In one trust there was an IT audit trail, and in

another internal emails to the SLO. In three trusts we saw evidence that patients attended for a review within a date of the issuing of the alert, there was also some evidence in patients' notes and in the appointment schedules for two trusts. In three trusts we also saw evidence that patients attended for a review within a date of the completion date for action of the alert.

In all five trusts, it was possible to identify the time elapsing between issuing of alert and patient being seen, the lowest value recorded was one day, although in two trusts this was one week and four weeks, and the highest value was 6 weeks. Trusts were not able to identify the last date on which a patient was implanted using one of the affected ICDs.

12.4.3 Patient Follow-Up

The normal pattern for follow-up again varies depending on the model, or on the patient, with three trusts stating that there is a sliding scale. One trust also said that the normal follow-up period is after one, two and then six months, and another that patients are seen frequently with a three month review and a maximum of six monthly. When a patient attends a clinic, the staff know that their device is one highlighted in the alert in two trusts by flagging on the computer database, in three trusts as they see all affected patients in one clinic and in all five by putting a note in the patients' notes. One trust also writes 'alert device' on the top of the patient folders.

When the patient attends the clinic, one trust flags on their computer database that the appropriate actions have been carried out, one puts a sticker on the patients' notes, and three check against a list. Other mechanisms deployed included a manual system of all patients affected against which outcomes are recorded, double checking all notes, and recording in dedicated records. None reported using barcode devices. In one trust patients are given copies of the alerts at the clinic and told of warning signs and who to contact if they have any concerns. This trust tries to ensure that an ICD manufacturer's representative attends the clinic. Other trusts offer counselling support.

Only four trusts had undertaken explants. Two trusts had explanted 1-5 ICDs and one more than 10 as a result of the alert. The processes for reporting explants to the ICD database included an electronic link to the HRS UK database, a paper link to the HRS UK database, and informing the MHRA. One trust described sending the explanted device to the company that supplied it, who then may notify the database. This trust explained that devices are likely to be changed every 4-6 years: a form for the database in also completed and a second part of the form is used for explants.

12.4.4 Management of Stocks

Four of the trusts reported not keeping local stocks. Only one trust reported having local stocks checked by the technician identifying affected ICDs via the serial numbers issued. In two trusts, the ICD technician was responsible for managing stocks, and others reported receiving assistance from the companies. Only one trust reported having a paper record for the movement of stocks.

During the departmental audits, in no trust did we find a policy or departmental guidance on the management of recalls. Three trusts had electronic databases, containing data such as model, serial number, implant date, battery voltage, charge times, summary of episodes, and leads used. One of these electronic databases was not working and this had been reported. Four of the trusts used ICDs from Guidant, two from St Jude, five from Medtronic, and one Biotronik. One trust reported changing their contract from Guidant to St Jude. All five trusts reported having models in use that were covered by the ICD alert, one reporting the Medtronic Marquis, one a Guidant, one a Guidant Prism, and one reported that all were affected. One trust reported having one patient recalled as a result of the alert and one between 150-200 patients. None of the trusts had recalled devices in stock.

12.5 SUMMARY

Ten of our trusts implanted ICDs or looked after patients with devices implanted elsewhere. All had some patients affected by the alerts issued by the MHRA in the summer of 2005. All reported checking the alerts against their databases, taking action either by flagging patient files electronically or marking patient notes. For one trust who used just one make and model this was comparatively easy, but others used a variety of makes and models. Searching for affected serial numbers is a time-consuming process in either case, although more so in trusts with paper systems. All made provision to see patients within the timescale indicated by extending clinic times or putting on extra clinics, although for one trust this involved more than 100 patients. Several trusts made counselling available and one took very great care to support affected patients.

Section 13: Safe Delivery of Radiotherapy Treatment

13.1 SUMMARY OF ALERT

Safe delivery of radiotherapy treatment	Department of Health Alert	Ref no: none
		Action
		23 rd December 2004
To reduce the risks in the delivery of radiotherapy treatment as a result of data errors from manual transposition of machine parameters		
• Review practice and procedure relating to data entry into linear accelerator record and verify systems (R&V); • Review and identify primary sources of information for checking data in R&V systems prior to treatment delivery; • Review provision of appropriate environment for data related tasks and at treatment console; • Take any necessary actions to address changes in procedure and practice to minimise the risk of this type of incident being repeated.		

13.2 INTRODUCTION

This was one of the first alerts to have been issued through the SABS system and many SLOs were unable to give precise information as to how it had been handled. Memories as to precise action were poor. In addition, to the senior managers, we interviewed radiotherapy services managers, and audited the checking mechanisms used.

13.3 MANAGEMENT OF THE ALERT

We visited five trusts that offer radiotherapy, interviewing three radiotherapy services managers, one head of radiation services and one consultant physicist together with a treatment radiographer. Two had received the alert from the radiation protection adviser, one from their manager and one directly from the SLO.

In only one trust was there a specific memory of the receipt of the alert. The respondent stated that when the alert was received, the practice and procedures relating to the use of wedges and the transfer of data to record and verify system was reviewed by superintendent radiographers who also reviewed primary sources of information and checking procedures. An office was already provided for processing of data related tasks. Measures were considered to improve environment at the treatment console, but this has been a longstanding issue, still unresolved at time of visit.

13.4 DELIVERY OF RADIOTHERAPY TREATMENT TO PATIENTS

Two of the respondents specifically stated that they worked to ISO 9001 and three to Trust policies and protocols. In four trusts, the treatment plan is devised by physicists working in an area devoted to planning, whereas the radiotherapists devise the plan in the fifth. In all cases the plan is signed by two people, and then by a medical oncologist. One respondent told us that there were specific competencies to be permitted to check a plan which differed from those required to prepare it. One respondent explained:

"The clinical oncologist prescribes a dose that should be planned to deliver radiation to a particular point. From that information the physicists calculate how to give that dose at that point whilst giving the minimal dose to the areas at risk. So the oncologist prescribes the total dose and the physicists break it down to give the best way of getting that does to the area outlined whilst minimising the dose to other areas and sometimes as you can imagine it is a bit of a compromise so you get that great dose but it's compromising the spinal cord so it all has to be moved around. Each plan is done individually for each patient to produce the best plan that they can."

All treatment sheets seen had been signed as requested by the protocol. Once signed, the plan is then passed to radiotherapists either electronically or by using a paper plan. Even if the plan is transferred electronically, the radiotherapists re-check the parameters and programme the linear accelerator (LINAC) machine. Before activating the LINAC, two radiotherapists check the paper plan against settings on the screen, although one interviewee pointed out:

"So what the radiotherapist is doing is basically looking for transcription errors or mistakes – they are not at any point checking the calculations. They do not have the ability to do that."

"Before a treatment unit is energised, two radiographers have to agree. One reads the linac screen and the other the treatment sheet which is what they are expecting to be set on the treatment unit. Only once the second radiographer agrees that the parameters are correct that the beam can be energised."

Occasionally, radiotherapists have to override the parameters set, for example because one measurement (such as bed height) is more than 3mm out of true. If this is necessary, two people must check it, and one is usually required to be sufficiently senior.

Systems are predictably complex, but we observed no indication that any stage of the process was not followed, the limited evidence observed (two plans in each trust) suggesting that treatment plans were signed by the required number of people.

Programming of the LINAC is usually carried out in a shared office facility. In two trusts this was still happening in the treatment area whilst in the other three there was an office remote from the treatment area for this purpose. In one trust the treatment console was in a corridor:

"We are just trying to order a desk and a chair and some signs so that again we are trying to get people away from the treatment consoles. That is something we have been pushing for."

A variety of treatment machines are in use, some requiring the use of manual wedges and some having programmed wedges. The transfer of data to Record and verify systems relating to wedged treatments is electronic, but in one trust was still checked three times. The use of the wedge is displayed on paper treatment plan and on machine console at time of delivery. One respondent explained the safety features of a virtual rather than a physical wedge:

"*If you use a physical wedge what you are doing is putting a big chunk of metal in the beam that is tapered and that chunk of metal attenuates the beam so you have to have the machine operating for longer in order to get the same amount of radiation out the other side. Now if you have a virtual wedge you don't use the chunk of metal what we do is you use one of the jaws to start with a practically closed field apart from 1cm at one edge and then that jaw gradually opens during the treatment so the amount of time the beam is on delivering the radiation dose at the centre of the field is the same whether we use the wedge or an open field. It wouldn't have the same beam profile that we were aiming for but the effect would not be so disastrous."*

In vivo dosimetry is increasingly employed for the first treatment and this offers another safeguard. This involves a diode or silicone chip which is placed on the patient and records both the radiation intensity and also the cumulative dose received by the patient. This still involves a calculation as the dosimeter is placed on the surface of the patient and the focus of the therapy is the tumour which may be some distance below the surface. In recognition of the checking and re-checking procedures, one interviewee stated:

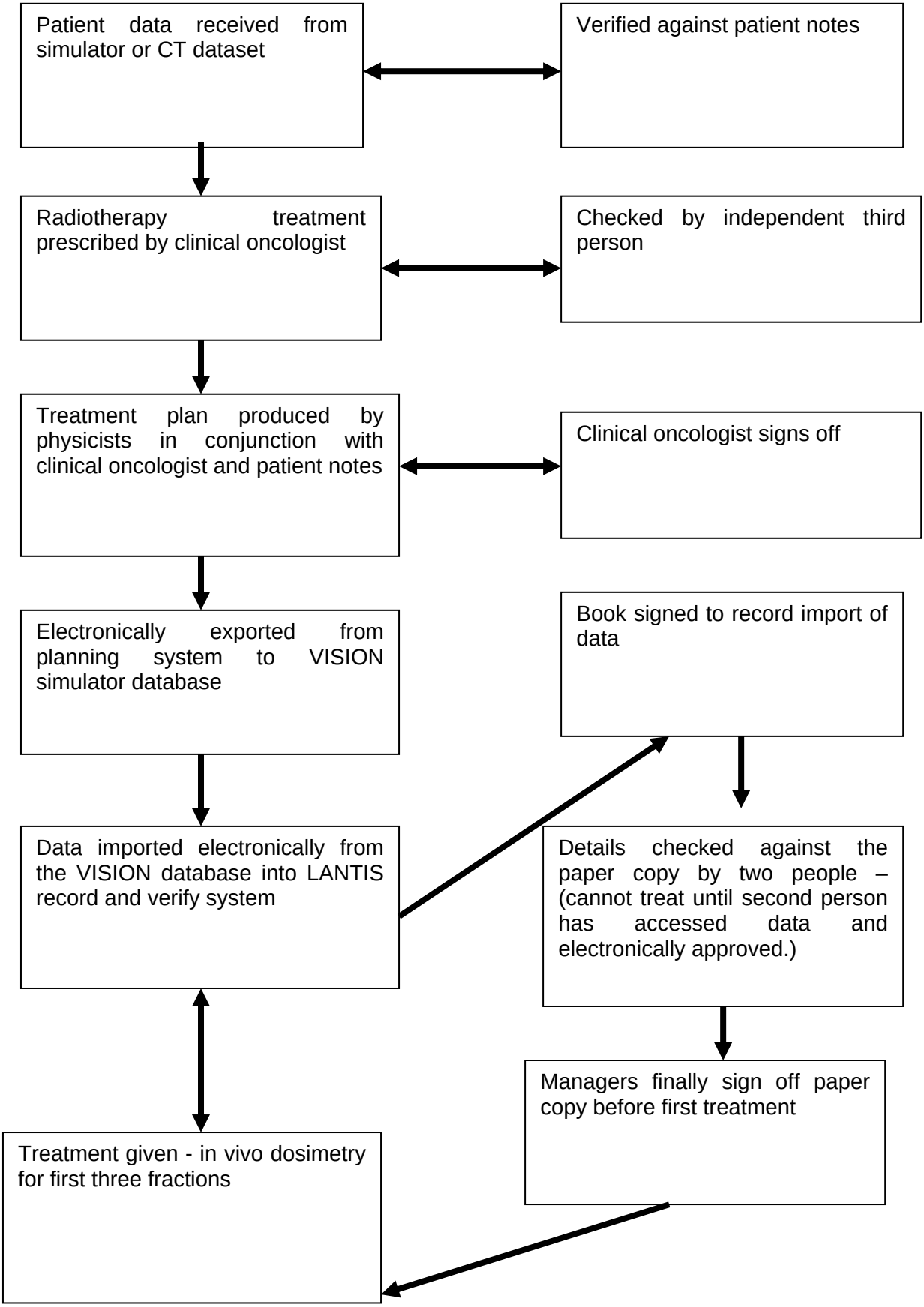
"We can't think of any other steps to put in place. The problems with putting too many steps in place is that people then think well three other people are going to check this so I don't need to be quite so careful. So you have to strike a balance."

A diagram of the checking processes described in one trust is found at Figure 13.1.

13.5 SUMMARY

There was limited memory of the handling of this alert, the first to be issued through the SABS system, and only one trust could provide us with documentary evidence of action. Only two of the organisations we visited, however, still used manual wedges and one of these was expecting a new linear accelerator to be installed at the end of the year. The trusts were very happy to walk us through their many checking procedures and we found no instance of missing signatures on any treatment sheet

Figure 13.1 Radiotherapy checking processes in one trust



Section 14: Electrically Operated Beds

14.1 SUMMARY OF ALERT

Electrically operated beds	Medical Devices Alert	Ref no: MDA/2005/034
		Action
		22 June 2005
Risk of entrapment and crushing from accidental operation of foot controls		
• Determine if your organisation has electrically operated beds fitted with foot operated controls; • Lock-out functions should be used in accordance with the manufacturers instructions for use; • If lock-out functions are to fitted, take alternative steps to reduce the risk of patient entrapment; • Consult with the manufacturer of the bed to assess available options.		

14.2 INTRODUCTION

This alert was only explored in PCTs, and in respect of electrically operated beds that were in patients' homes.

14.3 MANAGEMENT OF ALERT

Senior managers were asked how the PCT managed the alert issued in June 2006. One reported that the PCT was already compliant and two reported that community nurses reported suppliers of patients at risk. One SABS system recorded the following:

"Nurse Executive sent out email to all staff to warn staff that nurses should ensure beds are at lowest level when patients left. Sent alert to Social Services. Nurses received the alert. No audit done, but asked teams to check caseload. Nurses should provide training to carers. Agreed equipment should come with written instructions."

The remainder of the respondents either did not know (7) or stated that it was the responsibility of the supplier to take action (4). Comments from senior managers included:

"Alert sent to community nurses, hospice and nursing homes."

"Checked all beds and were compliant. Independent living centre who supply beds made aware of issues re this alert."

"Don't carry foot operated beds – use hand control."

The majority of PEC chairs/medical directors could not remember the actions for this alert, as others had implemented it. One commented:

"The nurses generally deal with all that sort of thing."

17 (58%) Community nurse managers acknowledged that they had received the alert issued in June 2006, one was told about it, 3 (10%) had not received it and one did not know. Community nurse managers were also asked if community nurses were involved with this alert. Fourteen (48.3%) said they were, whilst five (17.2%) said they were not and seven (24.1%) did not know. Comments included:

"A lot of people use electric beds. I asked that we check the type of bed. One member of staff went to the nursing provider of community equipment and also checked with Social services."

"Equipment loan stores provided them hand held."

"Came at similar time to one on hand rails."

Additional actions reported included making sure that in future the PCT avoided purchasing foot operated models, checking to see whether nursing homes had received the alert and carrying out a full risk assessment of patients before being given a bed. One reported that she "*went into joint loans with Local Authority, and the Health and Safety file was observed for all equipment."*

14.4 EVIDENCE FROM COMMUNITY NURSE INTERVIEWS

22 (34.9%) interviewees received the alert on electric beds issued in June 2005, one was told about it, 14 (22.2%) did not receive the alert and a further 14 (22.2%) did not know. Two mentioned the alert to carers, five (8.1%) did a risk assessment, two notified the suppliers of the beds, and one took other action. 27 (42.9%) did nothing. Other actions reported included checking anyone on the caseload with a bed, checking hand controlled beds, and risk assessing patients before they get a bed. Several commented that they only have hand-operated beds, or that the patients would be assessed by someone else, such as an Occupational Therapist.

14.5 SUMMARY

The actioning of this alert in PCTs was variable, reflecting the differing responsibilities for the management of equipment in the patients' homes. We were slightly concerned that a number of PCTs did not circulate this alert on the grounds that the safety features of these beds was deemed to be the responsibility of the equipment supplier or other body.

Additionally, we found that many PCTs or loan stores did not use these models of beds and were not affected by the alert.

Section 15: Guedel Airways

15.1 SUMMARY OF ALERT

Universal Hospital Supplies Guedel Airways	MHRA Medical device alert	Ref No: MDA/2006/026
		Immediate Action
		3rd May 2006
Due to manufacturing problems, the Guedel airways may be split around the bite block allowing the colour insert to become dislodged from the main body of the airway		
• Remove this product from use and quarantine; • Arrange collection and refund of recalled stock via usual distribution channels; • Be aware that comparable product is available from other manufacturers. If alternatives are not immediately available, ensure there are no splits or occlusion before use and that staff are aware of the possible failures; • The supplier is recalling affected lot numbers of Universal Guedel Airways sizes 1, 2, 3 and 4.		

15.2 INTRODUCTION

This alert was only explored in the four ambulance trusts in our sample. Fourteen (64%) of those front line staff interviewed said that they used Guedel Airways. One respondent stated that only one make was used and two that many different makes were used. A further two did not know.

15.3 MANAGEMENT OF THE ALERT

These were recalled by sending the alert or a clinical notice to team leaders or clinical support officers who then ask crews to check all vehicles and stores and to sign when all equipment is removed. Staff are detailed to attend to spare vehicles.

15.4 IMPLEMENTATION OF THE ALERT

Three (27%) paramedic staff interviewed recalled this event and confirmed that they had participated in the action. Three respondents (14%) said that they routinely check to see if the airway is damaged, five (23%) said that they did not, and a further six (27%) said they did not know. Eight (36%) did not respond. Three team leaders interviewed stated that they were unaware of the problem (although the Clinical Development Manager at this trust stated that they did not use the Guedel Airway that was the subject of the alert). When asked what would they do if they found a damaged Guedel Airway, two said they would throw it away, three that they would keep it and pass it to a senior member of staff. There was no response to this question recorded for sixteen interviews, as the alert did not appear to apply. One individual commented that new stock was ordered and that the entire stock of old airways was withdrawn: a clinical guidance notice was put on the notice board to this effect.

15.5 SUMMARY

This alert appeared to have been quickly and efficiently handled in two of the ambulance trusts visited. In another the alert was not circulated as this type of airway is not used.

Section 16: Shower Heads

16.1 SUMMARY OF ALERT

Shower heads	DH Estates and Facilities Division	Ref No: DH (2006) 05
		Immediate Action
		25th July 2006
Patients can die if using shower heads that are 'vandal resistant' as ligature points		
• A check be made of all shower heads in those wards and departments accommodating mental health patients to assess the likely risk of the shower head being used as a ligature point; • Where shower heads present a risk, they should either be removed, or measures be taken to eliminate the risk; • In other healthcare premises where there is a risk of patients self-harming or where patients with a suicidal tendency are accommodated, all shower heads should be examined for their potential use as ligature points.		

16.2 INTRODUCTION

This alert was explored in one mental health trust only. We interviewed senior managers and ward managers and inspected showerheads in the clinical areas visited.

16.3 IMPLEMENTATION OF THE ALERT

When the first alerts came out a full audit was carried out led by the clinical governance manager, capital planning manager and involving ward managers (or one ward manager covering several wards). All staff interviewed were either aware of the audit that had been carried out or had been involved in it. All were aware of the alert on showerheads and claimed that either they had been replaced or had already been dealt with in the major audit. Staff also quoted other relevant alerts (withdrawal of gloves; suicide from doors) with which they had been involved.

Not all ligature points had been removed, the preference being to risk assess individuals and manage them through observation. Bed curtain rails have been replaced by collapsing rails. Ceiling tiles have been fixed to deny access to beams. Coat hooks have been removed and where it was necessary to retain them, such as in bathrooms, these are kept locked. In one area the window was sealed shut in the bathroom and handle removed, with ventilation provided by Expelair fans. Some ligature points remain – window opening handles have been retained in communal rooms and door closing devices retained for fire purposes. Grab rails in toilets are necessary for disabled residents. During the audit we found only one shower head which provided a ligature point but it was not fixed to the wall but slotted into a holder which would probably not be sufficient to hold weight.

16.4 SUMMARY

Although we only investigated this alert in one mental health trust, this alert was highlighted during visits made to acute trusts, where it was cited as an example of an alert which may not be fully implemented since the trusts' risk management processes had identified this alert as low risk and low priority. Shower heads in wards used primarily by acute patients without mental health problems were not necessarily replaced as these patients were not seen as high risk of using these shower heads as ligature points. Other similar alerts were also cited, for example, curtain rails as potential ligature points were treated similarly.

SECTION D

Discussion of Findings

Section 17: Assessment of the Effectiveness of the SABS System

17.1 OVERVIEW

This section brings together all the information provided by interviewees and survey respondents. The SLO survey gave the opportunity for respondents to comment on any aspect of the SABS system, and interviews with the SLOs and senior managers during site visits included an open question at the end of the interview in which we asked people to comment on what they liked about the system and whether there was any way in which the system could be improved. Inevitably, there were comments related to the alerts themselves, including their subjects and how they were written, of the organisations who issued them, the safety alert broadcast system and how effective it was at trust level.

17.2 PERCEIVED PROBLEMS WITH THE SYSTEM

17.2.1 Technical

SABS liaison officers frequently commented on technical anomalies in the system, relating to time delays in acknowledging receipt of the alert (said to be 20 minutes) and delays in recording that the alert had been completed (reported to be weeks on occasion). This last was particularly annoying for the SLOs who had pressed others for the responses in order to sign an alert off on time, only for the system to record the response as late.

Nearly all respondents from the SHA group commented on the inaccuracy of the data on the webpage. They have repeatedly found that when they approach a Trust flagged up as not responding, the Trusts have demonstrated that they have taken action and recorded the fact but the system has not updated this information in real time so the SHA see one thing and the Trusts see another. This mismatch was also raised by a respondent in one of the originating bodies, who also monitor completion of alerts.

17.2.2 Number and Relevance of Alerts

The sheer number of alerts was mentioned as a problem by 9 respondents but for the majority of those who commented (47), the problem was one of poor targeting. This subject was especially high on the agenda for respondents from PCTs and mental health trusts. There was a general feeling that it was easier (and carried less corporate risk) for the originating bodies to opt for blanket coverage, but it created work for SLOs in trusts in acknowledging receipt and assessing relevance and there was an inherent danger that the important would get lost in the mass of irrelevance.

"If we received alerts only applicable to Mental Health Trust instead of all, I understand there may be difficulties knowing exactly what is applicable but some are quite obvious e.g. Breast implants, cardiology."

"Consideration could be given to primary care alerts rather than primary care getting all alerts that are only obviously for secondary care purpose."

There was a view that the circulation of a large number of irrelevant alerts made it less likely that recipients would read and action those that were both relevant and important.

A total of 26 people commented on the timing of the alerts, many asking that the sending of alerts on a Friday afternoon be avoided. Although the dissemination of an alert is a last step in the process for those sending it out, it is the first step for the recipient. Respondents also raised the difficulties caused by sending out several alerts together, reminding us that their management is a reactive process for the SLOs who cannot put aside time in the diary to deal with unexpected alerts. There was a view that 'clumping' of alerts or late Friday alerts could lead to some being missed, especially if the Friday fell before annual leave or a statutory holiday.

Overall, there were felt to be simply too many alerts, and respondents felt this was exacerbated by sending out alerts "that were not alerts" – such as those designed to give information about the management of alerts.

Forty five respondents expressed concerns about the responsibility assumed in signing off the alert as complete. One respondent commented that this action is taken on the basis of a manager's promise to take action within the prescribed time. A few commented that their responsibilities in this area were not clear, and bemoaned problems with managers who simply would not respond. One respondent who worked for several PCTs noted that some organisations were signing off alerts on the basis of disseminating the alert or on receipt of an action plan whereas others waited until they were notified that action was complete:

"I get a response from the lead for that area and take it on trust that the actions they have stated they will complete are actually completed within the timescale."

"It remains unclear when a SABS alert should be closed: when an action plan has been established or when all actions completed."

"One PCT closed the SABS almost as soon as disseminated. Whilst the other 2 PCTs ensure responses are collected before closing down alert as some needed action."

It was SLOs in PCTs who had the greatest problems in that independent contractors such as GPs and dentists would simply not give feedback on alerts – and may even object to receiving it. This left the liaison officers in a quandary as to whether to sign the alert off on the basis of having distributed it or to persist in trying to get responses way beyond the deadline:

"Unfair that PCTs have to be non-compliant because GPs will not take part."

"Implementation of the SABS alerts by independent contractors remains in its infancy despite being a requirement to be fully compliant with the core standards for better health from April 2007."

It seems therefore that there is a danger that alert completion may be interpreted both by the DH and by the issuing agency as 'all action carried out', whereas in some trusts it clearly has the more restricted meaning of 'alert distributed and the need for action acknowledged.'

Additionally, the point was made by two respondents that cluttering the system with imprecise alerts and general information was not helpful. General warning alerts were felt by some not to be alerts – such as some NHS estates alerts and some general warnings without specific action recommended.

"Some alerts, to me, do not warrant to be classed as an alert."

"I think there needs to be careful thought about some of the MHRA alerts. Some of these appear to relate to be "concerns" but not clearly defined hazards. Some of these alerts do not offer clear advice re actions to be taken and leave the Trust in an unclear position. An example of this is the Baxter Colleague (volumetric pumps) alert from 2005."

Three remarked on the design of alerts, believing that the action to be taken was not always clear, and two remarked that having too many action points on one alert made it difficult to sign off.

17.3 ADVANTAGES

36 (72%) of senior managers interviewed believed that the SABS system has advantages over previous systems. Examples of advantages are discussed below.

17.3.1 A Single Point of Entry to the System

Respondents valued the clear tracking that SABS allowed. The system makes it unlikely that alerts go missing, unlike the previous system where different people received different categories of alerts and no-one but the recipient was aware of the issue.

17.3.2 Clearer Accountability

The system permits regular reporting to committees, in some trusts the named lead is also reported. It also ensures that each recipient must acknowledge receipt and respond to state that action will be, or has been, taken or that action is unnecessary.

17.3.3 Similar Formatting of Alerts

Respondents, especially SLOs, liked the formatting of alerts which enabled them to find quickly required information.

17.3.4 Streamlined and Quicker Electronic System

The electronic delivery system was appreciated by SLOs and those in risk departments. Prior to its instigation many person-hours had been spent photocopying and disseminating alerts. It should be noted, however, that in many organisations, the electronic dissemination only works to middle management level. Front line staff in acute trusts, PCTs, and ambulance trusts relied heavily on paper copies or verbal information. Even the production of a paper copy could prove difficult in some outlying parts of organisations where IT access to the intranet was slow and uncertain. In settings such as this, staff preferred the earlier system in which paper copies were distributed.

17.3.5 Alerts More Focused and Specific

The MHRA alerts in particular were commended for being concise and specific, largely because of their nature. SLOs liked the clear action stated and the fact that these could be managed relatively easily. It was felt that these carried with less risk of issues not being followed through.

17.3.6 Organised Tracking System

The concept of requiring responses from everyone to whom the alert was disseminated, meant, at trust level that if a query arose, it could be tracked back. In most organisations, although not all, researchers were able to track the progress of the alert to middle management level.

17.3.7 Reliable Archive

All managers tended to know who their SLO was, and ward and clinic staff who their line manager was, so that access to old alerts could be gained if required.

Many could not think of any improvements to the system. Indeed, and in sharp contract to the complaint set out below of there being too many alerts, respondents at all levels of the organisation, including SLOs wanted other types of alerts included, as explained below. Inevitably, we spend more time on the negatives (that were articulated and probed) rather than the overall satisfaction, which was not.

17.4 SYSTEM IMPROVEMENTS

17.4.1 Better Targeting

As with the survey, the main complaint from senior managers, particularly those in PCTs, mental health and ambulance trusts, was the number of irrelevant alerts received which are time consuming to process. This was linked in many cases to general information overload, most of which now came in the form of email attachments. Comments were as follows:

"They need to be more targeted as they take up a lot of resource. Stop the blanket system and filter."

The majority of practice manager respondents believed SABS to be time consuming and generally not relevant to general practice. Common themes occur through the findings such as the desire to ensure all alerts are filtered prior to sending them out to general practice, preventing duplication and reducing the number of 'not applicable' alerts as well as ensuring realistic deadlines are set .

17.4.2 Use of More Appropriate Terminology

This related to the alerts themselves rather than the system. Those SLOs without either a clinical or technical background were frequently completely unable to interpret some alerts, to the extent that they did not even know who to ask. It was suggested that each alert should carry a simple explanation of the equipment or device and who might use it. One nurse respondent stated:

"Sometimes have to identify if you are using the piece of equipment alerted. Explanation about action could be better…Photographic evidence/guidance would help."

17.4.3 Clearer, More Concise Alerts

Although the majority of senior managers stated that alerts were clear and easy to read there was a plea for something more concise from front line staff, especially in community and primary care. Several thought that they *"Waffled on a bit."* The bottom line from one GP was that the message had to be in the email subject line and the whole alert should be one page – otherwise they just delete them. One commented:

"They are not user friendly - not succinct. There is too much other information in the Alert."

17.4.4 Joining up the different alert systems

Despite the many complaints about the number of alerts, the system itself was felt to be so useful that many SLO and other respondents felt that it should be used for all types of information coming into the trust, including (popularly) public health medicine alerts security alerts and missing person's data.

17.4.5 More Appropriate Grading of Alerts as to Risk and Importance

It was pointed out that alerts, and their consequences, varied widely. Whilst some took minutes to enact fully, others required significant amounts of work amounting to years in some cases. Indeed it was stated by a few SLOs that some of the early estates alerts were still open, because of the difficulties caused. There was also a variation in complexity, some requiring behavioural change in many hundreds of front-line clinical staff. They were also believed to vary in importance, clarity and significance.

17.4.6 Improved Risk Assessment of Alerts

In two trusts there was a dispute about the importance of the alert on the fire risk from alcohol based hand rub. In one, the fire officer had actually soaked some material in the substance and attempted, unsuccessfully, to set fire to it. A clinical governance manager thought that many estates alerts were simple common sense, which should be covered in training. An example was that of keeping helicopter pads free from rubble. Others complained about the subjects chosen, one stating:

"NPSA alerts and system behind the times. They send out work that's taken months and it already exists within the Trust and does not bring any added value to the organisation. NPSA do not liaise with trusts to gain knowledge and this would help if engagement took place. Not one alert sent to the Trust has made us say 'wow' we need to do that."

"Some alerts around MHRA are easy. The system needs to be responsive. The NPSA are so prescriptive. They want to micromanage how the NHS work. They involve change management and this takes time."

A Medical director in a mental health trust commented on the ligature alert, following which the trust had replaced all curtain rails with collapsible ones. Since that time, 3 or 4 accident resulting in litigations had occurred as a result of the rails falling down on the heads of patients and staff. He expressed the view that alerts may sometimes put disproportionate emphasis on some things at the expense of others. This respondent was of the opinion that time and money spent on implementing changes could at times be more costly than the benefits. He pointed out that 50 patients commit suicide every year and only one was saved by a collapsible curtain rail yet the trust had been forced into the considerable expense of changing all rails. It was believed that better risk and cost-effectiveness analysis should be carried out prior to releasing alerts.

Another respondent, an estates manager, expressed anger at the time inherent in tracing and maintaining all electric fans because of a fire risk, pointing out that the very building did not meet fire safety standards, as it lacked proper compartmentalisation. The alert was compared to re-arranging deckchairs on the Titanic.

One respondent felt the SABS system was an inappropriate medium for issuing alerts about behaviour change, and that it should be restricted to issues that could be dealt with quickly:

"They need to have absolute clarity of which alerts to issue and it needs to be do-able within a day e.g. product withdrawal. We need to be selective what we use SABS for."

A few respondents expressed concerns about the focus of the system (and therefore of the trust) being on closing the alert on the DH database rather than on actioning the alert.

17.4.7 Sequential Numbering of Alerts rather than Numbering with Issuing Bodies

Most of the SABS systems developed by trusts to track the responses to alerts rely on a numbering system. Several found the NPSA system of numbering each of their series (Patient Safety Alert, Safer Practice Notice etc) separately confusing. Others would prefer that there be a sequential SABS number for all alerts.

17.4.8 Improved Access to Archive of Alerts

An acute trust respondent noted that SABs is not accessible from the CNO website, *"yet it is nurses who are implementing most of the alerts."* One community nurse manager pleaded for a better search engine on the SABS site. In discussion we found that she had failed to find the nasogastric tube alert from the MHRA as the term used in the latter was "enteral feeding tubes."

The research team have noted that the search engine on the new SABS website operational from October 2006, does not retrieve alerts prior to this time so that two searches have to be carried out on different websites to locate an alert if the date is not known.

17.4.9 Implementation

Some trusts were extremely positive about the system, believing that it had assisted in supporting a culture in which risk reduction was high on the agenda*:*

"An excellent system within the trust because the SABS LO has a clinical background and therefore only sends out appropriate alerts."

"We have become good at identifying and managing risk. I think it is working well now when we report internally. We need an open culture where risk can be discussed. Surprising that it has taken so long to get unified system in place. The systems ensure relevant staff take action and report back."

Other comments made by senior managers, however, related to the ability of their organisations to implement alerts, especially those that required changes in staff behaviour:

"A limited system. It ticks a box but does not actually give evidence that culture or practice has changed."
"It is hard to ensure the correct people know about them and are acting on them. We don't know how effective people are on completing the cycle and due to turn over of staff, constant training programmes are needed so potentially gaps exist."

"MHRA alerts are easier to deal with due to specific information and so easier to act on. NPSA guidelines can take time and how do we check that it is working in practice. Often some alerts can be for nurse specific and therefore doctors are unaware so can go against guidelines due to lack of knowledge."

One district nurse pointed out that they frequently received alerts but did not know how the organisation had handled them:

"No reporting back mechanism which is a problem as staff not aware what action has been taken."

When asked how the system could be improved, four respondents believed it would be beneficial to have one central system for all alerts and this would help prevent duplication. A more user friendly system was one perspective and six said they would like the system to reflect what is actually happening in real time. Four stated that they would like to see alerts targeted more effectively instead of the blanket system that currently exists. One locality in an SHA did not feel sufficiently informed to comment. One suggestion was to allow the SHA to add or change action agreed by date and one believed that it would be helpful if the SABS team recognised the limitations of the system by weighting the importance of the alerts. Time to completion may be less important than the thoroughness of that completion.

17.5 OTHER COMMENTS

Finally the interviewees were given a chance to make any other comments on any aspect of the SABS system. Two areas thought it would be useful for the SABS team to engage with the SHA and Trusts via networking by attending existing forums to allow feedback and help with the overall management of the system. Seven of the people interviewed stated that they had foundation trusts within their patch and have continued to maintain links and send out SABS and monitor performance of these trusts as requested by the individual foundation trusts. Three interviewees had no foundation trusts within their areas and 3 did not feel it was their responsibility to monitor these trusts. One stated that the PCT was accountable for monitoring the performance of their foundation trust.

17.6 SUMMARY

The majority of respondents believed SABS to be useful in terms of assisting the SHA with monitoring the Trusts performance, however this does depend on whether the SABS lead is actively involved within the process.

In light of the recent changes within the SHA re structuring, some areas had dedicated one SABS lead for the whole of the SHA whereas others had continued to work within the previous structure and had four. Within these areas, the interviews highlighted that different practices are occurring within one SHA where they have more than one officer. Some SHA

leads believe the SABS system is a useful tool to assist in audit whereas others feel it serves little purpose other than annually help to produce the Healthcare commission annual commentary.

Common themes occur through the findings such as inaccurate, out of date information on the website, pulling together all alerts into a single system, preventing duplication and reducing the number of not applicable alerts as well as ensuring realistic deadlines are set were some of the examples given.

Some areas are more proactive in terms of utilising the SABS system to assist in data collection for audit whilst others feel that SABS is not robust enough to make real changes due to inaccurate data, unrealistic deadlines and too many alerts that do not apply to their organisations.

Section 18: Conclusions and Recommendations

18.1 INTRODUCTION

We stated at the commencement of this study that there were four steps in the process to be studied: receipt of the alert; dissemination; implementation; and monitoring. We conclude that there are in reality, several more. We have arranged our conclusions under 10 headings:

- Preparation of the alerts;
- Publication of the alert by the safety alert broadcast system (SABS);
- Management of SABS within Trusts;
- Receipt of the alert;
- Assessment of relevance;
- Dissemination;
- Implementation;
- Completion/signing off;
- Audit;
- Performance monitoring.

We discuss each of these below.

18.2 PREPARATION OF THE ALERTS

The Safety Alerts are issued by three main agencies – the National Patient Safety Agency, the Medicines and Healthcare Regulatory Agency and DH Estates and Facilities. One alert (radiotherapy) was issued directly by the Department of Health (DH). The documents incorporate a wide range of safety issues from clinical to estates issues and vary in clarity, length, urgency, perceived importance, complexity, focus, implementability, strategic significance, organisational impact and sustainability.

From the setting up of SABS in December 2004 until March 31, 2007, 221 alerts were issued by the MHRA, 26 by the NPSA, 39 by DH Estates and Facilities and one by the Department of Health. Normally, an alert is graded as to urgency; has a date by which action must be commenced and a second by which action should be complete; and contains some background information and a statement of actions required. Each also carries a list of people to whom the alert should be distributed and the name of the person in the originating body to whom enquiries can be made.

We have been informed both in the survey and in the interviews with SABS liaison officers (SLOs) that, overall, the alerts from the MHRA tend to be easier to implement as they usually deal with clearly identified equipment and the action required is unequivocal and relatively simple to execute. One of our 'tracker alerts' (those that we chose to follow through from receipt to implementation) issued by this body, was, however, unrecognised by those using the device as the terminology (obvious to the writers) was unfamiliar to the users. Those who had to implement the alerts were also unhappy about those alerts that issued vague warnings about what might happen, rather than specific instructions as to what preventive steps should be taken.

Those from the NPSA were commended by managers for being well written and informative but were more difficult to implement as they generally required complex action resulting in changes in practice, often involving negotiation, staff training and the formulation and ratification of policies. We were told that in some cases it was difficult to sign off an alert, as the trust may have taken all possible steps to implement the alert, but, as with the alert on methotrexate issued in 2004, have failed to convince all clinicians to accept the recommendations. We found no evidence that trusts differentiate between the different types of notice issued by the NPSA – Safer Practice Notice; Patient Safety Information and Patient Safety Alert. All enter the organisation as 'alerts' and were dealt with as such. (We have no information about the new rapid response report format as the data collection phase of this study pre-dated the development of the first of these.) In addition, the colour coding used to differentiate these various publications is often lost at the level of the ward or clinic where electronically disseminated alerts are printed and circulated in black and white paper format. Most electronic filing systems devised by SLOs rely on the number of the alert and many find it irritating that each type of NPSA publication has its own numbering system.

Recommendation 1:

That NPSA alerts are given sequential numbers to prevent confusion and to facilitate retrieval from numerically ordered filing systems.

Alerts issued by DH Estates and Facilities were thought again to be clearly written, but many required significant investments in staff time to identify and deal with thousands of items of equipment on multiple sites. A few respondents volunteered the information that some of the early estates alerts were still open after two years.

Front line staff, especially GPs and district nurses, complained about the length of alerts. Clearly senior people in organisations need background and detail, but front line staff may need clear and concise messages that contain the only the information that staff need to know in order to enhance patient care. We believe that alerts could follow the model used in some evidence based journals, in which the main message is given in the title, and the message for busy front line staff is given in not more than one page.

Recommendation 2:

That alerts be given a title that contains the main message and are accompanied by a summary version for dissemination to front line practitioners.

From our own experience, and that of some of our respondents, we would like to see key words given in each alert and entered into the SABS search engine, so that different alerts on the same topic may be traced in one search and without prior knowledge of the precise title. A search should also cover alerts issued before and after October 2006 when the SABS website changed.

Recommendation 3:

That the SABS webpage is searchable using key words given in the alerts and alerts issued before and after October 2006 be accessible to the search engine.

Several respondents commented that alerts can have widely different consequences, ranging from a few minutes work by one person to ongoing education over many years involving hundreds of different professional groups. Because devices alerts predominate, we did find one organisation whose systems were geared solely to these with the effect that no senior manager had seen any of our tracker alerts.

Some respondents suggested that a classification system for alerts would be useful and we suggest that a simple score based on the following dimensions might aid the differential management of alerts. High scoring alerts might be deemed to require high level management input in order to instigate risk assessments, the development of local policies, changes in the behaviour of a large number of staff or ongoing educational programmes. We have omitted an obvious dimension – that of importance - as we believe that all alerts are by their nature important, and that failure to implement the recommendations might result in serious harm or death.

Urgency:
Must action be taken quickly?

Complexity:
Does alert require a number of actions, possibly by several people at different levels of the organisation?

Staff Focus:
Does alert focus on changes in behaviour of staff as opposed to equipment?

Local interpretation:
Does alert require translation into a local policy possibly following a risk assessment?

Financial significance:

Might alert have significant financial consequences?

Organisational impact:
Will a significant number of people (more than 10) have to take action as a result of the alert

Sustainability:
Does the alert have ongoing implications possibly involving staff training?

Patient recall:
Does the alert require the recall of patients?

Using the above classification, we note that our tracker alerts would score quite highly (see Table 18.1). This is a feature of our selection, as we chose alerts that would allow us to follow auditable action over a sustained period, rather than those requiring the simple removal of identified equipment.

Table 18.1:

	NPSA			**MHRA**				**DH E&F**			**DH**
	Latex allergy	**NGtubes**	**Methotrexate**	**ICDs**	**Needle-free intravascular**	**Electric beds**	**Guedel airways**	**Mobile heated food trolleys**	**Alcohol based hand rub**	**Shower heads**	**Radiotherapy**
Urgency	0	1	0	1	0		1	0	0	1	1
Complexity	1	1	1	1	1		1	1	0	1	1
Staff focus	1	1	1	1	1		0	1	0	0	1
Local interpretation	1	1	1	0	1		0	1	0	0	0
Financial cons.	1	1	1	1	0		0	0	1	1	0
Organisational impact	1	1	1	0	1		1	1	0	0	1
sustainability	1	1	1	0	1		0	1	0	0	1
Patient recall	0	0	0	1	0		0	0	0	0	0
Score	6	7	6	5	5		3	5	1	3	5

Recommendation 4:

That alerts be given a classification based on the above dimensions to facilitate differential management of alerts within trusts and to assist trusts to make decisions as to the level of resources required to implement alerts.

18.3 THE SABS SYSTEM

The alerts are disseminated electronically to named SABS Liaison officers (SLOs) in each trust by members of the Patient Safety Team at the DH.

The SABS system is liked by SLOs and other senior managers without exception. They appreciate the fact that the receipt of all alerts is transparent, dissemination is easy, and reports of action are stored and auditable.

Respondents valued the clear tracking that SABS allowed, making it much less likely than previously that alerts are missed. The electronic delivery system was appreciated by SLOs for ease of dissemination. They also liked the accountability offered by regular reporting to committees, although we found that the information received was often simply noted. The system also requires that each recipient respond to the SLO, stating action planned or taken.

The sheer volume of alerts was an issue for many respondents, as was the relevance of many of the highly technical acute sector alerts for Mental Health Trusts, PCTs and GPs, although complainants did recognise the difficulties of knowing who required what information. Many, however, fear that wheat is being lost amongst the chaff and better assessment of relevance to organisations is recommended. .

Recommendation 5:

That alerts be assessed for relevance to the organisations to which they are sent.

Two GP PEC Chairs asked that the subject of the alert be placed early in the strap-line so that GPs can make an instant decision on relevance. At present what is visible on the email subject line in the inbox is “Safety Alert Broadcast System followed by the source of the alert. The alert title follows later and is not immediately obvious to recipients, many of whom have formed the habit of deleting the emails without opening them.”

Recommendation 6:

That the subject of the alert be placed early in the email subject line so that GPs and others can make an instant decision on the relevance of the email when viewing their inbox.

Some respondents in both the SLO survey and in the interviews felt that some alerts overstated the risk of harm, converting one incident (their perception) into action across the NHS and possibly, in so doing, creating other hazards. Examples included the replacement of bed and shower curtain rails as ligature points in mental health trusts [NHSE (2004) 10] (which was reported to have resulted in a number of injuries from falling rails), clearing helicopter landing pads [DH (2007) 02] and a number that fell under the heading of routine maintenance.

Recommendation 7:

That careful risk assessment of alerts be carried out before dissemination to the NHS.

SLO respondents reported a number of small but irritating “glitches” in the electronic system, such as:

- The time delay between receiving the alerts and being able to acknowledge receipt formally;
- The discrepancy between signing off an alert and this being updated on the SHA-level website (reported by one respondent to be in the order of several weeks) resulting in organisations being castigated for failing to do that which they had done;
- The closure of the system some time after the completion date which meant that some organisations that had experienced an implementation delay were unable to record completion.

Recommendation 8:

That the system be revised to remove time-consuming delays in its use and to promote more accurate feedback to those charged with performance monitoring.

18.4 MANAGEMENT OF THE ALERTS

It was striking how differently senior staff viewed the need to be aware of those alerts (particularly those from the NPSA) which required changes in nursing and medical practice. In most of the acute trusts the director of nursing was aware of who was leading on these alerts and, in broad terms, what action had been taken. However, others in the same role had delegated the responsibility in its entirety to a clinical governance manager or patient safety manager and had little or no awareness of how or whether the alerts had been implemented. A small number of senior managers clearly stated that the management of safety alerts was not at the top of their list of priorities, nor that of their SHA.

In some cases, then, it seemed that the responsibility for reducing risk, other than that associated with performance targets and finance, was firmly isolated within the clinical governance and risk departments. It was sometimes the case that these individuals within the risk department, carrying the responsibility for all safety alerts (as well as complaints and incident recording) did not have a seat at meetings of the divisional managers /divisional nurses who in turn had the responsibility for managing the implementation of alerts. In other trusts one member of each service division carried a responsibility for patient safety, and it was this person who was responsible for ensuring that alerts were implemented within their division.

Recommendation 9:

That trusts should ensure that a senior figure with a clinical background is intimately involved with decision making around clinical alerts. This individual should have sufficient authority in the organisation to delegate projects to appropriate individuals and to hold them to account.

Recommendation 10:

That named managers with direct responsibility for service delivery should have explicit responsibility for patient safety for a division or directorate, including the implementation of safety alerts.

SLOs come from a wide variety of backgrounds and have an equally wide range of roles within the organisations. They reported 216 different job titles, the vast majority related to clinical governance, risk or health and safety. One quarter have a health and safety background and a further one third clinical, most commonly nursing. Around a half were either on the trust board or reported to someone on the Board. Many were appointed by virtue of the fact that they had previously undertaken the role of Medical Devices Officer.

Within Trusts, the process of managing the alerts includes a substantial administrative element (disseminating alerts and collecting and collating responses) but also requires that decisions are made about the relevance of alerts to the organisation and dissemination to the most appropriate people for action. It is unsurprising then that the concept of the SLO is a complex one, and those appointed to the role vary from administrative staff to very senior people in the organisation. In one organisation, a secretary may be appointed SLO but her line manager be expected to make the decisions. In another, a senior manager may be the named SLO but expect his or her secretary to make dissemination decisions and in a third a technician or administrator may undertake all of the functions of the role without direct input from another except where assistance is specifically requested.

In almost all of the acute trusts and in about a third of PCTs visited, we found that a senior manager (head of clinical governance or patient safety or director of nursing/nurse adviser) was actively involved in the management of safety alerts. From the survey and some interviews we established that some risk managers, often from non-clinical backgrounds, occasionally struggled to establish leads for the more complex alerts and some claimed that the extent of the responsibility assumed was not commensurate with their position in the organisation.

Recommendation 11:

That trusts consider whether their designated SLO has the authority (or immediate access to those with the authority) to change the behaviour of medical and nursing staff.

The majority (61%) of SLOs indicated that they spent between 2 and 10% of their time in the role of SLO, while 23% spent between 11 and 25%. Many of these suggested that the growth of the system had been unanticipated and that as a group they felt overworked, and a few, unsupported, in what was a demanding role.

Recommendation 12:

That trusts review the role of the SLO and determine whether the time allocated to the role is sufficient to service the system.

A few of the doctors (medical directors and PEC chairs) interviewed were aware of or involved in the methotrexate alert. With this exception, a majority of medical directors believed that alert implementation was the responsibility of others in the organisation and could tell us nothing about the management of alerts such as those dealing with latex allergy or nasogastric tubes. The responsibility for creating a safe environment for patients was viewed as the responsibility of the clinical governance and nursing directorates. One Medical Director expressed the view that alerts “were aimed” at nurses and regretted the fact that junior doctors would be unaware of most of our tracker alerts.

Recommendation 13:

That alerts that require changes in behaviour of both doctors and nurses be marked for action by both medical directors and directors of nursing.

22% of organisations in which our survey respondents worked were said not to have a policy or procedure for the management of alerts and in a few cases old medical devices policies are in use. These are not necessarily helpful to SLOs in managing some of the more complex alerts

Recommendation 14:

That trusts should review their SABS policies in the light of experience.

The majority of SABS policies devised by trusts stated that audit of alerts should be carried out by committees. Our visits and audit suggest that this is not an effective way to audit that alerts have been implemented.

Recommendation 15:

That trusts should undertake audits of action of selected alerts involving action by more than 10 staff and that this should be more rigorous than following a paper trail or asking a manager if all staff have complied.

18.5 RELEVANCE OF THE ALERT

Decisions on relevance of an alert may be taken by an SLO or their line manager (in consultation where necessary). Few trust SABS policies specify how decisions on relevance or patterns of dissemination should be taken and in our survey, 42% recorded that there was no independent scrutiny of their decisions on relevance. In a few organisations the policy requires that each alert goes to five or more senior members of staff, representing nursing, estates, pharmacy, medical equipment and supplies. One of this group is designated the lead for each alert that arrives, the whole being co-ordinated by the SLO.

In a number of PCTs the nasogastric tube alert was seen by the SLO and one other person before being rejected as irrelevant. We are concerned that in many organisations there is no corporate memory of key alerts and yet services are constantly changing.

Recommendation 16:

There should be systematic and recorded processes for deciding that an alert is not relevant to an organisation.

Some GPs reported that relevance is assessed by reading the title of the alert only.

Recommendation 17:

That titles of alerts should be concise and informative.

18.6 DISSEMINATION OF THE ALERTS

It is the assumption of those who draw up the alerts that they will be issued to all those named on its front page. In reality, all of the SLOs interviewed decide to whom in the organisation it should be sent, trying to keep the circulation of alerts to the minimum required for effective action. The argument for this is that the more relevant are the alerts received by a manager, the more likely they are to read and action them.

In almost all of the acute organisations visited we saw evidence of robust systems for the electronic disseminating of alerts to senior managers, pharmacists, technical staff, senior nurses and matrons. We found few delays in the transmission of alerts to this level, and very few “missed” alerts, defined as those which people should have received but did not. (This of course requires that they later became aware of a missed alert).

Electronic dissemination, however, does not reach all levels of the organisation. IT access at ward/clinic/ambulance station level is poor and alerts that reach this level are normally raised at team meetings and a paper copy retained for access by all staff. Policies and sometimes alerts are increasingly available on the intranet, but the ability of staff to locate them is sometimes lacking. The lack of IT access and IT literacy is particularly a problem

among district nurses. We found 22 district nurses in one PCT with no IT access at all. Paramedic staff in ambulance trusts were even more badly served.

Recommendation 18:

That trusts and PCTs continue to improve IT provision and education at ward and clinic level.

Commonly, at ward, clinic and ambulance station level one printed copy of the alert (normally in black and white) is said to be placed in a folder for staff to access. In some areas staff were said to be required to initial the documents once read, but it would be unusual for there to be any monitoring or follow up of this.

It should be noted that not all relevant alerts reach front-line staff in the form in which they are written. Where the organisation decides that a policy or organisational action is required, the alert will be transmuted into local policy and in some trusts it is that, rather than the alert, that is received by front-line staff. This may involve a delay of the order of months or even years in information reaching front-line staff.

Recommendation 19:

That if an alert requires the development of a complex local policy; trusts give consideration to the circulation of key messages at the time of the alert's publication.

With one exception, all PCTs visited disseminated alerts to GPs via email but to all other contractors by fax. This is a labour-intensive process with variable feedback. Primary Care Support Agencies (PCSAs) managed this dissemination to independent contractors on behalf of a number of PCTs yet as they were not statutory agencies, did not receive the alerts themselves. There was no evidence that PCTs approached the PCSAs for data on response rates.

We were not commissioned to investigate the communication of alerts to private contractors providing direct healthcare services, and so have only anecdotal evidence on this point, but some respondents informed us that PCTs believe that these organisations "carry their own risk" and it is not necessary for them to communicate the alerts.

Recommendation 20:

That clarification is given to PCTs regarding their responsibilities towards private and independent contractors.

18.7 IMPLEMENTATION OF ALERTS

We have found implementation of our tracker alerts to be mixed. The outcome, especially of complex alerts, in many organisations, depends largely on it reaching someone with a real interest in the subject and the authority to carry it through the organisation and put training in place.

Many local policies created in the wake of alerts took many months or years to formulate and agree, were lengthy, and did not necessarily contain the information that staff needed. It was clear that in the case of latex allergy, many staff had not read beyond the title of the policy.

Recommendation 21:

That local policies are developed in recognition of the fact that busy practitioners must assimilate key information in a short time.

Whilst we have not collected specific evidence on lost posts, we have become aware of significant staffing cuts in some governance and risk departments which, it is said, have impacted heavily on their work. In some risk departments staff indicated that they felt both demoralised and undervalued.

Even in trusts with good systems and with enthusiastic, energetic, committed patient safety managers we found that, whilst awareness of the importance of safety might be high, awareness of the requirements of individual alerts amongst front line staff was patchy. It is clear that the dissemination of policies and alerts and brief discussion at meetings is insufficient to change behaviour at the front line. The best evidence of implementation occurred either when staff had prior experience of harm or when the message was reinforced by discussion with individual staff.

Recommendation 22:

That trusts recognise that alerts and policies are not self-executive.

It was said that particular challenges for implementation were presented by the following factors:

18.7.1 Trusts with PFI Schemes

We found that alerts that were simple to manage in some small acute NHS trusts became very much more complex in others. In one of the trusts visited that had a PFI scheme, a change to the servicing of mobile food trolleys and to the location of alcohol based hand rub containers necessitated complex negotiations between Trust managers, managing agents and two companies respectively responsible for hard and soft facilities management. Depending on the wording of the alert, a change in servicing might require a change to the

contract. We understand that contractors are obliged to meet the requirements of mandatory alerts (must do) but can demand a higher price for suggested improvements (may like to consider…).

Recommendation 23:

That originating bodies are mindful of the issues raised by trusts with PFI schemes when they decide whether an alert should give guidance or absolute imperatives.

18.7.2 Merged Organisations

In recently merged organisations (PCTs and ambulance trusts) we found a high degree of disparity in the management of earlier alerts which suggests that some categories of closed SABS alerts might have to be re-opened and dealt with in the wake of merger.

Recommendation 24:

That merged organisations assume responsibility for ensuring that all previous alerts have been implemented.

18.7.3 Scattered Sites

Some PCTs and Mental Health trusts were responsible for a very high number of sites in the case of one mental health trust, making estates issues particularly difficult

18.7.4 Contracted-Out Services

PCTs and mental health trusts may also have service level agreements with acute trusts or independent shared service organisations for certain services, such as facilities management. As non-statutory bodies, these organisations did not receive alerts directly, but through a PCT. Such arrangements, whilst efficient, make accurate targeting of alerts difficult.

18.7.5 Independent Contractors

PCTs were unclear about their responsibilities in relation to signing off GP action, most taking the pragmatic view that they could not enforce action on independent contractors. Two PCTs in our study had delegated the responsibility for disseminating alerts to independent contractors to primary care support organisations and took no further interest in assessing compliance.

Recommendation 25:

That clarification is given to SLOs in PCTs on their responsibilities in respect of independent contractors.

18.8 COMPLETION OF ACTION

A manager to whom the alert is sent by the SLO have a responsibility to confirm that action is underway or is complete, but there may be several levels of management below this, and many hundreds of staff who have to implement some alerts.

The SLOs in both the survey and in the interviews reported difficulties in persuading some managers to respond. During the visits we found that the more senior the manager who held the SLO role, the less likely they were to report difficulties of this kind. Some SLOs expressed concern that they are expected to sign off alerts on the SABS website on the basis of trust with no clear knowledge that action has been taken and our findings support the thesis that this concern is well placed.

We were informed by some SLOs that they were required to sign off alerts on the basis of intended action, rather than action taken. In some PCTs (the survey was carried out prior to merger) the brief time lapse between receipt and signing off appeared to indicate that action taken was simply the dissemination of alerts.

Recommendation 26:

That the Department of Health take steps to discourage trusts from making declarations of completed action without clear evidence of successful implementation.

18.9 AUDIT OF ALERTS

When SABS liaison officers speak of an audit being carried out in respect of an alert, they are usually referring to checking the integrity of a paper-trail – i.e. that they received responses from all managers to whom the initial alert was sent for action. We found very few examples of audits of action, other than by pharmacists in relation to methotrexate.

Recommendation 27:
That trusts devise robust systems of audit for complex alerts designed to improve patient safety.

18.10 PERFORMANCE MANAGEMENT

Three trusts reported that they had been spurred into action after phone calls from the NPSA (2) or Deputy CMO (1) when they had failed to sign off an alert. Action was taken very promptly thereafter.

None of the trusts visited had ever been contacted by the SHA in respect of late completion of alerts.

However, SHAs did report regular monitoring of trusts, usually on an annual basis for the Healthcare Commission Annual Health Check. Regular updating of the SHA webpage would make this a more valuable resource. Some SHA respondents did indicate that the monitoring of alerts was not high on their list of priorities.

More active monitoring by bodies such as the Healthcare Commission would raise the importance of alert implementation to the level afforded to fiscal and performance targets.

Recommendation 28:

Performance monitoring of actual, rather than reported implementation of alerts, and action for non-compliance, would raise the profile of alerts within NHS organisations.

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APPENDIX 1

Steering Group Members

1. STEERING GROUP MEMBERS

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- Keith Aungiers, Department of Health, Public Health Group
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- Jennifer Benjamin, Patient Safety Team Lead, Department of Health
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- Peter Gorin, Trust Secretary and Governance Lead, Hereford Hospitals NHS Trust
- Wendy Harris, Head of Safety Solutions, National Patient Safety Agency
- Dr Annette Lankshear, Director of Graduate Programmes, School of Nursing and Midwifery, University of Cardiff
- Karin Lowson, Project Director, York Health Economics Consortium Ltd
- Sara Marsden, Policy Analyst for Safety Team, Healthcare Commission
- Jane Moore, SABS Liaison Officer, Guys and St Thomas' Hospitals NHS Trust
- Mohammed Pandor, Senior Knowledge Manager, Department of Health Estates and Facilities Division
- Christine Ranger Head of Safer Practice, NPSA
- Tony Sant, Medicines and Healthcare Products Regulatory Agency
- Linda Wintersgill, SABS Liaison Officer, Northumberland Tyne and Wear SHA and Gateshead PCT

APPENDIX 2

Summary of Alerts

2. SUMMARY OF ALERTS

Reducing the harm caused by oral methotrexate	NPSA	Ref. No: Patient Safety Alert 03
		Action:
		Issue Date: 29 July 2004
To reduce the risks associated with inappropriate dosage levels and monitoring of methotrexate.		
• Agree appropriate local risk reduction actions through the Drugs/Medicines and Therapeutic Committee; • Provide patient information before and during treatment, including leaflets and patient-held monitoring and dosage record; • Update prescribing and dispensing software programmes to include alerts and prompts; • Review purchasing to ensure tablets are visually distinguishable by shape and that packaging contains cautionary wording.		

Needle free intra-vascular connectors	MHRA Medical device alert	Ref. No: MDA/2005/030
		Action:
		Issue Date: 17 May 2005
The instructions for use of many brands of needle-free connectors have undergone significant change, in particular to the maximum period of use of the device.		
• Ensure that up to date instructions for use are available to users: if in doubt contact manufacturers; • Review local policies to ensure consistency with the current instructions for use, incorporate changes and modify training if required; • Previous editions of instructions should be disregarded and destroyed.		

Reduction of harm caused by misplaced nasogastric feeding tubes	NPSA	Ref. No: Patient Safety Alert 05
		Immediate Action:
		Issue Date: 21 February 2005
Reduction of likelihood of placing nasogastric tube into lungs, or moving out of stomach		
Provide staff, carers and patients in the community, with information on correct and incorrect testing methods: • Measuring the pH of aspirate using strips/paper; • Use of radiography for specific groups of patients, though not routinely; • Ceasing of use of 'whoosh test'; • Ceasing of use of blue litmus paper; • Ceasing of interpretation of lack of respiratory distress as positive indicator. • Carry out individual risk assessment prior to nasogastric feeding; • Review and agree local action; • Report misplacement incidents via local risk management systems.		

Protecting people with allergy associated with latex	NPSA	Ref. No: NPSA/2005/8
		Action:
		Issue Date: 26 May 2005

To reduce the risk associated with the use of latex products by those with allergy.

Trusts should develop a comprehensive policy or review their existing policy, which should include measures to:

- Substitute, control and eliminate latex where appropriate and possible;
- Ensure staff are aware of and have access to safe and effective latex-free alternatives;
- Limit latex to its most valuable uses;
- Identify and protect sensitised patients;
- Raise awareness about latex sensitivity amongst patients and staff;
- Ensure that latex-free alternatives do not replace the risk of reaction to latex with another risk.
- The policy should be backed up by efficient management arrangements and be audited.

Alcohol based hand rub	DH F&E (NHS Estates)	Ref no: NHSE (2005) 07
		Action
		16th June 2005

Reduction of potential fire risk associated with alcohol based hand rub

- Ensure that quantities of all flammable liquids, including alcohol based hand rub in the workplace does not exceed 50 litres;
- Reserve stock of alcohol based hand rub and other flammable liquids in the workplace is kept in a lockable metal cupboard;
- The hand rub is kept away from naked flames and ignition sources. Dispensers should not be sited directly above or adjacent to electrical sockets or switches;

Where hand rub is sited in corridors and accessible to visitors:

- Corridor width should be 2m or greater;
- Dispensers should be a minimum of 1.2m apart;
- Maximum container size should be 1 litre;
- Dispensers should not be in public areas that are carpeted;
- Ideally implement minimum stock levels via ward-based materials management approach;
- Bulk storage is in fire resisting cabinets, whether in pharmacy or main stores.

Reduction of risks associated with mobile food trolleys	DH Estates and Facilities Alert	Ref. No: DH (2005) 11
		Action:
		Issue Date: 17 August 2005

To reduce the likelihood of damage to the electrical power plug with consequential electric shock injury.

- Ensure plug is disconnected from power source and correctly located in trolley plug holder before moving the trolley;
- Ensure cable stowage devices are properly used when trolley is in motion;
- Carry out regular and frequent visual inspections of the plug and cable;
- Arrange for the device to undergo Portable Appliance Testing (PAT) more frequently than 6 monthly intervals;
- Consider appropriate training for operators under first three points.

Reduction of risk associated with problems with implantable cardioverter defibrillators (ICDs) **Series of ten alerts issued for several manufacturers' makes and models of ICDs**	MHRA Medical device alerts	Ref. No: MDA/2005/015 MDA/2005/018 MDA/2005/037 MDA/2005/038 MDA/2005/039 MDA/2005/041 MDA/2005/045 MDA/2005/046 MDA/2005/048 MDA/2006/006
		Action and updates:
		Issue Date: 2 & 17 March 2005 27 (3) & 30 June 2005 25 & 26 July 2005 11 August 2005 6 February 2006
Problems include premature battery depletion or failure, and other manufacturing and component faults. All problem ICDS are identified by manufacturer.		
• Be aware that premature battery depletion and prolonged charge time may occur during three-month follow up period; • Be aware that there may be other problems with the ICD, e.g. inadequate insulation within the device, random memory error, sticking of magnetic switch, high rate pacing due to out of specification component, seal failures; • Identify patient affected by alerts; • Ensure patients affected followed at intervals no longer than three monthly; • Advice affected patients to contact their ICD centre if experiencing problems; • Report all instances of unexpected battery depletion; • Return unused ICDs to manufacturer.		

Safe delivery of radiotherapy treatment	Department of Health Alert	Ref. No: None
		Action:
		Issue Date: 23 December 2004
To reduce the risks in the delivery of radiotherapy treatment as a result of data errors from manual transposition of machine parameters.		
• Review practice and procedure relating to data entry into linear accelerator record and verify systems (R&V); • Review and identify primary sources of information for checking data in R&V systems prior to treatment delivery; • Review provision of appropriate environment for data related tasks and at treatment console; • Take any necessary actions to address changes in procedure and practice to minimise the risk of this type of incident being repeated.		

Electrically operated beds - supplement to mda/2004/042	MHRA Medical device alert	Ref. No: MDA/2005/034 Action/Update Issue Date: 22 June 2005
Risk of entrapment and crushing from accidental operation of foot controls.		
• Determine if your organisation has electrically operated beds fitted with foot operated height controls; • Lock-out functions should be used in accordance with the manufacturer's instructions for use; • If lock-out functions are not fitted, take alternative steps to reduce the risk of patient entrapment; • Consult with the manufacturer of the bed to assess available options. **Action By:** • Those responsible for the purchase, issue and use of electrically operated beds.		

Universal hospital supplies guedel airways	MHRA Medical device alert	Ref. No: MDA/2006/026 Immediate Action: Issue Date: 03 May 2006
Due to manufacturing problems, the Guedel airways may be split around the bite block allowing the colour insert to become dislodged from the main body of the airway.		
• Remove this product from use and quarantine; • Arrange collection and refund of recalled stock via usual distribution channels; • Be aware that comparable product is available from other manufacturers. If alternatives are not immediately available, ensure there are no splits or occlusion before use and that staff are aware of the possible failures; • The supplier is recalling affected lot numbers of Universal Guedel Airways sizes 1, 2, 3 and 4.		

Shower heads	DH Estates and Facilities Division	Ref No: DH (2006) 05 Immediate Action 25th July 2006
Patients can die if using shower heads that are 'vandal resistant' as ligature points		
• A check be made of all shower heads in those wards and departments accommodating mental health patients to assess the likely risk of the shower head being used as a ligature point; • Where shower heads present a risk, they should either be removed, or measures be taken to eliminate the risk; • In other healthcare premises where there is a risk of patients self-harming or where patients with a suicidal tendency are accommodated, all shower heads should be examined for their potential use as ligature points.		