National Patient Safety Agency
Patient Safety Division

Putting patient safety first

A COMPENDIUM OF PATIENT SAFETY IN PRACTICE
Acknowledgements

The NPSA gratefully acknowledges the contribution made by the NHS trusts in England and Wales by agreeing to be interviewed for the case studies.

In particular, thanks go to:

Jackie Bird, Chief of Quality and Standards/Chief Nurse, The Rotherham NHS Foundation Trust
Gillian Cavell, Deputy Director of Pharmacy, Medication Safety, Kings College Hospital NHS Foundation Trust
Annie Davies, Chief Pharmacist, Epsom and St Helier University Hospitals NHS Trust
Ken Davie, Clinical Risk Manager, Conwy and Denbighshire NHS Trust
Neil Gammack, Clinical Pharmacy Services Manager, Gateshead Health NHS Foundation Trust
Sandra Hallett, Director of Safety and Quality, University College of London Hospitals NHS Trust
Janice Knight, Pharmacy Risk Manager, University Hospitals Coventry and Warwickshire NHS Trust
Avril Lowery, Head of SafeCare, Gateshead Health NHS Foundation Trust
Justin O’Brien, Head of Clinical Risk, South West London and St George’s Mental Health NHS Trust
Colin Pike, Infection Control Manager, Pontypidd and Rhondda NHS Trust
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In the six years since the National Patient Safety Agency (NPSA) was established, it has produced a comprehensive list of patient safety alerts, safer practice notices, Patient Safety Observatory reports and, more recently, Rapid Response Reports1, covering issues that have been raised locally by acute trusts (mainly) and reported through the National Reporting and Learning System (NRLS).

Issues have covered the whole spectrum of patient care. They have been analysed, evaluated and prioritised by experts and healthcare practitioners to determine what response will be the most effective.

Information about risks and hazards in many forms has then been disseminated to the NHS via the Safety Alert Broadcast System (SABS) in England, and by direct email in Wales, with an identified implementation date. Where appropriate, information has also been disseminated to targeted areas in the independent health sector.

This compendium focuses on safer practices in 10 areas in which the NPSA has provided advice and recommendations. For the first time we have attempted to gather in one place information about implementation and evaluation of this guidance, together with case studies of actual experience. This is important because the effectiveness of safety guidance cannot be judged unless and until the actions recommended are implemented and show an improvement in practice. The response system is more important than the reporting system.

The compendium demonstrates the commitment to improving patient safety by many trusts and organisations in England and Wales, the way they have adopted new models of behaviour and instituted a culture shift in their organisations, and ways in which the range of materials, products and tools produced by the NPSA have been implemented.

Their methods aren’t always orthodox, rather they are about engagement and challenge, about an inclusive approach to problem solving, and about team working. They are about good planning and positive action. They are also about starting with small steps and building progressively towards the end goal. And they are about strong and visible local leadership.

The compendium also demonstrates that implementing safety improvements can be difficult and time consuming.

Local action is sometimes too complex to be achieved within the required timeframe. Not all alerts and safer practice recommendations are clear enough. Some trusts believe if alerts are not interpreted locally as national directives, they will not be prioritised within their organisation and deadlines will be missed. Experience has shown that vital safety improvements don’t happen at all in some circumstances, in spite of well researched and proven recommendations.

How do we ensure better and quicker uptake of actions to reduce risks and improve patient safety?

This is the challenge which faces the patient safety movement nationally and internationally. For its part, the NPSA is working to make feedback and learning from the NRLS more actionable, to strengthen the involvement of frontline staff and clinicians, and to develop new approaches and tools which support implementation of safer practices by local organisations. A number of the tools we have already implemented are available on our website www.npsa.nhs.uk.

We commend this compendium and in particular the case studies from which much can be learnt. We invite your feedback on further steps which can be taken to ensure that improving the safety of patient care is at the core of frontline delivery of healthcare.

Martin Fletcher
Chief Executive

Kevin Cleary
Medical Director

1For a complete list see Appendix 1
Quicker and more reliable implementation of risk reduction strategies and safer practices are two of the major challenges for the patient safety movement internationally. This compendium highlights a number of action points:

**Local organisations need to:**

- Review implementation of key alerts and safety guidance in your organisation. What more can be done to ensure greater uptake?
- Put in place an ongoing implementation review programme as part of the patient safety strategy in your organisation. How can you assure your Board that safer practices are being consistently implemented?
- Feedback to the NPSA factors identified that help or hinder implementation of safety advice and recommendations. What will make our safety products more useful and actionable for you locally?

**The NPSA needs to:**

- Update and reissue safety advice and recommendations that have not been fully implemented. Where do we need to re-emphasise national action on risks to patient safety that are not yet fully addressed?
- Improve communication and dissemination strategies to ensure the learning from the NRLS is clear and actionable.
- Develop new approaches and tools to support local implementation.
We begin this compendium with the Seven steps to patient safety, its implementation and evaluation, and build on it with nine other pieces of work that demonstrate ways in which patient safety can be improved.

In February 2004, the NPSA published Seven steps to patient safety, a guide for staff who provide care in the NHS and for those engaged in clinical governance and risk management.2

It wasn’t the first advice issued to the NHS by the NPSA, however, it was one of the most comprehensive. Within each step, a suite of principles was identified to support the rationale behind the methodology. The success of the guide was immediate and copies of the first edition ‘sold out’ within three months.

In the intervening four years, the body of evidence supporting the imperative of patient safety has grown.

STEP 1: BUILD A SAFETY CULTURE - one that is open and fair
The key principles:
A safety culture is where staff within an organisation have a constant and active awareness of the potential for things to go wrong. Being open and fair means sharing information openly and freely and fair treatment for staff when an incident happens. Looking at what is wrong in the system helps organisations to learn lessons that can prevent incidents recurring.

STEP 2: LEAD AND SUPPORT YOUR STAFF - establish a clear and strong focus on patient safety throughout your organisation
The key principles:
Delivering the patient safety agenda requires motivation and commitment from the top of each NHS organisation and from leaders throughout the service, who must be visible and active in leading improvements. Staff should feel able to say if they do not feel that the care they provide is safe, irrespective of their position.

STEP 3: INTEGRATE YOUR RISK MANAGEMENT ACTIVITY - develop systems and processes to manage your risks and identify and assess things that could go wrong
The Key Principles:
Integrated risk management means lessons learned in one area can quickly be spread to another area. A central team should be responsible for pulling together the systems and processes for risk management and ensuring all staff across the organisation feed information into this.

STEP 4: PROMOTE REPORTING – ensure your staff can easily report incidents locally and nationally
The key principles:
Reporting patient safety incidents and prevented incidents nationally provides the opportunity to ensure that the learning gained from the experience of a patient in one part of the country is used to reduce the risk of something similar happening to future patients elsewhere.

STEP 5: INVOLVE AND COMMUNICATE WITH PATIENTS AND THE PUBLIC - develop ways to communicate openly with, and listen to, patients
The key principles:
Many patients are experts in their own condition and this expertise can be used to help identify risks and devise solutions to patient safety problems. Being open about what has happened and discussing the problem promptly, fully and compassionately can help patients cope better with the after-effects if things go wrong.

1This is a summary of the Seven steps to patient safety. For a complete guide, refer to the full reference guide: www.npsa.nhs.uk/patientsafety/improvingpatientsafety/patient-safety-tools-and-guidance/7steps/
In May 2004, a comprehensive independent evaluation of the awareness, effectiveness and usefulness of the Seven steps to patient safety was completed. It assessed the 200 page reference guide, as well as the summary version. The evaluation comprised a telephone interview with 32 NHS organisations across England and Wales. They covered acute settings as well as ambulance, mental health and primary care. Primary care was focused on because they make up the majority of NHS organisations, and there was a set of specific questions aimed at this sector.

There were some key findings:

- Effectiveness and usefulness of the content was rated very highly and respondents in the survey were able to give examples of how they had used the guides in their work.
- Generally, respondents found the information very helpful and able to be used/modified as a planning tool.
- One acute trust made the summary overview available on their intranet and another issued copies to all junior doctors.
- There was a general preference for the overview as a quick reference manual.
- The two guides were highly rated with a separate guide needed for primary care.
- The guides needed to be updated over time, informed by NPSA research and from NHS experiences – allowing people to learn from one another.
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NB: The NPSA published the Seven steps to patient safety in primary care in 2006, and will be revising the Seven steps to patient safety in 2008.

STEP 6: LEARN AND SHARE

SAFETY LESSONS – encourage staff to use root cause analysis to learn how and why incidents happen

The key principles:

- When a patient safety incident occurs the important issue is not ‘who is to blame for the incident?’ but ‘how and why did it occur?’ Local NHS organisations need a systematic approach in which staff know what type of incidents should be reported, what information is needed and when, and how to analyse and act on this information.

STEP 7: IMPLEMENT SOLUTIONS

TO PREVENT HARM – embed lessons through changes to practice, processes or systems

The key principles:

- Learning from patient safety incidents needs to be ‘active’ so changes are incorporated into the way all staff work at all levels. Any specific changes to systems and procedures need to be sustainable so they will survive once a crisis is perceived to be over. Solutions need to be realistic, sustainable and cost-effective. They need to draw on the experience of NHS staff, patients and the public to ensure they are achievable in practice. Before implementation, they must undergo risk assessment and evaluation.

THE EVALUATION

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Fact file:
Trust sites: 3
Beds: 619
Staff: 3,100 headcount

“It's about saving lives’
Avril Lowery, Head of SafeCare

In 2007, Gateshead launched its long-term strategy: SafeCare, A Responsibility we ALL share, a trust-wide initiative led by its Director of Nursing and Midwifery and its Medical Director. In developing the strategy, the trust realised that clinical governance and the importance of the patient as the central focus of the healthcare team was a priority for every member of staff, not just clinicians and frontline staff.

“Gateshead Health NHS Foundation Trust believes that the patient is the most important member of the healthcare team and that to ensure good quality care, the trust must send a clear and unambiguous signal that SafeCare is the trust’s number one priority.”

The strategy is based on the NPSA’s Seven steps to patient safety and includes six concise commitments:

1. The establishment of a SafeCare Council chaired jointly by the trust’s Director of Nursing and Midwifery and the Medical Director. As the ‘conscience’ of the trust, it will ask the question ‘Are we constantly improving the care we deliver?’.

2. The design and implementation of a local SafeCare campaign to engage patients, clinical and non-clinical staff to address the challenge of continuously improving the healthcare we provide.

3. The establishment of an accountability framework covering all divisions within the trust, clinical and non-clinical, with divisional SafeCare teams trained in root cause analysis, problem solving and data analysis.

4. Sharing of good practice with local alerts and bulletins to inform service delivery, and notification of risks and harm that must be repaired and remedied. Reporting systems will be constantly reviewed to ensure that reporting is encouraged and the systems are easy to use.

5. Greater openness with patients and their families so that when things go wrong there will be appropriate systems in place. Patients want to have confidence that staff will be open and honest and will support the patient in dealing with the consequences of a mistake.

6. Education and training prioritised. Learning lessons from mistakes is an important part of the strategy. Key pieces of work identified cover the areas of: palliative and end-of-life care, improving communication between primary and secondary care, surviving sepsis, reducing medication errors, reducing mortality rates, and improving the privacy and dignity of patients.

Responsibility for implementing the strategy rests with all staff, the leadership comes from the top.

The path to the strategy’s development and launch in 2007 came from the belief that the trust needed to ‘do something different’. It wasn’t an overnight revelation. Months of work went into talking with clinical staff, organising workshops across the trust, determining the priorities and exploring ways of creating a culture of openness and fairness, and of staff and patient empowerment.

The trust is an avid supporter of the IHI’s principles and applauds its US-based patient safety programme ‘Saving 100,000 Lives’. It has explored several different universal methodologies of safety from the Toyota model to the IHI global trigger tool. Ultimately, however, the trust believes safety and quality cannot be separated.

Turning patient safety into business-as-usual is the aim of the trust’s three-year strategy. Success, it says, will be realised when there is a sustained culture of patient safety in place throughout the organisation, at all levels.
The NPSA issued its first patient safety alert in July 2002. It identified safe medication practice recommendations concerning the prescription, distribution, storage and preparation of potassium chloride solutions in hospitals.¹ There was evidence to suggest that potassium chloride concentrate solution could be fatal if given inappropriately.

In developing the alert, the NPSA commissioned a survey between March and May 2002 to find out what arrangements for the storage and use of potassium chloride concentrate were in place within NHS hospitals.

The survey found that in the overwhelming majority of hospitals, undiluted potassium chloride was being stored and diluted in solutions outside pharmacy areas. Hospitals had not developed local policies for the storage of the concentrate or its dilution in patient care areas, and hospitals didn’t have 24 hour staffing by pharmacists in order to prepare dilutions outside clinical areas. Neither critical care physicians nor pharmacists were confident that pharmacy departments in every hospital could always prepare and deliver all the required dilutions of potassium solutions to critical care areas fast enough to ensure good patient care.

The purpose of the alert was two-fold:

1. to reduce the risk of accidental overdose of intravenous potassium arising from the use of potassium chloride concentrate solutions and other strong potassium solutions.
2. to ensure that seriously ill patients in critical care units who urgently require intravenous potassium as part of their treatment can continue to receive it promptly.

The alert identified four areas where specific actions needed to be taken (by 31 October 2002):

1. Storage and handling of potassium chloride concentrate and other strong potassium solutions.
2. Preparation of dilute solutions containing potassium.
3. Prescription of solutions containing potassium.
4. Checking the use of strong potassium solutions in clinical areas.

The NHS was required, by June 2003, to introduce training to identify and mitigate risks associated with the storage, prescription, preparation and administration of potassium chloride concentrate. They should be highlighted in patient safety induction training for all staff involved in the medication process and should also feature in specific training in intravenous drug preparation and administration.

The NPSA took responsibility for three tasks to be underway by April 2003.

1. Commission an audit to determine the use of potassium chloride concentrate and ready-to-use diluted solutions containing potassium within the NHS.
2. Work with PASA⁴, the Medicines Control Agency⁵ and the pharmaceutical industry to facilitate the manufacture and supply of an appropriate range of ready-to-use solutions to minimise the need for potassium chloride concentrate ampoules and vials in clinical areas.
3. Work with practitioners, the Medicines Control Agency and the pharmaceutical industry to determine the best method to ensure easy identification of potassium chloride concentrate and other strong potassium solutions and to implement distinctive standardised labelling and packaging of these products.

In November 2003, the NPSA issued an update to the alert which recommended the withdrawal of concentrated potassium solutions from ward stock and replacing them with ready-to-use infusion products. The NPSA also recommended introducing new control arrangements in critical care areas that continue to use potassium chloride concentrate ampoules. The update included the outcome of a ‘learning and sharing’ exercise organised by the NPSA for acute trusts earlier in the year and outlined further actions for the NHS.

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¹NHS Purchasing and Supply Agency
²Merged with the Medical Devices Agency in April 2003 to become the Medicines and Healthcare products Regulatory Agency.
The NPSA commissioned the York Health Economics Consortium to conduct an evaluation of the potassium chloride alert. It designed a multi-method study involving interviews and a physical inspection of 207 clinical areas in 20 randomly selected acute trusts in England and Wales over a period of three months from October 2002 to January 2003.

The study measured awareness and compliance of the alert’s requirements, the withdrawal of concentrated potassium chloride solutions from non-critical areas, and the provision of pre-diluted alternatives, storage and recording in accordance with controlled drug legislation.

The evaluation identified that the alert was effective and very well-received. It resulted in ‘rapid development and implementation of local policies to reduce the availability of concentrated potassium chloride solutions.’ The study revealed that:

- there was 100 per cent compliance for the requirement that all trusts store potassium chloride concentrate in a separate locked cupboard from common injectable diluents.
- all trusts required documentation control of the concentrate in clinical areas, but errors were recorded in 20 of the 207 clinical areas visited.
- there was a high awareness of the alert, 78 per cent of nurses interviewed and 30 per cent of junior doctors.

The study interviewed senior managers and found that several had taken action on the issue prior to the alert being issued by the NPSA. The alert was welcomed by all pharmacists interviewed, who said it gave ‘authority’ to their work.

The study commented on the lack of effort by pharmaceutical companies to make packaging and labelling more distinctive.
CASE STUDY
university college of london hospitals nhs trust

Fact file:
Locations: University College Hospital, Eastman Dental Hospital, Elizabeth Garrett Anderson Obstetric Hospital, The Heart Hospital, Hospital for Tropical Diseases, National Hospital for Neurology and Neurosurgery, Royal London Homeopathic Hospital
Beds: 1,000
Staff: 6,000

The alert gave the Head of Pharmacy the authority, credibility and framework to implement something that we knew was in the interests of patient safety. It was a good piece of guidance.

Dr Robert Urquart, Director of Pharmacy

As the first alert to be issued by the NPSA, it was seen as something new and innovative. Many hospitals had identified that the prescribing, storage and distribution of potassium chloride concentrate was a problem that was not easily resolved. Everyone in pharmacy circles knew it was an issue and by being given national guidance, implementation was easier to manage.

For the pharmacy staff at UCLH, the alert was viewed very positively.

'We were able to take a poorly controlled clinical risk, reduce it and understand and assess the areas in which the risk persisted.'

UCLH started with an assessment of use in all of its clinical areas. It removed potassium chloride ampoules from areas where they were not needed and from areas where they could be replaced with pre-prepared solutions containing potassium. This required flexible use of a broad range of potassium-containing solutions including some not licensed in the UK.

A small number of areas, including the critical care units, retained the ampoules on the grounds that mixes were not always appropriate or available in the required strengths.

Clinical pharmacists were central to the success of reviewing and challenging the continued need for potassium ampoules in clinical areas, and also in ensuring that appropriate practices were followed in any areas retaining a stock.

To ensure the procedures were properly embedded into the trust’s system, the drug was written into the controlled drug policy – with a process similar to an opiate. This controlled all requisitions and ensured the correct procedures are followed and pharmacy acts as the gatekeeper.

Implementation was relatively easy, in part because it was the first NPSA alert and therefore something of a novelty, and in part because the area being tackled was one that was known to be dangerous.

In 2008, as part of the trust’s medicines management plans, the pharmacy department at UCLH is developing a structured audit programme that will prioritise key medicines audits to be performed on an annual basis. One of the factors that will be assessed will be the issue of injectable potassium practice.

‘Our philosophy is to be self-auditing. That way we are one step ahead all the time.’
In July 2004, the NPSA issued an alert following reports of harm caused by oral methotrexate. It issued a revised alert in June 2006 to try and improve implementation across the NHS.

The first alert was issued following analysis of reports that had come to the NPSA via the NRLS\(^6\). It was found that 137 patient safety incidents had occurred over a 10-year period, including 25 patient deaths and 26 cases of serious harm. The NPSA’s review found that 67 per cent of the incidents involved prescribing the wrong dose frequency of the tablets, 19 per cent were due to a lack of, or poor monitoring of, therapy, and seven per cent were because of mis-identification of the tablets by the healthcare professional or the patient.

The similarity of the drug packs for 2.5mg tablets and 10mg tablets needed to be addressed. The NPSA proposed a patient record booklet should be produced by trusts based on generic information to better involve the patient in the prescribing and dosage regime.

Locally, trusts needed to review the shared care arrangements for prescribing and monitoring oral methotrexate in rheumatology, dermatology and other clinical areas using once-weekly methotrexate. Three specific checklists were required:

- Safe prescribing
- Safe dispensing
- Safe administration

Actions needed to be undertaken through the local drugs/medicines and therapeutic committee and the improvement programme needed to be in place by March 2005. In acute trusts, responsibility for managing the implementation of the alert was generally delegated to the chief pharmacist.

In June 2006, the alert was reissued to the NHS to ‘reinforce guidelines to reduce the risk of patient harm associated with the incorrect use of oral methotrexate.’ Feedback from the SABS system had shown that 104 out of 569 NHS organisations had not fully implemented the recommended actions.

The update advised NHS organisations in England and Wales to ensure that all actions described in the original alert were completed, and give patients the core patient information leaflet and monitoring document that were reviewed in collaboration with the British Society for Rheumatology and the British Association of Dermatologists.

The update of the alert also strengthened the role of the patient in ensuring safety, with more information being included in the booklet. It also gave specific deadlines for trusts and organisations to complete their implementation programme, including individual audits.

\(^{6}\)National Reporting and Learning System – the NPSA’s national reporting system for patient safety incidents.
The SABS data relating to the reissued patient safety alert, that had a deadline for action of 31 January 2007, showed that 72 per cent of trusts had completed implementation; five per cent were assessing the relevance of the alert, three per cent had yet to start implementation, 11 per cent were still implementing the alert, and for 12 per cent, action was not required.

An evaluation exercise sampled 20 acute trusts, 15 PCTs, four ambulance trusts and two mental health trusts. Key staff were interviewed in each trust about the management, reception, dissemination and implementation of the oral methotrexate alerts. The interviews also looked at evidence of the implementation of tracker alerts not all of which were relevant to every organisation. An audit of staff awareness was completed and the research group sought evidence of implementation.

The results showed that the alert was generally well implemented, and that action was led by chief pharmacists or their designated deputies. Seventeen of the acute trusts reported having taken action to discontinue the use of 10mg tablets. Those that had retained the use of the higher strength 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 reduced the need to take the larger number of tablets required by the use of 10mg tablets only.

Some trusts reported that although they had ceased to use the 10mg tablets, they 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 this was difficult to enforce. Strategies employed to try and reinforce this included:

- carrying the costs of ‘broken bulk’ to recompense pharmacists for the withdrawal of the 10mg tablets.
- conducting audits of community pharmacists.
- 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 compliance was seen as an ‘uphill struggle’.

Mergers had given PCT pharmacy leads new populations of GPs of whom they had no knowledge, necessitating the relaunching of all strategies to promote adherence to the policy.

There was reported disagreement about the first generation of patient information leaflets produced by the NPSA. However, it stimulated discussion either within the trust or in the wider health community and where a new leaflet was not produced the content of the existing leaflet was at least discussed.

In areas where new information leaflets were produced following the 2004 alert, there was little enthusiasm for reopening these discussions when the 2006 alert was issued. However, from the interviews in acute trusts and PCTs, 19 areas in total have adopted the NPSA patient leaflet and others adopted it with slight modifications. The remainder was satisfied that their patient information contained all the necessary information required by the 2006 alert.
Fact file:
Trust sites: 3
Pharmacy Staff: 89 WTEs
Drugs budget: £11million

“This was a very useful alert. Managing its implementation was time consuming involving a multidisciplinary approach including interfacing with primary care.”
Anne Davies, Chief Pharmacist

The initial alert on oral methotrexate took two years to be fully implemented at Epsom and St Helier University Hospitals NHS Trust. There were several reasons for the delay:

- Time was required initially to identify and obtain engagement from the main stakeholders.
- There were complex issues including the different clinical management systems and approaches applied by GPs, PCTs and the acute trust.
- There were existing purchasing contracts for methotrexate that had to run their course before new ones could be put in place.
- There was no funding available for producing the patient handbook that had to run their course before new ones could be put in place.
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- Lack of IT system compatibility between PCTs and acute trusts to allow sharing of blood results.
- Education programmes were in place but adding additional training sessions needed to be factored into future programmes.
- Competing priorities within the trust and between local NHS organisations.

Implementation of national alerts is coordinated by the trust’s medicines management committee. A process is agreed and a ‘task and finish’ group is identified.

For this alert, the trust invited the local NPSA’s Patient Safety Manager to attend an early meeting and explain in more detail about the NPSA and its role. A working group was set up including representatives from the two local PCTs: Sutton and Merton, and East Elmbridge and Mid-Surrey. Consultant representatives from rheumatology, dermatology, renal, gastroenterology and immunology as well as pharmacy were invited to participate (around 20 individuals were involved over the course of the project).

The project was championed by one of the trust’s consultant rheumatologists and aimed to establish a standard pathway of care for patients receiving methotrexate which worked across the interface with primary care.

The working group put a lot of time and energy into producing a local patient booklet and liaised with the local PPI committee as to content and design. The result is one of the project’s success stories.

Around this time, several local GP practices made the decision to refer patients requiring methotrexate back to secondary care. This was partly due to funding arrangements for shared care and partly due to lack of confidence amongst some GPs to safely monitor patients receiving methotrexate.

Positive outcomes of the work undertaken to implement the alert include:

- Improved working relationships between the health professionals.
- A clear expectation of roles and responsibilities for clinicians and patients. The GP and patient monitor drug toxicity and administer the drug if tests are acceptable. The specialist and patient monitor drug efficacy and make changes to the regimen according to response. This ensures that risk is reduced.
- Patients who have both consultant and GP support feel empowered to use their patient held handbooks (between 1,000 and 1,500 patients receiving methotrexate attend the trust-run outpatient clinics).
- Good clinical leadership and support encouraged engagement from other clinicians and GPs.
- Resolution of some IT issues for sharing blood results.
- Production of a leaflet for doctors, nurses and pharmacists explaining the prescribing, administering and dispensing of oral methotrexate.

The trust is now in the process of reviewing the patient handbook. Funding for the publication, however, remains an issue.
In 2004, the NPSA introduced a new web-based toolkit – explaining RCA, how to conduct a retrospective review of a patient safety incident, and how to use the results to identify areas for change and recommendations for sustainable improvement.

In part this was developed as a result of the issues raised in the report *Organisation with a Memory* and in part because there was a general lack of understanding and knowledge about conducting efficient root cause analyses in the NHS.

In its publication *Seven steps to patient safety* the NPSA had recommended the use of RCA to “help local organisations ensure that the investigation team they create is proficient in RCA by providing both online and face to face training.”

The NPSA developed an online RCA toolkit, and delivered a follow-up training programme for the NHS. It commissioned an external agency to produce the web-based e-learning training package, which is available online or in CD-ROM format.

The toolkit is divided into six modules, with each section explaining what is involved, resources required and where to access more information:

1. An introduction explaining the learning programme and what it contained.
2. Why things go wrong, how errors happen and whether they are accidents or violations etc.
3. Getting started – the type of analysis required, how to classify the incident and its severity, the type of review that might be needed.
4. Gathering and mapping information – looking at the data required, sources of information, pulling together a chronology of events, conducting interviews and compiling the notes and information that has been collected.
5. Analysing information – getting a team of people together to review the material, prioritising the problem, identifying the contributing factors and determining the root causes.
6. Generating solutions – who needs to agree the recommendations and actions, who implements any recommended solutions, who needs to know, what communications are required, identifying and understanding barriers, and finally developing the recommendations.

The toolkit was an immediate success. Explaining its use and why analysis of patient safety incidents is important to future learning was part of a larger NHS-wide exercise led by the NPSA as a formal training programme.

The training programme
Following the release of the online RCA toolkit, the NPSA developed and implemented a training programme, available to all NHS organisations in England and Wales. The response was overwhelming.

Each of the 607 NHS organisations were offered eight free places and most were taken up. The team of patient safety managers (PSMs) were responsible for organising and leading the training workshops, determining the locations, finding the venues and communicating the messages. The workshops were run as mini conferences with between 20 and 40 people attending each session. The sessions were spread over two or three days depending on numbers and location.

The workshops were structured in line with the design of the RCA toolkit and followed the logical progression of what, why, when and how. Each aspect of the toolkit was explained and then discussed by participants with a practical exercise to ensure everyone understood what was required as best practice.

The aim was to:

- Provide healthcare workers with the skills and knowledge to undertake an RCA.
- To develop local networks where incident investigation issues and good practice could be shared.
- To cascade information and learning by the workshop participants throughout their local organisations.

The workshops took over a year to complete.
Three evaluations of the NPSA’s networked training programme were undertaken:

- An independent evaluation of North England by the University of Manchester.
- An independent evaluation of England and Wales, excluding North England, by Coventry University Health Services Research Centre.
- NPSA post-evaluation in all geographical locations.

The evaluations produced some generic findings:

- The NPSA should actively engage in the setting up of RCA learning networks at local/regional levels.
- The cascade training element had limited effectiveness and needed more discussion about how it could be improved.
- The workshops were more effective than the e-learning package.
- Best practice RCA case studies should be developed and shared across the NHS.
- Consider including RCA standards in the new patient safety developmental standards being formulated by the Healthcare Commission and the NPSA.
- Quality reports are very important.

New template
As part of the NPSA’s response to Safety First+, it identified the need to support NHS organisations further in writing up the findings from RCA investigations. As a result, the NPSA has developed a new RCA Investigation Report Template which serves to:

- Systematically guide investigators through the RCA process.
- Standardise and structure reports to improve credibility and thoroughness.
- Capture requisite information for shared learning from investigation findings.

The template will be available to download from June 2008 via the NPSA website: www.npsa.nhs.uk
CASE STUDY

ymddirieddolaeth gig siroedd conwy a dinbych
conwy and denbighshire nhs trust

Fact file:
Location: North Wales
Staff: 5,600 headcount
Budget: £200 million (approx)

‘The challenge for our trust was how to use the toolkit in a timely way and how to conduct incident reviews’. Ken Dawes, Clinical Risk Manager

Conwy and Denbighshire NHS Trust is a large, diverse organisation, providing a full range of acute, community and mental healthcare through a network of hospitals, health centres and clinics.

In October 2006, the trust endorsed and validated a new risk management policy, giving greater emphasis to clinical risk and root cause analysis. It was, according to Ken Dawes, an approach that has found favour with staff across the organisation, clinical and non-clinical.

‘In the past, although we conducted RCA whenever an incident happened, the approach was fragmented; it was sometimes a challenge to get people to come to incident review meetings and there was no policy that required clinicians to attend. The incident wasn’t contextualised which made it difficult to implement change.’

Through the energy of the trust’s medical director, initially Dr David Gozzard and more recently Dr Brian Tehan, who made a personal commitment to improving the process and the trust’s clinical risk team, the system that has been in place for 18 months is proving its worth.

Many of the trust’s staff had attended the workshops organised by the NPSA when the toolkit was first promoted in 2005, however, Ken Dawes could see merit in running a seminar on site and he arranged for NPSA staff to come to Wales and train 50 staff members representing all parts the organisation.

‘It was important to give everyone the same message at the same time so that they would understand the value of RCA and its benefit to the trust.’

Several changes, including the procedures for identifying and managing incidents, were made as part of the policy development. The result is a real improvement with a stepped process that is led by the trust’s medical director.

“Our first step is to establish a chronology of events leading up to the incident which then forms the basis for the incident review. The chronology identifies the areas involved and therefore the staff who need to attend a review meeting. The medical director issues an invitation to a meeting at which the chronology is the main item on the agenda. We work out what we did well and what needs attention. We write up the minutes with recommendations for further action which is then sent to the Safer Patients Group.’

The Safer Patients Group was formerly known as the clinical risk group, but was renamed to better reflect the emphasis on patients.

The trust’s eight clinical divisions are represented at senior level and they debate the recommendations, ensure the cascade process is in place and take responsibility for implementation. According to Ken Dawes, this system is now fully accepted and is the root cause analysis tool that works for the trust.

‘Consultants are happier with the system and we are getting a greater level of attendance at review meetings. The emphasis is one of learning not blame. We also discuss issues that consultants have been unhappy about but haven’t had a forum for making improvements up till now. We are able to put incidents into a broader context that is valuable for everyone.’
Hand hygiene is one of the most critical factors in preventing the spread of infections in healthcare settings. Evidence shows that poor hand hygiene spreads some of the micro-organisms which can cause infections, including meticillin resistant Staphylococcus aureus (MRSA) and Clostridium difficile (C. diff).

In September 2004, the NPSA launched the cleanyourhands campaign to acute trusts in England and Wales. The campaign was based on international studies and research undertaken in England that suggested that infection rates could be reduced by up to 10-50 per cent when staff cleaned their hands at the point of care. In his 2006 annual report, the Chief Medical Officer for England, Sir Liam Donaldson, announced that the NPSA would initiate a patient empowerment pilot programme. This work began in December 2007, with a three-month feasibility study involving five acute trusts in England. Four surveys were undertaken – a survey of 500 members of the public, a survey of inpatients and healthcare workers at the five participating trusts, and a survey of campaign coordinators across all acute trusts in England.

The evaluation showed that patients had a good awareness of the use of the alcohol handrub, that if provided with a bottle of handrub, they would be prepared to use it as a prompt to remind healthcare workers to clean their hands, and that they would prefer the handrub with supporting information to be given to them by a nurse or a volunteer.

The results also showed that while healthcare workers thought it would be valuable as a reminder to them for patients to be given a bottle of handrub, they also expressed concern that the gesture as a prompt could create tension.

The findings of the feasibility study are being used to contribute to the development of a wider pilot initiative.

The National Audit Office (2004) had found that healthcare associated infections led to the deaths of 5,000 patients and cost the NHS over £1 billion a year.

The aim of the campaign was to encourage healthcare workers to clean their hands at the point of care, at the right time and in the right way using alcohol handrub and/or soap and water, depending on the situation and the circumstances.

The intention was to raise awareness and facilitate good hand hygiene practice amongst staff, and to create an environment for patients where it was ‘ok to ask’ clinical staff whether they had cleaned their hands prior to patient contact.

Detailed research was carried out by the NPSA, PASA (now NHS Supply Chain) and the NHS to find the best alcohol handrub products that could be contracted for supply.

The campaign consisted of a toolkit to help make hand hygiene an integral part of day-to-day healthcare. An implementation guide was developed which included visual prompts, guidance on involving patients, resources to support implementation, as well as materials for internal and external promotion.

After three years, the campaign is now well-embedded into the acute sector in England and Wales with all acute trusts signed up to the campaign. It is closely aligned to the World Health Organization’s Global Patient Safety Challenge on hand hygiene. It is now being extended into mental health, ambulance, care trusts and primary care NHS trusts.

In England, a percentage of sales of the handrub are used to support the campaign in acute trusts.

In England, a percentage of sales of the handrub are used to support the campaign in acute trusts.
An independent evaluation research programme of the cleanyourhands campaign in the acute sector was funded by the Department of Health (England) and commissioned by the Patient Safety Research Programme. It is being carried out by five collaborating institutions/professional societies and is supported with additional funding by Royal Free Hospital Trustees and GOJO Industries. There are two aspects to the research:

- **NOSEC** – a four-year multi-disciplinary study which looks at the effectiveness of the campaign and how its component parts are being implemented by acute trusts. Trusts are surveyed every six months to collect information on campaign implementation and HCAI rates. The latest results (December 2007) show:
  - all acute trusts and hospitals in England and Wales are signed up to the campaign.
  - 80 per cent say hand hygiene is a top priority.
  - the use of alcohol handrub and soap have risen significantly in 2007.
  - alcohol handrub is available in 90 per cent of all wards.
  - Patient involvement remains the least successful component of the campaign.

- **FIT** – this study draws upon what is understood about feedback from a behavioural science perspective, and applies this in a large study in intensive care units and acute elderly or general wards across 16 acute trusts in England and Wales. It is the first research study to aim to improve hand hygiene compliance using a feedback intervention informed by psychological theory. The trial began in October 2006 and will last for two and a half years.
CASE STUDY
pontypridd and rhondda nhs trust, royal glamorgan hospital

Fact file:
Location: 13 miles from Cardiff
Infection control nurses: 2
Responsible for: infection control in acute setting, primary care excluding GPs, residential nursing care and dental services

‘To see a real improvement, there has to be a culture change’
Colin Pike, Infection Control Manager

The trust is a strong advocate of quality hand hygiene practice encouraged from the chair of the trust board downwards. At their induction, all new staff, regardless of their position, are given training in how to clean their hands, when to use alcohol handrub and when to use soap and water. The Royal Glamorgan models the World Health Organization’s ‘five moments for hand hygiene’ as best practice.

The trust’s infection control team, led by Colin Pike, were early implementers of the clean your hands campaign. Now in its third year, hand hygiene is accepted as ‘normal’ ward practice and it is considered a good option. The coordinators are increasingly responsible for the regular compliance audits.

Levels of compliance are measured six monthly with three separate audits on three different days. The results are fed back to the trust board through the senior management.

Maintaining compliance remains one of the trust’s biggest problems, however, in spite of a trust-wide policy in place. Depending on the time, whether there are new staff present, and what is going on, compliance can go up and down from 40 to 100 per cent.

Nurses generally maintain the highest compliance levels which is in keeping with national trends. Junior doctors and new registrars are enthusiastic about hand hygiene when they come into the hospital, however, ongoing compliance depends on their seniors being strong advocates for best practice.

Some wards in the hospital have higher rates of compliance than others, notably paediatrics and neonatal care. However, promotion and ongoing education through training sessions are ways of maintaining momentum in all areas.

‘Infection control nurses cannot influence behaviours all the time. It needs to come from the healthcare specialist recognising the importance and value of good hand hygiene practice.’

Colin Pike, Infection Control Manager
Between November 2002 and April 2003, 15 patient safety incidents linked to surgery at the wrong site were also identified. Of these incidents, three were prevented, two led to the wrong procedure and one related to an intervention on the wrong side. The outcomes of the other nine incidents were not recorded.

Factors that contribute to wrong site surgery include:

• communication breakdown.
• failures of all types.
• increasing complexity of healthcare systems.

In developing its alert, the NPSA consulted with relevant stakeholders and then carried out a usability test with frontline staff on its proposed pre-operative marking recommendations and verification checklist. Staff in the two trusts involved used the checklist, adapted it to suit local needs and then provided feedback to the NPSA. The test proved positive, with most of the healthcare workers consulted agreeing that a national recommendation on pre-operative marking verification would help promote correct site surgery.

The alert, while designed for acute settings, can be adapted for use in other care settings, for example minor surgery in primary care.

An alert to acute trusts in England and Wales about correct site surgery was issued in March 2005 by the NPSA.

A pilot study by the NPSA looked at NRLS data from 28 acute trusts between September 2001 and June 2002. The results identified 44 patient safety incidents related to ‘wrong’ procedures, site, operating lists, consent, and patient name and notes.

The pre-operative marking verification checklist included specific areas relating to:

• the patient’s identity.
• reliability of documentation in relation to the intended site.
• marking the site with an arrow using an indelible pen.
• checking the mark before the patient leaves the ward/day care area for surgery against the patient’s supporting information.
• ensuring relevant images accompany the patient or are available in the operating theatre.
• prior to anaesthesia checking the mark again.
• re-checking the accompanying images.
• the availability of the correct implant if applicable.
• the surgical team pausing to confirm the marking of the correct site and the procedure to be performed.

The alert advised that if any aspect of the checklist failed, the surgeon in charge should assess the situation and either return the patient to the ward, or note and sign a decision to proceed at risk. The alert also identified procedures to be taken if the patient was returned to the ward, including an explanation and, where applicable, an apology.
SABS data identified that 92 per cent of acute trusts in England had completed implementation within the required period. The comparable figure in Wales was 54 per cent. There were 34 reports via the NRLS of surgery and/or procedures associated with the wrong side since the specified implementation of the alert. However this could reflect greater awareness of the problem rather than an increase in occurrence of wrong site procedures.

The NPSA commissioned an evaluation of the alert’s implementation. Five hospitals were randomly selected from NHS trusts in England and Wales, four hospitals were part of an existing clinical epidemiology research network, and four hospitals were part of the Health Foundation’s Safer Patient’s Initiative.

A ‘before and after’ study comprising interviews with clinical leads and a nominated nurse in each specialty was undertaken and an audit of case notes.

The findings included:

- Methods of dissemination in different trusts are variable and would benefit from a model of good practice.
- The factors most conducive to successful implementation included: adoption of the recommendations as trust-wide policy, multiple channels of communication, local consultation, clinical leadership, adaptation to the local context.
- The alert was successful in promoting marking practice, though less so in promoting compliance with the detail of the guidance and its underlying spirit patient safety.
- There was wide variation in the ways in which the new requirements were interpreted.
- The alert was successful in promoting marking practice, but was less effective in changing underlying attitudes.
- The alert had a positive role in prompting a review of current procedures and reconsideration of the value of pre-surgical marking, irrespective of whether or not staff decided to change their practice in line with the recommendations.
CASE STUDY

rotherham nhs foundation trust

Fact file:
Location: Rotherham
Trust headcount: 3,450
Quality and Standards Division headcount: 15

"It is all about improving patient safety, experience and outcomes".
Jackie Bird, Chief of Quality and Standards/Chief Nurse.

In July 2007, Rotherham NHS Foundation Trust reported a serious untoward incident when a patient recovered from surgery to find the wrong arm had been operated on. The resultant investigation showed that the NPSA’s alert had not been completely implemented by the trust.

In the intervening months, following a Serious Untoward Incident investigation, the Quality and Standards Division reviewed the alert and the work that was done locally when it was first issued in 2005. Staff have subsequently implemented every action described in the alert so that the trust can be confident of increased compliance.

It hasn’t been easy. In many ways, the Rotherham experience mirrors that of other acute trusts in England and Wales. Challenging existing practices and encouraging new ways of working when there are traditional modes of behaviour in place is complex. However the trust is determined to get it right this time.

In November 2007, the trust launched its patient safety strategy which aims to reduce mortality rates and increase reporting of adverse events. As part of the preliminary work in developing the strategy, the trust initiated an organisational culture survey and asked questions to get an idea of the staff’s views on patient safety. It has reviewed and strengthened its quality team, and changed direction to reflect the trust’s four key corporate objectives which are prioritised as:

- patient safety
- patient experience
- efficiency
- performance

All four are critical to the organisation’s success. Education and training are important components of each priority as the trust adopts a ‘quality and safety’ approach.

‘The pathway still isn’t perfect. But patient safety is a journey. We still have a very long way to go.’
The notice was the result of a study commissioned in 2002 to investigate the way in which trusts communicate with patients following an adverse event.

In its publication Seven steps to patient safety (2004), the NPSA identified the importance of being open with patients and the public about issues and incidents, and discussing the problem "promptly, fully and compassionately." The NPSA’s view was aligned with earlier recommendations by organisations such as the NHS Litigation Service and the Welsh Risk Pool, which encouraged healthcare workers to apologise to patients harmed as a result of treatment. Apologising was ‘not an admission of liability.’

The safer practice notice explained the key elements of being open, including informed consent and disciplinary processes. It outlined the ten principles as:

1. Acknowledgement.
2. Truthfulness, timeliness and clarity of communication.
3. Apology.
4. Recognising patient and carer expectation.
5. Professional support.
6. Risk management and systems improvement.
7. Multidisciplinary responsibility.
8. Clinical governance.

The safer practice notice contained a detailed section on how to initiate the ‘being open’ process, including: a preliminary team discussion of the incident and initial assessment, deciding who should communicate with the patient/carer, and who should be notified externally. The notice included information about how to complete the process including communication, continuity of care, monitoring and lessons learned.

A provisional analysis of the SABS data carried out in January 2007 showed that 182 healthcare organisations in England had completed their Being Open policy, 266 had ‘action ongoing’ and 40 organisations had yet to start.

To help support NHS staff, two training packages were developed by the NPSA in conjunction with an external provider, EBC Ltd, and were launched in November 2005. They include a web-based e-learning package and a Being open training workshop.

The NPSA trained 40 facilitators to deliver the workshops in a series of two-day training programmes.

As at January 2007, 58 workshops had been carried out in 30 healthcare organisations in England and Wales. In addition, six awareness-raising events had been organised by the NPSA to improve take-up of the training. A further 24 workshops were scheduled for the three-month period between January and April 2007.

‘Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems.’"
THE EVALUATION

The NPSA commissioned the York Health Economic Consortium to evaluate the Being open safer practice notice. The aims of the evaluation were:

- to assess the development of local Being open policies in England and Wales including an analysis of barriers and enablers that local healthcare organisations have experienced in their application of the NPSA guidance.
- to evaluate the Being open training products developed by the NPSA – workshops and the e-learning toolkit.
- to carry out a barrier analysis of a sample of healthcare organisations who have not invested in the workshops to identify the barriers that prevented their involvement.

The evaluation took the form of a survey with 397 questionnaires sent out to clinical governance and risk managers in all trusts in England, and three case studies involving a cancer centre, a large mental health trust and a strategic health authority. The trust response rate (26 per cent) was not high, however, this may be attributed to reorganisation and merger issues, and to problems in trusts identifying their Being open lead. Of the trusts that responded to the survey 66 per cent acted on the safer practice notice and 61 per cent stated that they had completed the recommended actions by 30 June 2006.

The conclusions drawn from the evaluation include:

- The guidance from the NPSA attracted a high level of acceptance by trusts at clinical and risk management levels.
- Staff attitudes were generally favourable and many organisations reported that they had already adopted a similar approach prior to the guidance being issued.
- Some organisations reported concerns from medical staff about the potential for litigation.
- Mental health trusts thought they were more likely than acute trusts to be comfortable with the principles of Being open.
- Finance was a major consideration for trusts that didn’t invest in the workshops.
- Although there was a reasonable response to the e-learning packages, cascading for use in trusts was limited, in part due to lack of access to computers, lack of awareness of availability of materials and the inappropriateness of e-learning for teaching communication skills.
- Delays to local implementation of Being open policies were attributed to reorganisations and mergers, lack of human and financial resources for training and the need to integrate Being open into other policies, for example those dealing with serious untoward incidents, complaints and disciplinary procedures.

Overall, the evaluation identified that the safer practice notice was well implemented with many reports of high-level leadership appropriate to its requirements and that the NPSA guidance was successful in changing or re-enforcing a culture of openness.
**CASE STUDY**

**south west london and st george's mental health nhs trust**

The trust was part of the NPSA’s independent evaluation study after the safer practice notice was issued, and therefore had good background knowledge and understanding of the principles behind the notice. It opted for the gold standard implementation and the trust agreed to invest money in buying the training required. It was a large exercise.

The trust developed its own policy based on the NPSA’s safer practice notice and, although there was comprehensive support for the policy, implementation has taken time.

“We deliberately held up implementation of the policy until October 2007 so that we could get maximum support.”

The general uptake has been high and staff are very positive about the way they communicate with clients and patients. This reflects the findings of the NPSA’s evaluation which suggested that mental health trusts would respond better to Being open than acute trusts.

The trust has developed its own training package and has made available to staff the e-learning packages developed by the NPSA. However, and in-line with the NPSA’s independent evaluation, cascading the learning through the organisation takes time.

“Some people are still defensive about the way they operate. Being open can be misinterpreted. However communication is a critical part of our work particularly with patients and clients and their families. We have to get it right.”

31 Action against Medical Accidents
Oral Anticoagulant Therapy
Important information for patients
A suite of five patient safety alerts specifically aimed at improving medicines management were issued to England and Wales NHS trusts in March 2007. The alerts covered the following areas:

- Actions that can make anticoagulant therapy safer.
- Promoting safer measurement and administration of liquid medicines administered via oral and other enteral routes.
- Promoting safer use of injectable medicines.
- Safer practice with epidural injections and infusions.
- Reducing the risk of hyponatraemia when administering intravenous infusions to children.

They were endorsed by the Chief Pharmaceutical Officer for England and the Chief Pharmaceutical Adviser in Wales, and a 12 month implementation period was identified, to be managed locally according to individual trust's priorities.

Producing a complete programme of medicines management in a single advice pack was a new way of working for the NPSA and it was designed to help with planning and implementation locally. It was based on feedback and advice from the NHS, ongoing support from an advisory group with expertise in the five alert areas, and drawing on a wide range of documented evidence from English and Welsh reports. The emphasis was on systems improvement, with practical solutions and recommendations to reduce the likelihood of systems failures, and thereby improving the safety of patients when medicines are procured, prescribed, dispensed, prepared, administered and monitored.

This compendium focuses on two of the alerts and their implementation – Patient Safety Alert 18: Actions that can make anticoagulant therapy safer, and Patient Safety Alert 20: Promoting the safer use of injectable medicines.

**Anticoagulants**

Patient safety issues linked with anticoagulant medicines have been raised in both primary and secondary care. In primary care they are one of the classes of medicines most commonly associated with fatal medication errors. In secondary care, warfarin is one of the 10 drugs most frequently associated with dispensing errors.xii

The NPSA alert on anticoagulants included:

- An audit checklist for pharmacists covering:
  1. Review of training and competence.
  2. Procedures and clinical protocols.
  3. Audit of safety indicators.
  4. Review of patient safety incident data involving anticoagulants for the preceding 12 months.
  5. Overall comments and actions recommended by Drugs and Therapeutics Committee.
Six workforce competence statements for healthcare professionals covering the following areas:

1. Initiating anticoagulant therapy
2. Maintaining oral anticoagulant therapy
3. Managing anticoagulants in patients requiring dental surgery
4. Dispensing oral anticoagulants
5. Preparing and administering heparin therapy
6. Reviewing the safety and effectiveness of an anticoagulant

- An information leaflet for patients
- A patient pack containing an information leaflet, a treatment record programme and an alert card which was endorsed by the British Society for Haematology.

The NPSA commissioned the York Health Economics Consortium to conduct a comprehensive evaluation of the medicines management guidance. The findings showed a 'high degree of consensus that there were problems in the management of anticoagulation services.'

In acute settings, 75 per cent of trusts said they had one or more protocols in place for the management of anticoagulation. The findings also showed that the existing patient booklet was not used as a means of recording all information, nor were they a reliable means of communicating between hospital and community health services.

Anticoagulant clinics were seen to be well run, although many staff said their training was informal and 'on the job'.

The study showed that there has been an increase in the number of hospital-run outpatient clinics and in most areas, a separate DVT clinic is also operating. The number of GPs involved in anticoagulation varies considerably with some areas having none and others having a high percentage.

The study compared the NPSA alert's recommendations with its findings:

- Training was considered to be a priority.
- Protocols were often out-of-date and there was some conflicting guidance in existence.
- There was a problem with lack of out-of-hours service.
- Few trusts were able to identify adverse events resulting from mismanagement of anticoagulants.
- The responsibility for educating inpatients was considered a high priority.

A review of SABS responses in April 2008 for implementation of the anticoagulation alert shows that:

- 40 acute trusts have completed implementation, 106 have action ongoing and 24 are still assessing relevance.
- 64 primary care trusts have completed implementation, 60 have action ongoing and 16 are assessing relevance.
- 18 mental health trusts have completed implementation, 21 have action ongoing and seven are assessing relevance.
CASE STUDY

King’s College Hospital
NHS Foundation Trust

Fact file:
Location: Denmark Hill, South East London
Pharmacy size: 115 staff
Pharmacy budget: £28 million

‘Nothing in the medicines management portfolio of alerts was a surprise. Some of the recommendations are difficult to monitor, but most of the advice in the alert was already work-in-progress for us.’
Gillian Cavell, Deputy Director of Pharmacy, Medication Safety

The Pharmacy team at King’s College Hospital works in a collegial environment. Medication safety is led by Gillian Cavell. Implementing the anticoagulant alert was managed effectively by Roz Perrott, the pharmacist in the multidisciplinary Anticoagulation Team. The hospital has an existing programme in place to optimise anticoagulant therapy, which meant the new alert was assessed in line with current and developing work practices.

An audit of adverse drug events with warfarin undertaken by the trust, that preceded the NPSA’s guidance, highlighted a lack of understanding from prescribers concerning interactions with warfarin, initiating and monitoring of therapy and also the treatment of over-anticoagulation. Although guidelines are in place, these needed to be tailored to individual needs and all risk factors taken into consideration. Pharmacists have a role to play in developing and leading training programmes for clinical staff and ensuring that drug charts and anticoagulant charts were endorsed correctly and completely, especially for patients being referred to anticoagulant clinics.

The effective management of anticoagulant usage in the trust has contributed to the smooth implementation of the NPSA’s alert. The hospital runs a nurse-led postal anticoagulant clinic that manages approximately 750 patients a week. There is also a face-to-face clinic run by pharmacists for patients who require more in-depth management, for example patients who are new to anticoagulation and perioperative patients. Approximately 50 patients are seen in this clinic each week including some 15 new patients.

King’s College Hospital has created a trust-wide lead anticoagulation pharmacist and a new rotational anticoagulation pharmacist post in order to continue the comprehensive management of anticoagulated outpatients and to aid in the improvement of the management of inpatients receiving anticoagulation.

The trust’s award-winning clinical thrombosis service has a staff of six nurses who look after patients with DVT and run the above outpatient anticoagulation service.

The patient pack was endorsed by staff as a good initiative, patients need to be informed and to know and understand the danger if they don’t take their medications as prescribed.

There was some concern expressed that not all the questions in the audit checklist work well. Additionally, organising training sessions for clinical staff can be complicated as other priorities take precedence.

Many hospitals have different protocols in place for anticoagulants. As a result, when clinical staff come from other trusts, they are inducted into the medicines management processes and the systems for anticoagulation that are practiced at King’s College Hospital.

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14Interview with G Cavell 14/3/08
15Deep vein thrombosis
One of the five patient safety alerts issued as part of the medicines management pack was on safer practice with injectable medicines. The alert contained a comprehensive outline of what to do and how to achieve the required result, including:

- Best practice standards for prescribing, preparing and administering injectable medicines in clinical areas.
- A template standard operating procedure.
- A workforce competence statement covering four specific areas:
  1. prescribing injectable medicines.
  2. preparation of injectable medicines.
  3. administration of injectable medicines.
  4. monitoring the administration of injectable medicines.
- A detailed audit checklist covering:
  1. review of policy and procedures.
  2. audit of injectable medication practice.
  3. review of patient safety incident data involving injectable medicines for the preceding 12 months.
- 4. overall comments and actions recommended by Drugs and Therapeutics Committee broken down into five areas:
  - Details of remaining high risk injectable medicine products and procedures to be added to the trust's risk register.
  - Actions concerning the further development of policies and procedures for injectable medicines.
  - Actions concerning the provision of technical information on injectable medicines in clinical areas.
  - Actions concerning the ‘purchasing for safety’ policy.
  - Actions concerning staff training on injectable medicines.
  - Signatures and dates of audit and review periods.
The York Health Economics Consortium was commissioned to evaluate the impact of the injectables alert. The study included site visits to several acute trusts, where interviews were conducted with key staff in the organisation.

In addition, examples of advisory documents regarding injectable medicines were collected for analysis. Interviews were structured according to topic areas to maximise the amount of information available and included discussions with clinicians as well as pharmacists.

All the chief pharmacists interviewed confirmed they had 24-hour pharmacy cover, but there were variations in service delivery.

As with the evaluation of the anticoagulants alert, the Consortium found there were multiple issues across the trusts.

Education and training was an issue for everyone. None of the trusts visited had any formal teaching programmes for medical staff in the management of injectable medicines. Where there was training, it was usually led by pharmacists.

There was a lack of clarity around audits of good practice involving the preparation and administering of injectables.

While all trusts recorded adverse drug events on a risk register, there was a wide variation in practice. Most of the trusts visited in the study had written protocols or guidelines in place to assist with the preparing, prescribing and administering injectable medicines.

A review of SABS responses for implementation of the injectable alert completed in April 2008 shows that:

- 38 acute trusts have completed implementation, 112 have action ongoing and 21 are assessing relevance.
- 65 primary care trusts have completed implementation, 56 have action ongoing and 18 are assessing relevance.
- 20 mental health trusts have completed implementation, 23 have action ongoing and six are assessing relevance.

NB: The NPSA has yet to commission an evaluation of the impact and uptake of Alerts 18 and 20.
CASE STUDY
university hospitals
coventry and warwickshire
nhs trust

Fact file:
Location: Walsgrave, Coventry
Size: 1,500 beds
Pharmacy budget: £20m

"Implementing patient safety alert 20 was a big exercise."
Janette Knight, Pharmacy Risk Manager

The University Hospitals Coventry and Warwickshire NHS trust's pharmacy department operates a drug purchasing and distribution system internally as well as other trusts in the region. Its clinical pharmacy services have been reconfigured to meet the increasing demand for medicines management.

In February 2008, representatives from regional acute, teaching and foundation trusts, mental health trusts, nurses and primary care trusts in the East and West Midlands came together to discuss how to implement the injectable medicines alert. It was an opportunity to share practice and how to make best use of existing resources.

The group developed a consensus view of what constitutes best practice.

Key issues identified were:
- time and resources – trying to maintain business as usual while carrying out risk assessments of injectable medicines.
- the need for further rationalisation of drugs nationally.
- there needs to be some national standard everyone aspires to.
- everyone practises differently – different specialties have different ways of doing things.
- the problem is how to change behaviours.

The University Hospital has:
- developed a project plan.
- risk-assessed the majority of injectable medicines.
- developed an action plan to reduce risk internally.

'We are continuing to carry out risk assessments of new and existing injectable medicines throughout the trust which identifies high risk injectables. This practice provides the opportunity to introduce further risk reducing measures, for example source previously unavailable commercially manufactured products.

However, the options for risk reduction methods are largely dependant upon the product.'

People assess risk differently depending on their perspective. The design of the risk assessment tool provided with the alert doesn't work very well for drugs that have a high therapeutic risk but require minimal manipulation and calculation during the preparation of the product.

'The rationale behind the alert is very good. It is the implementation, training and resources that are required to fully implement the alert that creates the difficulties. It would be useful if the alert had provided a tool to calculate the time and resources required to implement the actions.'

'The key to success is to continue to develop good working relationships between the clinical and pharmacy staff.'
In January 2008 the NPSA issued a Rapid Response Report on oral anti-cancer medicines. The NPSA had received reports of three recent deaths and 400 patient safety incidents that occurred between November 2003 and July 2007. Half of the reports concerned the wrong dosage, frequency, quantity or duration of oral anti-cancer medicines.

In its report to all acute and primary care NHS trusts, the NPSA recommended that doctors, nurses, pharmacists and their staff must be made aware that the prescribing, dispensing and administering of oral anti-cancer medicines should be carried out and monitored to the same standard as injected therapy. It recommended that the following seven actions to be implemented by July 2008:

1. Local policies and procedures to be developed that describe the safe use of the rapid response’s list of oral medicines.
2. Local treatment should be initiated by a cancer specialist.
3. All oral anti-cancer medicines should be prescribed with a written protocol and treatment plan in place.
4. Access to protocols and treatment plans should be available to non-specialists who prescribe or administer ongoing oral anti-cancer medication.
5. Staff dispensing oral anti-cancer medicines should be able to confirm that the prescribed dose is appropriate for the patient.
6. Patients should be fully informed and receive verbal and written information about their oral anti-cancer therapy programme.
7. Full use should be made of NHS cancer centre websites for staff, patients and carers.

Responsibility for implementing the rapid response’s requirements was generally delegated to pharmacists in acute trust settings.

In 2007, the NPSA piloted a new way of quickly finding out about patient safety problems, and rapidly disseminating them to the NHS.

Fifty-five test sites were set up in England and Wales, covering a range of healthcare services. Early evaluation has suggested that frontline staff appreciate the quick feedback of actions that can be taken to reduce risk to patient safety.

Four Rapid Response Reports were issued by the NPSA between June and November 2007.
The deadline for the NHS to implement the Rapid Response Report 6 on Oral Anti-Cancer Medicines is July 2008. A full evaluation will take place after that date.

**Case Study**

**Gateshead Health NHS Foundation Trust**

**Fact File:**
- **Gateshead Pharmacy Department**
  - Staff: 60 WTEs
  - Drugs budget: £8.3 million
  - Services: Across three sites, inpatient and outpatient

"Managing oral anti-cancer medicines is a serious issue. This NPSA initiative was widely regarded as important. We are all aware of the dangers when things don’t go according to plan. Responsibility for the individual’s drug regime should be jointly managed by the patient, clinician, nursing staff and the pharmacy, who all have a part to play in ensuring the safe use of these drugs.”

Neil Gammack, Clinical Pharmacy Services Manager, Queen Elizabeth Hospital, Gateshead.

The Gateshead Health NHS Foundation Trust’s pharmacy department has dedicated protocols and procedures in place for the dispensing and management of drugs. These apply to its inpatient and outpatient settings.

The department was aware of the issue regarding anti-cancer drugs, from both the Cancer Network and the NPSA, and was already working on its implementation strategy before the Rapid Response Report was issued.

Standard practice ensures all patients are well informed about the drugs they are given. The trust’s nursing staff developed a chemotherapy record card for patients to keep, containing information specific to the individual’s treatment plan.

**Implementation was managed by:**
- identifying a lead within the pharmacy department.
- setting up a pharmacy-led implementation group which worked through all the actions.
- highlighting the critical factors.
- writing an action plan with timelines.
- prioritising the actions.
- aligning the plan with the protocols and prescription processes already in place.
- ensuring patients are aware of the drugs they are prescribed including how they should be administered.
- checking the dispensing process against the Cancer Network regime.
- identifying issues.
- reporting to the trust.

The pharmacy department delegated responsibility for implementation to David Sproates, one of its senior pharmacists and maintains a watching brief on implementation through the trust’s Drug and Therapeutics Committee.
Note: All publications listed can be downloaded via the NPSA website.

**RAPID RESPONSE REPORTS**

**2007**
- Risk of confusion between Cytarabine and liposomal Cytarabine (Depocyt®)
- Risk of confusion between non-lipid and lipid formulations of injectable amphotericin
- Emergency support in surgical units: dealing with haemorrhage
- Fire hazard with paraffin-based skin products on dressings and clothing

**2008**
- Risks of incorrect dosing of oral anti-cancer medicines
- Risks with intravenous heparin flush solutions

**PATIENT SAFETY ALERTS**

**2002**
- Reducing error during the intravenous administration of potassium solutions
- Standardising crash call telephone numbers in hospitals
- Reducing risk in the use of methotrexate
- Reducing risk for spinal cord lesion patients in general hospitals
- Clean hands helps to save lives
- Update on producing patient information on methotrexate usage
- Reducing harm associated with misplaced nasogastric feeding tubes
- Reducing the risk of surgery on the wrong part of the body
- Reducing the harm caused by misplaced nasogastric feeding tubes to babies in neonatal units
- Improving compliance with oral methotrexate guidelines

**2005**
- Reducing the risk of hypotension when administering intravenous infusions to children

**PATIENT SAFETY OBSERVATORY REPORTS**

**2005**
- Building a memory: preventing harm, reducing risk and improving patient safety
- Safety in doses: medication incidents in the NHS

**2006**
- Slips, trips and falls in hospitals
- Safer care for the acutely ill patient

**2007**
- Improving compliance with oral methotrexate guidelines
- Reducing the risk of hypotension when administering intravenous infusions to children
- Reducing the risk of confusion between cytarabine and liposomal cytarabine (Depocyt®)
- Risk of confusion between non-lipid and lipid formulations of injectable amphotericin

**SAFER PRACTICE NOTICES**

**2004**
- Reducing risks associated with infusion pump devices
- Reducing risks associated with infusion pump devices
- Ensuring safer practice with repelvar and revaxus vaccines

**2005**
- Being open when patients are harmed
- Improving patient safety through patient identification wristbands in hospitals
- Ensuring safer practice with high dose ampoules of morphine and diamorphine
- Colour coding hospital cleaning materials and equipment
- Right patient, right blood – new advice for safer blood transfusions

**2006**
- Early identification of failure to act on radiological imaging reports
- Ensuring safer practice for adults with learning disabilities who have dysphagia
- Using bedrails safely and effectively

**2007**
- Standardising wristbands
- Improving patient safety
APPENDIX CONTINUED

PATIENT SAFETY INFORMATION

2005  IMPROVING EMERGENCY CARE FOR PATIENTS WHO BREATHE THROUGH THEIR NECK
2005  VACCINATION: REVIEW OF A CLINICAL INCIDENT IN A PCT
2005  PROTECTING PEOPLE WITH ALLERGY ASSOCIATED WITH LATEX

DESIGN FOR PATIENT SAFETY

2006  A GUIDE TO THE GRAPHIC DESIGN OF MEDICATION PACKAGING
2007  A GUIDE TO THE DESIGN OF DISPENSED MEDICINES
2007  A GUIDE TO THE DESIGN OF THE DISPENSING ENVIRONMENT
2007  DESIGN OF FUTURE AMBULANCES
2008  A GUIDE TO THE LABELLING AND PACKAGING OF INJECTABLE MEDICINES

DIRECTIVES AND GUIDANCE

2004  SEVEN STEPS TO PATIENT SAFETY
2004  THE INCIDENT DECISION TREE: AN ELECTRONIC INTERACTIVE TOOL DESIGNED FOR NHS MANAGERS DEALING WITH STAFF INVOLVED IN AN INCIDENT
2004  ROOT CAUSE ANALYSIS TOOLKIT: HOW TO CONDUCT A RETROSPECTIVE REVIEW OF A PATIENT SAFETY INCIDENT
2005  ENGAGING CLINICIANS: A RESOURCE PACK
2006  SEVEN STEPS TO PATIENT SAFETY IN PRIMARY CARE
2007  HOSPITAL AT NIGHT: A TOOLKIT TO ENABLE HOSPITALS TO ASSESS POTENTIAL RISKS OF PATIENT CARE AT NIGHT
2007  RECOGNISING AND RESPONDING APPROPRIATELY TO EARLY SIGNS OF DETERIORATION IN HOSPITALISED PATIENTS
2008  INDEPENDENT INVESTIGATION OF SERIOUS PATIENT SAFETY INCIDENTS IN MENTAL HEALTH SERVICES
2008  CLOSING THE GAP: A TOOLKIT FOR IMPROVING IMPLEMENTATION OF SAFER PRACTICES
2008  FORESIGHT TRAINING RESOURCE PACK

JOINT GUIDANCE

2005  JOINT NPSA - ROYAL COLLEGE OF PHYSICIANS: SAFE FOUNDATIONS
2007  NPSA – ROYAL COLLEGE OF NURSING: HOSPITAL HYDRATION BEST PRACTICE TOOLKIT
2007  JOINT NPSA-NICE GUIDANCE ON TECHNICAL PATIENT SAFETY SOLUTIONS FOR MEDICINES RECONCILIATION ON ADMISSION OF ADULTS TO HOSPITAL
2008  NPSA – ROYAL COLLEGE OF NURSING: 10 KEY CHARACTERISTICS: NUTRITIONAL FACT SHEETS
8 Department of Health, Safety First. 2006.
11 National Patient Safety Agency. Seven steps to patient safety;