



RISK MANAGEMENT AND PATIENT SAFETY: WHAT IS HAPPENING?

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Public concern about patient safety is increasing. Studies into harm from errors, including medication, for example from the Netherlands and the UK, have contributed to the drive to improve patient safety. Our guest editor, Ms Catherine Mooney, looks at the situation around Europe and at what initiatives are being taken.

Public awareness about patient safety issues and medicines varies in different countries

In the UK the level of public awareness has increased over the last six to seven years, following the publication of *An Organisation with a Memory*, Department of Health, UK, 2000. This identified four key areas to be addressed. These were: 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, and much wider appreciation of the value of the system approach in preventing, analysing and learning from errors. The safety issue that continues to cause the most attention and concern is healthcare-associated infection but medicines are also an issue.

In Switzerland the public are not highly aware of healthcare safety issues, although there is some interest, especially after the Institute of Medicine report in 1999 (*To err is human: building a safer health system*). Complaints against hospitals are rare, although this is increasing.

There is at present a high level of public awareness about patient safety issues, including medicines, in the Netherlands. This is due to the publication of two important Dutch studies on this topic, which received much media attention. One study reported that 1,750 patients die annually in Dutch hospitals due to preventable medical errors (150 of them due to preventable medication errors).

Another study (*HARM - hospital admissions related to medication*) reported that approximately 1,250 patients die annually after a preventable adverse drug event that led to a hospital admission.

In Finland social and healthcare units became more interested in risk management and patient safety a few years ago. Some started to look in more detail at patient safety incidents and found that medication errors were the most common source of risk. In other countries such as Spain the level of public interest is generally low and there is little media interest.

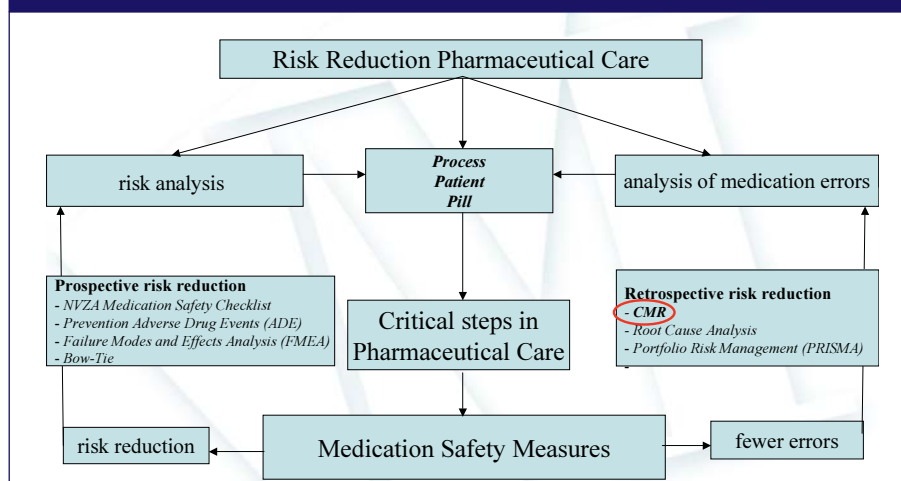
National organisations are being established and initiatives taken around patient safety and medicine use

Ireland has established a number of institutes with a focus on safety. These include the Clinical Indemnity Scheme which has a specific risk management

remit and, more recently, the Health Information and Quality Authority whose roles include standard setting, quality monitoring and technology assessment. This has joined forces with WHO's World Alliance for Patient Safety to undertake a collaborative project on patient safety. In addition, a Commission on Patient Safety and Quality Assurance was established in January 2007 to make recommendations on an overall framework for the delivery of a quality health service in a safe environment.

In the UK a major drive for risk management is the Clinical Negligence Scheme for Trusts run by the National Health Service Litigation Authority (NHSLA). This is a clinical indemnity scheme with supporting risk management standards. The NHSLA offers a discount to the scheme based on achievement of the standards. There is a standard specifically

Figure 1: NVZA Medication safety chart



relating to medicines management. Following the publication of *An Organisation with a Memory*, the National Patient Safety Agency (NPSA) was formed in 2004, with the aim of using information from incident reports and other sources to develop ways of reducing the risk of patient safety incidents in the NHS in England and Wales. The NPSA also provides practical tools to help NHS staff understand the root cause of problems and how to generate solutions. The NPSA has issued a number of alerts and safer practice notices of which approximately 50% are related to medicines. Visit www.npsa.nhs.uk

The NVZA (Dutch Society of Hospital Pharmacists) has been taking action on medication safety issues since 2003, when it became a major issue in the country's policy. A "medication safety" working group has been established and has introduced various measures to enhance medication safety (Figure 1).

In Switzerland the Swiss Patient Safety Foundation was created in 2003 and since then it has worked as a network organisation in numerous projects together with different partners, in order to promote patient safety. In September 2007 a 2-day congress was organised by the Foundation as the largest interdisciplinary congress on quality and safety in health care ever held in Switzerland.

The national government in Spain started a programme for patient safety about three years ago. The implementation is variable and depends on resources and the political party in power in the region. Each community has a director responsible for patient safety. The initiatives so far have included encouraging hand washing, preventing patient falls and the use of needle-free systems.

In Lithuania the main organisation responsible for patient safety is the Ministry of Health Care. An Act concerning good pharmacy practice came into force in June 2007. The section on "Pharmaceutical care" is especially significant. This sets out several requirements for informing patients about their treatment and obliges pharmacists to record and pass on reports of adverse effects.

Hospital reporting and follow-up systems are being introduced or made more effective

In Switzerland most hospitals have or are in the process of setting up critical incident reporting systems. These take the form of mandatory centralised declaration systems for major incidents with significant consequences to the patient, and voluntary decentralised systems for minor problems. All medical services must have a declaration and investigation system in place, and a web applica-

tion was recently launched to support these activities.

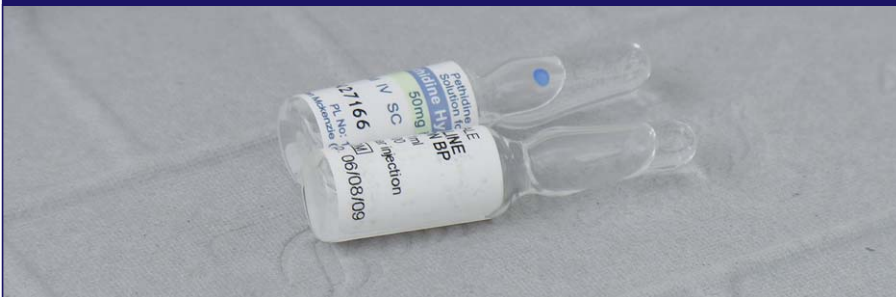
In the Netherlands, the Health Inspectorate is currently enforcing a risk management system. Each hospital has a mandatory committee on patient safety issues, including medication safety. Incidents are reported to this committee and passed to the Central Medication Error Recording (CMR) web-based system. An analysis is made which aims to prevent such incidents happening in the future. A new development is that incidents are reported on a ward level (decentralising error reporting). It is hoped that this will be a lower barrier to reporting and that analysis of the error and subsequent action will be of better quality.

Incident reporting is well established in the UK but there is a mixture of paper and electronic systems, with the majority being paper. It is well known that there is under-reporting of incidents. Hospitals will have local systems for analysis and reporting incidents but in addition all incidents are submitted to the NPSA. The NPSA produces reports that allow hospitals to compare both the rates and types of incidents reported with other similar hospitals. The NPSA uses the data to identify national trends and, as part of their Patient Safety Observatory programme (which involves working with a range of organisations), to identify solutions.

In Ireland the Clinical Indemnity Scheme has developed a web-based national database (STARSweb) for all clinical incident reports including medicine incident reports. In addition, those hospitals with a medicine safety programme usually use a specific database to facilitate more detailed local analysis and feedback. Some hospitals use systems such as Analyze-Err, developed by ISMP Canada, and some have customised them.

In Lithuania special committees are established in all regions and the main four teaching hospitals. There are usually four to five members representing the

Figure 2: Case history



The importance of safety in administering intravenous medication was emphasised in an incident where a patient was given intravenous epinephrine instead of pethidine. The "active failure" was selecting the incorrect ampoule as they looked similar and only the "...INE" was read. However, following a root cause analysis, many "system" factors were identified including poor lighting, failure to follow procedures, lack of regular staff, heavy workload and poor facilities.

deputy director, surgeons and physicians, nurses and the pharmacy. All reports are discussed at a local level, filed and if necessary passed on to this regional or central committee, where appropriate decisions are made.

Reporting is variable in Spain. Some communities such as Catalonia and Madrid do but others do not. The systems are electronic. When a report is made pharmacists analyse them and classify the error. However progress still needs to be made on implementing changes as part of the analysis of incidents.

The use of risk management tools varies

The main risk management system in UK hospitals is reactive, i.e. based on investigation of incidents and near misses, although not as much investigation into near misses occurs as it should. Risk assessments, where the likelihood and consequence of an incident happening in the future, do take place and the results are monitored through hospital risk registers, which record the risk and actions taken to mitigate risks. Another approach which is being used increasingly is retrospective case note review. Trained reviewers, using a set of triggers to identify potentially appropriate health records, review them to identify any adverse events. This approach can be used specifically for medicines. The Institute for Healthcare Improvement has developed an interactive trigger tool which helps to identify adverse drug events which is available on their website www.ihp.org or via www.saferhealthcare.org.uk.

In Switzerland activities vary among hospitals, e.g. one hospital frequently uses prospective risk analysis (Failure Modes, Effects and Criticality Analysis method) to assess safety. However Poland reports that risk management tools such as root cause analysis are not used very much.

Medication events committees in hospitals are not the norm

In most hospitals in Switzerland, the

Figure 3: The Medication Zone from National Patient Safety Agency website

The screenshot shows the NHS National Patient Safety Agency website. At the top, there are navigation links for 'NPSA home', 'Site map', and 'contact us'. A search bar is present with the text 'Keywords' and a 'Search' button. The NHS logo and 'National Patient Safety Agency' text are on the right, with 'Patient Safety Division' below it. A breadcrumb trail reads: 'Home | Reporting incidents | Patient safety incident data | Alerts & directives | Improving patient safety | Medication zone | Research | News | Links'. The main content area is titled 'Medication Zone' and is divided into several sections: 'Patient Safety' (with sub-links for Reporting Incidents, Patient Safety Incident Data, Alerts and Directives, Improving Patient Safety, and Medication zone), 'New' (with sub-links for New Joint NICE/NPSA Patient Safety Guidance on the reconciliation of medicines, New Design For Patient Safety Booklets Dispensed Medicines The Dispensing Environment, and A Rapid Response Report has been issued highlighting the dangers of a potential fire hazard with paraffin based skin products on dressings and clothing), 'Medication Publications' (with sub-links for Medication Alerts, Directives and Guidance, Review of Medication Incident Reports 2006-7, and Design For Patient Safety – Medication topics), and 'Current Work' (with sub-link for Rapid Response Report on safe practice with oral anti-cancer medicines). On the right, there is a 'NPSA Announcements' box with three items: 'Significant progress putting Safety First', 'NPSA alerts healthcare staff to potential fire hazard with paraffin based skin products on dressings and clothing', and 'NICE/NPSA issues guidance to improve medicines reconciliation at hospital admission'. Below this is an image of a medicine box and a syringe.

Pharmacy and Therapeutics Committee is in charge of medication safety, and the hospital pharmacist is strongly involved in these activities. In Geneva, there is a specific committee on Quality and Safety that is not only dedicated to drugs, but to any safety issue. It is composed of senior managers (i.e. CEO, medical director), and is more oriented towards strategy. An operational group is connected to this committee and works in close collaboration with the incident groups of the medical services.

In the UK most hospitals have a specific committee for medication events. They are multidisciplinary, focus on medication events and solutions and report to another committee, either a Drug and Therapeutic Committee or a Risk Management Committee. The committee may be chaired by the chief pharmacist, chief nurse or a doctor. It will typically look at trends across the hospital as well as serious incidents. Actions to reduce risk are identified and actions monitored by the committee. Some committees may compile a specific risk register for medication risks.

In Poland the term risk management is not used but it could be understood as medication safety, which is managed by the Director of Medical Affairs. Hospital pharmacists understand risk management as safe pharmacotherapy, and that their role is much wider than checking prescriptions.

In Spain all hospitals have a type of Drug and Therapeutics Committee but only a few have a multidisciplinary medication incident committee.

Training in medication safety: what and how?

In the Netherlands medication safety is part of the regular training programme for hospital pharmacist residents and hospital pharmacists who have already registered. Courses are also being developed for dedicated pharmacy technicians (who can thereafter call themselves pharmacy practitioners). A medication safety course will be developed for nurses.

Very little education on patient safety is currently included in Swiss undergraduate

studies for physicians, nurses and pharmacists. A recent report of an expert group recommended that this situation should be improved in the future, and proposed a structured programme and learning objectives that should be taken into consideration by the universities (report available on www.patientensicherheit.ch). Some hospitals have developed their own continuing education programme. In Geneva, any new nurse must follow a 1-day programme on patient safety, and any new physician also receives some information on his arrival. The objective is to ensure a large knowledge of the institutional procedures and to move towards developing a common culture around patient safety.

In the UK safety training is not a legal requirement but individual hospitals may decide that it is mandatory for their staff. Medicines management, which covers prescribing and administration, is required by the NSHLA risk management standards but specific medication safety training is not. Some hospitals, however, will have mandatory medication safety training for nurses, doctors and pharmacists. This may cover local risks, national patient safety alerts, high risk medicines, common errors and the promotion of incident reporting.

In Lithuania training is not obligatory, but is done in some clinical departments. It mainly depends on the person in charge. In Spain there is no training in medication safety.

Innovations that are improving safety in the hospital

The Dutch Ministry of Health decided that from 1 January 2008, each hospital in the Netherlands should have a Safety Management System. It is hoped that computerised physician prescribing order electronic systems will reduce prescribing errors, and application of clinical rules will reduce risk. For example, if a patient is aged 65 or over and is taking an NSAID, the system will prompt a proton pump inhibitor to prevent gastric problems.

The use of robots for dispensing and issuing of drugs for stock is increasing in the UK, and this has been shown to reduce dispensing errors. Both electronic prescribing and nursing administration systems are also in use in some hospitals but are not widespread. There is an increased trend to create posts specifically for medication safety.

In Lithuania work is nearly finished on updating the Health Ministry Act "Good Pharmacy Practice" which is due to take effect from 1 January 2010. The Lithuanian Pharmaceutical Association translates and publishes special information prepared by the European Association of Clinical Pharmacology and Therapeutics, where questions of patient and medicines safety are described www.eacpt.org. Younger hospital pharmacists generally have sufficient English to find *Medication Safety Forum* in the *EJHP Practice* helpful.

Conclusion

Public awareness of health issues in general and patient safety issues in particular has been increasing steadily in recent years, reflecting international trends, as well as factors such as increased wealth and education, access to information (internet, etc.) and expectations. In some countries, interest has been increased by media coverage of high profile cases and issues, such as nursing home care and hospital associated acquired infections.

While many countries report an increased emphasis on safety the pace of change, leadership from the governments and the response within countries are variable.

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