Patient safety first

More than 3500 participants from 74 countries gathered in Hamburg in March for the 20th Congress of EAHP. Key themes included medication safety, biosimilars, women's health issues and learning from the nuclear power industry

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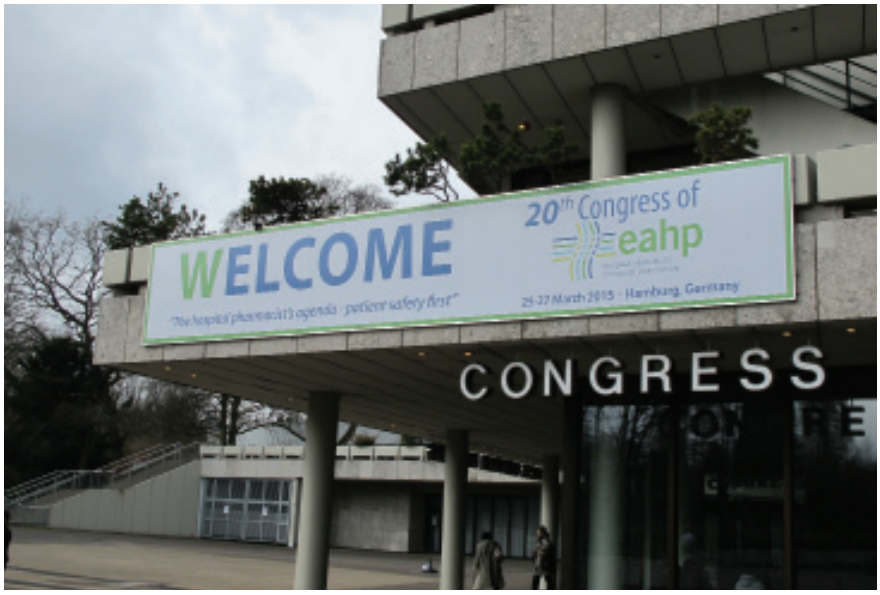

The European Association of Hospital Pharmacists (EAHP) could play a key role in the establishment of a European infrastructure to support patient safety, according to David Cousins (Medication and Medical Devices Safety officer, Healthcare at Home Ltd, UK). Preventable harm arising from medication-related incidents continues to affect patients in Europe. Large studies in the UK and The Netherlands have reported similar results in terms of the proportion of preventable adverse drug events (ADEs) suggesting that this is a pan-European problem, he said.

Several examples from the UK served to illustrate the problem. In one case a 12-fold overdose of phenytoin was administered to a baby – with fatal results. The staff had misunderstood how to give the loading dose and continued to administer the drug at that level for 10 hours. Another case involved a 10-fold overdose of potassium chloride – something that could have been prevented by the use of an administration pump with smart technology, commented Dr Cousins. Two fatal accidents arose from confusion about amphotericin products. In each case a patient was being treated for side effects of cancer treatment and received up to five times the recommended dose. Fungizone is prescribed at 1 mg per kg but Ambisome and Abelcet are dosed at 3-5 mg per kg. Both types of product were available on the wards and the staff were unaware of the differences.

A WHO resolution in 2002 said that healthcare organisations should "prioritise safety above financial and operational goals". However, the effectiveness of patient safety measures depends heavily on the safety culture in an organisation. The Manchester Patient Safety Framework is a tool that can be used by organisations to assess the maturity of their safety culture (see Table 1). European hospitals could use this simple tool to gauge their culture on an annual basis, suggested Dr Cousins.

At present, surveys show that there is more interest in gathering financial information about medicines than in reporting safety issues. "Even if managers do not ask for safety data, they should get it alongside the financial data", said Dr Cousins.

The National Reporting and Learning System in the UK had received 500,000 medication incident reports during the ten-year period 2005–2015. Omitted medicines and 'wrong dose' incidents were the most common causes of error. All large healthcare providers in England are now required to appoint Medication Safety Officers (MSOs) to support local medication error reporting and learning. So far, 363 organisations have appointed MSOs.

Feedback is given to healthcare organisations to enable them to assess their own position relative to others. One particularly useful metric is the proportion of harmful incidents (total

Table 1: Levels of patient safety culture

Level	Description
A – Pathological	Why do we need to waste our time on patient safety issues?
B - Reactive	We take patient safety seriously and do something when we have an accident
C - Bureaucratic	We have systems in place to manage patient safety
D – Proactive	We are always on the alert/thinking about patient safety issues that might emerge
E – Generative	Managing patient safety is an integral part of everything we do

David Cousins

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Irene Kraemer

number of incidents with harm divided by the total number of incidents reported). A high value is associated with poor reporting culture (that is, only reporting when harm occurs) whereas a low value reflects a good reporting culture, explained Dr Cousins.

Homecare medication services represent an important area of medicines' use that has received relatively little attention until recently. Approximately 200,000 patients in England are currently receiving homecare services. Reports show that the biggest category for errors is omitted or delayed doses – more than 60% of these are due to the prescription not coming from the hospital in a timely manner.

Dr Cousins concluded that hospital pharmacists should play a central role in increasing the governance of medicines and in reporting and learning from incidents.

Lessons from nuclear power

High reliability industries, such as the nuclear power industry, and health care have to tackle common challenges and the critical factor is how people respond to conditions, such as missing or unexpected data, an observed error or conflicting information, rather than the actual task, according to Howard Bergendahl (President, The Bergendahl Institute LLC, USA). Furthermore, working conditions determine behaviours, he added.

Root cause analysis of health care sentinel events suggests that communications failures play an important role. This parallels the position in aviation in the 1970s when the majority of aeroplane crashes were found to be caused by failures of communication among pilots, commented Mr Bergendahl.

Human behaviours create outcomes and it is important to understand the three principles of human performance. Even the best people make mistakes, error-prone situations are predictable, manageable and preventable and individual behaviour is influenced by organisational culture. Work processes can be changed to prevent or minimise the condition that provokes an error, explained Mr Bergendahl. In addition, specific error reduction tools, such as pre-task briefings and peer checking, can be utilised. The prevailing safety culture determines the effectiveness or otherwise of safety efforts. Culture is to an organisation what personality is to an individual. Moreover, "the safety culture can cause people to make decisions to do things contrary to their policies, their training and sometimes even their better judgment", he said.

Healthcare researchers have now recognised the importance of a positive patient safety culture in reducing the numbers of adverse events in hospitals and so leaders now need to focus on strengthening safety cultures in healthcare. In a strong safety culture, team members are able to stop and question if things do not seem right and they are aware of risks and are not over-confident. Sometimes awareness of risks diminishes over time in a process known as 'normalised deviance'. This was the case with the space shuttle Columbia – staff had become complacent about defects in heat shielding tiles although the risk had not altered, Mr Bergendahl explained. In addition, everyone is continuously focused on learning from adverse events and works together as a team to help each other to minimise errors. The mnemonic, SALT, standing for stop, awareness, learning and teamwork, is a useful way to remember these points. The leader's commitment to the goal of zero patient harm is a major factor in making progress towards high reliability, said Mr Bergendahl.

Matrix selection of biosimilars

The adoption of a matrix method, rather than a simple checklist, for selection of biosimilars was advocated by Irene Krämer (Director of Phamacy, University Hospital of Mainz, Germany). It is an approach that provides a mechanism for transparent decision-making as pharmacists and doctors both contribute to the process. It involves two key steps, the first of which is to determine the list of selection criteria, for example, efficacy, safety and ease of administration. The second step is to assign relative weights to each of the criteria – usually this is done by distributing 100 points across the criteria. Professor Krämer gave an example in which safety, efficacy and immunogenicity each received 25 points and the remaining 25 points were distributed over another seven factors. Each biosimilar is then evaluated to see how well it compares with the originator on each of the predetermined criteria. The scores are multiplied by the weighting factor and a final score is calculated.

A considerable amount of work is required to research the information to provide the comparative scores, explained Professor Krämer. However, once this task is complete the method provides an objective, rational way of evaluating biosimilar products that takes into account both price and quality aspects. Of course, hospital pharmacists would still have to consider the practical costs of making a change to a biosimilar product

Luca degli Esposti

Peggy Maguire

Robert Moots

such as education of staff and development of polices for managing patients who were already adapted to the originator product, she acknowledged.

Economic evaluation of biosimilars for rheumatoid arthritis

Treatment patterns, including dose escalation, and de-escalation, switching and persistence with treatment, can influence treatment costs profoundly for patients with rheumatoid arthritis (RA) treated with biosimilars, according to speakers at a satellite symposium sponsored by Pfizer.

RA is a serious disease that causes significant disability, and, if uncontrolled, can increase mortality. The introduction of biologics has been associated with considerable improvements in effectiveness compared with methotrexate, the previous gold standard treatment, explained Robert Moots (Professor of Rheumatology, University of Liverpool, UK) For example, in the COMET study, 25% of patients treated with methotrexate alone had given up work after one year, compared with fewer than 10% in the group treated with combined etanercept and methotrexate. Thus, it appears that early use of biologics can prevent disease progression and improve productivity.

Dose escalation is a phenomenon that has been observed in RA patients treated with biologics. An increasing dose is needed to preserve efficacy and this appears to be due to the formation of anti-drug antibodies. The effect is particularly marked with infliximab but occurs infrequently with etanercept, noted Professor Moots. Dose escalation is associated with increased costs, not only for the biologic itself but also for other disease-related costs, he added.

These observations have prompted more detailed studies of the real-world costs of biologic therapy. In contrast to clinical trial data, real-world evidence comprises observations of treatment or procedure effects where the researcher has no control over the subsequent medical management of the patients, explained Luca degli Esposti (CEO CliCon, Italy).

Research in Italy shows that patients receiving biologics have usually received less treatment with disease modifying drugs (DMARDs) than is recommended in guidelines. Dose escalation patterns are similar to those seen elsewhere, being greatest with infliximab and least with etanercept. Up to 18% of patients switch from one biologic to another in the first year of treatment. Persistence with treatment diminishes over a four year period for all biologics. By the end of the fourth year of follow up only 29% and 32% of patients on adalimumab and infliximab respectively are continuing to take the drugs, compared with 45% of those taking etanercept. The two most important factors for determining the overall costs were 'dose creep', which increased costs, and 'dose tapering' which decreased costs, said Dr degli Esposti. Treatment cost evaluations should take into account the complex real-world patterns of usage, including dose escalation and tapering, treatment switches and persistence, rather than be based on acquisition cost alone, he concluded.

Women's health

The European Public Health Alliance (EPHA) believes in equitable access to a sustainable health care system and more involvement of patients in the decision-making process in relation to their own health care, according to Peggy Maguire (President EPHA and Director General European Institute of Women's Health). There is some overlap with the work of the European Institute for Women's Health (EIWH) – a body that is concerned with far more than just reproductive health, it is also health across the lifespan - she explained. Gender can be an important determinant of access to healthcare, because "who you are, where you live and what you work at" has consequences for access to health services. Also women are often managers of family health, responsible for looking after children and older people, she added.

In 2010, EPHA published a charter for health equity. The organisation is also examining access to medicines and innovation in medical devices and the needs and difficulties of the health workforce in Europe. A further area of interest is sexual and reproductive health. One priority area for EPHA is health of the Roma community – one of the most marginalised groups at all levels, she said. Many Roma people cannot afford to consult GPs and undiagnosed diseases are a major problem. EPHA has been trying to build capacity amongst the Roma population, for example, by improving their health literacy so that they are able navigate the system in the country where they live, explained Mrs Maguire.

Turning to the work of the EIWH, Mrs Maguire said that the organisation had recently taken up the issue of women in clinical trials. Hitherto, women have been greatly under-represented in clinical trials and as a result there has been a lack of evidence about women's responses to medicines, although women have more adverse reactions, she said. The European Clinical Trials Regulation has now been revised and this should help to rectify the situation. ●