

Revisiting Breckenridge

Progress made since the Breckenridge report was published in 1976, and issues still to be addressed, were the subject of the joint meeting of the Hospital Pharmacists Group and the Pharmaceutical Aseptic Services Group. Rachel Graham reports

Many advances in practices associated with the addition of drugs to intravenous fluids have been made, according to Professor Sir Alasdair Breckenridge, chair of the Medicines and Healthcare products Regulatory Agency (MHRA) and author of the 1976 “Breckenridge report”. However, some issues remain to be addressed.

Setting out the situation in the 1970s, Professor Breckenridge said that there was a general lack of information regarding the stability and compatibility of drugs in intravenous fluids. Moreover, pharmacists were rarely involved in advising doctors and nurses about these issues, even though they were the experts in this area. Nurses were in a “wasteland”, with poor training being provided to them. Labels showing that a drug had been added were often not attached to fluid bags and it was common practice to, for example, add drugs to inappropriate fluids.

Recommendations of the Breckenridge report included that drug-infusion mixtures ideally should be prepared in pharmacy-run facilities. If this is not possible, then pharmacists should be at the front line in advising about the addition of drugs to fluids in clinical areas, and should be heavily involved in training doctors and nurses. The report also stressed that drugs should only be added to intravenous fluids where there is a positive indication to do so. If they are added, they should generally be well diluted, thoroughly mixed and given slowly. Maximum use should be made of ready-to-administer products.

Regarding the situation in 2005, Professor Breckenridge noted that a significant proportion of products were still prepared on wards and in theatres, including those that are “high risk” because, for example, they involve complicated dose calculations. He thought, however, that the role of pharmacists had increased dramatically — pharmacists are now at the front line, particularly when policies in this area are being developed. The



Professor Sir Alasdair Breckenridge (right) with Richard Needle, chief pharmacist at Essex Rivers Healthcare NHS Trust

training of nurses and doctors is better, although there is still more to be done, he said. Messages about only adding drugs to fluids where positively indicated and diluting drugs properly have largely been put across. More ready-to-administer products are available now, he added. There are also several good publications, such as the “CIVAS handbook” (edited by Richard Needle and Tim Sizer), the “Quality Assurance of Aseptic Services” (edited by Alison Beaney) and the Royal Pharmaceutical Society’s revised edition of the “Duthie report”, he pointed out.

Role of the MHRA

Moving on to MHRA-related issues, Professor Breckenridge said that product information has changed dramatically, with companies needing to provide technical leaflets (as well as patient information leaflets [PILs]) for their drugs, where appropriate. Considerable attention is also paid to labelling, with companies being required, in the interest of patient safety, to use positive statements, such as “for intravenous use only” rather than negative ones, such as “not for intrathecal use”. He added that more ready-to-administer products are available.

Tim Root, from Chelsea and Westminster Hospital, London, pointed out that a lack of stability and compatibility data is a considerable barrier to preparing products that are ready-to-administer in pharmacy-managed aseptic units. Frank Haines-Nutt, from Regional Quality Control, South West

added that the MHRA should challenge companies who give short shelf lives (ie, 24h) in their summary of product characteristics (SPCs) as to why a longer shelf life could not be given. The limited shelf lives that pharmacy production units can give products [because of what is stated in SPCs] contributes towards them being considerably more expensive to prepare in pharmacy facilities than on wards, he said.

Technical information leaflets are also an issue, according to Stephanie Williams, from Papworth Hospital, Cambridgeshire, who said that these are not yet supplied with some drugs commonly prepared in a clinical setting, for example, dopamine. Sue Kilby, head of practice at the Royal Pharmaceutical Society, added that even when they are supplied, they can be confusing and that consumer testing of the leaflets (as happens for PILs) would be useful. Professor Breckenridge agreed to take these issues back to the MHRA, pointing out that many of the information requirements were now the subject of European law.

Making Breckenridge work

Practical strategies for meeting the Breckenridge recommendations were set out by Peter Rhodes, principal pharmacist for technical services at Southampton University Hospitals Trust. These include targeting pharmacy production efforts towards “high-risk products” [see A.M. Beaney *et al*, *Hospital Pharmacist* 2005;12:150–4]. It was also important to find the “middle ground” between the focused attitude of pharmacy staff to contamination risk and the more relaxed attitude of many other professionals. Using computers to generate worksheets and labels also helps to provide an efficient service, as does the introduction of an on-call aseptic services technician to support the out-of-hours work of pharmacists.

Rationalising product ranges, for example, by “dose-banding” cytotoxics and antibiotics and by making up inotropes for neonates in standard concentrations, with the infusion rate then being adjusted in clinical areas (rather than making up individual concentrations to a set infusion rate) can help overcome capacity issues in aseptic units, Mr Rhodes said.

The joint meeting of the Royal Pharmaceutical Society’s Hospital Pharmacists Group and the Pharmaceutical Aseptic Services Group was held at the Society’s headquarters in London on 14 April. Rachel Graham is staff editor, *Hospital Pharmacist*.