

NEONATAL AND PAEDIATRIC PHARMACISTS GROUP

Drug errors and reactions in children — the role of the paediatric pharmacist

The Neonatal and Paediatric Pharmacists Group conference took place in Birmingham from 29 November to 1 December 2002.

Peter Mulholland, of the pharmacy department at Glasgow's Southern General Hospital, reports

Speaking on future research and development in children, Dr IAN WONG (Centre for Paediatric Research, London) suggested that politicians do not pay attention to the needs of children because they are not voters. The licensing system is there to ensure safe, effective, high quality medicines. However, children are not usually included in clinical trials for technical and ethical reasons and, as a result, are not included in subsequent marketing authorisations.

There is a scarcity of available facilities and insufficient numbers of qualified clinical investigators. Why are there no trials in children? It is difficult to get an answer from pharmaceutical companies, and the Government states that there is no money. There has, however, been progress recently. In the United States the introduction of the "paediatric rule" means that companies gain an extra six months on their patents if they carry out work on the use of the drug in children. Even so, the Food and Drug Administration cannot force companies to carry out paediatric trials. Other recent developments include the Best Pharmaceuticals for Children Act 2002 in the US and "Better medicines for children" published by the European Union in 2002.

There is a need to create an agenda for paediatric research. This can be covered by the acronym PULSE: pharmaceuticals, utilisation, learning and training, safety and efficacy.

Pharmaceuticals covers topics such as stability and compatibility data for paediatric formulations. There is a need for develop-

ment of new formulations such as slow release suspensions and taste-masked paediatric formulations. Funding for such work is best sourced via a consortium approach covering pharmaceutical companies, research councils, charities and the Department of Health.

To illustrate "utilisation", Dr Wong asked, how often do we ask children about their medicines, rather than just the parents? Do we know how children perceive their medicines? He said that nursing homes have pharmacists to look after their medicines and wondered whether there should be a similar arrangement in schools.

Turning to "learning and training", Dr Wong said there had been no applicants for a recent post of lecturer in paediatric clinical pharmacy — we need to ask why? There is a need to improve paediatric education at both undergraduate and postgraduate level, and to develop a research leader in the academic and clinical setting. Pharmacy needs to learn from the medical profession establishing research fellowships and have a specialist learning programme with larger research components

Dr Wong suggested a number of potential research areas looking at the safety of medicine use in children. These included: complementary medicine usage, including traditional Chinese medicines; over-the-counter medicine use in children and adolescents; adverse drug reactions to extemporaneously prepared medicines; long-term safety of medicines; and pharmacogenetics to identify children susceptible to adverse drug reactions.

Dr Wong added that there is very little evidence of the efficacy of either pharmaceutical care or medicines management in paediatrics. We know it works but need the evidence to back this up.

ADR REPORTING

Speaking on adverse event reporting in paediatrics, Dr ROBIN FERNER (West Midlands Regional Adverse Drug Reaction Reporting Centre) said that the introduction of pharmacist reporting on the yellow card scheme had resulted in an increase in ADR reporting, but not from children's hospitals. Most paediatric ADRs are for vaccines, in the 10 to 15 years of age range; there were few for other medicines.

He queried the reasons for the low number of ADRs in children. This could be because they may be rare in children, or because doctors expect the ADRs and do not report them as a result. Other reasons might include unlicensed or off label use of the drug or the fact that parents may not report ADRs. The basic premise with the yellow card system is "if in doubt, write it out". Not reporting an ADR may perpetuate a problem.

There are some similarities between ADRs in adults and children, but there are special problems that are specific to children: they are still developing, they exhibit different drug handling and response, they cannot all talk to report their symptoms, and they still have a lifetime ahead in which long-term effects could show.

Examples of these different reactions

have included tetracycline causing teeth staining, dopamine agonists causing oculogyric crisis rather than Parkinson symptoms, chloramphenicol causing "grey baby syndrome" and diethylstilbestrol causing carcinoma in young women as a result of their mothers taking the drug during pregnancy.

Medication errors in children are often difficult to detect and it is important to remember that, although pharmacists often pick up the errors before they cause harm, pharmacists make mistakes as well.

Systems need to be in place to help prevent errors before they happen. We need to reduce reliance on personal knowledge and use sources such as the British National Formulary and 'Medicines for children'. Safer systems need to be designed with better training, simpler and more visible methods of work, increased checking at each stage, less tolerance of broken rules but greater tolerance of reported errors. Even if all this is in place we need to remember that it is difficult, if not impossible, to construct a system which is completely foolproof.

In questioning Dr Ferner was asked if there was a role to extend ADR reporting in children beyond those drugs with a black triangle. The Medicines Control Agency is keen to receive details of any ADR in children, including already recognised reactions. It was noted that advice to this effect was in the BNF, but that this was a recent change, which had not been advertised.

RESEARCH IN PRACTICE

NEIL CALDWELL (Wirral Hospital) presented work undertaken on prescribing errors in children using computerised

physician order entry (CPOE). He said that paediatric prescribing errors occur because most drugs require weight-based dosing, thus creating the opportunity for incorrect dose calculation, with misplaced decimal points giving potential for significant harm. CPOE has great potential for improving safety by ensuring completeness and legibility.

In the study there were 89.5 errors per 100 admissions, with dosing error (22 per cent) being the most common. Some of these errors occurred because the adult prescribing pathway had been chosen, instead of a paediatric prescribing pathway. The paediatric prescribing pathway will decrease potential error, but its effectiveness is currently hampered by lack of use made of the facility and the limited number of drugs available.

Not all ADRs are as a result of the prescribed drug. CATHERINE HALL (Royal Victoria Hospital, Newcastle Upon Tyne) presented a case study on a premature baby who presented with neonatal gasping syndrome following administration of clindamycin injection for generalised sepsis. The SPC for clindamycin mentions "gasping syndrome" but the product is not licensed for babies aged under one month.

Clindamycin injection contains benzyl alcohol. This is normally oxidised to benzoic acid, conjugated with glycine in the liver and excreted as hippuric acid. If this pathway is not fully developed in the neonate a build up of benzoic acid can occur, leading to gasping syndrome. It is important to be aware of the potential for drug excipients to cause adverse reactions.

A busy poster session included work by researchers from Leicester Royal Infirmary on the introduction of a "prescribing work-

book" to improve prescribing habits and reduce medication errors. Results showed that, following the introduction of the workbook, prescribing problems including illegibility, incorrect dose units, *prn* medication and drug indication, fell by an average of about 33 per cent. It is hoped that the introduction of this system will reduce the potential for medication errors in paediatric patients.

The NPPG award for best poster went to SHEILA BUCKHAM and colleagues (Sheffield Children's Hospital) for their interactive poster on information for parents of children diagnosed with acute lymphoblastic leukaemia.

An interactive CD-ROM complements verbal and written information given to the parents. A documentary style account of the experiences of other parents in text, photographs and video clips provides emotional support. The design also includes information on disease facts, diagnostic tests and procedures, treatment and follow up care. It can be viewed as a whole, or in small sections, as parents are ready to seek further information. The factual content was compiled in conjunction with medical, nursing and pharmacy staff. Parents provided the documentary information.

SUMMARY

The conference highlighted the work being undertaken by pharmacists and their colleagues in the field of paediatric research. There is, however, still a long way to go until paediatric research is afforded the same status as adult research and work still needs to be undertaken to push the agenda forward.