

CHILDREN'S CARE — MANAGING THE RISKS 1

Getting medicines right for children

Improving access and information on medicines for children were discussed at two practice sessions on 16 September, organised in association with the Neonatal and Paediatric Pharmacists Group. Harriet Adcock reports

Adults expect their medicines to be researched, tried and tested, with scrutiny from regulatory agencies, Tony Nunn, director of pharmacy at the Royal Liverpool Children's Hospital NHS Trust, told conference participants. The situation for children, however, is different.

Mr Nunn, who is chairman of the Medicines External Working Group for the Children's National Service Framework, pointed out that a review of black triangle drugs in 1996 had revealed that only 30 per cent were appropriately licensed for children. About a fifth had the potential for paediatric use and half were already being used off label. "I have seen nothing to suggest that things have changed in the past seven years," he said.

He went on to describe the problems that can arise through the current licensing situation, such as use of inappropriate formulations, extemporaneous dispensing, use of chemicals of varying quality etc.

A particular problem is information provision. "Imported medicines, their labels and patient information leaflets may be in a foreign language," he said. In addition, patient information may not be available for unlicensed medicines and may be confusing when medicines are used off label. "We need better patient information with co-ordinated production for unlicensed medicines to avoid duplication of effort and to assure standards."

Parents and children also need better information about how specific drugs are used so they can make informed choices. Mr Nunn suggested that a parents and children version of the formulary "Medicines for Children" may be required.

Mr Nunn warned that if children are to become true partners in medicines management then patient information has to be understandable by children and should be produced in media that they could enjoy using. "Like it or not we are in the age of the text message and computer game and we must look to different ways of getting our message across."

He added that the availability of unlicensed medicines may be limited. Furthermore, there are problems transferring prescribing responsibility between primary and secondary care and in transferring information between hospital and community pharmacists. "If nothing else this is all inconvenient for patients."

There are additional risks surrounding the unlicensed-use of medicines. In terms of patient safety there has been a focus from the Department of Health on intrathecal administration errors and from the National Patient Safety Agency on potassium chloride. "I would now expect the NPSA to be

taking paediatric advice and looking at ways of improving dose calculation, practical prescribing and measuring and administration of medicines for children."

Mr Nunn pointed out that other issues, unrelated to licensing of medicines, could affect children's care. These include the content of practical paediatric medicines management in undergraduate courses, access to medicines in schools, effective prescribing and whether the needs of disadvantaged children are adequately catered for. Questions remain, too, about whether treatments should be offered at home rather than in hospital and whether enough assistance is currently provided to parents in managing their children's minor ailments.

"Much of what we can do to improve things is or will be covered by the Children's NSF," he said. This document is likely to have themes around:

- Improving the evidence base and licensing of medicines for children
- Provision of high quality medicines information to both professionals and the public
- Improving patient safety and increasing public access to medicines

The role of the community pharmacist is vital for delivering improvements to children's health. "Crucial to our ability to deliver improvements will be an appropriately trained workforce and an appropriate contractual environment," he said.

INCENTIVES OFFERED

Mr Nunn explained that regulations designed to improve the licensing of children's medicines are being developed in Europe and that these would offer incentives to pharmaceutical companies to develop and license suitable medicines for children. "Unfortunately the regulations are currently stalled because of the need for a Europe-wide impact assessment. In the meantime, we need to encourage the submission to Europe of data submitted in the US," he said.

Sharon Conroy, University of Nottingham and Derbyshire Children's Hospital NHS Trust, continued the theme of using unlicensed and off-label medicines in children. She highlighted the problem of transferring care from secondary to primary care. "There is a problem because children need



Sharon Conroy: many paediatric medicines are difficult to source

medicines at home. It is not acceptable for GPs to prescribe if they are not familiar with a particular drug."

She added that there are risk issues because unlicensed medicines are particularly patient specific. "We need systems to ensure patients get the same formulation and dose of medicines. If not — there can be serious consequences."

She pointed out that paediatric formulations are not necessarily readily accessible in the community and that information is not accessible in primary care. There is also a need to ensure that medicines are of adequate quality. "Much of the problem relates to logistics. Many paediatric medicines are difficult to source — industry can't advertise unlicensed medicines so they can be difficult to find and delays occur."

She explained that even when patients and carers have been warned that medicines might be difficult to obtain, they often do not follow advice to go straight to their general practitioner for a repeat prescription to give them time to source it.

Ian Costello, chief pharmacist, Birmingham Children's Hospital NHS Trust, described some of the advantages and disadvantages of alternative systems for supplying paediatric medicines. "I am sure that every day you have patients coming in [with a prescription for unlicensed medicines] and you have no way of knowing where to source a drug from. The patient then ends up back at hospital," he said.

Shared care protocols could work well but take time to set up.

Using an FP10HP form to prescribe the patient's unlicensed or off-label drug then posting it to the patient is a convenient solution. However, this system does not keep primary care professionals in the loop.

Hospital prescribing and supply allow the hospital to take responsibility for the patient's medicines but this system could be inconvenient for patients. Furthermore, the GP and community pharmacist are not involved.

Home delivery of hospital prescribed medicines minimises inconvenience to patients and allows responsibility of supply to be controlled by the hospital.

Using a managed home care company again minimises inconvenience and monitoring can be built into the system. However, the system again removes primary care health care professionals from the supply chain and introduces an additional cost.

How community pharmacists can help

Community pharmacists can play a pivotal role in reducing health inequalities among children.

Harriet Adcock reports on the second session focusing on managing risks in child care

Community pharmacists can play a pivotal role in reducing health inequalities among children, Georgina Craig, head of NHS service development at the National Pharmaceutical Association, told participants at this year's British Pharmaceutical Conference.

She highlighted recommendations from the 1998 Acheson Report that were of particular relevance to pharmacy. These included:

- A focus on improved retail provision in deprived communities
- A focus on improved mental and physical health and nutrition of women and children, including an increase in breast feeding
- Smoking cessation before and during pregnancy
- Improved sexual health and a reduction in teenage pregnancy
- A focus on services sensitive to minority ethnic groups

Another report — entitled "Plan for action" — also highlighted the need to make better use of community settings and services, including community pharmacies.

This is "a clear signal that pharmacy has a pivotal role to play in the health inequality and consequently the child health agenda", Ms Craig said.

The public health strategy for pharmacy, announced in "Vision for pharmacy" would undoubtedly focus on how pharmacy could help tackle inequalities.

Against this background, the Government has launched a host of policies, aimed at improving life chances for children, including Sure Start, the teenage pregnancy strategy, and the Children's National Service Framework. Ms Craig said pharmacy fits the bill as a location for health services in



Georgina Craig: Key is getting pharmacy's voice heard in the right circles

most communities. She explained that as part of Sure Start, children's centres and "extended schools" (both of which would house health care facilities) are being developed. "These may provide opportunities to develop new models of pharmacy targeted at the needs of families with young children," she said.

"Community pharmacists should find out if there is a local Sure Start programme in their area. If it is a deprived area, it is likely that there will be."

Ms Craig pointed out opportunities for community pharmacy to work with Sure Start. These are:

- Public health initiatives, eg, provision of information on nutrition, smoking cessation, breast feeding and immunisation
- Signposting parents to local services, eg, welfare benefit and parenting support
- Developing the role of support staff who speak the languages of local people
- Referral of parents to an appropriate professional, eg, when children have sleeping, feeding or behavioural problems

- Minor ailments schemes and, in the future, independent prescribing to increase access to medicines
- Development of new "concept pharmacies" in children's centres and extended schools

Ms Craig went on to say that pharmacy could play a part in helping reach the Government target of halving the rate of conceptions among those under 18 years in England by 2010.

"Pharmacy fulfils many of the criteria desired by young people from a sexual health service." Pharmacies provide an anonymous service, are easily accessible and look like shops rather than clinics.

"Community pharmacy has already shown, through schemes like those to supply emergency hormonal contraception that it can contribute to this agenda," she added.

Ms Craig explained how community pharmacy could contribute to the teenage pregnancy agenda.

Pharmacists could counsel routinely on the impact of antibiotics on the effectiveness of the contraceptive pill and become involved in public health initiatives aimed at providing information on safe sex and relationship education.

One theme from the Children's NSF of relevance to pharmacy is the emphasis on the need for women, children, young people and families to have access to local services that promote health, physical and emotional well-being in an imaginative way.

"This is a challenge to community pharmacy, in partnership with health visitors, midwives and others," she said.

Similarly, there is a focus on empowerment, self management and family support. "The role of the pharmacy in this is clearly pivotal. The key is getting pharmacy's voice heard in the right circles," she concluded.

Children unaware pharmacists are source of information and advice

Children may be unaware that pharmacists are a source of information and advice, Dr Bryony Beresford, York University, told conference participants.

She outlined research conducted at York involving 63 children who had one of five chronic conditions. The research identified two broad groups of information needs — medical information and psychosocial information. "Children had lots of concerns about treatments, especially side effects. There was a sense that information was being withheld," she said. Children believed that doctors were so concerned about

adherence that they would play down side effects. The fact that they were always told "not to worry" could lead them into a cycle of not bothering to ask questions. When asked about their preferred sources of information, Dr Beresford pointed out that none of the children in the study mentioned pharmacists. "This was surprising, since side effects were such an issue — maybe they just weren't aware of that facility."

Information provision should also be ongoing and it is important to separate the information needs of the parent and the information needs of the child, she said.

Clinicians must communicate

Formulation scientists are frequently unaware of what clinicians require in their clinics and clinicians often fail to say what they want, Dr Ian Wong, director, centre for paediatric pharmacy research, School of Pharmacy, University of London, said.

He pointed out that liquid formulations are believed by many to be the holy grail in terms of paediatric medicines, but they can be bulky and inconvenient for patients and their carers to take home.

"Lots of factors need to be considered. We need to tell [the industry] if there is a problem," he said.