

Getting medicines right for children

Our coverage of the World Congress of Pharmacy continues with reports from **Pamela Mason** on medicines in children (this page), **Steven Kayne** on chain pharmacies (p437), **Sonia Sanghani** on encouraging young pharmacists into hospital practice (p438) and pharmacists' role in diagnostics (p443), **Claire Anderson** on skills improvement (p439) and **Jane Nicholson** on self-medication (p440) and direct-to-consumer advertising (p441)



Pharmacists face many problems in providing appropriate dose forms of medicines for children. Few medicines are licensed for use in paediatric patients, requiring pharmacists to explore a range of options, which usually involve reformulating adult medicines to make them suitable for children. Speakers at two symposia on 7 and 9 September outlined the problems and the ways in which pharmacists, the industry and the regulatory agencies are starting to work together to present better treatment options for the population of smaller, younger patients.

Tony Nunn, clinical director of pharmacy, Royal Liverpool Children's NHS Trust, gave an overview of the issues involved in dealing with medicines for children. Beginning with his threefold vision of paediatric medicine, he said that, first, all children and young people should receive safe, effective medicines of good quality. Formulations should be easy to administer, appropriate for the age of the

child and have minimum impact on education and lifestyle. Secondly, medicines should be prescribed, dispensed and administered by professionals who are well trained, informed and competent to work with children to improve health outcomes while minimising harm and side effects of medicines. Thirdly, children, young people and their carers should be well-informed, supported to make choices about their medicines and competent in their administration.

He went on to say that children are not mini-adults. Children's diseases, adverse drug reactions, drug handling (pharmacokinetics and pharmacodynamics) and requirements for formulation and health service delivery are different from those of adults. There is a need to study and authorise medicines across a range of age groups. The reality, however, does not match up to the ideal. It is now more than 30 years since the American paediatrician and pharmacist, Harry Shirkey, described children as "therapeutic orphans". Shirkey was referring to the lack of appropriate labelled medicines for children.

Legislation in Europe and the US has been designed to improve the situation by encouraging specific research, development and marketing of children's medicines. However, the use of off-label and unlicensed medicines continues, with one hospital study showing that 30 per cent of paediatric prescribing is for off-label or unlicensed medicines. The proportion was as high as 65 per cent in in-

tensive care and more than 10 per cent among UK general practitioners.

Mr Nunn explained that the reason for this is that there are still relatively few medicines licensed for children. Of the new medicines which became available in the UK last year, only 34 per cent were licensed for children. A further 40 per cent had the potential for paediatric use and a further 11 per cent were actually used. Moreover, an Australian study found that 70 to 80 per cent of medicines were inadequately licensed for children in that dosing information was lacking. In 25 per cent of cases, dosing information was adequate, but there was no paediatric dosage form. The limited number of paediatric medicines is the result mainly of the lack of commercial incentive. Patient numbers are small, paediatric technologies are expensive and clinical trials are difficult. There are ethical issues to consider and manufacturers think the risks are not worthwhile.

Mr Nunn went on to say that although it is undesirable to use medicines tested and licensed only for adult use, it is inappropriate to withhold potentially effective treatments because the manufacturer has not obtained a licence for use in children. The problems associated with the use of unlicensed and off-label medicines include inappropriate formulations, leading to compliance issues. In addition, suitable medicines can often only be prepared extemporaneously. Alternatively, they can be imported from other countries,

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but there are difficulties with language and information. Patient information is a problem with all unlicensed and off-label uses, for example, if a medicine is labelled for a three-year-old, but is required for a two-year-old. The risks of using medicines in this way include a paucity of prescribing information, and an increased likelihood of ADRs and medication errors (eg, calculation and measuring errors).

Regulation and licensing of paediatric medicines is being led by the US, and an increasing range of medicines is now labelled for children. These include enalapril, gabapentin, midazolam and ranitidine. In the UK, 90 such products are now available, but most of the data have not been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA), a situation which could be improved with better exchange of information between the US and the UK.

Initiatives in Europe include the Orphan Drugs Regulation 2000 and the European Parliament and Council Regulation (EC) on medicinal products for paediatric use ("Better medicines for children"). However, these regulations are unlikely to come into force until 2006 and, as an interim strategy, the Department of Health is managing an initiative to try to use data from the US for UK paediatric medicines. The use of suitable formulations from other countries could also be used to fill the gap, but only in cases where the regulatory system of the country concerned is known to be satisfactory (eg, European countries, North America, Australia).

Mr Nunn went on to describe specific initiatives which include "Medicines for children" (a UK peer-reviewed national formulary containing over 600 drugs) and a British National Formulary for children due to be published in June 2005. In Liverpool, there is a drug information advisory line

Specific research needs for paediatric medicines development

James McElnay, of the Queen's University, Belfast, discussed the specific research needs around the development of paediatric medicines. Children are not simply small adults although, at present, children's doses are often based on adult information. Clearly, this is not acceptable, he said. Incentive schemes are in place in the US and Europe to encourage the pharmaceutical industry to carry out the necessary research to gain licences for paediatric use of new medicines coming on to the market. However, the situation is less clear for those medicines already being used off label in children.

The problem is that traditional research studies involve multiple blood sampling over prolonged periods, raising ethical issues in children and, particularly, in neonates. Professor McElnay went on to describe work in Belfast that is seeking to get round this difficulty by focusing on a population-based pharmacokinetic approach, coupled with micro-analytical techniques to quantify blood concentrations of drugs. With this approach, blood samples are obtained from neonates or children who have been prescribed off-label medicines but the samples are obtained when a blood sample is being taken for another clinical purpose.

Blood samples are increasingly taken as dried blood spots rather than as plasma samples. Using this method, blood spots from a heel prick or indwelling catheter are spotted on to a Guthrie card and drug concentrations determined by high-performance liquid chromatography. This method offers several advantages. Consent may be easier to obtain since the volume of blood required is much smaller, especially in neonates. The technique can be used to collect samples at outpatient clinics and in patients' homes since venopuncture is not required and transportation is facilitated, since drugs and metabolites are more stable in dried form.

The child is assessed for clinical outcome (eg, pain control) and the concentration of the drug is measured. Drugs which have been investigated include diclofenac for post-operative analgesia, enalapril for hypertension and heart failure, indometacin for patent ductus arteriosus and ranitidine for gastro-oesophageal reflux disease. Ongoing studies at Belfast are looking at metronidazole in neonates with necrotising enterocolitis and spironolactone in neonates with chronic pulmonary dysplasia. However, much more work is required, using innovative research methodologies (eg, pharmacogenetic analyses). Government support for industry and research networks is also required. "But let's be optimistic," Professor McElnay concluded. "The next five to 10 years should see a major increase in evidence available for the safe and effective use of medicines in children."

(DIAL), and of the 2,000 calls received each year, 70 per cent are about unlicensed or off-label use of medicines.

He told the congress that the UK National Service Framework for Children was due to be published within the next few days (see **News feature**, p413, and *PJ*, 18 September, p369). It would contain a specific module on medicines for children and young people, in which the role of the pharmacist is highlighted. Both community and hospital pharmacists are crucial in the care of chil-

dren. However, if pharmacists in the community are to become a true point of care, they must be prepared to relinquish their shop-keeper image. Specific roles for community pharmacists addressed in the module include distinguishing between minor illness and major disease, the management of minor ailments and emergency hormonal contraception and healthy lifestyle advice. Hospital pharmacists, working as part of multidisciplinary teams, can develop networks with primary and tertiary care and ensure the provision of appropriate unlicensed medicines together with information in the community. Through participation in research and development they can provide an infrastructure for industry.

Mr Nunn concluded by saying that the first decade of the 21st century should be the decade of "medicines for children". Knowledge and information are key to the safe use of medicines in children and the pharmacist's role is crucial.

Pharmaceutical care in children

Nadya Nalli, a pharmacist at the Hospital for Sick Children, Toronto, Canada, focused on the benefits of providing pharmaceutical care to children and the strategies required to achieve this. Although medicines are essential in disease management, if they are taken inappropriately, they can be the source of significant mortality and morbidity. Children with chronic disease are at particular risk since non-adherence and drug misadventure are more likely to occur when many medicines are prescribed.

Paediatric formulations and how they are being tackled

Milap Nahata, professor of pharmacy and pediatrics, Ohio State University, Columbus, Ohio, discussed the requirements for paediatric specific formulations and how these are being tackled. All too often there are no formulations suitable for children. In the absence of appropriate formulations, the only options are to refuse or delay treatment, call the manufacturer (which may not have the information), or prepare powders or a liquid with no proper data. Companies tend not to want to do the studies because of the competition to develop medicines for adults and the expectation that a drug required for a child will be used anyway even if it is only available in an adult formulation.

Infants and children less than seven years old have difficulties swallowing capsules and tablets and need a liquid formulation. Preparation of oral liquids is made difficult by the fact that most drugs are incompletely soluble and require the use of a suspending agent. Syrup must often be added as well as flavours, preservatives and colouring agents any of which can provoke allergic reactions. Recourse to intravenous solutions does not solve the problem because the volumes required are too small to allow for accurate dosing in children. Newer anticonvulsants such as gabapentin, lamotrigine, topiramate and levetiracetam are available only in appropriate dose forms for adults, not for children, yet they are desperately needed. A stable liquid dose form of sildenafil is needed for the management of pulmonary hypertension in infants.

Professor Nahata went on to describe the research activity in his own hospital, where over 100 paediatric formulations have now been prepared. Four hours a day is devoted to this work and six to 10 new formulations are made each year. However, the need for paediatric medicines will continue, but there is little funding available and incentives must be given to industry, he said. Sharing of research and experience is also vital.

Pharmacists can improve the use and outcomes of medication by working with the child and parent or caregiver to ensure effective, two-way flow of information. Once this relationship is established, pharmacists must start by effectively assessing the information needs and learning capacity of the child and caregiver. Children's understanding of their disease and the level of responsibility they can assume for their care depends on their level of development.

Literacy levels, cultural differences and how much information is required at any point in time must be considered. For example, it is not necessarily beneficial to discuss drug dosages and ADRs in great detail when a parent has just brought a sickly child home from hospital. It may be better to wait for a few hours until the parent is feeling less stressed.

Adolescents represent the greatest challenge and are at high risk of non-adherence. Pharmacists must be able to assess whether the adolescent is capable of accepting responsibility for their drug therapy and how best to manage the transition from childhood to adulthood.

Pharmacists are in a unique position to provide pharmaceutical care for children and young people. They can identify individual patient and family preferences and options which respect quality of life and optimise adherence. Liaison between hospital and community pharmacists, which is facilitated by good documentation, is important.

Ms Nalli concluded by saying that every

paediatric patient should grow up knowing "my pharmacist" and the role that pharmacist plays in their care. Children and young people who do know this will undoubtedly become adults who strive to be involved in their own care.

Practical solutions

Jean-Marc Aiache, of the biopharmaceutics department, faculty of pharmacy, University of Auvergne, France, highlighted some practical solutions to drug administration in children that his department has developed. This patient group needs help in three main ways, he said.

First, parents need help to administer drugs to their children when they are young babies and they do not know they are taking a medicine. Suppositories, which are commonly used in France, can be a useful means of delivering a drug to a sleeping infant. Pacifiers and teats, with which the child can play and at the same time take a dose of drug, can also be used. Professor Aiache went on to describe various packaging and measuring systems developed in his department. These include dosing glasses, syringes for oral liquids and several types of spoons. Generally, parents ask for products that are easy to open and use with precise dosing and attractive packaging which minimise stress for the parent and child.

Secondly, parents need help to get their older children (ie, those aged two to 10 years) to take their medicines. Taste is the biggest issue here, and taste evaluation studies must

be improved he said. One way to administer drugs is with food — any type of food, including yoghurt, soups, biscuits, fruit juices, fruit compotes, mousses, jellies and creams and chewing gum. These could be developed as nutraceuticals. Toys represent another method of improving children's acceptance of their medicine. Sachets containing the medicine can have a picture inside. Another development is a "pearl collar" each pearl being a quick dissolving tablet, with the reduction in number of pearls indicating compliance. Stories explaining the illness can be included as package inserts.

Thirdly, as children get older still, they need help to take their medicines and accept their treatments for themselves. Devices developed for this purpose include drugs contained in reservoirs or a neutral device implantable or hidden so that the child receives the drug in a regular manner but does not show at school that he or she has to take medicines. Other devices include those that remind the child to take the medicine at specific times.

Professor Aiache concluded by saying that the third millennium should be dedicated to the formulation of medicines for children and also for older people, two populations which have been completely forgotten by the pharmaceutical companies. Effort must be made to change not only this mentality, but also the methods of drug development which must take account of the unique physiology and diseases of these patient groups so that doses can be individualised for patients.

Problems of administering medicines to a diverse population of patients

In a presentation which focused primarily on the problems of administering drugs to paediatric patients, Kathleen Gura, clinical pharmacist, Children's Hospital, Boston, Massachusetts, said children constituted a diverse population of patients of all ages and sizes, frequently with rare diseases unique to childhood or chronic conditions that span into adulthood. Challenges in administering medicines include differences in absorption and distribution that vary with the age of the child. Neonates, for example, have thin skin tissue which means that use of topical preparations can easily lead to systemic toxicity. Immaturity of the organ systems results in changes in drug metabolism and excretion, this picture changing gradually as the child gets older.

Dr Gura went to describe a 12-year-old patient with metachromatic leukodystrophy whose gastro-oesophageal reflux was being treated with omeprazole. The patient was admitted to hospital on two occasions with frequent painful night awakenings, and eventually it was discovered that the omeprazole was being ground rather than dissolved in sodium bicarbonate, so leading to treatment failure. This arose because the pharmacist did not have access to adequate drug information.

Lack of adequate drug information is a problem for many paediatric pharmacists, Dr Gura said. In many instances, pharmacists must rely on the primary literature or specialised references which are often based on case reports rather than well designed clinical trials. Many practitioners do not have access to such references and will improvise with formulations or refuse to dispense the medicine, both having the potential to cause patient harm.

Another problem is that commercially available dose forms require further manipulation in order to deliver accurate doses. For example, tablets must be broken, cut or suspended, all of which can lead to inaccuracies. Removal of the contents of capsules is an art form and injectables often require further dilution. Suppositories can be cut across or length wise, which leads to different doses being given, but if this is not explained to parents they do not understand this. Dr

Gura described another patient who was discharged from hospital on a four-week course of enoxaprin. However, discharge had to be delayed for 48 hours until an outpatient pharmacy or home care company could be located that would be willing to prepare the appropriate dose of enoxaprin.

Dr Gura explained that patient compliance is a frequent problem in this group of patients, with 40 per cent of paediatricians reporting that their patients fail to take their medicines as prescribed. Unpleasant taste is a particular barrier to compliance that affects 91 per cent of paediatric patients, according to one study. Citing the example of an eight-year-old boy with Crohn's disease who preferred the symptoms of the disease to the taste of sulfasalazine liquid, she went on to say that taste is rarely studied in children. However, it is wrong to assume that because an adult likes the taste of a medicine, a child will, too. Children prefer sweet flavours, adults prefer tart-sweet and older patients prefer mint. Care must be taken with excipients. For example, sodium benzoate is associated with gasping syndrome in neonates, parabens with hypersensitivity reactions and ethanol may be included in formulations in high enough concentrations to result in interactions with drugs such as metronidazole.

These problems continue to make extemporaneous compounding necessary, Dr Gura concluded. It avoids the inclusion of undesirable excipients, improves palatability and avoids side effects and enables the provision of a different dosage form from those available commercially. Appropriate formulations are sometimes available in other parts of the world and it is frustrating for US pharmacists that they are unable to provide such medicines. This happens because the manufacturer considers it costly to repeat the studies in the US or the Food and Drug Administration refuses to accept foreign data. Pharmacists should have access to the same resources, including age appropriate formulations and drug information, both of which are taken for granted by practitioners working with adults. The provision of appropriate medicines will reduce risk of medication errors and ultimately improve patient care, she said.

Are chain pharmacies really the “bad guys”, as some people say they are?

During a Community Pharmacy Section meeting on 7 September, designed to promote discussion on whether chain pharmacies are really the “bad guys” many believe them to be, participants heard that “big isn’t all bad”.

Craig Fuller, president and chief executive officer of the National Association of Chain Drug Stores (NACDS) in Washington DC, said that his organisation exists to represent the views and policy positions of member chain drug companies that operate in all US states apart from North Dakota, where all multiple retail organisations are banned. This purpose is accomplished through a series of programmes and services provided by the association. For example, NACDS emphasises the value of community retail pharmacy in the national health care system, ensures the community retail pharmacy perspective is communicated to and understood by legislators and policy-makers, and develops programmes to improve distribution of goods and retail operations. In addition there are various training schemes available to members and their staff.

Mr Fuller suggested that none of these activities could be achieved efficiently by independent pharmacist proprietors working alone. There is no doubt that size conferred economies of scale and competitive advantage in business terms. The smallest members of NACDS had four branches and the biggest almost 5,000 branches, 80 per cent of which are situated in urban areas. Annual turnover of members ranges from \$5m to \$35bn.

Ten years ago the split between clients who paid cash for their prescriptions and those who had their prescription costs covered by a third party was 50:50. Now the balance had swung towards third party payment; in 2003 only 14 per cent of clients paid cash. Third party payers are squeezing dispensing margins and, with internet and mail order pharmacy increasing, this trend is likely to continue in the future. Despite this, Mr Fuller thought that there is a place for both chain and independent sectors, particularly in rural areas where 65 per cent of US independent pharmacies currently operate. He considered their activities as being complementary rather than in direct competition.

Independents will thrive

Independent community pharmacy will continue to thrive for many years, despite worries about it being unable to compete with the multiples. That was the view of Rob Darracott, director of corporate and strategic development at the Royal Pharmaceutical Society of Great Britain.

Mr Darracott said that there are benefits to

accrue from independent contractors and small multiples linking together in “virtual chains”. He defined these chains as being groups of pharmacies of various ownership that adopt chain behaviour for mutual advantage. Commercial advantages include co-operation in buying drugs and over-the-counter products, front store marketing support, store planning and advice on IT systems and strategic marketing. Virtual group activity can also counter professional isolation and promote a feeling of safety in numbers when dealing with central or local government.

The model has been adopted in several European countries, as well as in the US, and is providing a means of competing with corporate groups. In the UK, the virtual chain concept is being largely driven by wholesalers as a way of ensuring customer “stickability”, Mr Darracott said. He cited community pharmacy programmes for bone health and eczema and a study to assess the needs of patients with Parkinson’s disease as examples of projects set up through virtual chain activity in the UK.

Drawbacks of professional isolation

Inger Lise Eriksen, president of the Norwegian Pharmaceutical Association, illustrated what could happen when proprietors worked in isolation. She outlined the current position in Norway following the complete deregulation of pharmacy after 400 years of professional control. The Pharmacy Law passed in March 2001 has lifted the monopoly on professional ownership and removed all restrictions on the location and ownership of pharmacies, opening the door for wholesalers to own pharmacies. In addition generic substitution has been initiated. Worse was to come for, from 2003, the sale of OTC medicines in supermarkets, grocery stores and garages was allowed.

Ms Eriksen said that the Norwegian government had a strong belief in replacing monopolies with self-regulating markets and pharmacy was not alone in being targeted; electricity and telecommunications suppliers have suffered similar fates. Unfortunately she and her colleagues have been caught unprepared by the Government’s action and although they have formed an action group it is too late to make representation.

In the period 2001–02 there was a small rise in the number of pharmacists and technicians in Norway but numbers of pharmacies had risen by 26 per cent, most of the growth having been achieved by international groups buying out proprietors in urban areas. A survey has revealed that two out of three clients have not noticed any major changes in the distribution of medicines. Among pharmacists



Inger Lise Eriksen: complete deregulation of pharmacy in Norway

40 per cent have not experienced any change, but 32 per cent have noted fewer opportunities to counsel under the new arrangements; 40 per cent of physicians have enjoyed more contact with pharmacists.

Ms Eriksen said that Norwegian pharmacy has lost “the spirit of the professional pharmacy owner”. She had to acknowledge that there were advantages to the consumer for there are fewer deviations in the standard of service and increased efficiency in chain pharmacies than in independent pharmacies. The concept of virtual chain groups is helping her independent colleagues to survive.

Does bigger mean better?

The three speakers were clearly of the opinion that some form of chain behaviour was desirable — even inevitable — in modern community pharmacy practice. There were many in the audience who were not so sure that bigger meant better. Contributors to the panel discussion, chaired by Christine Glover, of Edinburgh, UK, highlighted the advantages to clients of the independent practitioner. These include flexibility to respond quickly to the changing health care environment and a tendency to have better continuity of staff allowing the development of proactive relationships with clients. The emphasis in independent practice is on quality of service rather than profit alone and although this might not be wholly appreciated in urban pharmacies, in rural areas the local pharmacy is still an important asset for the community. There is the possibility of involvement in a number of specialties, for example, veterinary pharmacy or complementary and alternative medicine, to enlarge the customer base.

How to encourage young pharmacists into hospital practice and to keep them

Why should young pharmacists be regarded as the leaders of tomorrow, when they can lead today? That question was posed by Rebekah Moles, associate lecturer in the faculty of pharmacy, University of Sydney, Australia, in a joint presentation with Lachlan Rose, a newly qualified pharmacy graduate based at St Vincent's Hospital, Sydney. They were speaking at a symposium organised by the Hospital Pharmacy Section entitled "The new hospital pharmacist" on 8 September.

Miss Moles and Mr Rose, in presenting the student's perspective on hospital pharmacy, urged participants to ensure that they involve or consult their young pharmacists early in departmental decisions by appointing them as representatives on committees. "As young pharmacists, we have a voice and want to be heard," she said.

To encourage more young pharmacists into the hospital setting, they have designed a novel mentoring system where younger, motivated pharmacists act as mentors to newly qualified graduates in order to ease their transition into daily hospital practice. Younger rather than older pharmacists were chosen as mentors because it was thought they could better empathise with the predicaments of first starting out in practice, and "they have an incredible enthusiasm and passion for their profession early in their career", she said.

A research team from Sydney, which includes Miss Moles, has labelled this model the "Partners for the future of our profession" initiative. The team's catchphrase for this project is "Maintain, retain and sustain!". Through their efforts, they hope to maintain the interest of young pharmacists and graduates in the profession, retain young pharmacists within the profession and thereby sustain the profession for the future.

There is plenty of evidence to support the need for such an initiative as many young pharmacists are leaving the hospital sector, which has to some extent already led to staff shortages in many establishments. This, according to the team's research, is due to disillusionment at the lack of application of skills learnt in university, alongside the large workload which makes them feel that their clinical knowledge is being eroded because they just "pump out scripts". Young pharmacists have been well trained in university to provide clinical pharmacy services incorporating elements such as counselling, interventions and medication reviews. Although current hospital pharmacy practice does not meet student expectations, the researchers believed that universities also do not adequately prepare students for the realities of practice. This "gap" prevents students from applying for po-



sitions in hospital settings, or encourages them to leave early in their career, because they do not wish to become jaded about their profession. There were also some myths circulating among students that pharmacy departments were usually found in hospital basements resulting in limited patient contact. Other myths included "only the best students need apply" and Mr Rose questioned this by stating that it was often attitude, rather than knowledge, that was the crucial factor. Many students thought that if they did not start their career in hospital they would not make it as a hospital pharmacist later on.

Mr Rose asked the audience why it was, then, that these pharmacists did not know about the excellent training, support and orientation that is provided to new staff? Although it is true that not everyone can do their hospital residency straight after their degree, better knowledge of training and support opportunities may encourage others to undertake these programmes later on in their careers, he suggested.

There were other myths relating to poor pay and poor working conditions. But, he said, he had friends who, in community pharmacies, barely got time to eat a sandwich whereas he enjoyed an hour-long lunch break, as well as support to attend national and international conferences.

Both presenters agreed that young pharmacists can become positive agents of change in their workplaces because they have many good ideas. New graduates are accustomed to expecting evidence-based practice and demonstrating competency. They want to practice in the best way possible, ie, by not just following custom and practice, but by

practising their profession and doing things in a way that they know works.

Miss Moles and Mr Rose also promoted the move towards a competency-based pre-registration period allowing for competent students to register faster than the compulsory 12 months currently stipulated. In pursuing the "Maintain, retain and sustain!" philosophy, the two presenters were passionate about reducing disillusionment within the younger members of the profession. Early results from their mentoring initiative show promise, with the establishment of a web-forum and expansion of the programme to include community and industry graduates. Miss Moles stated that the use of young pharmacists as mentors was an ideal mechanism by which to empower students to grow. As a take home message to participants, Mr Rose urged them to speak to their younger members of staff. If they did not have any in their establishments then they should ask themselves why not. He urged the audience to find out what would make those that are there stay.

Importance of dialogue

Speaking at the same session Sharon Murphy Enright, president of Envision Change LLC, Richmond, Virginia, said that given that change is a certainty and not an option, pharmacists may need some simple rules for improving medicines use. These rules could evolve from inclusive dialogue, in which opinion and judgements are suspended and people listen.

Each of our health systems, organisations and departments has unique issues, challenges and obstacles to overcome, she said. "There are no universal answers for these and the complexity that surrounds us creates confusion, signifying that we are failing to see the simple in the complex." People like checklist-driven solutions. However, these simple solutions are not applicable to real-world problems, which are fuzzy, messy issues imbedded in context.

What is certain, said Miss Murphy Enright, is that there are key elements that will see us through the transition. She addressed these in her talk, emphasising the need for mentoring relationships and collaboration.

With the different strengths mentoring can bring to an interaction, the learning opportunity is enormous and leads to better collaboration. "Anyone can be a mentor and everyone can benefit from having at least one. Don't wait until you're asked. Offer to be one," she suggested.

In human systems, culture defines the rules and these tend to fall into three categories:

general direction pointing, prohibitions, and resources and permission for provisions. Prohibitions are the least enabling, the most employed and the least effective of all the rules. Instead, Miss Murphy Enright recommended following three alternative rules used by, for example, migrating birds, schooling fish, etc. These were stated as matching one's speed to one's neighbour's, avoiding collisions and always moving to the centre of the mass. Simple rules, a good enough vision and wide space for innovation can create the space and motivation for great breakthrough changes to occur, she believed.

On describing the paradigm changes in health care, she suggested that they could be regarded as following two curves, with a vortex or void in the middle known as the area of transition. The first curve dates back to the turn of the 20th century, which has culminated in the present attention to health care quality issues prompting redesign of medical education, technical capability, innovation and standards of care. We are now, she said, embarking on a revolution that will result in a dramatic reforming of all that we know in our practice. To make the leap into the health care systems of our future we will need leaders with hindsight and foresight skills. "This is not about disguising the old as the new but about innovating for a better future," she emphasised.

On average, it takes around 18 years for best practices to be adopted in the US health care system. She suggested that if pharmacists

want to progress, they need to change, and that begins with each individual: "how we think about our role, our work and our commitment to doing better and the factors that influence us." Human beings deal best with change that is incremental, follows a pattern, is predictable and, in particular, where it offers some perceptible personal goal. This type of incremental change is not what is being faced by societies today. Discontinuous and dynamic change surrounds us, the rate of which is unprecedented. Chaotic events, whether natural such as the SARS outbreak, or man-made such as war, can transform lives in the blink of an eye.

Recognise limitations

Miss Murphy Enright stated that as we progress through the void between the old and new health care system paradigms, we have to acknowledge the limitations of our personal knowledge-based expertise and begin to adopt answers and solutions that come from sharing what we know. She reminded the audience that, according to a recent Institute of Medicine report, the most important competency for health care professionals is developing the skills, attitudes, traits and behaviours that build collaborative and co-operative teams of individuals across many disciplines. However, she warned that while competencies provide capacity to deliver, they do not guarantee delivery. To overcome this, individuals and systems change when they learn. Therefore developing new behav-

iours, with feedback, in the context of work, would allow individuals to adapt and evolve with new situations, turning competence into capability. This requires dialogue.

Dialogue represents a way of thinking and reflecting together in depth, and is a way of learning to shift attitudes, knowledge and relationships. Miss Murphy Enright urged pharmacists to begin the dialogue for change within their organisations and alter the flow of conversation by adding diversity. Rather than being followers waiting for solutions, she challenged pharmacists to be leaders and to innovate by committing to the pursuit of what matters and thinking about who, or what else, needs to be at the table to make progress towards goals. "Whatever your place in the health care system," she said, "I challenge you to provide diversity and become the producer of hopes." Nobody likes change, she continued, particularly when it affects our own lives and all areas are changing simultaneously. None the less, she reminded participants that small groups change the world.

Miss Murphy Enright concluded by saying that transforming the health care system will not be an easy process. The only way things change is when people do things differently and the challenge of closing the gap between what is, and what could be, is enormous. So she urged participants to "think big" and to remember that leaders need all the help they can get: "We could take advantage of these opportunities to make lasting and sustainable improvement," she concluded.

From skill mix to skills maintenance: developments from around the world

For pharmacists to achieve a central role in improving the quality of medicines use, pharmacy technicians will have to take a greater responsibility for dispensing and the routine aspects of medicines management.

So said Peter Noyce, professor of pharmacy practice, University of Manchester, UK, when he spoke at a pharmacy practice symposium, entitled "The changing role of the pharmacist in medicines management", on 9 September.

He described how there were a number of UK policy initiatives towards moving pharmacists centre stage in the management of medicines. He also predicted that we would begin to see consultant pharmacists who would be specialist drug therapists who would probably be the first pharmacists to become independent prescribers.

Professor Noyce said that the UK needs more qualified support staff in community pharmacy and needs to register them individually. At Manchester they have recently set up the workforce academy www.workforceacademy.man.ac.uk. The academy, as well as

hosting the Centre for Pharmacy Postgraduate Education, will be a centre for research about many of these issues. A recent survey indicated that 38 per cent of the UK profession are locums, many having a portfolio of jobs. This, Professor Noyce concluded, is a major challenge to clinical governance because of the lack of continuity of care.

A Swedish view

In Sweden, changes in society, issues such as well informed consumers and new technologies, as well as non-compliance, are placing new demands on pharmacy services. Asa Granath, of Uppsala University, Sweden, described a new training programme for pharmacists and support staff. It involves: "basics", a part common for all employees which covers communication with patients; "attitudes", which covers professionalism, self awareness and patient orientation; and "specialisation". The specialisation section depends on roles and services and provided examples include self medication, patient profiles, sales, health counselling and dealing with angry customers.

A US view

Giving a US view, Peter Vlasses explained that the Accreditation Council for Pharmacy Education (ACPE), of which he is executive director, is the US agency for accreditation of degree and continuing education providers. He referred the audience to the organisation's web site, where they could find further information (www.acpe-accredit.org)

ACPE standards address five competencies that the US Institute of Medicine and the World Health Organization recognise as important for health care professionals: to provide patient centred care, to work as an interdisciplinary team, to employ evidence based practice, to apply quality improvement methods and to make use of informatics. In the US there are CE requirements for relicensing pharmacists.

Recently regulatory bodies and health professional societies in the US have begun to explore the concept of continuing professional development as an enhancement to CE. There is now a CPD tool on the ACPE web site.

How does a self-medicating consumer decide what medicines to use?

As self-medication becomes more popular and as more medicines are made available to consumers on a non-prescription basis, access to good information to help the consumer make informed decisions is critical, said Keith Johnson, co-chairman of a Pharmacy Information Section symposium on 8 September. The symposium explored two primary sources of information on over-the-counter (OTC) medicines, namely product labelling and product advertising. The role of the pharmacist in advising consumers on the appropriate use of OTCs was considered.

Barbara Mintzes, of the University of British Columbia, Canada, remarked that in addition to serving its commercial function to stimulate product sales, advertising of OTC medicines has been described as a source of information about available treatments and a resource to support responsible self-care. The presumed outcome is improved medicines use, better quality of life and, ultimately, improved health outcomes.

On the other hand, advertising has been criticised as a poor means of providing the type of unbiased comparative information the public needs to make informed health care choices. A key concern is that it trivialises medicines use, it uses emotive images and messages that fail adequately to represent treatment benefits and risks, and it omits key information of relevance to the "purchasing and treatment" decision.

Dr Mintzes examined the research evidence on outcomes of OTC drug advertising. "How does advertising affect medicine use, health care services and ultimately health outcomes and what are the key gaps in evidence," she asked.

Her review was based on a systematic search for published empirical studies (randomised controlled trials, cohort and cross-sectional studies meeting minimal methodological inclusion criteria), from 1980 to the present, in computerised health and general databases.

She concluded that research is limited, self-regulation does not ensure a balanced and accurate content and safety remains a concern. In particular there should be a review of the practice of "grandfathering", which allows old established products with questionable safety (eg, phenylpropanolamine) to remain on the market.

Making labelling more effective

Yong Kwok, of the International Labelling Dialogue Group, Australia/US, discussed the efforts being made to make labelling of OTC medicines more effective. Major changes are taking place in the way labels and leaflets are developed, she explained. Not only have



Helen Darracott: controlled advertising can communicate health benefits

these changes been influenced by the consumer movement and through deregulation in the supply of medicines but also because of the promotion of self-medication. In addition, the discipline of information design, pioneered with government tax return forms, is being applied to medicinal products.

She said there is increasing technical and experiential knowledge on which to draw in order to produce more effective labeling. She described the performance-based approach used in Australia for the past five years. It is a co-regulatory system applied to the writing and testing of leaflets and packaging that involves the industry, consumers and the government. It enables consumers to select, use and dispose of medicines more safely and effectively. She stressed the value of legislative framework to facilitate the development of usable labels and leaflets.

Advertising messages

Advertising messages need to be short, said Helen Darracott, of the Proprietary Association of Great Britain, because research shows only one or two messages can be conveyed in any advertisement. The key messages are the product name, its use, and instructions to read the leaflet and label and to ask the pharmacist for advice.

Mrs Darracott remarked that the British are conservative users of medicines. Since over 80 per cent of purchases are repeat purchases, it is hard work to persuade people to try something new. However, consumer research has shown that the mass media remain the main sources of consumer advice on health care.

Companies have tried to market products by promoting them to pharmacists and relying on their recommendations but these efforts have all failed. As with doctors, pharmacists think that the short hand text used in advertising copy means that people do not have adequate information to choose a product. As a consequence, the industry and pharmacists need to work towards a common understanding of the roles of advertising and also towards labelling that will complement product advertising. Industry needs pharmacists to supplement the messages at the point of sale and thereby improve information to patients.

Research has shown that the essential information for patients in advertisements is the name, what the product is for and who it is for, said Mrs Darracott. At the point of sale, the essential information is the name, what it is for, who it is for, the kite mark and how to take it. At the point of administration, the essential information is the name, what it is for, who it is for, the kite mark, how to take it, when to take it and for how long, side effects, active and inactive ingredients, and the name of the manufacturer.

In February 2002, the UK minister of health launched a new procedure for switching medicines from prescription status to OTC, she explained, and set a target of 50 such switches during the next five years. To date, there have been few switches other than omeprazole and the statins and little sign of other products on the switch list, such as cyclo-oxygenase 2 inhibitors and various asthma products moving to "pharmacy only" status. She reminded the audience that switched products need to be advertised to the public and the PAGB has produced best practice guidance for advertising formerly restricted indications. Advertising materials for these new indications may need to convey more complex messages. In particular, this would apply when products are indicated for the management of long-term conditions and disease risk reduction.

Controlled advertising is an effective means of communicating the indications and benefits of products to the consumer but it needs to be supplemented with advice from pharmacists, concluded Mrs Darracott.

Pharmacist's role abrogated?

In presenting a developing country's perspective, Alexander Nii Oto Dodoo, a community pharmacist from Ghana, asked whether advertising and labelling have abrogated the role of the pharmacist in advising consumers on the appropriate use of OTC medicines.

How can pharmacists advise consumers on the appropriate use of OTC medicines when they are not always present to supervise sales?

This is a particular problem when consumers know the products they want, based on the stream of advertisements they receive. Medicines regulatory authorities in some developing countries are in their infancy and may be incapable of regulating laws governing promotion and supply of medicines. DTCA of medicines is rife and demand for products appears to be advertisement-driven.

The quality of labelling of products is variable, said Mr Dodoo, leading consumers to rely heavily on advertisements. Knowledge, attitudes, beliefs and practices were factors in a study of drug use in Ghana. This showed that 60 per cent of the population rely on radio for their information on medicines. These developments abrogate the role of the pharmacist in advising consumers on the appropriate use of medicines. However, they offer opportunities for pharmacists, especially those in resource-limited environments, to bridge the knowledge gap and supply appropriate products on the basis of suitable information and education. The development of protocols for the supply of OTC medicines in pharmacies and the provision of counselling areas will facilitate this process, affirmed Mr Dodoo.

Clementine Stuijt, of Stichting Health Base, the Netherlands, asked whether there is still a role for the pharmacist in advising consumers

Points of view

During the discussion period, a delegate from Costa Rica remarked that pharmacists had not grasped the wider role needed in response to the advertising to patients of prescription products that have been declassified. When attempts were made to introduce OTC products into Costa Rican pharmacies, this was a failure, due to a lack of profitability and misunderstanding of pharmacy practice in Latin America. Panellists commented that there is an increasing need for pharmacists when more potent medicines are becoming available over the counter, that internet information may not be reliable, that advertising medicines can never provide the public with an adequate overview of the available choices of medication and that labelling does not help consumer choice, only amplifies a particular product once the choice is made.

A US delegate indicated that she teaches schoolchildren how to obtain health information from the internet but she questioned whether all US pharmacists provide sufficient information when supplying OTC medicines. In Ghana, the public are bombarded with radio and television advertising so that it is essential for pharmacists to provide a balanced view to their patients, said Mr Dodoo.

A delegate from Australia felt that models for treatment rather than product based information should be available. It was noted that the European Agency for the Evaluation of Medicinal Products (EMEA) is considering the whole gamut of information to the public.

about OTCs. Over the past few years, the volume of business of OTC medicines compared with prescription only medicines has gradually diminished in European community pharmacies. This contrasts with the increased marketing activity in OTCs. In addition, in the Netherlands, the interest in a "first line OTC pharmacist" is declining, probably caused by the increased workload in pharmacies.

However, there is a trend in some European countries for pharmacies to be the

first port of call in primary care for minor ailments. This is encouraged by governments because it reduces GP workload without increasing health care costs. National education strategies are needed to support the appropriate use of OTC products, particularly those for treating minor ailments, said Ms Stuijt. She concluded that advertising to the public is a challenge to community pharmacists requiring them to have a new approach to the consumer.

Does direct-to-consumer advertising of medicines have any advantages?

One of the key policy decisions that divides opinion at present is whether or not to allow pharmaceutical manufacturers to engage in direct-to-consumer advertising (DTCA) of prescription only medicines. So commented Andy Gray, of the University of KwaZulu-Natal, South Africa, when he opened a joint symposium of the Hospital Pharmacy and Industrial Pharmacy Sections on 8 September

An argument based on the need to ensure an informed and empowered consumer and citing the paternalistic origin of current thinking, can be construed in favour of DTCA, he said. In contrast, opponents of DTCA point to the need to ensure patient access to unbiased, independent information about medicines and also to evidence regarding the impact DTCA has on patient demands for medicine, sometimes for inappropriate medicine. Although DTCA of prescription medicines is legal in only two industrialised countries (New Zealand and the US), the situation in developing countries is less easily described. Developing countries with effective medicines regulatory authorities may prohibit such practices, but in many countries there is no effective control.

Studies of the impact of DTCA on medi-

cine prescribing and use have generally been performed in developed countries and have focused predominantly on ambulatory, not hospital, care. However, quality use of medicines in hospitals and organised health care settings depends to a great extent on the effective use of essential medicines lists or formularies, standard treatment and local practice guidelines. Such tools are of more importance in resource-constrained settings and can be undermined by DTCA because there is a lack of effective control over medicines as a whole and lack of evidence of the impact on marketing activity.

The problem is that prescription medicines are not ordinary articles of commerce and advertisements do not provide patients with the information they need. The pharmaceutical industry likes to think that it is empowering the consumer to make independent decisions about medicines selection but "advertising" does not equate to "information", Mr Gray declared.

In South Africa, the Medicines and Related Substances Act bans advertising to the public of prescription and pharmacist prescription medicines but allows pharmacy sale and open sale medicines to be advertised under controlled conditions.

The concept of "health fraud" and measures to ban the advertising and sale of products not proven to be safe and effective are to be added to government regulations and controls of "unregistered uses" are being tightened. A code of advertising practice has been produced and will be enforced by a new "expert committee". Non-compliance with the code will be an offence.

Advertising does not include factual, accurate information, trade catalogues and price lists. "But who decides what is factual information and what is a product claim, measure or trade practice," queried Mr Gray.

Areas identified as specific problems are vitamins, weight management products and claims of "traditional use". DTCA is often directed at a few new and expensive drugs. At the Second International Conference on Improving Use of Medicines (ICIUM), a report from Karnataka, India showed that between 1999 and 2002, 10 per cent of total public sector budget was taken up by a single agent (a non-steroidal anti-inflammatory). Mr Gray reported on evidence from Thailand that showed how intensive promotion to prescribers can alter health professionals' behaviour and counter rationale medicines policies.

Because of weak legislation, the move to

Do benefits outweigh harm?

Barbara Mintzes, of the University of British Columbia, Canada, asked whether benefits outweigh harm. She said that she had examined the empirical research evidence on DTCA through a systematic search of computerised health and general databases from 1991–2003.

She classified both print and broadcast advertisements into three types, namely “full advertisements” (brand name and health claims), “reminder” (brand name only) and “disease oriented or help seeking” (no brand mentioned — ask your doctor about new treatments for condition X). She noted that over a five-year period in the US from 1996–2001, dollars spent on DTCA had increased over four-fold to \$2,500m.

The key claims of benefit are that advertisements provide needed information on health and medicines, there is better doctor/patient communication, that people with undiagnosed diseases seek health care sooner, that advertisements lead to better compliance and that a doctor’s prescription is needed so the patient is protected. Key claims of harm are that advertisements aim to persuade rather than inform or educate, that information is biased and incomplete, that unnecessary or inappropriate drugs are used, that it is a threat to public health care as it causes an unsustainable increase in drug costs and that it puts pressure on doctors and harms the doctor/patient relationship.

Dr Mintzes said that in a systematic review of empirical research on DTCA, she had found no reliable information on its effect on patient compliance, admissions to hospital, total health care costs or whether the advertisements help people get the treatment they need earlier.

A 2003 US telephone survey about advertising involving 1,039 patients had addressed the question of new and earlier diagnosis but Dr Mintzes considered this to be a flawed study as there was no control group and thus no way to know whether consultations stimulated by DTCA resulted in fewer or more new diagnoses than other consultations. Recall bias is likely because the study relied on unconfirmed self-reporting.

She cited examples of large increases in sales of advertised medicines in New Zealand and the US. According to consumer surveys, one in 14 US patients asked for a specific brand of medicines and 70 per cent received a prescription, and one in eight New Zealand patients asked for a specific brand and 62 per cent received a prescription.

Dr Mintzes provided comparative data from two cities — Vancouver, Canada, and Sacramento, US — that indicate that DTCA affects prescribing decisions in primary care. Patients in Sacramento reported more exposure and requested more medicines but in both settings physicians prescribed three quarters of requested brands. The results of this study were consistent with surveys of physicians in New Zealand and the US that report pressure to prescribe products subject to DTCA.

In considering examples of printed DTCA, Dr Mintzes concluded that their educational value is minimal.

“free trade” has led to increases in unethical promotion in the media. Four South East Asian countries (Indonesia, Laos, Thailand and Vietnam) are addressing this issue. A multi-country project to improve application of the World Health Organization “Ethical criteria for medicinal drug promotion” is being undertaken.

In considering the way forward, Mr Gray believed that effective policies and interventions needed to be based on evidence. He rejected the NERO defence (no evidence of risk is evidence of no risk). An important tool for those working in this area will be the recently launched WHO/Health Action International drug promotion database.

A view from the industry

Jane Nicholson, of Bristol-Myers Squibb, UK, discussing the provision of information to patients by the pharmaceutical industry, said that although DTCA of prescription medicines is illegal in Europe, some information can be provided to the public, such as the legally approved wording of patient information leaflets and summaries of product characteristics (SPCs). The Medicines Partnership set up by the NHS has shown that despite the introduction of new medicines which have fewer side effects and are more convenient to use, patients still do not take them as prescribed, resulting in massive costs to both the patient and the NHS. The most important predictor of compliance is the “beliefs that patients have about their medicines”. In line with the British Government’s plans for the future direction of pharmacy, the focus is on the move from patient compliance to concordance and the provision of information and support to patients as “partners in medicines taking”. The potential for collaboration between pharmacy and the pharmaceutical industry on the provision of information is clear, said Mrs Nicholson.

Although not supporting the type of “in your face” advertising employed in the US, Mrs Nicholson said she considers the industry in Europe should be able to provide far more information to patients about their products. The internet has revolutionised the availability of information from industry sites and she noted that health education, methods of disease prevention, positive information on why a medicine is important and how to get the most out of the treatment, should be available to patients on these sites. The printing of product information website addresses on packs should be allowed.

Mrs Nicholson described the medicines information project run by Datapharm Communications. The advisory board includes representatives from the Department of Health, the Medicines and healthcare products Regulatory Authority, NHS Direct Online, and patient and voluntary organisations, as well as the professional bodies of pharmacy, nursing and medicine. The current project is to produce medicines guides that will link the Electronic Medicines Compendium (of SPCs) and patient infor-



Jane Nicholson: potential for pharmacy and industry collaboration

mation leaflets with NHS Direct Online, the Government’s information service to patients.

For various conditions classified from a patient perspective, scoping groups are being established. Datapharm will arrange meetings between the companies involved, patient groups, health care specialists and health providers. Each group will identify specific issues (such as the background of the condition), consider patient specific knowledge, review problem areas and new treatments, and look at health professionals’ perceptions, specialist groups, the framework for the Guide and assessment of its effectiveness. A group of pharmacists working for Datapharm will write the guides from an agreed standard template.

High quality, patient-friendly information produced by the pharmaceutical industry helps to inform patients and well informed patients are more likely to adhere to prescribed medication, Mrs Nicholson concluded.

Criticism

Criticism of DTCA has taken three main themes said Dolly Judge, of Pfizer, US. They are that DTCA increases overall health care spend, that the pharmaceutical industry spends more on DTCA than research and development and that DTCA leads to inappropriate use of medicines.

“In the context of the overall criticism of the pharmaceutical industry, the value of pharmaceuticals is not well appreciated and the dynamics of innovation is not well understood by the public or Governments,” Mrs Judge said. She showed US Government figures indicating the pharmaceutical industry spends twice as much on R&D than on the whole of their marketing activities.

She demonstrated from graphs produced by the Centres of Medicare and Medicaid Services that, after 40 years, pharmaceuticals still amount for about 10 per cent of total US health care spend. There is almost no difference in premiums of health care plans that do or do not cover prescription medicines. New medicines have been shown to be cost effective, not only through substantial savings on inpatient costs but also on home help, office visits and outpatient costs. However, non-adherence to medication, which amounts to 50 per cent in patients with chronic condi-

tions, is costly. The main reason, she said, that patients reported lack of adherence to taking blood pressure lowering therapy was "I just forgot".

Co-payments for prescription medicines in the US are increasing faster than prescription medicines prices, noted Mrs Judge. She showed evidence in patients with diabetes, asthma and gastric disorders that reductions in medicines use because of higher patient co-payments resulted in substantial increases in overall health care costs due to the increased number of hospital visits.

The two "business problems" for the pharmaceutical industry are undiagnosed patients and patients who forget to take their medicines.

Concluding, Mrs Judge said that DTCA advertising is one of the tools patients use to become better educated health care consumers. Advertisements only work if patients speak to their physicians about prescription medicines and these consultations frequently lead to uncovering undiagnosed "high priority" conditions such as hypertension and diabetes.

Diagnosics — pharmacist and patient partnerships in health care

Pharmacists can be highly involved in educating patients before positron emission tomography (PET) or computed tomography (CT) investigations, said Laura Ponto, associate research scientist, PET Imaging Centre, University of Iowa. Speaking at a nuclear medicine/radiological pharmacy special interest group meeting on 6 September, Dr Ponto said that patients must be provided with the correct dietary advice to ensure that their glucose and insulin levels are within normal ranges. "If patients have diabetes, pharmacists need to be more involved in their management in order to bring their glucose and insulin levels under control," she added.

Control is vital because PET technology relies on competition between 2-fluoro-2-deoxy-D-glucose (FDG), a glucose analogue, and normal glucose molecules in the body along the glucose metabolic pathway. There is competition at two points: uptake into cells and phosphorylation. The main transporters of importance along this pathway are the GLUT1 and GLUT4 transporters. GLUT4 transporters are usually found in heart, lung and skeletal muscle areas. If the levels of glucose in the body increase at GLUT1 receptors, this halves FDG efficiency and vice versa. Bringing glucose levels into the normal range will minimise the risk of false positive readings, which can also occur if there is an infection present such as tuberculosis.

Other important pharmaceutical care issues involve ensuring that patients have fasted for a minimum of four hours before a procedure. When patients first come for a scan, Dr Ponto recommended that the first thing pharmacists should do is to measure their glucose levels. She suggested there is no excuse not to do so now, with the availability of small, hand-held meters that are quick to use and highly accurate. If the patient is taking other medicines, pharmacists should ensure that there are no interactions. These will typically be with those drugs that affect glucose in the body, such as laxatives, insulin, dopamine and



Laura Ponto: pharmacists must get involved in patient management

colony growth stimulators that may cause bone metastases to be masked, said Dr Ponto. Corticosteroid use in cancer patients poses particular problems because these have a tendency to cause glucose levels to fluctuate erratically.

Patients may also be rather anxious and tense. It is, therefore, important to ensure a warm, calm, supportive environment and, where necessary, sedation should be considered. She reminded pharmacists that if they were to recommend sedation then patients must be counselled about the effects of such medication on driving. They should not drive home themselves.

If patients are in pain, they should have adequate pain control administered before the procedure, which can last anything up to 20 minutes in an enclosed area, as they will not be able to maintain a steady position during this time. A common physiological issue is coughing. To overcome this, Dr Ponto suggested the use of a sugar-free cough mixture

to ensure glucose levels are not affected. Her recommendations are based on the assumption that the patient is being treated as an out-patient. However, some patients require admission to hospital before procedures and, in these cases, it is important to ensure that they are not administered glucose drips. Rather, a simple saline solution or water should be used to prevent adverse glucose effects, she said.

PET scans are useful for a range of cancers but are not so good for investigations along the gastrointestinal tract or the liver, kidney and bladder areas. These show up as "hot spots" due to the kidney recognising FDG as not being glucose and therefore, instead of re-absorbing it, eliminating it. Prostate cancer, apart from being close to the bladder "hotspot", is a slow metabolic cancer and therefore not suitable for investigation using PET technology. A newer version of the technology now operates on the principle of combining PET (functional) use with CT (anatomical) use. This has many advantages: it is less noisy, faster and allows anatomic co-registration so reducing the need to put the patient through two different scanning machines, thereby preventing diagnostic problems arising from inexact positioning. Also, the attenuation correction factor that needs to be applied to the PET can be applied much quicker. Whereas PET could not investigate areas such as the GI tract, the combined PET-CT scanner allows oral contrast enhancement procedures to be performed. In these cases, Foley catheterisation is sometimes required as well as treatment with furosemide 20mg, in intravenous form, around 30 minutes before scanning. Disadvantages with the machine include claustrophobia and interference with artefacts such as dental work, artificial joints, barium contrasts and implants as well as any metal or high-density devices. The arm positioning (elevation above the head) also proves to be uncomfortable. The main disadvantage, however, is the higher radiation doses delivered.