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FIP 2010: pharmacy's exploratory journey

/ COVER STORY THIS SUPPLEMENT TO THE PJ CONTAINS REPORTS FROM THE 70TH CONGRESS OF THE INTERNATIONAL PHARMACEUTICAL FEDERATION / PRACTICE DISCUSSION ON THE ROLE OF PHARMACISTS AND HOW THEY ADD VALUE / HOSPITAL ANTIBIOTIC RESISTANCE PATTERNS / INDUSTRY THE CONTINUING GLOBAL BATTLE AGAINST COUNTERFEIT MEDICINES

It is fundamental for pharmacists to be trained effectively to take on new roles

In his address at the opening ceremony of the 70th World Congress of Pharmacy and Pharmaceutical Sciences, Kamal Midha, departing president of the International Pharmaceutical Federation, drew parallels between a story of maritime explorations and pharmacy in 2010. Benedict Lam reports

What parallels can we draw between Portugal's 500-year history of maritime explorations and global pharmacy, healthcare and the International Pharmaceutical Federation in 2010, asked FIP president Kamal Midha during the congress opening ceremony. He answered: "Today, we continue a journey of exploration — not in navigating the seas, but in exploring the challenges and critical needs in our schools, laboratories and communities in pursuit of global health."

Quoting his presidential address at the Beijing congress in 2007, Dr Midha suggested that the future of pharmacy and global healthcare is in our hands, whether as a pharmacy in an isolated village in Africa or as a modern pharmaceutical unit in a plush private hospital in Europe. In becoming pharmacists and pharmaceutical scientists, we dedicate our lives to global health and quality of life to make our world a healthier world, he declared.

The vision set in the 2008 strategic plan promises and ensures that, where medicines and healthcare are discussed, FIP is at the table, Dr Midha reminded the audience. The ultimate goal of FIP's work is to make a positive impact on patients' health outcomes.

Dr Midha described some recent collaborative initiatives FIP has had with the World Health Organization. These include the rational use of medicines, strengthening the pharmaceutical workforce and patient safety.

As a founding member of the World Health Professions Alliance (WHPA), FIP is bridging together health professionals in medicine, nursing, dentistry, physical therapy and pharmacy at an international level, Dr Midha said. "Our joint initiatives build further recognition and visibility of pharmacists and pharmaceutical scientists as valuable and integral, effective and efficient members of healthcare teams," he added. Some specific initiatives include the positive practice environments campaign, the WHPA conference on regulation, and the counterfeits campaign. Dr Midha said that a joint vision of collaborative practice is also being developed with members of the WHPA.

Moving on to education, Dr Midha said the roles of pharmacists and pharmaceutical scientists are constantly evolving. He explained that FIP brings these roles together in the board of pharmacy practice and board of pharmaceutical sciences in the context of education. FIP has placed pharmacy practice and science, supported by education, on the international healthcare map, he said.

"It is fundamental for pharmacists to be well educated and effectively trained to take on new roles," Dr Midha emphasised. Again, quoting his address from the Beijing congress, he said: "For a truly collaborative patient-centred healthcare focus, pharmacists must be respected and have equal status as full healthcare team members based on competence established through contemporary and rigorous educational standards." Pharmaceutical scientists must be encouraged and empowered to develop new

Kamal Midha: Pharmacists are the most accessible healthcare professionals

The 70th **World Congress of Pharmacy and Pharmaceutical Sciences**, organised by the International Pharmaceutical Federation and the Portuguese National Association of Pharmacies, took place in Lisbon, Portugal, from 28 August to 2 September 2010

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FIP congress

The opening ceremony featured Katia Guerreiro singing traditional Portuguese Fado

There was also entertainment from "A Feminina", a musical group composed of pharmacy students from the Pharmacy University of Lisbon, Portugal

and innovative therapies, Dr Midha continued. The impact of the pharmaceutical sciences on health, through developing need-based therapies, has been impressive so far. However, resources — both human and financial — are needed for the developing world, he added.

Dr Midha explained that FIP invests in the education of thousands of pharmacists and pharmaceutical scientists. "Our efforts and achievements have increased through the work of the Global Pharmacy Education Taskforce," he added. FIP is instituting academic institutional membership, which will strengthen FIP networks among academia to advance pharmacy and pharmaceutical sciences education globally, he said.

As the global hub for pharmacy practice and pharmaceutical sciences, FIP provides the collaborative platform for pharmacists and pharmaceutical scientists worldwide to exchange and learn from one another, said Dr Midha. "We interweave our strengths to support better health outcomes. Through FIP, we do together, with and for each other, what we cannot do alone," he added.

To advance pharmacy as a profession, Dr Midha believes that pharmacists and pharmaceutical scientists need to:

- Use technology intelligently, such as information technology informatics systems for drug supply, electronic prescriptions and e-health records
- Innovate beyond established boundaries of fixed horizons, with a focus on public health programmes, such as health promotion services and disease management
- Plan thoughtfully and responsibly to meet unexpected changes in the way we do business, research and care for patients

Many pharmacists, in their daily practice, provide advice to patients without selling medicines, Dr Midha acknowledged. They are the most accessible healthcare professionals and this is a praiseworthy point. More importantly, he added, pharmacists' accessibility as health professionals provides clear benefits to patients everywhere.

"As students, practitioners, scientists, elected officers and members, we all have a stake in improving health," declared Dr Midha. "We must make suggestions for beneficial change then work towards implementing such change, and change will occur," he said.

NEW FIP PRESIDENT ELECTED

Michel Buchmann, of Switzerland, was elected the new International Pharmaceutical Federation president at the 70th FIP congress.

Dr Buchmann is assuming the role after extensive experience within FIP boards, community pharmacy practice and Swiss politics. Following the release of the election results, he emphasised his commitment to advancing FIP's strategic plan to advance pharmacy practice, the pharmaceutical sciences and pharmacy education at a global level.

Dr Buchmann will serve a four-year term (until 2014) following the presidency of Kamal Midha, who now takes up the office of FIP immediate past president.

What is the role of the pharmacist?

The role of the pharmacist is evolving, but what do patients think their roles in the health system are, and does pharmacists' changing role offer value for money and bring benefits to patients? Benedict Lam reports

Pharmacists have moved from a compounder of medicines to a dispenser of mass-produced products, suggested William Zellmer, president of Pharmacy Foresight. However, he added, from a long-term perspective, a dispenser role is not sustainable.

Mr Zellmer suggested that the pharmacist's role of providing medicines and ensuring patients know how to use them is an appealing vision because they have the ability to prevent and resolve medicines use problems. Mr Zellmer believes this vision is being realised in some areas, for example, in some hospital pharmacies. However, he thinks that "corporatisation" and "big business" are stopping this vision from being realised.

Mr Zellmer said that there are two profound unresolved issues in pharmacy:

- **What is the mission of the pharmacist?** Is the role of the pharmacist a supply function or a clinical function? Mr Zellmer believes that traditional pharmacist culture such as accuracy, control over everything and caution inhibits the clinical function from flourishing. Also, personality traits, such as introvertism, avoiding risk, low self-esteem (all of which are common traits in pharmacists) also hinder the clinical function of the pharmacist from developing
- **What drives pharmacy?** Mr Zellmer asked if the driver of pharmacy is a business imperative (ie, to create profits and amass wealth) or a professional obligation (ie, to provide a personal health service)

Creating a bright future

Mr Zellmer asked the audience which tactics may help ensure that the profession of pharmacy practice will have a bright future. He thinks the approach of regulatory protection is likely to fail over the long term. It would be better if pharmacists were given a legal scope of practice, he said, which would let them have the legal freedom to offer services and, in return, receive financial reward. Additionally, he believes that regulatory protection is often perceived as protecting the interests of pharmacies rather than of patients. Mr Zellmer suggested two type of changes are needed to transform the role of the pharmacist: structural changes (eg, educational reform, legal scope of practice, payment for clinical services, relationships with prescribers, patient privacy in pharmacies and technician empowerment) and changing the self-concept of the pharmacist.

What do patients expect?

Do patients' views and expectations of pharmacists match those of the profession, asked Janine Traulsen, faculty of pharmaceutical sciences, University of Copenhagen. In short, the answer is no, she declared.

William Zellmer: is it business imperative or professional obligation that is driving pharmacy?

Professor Traulsen said that, although there are many studies on patient/customer satisfaction, there is little research about patient/customer expectations of pharmacists. She believes currently the pharmacists' role in healthcare is invisible.

Her team conducted a small pilot study that surveyed 53 community pharmacists and 97 patients in Denmark to find out whether patients' views and expectations of pharmacists and pharmacy match those of the profession. The results revealed that patients expect that staff be service-oriented, including smiling and being friendly; staff give information and advice about medicines; staff have extensive knowledge about medicines; they are given a quick, efficient service; and that products are in stock.

Pharmacists think patients expect that staff have extensive knowledge about medicines; staff provide a quick, efficient service; products are in stock; pharmacy is an integrated part of the healthcare sector; staff help provide the best possible drug therapy; staff are service minded, including smiling and being friendly; pharmacy is only a retail shop and staff are only capable of selling; and staff are interested in making money for the pharmacy.

Professor Traulsen believes that, although there is some overlap between the views of patients and pharmacists, overall, the views do not match. Customers expectations are more focused on the service the pharmacist/pharmacy provides, while pharmacists have ideas about what patients think of pharmacy that the patients do not mention.

Professor Traulsen said that the differences between patient views and expectations and those of the profession need to be addressed. At the moment, patients' expectations of pharmacists are low (compared with physicians) and patients are generally satisfied with pharmacists and the services they provide.

Do pharmacists offer value for money?

Pharmacists' changing role has contributed to economic savings, said Suzete Costa, executive director, Centre for Health Evaluation and Research, National Association of Pharmacies Group, Portugal. This ranges from prescription interventions and screening and monitoring illnesses to compliance programmes and disease management. For example, she said that, in the US, the rate of generic substitution has increased from 61 per cent (2006) to 69 per cent (2008), which resulted in savings of €89.7m.

Ms Costa explained that value is the worth of goods or services as determined by the market. However, she asked how a monetary value could be placed on pharmacy services when there is no market price. She added that research on economic outcomes in community pharmacy is limited.

There are methods used by economists, said Ms Costa. The cost-benefit method measures the monetary value of both costs and benefits of a service. The second method, willingness-to-pay, is a contingent valuation technique that measures the maximum amount a person is willing for a service.

Ms Costa mentioned that a study that aimed to estimate the volume, cost and economic value of free Portuguese pharmacy services in 2008 revealed that the total monetary measure of society's welfare increment generated by the top three services (non-prescription medicines/minor ailments, prescription-only medicines and point-of-care measurements) is €48.1m. She believes that, in the future, comprehensive remuneration systems (not just payment of services) that combine product and service will need to be developed. She also believes economists need to be involved to measure pharmacy's value for money.

What is the added value of pharmacists in the supply of medicines to patients?

Benedict Lam reports from a session that addressed how pharmacists have had and will continue to have an impact on the use of medicines, allowing them to achieve their intended economical, clinical and humanistic outcomes

There have been dramatic changes in the practice of pharmacy over the past 40 years, said Glen Schumock, professor and director, Centre for Pharmacoeconomic Research, University of Illinois at Chicago. The most notable is the transition from product orientation to patient orientation, he added.

In literature, the following terms have been added to the profession of pharmacy through time:

- Clinical pharmacy services (1970s)
- Consultant pharmacy services (1980s)
- Pharmaceutical care (1990s)
- Medication therapy management (2000s)
- Medical home/patient-centred care (2010)

Traditionally, the value of the pharmacist in product-related functions has been closely tied to the price of a prescription, Dr Schumock said. However, pharmacist clinical services have been more difficult to place a value on. He believes that clinical pharmacy services can improve outcomes, save money and make money (eg, bill for clinical pharmacy services).

The value of clinical pharmacy is defined by the ability to improve clinical, humanistic and economic outcomes, given the cost to provide such services, explained Dr Schumock. There is evidence from literature that clinical pharmacy services are likely to improve clinical and humanistic outcomes, particularly for certain services or diseases. Also, clinical pharmacy services are likely to improve economic outcomes and reduce healthcare use, thus saving money, he said.

How to select the "right" service

There are some factors to consider when selecting the "right" clinical pharmacy service, Dr Schumock said. Some of these include patient population, the service provider's focus and strategic initiatives, the overall feasibility of offering the service and evidence that indicate a particular service works (see Panel for practical approaches that could be used to justify the uptake of a clinical pharmacy service). Additionally, Dr Schumock suggested that it may be helpful to develop a business plan when considering implementing a clinical pharmacy service.

Overall, Dr Schumock said the opportunity to implement clinical pharmacy services continues to increase with ageing of the population, increased use of pharmaceuticals, increased complexity of drug regimens and increased cost of pharmaceuticals and healthcare. Previous literature supports economic, clinical and humanistic outcomes of clinical pharmacy services but there is a need to be able to justify economic value of the service in its setting, he concluded.

PRACTICAL APPROACHES THAT COULD BE USED TO JUSTIFY THE UPTAKE OF A CLINICAL PHARMACY SERVICE

Practical approaches that could be used to justify the uptake of a clinical pharmacy service include:

- Interpret/generalise data from other studies
- Economic modelling/projection
- Prospective evaluation (ie, pilot study)

Data from other studies The advantages of interpreting/generalising data from published studies are that it is quick, inexpensive, peer-reviewed, has a variety of services and results available and has information available before implementation.

The disadvantages are that there are variations in quality of published studies, applicable studies may not be available for the service being planned and available studies may not be convincing to decision-makers.

Economic modelling/projection Economic modelling/projection:

- Combines evidence from literature with own internal estimates (ie, costs, benefits)
- Determines when/if programme will break even
- Incorporates sensitivity analysis in projections (ie, what if patients miss appointments?)

The advantages of this approach are that it is inexpensive and quick, it yields organisation-specific results, and sensitivity analysis can be used to confirm results. Additionally, data collection is unobtrusive and modelling/projection can be conducted before service implementation.

The disadvantages are that results depend on assumptions, there is a potential for bias, and decision-makers may not accept results of projection.

Prospective evaluation Prospective evaluation involves implementing the programme (on a trial basis, pilot study), measuring actual costs and benefits and comparing the programme with "no service" or the next best opportunity.

The advantages are that it is flexible, it provides organisation-specific data, there is high internal validity (when appropriately designed), and this approach is more likely to be accepted by decision makers.

The disadvantages are that it is expensive (time and money), there are many design challenges (control or randomisation may not be feasible), there is a potential for selection bias, it requires an adequate sample size, and it needs resources and authorisation to start.

Maigi/Dreamstime.com

Professional organisations are crucial to the advancement of the profession

Revolutionary changes in the healthcare sector are happening and pharmacy, being an important stakeholder in the healthcare value chain, has felt the need to adapt, too, said Bhojraj Suresh, vice-chancellor, JSS University, Mysore, India.

This has meant that pharmacists have to shift their attention to patient-centred, outcome-focused care in order to optimise the safe and effective use of medicines, he commented.

At the root of this change is a movement to revisit the true focus of the profession — the patient, Dr Suresh said. He believes that the profession is now dedicating itself to a philosophy of practice that clearly identifies the patient as its primary beneficiary.

These changes have brought about the consolidation of pharmacy as a practising profession and the formation of many professional organisations. The importance and status of the profession thus will grow in the near future, said Dr Suresh.

He added that, with the ever increasing need for globalised standardisation among industry and competition, it is evident that both the industry and practice will benefit from the formation of such professional organisations.

Dr Suresh defined a professional organisation as a non-profit organisation seeking to further a particular profession, the interests of individuals engaged in that profession and the public's interest. The role of professional organisations include theorising change, advocacy, professional representation, education and meetings, publications and information, standard development, research and statistics, leadership development and public service.

Bhojraj Suresh: professional organisations play a role in advocating the cause of the profession

An example from India

Using pharmacy in India as an example, Dr Suresh explained how a professional organisation could facilitate change in the public's view of the profession. In the 29th report of the Standing Committee on Petroleum and Chemicals (2002) under the Ministry of Chemicals and Fertilisers (Department of Chemicals and Petrochemicals), the professional role of a pharmacist was sidelined. In the report, the committee had recommended that the government should explore the possibility of relaxing the provisions of The Drugs and Cosmetic Act 1940 so that educated persons, other than pharmacists, could sell medicines after some short training through public distribution system. The committee further stated that the pharmacist is the main hurdle to easy accessibility of medicines and this move will provide better job opportunities to educated persons other than pharmacists. Only when the pharmacist has been accepted as a vital member of the healthcare team can the necessary supporting services be organised with the professionalism that they demand.

Dr Suresh said that, when the report was released, the Indian Pharmaceutical Association was vociferous in its opposition to the recommendations. The association initiated continuing professional development for pharmacists and recommended to the Pharmacy Council of India to make CPD mandatory for renewal of registration.

It also supported the initiative of the Pharmacy Council of India in the introduction of the PharmD programme. Additionally, it created consumer awareness through National Pharmacy Week, which celebrated the significance of pharmaceutical care and the role played by pharmacists in medicines management. Through its media campaign and the integration of pharmacists with other health professions, today, in India pharmacists' role in healthcare delivery is recognised, Dr Suresh said.

Dr Suresh believes that professional organisations provide unique opportunities for not only networking, career advancement and personal skills development, but also play a leadership role in advocating the cause of the profession. He thinks individuals, as well as organisations, should strive to assure the advancement of the profession.

It is cheaper to prevent than to treat

Pharmacists are at the frontline of healthcare and are trusted professionals, said Joao Silveira, president of the Portuguese Host Committee. He suggested their future roles would focus on disease prevention, screening (early diagnosis) and distribution of medical products and medication therapy management.

Mr Silveira emphasised that pharmacists should play a major role in disease prevention since it can improve quality of life and save money (ie, it is cheaper to prevent than to treat).

Some examples of disease prevention strategies that pharmacists could offer include self-care, education (eg, diabetes, smoking cessation, weight management), health promotion (eg, in pharmacies and schools) and immunisation promotion and delivery. He also believes that pharmacists would become more involved in the diagnosis and screening of diseases such as diabetes, hypertension, dyslipidaemias, HIV, hepatitis, asthma, etc.

In terms of medication therapy management, Mr Silveira said that, in the future, pharmacists would become more involved with medication reviews, adherence programmes, home care services, administration of medicines, directly observed therapy (eg, drug addiction, HIV, tuberculosis), monitoring treatment (eg, for adverse effects) and pharmacogenomics. Mr Silveira said that there will be increasing differentiation between pharmacies in the future since different pharmacies will offer different services to patients. He noted that pharmacists should not just be paid for the medicine supplied, but also for the services and outcomes, too.

In order for pharmacy to have an integrating role in the healthcare system, Mr Silveira suggested that strong pharmacists' organisations are needed, reliable relationships with patients are built and there needs to be an efficient partnership between pharmacists and physicians/other health professionals, and also wholesalers, pharmaceutical industries and payer authorities.

Current challenges for community, hospital and industrial pharmacy

The pharmacy profession is constantly challenged by changes globally. From this session organised by the FIP Young Pharmacists Group, Gordon Geddes reports on current and future challenges for the profession

Vibhuti Arya of the Department of Health, New York, US, described pharmacists as among the most accessible healthcare professionals, most of whom are based in the community. In an evolving profession, the role of community pharmacists is shifting, she said. Every opportunity should be taken to communicate with patients, for example, when a patient has a new pacemaker fitted.

Dr Arya continued by examining the perceived value of a pharmacist service from three perspectives, namely, those of the pharmacist, the patient and other health professionals. She said it is important to consider the overall public view of the pharmacist as an advocate of the patient.

Any changes to community pharmacy would have an impact on the business model, Dr Arya argued. The move from product to service would require payment models for sustainability to meet patient needs.

The pharmacists' role in public health was considered. Dr Vibhuti saw empowered community pharmacists as builders in the community. She asked how the audience envisioned future practice, and said there is a balance to be struck between access to medicines and patient education. Young pharmacists could be used as agents of change, she suggested.

Dr Arya concluded that the factors to be considered were: that the pharmacist is a gateway to patients' health; there should be synergy among community pharmacists and primary care providers; and there needs to be mobilisation of other agents to act as an advocate on behalf of pharmacists.

Pharmacists should take every opportunity to communicate with patients

Increased demand for pharmacists

Lynnae Mahaney, hospital chief from the US and immediate past president of the American Society of Health-System Pharmacists, discussed new challenges in hospital pharmacy, which covered workforce (demographics, training and the expanding roles of pharmacists), patient safety and implications of the 2008 International Pharmaceutical Federation global conference on the future of hospital pharmacy held in Basel, Switerland.

There are 57 countries that have a health workforce crisis, reported Ms Mahaney. Reasons for this include feminisation, part-time working and the proportion of the workforce that is actively practising. Additionally, changing pharmacist roles, including direct patient care and increased specialisation, contribute to the increased demand for pharmacists. The technician workforce should be developed to support the role of the pharmacist, she said.

Optimising research and development

Pedro Barata, from University Fernando Pessoa, Porto, Portugal, defined "big pharma" as the 12 pharmaceutical companies that appear in the Fortune 500. He reported that 80 per cent of "big pharma" revenues comes from drugs that were released in the early 1990s. There are 10 major drugs on the 2010 patent expiry list (the "patent cliff").

Dr Barata discussed the major methods used to optimise research and development, including co-operation between industry and academia and the use of biotechnology and nanotechnology. He outlined smaller innovations that could add value, such as production optimisation, new routes of administration, clever dosage forms, bioavailability forms, bioavailability enhancement, excipients, paediatric dosing, chronotherapeutics, pharmacogenomics and orphan drugs. However, counterfeit medicines are a huge challenge, he emphasised.

Dr Barata argued that there is a need for new drugs and there are opportunities for the generic industry. Small, less expensive innovations can be advantageous, he said. Although biotechnology and nanotechnology are arriving more slowly than expected, they will be of extreme importance, he said.

Collaboration Research in the pharmaceutical sciences required multidisciplinary expertise to achieve the dual goals of improving patient outcomes and industry profitability, said Bruno Sarmento, assistant professor, Department of Pharmaceutical Sciences, Higher Institute of Health Sciences, Portugal. He continued by comparing and contrasting industrial and academic viewpoints. He advocated synergy rather than separation.

Professor Sarmento outlined how better understanding could lead to collaboration between industry and universities. He discussed knowledge and technology transfer, giving an example of the largest academic-industry collaboration for drug discovery in depression and schizophrenia announced on 19 January 2010.

Political, economic and other forces have resulted in the emergence of corporate and entrepreneurial universities and "spin-off" companies. Professor Sarmento concluded that closing the gap between science and practice could offer new technological solutions to patients.

Shortage of pharmacists exacerbated by migration to developed nations

Carmel Giral Barnés, from the Mexican Council for Accreditation of Pharmacy Education, spoke about the "Pharmacy workforce and its influence on the future", reporting on the sharp asymmetry by country in parameters, including population median age, the percentage of government expenditure on healthcare, life expectancy, pregnancy, infant mortality and pharmacy/pharmacist density.

Ms Giral noted that rising healthcare costs were being driven by the spend on medical technology, prescription medicines, chronic disease, population ageing and administrative costs among other things. She outlined reasons for the global shortage of pharmacists, exacerbated by migration from less to more developed nations.

Ms Giral predicted a move to more sophisticated and expensive treatments in a technology-literate society with greater health expectations. The application of new health technologies in the postgenomics era would swiftly expand from rare monogenic disorders to complex but common diseases,

Migration from less to more developed nations has exacerbated the global shortage of pharmacists (Ashestosky/Dreamstime.com)

pharmacogenomics and personalised medicines.

According to the International Pharmaceutical Federation workforce report, the number of pharmacists may not be adequate to meet all population needs, she continued. There is a feminisation of the workforce in many countries due to the appeal to women of changing roles (eg, greater emphasis on patient care) and flexibility in working hours.

Pharmacy schools will be required to produce more graduates with a needs-based education. State pharmacy boards and government legislation will enable and facilitate pharmacists' patient care activities individually and in conjunction with other healthcare professionals and pharmacy technicians.

To meet the challenges, Ms Giral proposed building on the collective strengths of national pharmacy organisations to develop a co-ordinated strategy to secure financial compensation for pharmacists' patient care services that are not directly related to drug distribution. She concluded that the best solution is pharmacists — ideally a graduate of an academic programme that has been internationally accredited.

An understanding of leadership skills is required in all fields of pharmacy

Leadership skills are essential if pharmacists are to remain competitive in different fields of pharmacy. Gordon Geddes reports from a session organised by the International Pharmaceutical Students' Federation and the pharmacy education taskforce

Managers do things right, leaders do the right thing, said Catherine Duggan, director of professional development, Royal Pharmaceutical Society.

Providing leadership skills at every level of development is essential for pharmacy in order to ensure the best use of medicines and to establish the profession's place in healthcare, she said.

Dr Duggan believes a full understanding of leadership skills is required in all fields of pharmacy. What makes a good leader was analysed and examples of leadership qualities were given. She stated that leadership competencies include vision, motivation, governance, strategy, innovation and service planning.

Dr Duggan gave some examples of leadership qualities. She said that leaders should be able to take opportunities to change things, confidently exercise initiative,

Catherine Duggan: leaders need to be well informed

experiment and make mistakes and think creatively. She added that they should also be calm under pressure so they can make clear decisions, and be well informed and knowledgable about matters relating to the business. She summarised leadership qualities and skills as professionalism, being connected, achieving work-life balance and personal resources. After considering personality preference, Dr Duggan concluded that not everyone is the same; a team needs a good mix of skills; different people have different ways of communicating, processing and learning; and there is a need to learn from one another.

Dr Duggan summarised her presentation as follows:

- All pharmacists require leadership skills
- The skills needed to be a successful clinical pharmacy leader are known
- These skills must be transferable to different fields of pharmacy
- It is necessary to be able to work in uni- and multi-disciplinary teams
- Leadership in practice is the responsibility of all

Direct and indirect methods used for measuring medication adherence

Adherence to therapy is an important factor that contributes to the successful treatment of a patient. Benedict Lam reports from a session organised by the boards of pharmaceutical sciences and pharmaceutical practice that looks at methods of measuring adherence and pharmacists' role in medication adherence

Feign swallowing is when a patient pretends to swallow a medicine. This is an issue when direct observation is used to measure adherence (Ray22/Dreamstime.com)

Adherence is the extent to which a person's behaviour coincides with medical or health advice. Filipa Alves da Costa, lecturer at the Institute for Health Science, Egas Moniz, Portugal, explained there are several types of non-adherent behaviour:

- **Deviant adherence** The patient takes the medicine but deviates from the prescribed regimen
- **Null adherence** Patient fails to take any medicine
- **Non-persistent adherence** Patient discontinues the medicine permaturely

There are two types of method to measure adherence, Dr Alves da Costa listed these as:

- **Direct** Drug assays of blood or urine; use of drug makers with target medication; direct observation of patient receiving therapy
- **Indirect** Self-reporting, pill count, electronic monitoring devices, review of prescription or patient medication records

Direct methods

With drug assays of blood or urine, Dr Alves da Costa explained that the presence of the drug confirms that the patient has recently taken a dose of the medicine. However, she noted that this method does not detect "white coat adherence", where some patients take the drug only before they get tested. She also emphasised that the presence of drug in blood or urine does not necessarily equate to a patient being adherent or that the absence of drug does not necessarily equate to a patient being non-adherent. Sometimes, several samples may need to be taken to increase accuracy.

Dr Alves da Costa said that the use of drug markers with target medication is a similar method to drug assays, and is often used with drugs that have a long half-life (eg, phenobarbital, digoxin). This method is costly and time-consuming. However, it is useful for drugs that cannot be assayed in blood or urine, she said.

The direct observation of a patient receiving therapy is a costly method of measuring adherence, and can be impractical in some outpatient settings, said Dr Alves da Costa. There is also the issue of feign swallowing, where a patient pretends to swallow a medicine. This method is, however, justifiable for specific therapies (eg, supervised methadone consumption), Dr Alves da Costa explained.

Indirect methods

Self-reporting by patients to measure adherence includes patient-kept diaries, patient interviews and standardised questionnaires. Dr Alves da Costa said that this is a simple and cheap method of measuring adherence. However, it is important to note that, with patient interviews, the measure of adherence could be influenced by the interviewer's skills, while with standardised questionnaires it is important the wording and formulation of the questions do not affect the accuracy of measuring patient adherence. Additionally, these methods assume a patient's honesty.

The pill-count method is one of the most common, simple and cheap methods to measure adherence, Dr Alves da Costa suggested. This method is useful in clinical studies and sometimes in practice as well. However, it only provides partial information. For example, patients who are taking their medicines may be taking them at the wrong time of the day, she explained.

The review of prescription or pharmacy records as a method of measuring adherence requires data and days supplied to be accurate. It is a good method to identify initial null adherence, low persistence or periods of non-adherence, Dr Alves da Costa explained.

Providing long-term adherence support

Community pharmacists are in an ideal position to provide long-term adherence support, said Marie Schneider, lecturer, community pharmacy, Department of Ambulatory Care and Community Medicine, University of Lausanne, Switzerland. The pharmaceutical care movement has focused on the pharmacists' responsibility to care for patients' medication-related needs. She said that effective adherence support programmes need to be developed along with business-practice models.

Clinical trials have addressed the impact of interventions on adherence, Dr Schneider said. Some of the studies with pharmacists demonstrated benefits of such interventions, including a reduction in the risk of death. However, there is a lack of evaluation of uptake of these results into pharmacist education and practice, she commented.

Medication adherence support is a component of programmes, which tackle the right use of medicines, Dr Schneider said. Examples of medication adherence support from around the world include patient medication profile (Australia, Sweden) medicines use reviews (UK) and 30-minute "polycheck" interviews (Switzerland). There are also specific medication adherence programmes, such as medication adherence clinics (Switzerland) and a satellite pharmacy at an HIV clinic (Sweden).

Pharmacists who ensure medicines adherence in patients must be reimbursed appropriately (Chris Rose)

Dr Schneider said that important steps for success in medication adherence for patients include educating and training pharmacists (eg, communication skills, strategies to promote adherence), national policies and local advertisement.

Additionally, she emphasised that pharmacists must be reimbursed appropriately for ensuring medicines adherence in patients.

Long-term adherence interventions will sustain the invervention impact

Medication adherence is essential for effective pharmacotherapy, said Jeannie Kim Lee, clinical assistant professor, pharmacy practice and science, University of Arizona College of Pharmacy. Non-adherence is prevalent, difficult to manage, increases healthcare costs and diminishes health outcomes, she added.

There are numerous barriers to adherence, Dr Lee said. Some of these factors include complex treatment regimens, treatment of an asymptomatic condition, convenience, cost, patient-provider relationship, healthcare systems (eg, limited access), or general patient issues (eg, forgetfulness, cultural issues, emotional factors, low health literacy).

Patients who are on many medicines (polypharmacy) are more likely to face medication adherence issues, Dr Lee said. They are at risk of medical errors, adverse drug reactions, admission to hospital, disrupted daily routines and social activities, and increased fiscal costs (eg, owing to adverse events and monitoring).

Some interventions pharmacists could use to help patients increase adherence include education, regimen simplification, regimen organisation (eg, pillbox), and reminders (eg, alarms). Most patients require long-term interventions and team care is important to ensure adherence intervention is successful, suggested Dr Lee. This could be a pharmacist-physician collaboration or a pharmacist-nurse collaboration, she said.

Cost is one of many barriers to medicines adherence (Roughcollie/Dreamstime.com)

Dr Lee said that long-term interventions allow us to measure higher level outcomes, which enhances the potency of the intervention. She explained that many short-term adherence trials show no effect or mixed effect. Additionally, long-term interventions will sustain the intervention impact because adherence may decline after intervention is discontinued, Dr Lee said.

New and emerging pharmacy business models: trends in community pharmacy

Community pharmacy is undergoing important changes, with new business models entering the market and altering the pharmacy practice paradigm. Steven Kayne reports from a session organised by the community pharmacy and administrative pharmacy sections, Young Pharmacists Group and the International Pharmaceutical Students' Federation

The business of pharmacy is changing, said Thomas Menighan, of The American Pharmacists Association. Evolving and disruptive market forces are having a major impact on the business whose model has been static for decades.

Mr Menighan said that resisting change on moral, philosophical or political grounds will only slow but not stop the inexorable uptake of technology and systems that can deliver better, faster and cheaper healthcare. He told the congress that, in healthcare, particularly in pharmacy, there are major threats and opportunities. Today's debate is rarely a simple argument on independent versus chain pharmacy. Administrators are seizing control of many decisions and large portions of healthcare financing, while practitioners are asked to do more for less and with greater accountability.

Mr Menighan drew the audience's attention to the problems for single-store operations, pharmacist-owned multiple store locations, franchises, chains and virtual chains, compounding pharmacies, long term-care providers, specialty pharmacies, supermarket pharmacy operations, and internet pharmacies that want to continue to provide excellent care. He said higher standards for compounding and for provision of patient care were necessary. There should be better collaboration between managed care, mail order, community pharmacies and service-only pharmacies.

FROM DISPENSING AND COMPOUNDING TO SERVICES

Raj Patel, of the National Pharmacy Association, UK, said that historical trends in pharmacy show an evolution from compounding and dispensing to the special services offered today. He gave four examples of innovations in practice that are currently taking place in the UK:

- Paperless prescribing (when implemented, patients will nominate a pharmacy to which the GP will transmit their prescription)
- Co-location of pharmacy premises with other healthcare providers to form a focus of healthcare
- Service-based activities (eg, influenza vaccination and allergy screening)
- Advice on healthy living

Karin Graf: pharmaceutical services should be regulated centrally for all health insurance funds

The role of organisations

Community pharmacy organisations all over the world are developing and disseminating new cognitive services to strengthen the role of pharmacies, said Karin Graf, Federal Union of German Associations of Pharmacists (ABDA).

In her organisation, this involves identifying and developing suitable services, testing and evaluating them, defining quality standards, developing implementation tools, and negotiating contracts with health insurance companies in order to obtain an adequate remuneration. ABDA comprises 17 state chambers of pharmacists and 17 state pharmacists associations. It is responsible for developing and evaluating holistic and complex services (eg, pharmaceutical care services and medicines management) and less complex interventions, such as improving self-medicating skills.

Ms Graf mentioned trying to improve blood glucose self-monitoring in type 2 diabetic patients as an example. In this project, the aim was to implement the service in around 25 per cent of German pharmacies. A contract was negotiated with the largest German health insurance company, which has 6.8 million clients. ABDA monitored the implementation process in several pharmacies, as well as the number of services passed to the insurer for remuneration.

Despite high efforts nationwide, implementation was insufficient to sustain the service after one year, Ms Graf said. A major barrier was the low number of suitable patients per pharmacy. Another barrier was that the needs of patients are often not covered by a single service. Therefore, acceptance by the patients was poor, she explained.

In future, it is imperative to develop strategies and innovative business models to maintain and control the quality, safety and efficient availability of medicines, suggested Ms Graf. She said that, currently, ABDA is working on strategies to overcome these challenges. Pharmaceutical services should be adequately remunerated, Ms Graf added.

To reach feasibility and to increase acceptance, the demands of different stakeholders have to be considered, she added.

Similar problem in Finland Sirpa Peura of the Association of Finnish Pharmacies said that her association has experienced a similar problem to that described by Ms Graf. A smoking cessation programme failed to become established in Finnish pharmacies.

In Finland, healthcare is largely based on the public healthcare system, which is complemented by private sector services. Ms Peura said it is important to establish whether the service being proposed is needed and whether it can be integrated into the healthcare system to improve acceptability by potential patients.

Support Cairo Toledano, of the International Pharmaceutical Federation Young Pharmacists Group from Mexico, expressed worries that a reduction in face-to-face contact with patients resulting from automated services could jeopardise trust. He suggested that pharmacy organisations could offer support and evaluate new ideas for innovative practices.

Negotiating for new pharmacy services

As healthcare expenditure rises, there is greater scrutiny on costs associated with

pharmaceuticals, an area that governments see as a soft target, said Warwick Plunkett, of the Pharmacetical Society of Australia.

The external environment influences include changes in national medicines policy resulting from strong political engagement and influence, while internal environmental changes include acceptance of a new business model for pharmacy and the need for incentives (and disincentives) to drive change, he explained.

Mr Plunkett warned the congress that current levels of remuneration for dispensing pharmaceutical products are under threat. It is necessary to evolve the business model from the past product supply to one of product and service. He believes there are four important challenges in community pharmacy:

- The task of convincing community pharmacists of the need to change and start delivering services along with the sale and supply of products
- Identifying suitable health and medicines management services for pharmacy to deliver cost effectively
- Finding resources to provide support for community pharmacies to implement new services
- Developing the right strategy to negotiate payment from governments, health insurers and patients

Successive five-year agreements between the government and the Pharmacy Guild of Australia for the payment of dispensing fees and additional professional services have worked successfully over the past 20 years, Mr Plunkett said. In Australia, there is a link between results from research, health policy priority, support for practice change and the key ingredients for successful negotiating.

Developing and maintaining a strong and effective lobbying presence is one of the essential foundations for government negotiations, but it must be followed with a clear understanding of how services provided by community pharmacy can deliver cost-effective solutions that fit the needs of existing health policy, suggested Mr Plunkett. He emphasised the importance of satisfying the needs of other stakeholders as well as the government.

Patients want more control over healthcare, which must be delivered with consistent quality and give the best possible outcomes, he said, and pharmacists and medical practitioners must build bridges to facilitate a collaborative approach to all professional services. Funders should be convinced of the financial savings and healthcare benefits of pharmacy-based services, Mr Plunkett emphasised.

POM-to-P switches and the OTC market

The value of the over-the-counter market is expected to outgrow the prescription medicines market in the future. Steven Kayne reports from a session organised by the FIP community pharmacy section

The over-the-counter market is currently worth €69bn and the trend is for the value to outgrow the prescription medicines market, said Per Troein, VP Strategic Partners, IMS Health UK.

In developing nations, the growth of the OTC market is set to overtake that in the developed world, Mr Troein said. At present, their share of global sales revenue is 33 per cent and share of growth is 76.8 per cent, with South East Asia and China accounting for over 40 per cent of this. Mr Troein believes pharmaceutical manufacturers are experiencing a number of constraints, including low numbers and quality of innovations from research and development departments and pressure on prices from payers. In Europe, a wave of reforms is under way to curb healthcare expense. Mr Troein gave several examples, including: in Turkey, original products with generic competition will be priced at 66 per cent of the lowest reference price; in Germany, manufacturers must negotiate prices for new original brands with public health insurers or accept fixed-price ceilings; and in Greece, original brands must be priced at the average of the three lowest prices in the EU.

By contrast, Mr Troein thinks the OTC market is benefiting from a series of growth drivers. Emerging markets in China and Russia have sufficient critical mass to influence growth and, elsewhere, payers are keen to promote self-medication to protect health budgets, he said.

Mr Troein predicted that, over the next 10 years, there will not be a drastic shift in patients' willingness to spend on OTC products, except on items from which they will enjoy immediate benefit, such as headache remedies. Also, most patients believe that medicines prescribed by their GPs will be more effective than OTC products, he said.

Mr Troein said non-pharmacy distribution of OTC products is emerging in Europe, but much of the OTC market is still, and will remain, pharmacy-driven, with some notable exceptions: in The Netherlands, drug stores and supermarkets dominate; in the UK, supermarkets are promoting strong own-label brands; and in Germany, mail order is returning significant growth.

Mr Troein believes centralised switching will offer opportunities for growth of the OTC market in the EU, where pharmacies will continue to be important despite a growth in non-pharmacy distribution,

The industry's perspective

Mafelda Martins, GlaxoSmithKline Consumer Health, Portugal, identified a group of products she called "downstream switches". These included medicines that were time-and-extent driven, for example, ibuprofen and proton pump inhibitors, and others are influenced by cost containment and delisting motives, for example, some cough medicines and decongestants.

Demand for "upstream switches" came from consumers and include: convenience medicines (eg, antacids and antihistamines); urgency medicines (eg, products for headache or coughs and colds); embarrassment medicines (eg, medicines for overactive bladder, emergency contraception, chlamydia); and efficacy medicines (eg, smoking cessation, weight management).

Ms Martins said that self-medication can enable comprehensive consumer interventions, but safe and effective medicines are needed, as well as comprehensive information about the product (both on the pack and at pharmacy level) and counselling. Providing ongoing support and encouraging associated lifestyle changes where appropriate are also important, she said. Self-medication has a beneficial impact on public health thus reducing the burden on healthcare resources and promoting the contribution made by pharmacies to supporting the healthcare system.

The EU has taken steps to support switching. New molecules that have been approved by centralised procedures may now apply for a centralised switch, Ms Martins said. She gave the example of Alli (orlistat 60mg), an OTC product recommended for the treatment of overweight conditions in patients with a body mass index in excess of 25. This was the first OTC product for weight loss to receive an EU centrally approved marketing authorisation.

The success of self-medication depends on trust of all parties involved, suggested Ms Martins. Consumers must be trusted to choose the correct medicine and use it appropriately; manufacturers should market their products responsibly; and pharmacists with appropriate training should be trusted as first-line healthcare providers. Regulators should accept healthcare provision beyond prescription-only medicines, she added.

Patient packs verus dispensing from bulk — what are the pros and cons?

Dispensing from original packs is common in Europe while in the US and most developing countries dispensing from bulk is a dominant practice. The implications of these practices to patients and pharmacists are varied. Steven Kayne reports from a session organised by the pharmacy information and administrative pharmacy sections

Dispensing from bulk is common practice in the US, said Jeannie Lee, clinical assistant professor, pharmacy practice and science, University of Arizona College of Pharmacy. She discussed the logistics and patient safety implications of dispensing from bulk. The issues include:

- Confusion and inconvenience to patients by the use of multiple brands of generics
- Non-adherence to drug regimens (estimated to be as high as 50 per cent of patients)
- The need for multiple bottles for patients taking large numbers of treatments
- The increased pharmacy workload associated with taking medicines from their original containers
- The potential risks of counting, labelling and medication errors

Dr Lee said that medication errors have a considerable effect on morbidity and mortality. They may be reduced by a range of new automation technologies. She said that a highly automated pharmacy can achieve a dispensing error rate as low as less than one in a thousand prescriptions.

Dr Lee said that, when discussing all the methods of packaging medicines, there is a need to consider patient safety and adherence implications. With the number of adults in the age group 65 years and older expected to almost double to 1.3 billion in the next 30 years, the demand for medicines will also continue to increase, resulting in a corresponding rise in the market for pharmaceutical packaging, she said. In 2009, the annual rate of increase was 6.3 per cent. Plastic bottles, with quality and design improvements, are likely to satisfy the largest share of this demand, said Dr Lee.

The US, Europe and Japan account for 70 per cent of all packaging demand. The fastest growing areas are in prefilled syringes and inhalers.

Dr Lee explained there are a number of advantages with using plastic bottles as the container for dispensing from bulk, including:

- Wide availability
- Low cost
- Versatility
- Tamper-evident and elderly-friendly caps
- Opportunities for adherence-enhanced innovations

Jeannie Lee: there is a need to consider patient safety and adherence implications when discussing methods of packaging medicines

Dr Lee said there are extensive government mandates in several countries to upgrade the packaging standards of plastic bottles.

Bulk versus original pack

Is bulk dispensing the best practice or is it time to change, asked Vaiyapuri Subramaniam, associate chief consultant for the Pharmacy Benefits Management Services at the US Department of Veterans Affairs. In original pack dispensing, medicines are dispensed in the pack produced by the manufacturer and, although it is standard practice in most of Europe, in the US, it is only routinely used for oral contraceptives, topical products, selected antibiotics and some liquids.

Professor Subramaniam said that the advantages of dispensing original packs include:

- Retention of manufactuers' identity and batch numbers, which is important for effective drug recalls
- Retention of expiry dates
- Rapid identification in cases of overdose
- Improved quality assurance
- Opportunity to enclose patient information leaflets
- Improved compliance resulting in better outcomes and reduced drug waste
- Fewer steps in the dispensing process
- Reduced opportunities for medication errors

The disadvantages of original packs include:

- Difficulty for patients to remove medicines from manufacturers' packs
- Associated higher drug costs to pharmacies
- Increased storage space needs
- Loss of flexibility in prescribing
- Increased potential for drug waste

Bulk dispensing requires less pharmacy storage space and can be cost-effective. However, it is more labour-intensive in terms of counting, labelling, and packaging the medicine, Professor Subramaniam said.

Expanded use of patient pack dispensing in the US would depend on the impact of its healthcare system on pharmaceutical pricing and insurance, prescription drug costs, physician prescribing patterns and pharmacy systems.

Professor Subramaniam suggested that, if patient pack costs were competitively similar to bulk medicines, patient pack dispensing may increasingly be a feasible alternative to bulk dispensing.

Concerns with bulk dispensing in Africa

Alexander Dodoo, President of the Pharmaceutical Society of Ghana, described the reality and concerns surrounding bulk dispensing in Africa. There are problems associated with the quality of bulk supplies of medicines from which prescriptions are dispensed. The original source of the supplies may be unknown, labelling incorrect and expiry dates missing, he said. In addition, poor storage conditions may contribute to loss of quality.

There is a tendency for patients to seek the cheapest price, with little regard for quality. To save money, medicines may be supplied in envelopes or patients may bring their own container to the pharmacy to be filled with the required medicine. Simple hygiene procedures like cleaning spoons between doses of liquid medicines are often not observed, he said.

Dr Dodoo suggested there were great opportunities to improve the situation and improve outcomes.

UK may be the last European country to complete the shift to original packs

Stein Lyftingsmo, a hospital pharmacist in Elverum, Norway, discussed the various types of patient packs found in Europe.

He gave an overview of pharmacy software, explaining that most countries have more than one system. Mr Lyftingsmo identified a number of functions of software, including therapeutic functions (drug records, interactions, etc), accounting and stock control, and labelling. Attendees were told that labelling of dispensed medicines is vital because it links the patient with the package and the therapeutic solution.

In some European countries, for example, the UK and the Nordic countries, pharmacy labels with individual dosage instructions are usually affixed to the patient (original) packs, said Mr Lyftingsmo. In cases where pharmacy labels are not used, there is a need for a dedicated space on the patient pack for dosage instructions, he added. Such information may be handwritten in the space.

Turning to the differing sizes of patient packs, Mr Lyftingsmo said that the UK is possibly the last country in Europe to complete the shift to patient packs. In England and Wales, about 30 per cent of prescriptions for blister packed medicines require adjustment by cutting the strips to give the right number of tablets or capsules. In The Netherlands, pharmacists also adjust pack sizes.

Mr Lyftingsmo concluded by saying that it is not commercially possible for small pharmacies to deliver medicines dispensed from bulk to appropriate standards. This can only be achieved by the large automated pharmacies found in the US.

Stein Lyftingsmo: most countries have more than one pharmacy software system

Pharmacy building bridges — working with other stakeholders for patients

Working in partnership with health administrators, policy makers and other healthcare professionals can benefit patients and society. Roger Tredree reports from a session organised by FIP's community pharmacy and hospital pharmacy sections

Mario Beja Santos, from Health in Dialogue, Portugal, gave an overview of how, since 1970, advances in health practices and awareness of healthy lifestyles have changed the healthcare paradigm. Increased life expectancy, expanded patient responsibility, the creation of associations for patients with chronic diseases, health literacy and equal access to medicines have all changed the way that citizens engage with providers, he said. In Lisbon, Health in Dialogue has served as a platform to engage decision-making bodies in policy making. The group includes patient representatives, nurses and pharmacists. It seeks greater representation for patients at consumer and health promoter level to achieve better quality of life for the people.

Seamless care

Andrew Gray, of the University of KwaZulu-Natal, South Africa, discussed how seamless care might be achieved between hospital and open care. In 1998, "seamless care" was defined by a joint Canadian hospital and community pharmacy workshop as "the desirable continuity of care delivered to a patient in the healthcare system across the spectrum of caregivers and their environments". This workshop then defined the pharmacy component: "Pharmacy care is carried out without interruption such that, when one pharmacist ceases to be responsible for the patient's care, another pharmacist or healthcare professional accepts responsibility for the patient's care."

There are many barriers that prevent such seamless care, said Mr Gray. Such barriers persist despite the extensive evidence of the risks that present when patients are transitioned from one care site to another. Building an effective bridge between our practice settings remains a challenge for pharmacy in all health systems, Mr Gray said.

Pharmacy public health programmes

Sirpa Peura, representing the Association of Finnish Pharmacies, outlined the way in which Finnish pharmacists have implemented pharmacy public health programmes that are integrated with national health programmes.

All the programmes are planned and implemented together with relevant stakeholders and patient organisations, she explained. The Pharmacy Asthma Programme was part of the national asthma programme (1994–2004) and it was launched by the group with representatives from the Ministry of Social Affairs and Health, the Association of the Pulmonary Disabled, Allergy and Asthma Federation and the Finnish Lung Health Association, said Ms Peura.

The Pharmacy Diabetes Programme is part of the National Development Programme for the Prevention and Care of Diabetes in Finland (2000–10), and it was created in co-operation with the Finnish Diabetes Association. The Pharmacy Heart Programme is integrated into the national Action Plan for Promoting Finnish Heart Health for the years 2005–11, and it was built up with the Finnish Heart Association, she said. Ms Peura said that the public health programmes have been valuable tools in promoting successful drug therapy for patients, increasing pharmacy personnel's knowledge and expertise in these public health areas and intensifying co-operation between pharmacies, otherhealth care service providers and various associations.

Implementing the Basel Statements: an update from different countries

In 2008, countries from all over the world expressed their vision for their best preferred future for hospital pharmacy, resulting in the so-called Basel Statements. Roger Tredree reports from this session organised by FIP's hospital pharmacy section, which demonstrates how these statements have been used to improve practice in various regions of the world

Rebekah Moles, lecturer in pharmacy practice, University of Sydney, Australia, described the Western Pacific Regional Programme where the hospital pharmacy section vice-presidents for Australasia and Japan had teamed with the Western Pacific Pharmaceutical Forum to translate, disseminate and discuss the Basel Statements in the 38 countries in the region.

Translation of statements into major languages spoken in the region has been ongoing. To date, the statements are available in English, Chinese, French, Japanese, Korean and Vietnamese. Dissemination of the statements has been widespread. All pharmacy and hospital pharmacy organisations in the region have been sent the statements, Dr Moles said, and discussion regarding the statements has been a priority in the region.

A hospital web-network has been established and is hosted on the Western Pacific Pharmaceutical Forum website (www.wppf.org). Many discussion topics based on the statements have been posted and there is healthy participation, said Dr Moles. Countries have been surveyed about statement dissemination as well as their willingness to participate and disseminate future questionnaires as part of a large PhD study, she said. Currently, responses have been received from six large countries. A PhD project proposal has been presented to the Western Pacific Regional Office of the World Health Organization and an executive committee to oversee this large PhD project will be formed with representatives already identified from Singapore, Philippines, Taiwan, Japan and Australia, she said. The PhD research student had started his studies (see Panel), which will aim to develop, validate and implement a series of surveys regarding the Basel Statements in the Western Pacific Region, explained Dr Moles.

A-year-and-a-half on from the Basel FIP congress, the Western Pacific Region has created momentum, Dr Moles said.

Progress in China

Dechun Jiang, from Xuanwu Hospital, Beijing, China, reported on progress at his hospital. China, one of the biggest developing countries, has a large population and thus a large number of patients, he said. Therefore, the safe, effective and economic use of medicines for patients has become a critical problem. Hospital pharmacy plays an important role in ensuring that patients use medicines rationally, he said. According to the framework and terms of the consensus statements, medication practices were introduced at Xuanwu Hospital around medicines procurement, preparation, prescription, dispensing, monitoring, administration and clinical pharmacists' training. Results were compared with global consensus statements, Mr Jiang said, and healthcare, education and research, and innovation of these aspects were the main focus. The hospital pharmacy's focus was changed from medicinal product to pharmaceutical service, he explained. Rational use of medicines has become our core service, he added, and the pharmacist's role has become more important in patient treatment. Mr Jiang said the direction has been correct and is consistent with the consensus statements.

Mr Jiang noted that information systems and adminstration regulation should be enhanced and a good pharmacy practice evaluation system needs to be developed at the hospital.

He said the global consensus statements have been helpful in improving practice for China, and should continue to be implemented according to Chinese conditions.

High performance model

Tom Thielke, of the University of Wisconsin, US, presented a comparison of the High Performance Hospital Pharmacy statements in the US and those developed at the Global Conference on the Future of Hospital Pharmacy in 2008.

The High Performance Hospital Pharmacy statements were developed by several pharmacy leaders in the US and published in 2007. They include eight dimensions of hospital pharmacy practice and 77 individual statements. The Basel Statements include seven dimensions and 75 individual statements. A comparison was made of the two groups of statements and over 85 per cent had a match that demonstrated a great synergy between the two sets of statements. The six keynote speakers at the global conference used the high performance standards and references as a foundation for their presentations.

THE HOSPITAL PHARMACY SECTION COUNTRY SURVEY TOOL

Research shows that hospital pharmacists can reduce patients' length of hospital stay, medication errors and adverse events, said Jonathan Penm, PhD candidate from the University of Sydney, Australia. However, hospital pharmacy practices vary greatly around the world.

To standardise practice and ensure optimal patient outcomes, the hospital section of the International Pharmaceutical Federation facilitated the development of the first global consensus statements (the Basel Statements). Each statement is evidenced-based and has a strong focus on medication safety. The aim of Mr Penm's PhD project is to develop and validate a survey to assess hospital pharmacy practice based on the Basel Statements, focusing on the Western Pacific region.

The survey focuses on pharmacists' influence on prescribing, one of the six themes in the Basel Statements. Questions were developed and piloted for face validity and clarity. The questionnaire will be distributed via the internet using Survey Monkey to hospitals in the Western Pacific region. It will collect measurable outcomes of key aspects of each Basel Statement, as well as demographic data that may affect compliance with the statements.

Survey results will be collected and analysed. He concluded that the development of this survey to monitor pharmacists' influences on prescribing will allow factors that affect service provision to be identified and targeted interventions to improve practice to be developed. This validated tool can then be used in other regions.

In addition, the research process can be modelled to develop further surveys based on other Basel Statements. Ultimately, we will have a series of surveys that can be used globally (on a rotational basis) to monitor and influence change in hospital pharmacy practice for the future, Mr Penm said.

After publication of the high performance statements, a website (www.highperformancepharmacy.com) was developed to allow US hospital pharmacists to access the statements online along with all the references that support them. Data were presented on the use of this website by pharmacists. A self-assessment tool was also developed as part of the website, which allows hospital pharmacists to assess their hospital pharmacy's completion rate of the 77 individual elements. It also allows pharmacy directors to benchmark against the national norms.

Breaking new ground

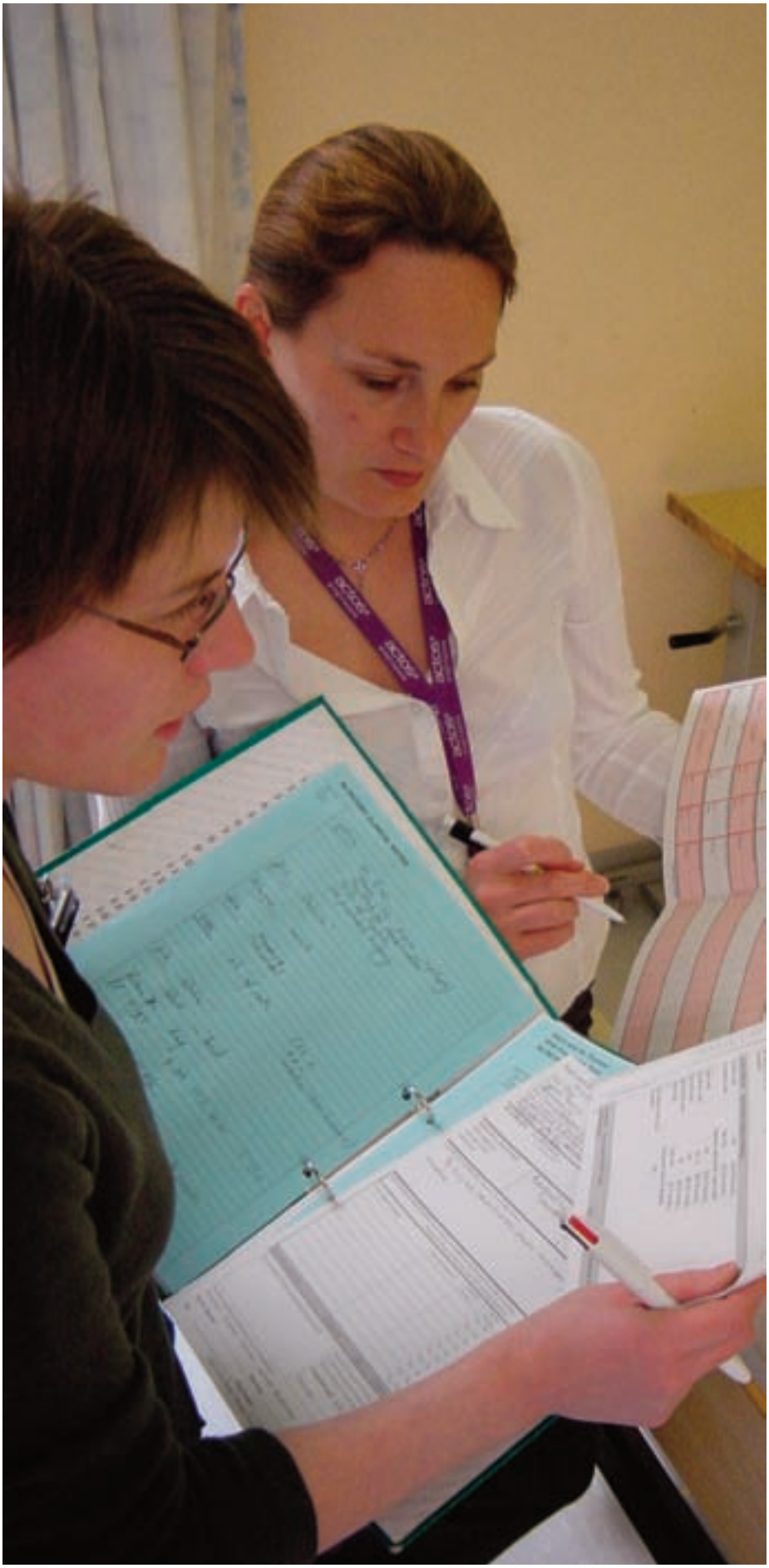
Nora Gerpe, from the South American Pharmaceutical Federation, described how the Basel Statements represented a trigger tool to accelerate the implementation of good pharmacy practice in Uruguay. She described the background to the current position starting in 2004, when the National Technical Group implemented agreements with the Ministry of Health to develop pharmaceutical services. This gave rise to a multi-centre study on pharmaceutical care on patients with hypertension.

A workshop series looked at three good pharmacy practice standards: self-medication, rational use of drugs and good dispensing practice.

Changes have been accomplished within the Paraguay-Uruguay good pharmacy practice project framework and, in order to establish a baseline, a first national survey on good pharmacy practice in hospital pharmacy was conducted. The sample covered 60 per cent of the private and public hospital pharmacies in cities, towns and rural areas. This was validated in April 2009 and implementation took place between May and June 2009. Further work was done at the XIII HP National Congress: Workshop on "Basel Statements" (November 2009).

As a result, there has been an internalisation of the Basel Statements. The advances on the good pharmacy practice Paraguay-Uruguay project have been shared in the region.

Miss Gerpe concluded that good pharmacy practice implementation is a process that challenges each pharmacist to outline a strategic plan that meets local health policies, keeping in mind a long-term vision for hospital pharmacy services.



Hospital pharmacists can reduce patients' length of stay, medication errors and adverse events

Using clinical microbiology data to improve anti-infective use in hospitals

Roger Tredree reports from a session organised by the clinical biology section, hospital pharmacy section and the young pharmacists group, which looks at antibiotic resistance patterns in intensive care units, pathogens identification and using microbiological data to prevent anti-infective resistance in ICU patients

The intensive care unit environment is highly favourable to the emergence and spread of antimicrobial-resistant pathogens due to increased cross-transmission risk and the intensive use of broad-spectrum antibiotics, said Angela Novais, Laboratory of Microbiology, Faculty of Pharmacy, University of Porto, Portugal.

Despite the measures adopted worldwide to control antibiotic resistance spread, resistance rates have significantly increased among pathogens most often implicated in nosocomial infections, which are increasingly associated with multidrug resistance phenotypes, she said.

Currently, one of the most worrying situations is the global dissemination of uropathogenic *Escherichia coli* strains that are simultaneously resistant to fluoroquinolones and extended-spectrum cephalosporins. This has a strong impact both in the outcome of infections and resistance spread, Dr Novais explained.

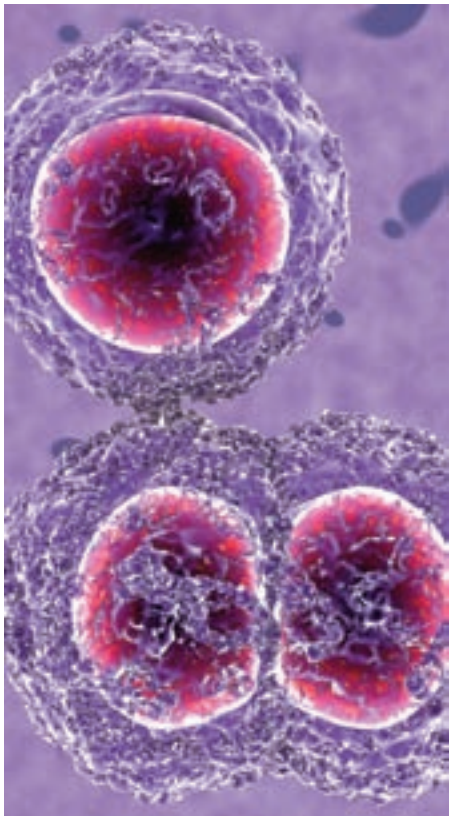
In hospitals, the implementation of epidemiological surveillance studies aiming to detect and characterise particular antibiotic-resistant pathogens, identify and control epidemic or endemic situations, and monitor antibiotic resistance trends is crucial to define and reinforce infection control measures and to optimise antibiotic prescription policies, said Dr Novais.

Bacterial identification and preliminary antibiotic susceptibility testing is frequently assessed by semi-automated systems and epidemiological typing of antibiotic-resistant bacteria is complemented with genotype-based molecular biology approaches. Dr Novais said that, more recently, high-throughput technologies have become promising tools for both clinical practice and antibiotic resistance control.

Educating patients

Aldo Alvarez Risco, of the South American Network of Pharmaceutical Care, Peru, said that, despite laboratory results and the theory behind good anti-infective use, hospitals often do not follow the rules. Everyone should work as a team, he added.

Also, patients must understand (not just be told) why they should finish their course of antibiotics and why they must not stop even if they feel better. One of the key skills of a pharmacist is to be a good communicator, he added.



A computer graphics render of meticillin-resistant *Staphylococcus aureus*: infections caused by multidrug-resistant pathogens, such as MRSA, causes greater morbidity and mortality (Pseudolongino/Dreamstime.com)

Infection versus colonisation

The control of nosocomial infections is a public health priority worldwide and, in the past decade, there has been a dramatic increase in community-associated infections, said Aida Duarte, Faculty of Pharmacy, University of Lisbon, Portugal.

Although viruses, fungi and parasites are recognised as sources of nosocomial infections, bacteria remain the most commonly recognised cause. Professor Duarte said morbidity and mortality are greater when infections are caused by multidrug-resistant pathogens, mainly meticillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococci, certain gram-negative bacteria, including those producing extended-spectrum β-lactamases, *Acinetobacter baumannii*, and *Pseudomonas aeruginosa*-producing carbapenemases. Professor Duarte said that patients may be colonised with these strains before admission and provide a source for spread.

Colonisation occurs when micro-organisms inhabit a specific body site, but do not cause infection. However, colonised pathogens have the potential to cause infection if they spread to a different site on the same patient, for example, from the skin to the urinary tract or blood, she explained.

Most hospital infections are endemic, she said, although several studies report the major reservoir of multidrug resistance as intensive care unit patients' endogenous flora. Other studies have shown patient-to-patient (cross-transmission) spread via hands of healthcare workers or via fomites (exogenous colonisation).

Professor Duarte said that understanding the epidemiology of multidrug resistance requires the use of accurate epidemiological markers that are able to differentiate between strains. Epidemiological data could indicate one colony or several colonies associated with sporadic infection, cross-transmission or exogenous colonisation. Several of the highly adapted colonies could carry virulence-associated genes, which encode toxins, capsules, invasins, adhesins and other virulence factors, that enable them to overcome host defences, to proliferate and to cause tissue damage and disease, she said.

Strategies to prevent resistance in ICUs

Stephen Eckel, assistant director of pharmacy, University of North Carolina Hospitals, US, said that there is no shortage of literature outlining strategies to contain resistance, but there is a lack of scientific evidence to show a relationship between the overuse of anti-infectives and resistance. Without monitoring, you cannot prove the point, Dr Eckel pointed out. In addition, having a policy does not mean that it is adhered to because, in many places, there is no institutional commitment.

He quoted the following seven-point strategy to prevent antimicrobial resistance in intensive care units:

- Promote appropriate use of multiple drug classes and avoid highly restricted formularies
- De-escalate or narrow broad-spectrum initial empiric antibiotic regimens based on culture and sensitivity results

- Decrease unnecessary use
- Avoid prophylactic use of antibiotics
- Discontinue drugs 24–48 hours after response
- Formulary control, removal or restriction on the basis of antibiotic-resistant outbreaks
- Develop guidelines and protocols to optimise appropriate antibiotic use

Algorithms to shorten the course of antimicrobial therapy in ventilator-acquired pneumonia (VAP) led to significantly lower antimicrobial therapy use with reduction in costs, antimicrobial resistance and super-infections without adversely affecting the length of stay or mortality, Dr Eckel said.

He believes reduction in bacterial resistance is touted as the main advantage of antimicrobial stewardship programmes, but there is a lack of scientific evidence to support it. In a recent study of 33 US hospitals, there was no significant correlation between antibiotic guideline adherence by physicians and resistance rates.

He quoted the basis of an sntimicrobial stewardship programme (ASP):

- [ASPs] should be adapted [according to] individual needs of institutions, but should be adequately resourced to achieve their intended aims
- ICUs should have an ASP accompanied by a system to monitor clinically meaningful outcomes, such as mortality and length of stay
- In the absence of such monitoring, antimicrobial stewardship programmes are nothing more than programmes to reduce antimicrobial use with the largely unproved effect on patient care

He suggested that useful antimicrobial use strategies to reduce resistance to antibiotic use to a minimum include:

- **Before prescribing** Treat only those who are infected
- **During therapy** Avoid combination therapy when single therapy will suffice
- **End of therapy** Treat only for as long as required
- **Get it right the first time** Serious infections require early broad-spectrum therapy

He said that there are few investigations regarding the use of microbiological data to influence antimicrobial therapy and reduce resistance in ICUs. The limited available data point to a reduction in the use of antimicrobial drugs — either stop therapy in patients at low risk of infection, or shorten the duration of therapy — as being most strongly predictive of reduced resistance. He said additional data are needed to provide the evidence base for strategies to reduce resistance in ICUs.

Influenza A (H1N1) pandemic — global challenges and the lessons learnt

Speakers from several countries shared their experience on the planning and strategies used during the influenza A pandemic crisis. Roger Tredree reports from a session organised by the military and emergency pharmacy, and the hospital pharmacy sections

Hospitals and health systems invest substantial resources to maintain an appropriate level of preparedness in anticipation of man-made and natural disasters, said Lee Vermeulen, director of the Centre for Drug Policy, Department of Pharmacy, University of Wisconsin Hospital and Clinics, US.

Preparing for and responding to pandemics of infectious diseases pose several difficult challenges. In April 2009, a virulent and easily transmissible strain of influenza virus (2009 novel H1N1) emerged and began circulating in Mexico, resulting in a number of deaths. Concerns regarding pandemic spread of this virus led to a worldwide response, Professor Vermeulen said. This strain of virus emerged just as countries in the southern hemisphere began their influenza season, and thus had little time to prepare.

Despite having several months to prepare for the arrival of influenza season in the northern hemisphere, planning at national and local levels was difficult, providing many lessons that can inform future preparation efforts, he said. In particular, there had been a conflict between distributing small amounts of available vaccine to a lot of places versus bringing all the patients together. In addition, vaccination of household contacts was not easy to document. In a departure from normal practice, the pharmacy and therapeutics committee had to defer responsibility to infection control. Professor Vermeulen suggested that, to maintain a consistent message, a team must control communication and keep messages brief but highlight changes.

Lee Vermeulen: vaccination of household contacts was not easy to document

Communication is vital

In Canada, there had been widespread fears about the H1N1 pandemic due to its experience with severe acute respiratory syndrome, said Susan Groves, from Canada.

The main lesson learnt was that there had been an age shift for risk from elderly to young people. Lieutenant Colonel Groves said multiple players had resulted in variations in recommendations and policies. In addition, news headlines did not support the positive activity that took place. She said communication needs to be improved and effective knowledge transfer to healthcare providers and the public need to be achieved. She added that technology of the 21st century should be embraced and social media such as Twitter, Facebook, etc, should be used to desseminate information. She said that, during pandemics, explanation must be given quickly and clearly to the public why one group should be vaccinated before another and why antivirals are only suitable for some patients.

"There is insufficient evidence to advocate the use of face masks"

Unnecessary use of antivirals

Zanamivir and oseltamivir, classified as neuraminidase inhibitors, have therapeutic effectiveness for influenza A (H1N1), said Yoshikazu Tasaki, from Asahikawa Medical College, Japan.

Japan has been the greatest antiviral drug-consuming country in the world. Last winter, with the new type of pandemic influenza, many problems were experienced, such as oseltamivir-related abnormal behaviour and inappropriate preventive administration of antivirals.

In 2007, there were post-marketing reports from Japan of neuropsychiatric events, such as self-injury and delirium, with the use of oseltamivir in young patients with influenza. The results of clinical studies over two years, publicised in June 2009, could not show a clear causal association between suicidal events and oseltamivir consumption by teenagers, although the odds ratio was 1.54 times higher, Dr Tasaki said. The government now directs that oseltamivir should not be used for teenagers. However, the conclusion was that behaviour abnormalities developed with influenza itself regardless of taking oseltamivir.

Refering to the efficacy of antivirals for influenza, Dr Tasaki said that there have been numerous controversial reports. Interestingly, the mortality rate in this pandemic season caused by H1N1 was only 0.15 per cent in Japan, which was the lowest in the world. One of the possible reasons, Dr Tasaki suggested, could be that Japan held many stocks of the antivirals prepared for a pandemic influenza.

Correspondingly, oseltamivir-resistant H1N1 viruses emerged in Japan. The ratio of the resistant virus reached 99.7 per cent in the 2008–09 season, compared with 2.6 per cent in the 2007–08 season. Zanamivir is still effective to the resistant virus, however, unnecessary preventive use of the antivirals should be avoided, Dr Tasaki emphasised.

Use of face masks controversial

Margaret Dolan, from National Services Scotland, confirmed that the experience in the UK of the H1N1 pandemic had been similar. It was notable that the outbreak had failed to follow any previous pattern. Until 2009, avian influenza had been the focus and it was expected that it would come from South East Asia, but the pandemic came from Mexico and originated in pigs.

Ms Dolan said most of the public developed a mild illness, with a small subset developing severe progressive pneumonia. Underlying medical conditions (and pregnancy) increased risk, but most severe cases were in previously healthy young people, she said. A number of public information campaigns were run by the Government and these appeared to have had some impact. However, she said, these need to be timely and appropriate in order to maintain a clear and unambiguous message. Ms Dolan referred to the use of face masks by the public and healthcare workers. She explained there are many practical issues, such as making sure the mask fit the individual.

Masks remain a controversial issue for a number of reasons but primarily there is insufficient evidence to show any advantage, she said.

Combating counterfeit medicines: the current global problems and solutions

Gordon Geddes reports from a session organised by the industrial pharmacy and laboratory and medicines control sections that looked at the continuing global battle against counterfeit medicines

There are three strategies involved in combating counterfeit medicines: providing tools, international norms and standards; supporting member states; and developing global activities, said Sabine Kopp, World Health Organization, Geneva, Switerland. Current examples of counterfeit medicines were given, including the antimalarial drug metakelfine, the use of which was suspended in Tanzania in August 2010.

Work on counterfeit medicines started in May 1988 following World Health Assembly resolution 41.16 leading to the formation of the International Medical Products Anti-counterfeiting Taskforce (IMPACT). A definition of "counterfeit drug" emerged in 1992, she said, and terms other than "counterfeit" (eg, "falsified") are used in some member states. Dr Kopp concluded that, although work on fighting counterfeit medicines continues, disagreement among member states hampers progress.

Counterfeit problems: India

In India, radical revisions to the Drug and Cosmetic Act (1940) have been proposed over the years, said Kapil Khambholja, who presented Bhushan Patwardhan's paper on counterfeit problems and solutions in India. A 2007 bill proposes an autonomous central drugs authority of India that, among other improvements, would strengthen the penal provisions for offences such as counterfeiting.

Heidi Wright: margin on fake Viagra is significantly higher than that on real cocaine

Dr Khambholja said that, although the preparation that is most commonly counterfeited is sildenafil, there is an increasing number of reports of counterfeiting in herbal drugs. The detection of counterfeited herbal drugs presents a number of quality control challenges.

The underlying assumption behind phytomedicines is that the whole plant or extract is active, Dr Khambholja explained. Despite many years of research, the active ingredient remains unknown for most plants. In many cases, detailed specifications are unavailable.

Dr Khambholja outlined several quality control approaches and considered herbal drug stability. He said that, despite improved regulations and research initiatives, progress is slow.

Counterfeit problems: China

In China, both modern drugs and traditional Chinese medicines (TCMs) are susceptible to counterfeiting, said Zhong-Yuan Yang, of the Guangzhou Municipal Institute for Drug Control, China. This extends to health foods, some of which may be produced with TCMs. An adulterated health food may illegally contain pharmacologically active substances.

To combat counterfeit drugs, samples selected by the regulatory authorities are tested. Following WHO basic tests for pharmaceutical substances, the drug-testing institutions have developed screening methods for detecting counterfeit medicines according to the logistics in the region. Chemical methods and simple chromatography are supplemented by near infrared spectrometers and chromatographs housed in mobile laboratories. Counterfeit drugs detected by screening are confirmed by an official method, Professor Yang explained. Drug manufacturers are active in combating counterfeit medicines through product-tracing systems, he said. Certain monographs in the 2010 Chinese Pharmacopoeia have been revised to include tests for undesirable related substances (eg, diethylene glycol in, say, propylene glycol). Professor Yang believes that a co-operative effort is required to combat counterfeit drugs.

Screening methods

Robert Watt, of the School of Pharmacy, University of London, discussed methods of medicines authentication, which include:

- Supply chain verification
- Product licence and pharmacopoeia standard analysis
- Conventional chemical analysis
- Spectroscopic analysis
- Combination techniques (eg, minilab)

Near infrared spectroscopy (NIRS) has gained widespread acceptance as a tool for rapid materials characterisation in the pharmaceutical community, Dr Watt said. The principles of NIRS were outlined and the scope and limitations of NIRS methodology as applied to pharmaceutical products were reviewed. NIRS methodology includes sampling, instrumentation, spectral processing, library generation and the interpretation of results.

The task of Dr Watt's research group is to devise a general procedure for the reliable quantification of the active ingredients in tablet samples from the market. The samples may be from different manufacturing sites of the same company, from different manufacturers, generics and parallel imports, as well as counterfeits. Such a procedure might at least ensure the presence of safe and therapeutic levels of the active ingredients, he said. A number of specific examples of the use of NIRS to identify potential counterfeits in model classes of therapeutic products (eg, ciprofloxacin) were described. In reply to a question, Dr Watt said that no technique for the detection of counterfeits was absolute, and that each technique had its advantages and disadvantages.

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Tackling the internet

The Royal Pharmaceutical Society is working on a number of campaigns to increase patient safety and develop processes for the verification of internet sites, said Heidi Wright, practice and policy lead for England, Royal Pharmaceutical Society. These include issuing guidelines in conjunction with other bodies. Professional standards and guidance for providers of internet pharmacy services are available together with permission to incorporate in the site an internet pharmacy logo subject to conditions of use. The logo reduces risks to public health, but it is not foolproof, she said.

Commenting on the profits to be made from counterfeit medicines, Mrs Wright reported that the margin on fake Viagra is significantly higher than that on real cocaine. Wider dispensing of original or patient packs would, she said, ensure product integrity, assist compliance and promote automation and verification.

IDAs Nimo Ahmed, head of intelligence, enforcement and intelligence group, Medicines and Healthcare products Regulatory Agency, described the concept of internet days of action (IDAs), the aims of which are:

- To warn patients and consumers of the risks posed from obtaining medicines on the internet
- To use enforcement activity to safeguard public health
- To maximise media coverage
- To provide advice to the public

Statistics were reported for five IDAs demonstrating their success and leading to international IDAs (Operations PANGEA) involving WHO and Interpol. In 2009, Operation PANGEA II received considerable media coverage, including a report in BBC1's "The one show" in which the Society's internet logo was commended.

Operation PANGEA III is planned for later in 2010. Mr Ahmed noted that enforcement activity alone would not solve the problem. Providing patients with sufficient information to make an informed choice on the safest way to obtain their medicines is the most effective policy.

How the biowaiver procedure could keep costs of drug products down

With the advent of the so-called biopharmaceutics classification scheme, it is now possible to assess bioequivalence for some generic products using dissolution studies. Steven Kayne reports from a session organised by the board of pharmaceutical sciences

José Augusto Guimarães Morais, of INFARMED (Portuguese National Authority of Medicines and Health Products) and the Faculty of Pharmacy at the University of Lisbon, defined bioavailabilty as being the rate and extent to which an active substance, or an active therapeutic moiety, is absorbed from a pharmaceutical form and becomes available in the general circulation or at the required site of action. He presented a pharmacokinetic model to validate the use of the bioavailabilty concept. Bioavailability is related to the active substance, as well as to the formulation and is influenced by food effects, drug-drug interaction and intrinsic factors, he explained.

Bioequivalence is the term used to assess the *in vivo* therapeutic equivalence of two similar active substances, said Professor Morais. He explained that it is determined by making a comparison of bioavailability of the substances under investigation under strict criteria and has proved to be the gold standard for the approval of generic medicinal products with about 40 years of experience without major incidents.

In bioequivalence studies, the factors affecting bioavailabilty (mentioned above), apart from formulation, do so to the same extent for both reference and test substances, Professor Morais said.

Two medicinal products containing the same active substance are considered bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternates, and their bioavailability after administration in the same molar dose lie within acceptable predetermined limits, said Professor Morais. These limits are set to ensure comparable safety and efficacy.

In applications to register generic medicinal products, bioequivalence is established to demonstrate equivalence in biopharmaceutic quality between the generic product and an innovator product in order to allow the use of clinical data (bridging data) associated with the innovator product, Professor Morais explained.

The biowaiver procedure

Jennifer Dressman, professor of pharmaceutical technology at Johann Wolfgang Goethe University in Frankfurt, Germany, discussed whether generics could be approved by regulatory agencies without human bioequivalence studies. She explained that therapeutic equivalence is the sum of pharmaceutical equivalence and bioequivalence. The latter is established by pharmackinetic studies or by using a biowaiver-based submission.

Jan Welink: *in vivo* studies can be expensive

In biowaiver, a procedure validated by the US Food and Drug Administration in 1995, bioequivalence is tested with *in vitro* dissolution. The method can only be applied to approval of generics, products at low doses and products with variations in manufacture.

Professor Dressman outlined the biopharmaceutics classification scheme, which is based on solubility and permeability properties, and explained how it was applied by the Europe Medicines Agency in considering applications. She provided a suggested step-wise procedure for application of biowaiver to generics at the EMEA.

Dick Berends: if a biowaiver is granted for a new formulation, there may be restrictions placed on it

The WHO biowaiver programme

Jan Welink, of the World Health Organization, The Netherlands, described the features of the WHO biowaiver programme, a set of guidelines for national regulatory authorities, particularly those that do not currently have their own policies for such a scheme.

Under these guidelines, an *in vivo* bioavailability and/or bioequivalence is considered unnecessary before product approval. Mr Welink explained that *in vivo* studies can be expensive and time-consuming. Under certain circumstances, a dissolution test can be used as a surrogate basis for the decision on equivalent product performance, he said. He explained that biowaivers are normally accepted for immediate release dosage forms and may also be available for aqueous solutions, gases, aqueous eye and ear drops, inhalers and nasal sprays.

Mr Welink said that WHO also organises and manages a prequalification programme on behalf of the United Nations. The object of the programme is to ensure quality, efficacy and safety of prioritised essential medicines procured using international funds. The programme requires inspections of the manufacturers and monitoring of products after prequalification and prequalification of quality control laboratories, he explained. In July 2009, there were a total of 286 prequalified medicines, of which 244 were HIV/AIDS products, 23 were for tuberculosis and 16 were for malaria, he said.

Biowavier monographs

Dick Barends, National Institute of Public Health (RIVM) Bilthoven, The Netherlands, discussed the application of biowaiver monographs. He explained that the goal of the monographs is to provide information from literature reviews on a known active pharmaceutical ingredient. This information is considered while assessing whether a biowaiver may be granted for a new fomulation. If it is granted, there may be restrictions (eg, with respect to excipients) or conditions and criteria for *in vitro* testing. Mr Barends cited isoniazid as an example of a drug that received such conditions.

Mr Barends said biowaiver monographs can give negative biowaiver recommendations as well as positve. They have no formal regulatory status but represent the best scientific opinions currently available, he suggested.

Improving patient care with pharmacy IT

Lindsay McClure reports from a session organised by the pharmacy information section, which showcased the latest pharmacy IT developments from around the world

Mirixa, a new web-based clinical software platform, is supporting community pharmacists in Australia to deliver national, systemised patient care programmes. Outlining the initiative, Jana Fulcher, a community pharmacist from Queensland, Australia, said that this technology is designed to support the strategic shift towards increased provision of professional services by pharmacists.

The system is made up of two software pieces. First, at the point of dispensing, the MirixaFind desktop software analyses the pharmacy patient medication record system to identify patients who may be eligible to receive a particular service. After approaching and enrolling the consenting patient, pharmacists would then use the MirixaPro web-based clinical platform to support the delivery of clinical care. Specially designed online forms are used to guide pharmacists through consultations, supporting the streamlining of pharmacy workflow and delivering consistency and reproducibility in clinical programmes. The system also supports the documentation of interventions and managing follow-ups.

A number of pharmaceutical companies, including GSK and Pfizer, have supported the initiative to create pharmacy medicines management programmes delivered through Australia's network of community pharmacies using the Mirixa technology, Ms Fulcher said. There are three types of services currently being delivered, the most popular being medication adherence services and services to support patients who have been prescribed a new medicine, she said. The service is also being used to support clinical trials, with the MirixaFind software identifying patients who are eligible to participate in a clinical trial enabling the pharmacist to refer a consenting patient to a clinical trial site. Miss Fulcher said that, in the long term, it is hoped the system will support the delivery of comprehensive medication reviews and targeted patient education programmes.

Poor use of technology an issue

In Ghana, as in most resource-limited countries, there has been poor use of technology, said Alexander Dodoo, from the University of Ghana Medical School.

Dr Dodoo explained that many pharmacies have access to computers, but these are almost exclusively used for stock and financial management. Few, if any, pharmacies use computers to label medicines for patients or to keep patient medication records, often resulting in poor patient understanding of medicines, he said.

Emily Alexander: telepharmacy supports access to trained professionals where traditional staffing models are not advantageous

Dr Dodoo outlined an initiative eight years ago to introduce a British PMR system to Ghana called Mediphase. Once it was installed, the software worked well, but a range of practical problems were encountered, for example, self-adhesive dispensing labels purchased in Britain were not suitable for the tropical environment and quickly lost their adhesive properties, he said.

The key lessons learnt from the experience were that systems need to be integrated and support workflow, there needs to be readily available consumables, for example, labels and tablet cartons, and technical support must be available when problems arise, Dr Doodo suggested. There also needs to be flexibility to customise software for the local setting, for example, adding the names of products only available in a particular country, and key opinion leaders, policy makers and pharmacists must be engaged to ensure user buy-in, he said.

Dr Dodoo said that, after this experience, the Pharmaceutical Society of Ghana believed that better use should be made of the existing IT infrastructure and, because mobile telephones are readily available in Ghana, work has begun to make use of these to create "portable PMRs" for patients through the "mHealth" service. After a patient registers and provides informed consent, each time a prescription is dispensed, a message is sent to the patient's mobile telephone and stored on a specially developed application. The technology is also being used to provide medication reminders via text messages, for example, linked to a tuberculosis medicines adherence service, patients are sent reminders to attend sputum tests. The service is in the final stages of piloting, with national roll-out expected to begin later in the year, Dr Dodoo said.

As part of efforts to meet the United Nations Millennium Development Goals, Dr Dodoo said several donor agencies, including the Global Fund against AIDS, Tuberculosis and Malaria, and the Bill and Melinda Gates Foundation, have contributed billions of dollars towards the provision of medicines to control or eliminate priority diseases. These funds can also be used for supporting interventions, including those necessary to ensure the rational and cost-effective use of medicines.

Telepharmacy and remote supervision

One solution that could help overcome infrastructure and resource barriers to accessing medicines is telepharmacy, said Emily Alexander, from Envision Telepharmacy, US.

Telepharmacy supports access to trained professionals where traditional staffing models are not advantageous, affordable or possible, for example, in rural areas and out of hours, explained Ms Alexander. Manual-, email- and fax-based telepharmacy solutions have now been replaced by web-based systems, which are integrated with different practice models, she said.

Remote medication ordering provides pharmacists with access to prescriptions via a secure website to undertake a clinical review of medicines ordered, Ms Alexander said. The review would be undertaken in the same way as if the pharmacist were physically present, she added. The remote pharmacist has online access to the patient history and the option to initiate a verification or clarification of an order, flag an issue for another staff member to consider, report an adverse drug event and enter the order into the system.

An alternative telepharmacy model is "pharmacist electronic supervision", which enables joint working between a pharmacist and a technician across different locations. Images of dispensed products are shared by the technician via a secure website for the pharmacist to check. Remote supervising pharmacists use web-based tools and imaging systems to provide real-time web-based oversight, control and consultation. All communication is documented and is later retrievable.

Ms Alexander said the regulations surrounding supervision vary in different states across the US. In some states, as long as the remote supervising pharmacist is appropriately licensed in that state, they could be physically located in another state or even in another country.