

PHARMACEUTICAL CARE

D. K. LUSCOMBE*

With the advent of potent modern medicines and the realisation that absolute safety is impossible to achieve, the clinical pharmacist has assumed a central role in ensuring that medicines are only administered when necessary and then only when the intended beneficial effects of drug therapy have been balanced against the risks. This embraces the concept of pharmaceutical care which Hepler & Strand have described as 'that component of pharmacy practice which entails the direct interaction of the pharmacist with the patient for the purpose of caring for that patient's drug-related needs' (1).

During each of the three primary stages in the drug administration process (information gathering; monitoring; follow-up), protection of the patient from the potentially harmful effects of medication should be uppermost in the mind of the pharmacist if drug-related problems are to be avoided. Such problems include: determining whether a patient is in need of drug therapy but not receiving it; receiving the wrong drug; receiving too little of the correct drug; receiving too much of the correct drug; experiencing an adverse drug reaction; experiencing a drug interaction.

The *information gathering stage* provides the opportunity to take the patient's drug history and evaluate the various 'safety' risk factors associated with drug therapy. These include age, the young and elderly being particularly vulnerable to the harmful effects of drug, whether patients have renal impairment, liver disease (jaundice, ascites, cirrhosis), associated pathology (diabetes, thyroid dysfunction), are pregnant, have a history of allergy (penicillin, aspirin) or previously suffered side-effects to drugs (NSAIDs). In reaching a decision on the choice of medication for an individual, the safety record of the drugs intended for use must also be considered. For example, digoxin and cytotoxic agents have narrow therapeutic indices and in consequence will require close monitoring. Likewise, attention must be focused on the potential for drug interactions and the possibility of non-compliance.

Despite an appropriate medicine being initially selected during the information gathering stage, there remains the possibility that the patient will experience an unwanted drug-induced effect. At best this may be a minor side-effect whilst at worse a serious adverse drug reaction or interaction may result. Thus, the responsibility of the pharmacist during the next so-called *monitoring stage* of the drug administration process is to ensure that a satisfactory balance is

* Wels School of Pharmacy, University o Wales, Cardiff CF1 3XF, U.K.

achieved between the benefits of drugs being administered and the risk of harm being caused to the patient. This is fundamental to pharmaceutical care. Many of the unwanted effects are readily predictable from a knowledge of the mode of action of the drug (or drugs) involved whilst others are unrelated to the drug's pharmacological profile. Tricyclic antidepressants such as imipramine and amitriptyline induce dry mouth, blurred vision, sedation, urine retention; effects related to their anticholinergic properties. Such side-effects generally subside within a week or so of starting treatment. Many antibiotics such as ampicillin and its derivatives frequently cause diarrhoea as a result of interference with normal gut flora. Older antihistamines (H_1 receptor antagonists) cause drowsiness as a result of associated anticholinergic activity, requiring the patient to be warned that their ability to drive or operate machinery safely may be impaired. Generally, unwanted effects due to the principal pharmacological action are reversible and the problem can be resolved by reducing the dose (ie, bleeding with anticoagulants) or changing to a different drug. However, they are not always reversible, for example, tardive dyskinesia induced by neuroleptic drugs. Fortunately, these do not occur very frequently.

Adverse reactions pose a particular problem for pharmacists. They are usually more serious than side-effects, such as hepatotoxicity with paracetamol and nephrotoxicity with cyclosporin. The considerable problems associated with adverse reactions cannot be over-emphasized: 10-20% of hospital in-patients suffer an adverse reaction; 0.24-2.9% of deaths in hospital are drug related; 0.3-5.0% of hospital admissions result from adverse drug reactions (ADRs). The elderly are particularly susceptible, with 15.4% of these patients experiencing an ADR compared with 6.3% of those aged under 60 years (2). Furthermore, it has been reported that 1 in 10 admissions to care of the elderly units are due to an ADR (3). Many drugs have induced such harmful effects that they have had their product licences revoked. For example, zimelidine induced hepatotoxicity and convulsions and was withdrawn from the market (4). Likewise, Osmosin, a novel oral dosage form of indomethacin which caused bowel perforation (5) was withdrawn from the market. Drugs such as stilboestrol which induces vaginal cancer in the offspring of mothers who received this drug in pregnancy (6) and phenylbutazone which leads to agranulocytosis (7) have restricted use due to their known toxicity. Females of childbearing age should not be administered stilboestrol while phenylbutazone may only be used in the UK for the treatment of ankylosing spondylitis where other therapy is unsuitable. Other examples of serious ADRs include the oculomucocutaneous syndrome induced by practolol (8-10) and hepatic and renal damage induced by the anti-inflammatory agent, benoxaprofen (11). Pharmacists should always be on the alert for possible ADRs by noting whether patients have recently had a medication change (dose reduction or stoppage) or whether a new drug has been started. Although few pharmacists are involved in ADR monitoring, Booth *et al* (12) have clearly demonstrated that pharmacists can help in limiting the harmful effects of ADRs. They established a rapid alerting system in which a 'dedicated' ADR monitoring pharmacist made

daily visits to all medical wards of a University hospital, collecting and assessing every report of a possible ADR. Causality was determined using a Kramer algorithm and the prescriber and regulatory authority informed of the outcome. In the community, Whittlesea *et al* have recently established a successful ADR scheme confirming that community pharmacists also have a potential role in monitoring ADRs (13). Importantly, the scheme was well received by the community pharmacists recruited to the study and also by the general practice physicians whose patients were monitored.

Drug-induced side-effects are generally a less serious problem than ADRs and may in some instances be avoided by direct measurement of a pharmacological or clinical effect of the drug or by measuring the parent drug and metabolite concentrations in body fluids and determining its pharmacokinetic profile. The role of the pharmacist in limiting drug interactions is two-fold: to anticipate such interactions thus avoiding them if possible, and to recognise them early if they occur in order to limit their harmful effects. Particular care is needed with high-risk drugs such as (a) warfarin and morphine which affect vital processes; (b) digoxin, aminoglycosides and lithium which exhibit concentration dependent toxicity; (c) phenytoin with its saturable hepatic metabolism; (d) drugs such as oral contraceptives and anticonvulsants in which their prophylactic effectiveness may be overcome. One should also remember that certain groups of patients are particularly susceptible to interactions. For example, the elderly who are frequently receiving a number of drugs, the acutely ill (severe anaemia, asthma, congestive cardiac failure), patients with unstable disease (diabetics, epilepsy), patients in whom drug therapy is vital (transplant patients) and those with renal or hepatic impairment. Drug interactions can be minimised by taking a careful drug history, avoiding multiple drug therapy if possible, being alert to high risk drugs, by keeping drug changes to a minimum, and monitoring changes. A new approach to assessing drug safety has resulted from the development of health-related quality of life instruments. Such instruments have proved useful in quantifying the side-effect profile of individual patients to drug therapy (14).

The *follow-up* stage involves the pharmacist in the concept of 'seamless care'. Clearly, safety of the individual patient should not stop on hospital discharge but should continue in the community setting, whether this be the patient's own home or a residential or nursing home. Immediately prior to hospital discharge the pharmacist has a duty to ensure that prescribed medication continues to be taken correctly. The accuracy of discharge prescription should always be monitored since they frequently contain errors which could lead to patient morbidity. In a recent study (15) of 147 hospital discharge prescriptions, some 34.7% were found to contain at least one error. A further 41% were found to be incomplete with items such as analgesics and hypnotics being omitted. Failure to update accounted for 15% of errors and were mainly associated with a failure to register a change in antibiotic while 4% were transcription errors such as an incorrect dose being transferred from the medication chart to the discharge

prescription. The clear message is for clinical pharmacists always to compare the discharge prescription to the medication chart in the interest of patient safety. Other services which aid drug safety during the *follow-up* stage of the drug administration process include structured self-medication programmes in order to assess the patient's ability to self-dose on returning to the community. This is particularly helpful for the elderly. Likewise, discharge counselling ensures that patients understand their dosing regimen. Although not widely practised, home visits, particularly for the elderly, provide the pharmacist with the opportunity to monitor compliance. It is seldom realised that non-compliance can be a safety hazard as highlighted by the fact that it is a leading cause of organ rejection and death following kidney transplantation. Medication checks on storage can also be carried out during home visits and out-of-date or unwanted medicines removed to reduce risk factors.

In conclusion, pharmaceutical care encompasses all aspects of clinical pharmacy. It represents a systematic approach designed to identify and resolve drug-related problems and determine what therapies, services, and advice each individual patient needs. Providing pharmacy practitioners embrace the concept of pharmaceutical care then the profession of pharmacy will be a major contributor to health care for many years to come.

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IMPACT OF CLINICAL PHARMACY EDUCATION ON PHARMACY PRACTICE IN MALAYSIA

Ee-Kiang GAN*

Meeting manpower need is obviously one of the roles educators in institution of higher learning is expected to play. However, more importantly, educators must ensure that the graduates produced must not only be educationally sound, but also professionally competent and adequately tuned to conditions that are prevailing so that upon graduation, they can perform their duty effectively. We, as pharmacy educators, must be responsive towards the trend of professional practice in order that we can plan and design our curriculum, so that graduates in pharmacy are adequately exposed to the relevant area of practice which will help them to face the challenges ahead. World-wide, the entire healthcare system is changing rapidly. New areas and new opportunities are surfacing. We must not only be aware of these developments. We must analyse these changes and see what opportunities there are for pharmacist. In short, we must be innovative, we must prepare graduates that are not only knowledgeable, but also versatile, so that they can venture into new areas of practice for the good of the patient. The practice of pharmacy is entering an exciting era. Many things are happening to pharmacy and pharmacy practice. Needless to say, there are new and exciting opportunities. It is up to the pharmacist to grasp them.

DEVELOPMENT OF PHARMACY PRACTICE WORLD WIDE

If we look back on the historical perspective of pharmacy practice, there appeared to be three stages in the evolution process. In the early days, pharmacists are mainly involved in the compounding of medication. Knowledge base included the theory behind the dosage design and the dose formulation, and how individual drug ingredients were compounded into a finished dosage form, such as a capsule, a suppository or a mixture. The standard of pharmacy service is measured by the dispensing abilities of the pharmacist. Pharmacist then maintained a passive posture in regard to drug therapy. Curriculum in schools of pharmacy then only emphasized on basic chemical/physical sciences. The training of pharmacist then was very much apprenticed, with the student working under a qualified pharmacist to acquire knowledge and skill in compounding. Automation and dispensing by pharmacy technician were factors responsible to thrust the pharmacy profession into the second stage of the evolution process. This resulted in the

* School of Pharmaceutical Sciences, University Sains Malaysia., Minden. 11800 Penang, MALAYSIA.

pharmacist abandoning the compounding duty and began to centre its role on the distribution of prescription and nonprescription (over the counter) drugs. In discharging their duty, pharmacists were meticulous in assuring that prescriptions were correctly filled, that overdose and incompatibility were recorded, that adequate drug supplies were maintained and proper records on all transactions kept. Some pharmacist also served as information sources for patients who enquired about the medication prescribed. This aspect, however, was restricted to providing information that could be read from a drug catalog or obtained from the package insert. Often the information provided was limited to dose and frequency of administration and storage condition. Pharmacy profession had no idea of how to utilize its science-base graduates to provide patient-oriented health services anymore than the schools were educating them knew how to merge the scientific knowledge with the patient need. The pharmacy curriculum was a very product oriented one. In the product oriented curriculum, there is a heavy emphasis on the synthesis, analysis and physical/chemical properties of drugs, as well as design of dosage forms. Students also studied pharmacology, but it was neither a major emphasis of the curriculum nor clinically oriented and did little to enhance the understanding of disease or drug therapy. This stage coincided with the birth of drug store concept, both independent and chain, particularly in United States where everything imaginable could be purchased. Many pharmacy schools then devoted significant portions of the curriculum to pharmacy management. Some pharmacy schools even experimented with business course including accounting to further enhance the image of pharmacist as one who conducts business rather than one who is an important health care provider. So prominent have these activities become that in the minds of the public, the pharmacist has come to be looked upon primarily as one who conducts a business or a commercial establishment rather than one who is engaged in the practice of a profession (1). This to my mind represents the second stage of development in pharmacy practice in the evolution process.

The third stage of development actually began in the sixties. Suddenly, the medical literature was blossoming with information that indicated serious problems existed in the use of drugs (2). It was noted that:

- a. significant portion of all drugs prescribed were underdosed, leading to therapeutic failure or overdosed,, causing toxicity
- b. drug interactions were more prevalent than anticipated, some of these were life-threatening
- c. the cost of drug therapy was being driven up by prescribing drugs which offered no advantage over less expensive, sometimes safer medication
- d. non-compliance in drug usage is more widespread than originally anticipated

If we examine these observations., it is not surprising as many drugs that are released in these period are more specific in effect, more effective and in many instances can bring about more serious adverse effects. Moreover, many of these modern drugs require individual dosage which may differ substantially between individuals because of genetic factor, because of

pathophysiological conditions and because of other factors that are likely to interfere with the dosage. There is thus a growing need for drug therapy experts who can advise physicians concerning the selection of the optimum therapeutic agent for specific patients, the drug dosage form, the avoidance and/or reduction of undesirable drug reactions and interactions, and the opportunities for economic savings in the ever escalating health cost (3). Due to the explosion of knowledge in diagnosis of disease, medical schools are not able to provide adequate coverage on drug therapy to medical students. And since pharmacy practice has always been centred on drugs, it is natural that this important role be shouldered by pharmacists. Thus we see the birth of clinical pharmacy practice. Direct pharmacist involvement with patients occur on admission if a detailed medical/drug history must be elicited, during the treatment phase when pharmacokinetic and adverse reaction monitoring are indicated, and on discharge when it may be necessary to give medication-related instruction to patients through counselling process. The orientation of pharmacy service shifted from one that is very product-oriented to one that is patient oriented. In the process, pharmacy profession was thrust into the front line, side-by-side with other health professionals in delivering health care services particularly in relation to rational use of drug. In so doing, pharmacist became an important member of the health care team. This change has not been easy, neither has it been smooth. One important contributing factor for the success of clinical pharmacy practice is the professional pharmacy curriculum, which provided the intellectual basis for the practice.

EDUCATING PHARMACIST TO SUIT THE CURRENT PRACTICE ROLE

New knowledge and new skill are therefore needed for successful clinical pharmacy practice. Before the introduction of clinical pharmacy practice, the required knowledge and skill are in the area of handling and dispensing a drug product. The knowledge required then had been in the area of chemical/physical sciences. The skill required had been essentially mechanical and related to drug as a product. Skills in business management were added during the peak of development of drug store concept. With clinical pharmacy practice, the knowledge and skill required has changed. They must be of drugs and their effect on the patient. **Pharmaceutical Care** has become pharmacy's new mission. Pharmaceutical care as described by the report of Pew's Health Profession Commission (4) is about safe and appropriate use of drugs. It is about achieving specific outcome through the optimal use of drugs that improve a patient's quality of life and this includes the curing of a disease, elimination or reduction of a patient's symptom of the disease, arresting or slowing of a disease process and preventing a disease or symptom of the disease. In line with this, colleges of pharmacy must therefore commit themselves to curriculum reform and curriculum change. This is being done in order that pharmacist can continue to serve the society needs. The orientation of pharmacy education must be towards training a pharmacist to provide pharmaceutical care. The curriculum must enable pharmacists manage drug therapies in patient so that there is rational drug use. To achieve this, the Commission listed the following activities:

- * participate in the decision-making process in drug therapy
- * determine dose and dosage schedule
- * selection of appropriate dosage form, administration, and/or delivery system
- * prepare and provide drug product to patient
- * counsel patient
- * monitor patient to ensure compliance
- * monitor patient progress with the aim of achieving therapeutic objective
- * monitor patient to prevent/reduce adverse drug reactions and drug interactions

IMPACT OF CLINICAL PHARMACY EDUCATION ON PHARMACY PRACTICE IN MALAYSIA

The wave of clinical pharmacy that swept through the United States of America in the late sixties had a dramatic influence on our pharmacy curriculum. Clinical pharmacy course was introduced into our curriculum in the seventies. The introduction of clinical pharmacy into our curriculum was not without problems. The school was faced with not having properly trained practitioners to conduct this clinical component of education. The clinical pharmacy course then was conducted by physicians and Ph.Ds in the biological sciences mainly by experimenting, and by trial and error. Structured clinical pharmacy course was only introduced into our curriculum in Malaysia in the early eighties. Currently our undergraduate in pharmacy spent the final year (4th year) undertaking clinical pharmacy programme in the teaching hospital following courses in pathophysiology, clinical pharmacokinetics (and its application in therapeutic drug monitoring), therapeutics and pharmacoinformatics. This was made possible when we were able to engage several Pharm.D graduates (from U.S. university) to serve in our faculty. It was this critical mass of Pharm. D staff (7 in total) that spearheaded our clinical pharmacy education that sets the pace for the changing role in the practice of Pharmacy in Malaysia. Prior to this the practice of pharmacy in Malaysia was very much product-oriented playing a very passive role. Today the practice of pharmacy in Malaysia is very much patient-oriental enjoying a high profile as an important member of a healthcare team. In all the major hospitals and in many of the community pharmacy practice in the country, clinical pharmacy and pharmaceutical care concept are being practiced. This would not have been possible without our introduction of clinical pharmacy education into our curriculum. While emphasis is placed on patient-oriental curriculum, the school is fully aware of the importance of basis sciences in the pharmacy curriculum. One is reminded that it was research in biopharmaceutics and pharmacokinetics and the incorporation of these areas of study into the curriculum of schools of pharmacy that was responsible for the initiation and subsequent development of clinical pharmacy. These two areas focused the attention on drug as a therapeutic agent rather than drug as a product and provided pharmacists with the knowledge base and intellectual qualifications that make them functional, that made them useful members of the healthcare team (3). The clinical pharmacy component in the school is therefore an "add on"

rather than replacement of some of the basic science component. We believe that this is a good strategy to ensure that the scientific component of the pharmacy education is not sacrificed, so that the pharmacists trained by us remained component scientifically.

The experience we gained in clinical pharmacy education at undergraduate level for the last ten years put us in a very good position to consider offering a postgraduate programme at Master level through course work studies. This indeed was launched in 1992 with a first intake of 12 students including some students from neighboring country. In addition to the didactic teaching, the Masters course is supplemented with clerkships rotating amongst the various area of specialisation in the ambulatory setting. This is a very effective means of teaching. As we enter the third year since the Masters programme is initiated, the school continues to receive application from candidates both from within Malaysia and from overseas. Through this course we hope to increase the number of specialized clinical pharmacist that will continue to provide and upgrade the pharmaceutical care concept. Through this course, pharmacist in Malaysia can be expected to play a more effective role as member of a healthcare team, bringing along specialized knowledge on rational drug use.

CONCLUSION

I have talked about the changing role of pharmacist world wide. I have attempted to trace the historical development of pharmacy practice and illustrate how education can influence the practice of pharmacy. The introduction of clinical pharmacy in our curriculum has definitely set the pace of change in pharmacy practice in Malaysia. It has transformed the profession from a passive, product-based practitioner to that of an effective healthcare team member, well versed in scientific methods and at the same time competent in social/behavioral and biomedical/clinical sciences.

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