MALAYSIAN JOURNAL OF PHARMACY

In this issue:
- Pharmacy Practice in Malaysia
- Bioethics
- Career choice of Malaysian pharmacy students
- Public awareness of community pharmacy
- Analysis of glibenclamide by HPLC

A Publication of the Malaysian Pharmaceutical Society
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Publish and disseminate

Research in pharmacy-related areas within this country is growing. If not for anything else, the job promotion tied to research publications should serve as a carrot to academicians, and yet many useful local research findings have ended up as dissertations kept in the darkest corners of the library. While research is normally associated with academicians, it is not confined to that group. Practising pharmacists also play an important role. For example, the Malaysian Pharmaceutical Society has supported studies such as “Survey on Diabetic Care Management”, that was presented by the Pharmacy Practice Chapter at the Society’s Project 2003 Workshop II held at Kuala Lumpur in 1999. The findings however were only shared among the group of pharmacists who were able to attend. Many hospital pharmacists also do carry out small research projects, but presentation of the results is often limited to members of that department. All these highlight the need for proper documentation, where valuable findings can be widely disseminated and discussed, and help reduce repetitions in research.

So, for a long time now, it has been the aim of the Malaysian Pharmaceutical Society to publish its own journal. As well as to encourage research and publication, this journal intends to keep local pharmacists, academicians and others in the related areas in touch with the profession. This bi-annual nationally peer-reviewed journal covers areas related to Pharmacy in the form of General Articles, Invited Reviews, Research Papers and Book Reviews. In addition, the Continuing Pharmacy Education section allows members to earn CPE points. The editors would like to invite you to submit manuscripts for the areas above, which will be reviewed year round. Please refer to the Instructions for Authors on page 36 for more information. Feedback on articles in each issue is welcomed, and these will be published in the Letters to the Editor section in the following issue.

In order for the widest readership possible, this journal will be distributed to members of the Society throughout the country, and later on, to allied health professional organizations, universities and relevant government agencies. We hope that for now, this journal will be the avenue for pharmacy publications within the country, and that our boundaries will expand regionally in the future.

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Pharmacy Practice in Malaysia
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ABSTRACT
Pharmacists in Malaysia practise their profession in rugged terrains which demand both professional skills and pioneering spirits. Many of the current pharmaceutical standards, practices, and legislations need overhauling in order to meet the aspiration of the nation in this new millennium. The Malaysian Pharmaceutical Society has a vital role to play. The profession requires the greatest understanding of the Malaysian Medical Association and the Government in this transition period.

Keywords: pharmacy practice, pharmacy standards, legislations, healthcare, Malaysia

INTRODUCTION
Pharmacy is a learned profession. It is a well-established science-based profession which possesses all the essential characteristics of a professional group. Four main characteristics reflect the profession’s distinctiveness: the special sphere of knowledge and intellectual discipline, well defined functions, professional ethics and conduct, and practitioners representative body. Persons who desire to partake in the profession need to master the pharmaceutical sciences.

The first distinctive characteristic concerns the special sphere of knowledge and intellectual discipline. Knowledge in the pharmaceutical sciences may be acquired through undergraduate pharmacy degree courses presently available locally in Universiti Sains Malaysia, Universiti Malaya, Universiti Kebangsaan Malaysia, International Medical University, Sepang Institute of Technology and Sedaya College. In addition to these six institutions of higher education, Universiti Teknologi Mara and International Islamic University are expected to offer pharmacy degree course soon. Pharmacy graduates from 56 other overseas universities, in 13 countries, are also recognized by the Pharmacy Board (1). Only pharmacy students who have satisfactorily completed the prescribed course are permitted to embark upon the compulsory twelve months of pre-registration training in an establishment recognized by the Pharmacy Board. Currently a pre-registration pharmacy graduate has a choice to receive training in either hospital pharmacy, community pharmacy, manufacturing pharmacy or wholesale trading pharmacy.

The second feature is the presence of a national body representing all the pharmacy practitioners. Malaysian Pharmaceutical Society (MPS) was formed and incorporated under the Society Act in 1965. It promotes pharmaceutical practice, protects the interests of the practitioners and end-users, and encourages the advancement of the pharmaceutical sciences. It is interesting to add here that another two pharmaceutical societies, namely Sabah Pharmaceutical Society and Sarawak Pharmaceutical Society also co-exist to champion the pharmacy profession in the states of Sabah and Sarawak, respectively.

The third feature relates to the professional ethics and conduct which guide all members. The Council of MPS had issued a guideline on the matter. Uniquely the Pharmacy Board had also issued the “Code of Conduct For Pharmacists and Body Corporates”. By virtue of the power given to
the Pharmacy Board under Section 22(1)(e) and (j) of the Registration of Pharmacists Act 1951, this document may be legally binding upon the pharmacists.

The fourth feature of a learned profession is the provision by its practitioners of uniform professional services and advice to the public. This refers to the supply of medicines to the public, accompanied by appropriate advice (that is, patient medication counseling) during the dispensing process.

Pharmacy, as a learned profession, was rarely challenged since time immemorial. The inherent dynamism has brought it through several rounds of professional metamorphosis. As a result, the practice of pharmacy has been described in a variety of ways.

WHAT IS PHARMACY PRACTICE?

Differing views have been presented on this matter. Some consider it a profession, others look at it as a trade – albeit a professional one. There is no concise and precise description on what pharmacy practice should be. Perhaps the difficulty is due to the co-existence of both specialized and generalized professional services which the profession offers.

Nonetheless, pharmacy practitioners all agree that pharmacists ought to know the properties (which include pharmacodynamics, pharmacokinetics, mechanisms of drug action, side-effects, adverse drug-drug reactions, adverse drug-food reactions, and drug toxicity) of all the medicines, their formulation processes, proper storage conditions, and appropriate usage. Such knowledge should be applied primarily towards public interests during the course of our profession activities. These professional activities pertain to the supply of medicines for humans, supply of veterinary medicines, infant and enriched formulas for adults, sick-room appliances, agricultural, horticultural and industrial chemicals, scientific apparatus (such as stethoscopes and clinical thermometers), surgical appliances and instruments, electro-medical therapeutic apparatus (such as blood pressure meters and blood glucose or cholesterol monitors). But many pharmacies also offer non-professional activities which are often closely associated with pharmacy, such as the supply of perfumes, cosmetics, toilet requisites and photographic materials.

Pharmacy practice in Malaysia varies from one pharmacy to another. Chain-store pharmacies usually offer a significant proportion of non-professional services and activities alongside the traditional professional services. Smaller independent pharmacies normally focus on professional pharmacy services. Both types are representative of private pharmacy practice in Malaysia. On the other hand, pharmacy practice in the government sector is quite different. Government pharmacists enjoy a more favourable legal environment which permits them complete control over the supply of medicines. Government doctors do not provide pharmacy services to patients, unlike their counterparts in private practice. Consequently, private pharmacies operate under very harsh and unfavourable conditions imposed by legal and historical limits. Many community pharmacies do not even receive one prescription chit a day! This unhealthy scenario should be rectified by the government, with the full understanding of the Malaysian medical profession. It is hoped that the pharmacy profession will be granted a new lease of life in this new millennium.

PHARMACY PRACTICE IN THE NEW MILLENNIUM

Malaysia is one of the front-runners amongst developing countries in this high technology information era through the creation and implementation of the world renowned Multimedia Super Corridor. Our nation ranks 16th as a world trading nation, and we are a signatory to almost all international treaties including global trade liberalization related to the World Trade Organization. Global trade liberation will inevitably be accompanied by a free flow of professionals (such as lawyers, accountants, pharmacists and doctors). With a relatively lower pharmacist to population ratio coupled with a comparatively higher salary in our country, neighbouring foreign pharmacists will flow into Malaysia to fill up any shortage. We may not be prepared sufficiently to handle the situation to the national advantage. The interests of local practitioners may be damaged. In this context, the pharmacy profession in Malaysia needs to work doubly hard so as not to be caught unprepared.

Against such a background, MPS has risen to the occasion by examining the various professional issues and putting in place necessary strategies to enhance professionalism in every aspect of the
pharmacy practice. The undersigned feels strongly that Malaysian pharmacists need to address the following matters in order to be able to contribute more meaningfully, as an important primary healthcare team member, to the overall health of the nation:

(a) Control over the supply of medicines

As mentioned earlier, private medical doctors control a large percentage of medicines supplied to patients. It is high time that this control be exclusively given to pharmacists who, after all, are the only professionals properly trained for the job. In 1984, the Malaysian Medical Association (MMA) had agreed, in principle, that the present system should change for the better. Physicians should focus on diagnosis and prescribing. The dispensing of medicines had been mutually agreed to be the professional role of pharmacists and should, therefore, be implemented for both the public, as well as the private sector.

Many brainstorming sessions have been held on this matter. Finally, MPS launched in 1998 Project 2003 to spearhead this professional activity. Seven sub-committees (namely Pharmacy Practice Standards Committee, Professional Competence Committee, Professional Image and Public Education Committee, Telepharmacy Committee, Pharmacy Legislation Committee, Manpower Projection Committee, and National Drug Policy and National Healthcare System Committee) were established to examine and prepare reports on various important aspects of the profession. It is hoped that a formal official recommendation will be ready for submission to the Government by the middle of 2001.

(b) National Healthcare Fund

National healthcare bills have risen sharply in recent years. Health expenses in 1999 were reported at about four and a half billion ringgit. There is a need to cap and control the bill and to involve citizens in this important matter. As a caring and well-planned nation, it seems an excellent idea to introduce a National Healthcare Fund to finance all future needs of the people in our medication-treatment. It should be by and for the people. The government also needs to budget for it because about one-third of the population will require subsidy.

Indeed, Malaysia cannot afford not to plan ahead for a National Healthcare Fund or a similar scheme because in about 10 years’ time, a fifth of our population would have aged beyond 65 years. The geriatric population requires a bigger budget for health matters. And it will not get cheaper as the years go by.

The National Healthcare Fund should finance all medicines supplied. Pharmacists should be paid a professional fee for services rendered to the public. This will enhance the professional image of pharmacists, and place us at par with other professionals in Malaysia. MPS needs to contribute proactively, through seminars and public talks, singularly as well as collectively, with other stakeholders (namely MMA, allied health bodies, consumer groups, Insurance and Managed Care Organizations) to work out a win-win formula for all the health service providers and users.

(c) Even distribution of pharmacy services

The present 3000-plus registered pharmacists is expected to increase to about 5000 by the year 2004. MPS needs to ensure an even distribution of pharmacies throughout the country. Some sort of pharmacy zoning system may be necessary. The populace should be entitled to receive similar standards of pharmacy services to that in the big cities. A duty roster will ensure round-the-clock availability of medicines to needy patients.

In cities such as Kuala Lumpur, Kota Kinabalu, Kuching, Johore Bahru and Penang, there are probably too many private community pharmacies catering to the needs of city dwellers. Perhaps newcomers should be given incentives or legislated to set up pharmacies in small towns and rural areas. In rural places where there are no private clinics, private community pharmacies can still complement the services provided by the government's rural clinics. A town of 30,000 people requires about three private community pharmacies to work side by side with the public/hospital pharmacies. Distribution of pharmacies should be worked out on a district basis.

It was reported that there are about 350 pharmacists working in government hospitals, clinics, laboratories and stores (MMA press release, 24th August 2000). This represents about 13% of all practising pharmacists. However, 45% of the medical practitioners work in the public sector. Obviously the national pharmacist shortage lies in the public sector. Urgent action needs to be
taken by the government to rectify this problem.

The Health Minister announced, on 9th December 2000, the requirement for a compulsory three-year government service for all newly qualified dentists, effective from 1st January 2001. It is time that pharmacists join the doctors and dentists in compulsory national government service. This is in line with the present global paradigm shift in healthcare delivery.

(d) Self-regulation in pharmacy standards and practice

There is a need for a paradigm shift in allowing the learned profession to be self-regulated in matters pertaining to pharmacy standards and practice. These refer to ethics and conduct of pharmacists, the continuing competence of members to practise, and assessment of new entrants into the profession.

Some other professional groups in Malaysia (such as the MMA and Malaysian Advocates Society) have been self-regulating in these matters. It is a step forward which will inevitably bring much benefit to the people.

Continuing Pharmacy Education (CPE) for the practising pharmacists is a universal trend carried out by most advanced nations. The United States of America and the United Kingdom adopt different CPE systems. Perhaps the MPS-CPE pioneering project can form the basic framework to build upon. Seminars, conferences and certain write-ups can be a basis for assessment. To capture all CPE efforts, it may be reasonable and feasible to adopt the American Log-Book system where the onus to maintain records lies with the practitioners. The Royal Pharmaceutical Society of Great Britain (RPSGB) had introduced the Continuing Education Logbook in 1995 (2). The RPSGB are in the process of consulting its 40,000 members in working out a new framework for professional regulation with measures to ensure professional competence and lifelong learning (3).

Our present pre-registration training programme has its form but lacks mechanisms for monitoring the actual progress of students. Visual assessment may not be sufficient and objective enough. Regular intervals of written assessments are preferable. The pharmacist-supervisors' input will depend on his/her experience and knowledge. A systematic write-up on what to impart and a standard list of reference books/materials should standardize the supervision. Wholesale trading pharmacy and manufacturing pharmacy do not expose the pre-registration students to adequate patient counseling. Many students are left to ‘learn on their own’. It is vital for the profession to ascertain whether it is important for all students to attain the same breath and depth of professionalism in the different disciplines.

The undersigned recommends the New Zealand system that was recently implemented. Since 1997, all newly qualified pharmacy graduates in New Zealand undergo a twelve-month pharmacy pre-registration training program which defines seven professional competency standards expected of a registered pharmacist. A combination of on-the-job assessment, submission of assignments, performance at training days, completion of a learning record, and attendance at a final assessment centre determines the standards achieved (4). Australia is likely to follow a similar competence-based accreditation for pharmacists (5).

(e) Education and research

Pharmacy has been designated as one of the priority development areas in our knowledge – based new economy which our government is very determined to nurture. Pharmacy educationists need to ensure that our profession is well positioned to derive optimal growth. The choice of subjects in undergraduate pharmacy degree programmes ought to provide wide coverage and sufficient depth in all the pharmaceutical sciences. Postgraduate studies should produce specialists in various disciplines such as pharmaceutics, pharmacognosy, synthetic-medicinal chemistry, clinical pharmacy and pharmaceutical biotechnology. Our educational system needs to produce both generalists as well as specialists who will contribute to the further advancement of the profession.

The local pharmaceutical industry may form a symbiotic partnership with academicians. The latter can generate the much needed input in basic pharmaceutical science research. The former can commercialize useful products or applications for mutual benefit. This modulus of operation is a norm in many advanced countries.

A sound pharmacy education system with emphasis and smart partnership in research and development will surely bring forth tremendous progress to the pharmacy profession in Malaysia. Greater and closer co-operation between
pharmaceutical scientists in universities and the pharmaceutical industry in areas such as production of raw material for pharmaceuticals, synthesis of new and useful chemical entities, biotechnology in manufacturing, design of new and better methods in extraction of active ingredients from local medicinal plants, formulation, and general transfer of technology from the academic scientists to the pharmaceutical industry should be encouraged.

(f) National Formulary and Pharmacopoeia:

A hallmark of a learned profession is a systematic accumulation and compilation of new knowledge into reference standards or specifications which posterity can build upon for greater advancement. The legal profession has unmatched achievement in this matter. All advanced western nations have built up their own wealth of knowledge and technology over a long period of time. After being independent for four and a half decades, Malaysia should begin to build its own Pharmacopoeia and National Formulary.

It is a matter of grave concern that many locally concocted medicinal preparations are not properly documented. Many rural folks ("village doctors") have been using selected plants as medicines for generations. This knowledge of traditional medicine needs to be preserved in writing (into Formulary or Pharmacopoeia) before these old folks leave us for good.

Even worse still is the fact that we may lose a large range of indigenous plants during our rapid economic development. Malaysia is blessed with about 12,500 species of medicinal plants (6) which can be a valuable source of new drugs. As much as 50% of modern medicines have been derived from plants, the majority of them from the tropical forest (7). The Malaysian forest represents one of the richest of the region's tropical forest but is also in serious danger of over-exploitation.

Much research has been initiated by local scientists in the fields of natural product chemistry but the scientific impact these efforts has generated is minimal. Much of the activities are confined to detecting and identifying the chemical constituents that possess biological activity and are often discontinued at the juncture where critical animal or human testing is required further (8).

The Malaysian Herbal Products Blueprint was launched in September 2000 by the Malaysian Industry-Government Group for High Technology (MIGHT). It is hoped that MIGHT will give equal emphasis to research and development and produce monographs on Malaysian herbs, in addition to developing and promoting the local herbal industry (9).

Perhaps it is the right time for all the six local institutions of higher learning where pharmacy is taught to jointly initiate and spearhead a national project in establishing an Institute of Pharmaceutical Research, parallel to the Institute of Medical Research.

It is also high time for MPS to work side by side with MMA in recommending to the government of a permanent committee, comprising of experts from various medical and pharmaceutical specialities, to bring into being a National Pharmacopoeia and Formulary.

(g) Pharmacy legislation:

The Poisons Act 1952 (Revised 1989) and Registration of Pharmacists Act 1951 (Revised 1989) are the two main pillars of pharmacy law in Malaysia. Other pieces of legislation such as the Dangerous Drugs Act 1952 (Revised 1980), Sale of Drugs Act 1952 (Revised 1989), and Medicines (Advertisement and Sale) Act 1956 (Revised 1983) are built upon these two laws. It is quite apparent that these acts were first formulated with strong British Colonial characteristics. Although these laws have been reviewed during the last decade, much of the reviews were piecemeal in nature without much forward vision and strategy in developing the pharmacy profession. With the advent of the Information Technology Era, our present pharmacy legislations are obviously not equipped to deal with matters such as electronic prescribing, digital signature, Telemedicine and Telepharmacy. Significant overhauls are the order of the day.

It is imperative that Telepharmacy and Internet pharmacy should also comply completely with all pharmacy legislations. Professional ethics and high standards should be maintained. Medicines should only be delivered to patients in person. Systems and mechanisms to detect and to verify the prescriber’s signature that come with electronic prescribing should be in place. Malaysian cyberspace legislations for pharmacy practice need to be incorporated.

A paradigm shift and legislation overhaul are
suggested for the following areas of pharmacy practice:
(i) exclusive control over the supply of medicines by the pharmacists;
(ii) re-classification Group D Poisons as Group C Poisons;
(iii) pharmacists’ control over the supply of herbal and traditional medicines/products;
(iv) introduction of an annual practising certificate to replace the present annual retention certificate and Type A Licence;
(v) self-regulation in professional matters such as ethics and conduct, practice standards, and continuing education;
(vi) introduction of a compulsory three-year national service for all new pharmacists; and
(vii) introduction of pharmacy cyberspace legislation to deal with Telepharmacy and Internet-Pharmacy.

CONCLUSION

Pharmacists in Malaysia practise under two different sets of legal-historical framework. Government employed pharmacists enjoy complete control over the supply of medicines. They are even exempted from many pharmacy regulation provisions. On the other hand, private pharmacists do not have full control over the supply of medicines. Medical doctors, in the private clinics and private hospitals, still dispense medicines to their own patients. This doctor-dispensing practice has been allowed since the Colonial era when Malaysia suffered from acute shortage of all professionals. This outdated and unhealthy situation must change in the near future. The government needs to legislate such a change. As a developing country, Malaysia has already been served with a reasonable ratio of pharmacists to doctors per given population. The national ratio of private pharmacists to private doctors is 1 to 2.4. There are 5400 private practising doctors and 2300 private practising pharmacists. We have already achieved the optimal ratio of one doctor to three pharmacists in the urban places. With the annual increase of about 450 new pharmacists from now on, there is a serious threat of unemployment for the pharmacists in a few years' time.

On the other hand, there are insufficient numbers of pharmacists working in the public sector. Urgent measures must be worked out to rectify the situation. The acute shortage of pharmacists in the public sector may be overcome with the new entrants. The government's 118 hospitals, 772 health clinics and 1992 rural clinics (Statistics Dept. Bulletin-1999) certainly need to employ many more pharmacists in order to render quality services to the people.

MPS needs to work hand-in-hand with the Government Planning Unit to map out a thorough manpower projection for pharmacists and the supporting staff over the next decade.

The pharmacy profession needs the greatest understanding of the medical profession and the consumer groups in working out the most appropriate healthcare delivery system in the interests of the people in this country. MPS has a vital role in leading pharmacists through this transition period into a new type of pharmacy practice. This new kind of pharmacy profession envisaged will be more fitting for a fast developing country like Malaysia. Vision 2020 will certainly be incomplete if pharmacists fail to rise to the occasion in building a professional and caring pharmacy practice for the nation.

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Continuing Pharmacy Education question:

Study this case and give your response (100-200 words) based on the bioethical principles outlined in the CPE article on page 9. You may earn 2 CPE points if you submit a credible response to the MPS-CPE Secretariat at the Malaysian Pharmaceutical Society, P.O. Box 158, Jalan Sultan, 46710 Petaling Jaya, Selangor.

As a pharmacist at a regional transplant centre, you are in the team that allocates organs for transplantation. Your committee is at a deadlock as to which option to choose. The first is to allocate according to need (the sickest person gets the organ). The second option is to allocate according to an ordered pair. In the ordered pair formula, people who have abused their bodies (a heavy smoker) will be considered only after others who have not abused their bodies have received their transplants. The third proposal suggests that those who have agreed to be organ donors (usually by a pledger card that they carry) should be put at the top of the list. Your vote is key for the majority. Who will you vote for? Why?
Continuing Pharmacy Education

Bioethics

Abu Bakar Abdul Majeed

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ABSTRACT

Bioethics was originally proposed in the early 1970s to denote ‘the incorporation of biological knowledge and human values’. It is becoming more relevant in the biological age. This paper looks at some of the biological issues that require an ethical input. These include the Human Genome Project, human cloning and assisted reproductive technologies, contraception and abortion, organ donation and transplantation, euthanasia, brain death, human embryonic cells and AIDS. Examples of issues that have been raised in this area: Who owns our genes? Can we ‘design’ our babies? Should humans be cloned? Can pregnancy be terminated? Is mercy killing all right? Is brain death equivalent to death? Can embryonic cells be used in experiments? While some have been settled, others still persist till today. The numerous ethical questions pertaining to biology beg serious efforts on the part of ethical theorists to dig deep into their established principles. Similarly those working within applied ethics cannot operate effectively without referring to theoretical ethics. Hence thus far, many of the bioethical issues have been tackled. It is proposed that as a member of the health team, pharmacists too need to be well versed in issues pertaining to bioethics.

Keywords: ethics, biotechnology, cloning, euthanasia, brain death

INTRODUCTION

A new revolution in the making

The 20th century was an auspicious century indeed. It showcased numerous achievements in science and technology. This is especially true of research in the field of biology and its related discipline, biotechnology. It is not an exaggeration to state that so soon after the information revolution of the last few decades, the dawn of the 21st century marks the start of yet another revolution, the biological revolution.

Although advances in the various fields of biology have thus far resulted in major achievements, they also pose an inventory of real and potential hazards, as well as create new ethical conundrums. According to Lemkow (1993), an American study on “Public Perceptions of Biotechnology” reveals that the public accepts science and technology in general (1). However, attitudes to biological research indicate certain ambivalence. Sixty-six percent felt that genetic engineering would improve life compared with 92 percent for solar energy and 51 percent for nuclear energy.
However, 42 percent of the respondents said that it was “morally wrong” to change the genetic makeup of human cells.

In a similar European study, the main ethical issues in science and technology centre on human genetics (1). Apprehension and anxiety were expressed about the manipulation of human genetic material even when diagnostic benefits could be demonstrated. While therapeutic and diagnostic applications found much support, there was concern about the use of genetic information, such as the social pressure to have an abortion in the face of negative prenatal diagnostic information, although this does not necessarily require genetic engineering techniques. Concern was also expressed about the requirement of genetic information at work in relation to the right to privacy.

A TIME/CNN telephone poll of 1,1015 adult Americans conducted in early 2001 on the issue of human cloning, found that 90 percent of respondents thought that human cloning is a bad idea (2). The reasons for opposing cloning are: religious belief (34 percent), interference of human distinctiveness and individuality (22 percent), fear of it being used to breed a superior race (22 percent) and that the technology is dangerous (14 percent). Further, 93 percent of respondents would not want to have themselves cloned if they had the chance to do it.

The aim of this article is to look at several contemporary biological issues that beg an ethical input and to consider bioethical principles thus far applied to cope with some of these issues.

**Human Genome Project**

The Human Genome Project is aimed at figuring out what protein each gene produces and for what purpose. This human encyclopaedia may be used to identify diseased genes and design methods to substitute them with healthy ones. Hopefully, this type of disease prevention envisaged by proponents of gene therapy will be able to deal with many debilitating disorders such as Alzheimer’s Disease, Parkinson’s Disease and Huntington’s Disease, problems that have been attributed to genetic malfunctions.

Other spin-offs from the Human Genome Project include the ability to predetermine the baby’s attributes, grow new tissues and organs for transplantations, slow aging body parts and prepare more effective vaccines. However all these procedures are not about to happen soon. In fact, not only do several technical posers appear to be daunting, the moral implications of the project are equally mind-boggling. First and foremost is of course the question of ownership. Who owns our genes?

Thus, scientists have begun to patent whichever sections of the genome that they can lay their hands on (3). Patenting proponents insist on the need to have such protection to ensure returns on their investment. Naturally ethicists have different opinions. Were the early anatomists granted entitlements to the various bodily organs they discovered? Galen could have staked claims to some of our veins and arteries. Ibn Sina too should have been granted rights to certain parts of the brain.

The other question is whether the benefits of genetic science research like the Human Genome Project could be distributed to the world’s population in a just manner. While some researchers prefer the human genome data to be freely available, others want a premium be put for using it. Therefore those who have had no part in the venture at all will have to wait and see if they can afford to pay for the information on human genes, should they need it for research and development.

Similarly, on the application side of this type of research, since gene therapy involves a high cost, only the minority already well supplied with medical goods and services will be able to afford it. This will only widen the existing differentials in health status between different social classes, and further broaden the North-South divide in terms of accessibility to modern medical treatment.

**Genetic engineering and eugenics**

Genetic engineering may help doctors develop ways to correct or compensate for some genetic defects, perhaps even during conception. This will surely give rise to ethical questions. Although at this stage we are talking about preventing or protecting our children from genetic diseases, artificial improvement of other traits of the developing embryo would surely be sought not too long in the future. This opens a whole new possibility of designing babies. Many agree that genetic engineering must not be adopted as a means for changing the human genetic constitution, in what is called the improvement of
the human breed, or in genetically tampering with
the human personality or interfering in human
competence or individual responsibility.

Cloning, assisted reproductive technologies and
surrogacy

In 1997, there was a focus on the success of an
animal cloning procedure using matured, rather
than the usual embryonic cells (4). As this
experiment involved a large mammal, the
possibility of cloning a human becomes real
indeed. The greatest motivation of cloning
experiments described above is in finding ways of
providing infertile couples with the opportunity to
secure an offspring. But is human cloning
desirable? Should parents be allowed to clone a
child they lost? Should they clone to have twins at
different times? Should cloning be allowed to
produce vital organs for use to help others?

The birth of the first ‘test tube baby’ in 1978 marked
yet another milestone in the history of reproductive
technologies. In vitro fertilization became well
accepted as a relatively-risk-free technique and by
1990, there were more than 25,000 ‘test-tube babies’
in the world. Related to artificial reproductive
technologies are the issues of sperm banks and
surrogate motherhood. There are men who are not
able to produce viable sperms for fertilization to
happen. The wife in this case, probably would need
to request sperms from donors. In order to facilitate
this procedure, sperm banks have been established as
a resource centre to provide sperms on demand.
Then there are women who are physiologically
unable to conceive and nourish foetuses. Conception
of embryos prepared in laboratories will have to be
done in a third party’s womb, thus the term surrogate
motherhood. Surrogacy is considered a legal
procedure in some developed countries. Artificial
reproductive technologies, though implemented
previously, still attract public attention as moral
questions with regard to these procedures keep
cropping up.

Contraception and abortion

These are two biological issues that simply refuse
to go away. Contraception is vital for family
planning. Various types of contraception are
available, either natural or artificial, and ethical
issues that are still being debated today pertain to
the suitability and permissibility of these methods.
Abortion in particular generates moral questions of
everlasting magnitude. At what stage of the embryo
does life begin? Does it start with the very first
beat of the developing heart? And when this
happens, how does one justify terminating the
pregnancy?

Organ donation and transplantation

Numerous ethical questions have been raised
regarding tissue and organ transplantation
procedures. They include whether human beings
have the right to give away a part of their body
such as the kidney or a portion of their liver,
whether it is all right to harvest body parts of a
cadaver, and how available parts are assigned to
those who are in need of them. Although these
issues may appear to be rather straightforward in
some of today’s societies, there are still those who
are unsure of how to deal with them.

Then there is always the question of
xenotransplantation, or transplantation using parts
from animals. There may well be a lot of
reservations among certain communities around
the world regarding the suitability and
permissibility of this method. In any case, there are
contemporary ethical issues regarding “offspring
donor” where for reasons of genetic compatibility,
a couple decides to conceive a second child in the
hope that he or she would become a donor for the
first child who is in need of certain bodily parts,
for example, the bone marrow. And with the
coming of therapeutic cloning and new procedures
like organogenesis (where specific organs rather
than a whole human may be grown from
embryonic stem cells), tougher ethical issues are
bound to crop up.

Euthanasia

Euthanasia or mercy killing may be active or
passive. Active euthanasia means patients are
deliberately killed, for example by injecting an
overdose of sedatives. Active euthanasia is
normally voluntary, where a patient with a rational
frame of mind requests and is granted death.
Passive euthanasia happens when a patient is
deliberately allowed to die from whatever illness
he is suffering from, by refusing to perform
surgery, initiate heart resuscitation procedure, or
administer medication. Passive euthanasia may be
voluntary, when the patient consents to it, or non-
voluntary, when he does not express the desire to
die.

Euthanasia has always been a prime issue in the
debate on the right to die. It, however, is legally
permitted in at least one western nation, that is,
Holland. In 1973, the Royal Dutch Medical Association approved guidelines for physician-assisted suicide (PAS), a form of euthanasia. These guidelines are: euthanasia must be done by a physician; a second physician must concur with the decision; death must be requested by the patient while competent; the request must be free of doubt, well-documented and repeated; the request must not have been coerced; the patient’s condition must be intolerable; and that, there must be no way to improve the patient’s lot.

The American Medical Association takes a very different approach on PAS. Although active euthanasia is forbidden, passive euthanasia appears to be allowed. The practice of allowing patients to die by not treating them, endorsed by thinkers as early as Socrates, is an inescapable part of modern medicine. Today more than 80% of people die in hospitals, and advances in medical technology have made it possible to keep almost anyone alive indefinitely, even after they have no thought or feeling or hope of recovery. The maintenance of life by artificial means in such cases is deemed pointless, as the hospitals would quickly be filled with living corpses, leaving more deserving patients no beds. Thus, many would agree that it is ethically acceptable to cease treatment and let such patients die (5).

**Brain death**

The traditional criteria for determining death, until recently, was the permanent cessation of heart and lung function. When a person stopped breathing and the heart stopped beating for more than a few minutes, that person was declared dead. The loss of oxygen to the brain would almost instantly produce irreversible brain damage and loss of all cognitive function (6).

However, the introduction of new medical technology, and most importantly of respirators, has enabled modern medicine to continue artificially maintaining patients’ heart and lung function. This can often save lives that previously would have been lost. Sometimes, it may even permit the patient to recover a normal level of function.

In other cases, however, heart and lung function can be restored or continued by these artificial means after brain function has been partially or completely destroyed, for example, from prolonged loss of oxygen or severe trauma of the brain. Such possibilities have forced a rethinking of the traditional criteria for the determination of death. There is now an additional criterion for death, that is, the complete and irreversible loss of all brain function, or so-called brain death. The concept of ‘brain death’ was first proposed in 1959 by a team of French doctors. The criteria adopted for brain death were coma, cessation of breathing, the absence of brainstem and tendon reflexes, and the absence of electroencephalographic (EEG) waves. If these conditions persisted in the patient for more than 24 hours, then he or she would be pronounced dead, and the ventilator switched off, even though the heart might still be beating.

Further discussions led to the announcement at the 22nd World Medical Assembly in Sydney in 1968, which in a nutshell stated that death had occurred if there were no means of saving the patient, regardless of whether some of his organs were still functioning. In the same year, the ‘Harvard criteria to determine death’ was introduced. In addition to the original French criteria, the Harvard criteria stipulates that there must also be an absence of pupil and spinal reflexes, no movement of the patient for an hour, and that breathing should cease three minutes after switching off the ventilator (7).

**Human embryonic cells**

Most recently in several countries, scientists and policy-makers are revisiting the issue on the use of human stem cells and embryos for research. Stem cells have the capability of developing into any type of tissue, as well as growing into human beings. Thus, in the United States, current laws forbid the use of public funds to obtain stem cells from human embryos (8). In Germany, a human embryo is protected under the law from the fertilization to the implantation stage. Any research on or with human embryos is prohibited unless the embryo can be ascertained of an immediate and direct benefit to it (9). But efforts are underway to reverse this situation (10). For example, the American National Institute of Health (NIH) recently issued guidelines on funding of medical research that makes use of human embryos (11). Similarly the British government has allowed cloning of stem cells for scientific study of transplants. This study would help bolster the prospect of therapeutic cloning that could develop new treatments for diseases such as Alzheimer’s Disease and Parkinson’s Disease.

**Acquired Immunodeficiency Syndrome (AIDS)**

The human immunodeficiency virus (HIV) that
causes AIDS continues to be a major threat to the health of millions of people worldwide. Sadly though, there is little sign that the disease is abating. Today it has been established that apart from the sharing of infected needles and blood transfusion, indiscriminate sexual practices are the main modes of HIV transmission. In view of the gravity of the situation, whatever means that can help to wipe out the scourge are strongly recommended, regardless of whether they are of preventive, curative or palliative in nature.

Prevention must be the primary strategy adopted to minimize the risk of HIV transmission. However, in relation to the compulsory HIV antigen or antibody screening that has been proposed for members of the high-risk groups, many ethical issues have to be surmounted. Is it morally correct to simply focus on the high-risk HIV-carriers, such as drug addicts, prostitutes, transsexuals and convicts? In order to avoid transfusion of contaminated blood, should donors, rather than the blood per se, be tested for HIV antibody or antigen? Should compulsory screening be imposed on brides and bridegrooms to ensure that they are free from HIV, thus preventing them from passing on the virus to their potential spouses or later even to their offspring? These are no doubt difficult and challenging questions. They must be dealt with extreme care and heartfelt concern for the parties involved. When it comes to ethics, there is always the dilemma of choosing between the interests of the community and those of the individual.

Ethics

Let’s turn now to the issue of ethics and how humans have developed a system to tackle it. Bertrand Russel elegantly describes ethics as “in origin the art of recommending to others the sacrifices required for cooperation with oneself”. Ethics, or the study of morality, makes up one of the four main divisions of philosophy. Here it is further subdivided into categories of meta-ethics or theoretical ethics, that is the study of meanings of ethical terms and the forms of ethical argument; descriptive ethics, that deals with the study of moral and ethical beliefs and customs of different cultures; normative ethics, which is the study of ethical principles that have been accepted as norms or right behaviour; and applied ethics, that relates to the application of moral standards used in decision-making to concrete rather than abstract conditions (12).

The various ethical questions pertaining to biological sciences in the contemporary world are clear indications that the time has come when ethical theorists can no longer ignore the problems of application. Similarly, those working within applied ethics can no longer operate effectively without taking theoretical considerations into account. This is especially true where principles and codes appear to make conflicting claims on the condition or situation under examination. When such conflicting claims occur it is referred to as an ethical dilemma. When this occurs, we will have to resort to ethical reasoning that is, the process of analysis in determining what is right or wrong, and what is the correct or more responsible choice in a given situation. It is also an examination of our moral judgements, and an attempt to determine the grounds on which these judgements are based.

The literature is filled with the various classifications of ethical theories. For example, they can be classified as, one, principle-based theories (normative ethics), and two, virtue-based theories (12). Principle-based theories are of either the deontological or consequentialist (utilitarianism) types. The former relates to the theory of obligation or duties, or rules and rights, while the latter links the rightness of an act to the goodness of the state of affairs it brings about. Judgements made may be general or specific. They are all normative, they affirm or apply norms or standards to making decisions. They must be universal, applicable to all relevant cases, impartial and objective. The procedure to implement principle-based ethical theory are, (i) identify ethical principles, and (ii) evaluate ethical choices in terms of how well they fit with those principles.

Virtue-based theories include communitarianism that applies the Aristotelian approach where practical wisdom is employed in the reasoning process, the focus is on the uniqueness of each ethical situation, and is based on shared community values. It also includes relationalism that emphasizes the values of love, family and friendship inherent to the situation at hand. The procedure to do this is by identifying the ethically virtuous person, and evaluating ethical choices in terms of how well they exemplify the deliberations of the ethically virtuous person. This theory is very much situation-based.

Bioethics

Bioethics can be defined as the study of the rightness and wrongness of acts performed within the life sciences, through the application of both
ethical theory and casuistry (case-study method) to the complexity of development in the biological sciences. The bioethics practiced today mostly derives its rulings from the normative and situational ethical principles. The word ‘bioethics’ was first coined by the oncologist Professor Van Rensselaer Potter II in 1970 in an article entitled “Bioethics: The Science of Survival” (13). After doing much work in the field of cancer research where he managed to establish links between certain types of cancer and environmental pollutants, Potter argued that a science of survival must be more than science alone. It should incorporate two ingredients, namely, biological knowledge and human values. Later, Potter (1975) refined the definition of bioethics as a product of cross-fertilization between the two branches, “medical bioethics” and “ecological bioethics”(14). However, medical practitioners did not generally accept these concepts. They preferred to redefine bioethics to mean clinical ethics.

And thus, from then on bioethics conjured a much narrower meaning than its original scope and breadth. And it is in this context that many of the recent and contemporary discussions on issues related to health, life and death are being looked at. This was particularly true during the era of heightened debates on reproductive sciences like contraception and abortion in the 1950s and 1960s. At the time, the founder-director of the Kennedy Center of Ethics at Georgetown University, Professor André Hellegers seized the opportunity to turn bioethics into an academic discipline that reflected the needs of the time. This was rather easily acceptable as bioethics can readily be identified with the established field of medical ethics. In essence medical ethics began with the advent of medicine itself, that is, the ‘Hippocrates Oath’. And then there was the anti-vivisectionist movement (15) that was already influential in the 19th century that helped to keep researchers who use animals as subjects for experiments, on their toes.

**CONCLUSION**

Today, bioethics is a full-fledged subject matter with a number of international professional societies, and courses offered in universities throughout the world. It will become even more important in the future. As a member of the professional healthcare team, pharmacists too need to be aware of the controversial issues pertaining to medical practice and how to deal with them. One way in which this can be done is to refer to long-established ethical guidelines. With this, pharmacists can play an important role in alleviating patients’ and their relatives’ anxiety, as well as clear their conscience on morally-challenging issues.

See page 8 for the CPE question

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**REFERENCES**

Career Choice of Malaysian Pharmacy Students: A Preliminary Analysis

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ABSTRACT

A cross-sectional study was conducted among pharmacy students to determine factors influencing their choice of work place and to evaluate whether a one-year hospital pre-registration training programme had any effect on these choices. Questionnaires were distributed to graduating students at the School of Pharmaceutical Sciences, Universiti Sains Malaysia. The questionnaires were again sent to the same group of students by post at the end of their pre-registration training year. The response rate during the follow-up stage was 46%. Results indicated that students in the survey were more interested in independent and chain community pharmacies compared to other practice settings. Students’ choices of first place of practice appeared to be influenced by both intrinsic and extrinsic job factors. Our findings did not show major changes in students’ preferences for practice sites before and after the hospital pre-registration period. This information is expected to be useful for pharmacy employers.

Key words: pharmacy, career choice, job factor, workplace, Malaysia

INTRODUCTION

Changes within the pharmacy profession over the past 15 – 20 years have been inspiring. Pharmacy is expected to continue to be an exciting and innovative field in the coming new systems of health care. It will provide new roles and opportunities for pharmacists to serve the health care needs of the society. Therefore, future pharmacists need to make wise decisions regarding educational and professional preparedness, keeping in mind the mobility and flexibility of career positions.

Until 1995, there was only one pharmacy school in Malaysia. Pharmacy students at Universiti Sains Malaysia (USM) undergo a 4-year academic programme towards a Bachelor of Pharmacy degree. The curriculum for the first three years consists of basic pharmaceutical science subjects under the general categories of pharmaceutical chemistry, pharmaceutical technology, physiology and pharmacology. Students are exposed to clinical pharmacy curriculum during their fourth academic year (1). They spend an average of 20 hours per week at a university hospital for their clinical attachments. They rotate through various clinical pharmacy services, medical and surgical-
based attachments, including attachments at various community pharmacy outlets. After graduating, they undergo a one-year training programme at a recognized pharmacy institution before they are registered with the Malaysian Pharmacy Board. This training is also known as pre-registration training, similar to that practised in the United Kingdom.

As a preliminary study, we decided to evaluate pharmacy students’ choices of practice sites upon graduation and the factors influencing these choices. Since this coincided with the compulsory one-year pre-registration training programme, we were also interested to see whether this training had any influence on the students’ choices. We believe that this information will be useful to potential employers when recruiting newly registered pharmacists.

METHODS

Survey questionnaires were distributed to 71 graduating pharmacy students at USM after their final examinations. The questionnaires asked for demographic data, preference of practice sites, previous experience or work, and whether any of their immediate family members were health professionals. Students were also asked to rate the importance of identified factors (2), which they thought would affect their preference of practice sites. These were rated on the Likert scale of 1 to 5 (1 = extremely important, 5 = extremely unimportant). These questionnaires were designed in the national language (i.e., Malay). To determine its clarity, the questionnaire was pre-tested on hospital pharmacists and Master of Clinical Pharmacy students at the university. For some questions, students were allowed to check more than one answer. Towards the end of the one-year pre-registration training, another questionnaire was mailed to the same batch of students to their respective home addresses.

Data were analysed using the Statistical Package for Social Sciences (SPSS) Version 7.5 (SPSS Inc., Ill). Descriptive data are presented as percentages. Discrete data were analysed by chi-square or Fisher’s Exact tests. Significance level chosen for statistical testing was 0.05.

RESULTS

All 71 final year students (100%) took part in the first evaluation (before pre-registration). Thirty-three responded after pre-registration training giving a response rate of 46%. All students underwent a one-year period of pre-registration training at government hospitals.

Demographic data

The mean age of students at the time of graduation was 24.3 years old and nearly two-thirds were females. Malay students constituted approximately half of the graduating class. The number of respondents before and after pre-registration training based on gender and race were not statistically significant (Table 1).

<table>
<thead>
<tr>
<th>Table 1. Demographic data of students who responded to both surveys.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before pre-registration (n=71)</strong></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td><strong>Race</strong></td>
</tr>
<tr>
<td>Malay</td>
</tr>
<tr>
<td>Chinese</td>
</tr>
<tr>
<td>Indian</td>
</tr>
<tr>
<td>Other</td>
</tr>
</tbody>
</table>

Note: The total percentages are not equal to 100 due to missing values
NS=not significant
Majority of students did not have a family member (defined as parents or siblings) as a health professional. Five however, had a pharmacist, three had doctors, one had a dentist, four had nurses, one had a pharmacy technician and one had a medical assistant among their family members.

**Relationship between gender and race with desired place of work**

The most common preferred place of work in decreasing order was, independent community pharmacy, chain community pharmacy, government hospital, private hospital, and pharmaceutical industry (Table 2).

When grouped according to three major places of work (i.e. hospital pharmacy, community pharmacy, industry), over 60% of female students planned on going into community pharmacy, and just under 30% planned on pursuing hospital work. Among male students, about 50% preferred community pharmacy, and about 30% planned to enter hospital pharmacy practice. The differences between gender preferences were not statistically significant (p>0.05).

Community pharmacy was the first choice among 87% Chinese students and 58.3% of the Malay students (Table 3). On the other hand, about 36% of the Malay students chose hospital pharmacy as compared to about 4% of the Chinese students. Indian students were relatively equally divided in their choice of desired places of work. The differences between races in terms of their desired places of work were not statistically significant (p>0.05).

**Relationships between previous working experiences with the desired place of work**

Table 4 shows that 60.6% students had experience working at pharmacies or drug stores; 43.7% at hospital pharmacies and 5.6% at pharmaceutical industries. When results for independent and chain community pharmacies were combined to give an overall picture of the choice for community pharmacy practice, a total of 43 students (61%) preferred to work at this site. Of these, 29 (67%) had worked at a pharmacy or drug store previously, 20 (46%) at a hospital pharmacy, and 2 (5%) in the pharmaceutical industry.

<table>
<thead>
<tr>
<th>Table 2. Relationship between gender and desired place of work (first survey).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male</strong>&lt;br&gt;<strong>N (%)</strong>&lt;br&gt;<strong>Female</strong>&lt;br&gt;<strong>N (%)</strong>&lt;br&gt;<strong>Total</strong>&lt;br&gt;<strong>N (%)</strong>&lt;br&gt;<strong>Fisher’s Exact Test</strong></td>
</tr>
<tr>
<td>Government hospital 1 (4.3)</td>
</tr>
<tr>
<td>Private hospital 6 (26.1)</td>
</tr>
<tr>
<td>Independent community pharmacy 7 (30.4)</td>
</tr>
<tr>
<td>Chain community pharmacy 5 (21.7)</td>
</tr>
<tr>
<td>Pharmaceutical industry 2 (8.7)</td>
</tr>
<tr>
<td>Postgraduate studies 1 (4.3)</td>
</tr>
<tr>
<td>Others 1 (4.3)</td>
</tr>
<tr>
<td>Total 23 (100)</td>
</tr>
</tbody>
</table>

Note: The total number of students are not equal to 71 due to missing values. The percentages are based on the number of students responded on the items NS=not significant
Table 3. Relationship between race and desired place of work (first survey).

<table>
<thead>
<tr>
<th></th>
<th>Malay N (%)</th>
<th>Chinese N (%)</th>
<th>Indian N (%)</th>
<th>Other N (%)</th>
<th>Total N (%)</th>
<th>Fisher’s Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government hospital</td>
<td>9 (25.0)</td>
<td>1 (4.3)</td>
<td>1 (14.3)</td>
<td>1 (33.3)</td>
<td>12 (17.4)</td>
<td>0.06 (NS)</td>
</tr>
<tr>
<td>Private hospital</td>
<td>4 (11.1)</td>
<td>0 (0)</td>
<td>2 (28.6)</td>
<td>2 (66.6)</td>
<td>8 (11.6)</td>
<td></td>
</tr>
<tr>
<td>Independent community pharmacy</td>
<td>11 (30.5)</td>
<td>12 (52.2)</td>
<td>1 (14.3)</td>
<td>0</td>
<td>24 (34.8)</td>
<td></td>
</tr>
<tr>
<td>Chain community pharmacy</td>
<td>10 (27.8)</td>
<td>8 (34.8)</td>
<td>1 (14.3)</td>
<td>0</td>
<td>19 (27.5)</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical industry</td>
<td>2 (5.6)</td>
<td>1 (4.3)</td>
<td>1 (14.3)</td>
<td>0</td>
<td>4 (5.8)</td>
<td></td>
</tr>
<tr>
<td>Postgraduate studies</td>
<td>0</td>
<td>0</td>
<td>1 (14.3)</td>
<td>0</td>
<td>1 (1.4)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>1 (4.3)</td>
<td>0</td>
<td>0</td>
<td>1 (1.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>36 (100)</strong></td>
<td><strong>23 (100)</strong></td>
<td><strong>7 (100)</strong></td>
<td><strong>3 (100)</strong></td>
<td><strong>69 (100)</strong></td>
<td></td>
</tr>
</tbody>
</table>

Note: The total number of students are not equal to 71 due to missing values. The percentages are based on the number of students responded on the items. NS=not significant.

Table 4. Relationship between previous working experiences with the desired place of work (first survey).

<table>
<thead>
<tr>
<th>Previous working experience</th>
<th>Desired place of work(^a)</th>
<th>Government hospital N (%)</th>
<th>Private hospital N (%)</th>
<th>Independent community pharmacy N (%)</th>
<th>Chain community pharmacy N (%)</th>
<th>Pharmaceutical industry N (%)</th>
<th>Post graduate studies N (%)</th>
<th>Other N (%)</th>
<th>Total N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy/drug store</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7 (16.3)</td>
<td>6 (14.0)</td>
<td>16 (37.2)</td>
<td>13 (30.2)</td>
<td>1 (2.3)</td>
<td>0</td>
<td>13 (3.6)</td>
<td>0</td>
<td>43 (100)</td>
</tr>
<tr>
<td>No</td>
<td>6 (21.4)</td>
<td>3 (10.7)</td>
<td>8 (28.6)</td>
<td>6 (21.4)</td>
<td>3 (10.7)</td>
<td>13 (3.6)</td>
<td>1 (3.6)</td>
<td>28 (100)</td>
<td></td>
</tr>
<tr>
<td>Hospital pharmacy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (12.9)</td>
<td>5 (16.1)</td>
<td>8 (25.8)</td>
<td>12 (38.7)</td>
<td>2 (6.5)</td>
<td>0</td>
<td>1 (0.03)</td>
<td>0</td>
<td>31 (100)</td>
</tr>
<tr>
<td>No</td>
<td>9 (22.5)</td>
<td>4 (10.0)</td>
<td>16 (40.0)</td>
<td>7 (17.5)</td>
<td>2 (5.0)</td>
<td>1 (0.03)</td>
<td>1 (0.03)</td>
<td>40 (100)</td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical industry</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>1 (25.0)</td>
<td>1 (25.0)</td>
<td>1 (25.0)</td>
<td>1 (25.0)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4 (100)</td>
</tr>
<tr>
<td>No</td>
<td>12 (17.9)</td>
<td>8 (11.9)</td>
<td>23 (34.3)</td>
<td>18 (26.9)</td>
<td>4 (6.0)</td>
<td>1 (1.5)</td>
<td>1 (1.5)</td>
<td>67 (100)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) only one practice choice was allowed  
\(^b\) each student may choose more than one answer
Similarly, when results for government and private hospitals were combined as hospital pharmacy practice, a total of 22 students (31%) preferred to work at this site. Of these, 13 (59%) had previously worked at pharmacies or drug-stores, 9 (41%) at hospital pharmacies and 2 (9%) at industry-based pharmacies.

Thus, the majority of those who preferred community pharmacy had previous experience at pharmacies or drug-stores. On the other hand, among those who preferred hospital pharmacy as their future place of work, only 41% had previous experience with hospital work.

Of the four students who preferred industry-based pharmacies, one had worked at a pharmacy or a drug-store and two at hospital pharmacies. None worked at industry-based pharmacies before.

** Desired place of work/practice before and after pre-registration training

Table 5 demonstrates the students’ desired places of work before and after pre-registration training. The majority showed interest in community pharmacy (i.e., independent and chain) both before and after the training (61% and 57%, respectively). The percentages of students who chose hospital setting (combined both government and private settings) before and after pre-registration period were 31% and 24%, respectively. Only a small percentage chose pharmaceutical industry. Overall, the results did not show major changes in students’ preferences for practice sites before and after the pre-registration training. However, overall results showed a drop in percentages for most practice sites.

**Factors affecting practice choices

The top ten factors that students believed affected their choices of future practice sites before pre-registration training were desire for a satisfying and self-fulfilling position, job security, opportunity for advancement, salary, sense of accomplishment, opportunity to use one’s abilities and education, opportunity to serve the community, geographic location, nature of work and employer’s policies (Table 6). Except for employer’s policies, these remained in the top ten categories of factors even after the pre-registration training period. None of the changes in ratings which occurred after the pre-registration period were statistically significant.

**DISCUSSION

There was not much difference between the proportion of female and male students in our student population as compared to recent enrollments in the US schools of pharmacy (3). The majority of our students did not have any family member working as a health professional.

Parents might exert significant influence on students’ decision to choose pharmacy as a career.

| Table 5. Respondents desired place of work before and after pre-registration training |
|---------------------------------|---------------------------------|---------------------------------|
| Desired place of work           | Before pre-registration         | After pre-registration          |
|                                 | (n=71)                          | (n=33)                          |
| Independent community Pharmacy  | 24 (34%)                        | 7 (21%)                         |
| Chain community Pharmacy        | 19 (27%)                        | 12 (36%)                        |
| Government hospital             | 13 (18%)                        | 4 (12%)                         |
| Private hospital                | 9 (13%)                         | 4 (12%)                         |
| Pharmaceutical industry         | 4 (6%)                          | 1 (3%)                          |
| Postgraduate studies            | 1 (1%)                          | 1 (3%)                          |
| Others                          | 1 (1%)                          | 3 (9%)                          |

Note: The total percentages are not equal to 100 due to missing values
but our results showed that this factor was not among the ten most important factors (Table 6) in influencing their choice of field work as a pharmacist.

It is interesting to see that government and private hospital practices were less favoured by students compared to independent or chain community pharmacies. These choices were similar to those reported by others (2,4). The findings may partially explain the consistently low “filling rate” for the positions of pharmacist in government hospitals. In 1995, the Malaysian Ministry of Health (MOH) annual report showed that of the 570 positions for staff pharmacists available at government hospitals, only 341 were filled (5). This trend has been consistent for the last few years where the “filling rate” was only around 60% (6,7).

Studies on gender difference in preference for practice sites have shown conflicting results (4,8). Our results showed that only about one-third of the total number of female students would like to go into hospital pharmacy practice. However, intended and actual practice settings tend to differ. In fact, among pharmacy practitioners, investigators have shown a growing trend of similarity in gender distributions of practice settings (9, 10). It is interesting to see from our findings that community pharmacy practice seemed to be more favourable among Chinese students whereas hospital pharmacy practice seemed to be more favourable among Malay students. This tendency for a difference in racial preference of practice sites needs to be further explored.

Approximately half of our students had previous experiences either at hospital pharmacies, community pharmacies or drug stores. Previous experience at a hospital pharmacy did not have much effect on students’ preference to practise at hospitals (29%). On the other hand, previous experience at a pharmacy or drug-store might have influenced many students (67%) on their preference to practise at a community pharmacy. In general, regardless of whether students had previous working experience or not, the community pharmacy setting was the most desired place of work.

Factors known as intrinsic factors are associated with good feelings about a job, and that bad

Table 6. Top ten rating of respondents’ perception of factors affecting choice of future workplace

<table>
<thead>
<tr>
<th>Factors</th>
<th>Before pre-registration mean (SD)</th>
<th>After pre-registration mean (SD)</th>
<th>Student’s t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Desire for a satisfying and self-fulfilling position</td>
<td>1.6 (0.6)</td>
<td>1.7 (0.9)</td>
<td>NS^a</td>
</tr>
<tr>
<td>2 Job security</td>
<td>1.6 (0.8)</td>
<td>1.9 (1.0)</td>
<td>NS^a</td>
</tr>
<tr>
<td>3 Opportunity for advancement</td>
<td>1.6 (0.7)</td>
<td>1.6 (0.9)</td>
<td>NS^a</td>
</tr>
<tr>
<td>4 Salary</td>
<td>1.7 (0.7)</td>
<td>1.8 (0.7)</td>
<td>NS^a</td>
</tr>
<tr>
<td>5 Sense of accomplishment</td>
<td>1.8 (0.8)</td>
<td>1.7 (0.7)</td>
<td>NS^a</td>
</tr>
<tr>
<td>6 Opportunity to use one’s abilities and education</td>
<td>1.8 (0.8)</td>
<td>1.5 (0.8)</td>
<td>NS^a</td>
</tr>
<tr>
<td>7 Opportunity to serve community</td>
<td>1.8 (0.7)</td>
<td>1.8 (0.7)</td>
<td>NS^a</td>
</tr>
<tr>
<td>8 Geographic location</td>
<td>1.8 (0.8)</td>
<td>1.8 (0.8)</td>
<td>NS^a</td>
</tr>
<tr>
<td>9 Nature of work</td>
<td>1.9 (0.8)</td>
<td>1.8 (0.8)</td>
<td>NS^a</td>
</tr>
<tr>
<td>10 Employer’s policies</td>
<td>1.9 (0.8)</td>
<td>2.1 (0.9)</td>
<td>NS^a</td>
</tr>
</tbody>
</table>

^a All comparisons were not significantly different at alpha level of 0.05
feelings are associated with extrinsic factors. Intrinsic factors include the nature of work, desire for a satisfying and self-fulfilling position, opportunity for advancement, sense of accomplishment, opportunity to use one’s abilities and education, and opportunity to serve the community. Extrinsic factors include job security, salary, geographic location, availability of position, working conditions, influence of family, friends or professors, and employer’s policies. As reported by others (1,11), the results from our survey showed that a combination of these job factors were involved in students’ selection of practice sites. Although six out of ten were intrinsic factors, this may change once in the profession. Other factors may also affect pharmacists’ choice of current practice sites (12) and most of them can be considered as extrinsic factors (e.g. income potential, and influence of spouse).

Our findings showed that hospital pre-registration experience did not have a major effect on the choice of practice sites. In one study, it was found that although the percentage of students who participated in a hospital internship programme was high, there was a lower percentage of students who selected a career in hospital pharmacies when compared to community pharmacies (11). The authors suggested that the activities students did during their internship might not be viewed as personally rewarding by many of them. This might have influenced their lack of preference for hospital pharmacy practice. Hospital pre-registration in our setting may not be similar to hospital internship programme practised in the US but suggestions to improve students’ experience in hospital setting (11) may be applicable to ours. This includes providing a more structured programme which provides emphasis in the operations, administration and patient-oriented pharmaceutical services to enable students to experience hospital pharmacy practice in greater depth.

**CONCLUSION**

This survey provides some insights into the reasons why pharmacy graduates choose their first site of practice. An understanding of the factors that influence graduates’ practice-site choices is important if employers wish to design effective strategies to employ future pharmacists. Our findings did not show major changes in students’ preferences for practice sites before and after the hospital pre-registration period. Speculation that students would be more inclined toward hospital practice because of additional clinical education in their final year is not supported by our data.

*REFERENCES*

Public Awareness of Community Pharmacy and Pharmacists

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ABSTRACT

An exploratory study to ascertain the public’s awareness of community pharmacy and pharmacists in a selected subset of the Malaysian population was undertaken, utilising an interviewer-administered structured questionnaire approach. A total score was computed for each respondent, ranging from a possible minimum of 0 and a maximum of 24. The scores achieved were arbitrarily categorised into poor (<11), fair (11 – 14), good (15 – 19) and excellent (>19) levels of general knowledge regarding community pharmacy and pharmacists. The scores achieved ranged from 3 to 21, with an average “fair” score of 13.7. The results showed that 93.6% of the respondents (n = 561) interviewed had heard of the term “pharmacist” before. Interestingly, 17.5% of the respondents were of the opinion that pharmacists worked on farms. A significant 77.4% perceived that a pharmacist served in a doctor’s clinic. It was noted that 84.1% of those surveyed would go to doctors for advice on medicine, while only 49.4% would seek a pharmacist. A majority (76.7%) of the respondents interviewed chose to go to a doctor’s clinic for a screening test. The study amplifies the need for a more aggressive projection of the pharmacist’s image in the community in order to be recognized and accepted by the public as an integral partner in the health care profession.

Keywords: pharmacy, pharmacists, survey, perception, awareness

INTRODUCTION

In this day and age, pharmacists play an essential role in educating patients regarding drug therapy as patients become increasingly responsible for their own health care. Community pharmacists are the health care professionals most accessible to the public (1). The community setting is a platform for the pharmacist to project himself beyond the traditional image of being simply a “drug supplier” in that he is able to provide
pharmacotherapeutic counselling to patients, apart from general health care information to the public. This is in line with Hepler and Strand’s concept of pharmaceutical care (2).

However, this professional expertise will only be fully utilised if the public is aware of and understands the role played by the pharmacist in the community. Hence, this exploratory study was conducted to ascertain the public’s awareness regarding the community pharmacy profession and pharmacists.

**AIM**

The aim of this study is to examine the public’s awareness about community pharmacy and pharmacists, in a selected subset of the Malaysian population.

**METHOD**

**Study design**

This public opinion survey was conducted using a structured interview technique, in which the respondents were asked questions by trained researchers (25 undergraduate students and 1 pharmacist). It took place over a 4-day period in August 1997, during the University of Malaya Convocation Festival. Visitors to the Pharmacy booth who appeared to be over 18 years of age were approached about participation in the survey. The sampling method used was that of convenience sampling. Only those who agreed (97.9%) participated in the study, with each interview taking approximately 8 to 10 minutes to complete.

**Questionnaire**

A structured questionnaire was used. Apart from the portion relating to the demographic profile of the respondents, there were altogether 10 questions focussed on the following aspects:

a) the respondents’ general awareness of pharmacists and their places of work
b) the purchasing pattern of respondents in relation to pharmacies, sinseh (traditional Chinese medicine practitioner) shops and other places
c) the awareness of services offered by community pharmacies such as treatment of minor ailments, screening tests and advice on medications.

Each question had pre-formulated responses. The questionnaire designed by the research team was piloted with a sample of 25 staff members of the Faculty of Medicine, University of Malaya.

**Data analysis**

The data was entered into a worksheet and analysed using Microsoft Excel®. A scoring system was practised as follows:

a) For any question requiring either a “Yes” or “No” or “Unsure” response, only the positive response was given a score of 1, whilst any of the other two responses was awarded a score of 0 each. As an example, for the question “Have you heard of the term ‘Pharmacist’?” a “Yes” response was scored as 1.

b) For any question requiring the choice of one or more than one answer, only the answers deemed appropriate was given a score of 1 each and a deduction of 1 was made for each inappropriate answer, with the lowest possible final score of 0 for any question. As an example, for the question “To whom would you go for advice on medicines?” where more than one answer may be given, a respondent who chose “Pharmacist”, “Doctor” and/or “Nurse” was given a score of 1 for each of the answers with a deduction of 1 if “Sinseh” was also selected along with any of the appropriate answers. If “Sinseh” was the only answer selected, the respondent received a final score of 0 for that question.

A total score was computed for each respondent, ranging from a possible minimum of 0 and a maximum of 24. The scores achieved were arbitrarily categorised into poor (<11), fair (11 – 14), good (15 – 19) and excellent (>19) levels of general knowledge regarding community pharmacy and pharmacists.

**RESULTS AND DISCUSSION**

**General**

There were 561 respondents, who were mainly Malaysians (97.5%). The ethnic representation was 59% Malays, 29% Chinese and 9% Indians. The majority (61.5%) of the respondents were between 18 – 25 years old with 18.2% and 17.1% aged between 26 – 35
years and 36–50 years respectively. In terms of gender distribution, 41% of the respondents were male. The composition of the respondents include undergraduates (55.1%), professionals (16.6%), non-professionals (20.3%), school-going students (3.7%), postgraduate students (2.3%), housewives (1.1%) and pensioners (0.9%). The majority (75%) of respondents lived in urban areas.

The respondents’ scores ranged between 3 to 21 out of a possible maximum of 24. The majority of the respondents obtained scores in the “fair” (48%) and “good” (39.6%) categories. The mean score was 13.7 and the mode was 14 (both in the “fair” category). Figure 1 reflects an almost normal distribution. The generally fair scores achieved by the respondents were not unexpected with almost three-quarters (74%) of them either undertaking or had attained a tertiary level of education. There were only four respondents who obtained excellent scores: two were undergraduates, one was a housewife while the other was a sales executive. Surprisingly, no professional achieved an “excellent” score. The scores for the different occupations, genders and ethnic groups were not significantly different based on the student’s t-test (p>0.05).

Public image of pharmacists

The respondents were assessed on their level of awareness of the term “Pharmacist” as well as the nature of work and workplace of a pharmacist. Most respondents (93.6%) had heard of the term “pharmacist” while 89.7% and 88.2% respectively, thought they knew what the pharmacist did and where the pharmacist worked. However, the following question, which required the respondents to choose the workplace of the pharmacist, disproved the above notion. While most respondents associated the pharmacist with the retail sector, hospitals, academia and factories, a shocking 77.4% associated pharmacists with doctors’ clinics and 17.5% with farms! [Figure 2]. Obviously, the respondents had heard of the term “pharmacist”; however, their awareness of a pharmacist’s role in the community was not completely accurate. The association with working in a doctor’s clinic suggested a confusion between the roles of dispensers and pharmacists. Farms were also associated with pharmacists, possibly due to the perceived similarity between the words “pharmacy” and “farm”. Most of the study population (91.1%) associated pharmacists with the community or retail pharmacies and less with hospitals, factories and pharmaceutical trading houses. This confirms that community pharmacists have a higher visibility and hence would be in a better position to disseminate information and influence public opinion on pharmacy.

![Figure 1. Distribution of the respondents’ scores based on the appropriateness of the responses given to the questions administered.](image-url)
people interviewed (77.2%) identified the university as a place of work for pharmacists. This was not surprising since this study was conducted on university grounds during the convocation festival. This percentage would, however, be expected to be smaller if the study was conducted in the general population.

Sale items associated with community/retail pharmacies

The familiarity of the respondents with the pharmacy and sinseh shop was established before the respondents were asked questions on their purchasing patterns at these two places. It was found that 88.4% of the respondents had visited a pharmacy before as compared to a sinseh shop (67.4%).

The respondents were interviewed on their preferred places for purchasing groceries, toiletries, health supplements, woundcare products, crude herbs, over-the-counter (OTC) medicines and prescription drugs, with more than one response permitted for these questions. It was seen that a pharmacy was generally associated with multivitamins (89.9%), woundcare products (83.2%) and prescription drugs (79.7%), as displayed in Figure 3. The majority of the respondents (55.4%) preferred to buy OTC medicines from places other than the pharmacy and the sinseh shop. Could price and accessibility be a contributing factor? In comparison, a public opinion survey of community pharmaceutical services in Malta (3) revealed that almost 31% of their study population visited a pharmacy primarily to purchase prescribed medication while only 23.3% did so mainly to obtain OTC products.

It was interesting to note that almost 40% of the respondents would also purchase prescription medicines from another doctor’s clinic having acquired the prescription from a clinic or hospital. This is certainly an alarming situation as it indicates an evident lack of awareness of the function of a community pharmacy.

Community pharmacies are also often associated with the sale and supply of products other than drugs and medical supplies. Fortunately, although a pharmacy was not the favoured place the respondents would go for the purchase of groceries and toiletries, a certain percentage of the respondents do associate a pharmacy with these items (23% and 43% respectively). There is certainly justification for the diversification of sales range for these community pharmacies. Profitability, competition and service are probably the motivation for these premises to offer items other than drugs and medical supplies. Hence, a significant proportion of the respondents inevitably perceived the pharmacies that they frequent as a
“convenience store”.

**Services offered by community/retail pharmacies**

The final section surveyed the respondents’ preferences in sourcing treatment for minor ailments and screening tests [Figure 4] and advice on medications [Figure 5]. The respondents were given a choice of a pharmacy, clinic, sinseh shop and hospital for the treatment of minor ailments such as cough, cold or minor aches and

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**Figure 3: Sale items associated with community pharmacies, sinseh shops and others.**

**Figure 4: Utilisation of services.**
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Although treatment for minor ailments can be obtained at the community pharmacies after consultation with the pharmacists, the majority of the respondents (73.6%) preferred the doctor’s clinic, with only 41.7% selecting the pharmacy. Should we be surprised? This phenomenon was also reflected in a survey conducted in Malta (3), where respondents were reported to more likely consult their doctor or self-medicate for the treatment of minor ailments rather seek advice from the pharmacist. Similarly, Hargie et al (1992) also reported that in Northern Ireland, general practitioners were the first preference for the majority of the patients with regards to the treatment of minor conditions (4).

Correspondingly, when the respondents were questioned on the places associated with offering screening tests, the popular choices were the clinic (76.7%) and the hospital (59%). Only 11.2% of respondents would go to a pharmacy for screening tests. Some community pharmacies do offer services such as screening tests to the public. This study indicates that perhaps a majority of the public is unaware of such services being available in the community pharmacies and thus would prefer to go to general practitioners and hospitals for the treatment of minor ailments as well as for screening tests.

The next question quizzed the respondents on whom they would go to for advice on medications, where more than one answer was permitted. It was disappointing to note that only 49.4% of the respondents would go to a pharmacist for information concerning medicines, compared to 84.1% of the respondents who would choose a doctor. [Figure 5]

Thus, although pharmacists are deemed to be experts on drugs (1), it is unfortunately not perceived as such in the eyes of the majority of the respondents interviewed. This result is in concurrence with the findings of a recent survey conducted in Northern Ireland by Bell et al (2000). The latter revealed that although the majority of those interviewed (87.8%) considered pharmacists as experts in the field of medicines, however, only 64.6% reported that they would talk initially to a pharmacist regarding information or advice concerning medicines (5). One possible reason for this situation may be the lack of rapport between the patients/public and the pharmacists as compared to doctors or nurses. Another reason may be the fact that pharmacists are often viewed by the public as business people concerned with making money rather than health-oriented care-driven professionals. Two surveys conducted in Northern Ireland (4,5) found that about one-third of their study populations...
harboured that perception.

In examining the situation in other countries, it was found that in India, community pharmacies were not perceived to be respectable (6). In Great Britain, on the other hand, two national representative surveys had demonstrated that the public interviewed do perceive pharmacists as appropriate advisers for common ailments but not for more general health matters (7). In the United States of America, the 1998 Schering Report XXI showed strong gains in terms of the patients’ perception of community pharmacists, compared to a similar 1978 survey (8). It is imperative that the Malaysian public should be made aware of and understand the role of pharmacists in the community, in order for the profession to realise its full potential and the public to benefit from the expertise available. Improved social interactions between the public and the pharmacists, in particular personal attention in relation to advice on the treatment of minor ailments, self-care and dispensed medications, is probably the key to increasing the level of public awareness.

**Limitations of the study**

Admittedly, the study population used in this survey was biased towards the more educated and urban portion of the Malaysian public, specifically those who visited the Pharmacy booth during the University of Malaya Convocation Festival. This study was, however, designed for a quick snapshot of this subset’s perception of community pharmacies and pharmacists with the thought in mind that if this subset demonstrates a lack of awareness, then it is most unlikely that the less educated and rural subsets of the Malaysian public will be any better. Another limitation of this study was its setting that did not permit a more extensive line of questioning.

**CONCLUSION**

Although this study was conducted in a selected subset of the population, it does offer a baseline relating to the public perception of community pharmacy and the pharmacy profession in 1997, at least in relation to the more educated and urban section of the public. Of late, with increasing attention in the mass media on the issue of dispensing separation and the role of the pharmacists, particularly in the community, the public’s perception towards the pharmacists may have since improved. Its significance or the lack of it can only be demonstrated through the conduct of a second survey, preferably using a bigger study population and a stratified random selection of the interview sites representing the various states/territories in Malaysia. Nonetheless, the findings of this survey have clearly impressed the urgent need for the pharmacy profession, particularly the community pharmacy sector, to project itself in the eyes of the public as uniquely qualified professionals on drugs, and a reliable source of unbiased information as well as advice on medications and general health care.

**ACKNOWLEDGMENTS**

The authors wish to thank all the 25 undergraduate students, who conducted the interviews for this study after undergoing the training provided, and Mr. Mohamed Azmi bin Ahmad Hassali for his assistance in the procurement of the literature.

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**REFERENCES**

Development of a High-Performance Liquid Chromatographic Method for Analysis of Glibenclamide from Dissolution Studies

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ABSTRACT

A HPLC method for the detection and quantification of glibenclamide, from dissolution studies of glibenclamide tablets (5 mg), was developed. The dissolution test employed was the basket method, operating at 100 rpm, using 1000ml phosphate buffer pH 7.4 as the dissolution medium. Elution was performed on LC-18 reverse phase, Supelcosil™ ODS column (4.6mm x 25cm, 5µm) using a mobile phase consisting of 0.02M monobasic ammonium phosphate in 60%v/v acetonitrile in water at a flow rate of 2ml/min, using phenacetin as the internal standard. The eluent was monitored at 254nm with an UV detector. Retention times of the glibenclamide and phenacetin peaks were 3.61 minutes and 1.8 minutes respectively.

Key words: glibenclamide, dissolution studies, in vitro, HPLC analysis

INTRODUCTION

Glibenclamide is the most extensively used sulphonylurea in many parts of the world for the management of non-insulin-dependent diabetes mellitus (NIDDM) (1). A search of the registry of drugs approved for marketing in Malaysia, kept at the Drug Evaluation and Safety Division of the National Pharmaceutical Control Bureau, revealed a total of 32 glibenclamide preparations registered as at July 1999. These included the innovator products, namely Daonil® and Euglucon®, as well as 30 generic preparations, of which 14 were imported.

Glibenclamide is documented to possess low aqueous solubility (2). Large inter- and intra-individual responses following administration of glibenclamide preparations have also been reported (3-5). Such variations are undesirable and may expose susceptible patients to the danger of hypoglycaemia or other hazards when changing a patient’s therapy from one preparation to another.

Since 1970, dissolution requirements have been added to tablet and capsule monographs, in general, in response to concerns for bioavailability. Of equal significance is the recognition of the immense value of dissolution testing as a tool for quality control. Thus, equivalence in dissolution behaviour was sought in light of both bioavailability and quality control considerations (2). The United States Pharmacopoeia (USP) 1995, however, does not require glibenclamide tablets to
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comply to the dissolution test (2). Nonetheless, dissolution profiles are often used by the industry to ascertain the release rates of glibenclamide from tablet formulations as a quality assurance tool.

Signoretti et al (1983) and El-Sayed et al (1989) conducted studies to evaluate the physico-chemical characteristics, including the dissolution profiles, of various glibenclamide preparations which might contribute to the unpredictable behaviour of the drug products (6,4). In their studies, Signoretti et al (1983) used a method based on ultraviolet spectrophotometry to analyze glibenclamide from dissolution samples.

However, in terms of sensitivity, precision and specificity, a high-performance liquid chromatographic (HPLC) method may offer additional advantages (5,7-9). The USP (1995) documents a HPLC method for the assay of glibenclamide tablets using progesterone as the internal standard (2). The use of an internal standard is required for evaluating system suitability and is not necessary for assays, which have been proven to be accurate, precise, sensitive and specific. However, the authors felt that the incorporation of a suitable internal standard provides an added value to a HPLC technique, as an additional calibration tool, to accommodate any changes in the system and to improve retention reproducibility throughout the analytical period (10).

AIM

This study aims to develop a HPLC method, with the incorporation of an internal standard, for the detection and quantification of glibenclamide from dissolution studies.

MATERIALS AND METHODS

Materials

Two of the 5mg glibenclamide tablet preparations available in the Malaysian market namely, Brand A (expiry date: August 2002) and Brand B (expiry date: April 2002) were used in the dissolution studies. Glibenclamide RS, progesterone RS and phenacetin RS were obtained from the Reference Standard Unit, National Pharmaceutical Control Bureau (NPCB). HPLC-grade acetonitrile and methanol as well as AR-grade monobasic ammonium phosphate and phosphoric acid were used in preparing the mobile phase.

Apparatus

In vitro dissolution studies were carried out in a Erweka® DT 70 dissolution apparatus using the basket method, operated at 100 rpm. The HPLC system consisted of a dual-pump Waters® solvent delivery system (Model 600E) a Rheodyne® (7725 i) variable-volume, syringe-loading sample injector, a Waters® UV detector (Model 486) set at 254 nm and Millennium® 2010 chromatography Manager, version 2.1 data system as the integrator. A stainless steel Supelcosil™ LC-18 ODS (4.6 mm x 25 cm, 5 µm) column was used as the stationary phase.

Assay procedures and validation

Stock solutions of 0.05%w/v of glibenclamide RS in methanol:phosphate buffer pH7.4 (2:98%v/v), 0.001%w/v progesterone RS in acetonitrile and 0.001%w/v of phenacetin RS in phosphate buffer were prepared separately. Standard solutions of varying concentrations of glibenclamide (0.05, 0.1, 0.2, 0.5, 0.75, 0.8, 1, 1.5, 2 and 5µg/ml) were prepared. This range was selected based on 5µg/ml being the maximum concentration of glibenclamide in the dissolution medium, upon complete dissolution of the tablet.

To each 1ml aliquot of the standard solutions, 0.5ml of the internal standard solution (0.001%w/v progesterone or 0.001%w/v phenacetin) was added. 10µl aliquots of the mixture were then injected into the HPLC (minimum of n=5 for each mixture). For the mixtures incorporating progesterone as the internal standard, the following mobile phases were used:

a) 0.02M monobasic ammonium phosphate in acetonitrile:water (55:45%v/v)

b) 0.02M monobasic ammonium phosphate in acetonitrile:water (60:40%v/v)

For each of the mobile phases, the pH was adjusted to 5.25 ± 0.10, using phosphoric acid, and it was delivered isocratically at 2ml/min. Mobile phase (b) was also used for aliquots of mixtures containing phenacetin as the internal standard.

For the assessment of intra-day precision, 10µl aliquots of the complete set of glibenclamide standard and the internal standard (phenacetin) mixtures were injected (n=3) at 4 different times over an 18-hour period, namely in the early
morning, noon, mid-evening and night. This was repeated over 3 days to measure inter-day precision.

To further validate the accuracy of the assay technique, the phosphate buffer pH 7.4 used in the dissolution experiments was spiked with 3 different known concentrations of the glibenclamide standard (0.65, 1.30 and 1.95 µg/ml) and assayed. Phenacetin was used as the internal standard for the assay of the spiked samples.

Apart from measuring the retention times of the analyte peaks, calibration curves of peak area ratios (PAR) of glibenclamide:internal standard versus the known glibenclamide concentrations were also constructed.

**Dissolution experiments**

1000 ml of phosphate buffer pH 7.4 @ 37°C was used as the dissolution medium. Dissolution of the tablets was carried simultaneously in 6 vessels, using the basket method, operating at 100 rpm. 2ml samples were drawn at 5, 10, 15, 30, 60, 90 and 120 minutes from the onset of the dissolution studies. Equal volumes of phosphate buffer pH 7.4 preheated to 37°C, was added into each vessel to replace the withdrawn volumes. The samples were filtered through a 0.45µm (millipore) membrane filter. To each 1ml aliquot of the samples, 0.5ml of 0.01mg/ml phenacetin in phosphate buffer pH7.4 was added as the internal standard. 10µl aliquots of the sample and internal standard mixture were then analysed by HPLC (n=3).

**RESULTS AND DISCUSSION**

A mobile phase composing of 0.02M monobasic ammonium phosphate in 55%v/v acetonitrile in water was initially used, with progesterone as the internal standard, as recommended by the United States Pharmacopoeia (1995). The retention times for the glibenclamide and progesterone peaks were 4.5 minutes and 7.9 minutes respectively. The prolonged retention time of progesterone coupled with its extremely poor aqueous solubility rendered it unsuitable as an internal standard for this assay. It was subsequently substituted with phenacetin. To reduce the retention time of the glibenclamide peak, the composition of the acetonitrile in the mobile phase was increased to 60%v/v. The retention time of phenacetin was found to be 1.8 minutes (Figure 1) while the mean retention time for the glibenclamide peaks was 3.61 minutes with Relative Standard Deviation (RSD) values between 0.08% and 1.6% (n=12). The maximum RSD at 1.6% showed that the precision of this method was acceptable.

The calibration curve for glibenclamide was linear in the concentration range 0.05 to 5 µg/ml ($R^2 = 0.997; \ y = 0.1384x + 0.0138$). The intercept was

![Figure 1. Retention times for glibenclamide and phenacetin peaks (mobile phase:0.02M monobasic ammonium phosphate in acetonitrile:water, 60:40% v/v)](attachment:image)
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not significantly different from zero. However, for the dissolution experiments, preliminary studies revealed that there was incomplete dissolution of the glibenclamide tablets from both Brands A and B. Less than 2 µg/ml of glibenclamide was detected in the dissolution medium at 120 minutes from the onset of the dissolution studies. As such, the concentration range for the calibration curve utilized for the dissolution studies was narrowed down to 0.05-2 µg/ml. The linearity ($R^2 = 0.9908$) was found to be acceptable for this range as displayed in Figure 2.

Using peak area ratios of glibenclamide:phenacetin (internal standard), the coefficients of variation for both intra- and inter-day analyses were shown to range from 0.91% to 5.91% and 0.39% to 6.26% respectively for the complete range of glibenclamide standards. As such the intra- and inter- day precision of the assay were found to be acceptable.

Table 1 compares the results of the assayed concentrations (calculated from the standard curve) of the spiked samples of phosphate buffer pH 7.4 to the known concentrations of glibenclamide added. The differences between the known concentration values and the values quantitated from the assay method were not significant as reflected by the very low values (<2%) of the percentage of the difference ÷ known concentration. This further validated the accuracy of the assay method.

Figures 3 and 4 display the dissolution profiles from the studies conducted on the two commercial glibenclamide preparations, Brands A and B, using the HPLC method developed. It was found that the HPLC method developed was suitable to measure the low levels of glibenclamide released into the dissolution medium.

For both brands, dissolution of the tablets were not complete, even at 120 minutes. USP (1995) generally requires that, for an immediate release tablet, at least 75% of its active ingredient is dissolved within 45 minutes (2). However, the pharmacopoeia does not specify dissolution testing.

![Figure 2. Calibration curve of glibenclamide for dissolution studies.](image)

### Table 1. Analysis data of phosphate buffer pH 7.4 spiked with known concentrations of glibenclamide.

<table>
<thead>
<tr>
<th>Known concentration of glibenclamide added to buffer solutions (µg/ml) [a]</th>
<th>Quantitated mean concentration of glibenclamide from HPLC assay (µg/ml) [b]</th>
<th>Difference between known concentration and detected mean concentration (µg/ml) [a]-[b]</th>
<th>Percentage of difference from known concentration (%)[(][a]-[b] x 100)/[a]]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.65</td>
<td>0.65</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1.30</td>
<td>1.28</td>
<td>0.02</td>
<td>1.54</td>
</tr>
<tr>
<td>1.95</td>
<td>1.93</td>
<td>0.02</td>
<td>1.03</td>
</tr>
</tbody>
</table>
in the glibenclamide tablet monograph and as such these tablets need not comply to the general requirement. Nonetheless, due to its poor aqueous solubility, glibenclamide tablet formulations may potentially face bioavailability problems if its dissolution profile is found to be relatively poor. Thus, the industry does utilize dissolution studies as a quality assurance tool.

**CONCLUSION**

A HPLC method for the detection and quantification of glibenclamide from dissolution studies had been successfully developed, with acceptable retention times of the drug and internal standard peaks, of less than 4 minutes per assay. The HPLC method is able to detect glibenclamide concentrations as low as 0.05 µg/ml with a Relative Standard Deviation ranging between 0.08% and 1.6%. Apart from the greater precision and sensitivity attained using this HPLC method, the specificity offered is undoubtedly another advantage compared to the UV method of analysis.

**ACKNOWLEDGEMENTS**

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Pharmaceutical Control Bureau, Ministry of Health Malaysia for his prompt supply of the reference standards.

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REFERENCES

One of the first things that we do upon being given a new book is to quickly flick through the pages to see if the book is of any interest or of any value to us. This was my first action upon receiving the translated version of Medical Pharmacology at a Glance, third edition, by Michael J. Neal. This book was translated by Universiti Sains Malaysia’s Translation Unit, with Abas Hj. Hussin as the editor. At first glance, “Medical Pharmacology at a Glance” appeared to be a simply written pharmacology book which is illustrated with well-drawn, yet simple diagrams packed with information. The Malay translation is easy to read and understand. All major topics in pharmacology are covered and these are arranged in chapters beginning with basic topics in pharmacology and concluding with poisoning and adverse effects. Drugs are grouped according to their indications, for example, drugs for treatment of hypertension, drugs for gout and so on.

Upon further examination, I find this book to be useful as an additional reference material. It should ideally be used together with other textbooks in pharmacology. The strength of “Medical Pharmacology at a Glance” lies in its well-drawn out and informative diagrams. It should ideally be used as a quick reference by students and teachers of pharmacology. It would also be very beneficial for use in tutorials or as revision. The text in this book is simple and concise and must be read with reference to the diagrams. This book is suitable not only for pharmacy or medical students, but also students of dentistry, nursing or other courses that incorporate pharmacology in the curriculum.

The reviewer would like to draw attention to the use of drug names written in the Malay form. For example, chloroquine is written as “klorokuina”, theophylline as “teofilina” and so on. The reviewer’s personal opinion is that the names of drugs should be maintained in their original form. This will make it easier for the student and newly practising professional to identify these drugs. It is very rare indeed for the student or professional to encounter Malay versions of drug names in practice. What should be translated to the Malay language should be drug class or chemical names of drugs. Another reason to maintain original drug names is to avoid confusion between the different drugs. As it is, with the enormous numbers of drugs in the market, confusion pertaining to drugs of almost similar names already exists. In addition most references and new literature refer to a drug by its internationally recognized name. It is perhaps timely for teachers of pharmacology in Malaysia to come to an agreement with regards to this matter.

In summary, “Farmakologi Perubatan Sekali Imbas Edisi Ketiga” is excellent material for quick referencing.

Aishah Adam

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This book costs RM26.00 and it can be ordered from Kooperasi Kedai Buku USM Bhd, 11800 Pulau Pinang (Fax : 04-6575688) or for bulk orders where up to 30% discount is given, contact: Penerbit USM, Perpustakaan Utama 2, 11800 Pulau Pinang (Fax : 04-6575714, email : penerbitusm@notes.usm.my).
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