THE GHANA PHARMACEUTICAL JOURNAL

Vol. 21 No. 3 September 1999

Bonne Arrivée Madame. Mes Félicitations!

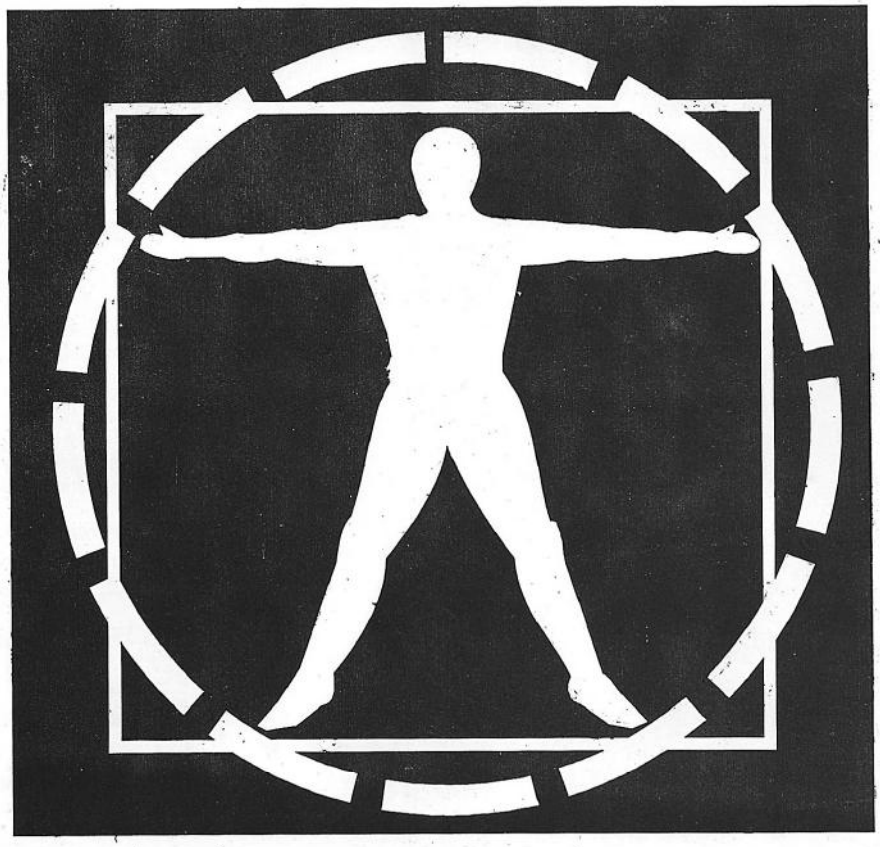
In This Issue

Official Organ of the Pharmaceutical Society of Ghana

Unichem (Ghana) Limited

Location: 17 Dadeban Road, North Industrial Area
(Next to SSB)
P.O. Box 15146, Accra-North, Ghana
Tel: 227722, 238130
Fax: 00 - 233 - 21- 233529
E-mail: unichem@africaonline.com.gh

A GREAT NAME IN PHARMACEUTICALS



3M HealthCare (UK)

FISHERMAN'S FRIEND LOFTHOUSE/ IMPEX (U.K.)

TROGE
TROGE MEDICAL GMHB

sanofi
SANOFI-WINTHROP
(FRANCE)

WALLACE
MANUFACTURING CHEMISTS LTD

WALTER RITTER
PHARMACEUTICA

SHIELD OF PROTECTION
L.U.E.X.(U.K.)

Pfizer Specialities Ltd.

PARKE-DAVIS
WARNER/PARKE-DAVIS (UK)

Seton Scholl
Healthcare plc

MERCK KGaA

TEVA
TEVA / ABIC (ISRAEL)

MEDICAL USE OF MARIJUANA AND ITS SOCIAL IMPLICATIONS

By: P.F. D'Arcy, O.B.E., Emeritus Professor of Pharmacy in The Queen's University of Belfast, Northern Ireland, UK.

Taylor (1), a critical care pharmacist from Sparrow Hospital, Lansing, MI, USA, has reviewed the pharmacology, therapeutics, adverse events and social implications of the medicinal use of marijuana. In the USA, many patients with AIDS, cancer, glaucoma, multiple sclerosis, and other illnesses smoke marijuana for medicinal purposes.

In November 1996, California and Arizona voters approved a referenda to allow physicians to prescribe marijuana. This has galvanised the campaign to legalise marijuana as a therapeutic agent. The issues surrounding marijuana as a medication versus as an illegal drug are clouded by misunderstanding and misinformation and the present review by Taylor is intended to help pharmacists disseminate accurate information to their patients and their communities.

The most prominent effects of marijuana are mediated by receptors in the brain. Acute intoxication is characterised by euphoria, loss of short-term memory, stimulation of the senses, and impaired linear thinking. Depersonalisation and panic attacks are adverse effects. Increase heart rate and redened conjunctivae are common physical effects. Chronic, high doses may cause impairment of cognitive abilities.

Marijuana may be a risk factor for individuals with underlying mental illness. It causes dependence, but compared with cocaine, alcohol, heroin and nicotine, marijuana has little addictive power and produces only mild withdrawal symptoms. Marijuana shows clinical promise for glaucoma, nausea and vomiting, analgesia, spasticity, multiple sclerosis, and AIDS wasting syndrome. Taylor reached the conclusion that as a recreational drug (I dislike this term but it is commonly used in American literature) marijuana should not be available to adolescents and young adulths. As a medicinal drug, marijuana should be available for patients who do not adequately respond to currently available therapies.

Current disadvantages of marijuana use are that it is a crude drug of variable potency. It is toxic to the lungs, it may impair the immune system and the crude form may contain disease-producing contaminants. Effective doses are often accompanied by the acute intoxicant effects which are distressing to many individuals. Taylor stresses that marijuana should be subject to the same risk/benefit calculations applied to any FDA-approved drug. More studies are needed, especially relative to purity, efficacy and safety, but in the interim period, he urges that seriously ill patients should be allowed to use prescribed marijuana.

Pharmacists have an obvious role in counseling patients and supplying information to their communities. And in this role it is especially important that they separate the social and illegal-use issues from the patient-care aspects of marijuana use and give pharmaceutical care to patients who avail themselves of medical marijuana.

Reference: 1. Taylor, MG. 1998). Analysis of the medical use of marijuana and its social implications. J. Am Pharm. Assoc. 38, 220-227 ●

CANNABIS CONFUSION

There is much confused thinking over the possibility of using cannabis as a therapeutic agent in certain circumstances and its status as a menace to public health and social stability. The Institute of Medicine in the United States has issued an interesting report on the possibility of using cannabis in the treatment of nausea, pain and other symptoms in certain patients suffering from debilitating disease. Significantly, the Institute could find no compelling evidence that people using cannabis are more likely than others to slide into worse drug abuses, particularly abuse of diamorphine. It is this "slippery slope" philosophy which has persuaded governments to take an unyielding stance towards any liberation of cannabis for medical purposes. Moreover, the institute could find no good reason for supposing that permitting sick individuals to use it under minimal supervision was likely to encourage wider abuse by the public at large.

One aspect, however, came in for criticism in the report. Smoking is the usual way of taking cannabis, but anything, whether it is tobacco, cannabis or brown paper, carries with it the risk of respiratory irritation and worse. Cannabis smoke is as hazardous as tobacco smoke on account of its tar content. Thus, it is proposed that any clinical trial of cannabis should be associated with a safer delivery system, probably involving derived cannabinoids. Perhaps an inhaler device such as is now used to treat asthma patients might prove useful to deliver the active principles of cannabis.

In contrast to this approach, it is sobering to note that a British report from the House of Lords last year, recommending that the law amended to enable doctors to prescribe cannabis for distressing symptoms in certain patients, was recently rejected by the government. One wonders who makes these decisions.

Credit: The Pharmaceutical Journal (Vol. 262) ●

CANNABIS CODE OF ETHICS AMENDMENT NOT SUPPORTED

Branch representatives of the Royal Pharmaceutical Society did not support a motion calling for the Code of Ethics to be amended so that, in the event that cannabis be legalised for retail sale, its sale from pharmacies for recreational use would become a breach of the code.

Proposing the motion on behalf of the East Metropolitan Branch, Mr. Alan Asher said he had no problem with supplying licensed medical products – including products of Indian hemp and its derivatives – for legitimate purposes. But pharmacists, as the custodians of all drugs for legitimate medical use, would not wish to be associated with the sale of so-called recreational drugs to the populace at large. The Council has implied that, should legislation be enacted, it might endorse the sale of cannabis preparations. That was surrender of the custodianship of the profession and brought shame on the Council. The Council should issue an unequivocal statement that at no time would it endorse such a course of action.

Miss Eileen Thomasson (East Metropolitan) formally seconded the motion. Mr. Roger Mills (Slough) did not believe that is was the function of the meeting to discuss possibilities that might or might not happen at some time in the future.

Mr. Asher responded that it has taken many years for the Council to accept the will of the membership in making the sale of cigarettes and tobacco products from a pharmacy a breach of the Code of Ethics. He felt the Society had to lay down a marker at an early stage, when every day there was pressure for the liberalisation of the availability of drugs for recreational and other purposes.

The motion was *lost* ●

MEMBERS OF THE PHARMACY COUNCIL

MRS. ENITON RUTH GAVU, MANAGING DIRECTOR, ENIMIRA PHARMACY.	*- CHAIRMAN*
MR, EMMANUEL FOFIE CHIEF PHARMACIST, MINISTRY OF HEALTH, ACCRA.	*- MEMBER*
PROF. J.S.K. AYIM, DEAN, FACULTY OF PHARMACY, KNUST, KUMAS.I	*- MEMBER*
MR. DELA C. AHIABOR PRESIDENT, PSGH	*- MEMBER*
MR. EBENEZER OSEI-TUTU, MANAGING DIRECTOR, O.T PHARMACY.	*- MEMBER*
MRS. ESTELLE APPIAH, ATTORNEY-GENERAL'S DEPARTMENT, ACCRA.	*- MEMBER*
MRS. ESTHER A. OSEI, CHIEF SUPERINTENDENT, POLICE HOSPITAL, ACCRA.	*- MEMBER*
MR. M. F. AWUKU-KWATIA, AG. REGSITRAR, PHARMACY COUNCIL.	*- MEMBER*

CONTENTS

AGM "99-PROMOTING RATIONAL DRUG USE

Once again it is time for Pharmacists in Ghana to take stock of their activities for the past year.

The AGM is the single largest gathering of Pharmacists in Ghana. It affords a unique opportunity for individual Pharmacists to compare notes with colleagues from other regions and other areas of Pharmacy practice.

The Society also has the opportunity to account to members its sucesses and failures and explain its proposed programmes for the year ahead.

At last year's AGM held at Cape Coast, Pharmacists decided to build capacity sufficient enough to raise and maintain the quality of pharmaceutical care in this country.

As Pharmacists gather again in Accra at the Osu Ebenezer Presby Church Hall to deliberate on another theme, it is prudent to pause and ask: how far have we progressed with our capacity building to help us confront the challenges of the next millennium and remain relevant to society even in the face of this threat of massive encroachment by other professionals?

As individuals and as a professional association, are we putting in place structures that would enable us overcome the problems we identified in Cape Coast?

While we ponder over these, may we remind ourselves of the theme for this year's AGM: Promoting Rational drug use.

Rational drug use can be possible only through the collective effort of all the players in the health care delivery team, as well as the patient, regulatory bodies and other major stake holders.

However, as Pharmacists, experts and custodians of drugs, we have a greater responsibility to ensure that drugs are rationally used. We are in the position to positively influence all the others and we must be seen to be doing the right thing for others to take us serious.

Rational drug use as we all know involves giving the right drug, at the right time, in the right doses, to the right patient. Under normal circumstances, this should pose no problem to anyone.

However, when the economic/ business variable is introduced, professionalism suffers and some degree of "irrationality" sifts in. As we deliberate on these issues and others that might come up, shall we resolve to practice our profession with the principles of rational drug use in mind and " Amicus Humani Generis" as our guiding principle ●

COVER STORY

THE HON. MINISTER OF HEALTH, MR. SAMUEL NUAMAH-DONKOR CONGRATULATING MRS. ENITON GAVU THE CHAIRMAN OF THE PHARMACY COUCIL AFTER THE INAUGURATION OF THE COUNCIL ON JULY 27, 1999 AT THE CONFERENCE ROOM OF THE PHARMACY COUNCIL.

The Ghana Pharmaceutical Journal is published three times a year by the Pharmaceutical Society of Ghana in Accra. Correspondence concerning editorial contents and advertisements should be submitted typewritten, in double spacing on one side of the paper and in duplicate. Materials accepted for publication may be subjected to editorial revision and, in the case of original papers, once they are published in this Journal, they cannot be published elsewhere except by agreement. Authors should conform with current style in the presentation of papers, indicating where tables, and figures should be inserted. Views expressed by contributors do not necessarily reflect the opinion of the editor. Partial or total reproduction of the contents of this issue in any manner or form is prohibited.

National Headquaters of the Pharmaceutical Society of Ghana is located in the Social Advance Institute Building * P. O. Box 2133, Accra * Tel: (233-21)228341 Fax: (233-21)239583 E-mail: PSGH@ighmail.com

NO SIGNIFICANT LINK BETWEEN PILL AND MYOCARDIAL INFARCTION IN NEW STUDY

There is no significant increase in risk of myocardial infarction (MI) in users of oral contraceptives, according to a study by Dr. Nicholas Dunn (Senior research fellow, Drug Safety Research Unit, Southampton) and colleagues.

The study was designed to determine the association between MI and the use of different types of oral contraception in young women.

The researchers collected data from 448 women aged between 16 and 44 who had experienced an MI. They compared these with data collected from 1,728 female controls who had not had an MI. In each case, the investigators asked about exposure to oral contraceptives. In addition, they investigated cardiovascular risk factors, which included smoking, diabetes mellitus and history of angina.

One or more cardiovascular risk factors was found in 88 per cent of the cases compared with 36 per cent of controls. In particular, 80 per cent of cases of controls and there was a clear correlation between MI risk and increasing number of cigarettes smoked per day. The investigators also found that 87 per cent of cases were not taking on oral contraceptive three months before their MI. They found no effect of duration of use in those who were taking oral contraceptives.

There was no significant difference between the second and third generations of oral contraceptive with regard to risk of MI. The authors note that the results do not agree with those of the European transnational study, which suggested a lower risk for third generation products than for second generation products, but add that the United Kingdom results from that study and the present study show considerable overlap.

"Smoking and other risk factors are of overriding importance in the aetiology of MI in this age group and, in comparison, the use of oral contraception makes little or no difference," conclude the authors.

The study is published in the *British Medical Journal* (1999; 318:1579). In an accompanying commentary, Professor Ojvind Lidegaard (department of obstetrics and gynaecology, University of Copenhagen) says that the study is an important, reassuring contribution to the assessment of the risk of acute MI in users of oral contraceptives ●

PAY YOUR CONTRIBUTION NOW TO SUPPORT THE FACULTY OF PHARMACY ENDOWMENT FUND.

MEMBERS OF THE FOOD AND DRUGS BOARD

1.PROF. J. S. K. AYIM DEAN, FACULTY OF PHARMACY, KNUST, KUMASI	-	CHAIRMAN
2. MR. T. C. CORQUAYE CHIEF EXECUTIVE	-	MEMBER
3. MRS. ABIGAIL ANDAH REP. FOOD RESEARCH INSTITUTE	-	MEMBER
4. DR. M. A. MENSAH DIRECTOR, DEPT. OF FISHERIES	-	MEMBER
5. DR. H. A. ADDO REP.- GHANA MEDICAL ASSOCIATION	-	MEMBER
6. DR. A. NTIFORO REP.- GHANA STANDARDS BOARD	-	MEMBER
7. DR. E. ASIBEY-BERKOE HEAD, DEPT. OF NUTRITION & FOOD SCIENCE UNIV. OF GHANA	-	MEMBER
8. DR. J.K. OBINIM REP.- VETERINARY SERVICES, MIN. FOOD & AGRIC.	-	MEMBER
9. MR. J. R. TURKSON DIRECTOR, CROP SERVICES, MIN. FOOD & AGRIC.	-	MEMBER
10. MR. G.S.M. KLUFIO REP.- ENVIROMENTAL PROTECTION AGENCY	-	MEMBER
11. MR. YUSIF AHMED PRACTITIONER OF HERBAL MEDICINE	-	MEMBER
12. MR. M. F. AWUKU-KWATIA AG. REGISTRAR, PHARMACY COUNCIL	-	MEMBER
13. MS. VALERIE O. AMATE REP. - OF THE ATTORNEY- GENERAL'S DEPT.	-	MEMBER
14. MS. FAUSTINA NELSON REP.- CONSUMER INTEREST	-	MEMBER
15. MRS. CLARA OPARE OBISIAW REP.- CONSUMER INTEREST	-	MEMBER

CLINICAL SIGNIFICANCE OF DRUG/FOOD INTERACTIONS

by

Samuel M. Heman-Ackah, B.Pharm., Ph.D, MPSGH

Professor Emeritus of Pharmaceutics

Howard University, Washington, DC

Various types of drug interactions have been reported in the literature to affect drug therapy in-patients. They include the following categories:

1. Drug/drug interactions, which are interactions of an administered drug with another drug(s) administered to the body previously, concurrently, or subsequently from multiple drug therapy and widespread polypharmacy.
2. Drug/food interactions, which are interactions of an administered drug with ingested foods and dietary components; and
3. Drug/laboratory test interactions, which are interactions of an administered drug with diagnostic agents to produce interference in laboratory test values.

The principal mechanisms of drug/food interactions are identified as: -

1. Interference with bioavailability of an administered drug;
2. Interference in clinical laboratory test values;
3. Modification of pharmacologic action of an administered action of an administered drug; and
4. Interference with nutritional value of foods and dietary components.

These interactions have been reported to:-

1. decrease the effectiveness of drug therapy;
2. increase the potential for an administered drug to be toxic;
3. yield false +ve or –ve result in clinical laboratory test values to mislead diagnosis;
4. create malnutrition problems.

Though numerous drug/food interactions are clinically insignificant, yet there are some of the interactions which must be targeted for frequency of use and/or clinical significance. Few examples of interactions with significant clinical outcomes include:

1. The interactions of polyvalent cations in calcium-rich foods (e.g. milk and dairy products, clams, oysters, tofu etc.), iron-rich foods (e.g. meat, leafy green vegetables, prunes, peaches, etc.) and magnesium-rich foods (e.g. whole grains, legumes, leafy vegetables etc.) with tetrayclines and ciprofloxacin (Cipro) to form insoluble complexes that result in a decrease of the bioavailability and clinical effectiveness of the drugs.
2. The interference of vit. C. (ascorbic acid) in citrus fruits (e.g. oranges, grapefruit, kiwi, etc.), berries (e.g. strawberries, gooseberries, raspberries), green and red peppers, tomatoes, etc. with diagnostic agents for test of glucose in blood and urine to yield false –ve (Testape, Chemistrip G. Clinistix) or false +ve (Clinitest) results that mislead diagnosis and treatment of diabetes.
3. The interaction of tyramine containing foods (e.g. aged cheeses, avocado, broad, over-ripe bananas and pineapples, chianti and red wines, etc.) with mnoamine oxidase inhibitors (MAOI) drugs (e.g. Isoarboxazid, phenelzine, tranylcypramine, nialamide, iproniad, pargylline, etc.) to precipitate hypertensive crisis and cardiac arrhythmias.
4. An excessive consumption of vit. K-rich foods (e.g. leafy vegetables, avocado, liver etc.) can alter prothrombin time in-patients on anticoagulant therapy e,g. coumarin to necessitate significant significant dosage adjustment in the anticoagulant therapy.
5. The interaction of ingested alcoholic beverages with metronidazole and other drugs with "antabuse" type of reaction (e.g. sulfonylurea hypoglycemics, furazolidone, cefoperazone, etc.) to precipitate potentially undesirable clinical effects (e.g. flushing, vomiting, nausea, hypotension, palpitation, etc.)
6. The inhibition of metabolism of many drugs (e.g. carbamezipine, cyclosporin, lovastatin, benzodiaze, etc.) psoralen in grapefruit juice to increase plasma concentration of the drugs with resultant increase in pharmacodynamic effects, which may be clinically significant, especially in geriatric patients and those with liver cirrhosis.

Clinical outcomes of drug/food interactions necessitate a need for patient education on dietary habits, while on certain types of medication. Drugs which must be targeted for frequency of use and/or significance of clinical outcome include: cyclosporine, ketoconazole, lithium, warfarin, metronidazole, oflaxacin/ciprofloxacin, tetracycline and monoamine oxidase inhibitors with specific food and/or dietary components. The involvement of the pharmacist, physician and nurse in an interdisciplinary approach to counselling and advisement on drug/food interactions of clinical significance, cannot be over emphasised.

This is an abstract of his AGM '99 lecture ●

AREPIANS MEET

The Ministry of Health is seeking practical ways of collaborating with the private sector in the creation of the necessary environment for health development in Ghana. In this direction the MOH is involved in collaborative consultations with all stakeholders.

The MOH thus expect all its collaborators in the private sector to patiently and painstakingly research its policies so as to understand the rationale behind the policies of the Ministry.

The policies of the MOH are underpinned by broader social objectives with built in measures for people who may be at a disadvantage. The Ministry is desirous of establishing a natural equitable health care delivery system in which patients are made the centre of all decisions at all levels. With the increasing awareness of the general public of their right to quality services, particularly pharmaceutical services, medical representation should be used as a tool to promote genuine involvement of the prescriber and the patient in managing health problems.

Nana Paddy Acheampong, Hon. Deputy Minister of Health made these known in his address to the 7th AGM of AREPI held at the Miklin Hotel in Accra, in August. The theme for the AGM was "Developing Rational Drug Use through the use of appropriate information".

Touching on the theme, the Deputy Minister reiterated the indispensable role of the Medical Representative as an expert in providing the appropriate information that will empower people, including prescribers to make right choices. This must however be provided within the usual framework of quality improvement, increasing access to health care and encouraging a healthier life.

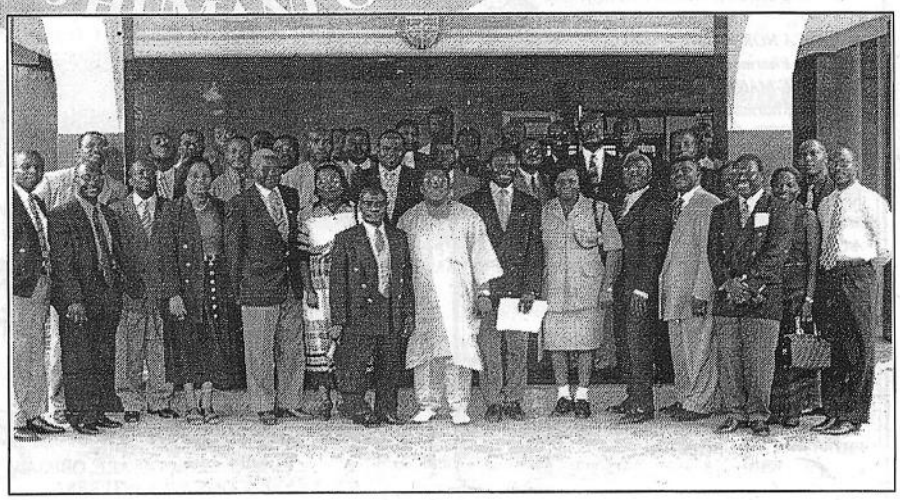
He deplored the packaging and delivery of information by some AREPIans that portray them more as vendors rather than as experts. Sometimes, the information provided is "not presented in a way that will make for a rational debate and for that matter a rational choice in the context of sector (MOH) policies".

Nana Acheampong thus called for a closer collaboration between the MOH and representatives of ethical pharmaceutical industries in the implementation of the policy of procuring affordable, yet quality drugs for the health sector. He stressed that "buying generic is only a means for ensuring affordability".

In his welcome address, the outgoing chairman Mr. Louis Nortey indicated that the choice of the theme for the AGM reflects the leading role of AREPI in packaging and disseminating medical information to the client through seminars, workshops, sponsorships, and new drug launches.

To emphasise the role of medical representatives in the dissemination of medical information nationwide, Mr. Nortey noted that, although the bulk of pharmaceutical activities are centered within Accra and Kumasi, the activities of Medical Representatives are widely dispersed nationwide.

He pledged that AREPIans would "continue



THE DEPUTY MINISTER OF HEALTH IN A GROUP PICTURE WITH INVITED GUESTS AND AREPIANS.

to channel the course of continuing medical education with zeal and help provide the resources to do so" by collaborating with their major partners like the MOH ,PSGH, GMA and GRNA.

Mr. Derx Baffour, an AREPIan spoke on the topic "Pharmaceutical Marketing and Rational Drug Use". He spoke about the conflict between multinational drug companies and agencies like the WHO. The multinational companies spend a lot of money on R&D and thus employ aggressive marketing strategies to recoup their investment and profits. On the other hand agencies like the WHO, pursuing policies aimed at ensuring that all people, irrespective of where they are on the face of the globe, should be able to obtain their safe and effective drugs supplies at the lowest possible cost. There is the need to find a common ground for the benefit of the patient.

Rational drug use, according in Mr. Baffour, should not be an end to itself. It must involve efficiency and cost effectiveness in health care delivery and active patient participation (patient empowerment).

According to Mr. Baffour, the trade liberalisation policy currently being pursued in Ghana has led to the influx of all types of drugs, leading to the application of unethical, unorthodox and very crude methods of marketing. He cautioned his colleagues, whose performance is invariably judged by the volume of sales they make, not to practice these unorthodox marketing strategies.

Mr. Baffour also called on the multinational drug companies to consider drastically reducing their profit margins, especially on their "old but popular products" to make such products available to the majority of people.

He also cautioned the MOH against the strict and dogmatic adherence to the Essential Drug List, since this can adversely affect investment in R&D and the introduction of new drugs.

Mrs. Joyce Addo-Attuah of the Police Hospital, also gave a lecture on the theme.

During the discussions it became clear that most AREPIans were not comfortable with the existence of the EDL and its use in public health institutions. They were of the view that sticking to generics because of price is a wrong way of assessing the cost of healthcare delivery. They were of the opinion that total cost of treatment and not the unit cost of drugs should be the determining factor.

Less expensive drugs, most of which are of doubtful efficacy, can be very expensive in the long run since they do not produce the desired results and might call for prolonged treatment. On a light-hearted note, it was suggested that buying a relatively expensive, yet quality branded product that would produce the desired results within a short time, would help MOH solve its "extra duty allowance" problem with its staff since there would be no need for extra duty.

It was explained that though the EDL (Essential Drug List) uses generic names when it comes to procurement, factors like quality and cost are considered.

The meeting was chaired by Mr. Harrison Abutiate of Paracelsus, a former Medical Representative. Other dignitaries at the function were the Chief Pharmacist, Mr. Fofie and the President of PSGH, Mr. D.C. Ashiagbor.

Mr. Ashiagbor took the opportunity to appeal to AREPIans to advertise in the Pharmaceutical Journal and also make donations to support the AGM/Conference of the PSGH.

Elections were held as part of the meeting.

The following were elected into office:

1. Chairman	-	Kwesi Eghan
2. Vice Chairman	-	Afful Duncan
Vice Chairman (Kumasi)	-	Emmanuel Acquah
3. Secretary	-	Egya Essilfie
4. Executive Member	-	Alex Ameyaw
5. Organising Secretary	-	Patrick Ansah

INAUGURATION OF SECOND PHARMACY COUNCIL

At long last a reconstituted Pharmacy Council has been inaugurated under the chairmanship of Mrs. Eniton R. Gavu, the first female to head this regulatory body in Ghana.

The inauguration was done by the Hon. Minister for Health, Mr. Samuel Nuamah-Donkor. Speaking at the function, Mr. Nuamah Donkor congratulated the outgoing Council for its numerous achievements. Notable among these were the increasing number of Pharmacies being opened in the district centers and residential areas instead of the central business areas of regional capitals; the opening of four new zonal offices of the Council in Kumasi, Sekondi, Tamale and Koforidua; the promulgation of LI 1645 which sets out rules and procedures for the work of the Disciplinary Committee of the Council; the on-going continuing education for Pharmacists and the training of chemical sellers; and the implementation of the decision to allow pharmacists in the public sector to use their spare time to offer services in the private sector as a means of making available their pharmaceutical expertise to the general public whilst at the same time making some extra income.

Mr. Nuamah-Donkor also charged the new Council to build on the achievements of the previous Council. He thus called on the Council to check drug peddling in areas such as lorry parks, rural communities and also endeavor to deal with the issue of unrestricted access to all classes of drugs by the public which is a direct result of the "emergence of dubious pharmaceutical businesses without any fixed address or location."

He also urged the Council to continue establishing regional offices so as to bring the work of the Council closer to the general public. The Council would also have to suggest review of the existing LI and develop new ones that would provide for the effective implementation of the Pharmacy Act.

Earlier in a welcome address, the Chairman of the outgoing Council, Mr. Ohene-Manu, appealed to pharmaceutical service providers and prospective ones to realise that "there are times when of necessity, individual interests have to give way to the common good." He stated that the Council had been steady and firm in principle in all its actions with the public interest as its guiding light and "malice towards none."

Mr. Ohene-Manu expressed the Council's appreciation to the staff of the Council's Secretariat for their cooperation even in the face of poor remuneration. As a way of solving this issue of poor remuneration, he appealed to the Minister to "permit the in-coming Council to start the necessary negotiations which will take the Council out of the Public Service organisation which receives subvention from Parliament" since the Council is now able to generate from its own resources "more than enough to meet its expenditure".

In response to this appeal the Hon. Minister acknowledged that in order to fully achieve its mandate and build the expected regulatory capacity, the Council ought to be financially independent. He thus pledged the Ministry's support to the Council in its effort at seeking special dispensation to utilise some of its internally generated funds for its operations whilst moving towards financial independence. The Ministry would support any justifiable allowance paid to the Council's staff.

Mrs. Gavu on her part expressed her appreciation and that of the other Council members to the President of the Republic and the Council of State for the "honour and privilege bestowed on us to serve Ghana."

Mindful of the arduous task ahead of them, Mrs. Gavu informed the Hon. Minister that the Council's success would be made possible when there is full government and political support and cooperation, the involvement of all major stakeholders in the decision making process, financial independence to execute strategic plans, and adequate legal and statutory regulations to back all actions.

Mrs Gavu did not miss the opportunity to play the gender card reminding one and all including the Minister of Health that she is a female and "ladies require from their male counterparts much attention to enable them respond positively to their needs". Consequently, she was hopeful that the Minister would support her with his maximum cooperation when dealing with Pharmacy Council matters, promising that she would not be asking too much in this regard as the one occupying the chair.

Mrs. Gavu assured the Minister that they, as a Council, appreciate the fact that society is dynamic and hence they do not "intend to operate a straight jacket system" whilst at the same time they would not be a "weather clock vacillating in ideas and policies to the detriment of society and the profession." She pledged that they shall stand by the principle of fairness, transparency, accountability, firmness and also lead the crusade to enhance the image of the Council as well as set "high standard of pharmacy practice" for the benefit of Ghanaians. ●

THE HON. MINISTER OF HEALTH AND HIS DEPUTY WITH THE COUNCIL MEMBERS AFTER THE INAUGURATION

CLINICAL PHARMACY

Four community Pharmacists have been admitted into the MSc course in Clinical Pharmacy organised by Robert Gordon University in Aberdeen, Scotland.This distance learning programme is being locally co-ordinated and funded by the Ghana National Drug Programme under the ministry of Health.

The four Pharmacists are Ms.Grace Ankrah, Mr. Eric D. Oduro, Mr K.T Okyere and Mr. Bandoh Mensah. They were part of six nominees presented by the Society for consideration.

Though this is the second batch of students admitted into the Programme, it is the first time community Pharmacists have been included in the Programme.

The criteria used for the selection of the candidates are:

i) current community practice;
ii) a strong but recent link with hospital practice; and
iii) a commitment to train other community pharmacists.

At an orientation course organised for the twenty students, the Chief Pharmacist reiterated the fact that current trends in Pharmaceutical care is patient-oriented and hence clinical pharmacy has become essential in the training of Pharmacists.

Mr. Fofie explained that the inclusion of the four community pharmacists and four from Quassi Government Health Institutions is in pursuance of the MOH's objective to foster close collaboration with the private sector.

Mr. Fofie also took the opportunity to congratulate the five Pharmacists who have successfully undergone the training up to the Diploma level and who will be continuing to the Masters degree level ●

THE AG. REGISTRAR

After the inauguration of the reconstituted Pharmacy Council, the Editor had a chat with the Ag. Registrar of the Council. Read on.

Mr. Awuku-Kwatia was convinced that the first Council did a good job. For instance, it set itself the task of ensuring equitable distribution of Pharmaceutical services throughout the country.This was to a large extent, achieved .

The trend has been the establishment of pharmacies in the central business areas of regional capitals to the detriment of other areas like the residential areas. The reason for this, explained the Ag. Registrar, is that the issue of offering service has been supplanted by that of business considerations. The philosophy behind the motto of the Society , "Amicus Humani Generis" has been lost on most Pharmacists.

According to the Ag. Registrar, when the Council took steps to ensure that it secures equitable distribution of Pharmaceutical service in Ghana, through the enforcement of the 400-metre rule, some pharmacists were not pleased. Some pharmacists believed that it was an infringement on their constitutional rights and also against the principle of trade liberalisation. However, the Ag. Registrar is of the opinion that,such constitutional claims do not hold in the light of the mandate given the Council by Act 489 which states that the Council shall "regulate the distribution of pharmacies in the country".

The Council is also engaged in consultations with the relevant stakeholders to revise the current course content for the trainning of Pharmacists in Ghana.

In line with this,the Chief Pharmacist travelled to the U.K to hold discussions with the appropriate agencies. Also, Pharmacy schools in South Africa have been contacted. A proposed visit to South Africa by a delegation of the Council is yet to materialise. However proposals on the revision of the course structure have been made to the Faculty of Pharmacy KNUST. Changes in the course structure would be gradual. The Academic Board of the Faculty and of the University would have to consider these.

Speaking on the on-going continuing education for Pharmacists, Mr Awuku-Kwatia reiterated its importance in keepng the Pharmacist abreast with current trends in Pharmacy practice. The Education Committee determines the educational needs of Pharmacists. It works in close collaboration with its cuonterpart of the PSGH. A joint committee of the two bodies is being formed.

Mr. Awuku-Kwatia also touched on the issue of allowing newly qualified pharmacists to supervise Pharmacies. He was of the view that the Council and indeed the Society should take another look at it. The overwhelming majority of these Pharmacists lack the necessary skills, both in terms of the profession and in management. Lured by monetary considerations and offers made by some non-pharmacist proprietors, these young Pharmacists enter into agreements which they hardly understand. Within six months they come back to Council with new proprietors claiming they have been cheated.

More importantly it is the inability of these newly-qualified pharmacists to offer the necessary pharmaceutical service that is worrying. They need to be guided to mature.

The Ag. Registrar believes that the two-year period between qualification as a Pharmacist and the ability to register to supervise a Pharmacy should be re-introduced. One way out is to delay the writing of the professional exams. On the other hand the standard of the professional exams should be significantly raised.

The decision to suspend the issuing of chemical sellers' license for the urban areas is still in force. Another measure to help control the number of chemical sellers is to ensure that any chemical sellers' shop should be at least 1km away from a Pharmacy.

Mr. Awuku-Akwatia says that the illegal activities of chemical sellers, are to a very large extent, supported by Pharmacists. It is Pharmacists who sell class A and B drugs to these chemical sellers and Council has documentary evidence to this effect.

"If Pharmacists, would close their ranks and determine to abide by their professional codes", the so called threat from the chemical sellers would be rendered impotent. He urged Pharmacists whose pharmacies are close to chemical sellers' shops to prove their worth by offering distinctive quality service which would convince clients to patronise the pharmacy instead of the chemical seller .

Mr. Awuku-Kwatia also hinted that there are discussions on the need to raise the standard or requirments for granting of chemical sellers' license.Mr. Awuku-Kwatia stated the obvious, the open secret: there is pressure from high , the powers that be in political circles for the granting of chemical sellers' licenses.

The Council has problems. Of late there has been a high staff turnover. The underlying factor has been low motivation for the staff. Fortunately the sector Minister gave a qualified approval to the Council to pay allowances to its staff. This must be justified and must be paid from the Council's internally generated funds.

Meawhile, what is the position of the Council on hospitals and clinics which have well established Pharmacies which are not supervised by Pharmacists? The Council, according to the Ag. Registrar, is working on the issue and as a result some of these hospitals have engaged the services of qualified Pharmacists to man these Pharmacies. The Council is also in the process of categorising hospitals and clinics to determine whish ones really need Pharmacists.

Does the Pharmacy Council control Dispensing Technicians ? No! Presently, the relationship between the Council and the DTs ends with the postings done by the Council. However, the Council is in the process of preparing the necessary framework to bring the activities of DTs under the control of the Council.

Sir, your final words. The future for Pharmacy can be bright. There must be a conscious effort by all Pharmacists to build this future. The fronting for non-pharmacist proprietors by Pharmacists should cease. The desire to serve, to offer quality service should override the economic conderations. Stop patronising the " I-get-am-boys". Be a true 'friend of the human race.' Let us all work with the Council to ensure a pharmacy practice that we can all be proud of●

THE VICE CHANCELLOR

Prof. J. S .K Ayim, Dean of the Faculty of Pharmacy has been appointed Vice Chancellor of the Kwame Nkrumah University of Science and Technology (KNUST), Kumasi.

The appointment of a substantive Vice Chancellor for KNUST has been the subject of a court action brought about by one of the three candidates short-listed by a search committee.

Recently a Kumasi high court gave its ruling on the issue, which paved the way for the appointment of Prof. Ayim as the Vice Chancellor. Prof. Ayim is a member of the Pharmacy Council. He is also the Chairman of the Food and Drugs Board, and a member of the National Council of PSGH.

On behalf of the Editorial Committee, the Standing Executive Committee, the National Council of the PSGH, and indeed all Pharmacists of Ghana, I wish to congratulate Prof. Ayim for his appointment.We all share in this honor and pledge to him our prayers and support.

Prof. Ayim, in this era of cost-sharing and user-fee "palaver" we hope and pray that the Good Lord Himself would grant you wisdom and direction●

PHARMACY HOUSE PROJECT

A delegation of the Standing Executive Committee visited the site acquired by the Society for the Pharmacy House Project. The site is opposite the Tema Exhibition site (TEXPO). It is close to the proposed site for the Nungua Secondary School.

The delegation , led by the President, Mr. Ashiabor, was taken round the plot by a son of Nii Shippi, head of one of the families that own the land.

Other members of the delegation were the Chairman of the Project, Mr Abutiate, the Vice-President, Mr. Arthur, the Executive Secretary, Mr. Tenkorang and the Editor. Mr. Bart-Plange, who has been instrumental in the efforts of the PSGH in acquiring the plot was also there.

Earlier in the day, the surveyor undertook the demarcation of the 12 plots and placed pegs at the appropriate places.

At the end of the visit it was decided that 5 trips of gravels be placed at the four corners and in the middle. This has since been done. Further payments were also made after the visit. An amount of fifty million cedis (¢ 50m) was paid in addition to the twenty million cedis (¢20m) already paid.

At its meeting on September 4, the National Council ratified the actions of the S. E.C and further asked that concrete pillars be erected around the plots. It has been proposed that trees should also be planted around the land●

THE FIRST LADY

By J. Y. B. Bennie, Editor

Is there anything in a name? Some people think there is. Yet others do not believe a person's name has anything to do with the individual's life. Naturally, others have no opinion on the issue. However, she believes there is something in a name and her life, in one way or the other, bears testimony to that.

Her name has two meanings. It means a child with a special history" or "shining forth". Indeed she has a special history and she's been shinning forth. You can add "First" to her name and it would fit perfectly.

In December 1941, she was born to her parents Mr. Enos Yawo Anku and the late Mrs.Vinolia Anku at the Tamale hospital. Mr. Anku was a vertinary officer stationed at Pong Tamale.

She started schooling at Gbadzeme in the Volta Region,due to the undeveloped school system at Pong Tamale. She later completed at Abor . She passed the Common Entrance Exams when she was in Middle School Form Two. She gained admission to Mawuli Secondary School from where she entered the Kwame Nkrumah University of Science and Technology.

Like some Pharmacists, Pharmacy as a profession was not part of her dream. She had wanted to be a Medical Officer or a nurse. Meanwhile,the government had just stopped sending students to Nigeria and started the Medical School in Ghana;the length of training was uncertain. Her dad thought that spending nearly seven years in the University would be too much. What if some " untamed he-goat" decided to tag her " teenage preg---------?".

She had by then gained admission to the Nurses Training College at Korle-Bu. It was around that time that the Degree programme in Pharmacy was introduced and she was therefore encouraged to read Pharmacy.

In 1965, her group graduated with the first lady pharmacists with B.Pharm. degree.Others inthe group included Mrs Lucy Asibi (Nee Pesew), the late Miss Victoria Anyetei (married to Dr. Konning) and the late Bright Takyi. Some of the men in the group are Professor Sarpong, Mr. T. C. Corquaye (Chief Executive, Food and Drugs Board), Mr. Fofie (Chief Pharmacist), and the late Prof. Dwuoma-Badu (former Dean of the Faculty of Pharmacy).

How can I forget? Who am I talking about ? Anyway she was called Miss Anku.

Miss Anku was the first graduate Pharmacist to work at the Korle-Bu Teaching Hospital (KBTH). She worked under Mr. Ebenezer Osei-Tutu. Incidentally Mr. Osei-Tutu is serving with her on the Council now

She started from the Main dispensary and helped to change the image of the Pharmacy deparment. As part of her schedule she trained the dispensing assistants.She was the first Pharmacist to work at the new Obstetrics and Gynaecology Department (Maternity Block dispensary) in 1966 when it was opened. She also worked at the Children's Block Dispensary.

In 1967 she left for Britain to do a one-year Brtish Technical Aid Programme in Hospital Pharmacy Practice at the Middlesex Teaching Hospital. She specialized in Hospital Production of Intravenous and Sterile Products. Miss Anku returned to Ghana with enhanced professional skills and social status !

Back home she was put in-charge of the Aseptic unit of KBTH, responsible for the infusionsneeds of the KBTH, and all other hospitals like the Ridge Hospital.

Soon after her arrival back at Korle-Bu there was a cholera outbreak. Ably supported by her hard-working boss, and armed with her training in Britain, Miss Anku, then Mrs. G....., had the needed confidence to lead the production of all IV Infusions required for the outbreak in the hospitals and the numerous cholera camps that sprang up.Something else happened in Britain.

Miss Anku decided, for good, to change her name. She became Mrs. Gavu! She got married to Mr. Christopher Yao Gavu an Electrical Engineer who was then pursuing a postgraduate programme in London. Make no mistake - they did not meet in London. The genesis of the relationship was at the pride of the Garden City-KNUST. Some are blessed.Two unrelated degrees from KNUST.

Talking to Mrs. Gavu, I sincerely desired to have a glimpse of the early days of her relationship with Efo Yawo. After 31 years of marriage, this lady speaks of her husband with such love, passion and respect that make you wonder how on earth some marriages end up on the e rocks, and whether she is not in the wrong profession. She's cut for a marriage counsellor.

Since the production division of their marriage was commissioned, Mrs. Enitón Ruth Gavu has been to the labour ward four times. Between the two of them, they are blessed with six sons.

This woman is different. All six boys are either university graduates, some with post graduate qualifications or are about to graduate. There is a Pharmacist to-be among them.

In 1971, Mrs. Gavu's immediate boss at KBTH, Mr. Osei-Tutu , was promoted. She then assumed acting responsibility for the Pharmacy department of the Hospital.

Mrs. Gavu resigned from the KBTH in 1973. Why ? " I was becoming frustrated with the service conditions of MOH. I was constantly serving on committees negotiating salaray enhancement to no avail ." GHOSPA, your woes started a long time ago; aluta continua!

When in 1973 the Cocoa Board decided to provide medical services for its staff, it became necessary to look for experienced and dedicated staff, people with vision and drive . Out of sixteen applicants, Mrs. Gavu was selected as the Pharmacist on the team. She became the founder and first Pharmacist of the Cocoa Clinic. Prof. Nyame was the team leader and together, from scratch, they established Cocoa Clinic.

The scope of work for the Clinic expanded to cater for the eleven cocoa growing areas in the country. These areas were covered by mobile clinics.The number was later reduced to six permanent staff clinics at CRIG in Tafo, Takoradi , Tema , Swedru , Tepa and Kumasi. Mrs.Gavu had oversight responsibility of all the Hospitals and regularly visited each of them. She was promoted to the post of Chief Pharmacist. Should I add that she is the first Chief Pharmacist of the Cocoa Clinic ?

After twenty (20) years of meritorious and dedicated service to the Cocoa Clinic , Mrs. Gavu resigned in 1993. In these days when some Pharmacists change jobs like President Yeltsin changes Prime Ministers, Mrs. Gavu has a lesson

or two for such Pharmacists.

She's always had the desire to do some community Pharmacy, She had also yearned to manage her own pharmacy. 1993 was ripe for resignation because in addition to other things, she had accumulated enough benefits for investment.

ENIMIRA: The end result was the birth of ENIMIRA pharmacy. When it came to choosing a name for the pharmacy, she decided that the meaning of Eniton must reflect on the shop. She recalled escaping from death in two inciednts in 1980 and 1992, where she virtually bled to death to an Hb of 3%. Her escape from death was indeed a miracle. A child with a special history, who has been shinning forth (Eniton), and who has been healed miraculously yielded ENIMIRA.

PSGH: Mrs. Gavu has served the Pharmaceutical Society of Ghana in many different capacities from 1966 to date.She has served on several Boards and Committees as PSGH representative. Some of these are the Mills Odoi Committee on salary of Pharmacists, Drug Importation Committee, Drug Standardisation and Quality Control Technical Committee, e.t.c.

Mrs. Gavu was the first woman to be elected to the National Council of PSGH serving as the Treasurer (1979-83). During her tenure of office, there was a remarkable chang in the accounts of PSGH for the first time in several years read " excess of income over expenditure". During that same period she served as a member of the Finance Committee of WAPF and later elected Honorary Treasurer of WAPF from (1983-87).

It is again interesting to note that during her tenure of office as Treasurer of WAPF, the accounts of WAPF for the first time was incorporated into the accounts of the West African Health Community (WAHC).

From 1985-93, Mrs. Gavu served on the Pharmacy Board as PSGH representative. She served on the Registration and Disciplinary Committees of the Board.

From 1994 to date Mrs. Gavu has been a member of the Korle-Bu Teaching Hospital Board.

LAPAG: The society has wings, Branches and Interest Groups that catered for their respective constituents. Topics perculiar to women were hardly discussed. Mrs. Gavu thought it would help the cause of the lady Pharmacists in Ghana if they could come together. By then the lady Pharmacists in Nigeria were also grouping.

Together with Mrs. Esther Osei, Mrs. Esther Amedzro, Ms. Irene Osam-Tawiah and Mrs.Bruce they started the ground work, meeting regularly at Cocoa Clinic. Later Ms. Nancy Milis , , Mrs. Addo-Attuah and others joined.

The primary aim of LAPAG was to give relevant information and thus educate women and their children on health and related issues and other issues of paticular interest to women.

Mrs. Gavu is the Founder of LAPAG and she served as the First National Chairperson of the Association and for two consecutive terms.

Some of the areas LAPAG covered initially were misuse, abuse, and use of drugs . Later they handled family planning in conjuntion with the GSMF which funded the project.

PHARMACY COUNCIL: The Pharmacy Council, by the laws of Ghana, is the only body that controls Pharmacists in Ghana and also regulate the practice of the profession. Why then would anyone reject the offer to serve on the Council , or better still to chair the Council ?

Daavi Eniton, do you see anything good for Pharmacy in the future?

Mrs. Gavu did turn down the offer the first time it was made to her. For over six months she resisted all the lobbying that was done to get her to change her mind. Her reasons were personal; personal reasons that have the potential to affect her performance as the Chairperson of the Council.

She later changed her mind. Have the personal problems vanished ? No. She is contending with them and believes that they have been tamed to a position that she can now sacrifice to do the job. But what really made her change her mind ? Three things.

Firstly, she is a fellow of PSGH.To be made Fellow implies that the Society has recognised the individual's invaluable service to the Society.There has never been any year that she did not serve the Society in one way or the other. She decided it was time to crown it all; put the icing on the cake !

Secondly, when she heard of some of the names being bandied about as possible Chairmen of the Council, she felt it would be a disservice to the profession to continue to refuse the offer.

The third reason, the most important, was the influence of her sweetheart, Mr. Gavu. When he decided that she should accept the offer, Mrs. Gavu was convinced she had to do it because Mr. Gavu, analytical as he is, would never support anything that he believes would disturb her.

Now, she is in the chair. How does she see the job? Challenging. Challenging because the Council is the institution that controls Pharmacists from " conception to death".

For some reason, everyone wants to practice Pharmacy- everyone who has money, including stark illiterates believe they can and should be allowed to practice Pharmacy; every other professional believes that he/she can practice pharmacy. These make the work of the Council very challenging. Let all Pharmacists pause to ask why other professionals want to practice pharmacy.

There is something else apart from money that makes people want to practice pharmacy even though they are not qualified. It appears, and rightly so ,that there is some honour and dignity in being called a Pharmacist.

It is time Pharmacists recognise this and make the conscious effort to rediscover these values and pursue them. It is time to work together, as colleagues to enhance the image of their profession.

Mrs. Gavu is very much concerned. It is time for the infighting and cheating to stop. It does not enhance the image of the profession to register to supervise a pharmacy and refuse to do the job , yet at the end of the month demand to be paid. Some pharmacists even boast that when they leave, the pharmacy would be closed down! These things must stop.

The lady in the chair believes that there is the need to launch a crusade that would place professional service , by the pharmacist, above all other considerations. Dear colleague, you are welcome to the crusade.

She has arrived. Ready to do the job. Her appeal is simple. Let's join forces to confront the common enemy. There is a bright future for the profession but we can only achieve that when , like the prodigal son we "can come to ourselves" and realise that our actions and inaction are ruining the profession.

But what do others think of Mrs.Gavu? Some of the people she worked with at the Cocoa Clinic describe her as "a mother". She is compassionate and caring. She has also been described as progressive and forward-looking. You cannot easily run over her, and where accepted and agreed upon principles exist, you can be sure you would have to abide by them.

Friends of the Human Race, this is Mrs. Eniton Ruth Gavu, the Chairperson of Pharmacy Council, for you ☺

MEDICATION ERRORS

INTRODUCTION

This place is produced as a co-operative effort between FIP and the institute for Safe Medication Practices (ISMP). As part of the efforts to create a forum for pharmacists to discuss the many items that cause, contribute to, or create an environment that allows medication errors to occur the Pharmaceutical Journal encouraged members of the Society to share their experiences. Following are some of the articles published. Such articles from PSGH members are welcome.

THE PATIENT HEARD ME BUT DID HE UNDERSTAND ME?

Sometimes we take for granted that patients fully understand our instructions. We assume that what is obvious to us is obvious to them, so we omitin air discussion routine details of proper medication use. Unfortunately, patients often misunderstand the instructions. We recently hear about an asthmatic patient who was not responding to therapy. During follow-up, the patient described how he was using his inhaler. He would get into his automobile, roll up the windows, release two puffs of medication into the air and breathe deeply for 15 minutes! At first, he did this in his house. Later he thought it might be more effective to use the inhaler in a confined space. He said he'd been instructed to do this by his doctor who picked up an inhaler, held it in the air and released two puffs to demonstrate its use. The doctor gave no additional instructions.

We need to be clear and complete in our instructions because patients may take them literally, or may erroneously fill in the gaps when information is omitted. Assume nothing regarding the patient's knowledge base and leave no room for patients to make erroneous assumptions. Provide thorough instructions always include the obvious!

COMPETENCE AND EXPERIENCE NOT ENOUGH TO STOP ERRORS

What follows speaks for itself. It is a letter we received from an experienced pharmacist who nearly made a fatal error with potassium chloride injection while preparing a baby's IV antibiotics in the pharmacy. The pharmacist deserves great praise for sharing this story. She hopes other pharmacists and technicians will learn from her experience.

To the editor: This is the story of the KCl mix-up. I swore would never happen. As the 3rd shift pharmacist at a community hospital, I usually prepare a few IVs each night. Because I work alone, I'm particularly conscientious about following therecommendations of ISMP, to read medication labels three times; before, during and after reconstitution. Last weekend I was finishing preparation of a potassium infusion for a newborn when an order arrived for ceftriaxone 300 mg in 10ml of diluent for a 12-week old infant. Grabbing a syringe containing 1 g/10ml and vial of 20ml sterile water for injection, I figured that there'd be enough water in the diluent vial to prepare the three 300mg syringes in the 10ml that I needed. However, the third syringe only made to 8.5ml. As I turned around to grab another sterile water vial, I noticed there was already a full sterile water for injection vial within the laminar flow hood. Since I'd only placed a single sterile water vial under the hood, I turned the empty vial around. To my shock, I found that I'd diluted the antibiotic using the potassium vial from the previous order! I hadn't bothered to perform the usual label check because I thought it was water. I knew that if I hadn't decided to make the third syringe (I only needed two doses, but decided to make a third syringe for use later), I would never have paused to look at the potassium vial. The syringes would have gone upstairs and a 12-week-old baby girl would have received an intravenous dose of potassium over just a few minutes. I do not want my name revealed, but I feel compelled to bring it to your attention. I am sickened at the thought that this could happen to someone else. If a confident pharmacist with 14 years of hospital experience could make this error, then it can happen to someone else out there. Now I will always organise materials under the laminar hood between jobs, and I will check everything, including vials of sterile water.

Preparing for a damaging medication error. All practice sites should have a plan of action for responding to serious errors, especially any that result in patient harm or death. The plan should address how, in the event of an incident, the organisation should interact with patients' families and outside organisations, including state and federal regulatory athorities and accrediting bodies. Since it is not uncommon for serious medical errors to receive press coverage, the plan should also address this issue. If not handled properly, the health-system's reputation can be severely damaged and may result in a long-lasting adverse effect on community relations. Managers attorneys, public relations specialists and risk managers need to be involved in the development of the overall plan. Key individuals, such as the CEO, manager of the pharmacy, director of nursing and chief of the medical staff, should be consulted. The following issues need to be addressed:

*.How should staff interact with patients and families involved in adverse events?

*What procedures must be undertaken for safe guarding applicable documents and involved containers and equipment?

*How should the risk managers' immediate review and investigation be carried out?

*In the event of inquiry from the news media, how will confidentiality of patient-related information be assured while providing useful and accurate information to the public?

*How will internal public relations activities be conducted so that staff knows the incident is being addressed properly?

*What process will be used to assure that appropriate immediate and long term remedial actions are taken?

*If a product or device is defectively labelled, packaged or designed, what steps should be undertaken to prevent future errors (i.e. should product be removed, brand or package type be changed, etc)?

*What is the internal and external notification process (government, manufacturers, department of health, coroner, professional staff, etc)?

*How will the practice site accommodate visits from regulatory agencies and other investigative agencies?

*What sort of psychological counselling and other forms of support are available for all involved in the incident?

In the investigation that immediately follows a serious error, it is important to learn as much as possible about the nature of the incident and exactly how it happened. Investigations must focus on system and process deficiencies, not on an individual's knowledge deficit or performance failures.

REFERENCES

Cohen, M.R responding to a serious medication error. Hosp. Pharm. 1991, 26, 1024 – 1025

- Heape, A. How to neutralize negative publicity. ECRI, Hospital Risk Control 1990.

Common symbols and abbreviations are easily misinterpreted

A pharmacist misread a hand-written prescription for 'Insulin N 70/30 10U qAM & 8U qPM and 10 units every morning and 28 units every evening when the prescriber placed the ampersand very close to the intended eight (8) unit dose (See fig 1). Although the pharmacist failed to review the instructions with the patient when dispensing the insulin, the patient realised that the wrong dose was written on the label and brought the insulin back to the pharmacy for clarification.

We also had a report about a 10-fold insulin overdose at a hospital. When a nurse attempted to give what appeared to be almost a full syringe of insulin, a family member present at the time questioned the volume and observed 60 units in the syringe. She told the nurse that her mother usually receives only 6 units. However, the nurse got the patient's chart, showed her a transcription of the order that read 60 units, and convinced the daughter that '60' was correct. The patient received that amount, fell asleep, later became unconscious and died the next day.

In the follow up on the incident, it was later recognised that the dose was originally written for '6U' of insulin but was misinterpreted and transcribed as 60 units. Besides demonstrating the danger of using 'U' to abbreviate 'units', the incident also speaks loudly about the need for practitioners to listen carefully and provide adequate follow up when patients or family members question what is being done to them.

Encourage prescribers as well as pharmacist and nurse colleagues to write the word 'and' and also write out 'units' because 'U' is often seen as a zero, a four or the letter 'h' for 'hour'. It would be best to prescribe by using separate orders for morning and evening insulin doses ●

POPULATION FACTORS IN THE DEVELOPMENTAL PROCESS

A Concern for us all

By
S. NKANSAH-AMANKRAH, MPSGH,
NATIONAL POPULATION COUNCIL
SECRETARIAT, ACCRA

Concerns about the growth and welfare of human numbers have dominated the thinking of men and women for generations. At one time it was thought that increase in the population is a sign of national wealth or prosperity, while at another time the perception was that large population size could potentially be a threat to its own survival. Neither of these views is right or wrong. What is important is look at a human being as a potentially useful resource with no comparison.

Like all useful resources, the value we attach to it is what will make them a valuable resource. This then implies that any factor or variable that promotes or enhances people to play their useful and proper roles in the society becomes a crucial factor to consider. For people to play their useful roles in a society, their basic needs as a human person will have to be taken care of. Amongst these needs are the material (e.g. clothing, food, shelter, education, health etc.) and non material (e.g. the need for expression, equality, ability to understand the master ones own destiny etc.)

In recent past the debate on population control measures and national development has been the subject of intense debate in many international forums. At one point many development experts; mainly from the western countries felt that provision of family planning services particularly contraceptives to developing countries to 'control their numbers' is the most important aspect of Aid to these countries. Starting with the world population conference in Bucharest (1974), many participants from the developing countries stated their positions that 'development is the best form of contraception'. Implying that improvement in the socio-economic conditions of people in the third world countries will precipitate fertility decline.

Since then the international debates on population issues have focused on two main topics: the rationale for reducing population growth in developing countries, and the legitimacy of the means used by governments to reduce high fertility in their countries. It is worthy of note that during this period, the rationale for reducing the rapid population growth was usually expressed in terms of benefit at the national level, while the benefits to be derived by the individuals are rarely specified.

At 1984 world population conference in Mexico City the U.S. delegation asserted that 'population is a neutral phenomenon' in the developmental process, and that excessive state control of the economy was more responsible for economic stagnation than rapid population growth.

However the focus of all these discussions changed during the International Conference on Population and Development (ICPD) in Cairo (1994). Meeting the reproductive and sexual health needs of individuals and couples became the centrepiece of this conference. The conference came out with a comprehensive document known as the 'Programme of Action'. Contained in the Programme of Action is the main message for improving individual well being. This comprises two elements:

- Provide contraceptive methods within broader reproductive health services, and,
- Advance women's equality in education, health and economic opportunities.

The ICPD document does not explicitly link the goals it set for itself with fertility reduction, however the emphasis here is meeting the reproductive health needs of individuals and couples to make responsible choices. It is assumed that this in itself will lead to reduction of fertility.

THE CONCEPT OF REPRODUCTIVE HEALTH AND REPRODUCTIVE RIGHT.

In the context of ICPD (1994), Reproductive health means 'a state of complete physical, mental and social well-being and not merely the absence of disease of infirmity in all matters related to the reproductive system and its functions and processes.' Reproductive rights embrace certain human rights recognised in international human rights charter. These rights rests on recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health. Reproductive and sexual health issues are now to be seen as an important aspect of general health.

However, it must be emphasised that the reproductive health approach is not as new as is being seen in the paradigms of ICPD, particularly those who insists that all early family planning programs were based on set demographic targets. Ghana's population policy of 1969 contained many elements of reproductive health. The point of difference here is that the strategy adopted by ICPD implies more balanced, comprehensive and humane approach to the reduction of fertility and therefore population growth worldwide.

THE ROLE OF COMMUNITY PHARMACIST.

As noted above, the paradigm of population agenda has assumed much of public health significance. This agenda includes national and international programmes to address the health and demographic impacts of high fertility, to reduce teenage pregnancies, to promote safe motherhood, to improve child survival, drug abuse, to halt the spread of HIV/AIDS and other sexually transmitted diseases, and to avert domestic violence against women and children. These are high priority issues on the population agenda worldwide and they also form the backbone of the concept of sustainable development. Furthermore, these issues are no longer being seen as only medial issues but more importantly as social and behavioural related issues.

Indeed some people argue that reproduction is not a public health issue, but rather should be left to the individual conscience, religious guidance, personal choice or family privacy. Nevertheless in matters of reproduction and sexual behaviour, private behaviour has public consequences. This is where Community Pharmacists have a crucial role to play in changing individual attitudes and behaviours through counselling and information sharing.

The ultimate purpose of knowledge sharing is to help individuals develop the capacity to take increasing control over their sexuality and health, family size, environment and the other factors that so critically impinge on their quality of life. Individuals and couples need to be helped to make informed choices about implications of family size, the scourge of HIV/AIDS, unwanted pregnancies, and methods of contraception. This involves more than just giving information. Rather it involves learning from people and the community how to make such issues socially acceptable and worthy of urgent action.

In the end, it is the change by individuals that could bring about the societal changes necessary for greater security and well being. Population growth and development are complex and inter-related issues that require multidisciplinary approach of the broad sectors of the society, especially professionals who act as agents of change at the community level ●

PUT IT IN WORDS

There is nothing new in the notion that expressing in some artistic form the recollection of an unpleasant experience or a painful incident is capable of relieving associated stress. This was the idea behind the ancient Greek tragedy and the Greeks had a word for it – catharsis.

If you put the painful experience into words, pictures or musical score you would banish it and so spare yourself the stress of further recollection. That is the reason why writers, painters and composers are in general more broad-minded and contented than their less gifted contemporaries. True, one can find exceptions, but they do not inactivate rule.

This theory of catharsis, like many which the ancient philosophers understood centuries ago and took as established truth, seems to be enjoying a revival today. In an editorial and a preliminary report published in the *Journal of the American Medical Association* for April 14, the authors have explained that adopting a suitable social environment can relieve stress by an effect upon the hypothalamic-pituitary-adrenal axis. Social integration, a gift afforded to all creative artists, can divert personal stress into something which is shared by the whole community, and so diminish its individual impact. Handling the emotions is a great gift which is capable of lessening the effect of a chronic physical illness in a person.

In a randomised trial in the United States, patients suffering from asthma or rheumatoid arthritis were actively encouraged to write every day about negative feelings, and their progress towards better objective health was noted. In chronic asthma patients, respiratory function was improved four months after they had started to write down an account of their emotional trauma. The activity of the rheumatic process was also reduced by daily writing.

These preliminary findings should encourage more research into the possibility of tackling chronic disease by persuading sufferers to give artistic vent to their feelings. No doubt other art forms would do just as much to help in chronic illnesses.

MAD AND BAD

Fanaticism is a curious and terrifying phenomenon. We see its manifestations time and time again in our society, usually associated with broad outbreaks of violence for which there is little or no logical reason.

The derivation of the word is from the Latin for a temple, *fanum*, with its derived adjective *fanaticus*. In modern language fanatical has come to denote frenzied, maniac or excessively enthusiastic. Although it was once used to describe an insane person, it became restricted to madness born of a religious enthusiasm. The problem of dealing with it is society has been complicated by the fact that if someone tells you that he (rarely she) is inspired in behaviour by some divinity or other, there is no logical basis for contradicting the claim.

It is unfortunate that fanaticism does not inspire good works but in practice condones are carries out murder. Brutality is one of its major features, with indulgence in wild and extravagant notions coming a close second.

Implied in fanaticism is a kind of narrow tunnel vision where only one aspect of an idea or course of action can be perceived. There is no doubt in the fanatic" mind that what he perceives is literally the truth, the whole truth and nothing but the truth, a formula which gives fanaticism a spurious gentility. Such a simplistic view of existence is a certain remedy for disaster. In educational terms, the relentless repetition of the doubtful idea or ideology serves to reinforce it.

The philosopher William James wrote in his book "The varieties of religious experience" (1902): "For many of the historical aberrations which have been laid to her charge, religion as such is not to blame. Yet of the charge that overzealousness or fanaticism is one of her liabilities we cannot wholly acquit her." He commented that the fruit of religion, like all human products, it liable to corruption by excess.

According to James, spiritual excitement takes pathological forms "whenever other interests are too few and the intellect too narrow." This seems the crux of the problem – interests which are too narrowly restricted, so that the sense of relativity and perspective is lost. As James goes on to remark, fanaticism is loyalty carried to extremes, and it goes with a character that is masterful and aggressive. The fact that you may devote yourself to what you judge a justified cause does not give you the right to murder those who disagree with you, which is what fanatics try to do.

What can be done about fanaticism in any of its modern manifestations? Possibly nothing but endure and restrain it. One possible antidote is better and wider education, so that narrowness of outlook can be avoided. Properly applied from early childhood, a wide education should open the eyes to the many conflicting possibilities in any human situation. But education, like most things, has its fanatics in influential place●

THE PSYCHOLOGY OF HEALTH

From the Editor's desk

In his speech to the AGM of PSGH at Cape Coast last year, the then Minister of Health-designate, Mr. Nuamah-Donkor, indicated that the noble objectives of vision 2020, the blue-print for Ghana's development cannot be achieved without a healthy population. He also indicated that the concept of health for all by the year 2000 implies that by that date the majority, if not all Ghanaians, should have enough knowledge about health so as to live healthy lives.

Indeed a healthy citizenry is a prerequisite for any meaningful national development. People can be made healthy through the acquisition of knowledge that enables them stay healthy, or by the elimination of the source(s) that create disease conditions.

The creation of a healthy nation is the duty of all stokeholders in the nation. However, the greater responsibility lies with the healthcare delivery team of which pharmacists are members.

The concept of health, like many other concepts, has varied definitions and interpretations. For example, the Churchill Medical dictionary quoted the WHO definition which says that 'health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'. The same dictionary quotes the office of Health Economics as stating that "a person should be regarded as healthy provided he can remain socially and economically active even though he may suffer some health disability or discomfort". Meanwhile, a health psychologist defines health as positive state of physical, mental and social well being that changes in degree over time. Health is seen as a continuum with premature death at one end and high level of wellness at the other end.

On the other hand, diseases can be classified in terms of their aetiology, such as an infective agent, biochemical abnormality or structural lesion. The symptoms of mental disorder involve abnormalities of behaviour, mood perception, thinking and intellectual function. Some of these abnormalities impair judgment or contact with reality so those patients become a danger to themselves and other people.

In effect whether one considers health or disease, one has to deal not only with physical but with the mental disposition of the individual concerned. Pharmacists must really appreciate this fact and bring it to bear on their dealings with their clients: dishing out medicines to patients without appreciating their mental disposition might be an exercise in futility.

It is an acknowledged fact that there are differences in the health status of individuals. Some people are always sick - they get illness more frequently than most people do and get well more slowly. These differences between people can result from biochemical sources, such as variation in physiological process and exposure to harmful microorganisms. Also important are the roles played by psychological and social factors. Behaviour and mental process are the focus of psychology and they involve cognition, emotion and motivation.

Cognition is a mental activity that encompasses perceiving, learning, remembering, thinking and problem solving. Emotion is a subjective feeling that affects and is affected by thoughts, behaviour and physiology. Motivation as a concept, explains why people behave the way they do.

Social psychologists assert that it is natural for people to cherish the feeling of having some measure of control over the things that happen in their lives. For example, through the mechanism of elections, individuals choose representatives to work for their point of view either in unions/ associations or through political processes in government. In other cases people take actions when they influence events directly.

In short, people strive for a sense of personal control which is basically the feeling that they can make decisions and take effective actions to produce desirable outcomes and avoid the undesirable ones. (Rodin, 1986).

The degree to which individuals believe they have control over their lives differ. Whilst some believe they have a great deal of control, others think they have almost none.

Those individuals described as possessing an internal locus of control are those who believe they have control over their success and failure - they are responsible for the outcomes of the events since they control such events. Those who have an extended locus of control are those who believe that their lives are controlled by forces outside themselves, example by luck.

Since it would certainly be unrealistic for individuals to assume that everything in their lives is under their control. It is the degree to which individuals attribute responsibility to themselves as against other forces, that determines their locus of control.

Apart from the internality and externality of personal control, there is another important issue about personal control. This is the individual's sense of self-efficacy. Simply put this is the belief that s/he can succeed at something s/he wants to do. Individuals decide whether to attempt an activity based on their expectations that the behaviour, if properly carried out, would lead to a favourable outcome, and that they can perform the behaviour properly. The implication of this is that people with a strong sense of self-efficacy show less psychological and physiological strain in response to stressors than do those with a weak sense of efficacy.

In what ways do personal control and health relate? To begin with, individuals who have a strong sense of personal control may be more likely or able to maintain their health and prevent illness than those who have weak sense of control. Secondly, in the event of a serious illness, those with a strong sense of control may adjust to the illness and provide their own rehabilitation better than those with a weak sense of control.

Further classifications can be made in relating health to personal control. The first is the internal health locus of control. Such people have an attitude that says, "the main thing that affects my health is what I myself do." The second is the powerful-others' health locus control; to such people their health is controlled by other people such as physicians. Their attitude is that "whenever I don't feel well, I should consult a medically trained professional." The third is the chance locus of control where the belief is that health is controlled by luck or fate and that "luck plays a big part in determining how soon I will recover from an illness."

There are five identifiable controls by which people can influence events in their lives. These are;

i) Behavioural control which involves the abilityto take concrete action to reduce the impact of a stressor. This action might reduce the intensity of the event or shorten its duration;

ii) Cognitive control is the ability to use thought processes or strategies to modify the impact of the stressor. These include thinking about the event differently or focusing on a pleasant or neutral thought or sensation;

iii) Decisional control is the opportunity choose between alternative procedures or courses of action;

iv) Informational control involves the

opportunity to get knowledge about a stressful event - what will happen, why , and what the consequences are likely to be; and

v) Retrospective control pertains to beliefs about what or who caused a stressful event after it has occurred. Although this gives no control over the event itself, it helps individuals modify the stress they experience by enabling them to perceive the world as orderly and meaningful. Cognitive control appears to have the most consistently beneficial effect (Cohen et al 1986).

A relevant question to ask is: does a strong sense of control help people adjust to becoming seriously ill and promote their recovery? According to Sarafino (1990) the answer is an unequivocal yes. This is particularly so if the patients perceive their condition as very severe.

The results of a study on the effect of people's personal control on their disease conditions indicated that patients with illnesses such as kidney failure or cancer who score high on either internal or 'powerful-others' health locus of control suffer less depression than those with strong beliefs in the role of chance. The explanation is that the belief that either they or someone else can influence the course of their illness allows patients to be hopeful about their future. Such patients with strong internal locus of control beliefs probably realise that they have effective ways for controlling their stress.

Another study also found that adjustment to serious illness was most strongly associated with patients use of cognitive control, such as by thinking about their lives differently and taking life more easily.

Again whilst patients who used behavioural control, example by exercising more than before, showed better adjustment than those who did not, the study revealed that adjustment was not related to their use of informational control such as reading books on their condition , example cancer. A possible reason for this anomaly may be that seeking information about the illness either leads the patient to materials that increase their fears or simply has little influence if the patient has no cognitive or behavioural possibilities for control.

Finally, it has been established that personal control also affects the efforts patients will make toward their own rehabilitation. Feelings of self-efficacy have been found to enhance such efforts. Some patients with serious respiratory diseases were given individualized prescriptions for exercise. Their levels of self-efficacy were also determined. Correlational analyses revealed that the greater the patients' self-efficacy for that physical activity, the more likely they were to adhere to the exercise prescription.

In our desire as pharmacists to assist people cope or overcome their conditions, it behoves us to appreciate their psychological dispositions to offer them better service. As pharmacists, we have a duty to respond to the Health Minister's call to help create a healthy population for national growth and development.

REFERENCES:

1. Robin, J. (1986). Health, control, and aging. In M.M. baltes & P.B. Baltes (Edus), The psychology of control and aging. Hillsdale, NJ : Exlbaum.

2. Cohen, S., Evans, G.W., Stokols, D., & Krantz, D.S. (1986). Behaviour health, and environ -mental stress. New York: Plenum

3. Sacrafino, E.P. (1990). Health psychology : Biopsychosocial interactions Wiley, N. Y. ●

SUICIDE! WHO IS ELIGIBLE?

From the Editor's desk

It was a normal Saturday morning at the Kaneshie Market complex. Sellers and buyers were at it doing brisk business. No one noticed this neatly dressed 50-plus gentleman enter the market, climbed up to the top floor and strolled quietly towards one of the open spaces. No one suspected that this man was about to disturb the life of some people in the market.

When our gentleman, Mr. S. decided that he was ready to carry out his plan he executed it to perfection. Before anyone could say 'stop' he lay splashed on the ground floor with his spectacles still tucked in his breast pocket. The life in him was gone.

In 1997, the national dailies reported the death of a third year social science student of the KNUST. He jumped to his death from the roof of the eighth floor of Unity hall. Unconfirmed reports had it that he couldn't stand the idea of a lady walking out of his life.

Again during the famous, or is it infamous ten-month UTAG strike action, a student who claimed he was fed up with lecturers because he thought they were out to sabotage the government committed suicide to register his protest.

But why would someone want to end his or her life when inspite of and despite the many sufferings and disappointments in this life, there is still much more to live for? Psychologists believe that there are several motives for committing or attempting to commit suicide. Davidoff , for example, identifies four such motives for suicide.

Escapist suicides are motivated by the desire to flee from an "intolerable" situation. They see the future as hopeless. Aggressive suicides are motivated by revenge; it is to create remorse in another person or to implicate another person in the death.
Oblative suicides occur when people sacrifice their lives for a higher cause such as a religious ideal or honour. Ludic suicides are committed as part of a game or test (example, Russian roulette) where risk of life is essential to demonstrate daring!

It is also documented that committing suicide as an escape is by far the most common motive. Davidoff again identified groups of people particularly likely to commit suicide as an escape. These include depressed people, alcoholics, drug pushers and the elderly, those over 70. The incidence of suicide is also said to be elevated among single people especially among the divorced, separated and widowed. Interestingly, more males than females kill themselves although females are said to make more abortive attempts.

Some identifiable social and psychological conditions are known to incline people towards committing escapist suicides.

* Social isolation and loneliness: Many have had cause to complain about the gradual breakdown of the extended family system in many African societies. In some cultures divorce and separation have become common place. Consequently many family members increasingly pursue their own personal development. The obvious outcome of these developments would be that more individuals experience loneliness and insecurity. Youths from broken, disintegrated, disorganised or brutal homes and those feeling isolated and alienated from all but the most minimal interactions are more likely than others to turn to suicide. Loneliness has also been implicated in the high suicide rates of the elderly. May we therefore pause and give a critical appraisal of our actions and inactions which are gradually bringing the extended family system down. This is eroding the essential social support system that we have taken for granted which other societies and cultures are yearning for.

Stresses: Stresses have been identified to account for the high suicide rates of young and old. It has been identified also that physiological and anatomical changes (and especially failing health in the case of the aged) are bewildering, frustrating and sometimes agonizing for both groups. Other sources of stress include unemployment, economic hardships and other financial pressures. Feelings of powerlessness and discrimination can also provoke suicidal tendencies among the elderly and the youth. Again, adolescents with a known history of prenatal complications or a difficult birth appear to be at considerably higher risk for suicide. It is postulated that the early stresses might have compromised the ability of these adolescents to cope.

*Goallessness: The absence of any personalised and individualised goal is a sure recipe for the development of suicidal tendencies. A society that lacks agreed-upon goals inadvertently creates the atmosphere for promoting suicide. Suicidal adolescents have been quoted as saying that there is no goal to strive after and nothing to stand for. It is thus a great challenge to those in responsible leadership positions to ensure that they become role models for the youth and create enduring and endearing values for people to strive after. Again in a youth-oriented society, many elderly people feel that their lives are over and nothing is left to live for.

* Impulsivity: Suicide can be conceptionalized as a way of solving a problem. In such a case those who select this solution might be said to exhibit distinctive problem-solving styles! Outrageous! But it is true.

Those who attempt suicide are often known to be impulsive in responding to challenging mental tasks. They are said to find it difficult to see alternative solutions to a problem. A physiological correlate of impulsivity, a low level of a metabolite of the neurotransmitter serotonin, has been found reliably in the spinal fluid of suicide victims who use active, violent methods.

Some common myths about suicide:

1. Myth: People who discuss suicide rarely follow through.
Fact: Approximately 75 percent of those who take their lives are thought to communicate intent beforehand. They may talk about suicide, ask for help, threaten, or taunt. In some cases, the signal is an indirect one, such as tidying up loose ends (paying bills, giving away possessions, and making apologies).

2. Myth: Suicide occurs mainly among the poor.

Continue on page 16

Fact: Financially advantaged individuals often take their own lives. Suicide rates are very high among physicians, lawyers, and psychologists, for example.

3. Myth: People of specific religious affiliations do not commit suicide.
Fact: Although some religions (Catholicism, for instance) prohibit suicide, identification with these faiths is no guarantee against suicide. Catholics do have somewhat lower rates of self-destruction (Templer & Veleber, 1980). People who attend church regularly are also at lower risk for suicide (Martin, 1984).

4. Myth: People with terminal illnesses do not kill themselves.
Fact: The fatally ill sometimes take their own lives, especially when they are suffering greatly or disrupting the lives of loved ones.

5. Myth: Primarily, insane people kill themselves.
Fact: Suicide is relatively common among hospitalized mental patients and among people with psychotic symptoms (Robins, 1985). Still, most people who kill themselves do not appear to be irrational or out of touch with reality. The social relationships of presuicides, however, are often troubled, and their thinking is often rigid and extreme.

6. Myth: Suicide is influenced by latitude, weather fronts, barometric pressure, humidity, precipitation, cloudiness, wind speed, temperature, sunspots, and phases of the moon.
Fact: There are no clear-cut relationships between suicide rates and any of these phenomena. Suicide rates do peak gently in May and dip to a low in December. Weather may influence the timing of a suicide attempt (Breuer *et al.*, 1984)

7. Myth: Suicides are particularly prevalent during festive holidays, when people feel keenly aware of misery and loneliness.
Fact: Although clinicians and lay public continue to endorse this reasonable idea, controlled studies find either no relationship between holidays and suicide rates or a reduction in suicides around major public holidays (Lester & Lester, 1971; Philips & Liu,1980; Zung & Green, 1974)

8. Myth: An improved emotional state removes the risk of suicide.
Fact: Depressed people sometimes commit suicide after their spirits rise at a time when they feel less paralyzed or passive.

9. Myth: Suicidal people want to die.
Fact: Many suicidal individuals, perhaps most, appear ambivalent about death, so professionals view suicidal acts as "cries for help." In a British study of people who attempted suicide in Bristol, fully half of the interviewees claimed to be seeking relief from an intolerable situation without having consciously evaluated the consequences (Morgan, 1979). They reported feeling convinced at the time that they would not die ●

A Bulletin on STDs/AIDS awareness and proper management sponsored in part by the West Africa Project to Combat AIDS (WAPTCA).

ROLES FOR PHARMACISTS IN THE PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED DISEASES

By:
ANDY STERGACHIS, PHD.

AS THE MOST ACCESSIBLE and trusted health care professional in the United States, pharmacists can be an important resource for sexually transmitted disease (STD) prevention and control. Pharmacists and pharmacies located in very type of community throughout the nation. The majority of the nation's 175,000 pharmacists practice in community pharmacy settings for extended hours everyday. Approximately 23,000 independent and 18,000 chain community pharmacies exist throughout the United States. The profession of pharmacy is positioned well to make a meaningful contribution to STD prevention and control. The accessibility to the public, the large number of pharmacy locations and the trust shared between pharmacists and the public they serve, combine to afford a unique opportunity to reach millions of individuals with STD prevention and control messages and other strategies.

THE PROFESSION OF PHARMACY

Historically, the professional functions of pharmacist primarily involved preparing the drug product and providing the product to the patient. Pharmacy education and practice has increasingly adopted a patient care orientation, beginning with what is referred to as "clinical pharmacy." This clinical emphasis has given pharmacists the knowledge base to interact with the patient and the prescriber to improve medication use. The term "pharmaceutical care" was coined in 1990 to describe a new approach by pharmacists towards patient care. Pharmaceutical care is a patient-centered, outcome-oriented pharmacy practice in which the pharmacist works in concert with the patient and with other healthcare providers to promote health, prevent disease and assess, monitor, initiate and modify medication use to assure that drug therapy regimens are safe and effective. The goal of pharmaceutical care optimise the patient's health-related quality of life and achieve positive clinical outcomes within realistic budgets. A growing number of pharmacists practice what can be considered as population-based pharmaceutical care, whereby subgroups of interest are identified, evidence-based methods are used to identify services to be provided, and delivery strategies rely on information systems and monitoring of outcomes.

As mentioned previously, there are approximately 175,000 licensed pharmacists in active practice. The number of pharmacist per 100,000 people was estimated at 64.4 in 1990. Pharmacy is practice in a wide range of settings including community pharmacies, hospitals, nursing homes, the pharmaceutical industry, managed care, and the government (such as in Veterans Affairs, the Department of Defence, Indian Health Service and in the Public Health Service). The number of independently owned and operated pharmacies has decreased over the past 10 years. Chain pharmacies, food stores and mass merchandisers with pharmacies have grown in prominence over the same period. However, in many busy community pharmacy practice settings, progress toward the provision of pharmaceutical care has been slow because of several barriers, including limitations in facility design, incomplete patient databases, re-training needs, staffing issues, and reimbursement structure base upon distribution of products.

FEATURES OF STD PREVENTION AND CONTROL ACTIVITIES OF PHARMACISTS

According to a 1997 report from the Institute of Medicine, STDs can be prevented by intervening at multiple points with behavioral, biomedical and structural interventions on individual and community levels. As part of a proposed national systems for STD prevention, the Institute of Medicine recommended four major strategies for the public and private sector.

1. Overcome barriers to adoption of healthy sexual behaviours;
2. Develop strong leadership, strengthen investment and improve information systems for STD prevention;
3. Design and implement essential STD-related services in innovative ways for adolescents and under-served population; and
4. Ensure access to and qualify of essential services for STDs.

The role of pharmacists in the prevention, screening, diagnosis, and treatment of STDs is presented within the context of all four strategies. To the extent possible, this report describes innovative activities involving pharmacists and pharmacies in services related to STDs other than HIV.

STRATEGIES INTENDED TO OVER-COME BARRIERS TO ADOPTION OF HEALTHY SEXUAL BEHAVIOURS

Long-term prevention of STDs depends, in part, on the adoption of new social norms of healthy sexual behaviour (such as delaying sexual intercourse and using condoms). Among the major barriers of healthy sexual behaviour are a lack of awareness among the public and health care providers regarding STDs and misperception of individual risk and consequences. Mass media messages and other public health programme regarding STDs and healthy sexual behaviour are needed. For example:

- The 21st Annual National Condom Week, founded by a pharmacist, is an example of a mass media event designed to inform, alert and educate the public about the use of condoms as an STD prevention strategy.
- Direct-to-consumer advertising of prescription drugs and over-the-counter products provides opportunities to encourage consumers to seek information from pharmacists.
- A mass media strategy involving pharmacies is sponsored by the manufacturers of an at-home HIV test service that is commercially available in more than 25,000 pharmacies nationwide. Home Access Health is sponsoring Miss America 1998, Kate Shindle in a year long effort to educate the public, policymakers and healthcare professionals (including pharmacists) about STDs with an emphasis on HIV and AIDS.

It is important that pharmacies have the requisite knowledge and awareness of sexual health issues and are comfortable discussing them with patients. The curriculum within schools of pharmacy should teach students the information and skills necessary for effective patient care for STDs. Moreover, academic institutions, professional societies and pharmaceutical manufacturers should collaborate to help pharmacy practitioners with continuing education programmes in STDs. Some examples of innovative professional education programmes in this regard are as follows:

- Each year, the University of Washington offers a popular, clinically-oriented course designed to provide a knowledge base for pharmacy students and other health sciences students to participate effectively in community outreach programmes for the prevention of STDs. It is offered cooperatively by the Schools of Pharmacy and Medicine. The majority of students in this course make presentations on STD-related topics in the community.
- Glaxo Inc. (now Glaxo-Wellcome) offered virtually every practicing pharmacist in home-study continuing pharmacy education guide on HIV/AIDS during the early years of the epidemic. In the early 1990s, Burroughs Wellcome Co. (now Glaxo-Wellcome) joined with nine national health organisations to launch an initiative emphasised the preparation and distribution of printed information (largely via pharmacies) to help consumers determine their risks of acquiring an STD, check for signs and symptoms and reduce their chances of becoming infected or infecting others.

Development of Strong Leadership, Strengthening Investment and Improving Information Systems for STD Prevention.

Unfortunately, there has been a lack of visible and strong leadership at the national and state level specifically encouraging pharmacists to get involved in the provision of STD-related services. Recommendations from the Centres for Disease Control and Prevention (CDC) are not generally directed to pharmacists. However, recommendations from the CDC and other groups for the prevention, screening and treatment of STDs are applicable to pharmacy practice. For example, recommendations exists on several topics relevant to pharmacy practice:

- Proper use of condoms and other barrier methods (CDC and the Food and Drug Administration). Consistent and appropriate use of latex condoms reduces the risk of many STDs. Moreover, use of other barrier methods is associated with a lower risk of certain STDs.
- Counselling to prevent sexually transmitted diseases (CDC, American Medical Association, United States Preventive Service Task Force). According to the United States Preventive Service Task Force report, clinical counselling in the primary care setting can reduce specific STD risk behaviours.
- Treatment guidelines for STDs (CDC). Where effective drugs are available and used appropriately, there have been significant decreases in the rates of STDs (such as Neisseria, Gonorrohoeae and Chlamydia trachomatis). Pharmacists must be knowledgeable about how the epedimiology of DTSs and newly marketed drugs change recommended therapy.

Although key elements of STD prevention and control are outlined in resources such as those noted above, pharmacist may not fully realise the potential benefits of these efforts. Pharmacists (just like other clinicians) encounter barriers to obtaining clinically important information: they lack the time necessary for keeping up-to-date, their text-books and journals may be out of date or disorganised, and guidelines from CDC and other relevant organisations may not even reach practicing pharmacists.

The most publicised public/private healthcare partnership concerning the pharmacist's role in STD prevention and control was launched in 1992 by the Foundation of Pharmacists & Corporate America for AIDS Education. With initial funding from DCD, pharmaceutical industry supporters and private foundations, FPCA launched the "Facts from Your Pharmacist: Answer about AIDS. Project to demonstrate the effectiveness of a community pharmacy-based HIV/AIDS programme. The Foundation of Pharmacists & Corporate America for AIDS Education worked closely with public health agencies, professional pharmacy association, schools of pharmacy and other health organisations towards the establishment of a national demonstration project in Alabama to test the effectiveness of a community pharmacy-based HIV?AIDS education prevention and treatment programme. Despite the existence of a strong board of directors and initial fundng from CDC and other organisations, the Foundation of Pharmacists & Corporate America for AIDS Education and its effort disappeared a few years ago. Certain elements that were supposed to be components of this failed demonstration effort were developed and are accessible, including the results of a survey of Alabama pharmacists' willingness to assume the distribution of STD information resources, pharmacist continuing education training material and in-pharmacist continuing educational material in their community.

As pharmacists continue to expand their practice toward patient-and population-centred health activities, it is important for professional associations and other agencies and organisations to provide more leadership for STD-related services provided by pharmacists. Moreover, it is important to federal agencies and private foundations to support research to advance the scientific basis for the expansion of pharmaceutical care agencies into STD prevention and control. The agency of Healthcare Policy and Research's Pharmaceutical Outcomes Research Initiative is an example of a programme which successfully involved the private and public sector in developing and supporting a cohesive research agenda pertaining to the effectiveness of pharmaceuticals and pharmaceutical care.

Pharmacists can also assist in improving surveillance for STDs by monitoring the epedemiology of STDs and the management and effectiveness of programmes. For example, automated pharmacy records have the potential to provide data to determine trends in the use of therapies for STDs and their sequel. Assuming that privacy concerns can be addressed, data from pharmacies should be examined to determine its utility in improving community-based STD surveillance systems. On an individual patient level, pharmacists can use patient medication profiles to assist in counselling women to use methods for STDs prevention when using oral contraceptives, for example. Also, pharmacist counselling van help reduce the occurrence of misdiagnoses when women self-treat with over-the-counter medications. According to a recent survey, 70% of women self-treat vaginal infections with over-the-counter medications before seeking medical attention.

Design and Implementation of Essential STD-related Services for Adolescents and the Under-served

The location of pharmacies in under-served and the anonymity they afford to adolescents makes them useful for providing essential STD prevention and control services. Also, pharmacists have recently begun providing immunisation services in the context of CDC-recommended immunisation schedules. The administration of hepatitis B vaccinations by pharmacists is one approach in providing STD prevention services to adolescents.

Access to and quality of Essential Services for STDs

Listed below are some examples of pharmacist-based services related to STD prevention and control:

1. Pharmacy-based syndromic protocol for STD counselling and treatment have been developed by Program for Appropriate Technology in Health (PATH) and are being tested in developing countries.
2. Washington State pharmacists are the first in the country to dispense birth control pills under protocol without a doctor's prescription for emergency contraception use. The project, funded by the David and Lucile Packard Foundation, is a collaboration among PATH the Washington State Pharmacists Association, the University of Washington, Department of Pharmacy, the Washington State Board of Pharmacy, and Elgbin DDB. The programme includes pharmacist-provided services directed at STD prevention.

CONCLUSION

The profession of pharmacy is recognising that its future rests on managing the rational and appropriate use of medications as well as upon other patient-focused an population-based services. The access that communities has to pharmacists and the high esteem in which pharmacists are held are important reason to incorporate STD prevention and control into pharmacy's infrastructure and professional capabilities. Barriers that need to be addressed include the need for improved training and education of pharmacist STD prevention and control, consideration of a reimbursement system that is not entirely based upon distribution of products and the need to expand the scientific basis for these roles through applied research. The numerous innovative activities involving pharmacists and pharmacies in STD-related services suggested an expanded role for pharmacy.

CONTROVERSY?

Is it mercy killing? Or is it assisted suicide?

If the state has the right to terminate the life of an individual, doesn't the individual has the right to determine when his life should end?

If Christians, Moslems and other religious adherents believe that every individual would account for his/her life on earth, shouldn't they agree that an individual must have the right to determine when to give that account?

For how long should life be preserved?

Are you provoked or intimidated? Don't!

Individual rights and societal rights, which takes precedence over the other?

If society, acting through medical science has failed to terminate the excruciating pains of the terminally ill patient, shouldn't that patient have a God-given right to determine when that pain should end?

Get the answers and read more in the next issue of the Pharmaceutical Journal.

REFERENCES:

1. American Pharmaceutical Association. Principles of Practice for Pharmaceutical Care, Washington, DC, 1995.
2. Hepler CD, Strand LM. Opportunity and responsibilities in pharmaceutical care. Am J. Hosp. Pharm. 1990; 47:533-543
3. Pew Health Professions Commission. Health Professions Education for the Future: Schools in Service to the Nation. San Francisco, Ca, 1993.
4. Institute of Medicine. The Hidden Epidemic: Confronting Sexually Transmitted Diseases. Institute of Medicine. Washington, DC, 1997.
5. Binkley D. Waller L. Potts L, et al. Pharmacist as HIV/AIDS information resources: survey of Alabama Pharmacist. AIDS Edu. Prev. 1995; 7:455-466
6. Cockerill RW, Meyers T, Worthington C, et al. Pharmacies and their role in the prevention of HIV/AIDS. J. Soc Admin. Pharm.
7. Pick S, Reyes J, Alvarez M, et al. AIDS prevention training for pharmacy workers in Mexico City. AIDS Care 1996; 8:55 – 69.
8. Pew Health Professions Commission. Critical Challenges; Revitalising th Health Professions for the Twenty-first Century. San Francisco, Ca, 1996 ●

BETTER ACCESS TO HIV DRUGS IN THIRD WORLD

The UN Program on AIDS(UNAIDS), in collaboration with major pharmaceutical companies, has launched the pilot phase of "UNAIDS HIV Drug Initiative" which will identify strategies to increase access to HIV-related drugs in developing countries.

Under the initiative, four developing countries-Chile, Cote d'Ivoire, Uganda, and Vietnam - will work to adapt their health infrastructures to ensure effective distribution and use of the drugs, and participating pharmaceutical and diagnostic companies will subsidize purchases of the appropriate medicines.

To date, Glaxo Wellcome(UK), Hoffman-La Roche (Swizterland) and Vicro (Belgium) have confirmed their participation. Companies such as Janssen Pharmaceuticals (Belgium) and Organon Teknika (Netherlands) are currently reviewing their possible involvement.

In each participating country, two new entities will be created, whose activities will be monitored by UNAIDS:

A national AIDS drugs advisory board, under the Minister of Health, which will devise a coordinated national policy for the provision of the needed drugs;

A non-profit company which will act as a clearing house for placing orders, as well as being a recipient and a channel for the subsidies from the companies. Financing for the pilot phase of the Initiative will come from pharmaceutical companies subsidies, health ministries and UNAIDS.

Participating companies will make available a range of AIDS -related medicines, including antiretrovirals. In addition, diagnostic companies will provide virological services and tests for patient monitoring.

According to UNAIDS, multiple barriers block wider access to AIDS drugs. These include insufficient health -care structures, the increasing complexity of HIV management and care at different levels, as well as distribution channels, cost of treatment, and administrative delays.

Glaxo Wellcome has joined the Initiative because "we believe that UNAIDS have devised a viable route for providing cheaper and better -informed HIV drugs access in developing countries whilst. Incoporating essential infrasturactural support and safety procedures". The company also feels "that it is important to recognize that where there is a demand for HIV drugs in developing countries, access will be gained with or without the necessary infrastructure". Problems associated with this should not be ignored ; instead the necessary support and information needed must be provided.

"Our company commends UNAIDS in undertaking a very ambitious effort" to increase the availability of AIDS drugs in the developing word , declared the US based company Merck. Considering the obstacles blocking the use of AIDS medicines in developing countries . "Improving medical infrastructure, training healthcare professionals, and improving public education in disease prevention and health education are vital to providing care to the millions of HIV people in the developing world today ," outlines Merck. The potential for the development of viral resistance to the AIDS drugs , if these are not properly used, " presents an enormous public health hazard ." Therefore, Merck " believes that many antiretroviral medicines at this time may not be appropriate for distribution through the proposed UNAIDS program."

But, Merck concludes that it would continue to closely monitor the project and "evaluate our participation in the UNAIDS Initiative: in the future ●

HIV THERAPY SUCCESS

The most solid evidence yet of the efficacy of newer combination drug therapy against HIV has been documented by Swiss researchers. Tracking a large study population, all of whom tested HIV positive, they found that mortality in those enrolled in the study from 1995 to 1996 had been reduced by 6 per cent, compared with those who enrolled from 1988 to 1990. In addition, the risk of progression to full-blown AIDS had been reduced by 73 per cent.

Triple drug therapy combines one of the first drugs found to inhibit the retrovirus's enzyme reverse transciptase (such as AZT) with two newer protease inhibitors. This therapy aims to overwhelm HIV's extraordinary ability to change and to resist attack; it interferes with viral replication in target cells. The therapy has been a breakthrough, diminishing HIV presence often to undetectable levels.

The investigators of the Swiss :HIV Cohort" study followed over 5,000 HIV-infected people for 10 years.

They compared the outcome for patients enrolled in different period. Blood tests supported the evidence of the drug' efficacy; many patients no longer showed signs of loss of immune system function, the researchers say.

The study was set up by the Federal Office of Public Health in Bern and covers all seven Swiss university clinics and major hospitals. Researchers were able to follow, anonymously, half of all those testing positive for HIV a remarkable study population, making possible epidemiological studies of unparalleled validity.

The researchers are alert to the possibility that the virus could develop resistance to those drugs and that some strains already are resistant. Patient non-Compliance - not following the very complex treatment schedule - could also account for some treatment failure ●

HIV PROTEASE INHIBITOR

Patients with HIV infection have the option to be treated with the new HIV protease inhibitor drugs as part of a multi-pronged drug regimen.However, these drugs are not innocuous and side-effects have been reported.One of the recent side effects reported is a syndrome called lipodystrophy. Lipodistrophy is a syndrome whereby fat metabolism is disturbed and fat is redistributed unevenly at sites in the body. The syndrome has 3 main components:. Wasting of fat from peripheral areas. Deposition of fat to the central (abdominal areas). Hyperlipidaema and insulin resistance.Classically fat is redistributed from areas such as the face,the arms,and legs anddeposited around the abdomen(central obesity),and the fat pads on the upper back /shoulder region (buffalohump). The most striking feature is an expanding waistline now called the "protease paunch". Other features include thinning of the legs, thinning and wrinkling of the face and prominence of subcutaneuos veins. Women who experience protease inhibitor lipodystrophy may also show an increase in breast size.The estimated incidence of lipodystrophy varies from 6 to 60 %, of protease inhibitor recipients. However, a causal relationship between the syndrome and protease inhibitor therapy has yet to be confirmed. All the protease inhibitors, i.e indinavir,ritonavir and saquinavir have been implicated.Besides the cosmetic appearance of fat redistribution, the associated hyperlipidermia and impaired glucose tolerance (insulinresistance) poses a medical threat to protease inhibitor recipients. Notable lipid profile changes are hypertriglyceridaemia and decreased high density lipoprotein (HDL-''good cholestrol'').The long-term impact of this syndrome on metabolic disturbances is not yet clear and studies are needed to clearly evaluate the effects of protease inhibitor therapy. Early evidence has shown that indinavir may be associated with the greatest risk of abnormal fat accumulation than other similar agents. Further evidence is required in order to confirm lipodystrophy as a class effect. Although the initial effects of lipodystrophy appear to be cosmetic, the long-term metabolic effects may become significant. The general consensus on the topic appears to be that patients with severe HIV disease should continue proease inhibitor therapy where posible ●

QUOTABLE QUOTES

1. Humility is not weakness. It is strength under intelligent control.
2. When God commands the only righteous response is obedience.
3. There is no right way to do a wrong thing.
4. You may not have a second chance for a first impression.
5. Freedom is not the power to do what we want, but the right to do what we ought to do.
6. Brilliance is sterile unless it is coupled with commitment.
7. It is good to know that some people will hate you; but it is better to know that those who hate you will not triumph until you hate them and destroy yourself.
8. Politicians are interested in people. Not that this is always a virtue. Fleas are interested in dogs.

PHARMACEUTICAL CARE IN MINNESOTA - A PROFOUNDLY DIFFERENT EXPERIENCE

Pamela Mason recently took part in an international workshop at the Peter's Institute of Pharmaceutical Care at the University of Minnesota College of Pharmacy. The following is her report of the discussions that took place.

Most pharmacists will by now be familiar with the definition of pharmaceutical care which states that "it is a practice in which the practitioner takes responsibility for a patient's drug related needs and holds him or herself accountable for meeting for those nees".[1] Adopted as a mission statement by many pharmaceutical bodies around the world, it is a definition that few people would disagree with in principle. But it is also one that has been frequently misunderstood and widely misinterpreted. Pharmaceutical care has come to be used to mean almost anything, over and above dispensing, that pharmacists do during their working day; anything from conducting medication reviews and running anticoagulant clinics to providing prescribing support to doctors and giving advice to patients about medications.

The pharmaceutical care is a patient-focused concept is recognised, but too often the term is limited to simply "care with pharmaceuticals" and viewed in this way, all the activities mentioned would come under this general description. Indeed, pharmaceutical care could include some of these activities, but as I found out on a recent workshop at the College of Pharmacy in Minnesota, where so much of the work on pharmaceutical care has been conducted, this does not get to the core of what it is really all about. This is partly because pharmaceutical care – as it is often interpreted – tends to be orientated towards activities that pharmacist want to do rather than activities that patients want.

PRACTICE

For pharmacy, the implications of orientating our activities towards patients – truly towards patients – are profound. It involves more than paying mere lip service tot he "product to patient" concept. This practice, as developed in Minnesota, is radically different from traditional pharmacy, even pharmacy that includes additional services; so different that it involved pharmacists actually building and running a practice – just like doctors and dentists – for the first time in their lives.

Challenging? Yes, it certainly is. Daunting – even terrifying? Yes, that too. But impossible? No. In Minnesota, there are about 30 practitioners currently building pharmaceutical care practices and a few more in other states. But in contrast to what many people believe, the whole of North America is not actively engaged in providing pharmaceutical care. There are also a few people building practices in other countries, such as South Africa, Australia, Canada and Spain. Nevertheless, this practice is still very much in its infancy, and it has taken almost seven years – not to mention a great deal of thought and preparation in the years before that – to start to build these practices in Minnesota. Yet build practices we must, according to Professor Linda Strand (associate Professor, Minnesota College of Pharmacy), because without a practice, you cannot truly look after patients and, moreover, you will never get reimbursed for doing it.

Professor Strand places great emphasis on the word "practice" – both the noun and verb. Used as the noun, it really does mean practice in the way that doctors, dentists and many other health care professionals have a practice. Even as a child, I was aware that my father and mother, both opticians, had a practice. I sometimes used to hear them use that term when describing what they did to people they met. Having a practice, which they built from scratch, meant a lot of things: hard work, long hours and serious financial investment – certainly, in the early days. But, above all, it meant seeing patients, testing patients' eyes, writing down, or documenting, what they as practitioners found and recommended, referring patients to a doctor when necessary and following patients up by appointment on a regular basis. As for every practice, patients were its *raison d'être.*

A few years later when I qualified and had my own pharmacy, I worked very differently, without really thinking about it. I had a shop which sold the usual mechandise common in community pharmacies and I dispensed prescriptions. At the end of each day, I counted those prescriptions, and very satisfying it was, too, when there had been plenty of them. After all, I was paid for dispensing products (which, in 1980, represented, in real terms, quite a bit more money than it does today) but not for looking after patients. Like pharmacists everywhere, I hope I was friendly and helpful to the people who came to my pharmacy and I like to think I gave them good advice about their medicines, checking with their GP on occasions when I thought the drug or the dose written on the prescription might not be appropriate. After a fashion, I may even have been patient focuses, but I most certainly did not have a practice, not as my parents did.

The verb to practise is also important. In pharmacy, Professor Strand thinks, "to practise" has been diluted so much that it has come to mean simply "doing". For example, "it is my practice to count the prescriptions first thing in the morning". Or, "it is my practice to visit the nursing home on Thursdays". In the context of pharmaceutical care, however, "to practise" means much more than doing. "It is the application of knowledge to promote the well-being of patients. Practices therefore contains a strong moral component and there must be a common understanding of and commitment to a moral purpose that defines the practice. This promotes solidarity between practitioners who are committed to a commonly held philosophy that defines role, rules and responsibilities."[2]

In contrast to medicine and dentistry, pharmacy, Professor Strand argues, has never had a strong philosophy of practice that binds pharmacists together with one common purpose. Pharmacy tends to be governed more by process than practice. This is perhaps never more obvious than when doing community pharmacy locum. Every locum pharmacist knows that the first thing he or she has to do on arrival at a pharmacy is to check on procedures. When do the orders arrive? Where is the Controlled Drugs cupboard? When are the orders telephoned through to the wholesaler? Contrast this with the situation of a locum doctor or dentist who on arriving at a practice has to check primarily on when the patients will arrive and who they are. For a doctor or dentist the practice is basically the same whether it is in the United States, Britain, France, Australia, or anywhere else. And for the pharmaceutical care practitioner it is just the same: because of its common philosophy, the practice is global.

Of course, this does not mean that every pharmaceutical care practitioner has to work in exactly the same way, or come to the same conclusions. Far from it. Just as one doctor may see a patient and come to one conclusion as to a diagnosis, so another may come to a different conclusion. All practitioners – doctors, dentists, opticians, chiropodists and dietitians – expect to use their own clinical judgement. This is part of what being a practitioner means So what do pharmaceutical care practitioners do? What is their practice? They look after patients drug-related needs, with all its attendant responsibilities in terms of accountability. According to Dr Robert Cipolle (director of the Peters Institution of Pharmaceutical of Care, College of Pharmacy, University of Minnesota), the pharmaceutical care practitioner is essentially a " drug therapy problem solver". Just as doctor diagnose what is wrong with your body and dentists diagnose what is wrong your teeth, so pharmaceutical care practitioners diagnose what is wrong with your drug therapy.

AN UNMET NEED

So what are the problems that patients have with their drug therapy? Is this practice really necessary or not? The answer to this question is important because a profession – and the practitioners who practise it – can only justify its existence if there is a genuine social need. In this context, the social need is clear, represented by a high and increasing inference of drug-related morbidity and mortality. In the US, drug-related morbidity and mortality for the ambulatory population has been estimated to cost $76.6bn, matching nearly dollar for dollar the amount spent on prescription medicines, and it has also been estimated that 59.6 per cent of this $76.6bn could be avoided if pharmacists intervened to address drug related problems. Moreover, a recent meta-analysis of 39 prospective studies, covering a period of 32 years, revealed that adverse drug reactions could account for more than 100,000 deaths in the US each year, making adverse drug reactions the fourth commonest cause of death after heart disease, cancer and stroke. In Britain, a survey of admissions to general medical and care of the elderly wards identified that 27 percent of patients on medication experienced ADRs and that 11.5 percent of admitted patients were taking drugs with absolute contraindications.

Much closer to home, most of us have relatives or friends who have problems related to drug therapy We all know people who are receiving medicines which are inappropriate for their condition or which do not work as effectively as they might. We all know people who suffer continuing adverse effects from their medication because they think they need to take it and that there is no alternative. And we all know of people who do not know what their medicines are for or how to take them properly. Many of us keep a watchful eye on relatives medication because we know we need to. And we also need to care for patients in just the same way. The social need for pharmaceutical care practice is clear – so clear, according to Professor Strand, that it will happen whether pharmacists do it or not.

It is important to realise that the drive for pharmaceutical care is not to reduce the drugs bill. Interestingly, in the Minnesota pharmaceutical care pilot project, reported in The Pharmaceutical journal two years ago, adverse drug reactions accounted for 2 percent of identified drug therapy problems, but the need for additional medicines accounted for 23 per cent of problems and represented the largest number. Providing pharmaceutical care, therefore, will not necessarily reduce the drug bill, but even after reimbursement for the service, it would still have a important impact on the hospital admissions bill.

This is something which primary care groups particular as they move to primary care trust status with control of a unified budget (a budget that includes more than drugs), could be interested in. True

individual GP practices will have a prescribing budget, and, in the early days in particular this will be an area on which they will want to focus, often with the help of pharmaceutical and prescribing advisers and practice pharmacists. Although prescribing support and formulary development will help GP practices to work within their drug budgets, it remains to be seen how much impact these will have on the drug therapy problems of individual patients and of hospital admission costs. This is where the value of pharmaceutical care really lies – at the individual patient level. But unless pharmaceutical care practices are established, no one will eve see this. For example, you cannot talk to primary care groups, health authorities or any other body about pharmaceutical care until they have seen what it is.

WHAT IS THE PRACTICE?

So, if there is a social need for pharmaceutical care, how is it practised? What do practitioners do? At the heart of pharmaceutical care practice is the process of patient care, a process which is no different from that employed by any other health care practitioner. In other words, it involves making an assessment to determine the patient's needs, developing a care plan and following up the patient to make sure that this or her needs have been met. There is really nothing new about this in health care terms, but it is new for pharmacists.

In pharmaceutical care practice, the level of caring for and working with the patient goes far beyond the traditional pharmacist-patient interaction. It is not just about giving patients advice with their dispensed medicines or checking for drug interactions and doses and telephoning the GP when appropriate. Providing pharmaceutical care means that pharmacists get to know patients much better than ever before. You may think that you know people who visit your pharmacy pretty well – I know that I did, especially working in a small town – but pharmaceutical care practitioners find out not only all the medicines patients take, including prescribed, over-the-counter and complementary therapies, but they also find out what patients know about their medicines, how they feel about them and what they believe about their health. Pharmaceutical care providers learn about adverse drug reactions and drug interactions, not just from text books, but from the "expert" in his or her health and medication – the patient. Pharmaceutical care is about caring for patients and spending the time and effort to help them.

Above all, it is a structured and systematic process. This is one of the hallmarks of pharmaceutical care practice. Indeed, if you want to find out whether pharmaceutical care is really being practised you have to look at what goes on between the practitioner and the patient. In the assessment, which drives the whole care process, the pharmaceutical care practitioner checks that all the medicines taken by the patient are appropriately indicated for the condition, effective for that condition and safe, and that they are convenient for the patient to take. "If you check that the drug is indicated, safe and effective, the problem of poor compliance almost goes away," says Dr. Cipolle. "Starting with compliance is the wrong place to start. If pharmacists were successful at improving compliance, without first checking that the drug is safe, effective and indicated, we would increase drug therapy problems even more."

Conducting the assessment requires a great deal of skill. Patients, of course, do not provide information under neat headings. They tell a story, and practitioners have to be skilled communicators to obtain all the important information and then document it in a form which can be used to identify drug therapy problems and also, importantly, to communicate with other health care practitioners. One of the many misconceptions that people sometimes have about pharmaceutical care is that it is about the practitioner working with the patient entirely in isolation. This is not true. What is true is that the pharmaceutical care practitioner is an independent professional, but he or she, along with doctors and dentists, is a member of the primary health care team and needs to communicate with other health care practitioners. Pharmaceutical care involves working with doctors, not for them, Professor Strand emphasizes. There is a big difference.

Having conducted the assessment, the practitioner then identifies any drug therapy problems and develops a care plan. Sometimes drug therapy problems can be found on the spot, but sometimes the practitioner has to go away and look things up. One pharmacist with a practice not far from Minneapolis says: "It can be hard for pharmacists to admit they don't know, but patients don't mind because they want real answers to their problems; they don't want to be just fobbed off. Many of them have already read articles or looked on the internet and they are pretty well informed. But what they do want is the information they have putting into context for them. The internet doesn't solve their problems. It just gives the a lot more questions. In fact, the internet is one of the best opportunities for pharmaceutical care that we've ever had."

Following up the patient is a vital part of pharmaceutical care, just as it is for dental care and optical care. Patients are asked to come back for "check ups", even if the practitioner found nothing wrong the first time round. "If we don't follow up we can feel good about ourselves," Dr. Cipolle says, "simply because we don't know whether what we've done has worked or not. Evaluation is essential – not only I it a professional responsibility, but it is also necessary to get better at the job."

DOCUMENTATION

Documentation is a crucial part not only of the patient care process, but also for running the practice itself. According to Dr. Cipolle, "if you didn't document, you didn't do it. Without documentation, there is no record of the problems you found, no record of what you did about them and no record of what your work with the patient achieved. No one will believe what you can do until you show them your data"

Documentation is part of what running a practice is all about and the institute has worked with Mr. Michael frakes (vice president of health Outcomes Management) to develop special softwae to enable this to be done. This is software with a purpose entirely different from labelling. And it is documentation with an aim different from keeping legal records. It enables practitioners to document all a patient's medical history, medication history and drug therapy problems. It produces among other things, a care plan and a "to do list" to remind the practitioner what he or she needs to do when the patient next visits. Not all drug therapy problems need to be sorted out at the first visit; some can be left , and the software enables the practitioner to make a note to this effect.

REIMBURSEMENT

Reimbursement is an issue for pharmaceutical care. Practitioners have to be able to make a living out of this. Developing a plan for reimbursement involves understanding your own country's system of paying its health care practitioners and identifying who possible payers could be. In Minnesota, a reimbursement system has been developed which mirrors the state's method for paying doctors. Neither a capitation fee nor a fee for service system , it takes account of the resources required to take care of a particular patients needs and is related to the complexity of those needs and the knowledge and skills needed.

It is one thing to develop a plan for reinbursement, but who is actually paying the bills in Minnesota? The original pilot project had financial support from a number of support from a number of sources - managed care organisations, social insurers and drug companies.

"Drug companies are interested in pharmaceutical care," says Dr. Cipolle. "They are in business to sell more drugs and if they have safe and effective drugs, the chances are that pharmaceutical care practice could increase their sales."

However, now that the pilot project is over, practitioners are doing a combination of things at the moment – charging private patients, charging health insurance companies or in one instance a managed care group has put money "up front" to provided pharmaceutical care for 3,000 patients. A few practitioner posts are being "pump primed" by the Minnesota college of pharmacy, but this is on the understanding that the practices will be viable within a couple of years. Professor Strand says: "We are not encouraging anyone to provide this service for free, except at the beginning when the practitioner provides a complementary service until they know what they're doing."

TRAINING

Knowing what you are doing involves training as well as experience of caring for patients. The four year PharmD programme at the college of pharmacy is gradually evolving towards teaching to a pharmaceutical care practice, but a completely new programme is also being designed for use in the future. The institute wants to make this programme of world-wide relevance and is looking to involve as many countries as possible in its development. "We would like to involve Britain in this process," Professor Strand says.

There is also an eight-week programme to train pharmacists to provide pharmaceutical care. Not surprisingly, patients are at the heart of this training, which involves each participant in providing and documenting pharmaceutical care for 50 patients within an eight-week period. Therapeutics is taught only in the context of the patients presented by the students; it is not taught as a separate discipline.

"Learning therapeutics teaches no one to practice pharmaceutical care," says Professor Stand. "Although your drug knowledge has to be good, you have to look after patients to know what it really means to practise pharmaceutical care."

BUILDING A PRACTICE

If building a practice is central to pharmaceutical care, how is it done? You have to recruit patients, just as any new practice does. This is why, according to this model of pharmaceutical care, recruiting patients with certain diseases (eg. diabetes, hypertension, asthma) does not work. It is not viable. One of the practitioners I spoke to, Melisa Atwood, had recruited, with her practitioner partner, 166 patients to the practice within a period of six months. Had they recruited only those patients with specific disease states, they would have had far fewer patients. And to make a living out of a practice, Professor Strand believes, you need about 2,000 patients, the number which also make a viable practice for a GP or a dentist.

Pharmacists sometimes thing they will be overwhelmed with patients on the first day, simply

because they may be dispensing 2,000 items a week. However, it is important to realise that the pharmaceutical care practice is separate from the dispensing business and not all people who come with prescriptions will want this service, nor will those who receive it need it on every occasion they bring in a prescription. In Minnesota, patients are generally followed up two to three times a year.

In addition according to Dr. Cipolle, recruiting patients with diabetes or asthma is unethical if you are running a patient-focused practice. "Whoever heard of a dentist recruiting only those patients with a huge number of fillings? Or a chiropodist caring for patients with four or more bunions? Or a doctor taking on only patients with diabetes or asthma? Moreover, in caring for only selected patients, you are actually operating a disease management model, not a pharmaceutical care practice. And the temptation with this is to focus on the disease and forget the patient's other potential drug therapy problems, and of course all your other potential patients too."

Where pharmaceutical care is provided, i.e., where the practice is built, does not matte, A traditional community pharmacy can be a good site, simply because there is easy access to patients, but it must be run separately from the dispensing business. In Britain, some large pharmacies and pharmacy chains now have a range of practitioners working on their premises. One of these could be a pharmaceutical care provider. And this individual need not be the current pharmacist. Indeed, if the pharmacy does a lot of prescriptions, the pharmacist will have difficulty in providing pharmaceutical care – you cannot easily do both. Product and patient must be separated, Professor Strand emphasises. This often means employing a second pharmacist, and this is a model currently being considered by the pharmacy chain Eckerd in the US and Shoppers Drug Mart in Canada. For independents, sharing one practitioner between, say, four or six pharmacists could be a feasible option. Interestingly, in Minnesota, now that traditional pharmacists are starting to understand what pharmaceutical care providers do, they are beginning to refer patients to them. These are pharmacists who have decided, at least for now, that they do not want to be pharmaceutical care providers, but they do recognise its value and they do understand the difference.

Pharmaceutical care can also take place in a doctor's surgery. Indeed, it may be easier to provide pharmaceutical care in a GP surgery, alongside the chiropodist, the dietitian and anyone else who cares for patients there, not because of easy access to medical records, although these can be useful, but because a GP surgery is where patients are. In Minnesota, once doctors have seen the value of pharmaceutical care they refer patients to the practitioner. Pharmaceutical care can also be provided in the hospital setting, again mirroring the model of other health care practitioners who work there, and will most likely be successful if pharmacists work alongside other practitioners in clinical units, Professor Strand thinks.

PRACTICE FIRST

At the conclusion of the workshop, participants were reminded that for pharmaceutical care to work, the practice must come first. Without building practices, there is nothing to show to other health care providers and potential payers, and nothing for patients to experience. "To convert the pharmacy profession to pharmaceutical care, you have to change everything – the regulatory system, the code of ethics, education and training as well as the practice," says Professor Strand. "But the practice must be first. Because without it, there will be no need for anything else."

But why should anyone believe that this will actually happen on a larger scale" "The patient!" she says. "The patient!"

"The social need is so huge and the solution so simple," adds Dr. Cipolle. Easier said than done? Maybe. But then most things that are worthwhile usually are. As Dr. Cipolle says: "Pharmacy has the opportunity of a lifetime, but it's an opportunity we won't have for ever."

REFERENCES

1. Simpson D. Pharmaceutical care: the Minnesota model. Pharm J 1997; 258:899-904.
2. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice. New York: McGraw Hill, 1998:27.
3. Johnson JA, Bootman JL. Drug-related morbidity and mortality: a cost of illness model. Arch Int Med 1995;155:1949-56.
4. Johnson JA, Bootman JL. Drug-related morbidity and mortality and the economic impact of pharmaceutical care. Am J Health-Syst Pharm1997;54:554-8.
5. Lazarou J, Pomeranz H, Corey PN. Incidence of adverse drug reactions in hospitalised patients. JAMA 1998;279:1200-5.
6. Ghose K. Hospital bed occupancy due to drug related problems. J R Soc Med. 1980;73:853-6 ●

TOWARDS THE SAFER USE OF MEDICINES

In Britain, the tools are now available to provide better information on safety of medicines in both hospital and community settings, and this could be done at relatively modest cost. The needs of patients, doctors and pharmacists are changing; although more research is needed, such information as is presently available must be both better and more widely publicised and understood. Universities, government, the pharmaceutical industry, and educated journalists all have an important part to play in this process.

Some 2,500 drugs are listed in the British National Formulary and Biotechnology will soon provide even more. An aging population with population with multiple illness will increasingly challenge therapeutic skills (figure).

Patients are asking for more information, which comes from various sources. Both doctors and patients are likely to be confused, and this will have a detrimental effect on the use of medicines. No human activity is risk free – cycling, driving, or even crossing the road carry surprisingly high risks. Taking modern medicines is a relatively safe activity, but because risks can never be wholly eliminated, vigilance and continuous re-evaluation are required.

DEFINITIONS AND SIZE OF THE PROBLEM

Adverse drug reaction are unwanted or unintended effects of a medicine which occur during its proper use. Adverse events are untoward occurrences following exposure to a medicine but not necessarily caused by the medicine. Most doctors understand risk to be the probability of a particular adverse outcome following exposure to a given amount of hazard. Other disciplines – and indeed patients – often use different definitions and this may be a source of confusion in discussions between doctors and their patients.

When a product license is granted, little is known about the safety of the new drug; on average only about 1,500 patients have been exposes to it. Therefore throughout the life cycle of a modern medicine there is a continuous process of risk identification, assessment and management. Risk can be measured but is always judged.

In the 1960s the incidence of adverse drug reactions ranges from 2.6% to 41%. These wide variations are due to differences in definition, methodology and clinical setting. From 4% to 12% hospital admissions are related to adverse drug reactions, but such figures reveal little about the incidence of adverse drug reaction in the community because drug exposure in the population is not known. Most of the British data on incidence of adverse drug reactions is old and needs to be updated. The "yellow card" scheme, which acts as a signal generator for regulators, can be used to relate the reported number of adverse reactions to drug sales and thus for calculating crude overall estimates. Confirmation and refinement are required, however, and with record linkage the British healthcare system has a unique opportunity to improve information on medicine.

STRATEGIES FOR REDUCING RISK

Adverse drug reaction may be caused by errors in manufacturing, supplying, prescribing, giving or taking medicine – these are the so called extrinsic adverse drug reactions. Alternatively, inherent properties of the medicine itself may cause unwanted effects; these are known as intrinsic reactions, their impact can be limited by legislative measures and by ensuring as far as possible that minimum effective does are prescribed.

Extrinsic adverse drug reactions are more easily averted. Errors in manufacturing, labelling, ampouling and dispensing are fortunately rare. The major cause of extrinsic reactions is errors by doctors. Abramson et al found that 98 of 145 untoward episodes identified on an intensive care unit were due to human error. Eighteen per cent of drugs related to adverse reactions in the Harvard Medical Practice study were judged to be due to negligence, defined as failure to meet the standard of care reasonably expected of a physician qualified to take of the patient in question. In a British study coroners' cases, medication errors accounted for 22% of all deaths due to adverse drug reactions. Extrinsic reactions could be reduced by improving doctors' prescribing practice.

ROLE OF THE PATIENT IN SAFER USE OF MEDICINES

An increasing proportion of patients and their caters wish to be partners in decisions about medication. Patients need information on benefit and risks of treatment so that they can make informed decisions. At any one time 46% of the British population is taking medicines, and of these 62% wish to have information leaflets. In January 1994 patients information leaflets for new medicines became compulsory under a European Commission direction (92/27). Patients information needs are shown in box 1; the directive obliges manufacturers to provide much more information and this may prove confusing . Demand for information about medicines goes beyond the provision of patient informa-

tion leaflets. The public need so be educated about the risks and benefits of medical interventions. The responsibility of such education should start in schools. It seems unlikely that British Schools will be eager to take on these extra responsibilities, even though modern video and computer education methods could introduce children to the notion of risk and benefits.

PATIENTS' PERCEPTION OF RISKS OF MEDICINES

Studies designed to measure perceived risk indicates that the degree of personnel control the risk taker has over the risk is of special importance because patients do perceive their doctor as putting them at risk. In Sweden, 961 people were interviewed about their attitudes to prescriptions drug. They thought that unwanted effects were mainly caused by sensitivity to particular drugs, improper prescribing, and incorrect diagnosis and also that improper monitoring by the doctor and failure to give patients adequate information were important causes of adverse drug reactions.

In an investigation of the attitudes of 1034 British patients suffering from ankylosing spondylitis, 47% reported serious adverse drug reactions associated with their medication. They regarded insufficient information and inadequate monitoring by the doctor as important causes of adverse drug reactions. To a lesser degree they felt that drugs were insufficiently tested and inadequately regulated.

In various studies, patients have been asked what gamble they would be prepared to take to change their present state to a future state that could be better but might be worse. This technique, known as the standard gamble, has shown that some patients are prepared to take more risk that their doctor offer them. Patients with sever rheumatoid athritis were prepared to risk using a drug that carried an 80% chance of death if the medicine being offered produce a complete cure to survivors. There is difficulty in interpreting the views of patients, for the high risk acceptance of patients with rheumatoid disease was nor borne out bye patients with ankylosing spondylitis – asked what should happen if a drug used to treat their disease was found to cause fatalities, 0.1% said it should be banned. However, the risk of blood dyscrasias from phenylbutazone (1 in 50,000) has been accepted by rheumatologists and regulators as acceptable for patients with ankylosing spondylitis. Do the patients suffering from ankylosing spondylitis who seem to risk averse know the risk inherent in taking this drug? Answers to questions such as this depend on how the question is framed and, given the contradiction referred to above, a uniform approach to discovering patients' views is needed.

It is not possible to generalise about the degree of risk and individual patient is prepared to take, but appropriate research can elucidate the views of groups of patients and form a basis for discussions with individuals. Even with the most rational central decisions, some people will consider that they are at undue risk. Nevertheless, all involved in helping to inform patients about medicine should be aware of patients' perceptions if the communication process is to be effective.

ROLE OF DOCTORS IN THE SAFER USE OF MEDICINE

Recently the doctor's task has become harder. Calls on practitioners' time have mounted, as have patients' expectations. The average length of a consultation with a general practitioner, 8 – 10 minutes, leaves little time for discussion of benefits and risks of medicines once doctor and patients have decided that drug treatment is required. Prescribing decisions leave some general practitioners uneasy, chiefly because of the complexity of assessing risks versus benefits in individual patients but also because therapeutic knowledge rapidly becomes outdated. Even for experts in therapeutics there is no simple way of deciding how much information to give a patient. Drury considered that explanation of risks of medicine may undermine patients' confidence in a successful outcome from treatment; legal opinion favours full discussions.

Doctors require more training in how to communicate with patients about medical benefit and risk. This training should inculcate awareness of the individual patient's grasp of the essential features of his or her own illness and its treatment. In addition, training in decision analysis can help doctors in the difficult job of balancing risks, costs and benefits if adverse reactions occur, doctors need to understand that a timely and straightforward explanation can often prevent a hostile and unrewarding confrontation.

If we accept that adverse drug reactions account for an important but still uncertain number of consultations and that a significant proportion of this is due to prescribers' errors of negligence, then the obvious way to achieve the safer use of medicines is to improve teaching of therapeutics. Education in therapeutics is far from adequate. Even in the most avant garde curriculum such as those of the University of Limburg in the Netherlands only 5% of teaching of time is devoted to therapeutics, and undergraduate curriculums in the United Kingdom probably do not fare much better. Eighty years ago there were fewer than 10 specific treatments (mercury for syphilis, quinine for malaria, and emetine for amoebic dysentery, for example); this has now grown to over 2,500 drugs. Both undergraduate and continuing education in therapeutics should be high on the agenda if we are to achieve safer use of medicines. An altogether different (but as yet untried) approach to improving the safety of prescribing was advocated by Vincent at al – selecting only the entrants to medical schools who are least prone to making errors.

ROLE OF PHARMACISTS

Medicines available only on prescription are increasingly being transferred to pharmacy products which patients buy themselves. The increase in prescription charge to 5.25 per item means that many simple remedies are now available more cheaply over the counter. These trends have placed more of the onus for advising patients on the shoulders of community pharmacists. Counselling patients is a service for which community pharmacists are paid as part of their dispensing fees? The conflicting evidence about the advice that is being provided in community pharmacies needs clarification and pharmacists need more training in how best to communicate information on medicines. The recent establishment of a chair in community pharmacy at the School of Pharmacy is a welcome step.

Moves enhancing the healthcare role of the pharmacist may relieve pressure on general practitioners and so allow them longer consultation times. On the other hand, general practitioners now need to have more knowledge of over the counter products and indeed of traditional medicines, which are becoming increasingly popular.

ROLE OF GOVERNMENT

As is well known, the Licensing Authority ensures the quality, safety and efficiency of medicines used in the United Kingdom, and the NHS research and development programme will contribute significantly to the evaluation of new healthcare technologies. The rapid spread of computer technology throughout general practices in Britain should now be harnessed to further enhance the safety of medicines and of practice of medicine. A start has already been made as the former VAMP database is now owned by the Department of Health. In addition, the Department of Health and the Scottish Home and Health Department ●

KINAPHARMA

Manufacturers of OTCs,
Generics, Ethicals &
Distributor of Janssen's Products

OTC

Anthipar Syrup
APC
Asmalin
Aspanol
Aspanol JNR
Coldex
Dextrolite (ORS)
Dextrolite Orange
Glucokin
Glucokin-C
Glucokin-D
Kinacin
Kinadol
Kinafen
Kinafen Forte
kinafen Plus
Kwik Action
Magacid
Malafan
Primadol Blister
Vigorix Caps
Vigovite Caps

Generics

Adrenaline
Ampi-250
Ampi+Clox
Analgin
Atropine
Cephalexin
Chloroquin
Cloxacillin
Dexamethasone
Diazepam
Diclofenac
Erythromycin
Folikin
Frusemide
Glibetics
Ibuprofen
Indokin
Isokin
Kinacol
Kinamox
Kinaquin
Librukin
Martin's B-Complex
Mebendazole
Metrokin
Multivite
Naproxen
Oxytet
Oxytocin
Pirikin
Piroxicam
Primadol
Procaine
Penicillin
Rifampicin
Tetrakin

Ethicals

Calcrete Tabs
Calcrete Syrup
Ciprokin
Diclokin TR
Germidine Oint
Germidine Solution
Honeypro
Locid
Mayfer Drops
Mayfer Tabs
Mayfer Syrup
Remulide
Tastymol Tabs
Tastymol Syrup

THE PHARMACIST'S ROLE IN PROMOTING HEALTHY INFANT FEEDING

By: James Akré, B.A., M.P.I.A.
Department of Nutrition for Health and Development, WHO.

Specialised knowledge of the management and properties of medicines brings pharmacists close to patients in any community setting. By virtue of their training and experience, and through the counsel they provide, they have an important – indeed a unique – role to play in promoting healthy nutrition. As members of a wider health tem, they are also key players in a potentially vast networking strategy – what the Word Health Organisation describes as 'partnerships for health'. Pharmacists are particularly well placed to make a difference in healthy infant nutrition.

The practical suggestions that follow apply, to some degree, to all pharmacists working in the community – to those in retail trade, and in hospitals and other health care facilities; to academic pharmacists who engage in undergraduate, postgraduate and continuing education, and in training other members of the health team; and to pharmacists who do research or who work in industrial pharmacy, because of the contribution they make to appropriate marketing practices and to providing accurate, complete information to health professionals and the general public alike.

PROMOTING HEALTHY INFANT FEEDING

What miracle medicine protects babies against diarrhoea, ear and respiratory infection yet cannot be sold in a pharmacy? The answer is breast milk, which presumably needs no introduction where pharmacists are concerned. As both responsible, informed adults and educated health professionals, pharmacists are already familiar with nature's wonder drug given its role as a baby's first immunisation and its continuing importance for a child's healthy growth and development. Pharmacists can help make this miracle medicine available at virtually no cost to themselves, but with great benefits in terms of customer satisfaction and loyalty, and increased respect in the community.

It is useful to put breast milk into an evolutionary perspective. Naturalists report that it was some 60 million years ago that mammals began nourishing their young with their milk. In terms of breast milk's role as an intergenerational survival strategy, it is said to predate even the placenta. Today, each of the world's estimated 4600 species of mammals produces a milk that is not only exactly right for its young; it is also unlike the milk of any other species. Put another way, where human babies are concerned, feeding initially anything other than human milk will always be a deviation from the biological norm for our species. In this light , and in the context of their vocation, pharmacists might like to reflect on the following not-so- rhetorical questions :

* Do I have the latest information about medication and how little is contra-indicated for the breastfeeding mother ?

* Do I have good community contacts – who are informed about lactation and committed to protecting, promoting and supporting breast feeding – that can be consulted if I or my customers have questions?

* Do I know about differences in growth velocity between breast-fed and artificially fed babies?

* Do I know about different classes of infant formula and any problems related to them?

* Do I know about safety standards for feeding bottles and teats?

* Do I know about the International Code of Marketing of Breast-milk Substitutes and its implications for pharmacists ?

* Do I know what action my government has taken to implement the International Code?

* Do I know what action my national pharmacist association has taken in support of the International Code?

* Do I know when solid food should be introduced in the young infant's diet?

* Do I have the latest scientific information about the nutritional needs of mothers?

Where most pharmacists are concerned, the knowledge required to answer these questions was probably not imparted fully, if at all, during their pre-service training. A helpful model for accomplishing this information transfer has been in use since 1994 at the Pharmacy College in Melbourne, Australia. Under four main lecture themes – understanding normal infant feeding; common nipple and breast problems; how babies grow; and allergy and infant feeding – the college's eight-hour infant-feeding course has enjoyed both record enrolments and excellent reviews from attendees.

Practical steps pharmacists can take to promote good infant-feeding practices.

Practising pharmacists can promote good infant feeding in a variety of ways, including by referring mothers and families to groups like:

La Leche League International (LLLI) and its national or local affiliates. The League is the world's foremost mother-to-mother breast-feeding support group. Founded in 1957 in the USA when ever-breast-fed rates were at an all-time low, the League now has some 7500 leaders and more than 30 000 members in 60 countries.

The International Lactation-Consultant Association (ILCA) whose members are lactation consultants, lay breastfeeding counsellors, and professionals in various fields that provide continuing education in breastfeeding. ILCA was established in 1985 and now has more than 4000 members in nearly 50 countries on five continents.

Pharmacists can get to know the LLLI and ILCA representatives in their city or town so that they can refer mothers to them when appropriate. Pharmacists can obtain copies of these organisations information materials. Which they can then make available to customers, members of the general public, and other health professionals.

Pharmacists can learn more about breastfeeding and maternal medication. Fortunately, there are only a few kinds of treatment during which breastfeeding is absolutely contraindicated, It is important to know which these are, which others are compatible with breastfeeding, which are to be monitored for side effects in the baby, and which are to be avoided altogether.

Retail pharmacists can make sure they have ample stock of appropriate breastfeeding aids, for example breast pumps (electric for rental and hand-operated for sale), and breast shells and pads. If they do not carry these items, they can tell their customers where to find them if needed.

Pharmacists can find out what specific action their national pharmaceutical associations may have taken. And if they have not acted, pharmacists can encourage their associations to follow the example of the Canadian Pharmaceutical Association which, in 1995, adopted a position statement on breastfeeding and infant nutrition that includes a summary of the International Code of marketing of Breast-milk Substitutes

Pharmacists can also get in touch with the paediatric, nurse, midwifery and other health professional associations operating in their country to find out what they are doing to promote breastfeeding among their membership and the general public.

For pharmacists with access to a computer, literally hundreds of Web sites with up-to-date information on breastfeeding and lactation are just a click of a computer mouse away.

ADVISING ON ALTERNATIVE NUTRITION FOR INFANTS THAT ARE NOT BREASTFED

As members of the health care team, pharmacists should be able to advise on the most suitable source of alternative nourishment for infants who, for whatever reason, are not breastfed. Indeed, infants who are not breastfed require special attention, since they constitute a risk group. Their mothers and other family members , as necessary, should receive adequate instructions for appropriate preparation of a breast-milk substitute, for example a commercial formula, or home-prepared formula with micronutrient supplements. They should also be warned against the health hazards of inappropriate preparation.

Where the special problem facing HIV-infected mothers are concerned, personnel dealing with health, nutrition and welfare issues, including pharmacists, are beginning to face a demand for information, advice and support from anxious mothers and families. Besides being intense personal concern, the issue of HIV transmission through breastfeeding is also of considerable public health importance – especially in countries where both fertility rates and HIV-infection rates among pregnant women are high. AIDS has already doubled the mortality of children under five years of age in some areas. Only part of this increase is the result of breastfeeding. Nevertheless, there is a pressing need for countries to develop and implement sound public health policies on HIV and infant feeding.

In 1997, WHO, the United Nations Children's Fund, and the Joint United Nation Program on HIV/AIDS issued a joint Policy Statement on HIV and Infant feeding that takes account of available scientific evidence of HIV transmission through breast milk and promotes fully informed choice of infant feeding methods by HIV-positive women. Based on the 1997 Statement, the agencies have prepared three manuals that offer the latest expert advice on recommended safe practices for infant feeding when the mother is infected with HIV:

* Guidelines for decision-makers
* A guide for health care managers and supervisors
* A review of HIV transmission through breastfeeding

Although the recommendations and advice in these manuals have universal relevance, particular attention is given to options for infant feeding in

resource – poor settings where infectious diseases and malnutrition are the leading causes of infant mortality, and where artificial feeding may be particularly hazardous as well as prohibitively expensive.

CONCLUSION

Because specialised knowledge brings pharmacists close to patients in any community setting, they are particularly well placed to make a difference in healthy infant nutrition. To encourage this, a number of practical suggestions are provided to help pharmacists play fully their role as care-givers and communicators on behalf of a large and particularly vulnerable segment of the population,. This approach is consistent with the International Pharmaceutical Federation's own vision of the requisite knowledge, attitudes, skills and behaviours that pharmacists everywhere should bring to their leadership positions on behalf of overall community welfare.

REFERENCES

1. International Code of Marketing Breast-milk Substitutes. Geneva, World Health Organisation, 1981
2. For a copy of the Melbourne Pharmacy College infant-feeding course outline and its companion tool, *best practice infant nutrition scheme for pharmacists*, con tact course director Maureen Minchin, Christ Church Vicarage, 14 Acland,St. St.Kilda, Vic 3182, Australia; Tel/fax + 613 9537 2640; email: minchin@netlink.com.au
3. La Leche League International, P.O. Box 4079, Schauburg, IL 60168-4079, USA Tel: + 1847 519 7730; fax +1847 519 0035; Email: Rmagalhaes@illi.org or http://www.lalecheleague.org
4. International Lactation Consultant Association, 4101 Lake Boone Trail, Suite 201, Raleigh, NC 27607-6518, USA; Tel: +1 919 787 5181, ext 234; Fax: +1 919 787 4916; Email: ilca@erols.com or http://www.erols.com/ilca/index.html
5. The World Health Organisation has pre pared recommendations on breastfeeding and maternal medication as part of its Eighth Model List of Essential Drugs. Breastfeeding and maternal medication Recommendation for drugs in the Eighth WHO Model List of Essential Drugs. Documented WHO/CDR/95. 11. Con -tact: Distribution and Sales; Email: publications@who.ch
6. Canadian Pharmaceutical Association 1785 Prom. Alta Vista Drive, Ottawa, Ontario K1G 3YG; Tel: +1 613 523 7877; Fax: +1 613 523 0445; Email: jcooper@cdnpharm.ca. The po -sition statement is available at http://www.cdnpham.ca/1311.htm
7. Two of the many lists of available breastfeeding sites are http://www.leron-line.com/internetsites.htm, and http://users.aol.com/kristachan/bflink.htm
8. Available on the Internet via the WHO home page http://www.who.int/dsa/justpub/justpub.htm
9. A hard copy of this three- volume set is available from WHO for US$14.40 Con -tact: Distribution and Sales : Email: publications@who.ch. See also http://www.who.int/dsa/juspub/justpub.htm

PUTTING YOUR OTCs TO THE TEST

By Jennifer Lee, Senior Medical Writer, and Simon Larkin, Head of Regulatory Affairs, Europe, Asia Pacific of ClinTrials Research Ltd.

Treatment of patients with medicinal products which are not subject to a medical prescription (that is, 'over the counter', or 'OTC' medicines) is gaining in scope and popularity. Surveys have show (1) that over time, General Practitioners are becoming more willing to recommend an OTC product, certainly as a short-term measure. They are also tending to refer patients to a pharmacist more frequently. Now that patients have access to product information from their local pharmacy with additional help from patients support groups and the Internet, they are making more decisions about their treatment alone, or in partnership with a health professional. Self-treatment allows the patients to avoid the time spent on a surgery visit and expense of prescription charge (£5.80 in the UK) and they can do this with confidence that they are receiving the best medication for the ailment in question. OTC products also are often formulated in easy-to-use combinations which have a number of active ingredients in one palatable dose, thus avoiding the need for complex dosing regimes. Seventy per cent of GPs agree that OTC recommendation is an integral part of their treatment approach to minor ailments, and it has been estimated that 39 per cent of a GP's time is spent dealing with minor ailments which may be treated with OTC medicines (2).

The key question to consider when deciding to register a drug as on OTC medicine is whether it can be used safely without medical supervision. The criteria for this decision are set out by directive 92/26/EEC article 3, which is explained in the document: *A guideline on changing the classification for the supply of a medicinal product for human use*. This presents two areas of information: firstly the criteria by which a medicine will be classified as suitable or not for marketing as an OTC product; secondly the data required to support the re-classification of a prescription medicine as an OTC. The criteria to be considered may be summarised as follows:

Direct safety
Indirect safety
Risk and likclihood of incorrect use
Extent of previous exposure in the target population
Route of administration

The direct safety criteria relate to the possibility that the administration of the drug will lead to adverse reaction that can be readily attributed to a toxic effect of drug. An example of this is the gastro-intestinal side effects commonly associated with non-steroidal anti inflammatory drugs (NSAIDs). Direct safety information is derived from both clinical and non-clinical work and pharmacovigilance reports derived from post-marketing surveillance studies and spontaneous adverse event report such as those from the UK yellow card system. The value of direct safety data will depend upon careful scrutiny of the scientific evidence demonstrating the toxico-pharmacologic properties of the drug. If preclinical data is available, the toxity, genotoxity, reproductive toxicity and carcinogenic potential seen in these studies should necessarily be low. However, for older drugs which have been marketed and registered as an OTC medicine under the License of right (LOR) system, such data may not be available. In this case experience of the drug in 'normal use' conditions will be more extensive and probably more relevant. The expected adverse reactions for an OTC medication should be mild and reversible. The risk will be assessed, however, in comparison with other treatments for the same direction.

An indirect safety issue would be where the adverse effect is not directly caused by a known property of the drug *per se*, but is an indirect consequence of its inappropriate use. A good example of this is 'masking', whereby a more serious condition in hidden by the symptomatic treatment of its presenting signs such as the headache associated with meningitis.

The nature and seriousness of the condition to be treated must be considered as well. However safe the product may be, it will not be given authorisation for marketing as an OTC medicine if the target indication is a serious one, and one which requires professional medical supervision. An OTC medication should be given for a condition that is self-limiting, and the pack should be clearly labelled with the permitted indications. To help illustrate this, consider the wide range of indications for which NSAIDs may be taken. At one extreme it is possible to by the drugs for the treatment of headache from retail outlets including garages; while close medical supervision and prescription are needed when they are used in more serious disease involving long-term anti-coagulation and anti-inflamatory properties. Approval for OTC use can clearly be supported in the former instance, but not in the latter.

Two other indirect safety considerations are worth mentioning here. Firstly, the question of whether the patient will easily identify the indication for which the medicine is prescribed. When looking at indications which may suitably be treated with OTC medicines, the list is restricted to those where the patient can be expected to diagnose the condition quite easily, and have some awareness of the anticipated course of the disease. Advice that a physician should be contacted if symptoms persist beyond this expected course should always be included in the pack leaflet. Secondly, can the symptoms of the ailment mask those of a more serious disease? Presenting symptoms may be associated with a number of disease states, and the target indication may be mistaken for an illness of more severe prognosis. If the medicine is an unsuitable treatment for this alternative disease, a patient may be at risk from the inappropriate use of the medicine, or simply by a delay in the correct diagnosis.

Indirect safety must also be considered on a wider scale. For example, would overuse cause a risk to the general population? Evidence of the overuse of antibiotics leading to resistant strains of bacteria is controversial but compelling.

Another safety aspect to be considered is the possibility of interactions with other commonly used drugs. Interaction with drugs generally used for the same target indication may of course be a risk which would occur more frequently and would therefore be more significant.

Incorrect use invariably happens, although this can be controlled to a certain extent by patient education. It is important that there is a reasonable margin of safety when it comes to use for the wrong indication, the wrong dose, for longer than recommended, or use without respect to the contraindications and warnings. Accordingly OTC medicines are often marketed with the recommended dose at the lower end of the scale of therapeutic usefulness and in a pack size which represents one course of treatment. The pack may contain only a single dose in the case of an anti-fugal drug for candida. This alerts the patient to the fact that medical intervention is needed, if response to the

drug is not immediately apparent.

"At one extreme it is possible to buy the drugs for the treatment of headache from retail outlets including garages; while close medical supervision and prescription are needed when they are used in more serious disease involving long-term anti-coagulation and anti-inflamatory properties. Approval for OTC use can clearly be supported in the former instance, but not in the latter."

The route of administration is important when being considered for OTC use, and injectable drugs are generally considered unsuitable. Administration using droppers or more complex actuated devices may be approved, depending on their case of use and potential for malfunction.

It is unlikely that an active substance will be considered suitable for OTC use before it has been in widespread use for five years. For special populations, such as the paediatric and neonatal age ranges, use in the target population should show a low risk of adverse reactions. Generally speaking, this should be in a broad cross-section of the target population and there should also be relevant data clearly outlining the proposed dose and the proposed formulation.

The second section of the guideline mentioned above explains the data to be submitted. In all cases an expert report should be written. This will provide a critical analysis of the risk of the proposed availability of the product without a prescription. It should be clear to the reviewer that all the information available about the product has been considered in the light of current scientific knowledge.

The safety summary will reference the pre-clinical experience with the product, and toxic effects in humans will be fully evaluated. Although a medical product is unlikely to be granted approval for sale as an OTC product before five years of prescription use, a shorter time may be acceptable if the active substance has been in use as a food supplement or health food. If pharmacovigilance information is available from other countries where the product is licensed for OTC use, details such as numbers of patients treated, demographical details of the treated, demographical details of the treated patients, the dose given and the indications for use should all be reported in the safety summary. The report should be formatted as for a marketing application – as described in the *'Notice to Applicants'* in the European Union – with post-marketing surveillance studies, clinical trials and published literature all included. Where known, the concomitant medications used in spontaneous reports of adverse events and those allowed in the clinical trails should be discussed, to show how extensive the search has been for interactions with other commonly prescribed drugs. The safety summary should consider the consequences of use by a patient who has incorrectly diagnosed his or her condition and the effects of an incorrect or delayed diagnosis. Will there be serious consequences if an accidents or intended overdose occurs? All these issues must be addressed.

Further substantial evidence of the product's efficacy is not normally necessary unless the dose or indication has changed from that which has represented normal use in the past. The pack size of the medicine should reflect the recommended duration of treatment, with a warning that if efficacy is not seen after a certain period, a physician should be consulted.

There are several actions to be taken to ensure that the above needs can be met. These are:

PATIENT INFORMATION AND LABELING

The content and style of patient information and labeling are now under more rigorous control by the authorities. The aim is to give complete yet understandable instructions for use and appraisal of the possible consequences of taking the medication, not least direct and indirect safety considerations.

PACK SIZE AND PACKAGING

These can be designed to maximise correct use and minimise both overuse and overdose.

RESTRICTIONS ON DOSE

Patients are often tempted to use either too much or too little of the drug. In the latter case, this is because they may have reservations about using drugs at all, which likely to be made worse by the lack of efficacy when insufficient is taken. On the other hand, some patients will believe that increasing the dose will improve efficacy without truly appreciating the potential for increased risk. It is clearly important to encourage the patient to take the correct dose within the correct dosing regime.

CONTRAINDICATIONS

These will often limit the use of the drug in patients with certain conditions, or concomitant use with other drugs or even foodstuffs.

WARNINGS

Warnings will often take the form of hard-hitting, clear labeling that emphasises special safety issues such as the risk of combining products with similar or identical active ingredients, like those seen with cold or flu treatments.

Marketing authorisation for a new chemical entity follows a well-established method and the data is subjected to rigorous analysis. At this point, however, information about the drug is drawn from a relatively low level of patient exposure in carefully selected patient populations. Although the criteria for approval to place the drug on the market as an OTC product seem to be onerous, the advantage of the prescription use experience is that the application can be backed by a substantial quantity of data obtained from broad-based populations under 'normal use' conditions. Assuming that the data obtained can be shown to be collected with a comprehensive scope and a high level of diligence, it is possible to demonstrate the risk/benefit obtained in a more representation population than those of clinical trials. Furthermore, because the exposure has been that much greater, a more accurate assessment can be given of the true risk of taking the drug. Assuming that the benefits have been confirmed in normal use, and the increased exposure has generated substantial evidence to support the initial safety assessment, the risk/benefit assessment will be far more accurate than at first registration.

At the point at which the case for an OTC medicine is considered, the risk/benefit balance can be better argued. However the proportion of risk to benefit contains no absolutes and requires medical and ethical considerations to balance the two sides of the ratio. This is difficult enough when an experienced practitioner applies the balancing process to a prescription product,, but is less accurate and more subjective in a less well-informed individual. Hazardous though his may be, evidence that members of the general public are capable of making such decisions is quite powerful (3). The success of OTC products lies principally with the reasonable assertion that these products are relatively safe, as shown by the low incidence of adverse reactions and indirect safety hazards in the exposure that they get. This is not to say that polypharmacy and overdose do not occur, but these can practically be addressed by the innovative methods of control that pack design and clear patient information ca n bring.

REFERENCES

1. Bradley et al. Attitudes and behaviour of Doctors and Patients with regard to over-the-counter medicines. 1976.
2. Bradley, Self –Medication and the G.P. 1997.
3. PAGB Everyday Healthcare Survey 1996 ●

GLOBAL WARMING AND PERFORMANCE OF ANTIBIOTICS AND ANTIBACTERIAL AGENTS

Dr. Subhash C. Arya Centre for Logistical Research and Innovation ; M-122 (of part 20 Greater Kailash –II, nel elhi – 110048, India

Bacterial infections are responsible for respiratory tract infections, diarrhoeal diseases in children under five years of age, that were the second and the fourth foremost killers globally during the early 1990s. Such infections were the first and second foremost causes for the global mortality during that interval. The efficacy of antibiotics and antibacterial agents, offered as the therapeutic agents, could be adversely affected during the global climate change and the frequent *El nino* effects. The antibiotics and antibacterial substances (Table 1) have to be stored between 2-8°C or between 15-25° or 30°C. At times, commercially available frozen antibiotic formulations have to be stored at –20°C. Following their reconstitution with diluents, they cannot be stored for very long periods at temperatures other than 4°C. Any inadvertent exposure to high heat could adversely lower their potency and bioavailability.

A new record for global temperature was established during July 1998 when the average global temperature reached was 15.5°C, and July 1998 was the hottest months during the past 120 years[3]. Such high temperatures, if accompanied by high humidity, would imply enormous heat transmission to different antibiotics and antibacterials.

In developing countries, heat waves are also associated with poor electricity supply that disturbs the working of electrical appliances designed to main tain temperatures at low level4.

Certainly, similar eventualities were unlikely in industrialised countries, even though during the 1995 heat wave in Chicago, the maximum atmospheric temperature reached was 40°c. That was associated with high humidity and heat-index, an estimate of radiative and evaporative transfer of heat was 48.3°C5. While such a high heat-index is extremely rare in industrialised countries, it would be a very frequent phenomenon in developing countries.

Environmental rigors have been associated with poor quality of ergometerine injections, with the recommended temperature of storage between 2 – 8°C[2], in Zambia. Seventeen (17) of the 26 dots failed during potency assays in the material prior to its

Continue on page 32

distribution to health centres outside Harare and Bulawayo. The field samples exhibited serious instability with a mean 17% subsequent loss in 5.8 months[6].

Qualification of active ingredients of chloroquine, amoxycillin, tetracycline, ampiclox in Nigeria and Thailand was shocking. Evaluation of the field samples, each with a storage temperature maxima of 25 or 30°C[2], showed 36.5% samples to be substandard. In six samples of chloroquine being used by patients, there was no active ingredient of chloroquine left[7]. Without any prejudice for similar investigations on antibiotics or antibacterials meant for storage in a frozen state or round 2 – 8°C, the ground realities about their field potency and bioavailability were not likely to be very optimistic.

Simplified, one-two step tests that do not require costly equipment and trained personnel would be essential to monitor potency of antibiotics and antibacterial substances in the premises of the clinicians. A semi-quantitative, paracetamol specific test for screening paracetamol potency in the field itself has been very encouraging[8]. The test does not require costly equipment. Similar tests for antibiotics would be of immense utility in pharmacy and non-pharmacy distribution centres.

The scourge of poor quality antibiotics and therapeutic failures including emergence of resistant organisms, would assume greater dimensions with climate change in developing countries. Frequent travel to such regions would encourage dissemination of such strains globally. The unfortunate development could be avoided by stabilisation of antibiotics and antibacterial substances to resist environment rigors. Stabilisation of labile vaccines by incorporation of trehalose, pirodavir, deuterium oxide, has been remarkable[10]. Well stabilised antibiotics and antibacterials should drastically reduce therapeutic failures in the individual and emergence of resistance strains in the community.

REFERENCES:

1. WHO. The World Health report 1995: Bridging the gaps. Geneva: WHO 1995 p.3
2. Martindale: The extra pharmacopoeia. 31st edition. Ed. Reynolds, J.E.F. The Pharmaceutical Press, London 1996.
3. United State Environmental Protection Agency: Global warming. Vice President Gore announces new data showing July 1998 was the hottest month on record. August 10, 1998.
4. Kumar, S. India's heat wave and rains result in massive death oil. Lancet 1998, 351, 1869.
5. Heat-related mortality Chicago, July 1995. M.M.W.R. 1995, 44, 577-579.
6. Nazerali, H., Hogerzeil, H.V. The quality and stability of essential drugs in rural Zimbabwe: Controlled longitudinal study. B.M.. 1998, 317, 1869.
7. Shakoor, O., Taylor, R.B., Behrens, R.H. Assessment of the incidence of substandard drugs in developing counries. Trop. Med. Int. Hilth. 1997, 2, 839-845.
8. Roy, J., Saha, P., Sultana, S., Kenyon, A.S. Rapid screening of marketed paracetamol tablets: Use of thin layer chromatography and a semiquantitative spot test. Bull. HWO 1997, 75, 19-22.
9. Taylor, R.B., Shakoor, O., Behrens, R.H. Drug quality, a contribution to drug resistance. Lancet 1995, 346, 122.
10. In Brown F., Ed: New approaches to stabilisation of vaccine potency. Karger, Basel: 1996 ●

PRESCRIBING MEDICINES – A NEW JOB FOR SOME HEALTH PROFESSIONALS

By Carina Livingston, Ph.D., MRPharms

The recent report of the review team headed by Dr. June Crown on prescribing, supply and administration of medicines could lead to fundamental changes in the way medicines are prescribed. The article describes some of the issue raised and includes comments from pharmacists who contributed to the review.

The establishment of a working party to review the prescribing and supply of medicines in primary care was announced at the end of 1996 under the previous, Conservative, government. The long-awaited final report from the working party was published in march this year, having taken two years to produce (pf, March 13, p346). Has it been worth it? And, will nurses, pharmacists, doctors and other health professionals support the findings?

GROUP PROTOCOLS

The second, final report from the working party says that changes in modern clinical practice provide the necessary impetus for the review of the arrangements for prescribing, supply and administration of medicines. The changes were brought to the fore in 1996 when the trade union Unison advised nurse not to proceed with group protocols for administering medicines because they could be in breach of Medicines Act (Pf, November 23, 1996, p765). Consequently, protocols were an urgent issue for the review team and an initial report on the supply of medicines under group protocols was published in April, 1998.

The initial report concluded that the supply and administration of medicines under group protocols was appropriate, but only in limited circumstances. Most patients should continue to receive medicines on an individual basis. The content of a protocol was clarified in the report and it was recommended that steps be taken to unsure that those acting under protocols were acting within the law. Essentially, the view taken was that existing practices which were safe and effective should continue and should be legal.

NEW PRESCRIBERS

The final report is more far reaching than the first report. It seeks to provide a robust framework for introducing new ways of prescribing which would improve patient care.

The report recommends extending NHS prescribing to a number of health professionals, although the general practitioner or hospital consultant would still co-ordinate patient care. The new prescribers would mostly be working in specific therapeutic areas, such as asthma and family planning. However, pharmacists are mentioned in the report as being one exception to this, where they might be continuing treatment for a wider range of conditions.

Two new types of prescribers are advocated: *independent prescribers*, who could only prescribe following assessment by an independent prescriber (see Panel). Suggestions in the report for independent prescribers include tissue viability, nurses, specialist podiatrists and optometrists. Dependent prescribers include specialist nurses and pharmacists undertaking medication reviews.

Prescribing rights would not be given to any particular professional group as a whole. Instead, professional groups would have to make their case for prescribing. The case made would have to address clinical need, patient safety, relevant education and training, and whether prescribing by the new group should be funded by the NHS. Assuming the case us successfully made, individuals from the relevant groups would undertake additional training. Those successfully completing the further training could then apply for inclusion in the list of prescribers.

Mr. Stephen Bazire (director pharmacy services, Norfolk mental health care NHS trust, and a member of the review subgroup on people with mental health problems) believes that pharmacists should be in the strongest position to become dependent prescribers and that the profession must act on this.

It would be in the patient's interest for pharmacists to prescribe, he says, since "drugs 'r' us". At the hospital where he works, pharmacists are already able to sing medicine charts following contact with relevant doctor (without the need for any counter signature by the doctor), but he feels that they would want to extend this to a dependent prescribing role. Mr. Bazire said that the UK Psychiatric Pharmacists Group was working on a system of specialist accreditation which would facilitate moves towards dependent prescriber status.

Several of the pharmacists who were involved in the review process identify hospital discharge planning as an area where pharmacists should become dependent prescribers.

Mrs. Helen Remington (chief pharmacist, Addenbrooke's hospital, Cambridge, and a member of the review team) explained that the Guild of Healthcare Pharmacists would be entering into early negotiations to allow discharge planning pharmacists to prescribe.

A dependent prescribing role managing repeat medications would be in line with the move by the pharmacy profession towards pharmaceutical care.

Dr. Terry Maguire (Queen's University, Belfast, and a member of the review subgroup on people with self-limiting conditions) feels that it would be possible, in some instances, for patients to be registered with one community pharmacist for dependent prescribing while still being able to get prescription dispensed at any pharmacy. Mrs. Remington suggests that a local primary care group might, for example, agree on a hypertension management plan which community pharmacists working as dependent prescribers could then implement.

Dr. Maguire stresses that pharmacists should not only look to a dependent prescribing role. He believes that community pharmacists should become independent NHS prescribers for people with minor ailments.

WHICH DRUGS?

The review team recommends that prescription-only medicines (POMs) should be prescribable by

new prescribers, but it proposes various limits. General exclusions from prescribing include Controlled Drugs, unlicensed drugs or drugs being used outside their licensed indications, and newly introduced "black triangle" drugs. However, the route to achieving prescribing status for any particular professional group would also include input by the Committee on Safety of Medicines on which POMs the group should prescribe, and from the Joint Formulatory Committee of the British National Formulary, on which pharmacy (p) and general sale list (GSL) medicines should be prescribed.

REPEATING DISPENSING

The final report advocates the introduction of NHS repeatable prescriptions. Few are likely to argue with this. It would improve patient convenience and facilitate adherence, as well as provide a more convenient system for doctors and pharmacists. A restriction on the number of repeats and time span for which a prescription is valid is recommended, with this applying to all prescription, NHS or private.

SEPARATING PRESCRIBING AND DISPENSING

The pharmacy profession has long argued against dispensing doctors, making the case that separating prescribing and dispensing provides a safeguard and affords considerable patient benefit. The report clearly supports this view, stating that there should normally be a separation of responsibilities for prescribing and dispensing. So, how can pharmacists start prescribing if they are also to continue dispensing?

Where there is more than one pharmacist in a pharmacy, as in most hospitals, some pharmacists could prescribe and other could dispensed . In a community pharmacy, where there is often only one pharmacist, separation of responsibilities is potentially more difficult.

The report recognises advice by pharmacist of P and GSL medicines (by responding to symptoms) as a special case where separating presribing and supply might not be in the patient's best interest. In this context, Dr. Maguire is a strong advocate of community pharmacists becoming independent prescribers so they could treat minor ailments within the NHS. This would be more convenient for patients who did not pay prescription charges and it would also reduce the amount of time GPs had to spend dealing with minor ailments.

In its submission to the review team, the British Medical Association (BMA) supported the supply of P medicines free of charge by pharmacists to people exempt from prescription charges.

The review team also feels that separating prescribing and supply might not be in the patient's best interest when pharmacists, acting as dependent prescribers, amend obvious errors in names or dosage as part of the dispensing process. However, the team expects that the independent prescriber would be contacted in advance or as soon as possible afterwards.

Mrs. Remington says that the risk of combing prescribing and supply needs to be considered for the particular patient-car model in place. Her view is that, for a dependent continuing care model with a well established treatment plan, the risk to patients would be low and one pharmacist might take on both functions.

PATIENT RECORDS

Extending prescribing rights to more health professionals carries with it the very real problem of maintaining communication between all those involved.

Patient records would need to be accessible to all prescribers. The review sub-groups recommend a single integrated patient record system. Communication between dependent and independent prescribers would be vital under the proposed system. Information technology (IT) systems are recommended, or patient-held records, until appropriate IT becomes available. The new electronic health records and electronic patient records proposed in the NHS IT strategy would be suitable, once in place.

LIABILITY

Liability has already been raised as one concern if prescribing rights are extended.At a meeting in January, Professor Clare Mackie (Robert Gordon University, Aberdeen, and a member of the review team) stressed tat liability would be relevant topharmacists irrespective of whether they aspired to obtaining prescribing rights. Pharmacists would be dispensing prescriptions written by the new prescribers so they would still have to ensure that a medicine prescribed was appropriate for the patient.

With less certainly of the background and the knowledge of the new prescribers, ensuring that medicines prescribed are appropriate could prove difficult.

The question of liability has also been raised by the medical profession. As more health professionals seek prescribing rights, sorting out where "the buck" stops could become much more difficult. However, the review team recognises as unacceptable current situations where a doctor who has no real involvement takes clinical responsibility, for example, for a district nurse's selection of a dressing.

COST

The final report was apparently delayed for some time at the Treasury because of concerns about the possible costs of implementing any proposed changes. There have been few rigorous economic studies in this field and cost issues prove difficult to address in any meaningful way. However, the nurse prescribing pilot projects in the UK have shown both increased and decreased costs, but, on balance, probably no overall increase. It has been shown that pharmacist consultation reduce referrals to GPs and that pharmacists could improve cost-effective prescribing.

The review team proposed that the new body responsible for assessing whether or not professional groups should be able to prescribe should also advise ministers on whether NHS funding for any such prescribing is appropriate. Allowing this body to advise on the cost-effectiveness of prescribing would require primary legislation and could have wide ramifications.

Costs and benefits are also noted in the report as issues which would have to be thoroughly evaluated before the general introduction of new prescribing practices. The evaluation of costs and benefits could be a very difficult hurdle to jump. Although the report says that such studies should not result in undue delay in introducing new practices, economic evaluations certainly could be used as a strong brake.

A final point in the second report warrants some mention. The report recommends that the remuneration for pharmacists and dispensing doctors should be reviewed to remove anomalies and "perverse" incentives.

NURSES, PHARMACISTS AND DOCTORS

When the Crown review was announced, Mr. Stephen Dorell (then Secretary of State for Health) said that the review was essentially around the issue of nurse prescribing.

Responses in the nursing press to the report are generally positive, although there is much criticism of the fact that the report is now going through a further consultation period (until June) before any action is taken. Even if the outcome of this further consultation is favourable, implementation could still be a slow process. Changes in primary legislation would be needed and there is no time slot for this in the current session of Parliament. A private members bill might afford one alternative route, and Baroness Cumberlege, a strong supporter of prescribing by nurses, might be the person to do this.

Ms. Sally Gooch (a Nurse Member of the Review Team) has stressed the need for further training before nurses take on a prescribing role. She has said that medical students and pharmacists do not do hundreds of hours of pharmaceutical and therapeutics study and say "we can do that". The need for all new prescribers to be familiar with issue relevant to multiple pathologies and co-morbility is recognised in the report.

The pharmacy profession appears supportive of the report, although the fact that implementation could take several years has been noted. The views of the medical profession are less clear, but one representative of the BMA has expressed concern about pharmacists being able to alter drug doses and their lack of clinical skills.

Dr. Ross Taylor (a GP member of the review team) is reported to have said that in his own practice (which contains a big pharmacy) the pharmacist might well take on a dependent prescriber role, but he could not see this happening with community pharmacists in small buildings. He also feels that most practices will want their practice nurses to prescribe.

Overall, the view of the pharmacist involved in the review is that the outcome is good. Change might prove slow but the framework to build on pharmaceutical care is in place and it is up to the profession to take up these opportunities. Mrs. Remington concludes that the report provides an opportunity to look beyond current practice and to see the pharmacy profession move forward.

ACKNOWLEDGEMENT

I am grateful to the pharmacists involved in the review for sharing their views

IMPROVING PHARMACY'S IMAGE AND USEFULNESS THROUGH CONTINUING EDUCATION

By:
John Ocran, Faculty of Pharmacy, UST, Kumasi, Ghana

In the eyes of the general public, pharmacists appear more as businessmen than professionals with scientific or academic background. This image is due to the activities of general practice pharmacists who form the highest percentage of the pharmacist population in most countries. To make the pharmacist more useful and respectable, a programme designed to keep him abreast with recent scientific and professional developments in pharmacy for up to ten years after he has qualified is being proposed for pharmacy graduates in hospital and general practice.

Essentially the programme consists of compulsory courses in Biopharmaceutics, Pharmacokinetics and Social and Administrative Pharmacy, with options for specialisation in various fields such as clinical pharmacy, information, etc., later. A pharmacist will be required to complete the programme within ten years after qualifying. The programme is spread over eight years so that graduates will acquire the habit of constant study throughout their working life; this will also reduce the pressure to the minimum. The award of a Masters Degree after successful completion is provided as an additional incentive. The question of making all Pharmacists go through similar programme of continuing education as a condition for retaining their names on the register of Pharmacists is discussed.

Innovation which have taken place in the pharmaceutical sciences and pharmacy practice within the last 15 years have necessitated the broadening of the curriculum for the first degree courses in pharmacy. One effect of this is that much detail has to be sacrificed if we are to stick to the present duration of the programmes, usually 3 – 4 years after college or 'A' level in most countries. Two solutions are open to educators; either increase the time taken for the first degree which mean turning prospective pharmacists into perpetual students. The other solution is to continue with the broad but shallow education and make it obligatory for the graduate to study for a higher qualification, diploma or degree, while practicing his profession. This second solution seems more reasonable even though, like the first, it may turn pharmacists into permanent students. The difference here is that pharmacists will all become permanent graduate students thus helping to wipe off that 'illiterate' image from the profession. In the past most people thought that once a person was registered as a pharmacist he did not need to study again but could go on working as a pharmacist all his life. Thus employers could not see why they should grant the pharmacist paid leave to study for a higher or specialist qualification, whereas they felt this was a bad image was a necessity for other categories of employees in the same establishment. Unfortunately, this bad image was created and accepted by some pharmacists, particularly those at the top in general practice and hospital pharmacy who did very little apart from ordering supplies and dispensing what was prescribed.

With the majority of pharmacists in every country in general and hospital practice, it is important to examine further education for these two groups, because the image created by these categories determines the total image of the profession in a country. There is no doubt that as authorities become more concerned about the toxic side effect of drugs and pharmaceuticals, the number of new drugs coming into the market in any given period will continue to decrease.

However, what pharmaceutical scientists are trying to do is to make use of technology to make the present drugs more effective and useful. Thus, it is now accepted more than ever before that the effectiveness of a pharmaceutical product is not determined merely by the quality of active ingredient present. This has mad the twin subjects of Biopharmaceutics and Pharmacokinetics so important for every practitioner to continuously update his knowledge in these disciplines. This will enable the pharmacists to make better choice of products, offer more useful advice to physicians and patients and make a more meaningful evaluation of the effect of a drug.

Another recent development of major significance is the greater realisation that pharmacy is a social profession and therefore need an injection of social and administrative sciences if it is to achieve its aim. Many school of pharmacy have introduced some social and administrative pharmacy into the first degree curriculum but, here again, time only allows very superficial and elementary treatment. It is essential for pharmacists in general and hospital practice to have deeper knowledge of these disciplines because no pharmacy business or department can be run successfully if the

key figures in control cannot appreciate sound administrative principles. In fact, at the very top, the administrative skill of the pharmacist is just as important as his knowledge of pharmacy for the success of his department or company. The need to promote closer links between pharmacists and patients and physicians cannot be overemphasised and this should be the primary objective in designing any course in social pharmacy for graduate students.

With this strong background in Biopharmaceutics, pharmacokinetics and social and administrative pharmacy, graduates can go on to specialise in any particular fields, e.g. information, clinical pharmacology, patient education and counselling, clinical research (investigating problems involving patients and drugs).

The course discussed in this paper is similar to what is being planed for pharmacists in Ghana. To make it more practical and emphasise the patient-oriented objective, only pharmacists working as community/general practice and hospital pharmacists will be admitted. Employers are being persuaded to accept the need for pharmacists to become specialists so that they will grant their employees permission to attend classes without loss of pay (one day a week). It is intended to collaborate with various experts at the University Hospital, a Teaching Hospital and some local pharmacies.

There has been much discussion about ways of ensuring that pharmacists keep in touch with current developments in pharmacy practice and pharmaceutical and related sciences but it appears no solution has been found yet. In some countries one of the suggestions made is for pharmacists to pass an examination every so often, say three years, in order to maintain their name on the register. There has also been a proposal to make it obligatory of pharmacists to attend short courses, conferences and symposia. Both suggestions have their associated problems and drawbacks. From my personal experience, most people who attend courses, etc. regard them more as holiday than anything else. What is being proposed in Ghana is that in order to retain his name on the register, every pharmacist will have to study a higher qualification within ten years after being registered. This may not be the most satisfactory solution to the problem but it is hoped that if accepted, this will make it possible to broaden the first degree curriculum to cover new developments in professional practice and the pharmaceutical sciences while at the same time laying a solid foundation for specialisation later. The days when the first degree was considered as enough for whatever the pharmacy graduate wanted to do in life are certainly over. It should now be accepted that there is absolute need for formal post graduate education if the pharmacist is to perform new roles expected of him. Apart from making him feel more confident it is hope that the higher training will enable him to win greater respect among the other members of the healthcare team and more important, improve the benefits derived by the patient from his service.

The intention behind the long duration proposed for the course, 8 years, is to maker pharmacists cultivate the habit of studying to keep up-to-date without subjecting them to the harsh pace demanded by most full-time formal courses. In this way, it is hoped that even after obtaining his qualification he would have accepted the fact that a pharmacist never stops studying. There will also be opportunity to discuss new developments over a reasonably long period so that up to 10 years after qualifying, he will still be up-to-date. The award of a degree is to be used only as an incentive and should not be regarded as the primary objective; people work harder when they can see some reward in physical term.

The tendency for the majority of pharmacists in general practice to portray themselves as businessmen rather than science-based professionals is not doing pharmacy any good and has to be reversed. In deed, in my opinion this is the main reason why pharmacists are finding it so difficult to climb up the social ladder in many countries and to be treated with the respect accorded other professionals with similar training. A programme of further education designed to make the pharmacist more useful by applying his scientific knowledge more during his practice is necessary for the continued survival of pharmacy as an important science-based social profession.

Reprinted from the Pharmaceutical Journal, September 1985. This piece has been reprinted in support of our editorial in the previous edition and to encourage the Pharmacy Council and the PSGH and indeed all Pharmacists in the quest to improve the knowledge base of all Pharmacists as a means of improving the quality of pharmaceutical care in the country ●

DRUG – INDUCED SKIN REACTIONS

By Anne Lee, MPhil, MRPPharmS, and John Thomson, MD, FRCP

The skin is the organ most frequently affected by adverse drug reactions. In 1997, 27 per cent of all reactions reported to the Committee on Safety of medicines featured skin and subcutaneous tissue reactions. In hospital, cutaneous reactions to drugs are thought to occur in up to 3 percent of medical inpatients.

Virtually all drugs may induce skin reactions. Although they are usually mild, some are serious and potentially life-threatening, such as the Stevens Johnson syndrome and toxic epidermal necrolysis. Drug eruptions can also occur as part of a spectrum of multi-organ involvement. For these reasons, all drug-associated rashes should be carefully evaluated. Drugs may also be implicated in nail abnormalities and disorders of hair growth, which are not considered here.

AETIOLOGY

The cause of skin reactions is often unknown although many have an allergic or toxic basis. Allergic reactions may be independent of dose and can persist long after the causative drug has been withdrawn. In penicillin hypersensitive reactions, for example, the skin condition may worsen for seven to 10 days after the drug is withdrawn. It is especially important that allergic skin reactions are correctly identified, since subsequent exposure to the same drug could cause a much more severe reaction. In contrast, toxic reactions are dose-dependent and skin symptoms generally resolve fairly soon after the causative agent is withdrawn.

There are several important predisposing factors. Genetic factors may be an important influence; for example, acetylator status may predispose to sulphonamide reactions. The role of atopy in predisposing to drug reactions is controversial. It may be important in reactions to iodinated contrast material but not in reactions to penicillins or reactions during anaesthesia. Patients who have a reliable history of drug allergy always need to be carefully monitored on the initiation of any drug, but particularly those commonly implicated in skin reactions. Hepatic disease, renal disease, systemic lupus erythematosus and AIDS are some of the disease states associated with an increased risk of skin reactions. Drugs allergy is more common in the elderly and may be related to the development of an immune response or to increased exposure to drugs. The route of administration can influence drug allergy; in general, topical application has the greatest propensity to induce allergy, followed by parenteral then oral administration.

DIAGNOSIS

It can be difficult to diagnose a drug eruption confidently. Most drugs are associated with a spectrum of skin reactions, and the dictum "any rash, any drug" has been used. A few drugs, however, seldom cause skin reactions; these include digoxin, ferrous sulphate and potassium chloride. Many reactions cannot be distinguished from naturally occurring eruptions so misdiagnosis is common. For example, it may be difficult to differentiate an antibiotic-induced morbilli-form eruption from a rash due to concomitant infection and this may unnecessarily limit the future use of a particular medication. Furthermore, patients are often taking more than one drug, making it more difficult to confirm the cause.

The timing of skin reactions is often a useful diagnostic tool. In general, the onset occurs within a short time afte: the introduction of the causative drug. However, there are important exceptions; the onset of hypersensitivity reactions to penicillins can occur within a few weeks after the drug has been discontinued.

Drugs suspected of causing skin reactions should usually be withdrawn and not used again in that patient. Symptomatic treatment with calamine lotion or systemic antihistamines may be required. For more serious reactions, systemic corticosteriods may be indicated. The main clinical features that are suggestive of a more severe reaction include mucous membrane involvement, blisters or skin detachment, high fever, angioedema or tongue swelling, facial oedema skin necrosis, lymphadenopathy or dyspnoea.

Although skin prick or blood tests may be used in the diagnosis of some reactions (eg, those dependent on IgE such as immediate-type reactions to penicillin), they are not usually helpful in skin manifestations of allergy. Skin prick tests can be dangerous and should only be carried out close to intensive care facilities. Re-challenge is seldom indicated in the diagnosis of skin reactions because of the inherent risks.

PANEL 1:SOME DRUGS THAT COMMONLY CAUSE EXANTHEMATOUS REACTIONS

Anti-tuberculous drugs	Barbiturates
Carbamazepine	Cephalosporins
Erythromycin	Frusemide
Gold	Gentamicin
Isoniazid	Nitrofurantoin
Penicillins	Phenothiazines
Phenylbutazone	Phenytoin
Sulphonamides	Thiazides

PHARMACIST'S ROLE

When a skin rash is potentially drug-induced, the pharmacist should take an accurate medication history. All current and recent medication should be noted, including over-the-counter, herbal preparations, and injections, including vaccines or contrast media.

Pharmacists may be more aware than other health professionals of the problems that can occur due to sensitivity to pharmaceutical excipients, which is often manifest as skin reactions. It can be useful to know when each drug was first taken relative to the onset of the reaction and whether there has been previous exposure to the drugs. The patient should be asked whether they have a previous history of drug sensitivity, contact dermatitis, or atopic disease with asthma or eczema. If possible, the rash should be examined. If possible, the rash should be examined to determine whether it appears typical of a classic drug-induced eruption.

EXANTHEMATOUS (ERYTHEMATOUS) REACTIONS

The term exanthema is an umbrella term for skin reactions which literally burst forth on the skin. Enanthematous reactions similarly occur on the mucous membranes. Typical characteristics of skin exanthemas include erythema (redness), or morbilliform (resembling measles) or maculopapular lesions. Macules are small, distinct, flat areas and papules are small, raised lesions. This is the most common type of drug-induced cutaneous reaction. The eruption often starts on the trunk; the extremitics and intertriginous areas are often involved, but the face may be spared. The rash is usually bright red colour and the skin may feel hot, burning itchy.

These reactions can occur with almost any drug at any time of to tow to three weeks after starting drug administration. But they are most common within the first days. If the causative drug is continued, then foliative dermatitis may develop. Occasionally, the eruption subsides desperate continuation of the medication. The eruptions usually resolve within a few week of discontinuing the causative drug. Ampicillin, amoxycillin and sulphonamides frequently cause these rashes. Drugs that commonly cause exanthentous reactions are shown in Panel 1 (above).

ERYTHRODERMAAND EXFOLIATIVE DERMATITIS

A widespread confluent erythematous (erythroderma) often associated with desquamation (exfoliative dermatitis) is of the most severe patterns of cutaneous actions to drug. It may follow exanthertous eruptions or may develop as erythen and exudation in the flexures. There may be systemic symptoms such as fever, lyphadenopathy and anorexia. Possible complications include hypothermia, fluid electrolyte loss, and infection. The non-drugs implicated are sulphonamides, chloroquine, penicillin, phenytoin and niazid.

PANEL 2: SOME DRUGS THAT MAY CAUSE FIXED DRUG ERUPTION

Barbiturates	Carbamazepine
Chlordiazepoxide	NSAIDs
Phenolphthalein	Phenylbutazone
Quinine	Salicylates
Tetracyclines	Trimethoprim

CASE STUDY

On a Saturday evening just before closing, one of your counter assistants asks if you could speak to Mrs. K, a young woman who is obviously anxious about her 14 months-old baby, Matthew, Mrs. K. has the baby with her. She explains that he is half-way through a prescribed course of amoxycillin for a middle ear infection. Yesterday she noticed that Matthew had developed three or four red blotches on his upper chest and shoulders. She telephoned the local emergency GP service and was advised to use calamine lotion and to continue with the antibiotic. She was asked to get back in touch if the rash became worse.

This morning the blotches has seemed much improved. However, when Mrs. K came back from work this afternoon she noticed that Mathew had a slight temperature and that the blotches had spread. The baby seems happy enough and is not otherwise well. Mrs. K is unsure what to do as she does not want to call the doctor out without good reason. The skin rash is now affecting most parts of the body. On examination the lesions are large, deep red, circles which look darker in the centre. There is no sign of blistering or exfoliation. Mathew seems fairly bright but he does seem feverish.

WHAT ARE THE MOST LIKELY POSSIBLE CAUSE OF SKIN RASH IN AN INFANT?

There are various possible causes, the most obvious of which are viral or bacterial infection (e.g.. chickenpox, measles), staphylococal superinfection of eczema or allergy to a chemical or drug.

What skin disorder does this type of lesion suggest?

They erythematous lesions described are suggestive of the "target-like" lesions which are characteristic of erythema multiforme. Penicillins are a recognised cuase of this sort of reaction but infection is also a common cause. The presence of fever could indicate progression to a more serious skin disorder.

Is there any other information that might be important?

It would be important to ascertain whether the baby has had any other medication recently (e.g., OTC cough mixtures, analgesics, vaccinations), exactly how long the antibiotic has been taken, whether there are any other signs or symptoms, particularly mucous membrane involvement (e.g. lesion in the mouth). It is also worth finding out what brand of amoxycillin was dispensed to that you can check the constituents for artificial colouring, etc.

What advice do you give Mrs. K and why?

You should tell Mrs. K that it is not possible for you to give a diagnosis but that skin rashes like this in children should always be taken seriously. You should explain that the rash might be due to an infection or a side effect of the medication. Mrs. K should not give Mathew any more of the antibiotic in the meantime. Because the rash has spread and because Mathew has a temperature, the best course of action would be to call out the doctor immediately or to go the hospital casualty department.

FIXED DRUG ERUPTION

A fixed drug eruption is the only coetaneous reaction for which drugs are the sole cause. It consists of erythematous round or oval lesions of a dusky purple or brown colour sometimes featuring blisters or vesicles. Initially, one lesion appears although others may subsequently occur. The affected individual may complain of itching or burning in the affected area but systemic involvement is usually absent.

The eruption generally appears within 14 hours of drug ingestion and can occur on any part of the skin or mucous membranes. The sites most frequently affected are the hands and feet, penis and perianal area. The site of the eruption is fixed, i.e., when the individual takes the causative drug again the eruption generally recurs within eight hours at exactly the same site as was previously affected. Healing occurs over seven to 10 days after the causative drug is stopped although there may be residual hyper-pigmentation. The pathogenesis of fixed drug eruption is not well understood. Phenolphthalein is probably the most common cause. Drugs implicated are shown on Panel 2.

PANEL 3: SOME DRUGS THAT MAY CAUSE URTICARIA/ANGIOEDEMA

ACE inhibitors	Anaesthetics (local and general)
Antibiotics	Dextrans
Enzymes (eg, streptokinase)	Hydralazine
Insulin	Muscle relaxants
NSAIDs	Opioids
Radiocontrast media	Salicylates

URTICARIA AND ANGIOEDEMA

Urticaria and angioedema are physical signs rather than specific diagnosis; both are common features of hypersensitivity reactions. Chronic urticaria may have many different causes or may be idiopathic. Acute urticaria, known as nettle rash or hives, is a common drug reaction, usually occurring within 36 hours of drug exposure. It presents as raised, itchy, red blotches or wheals which may be pale in the centre and red around the outside. Individual lesions rarely persist for more that 24 hours. On rechallenge, lesions may develop within minutes. Management of acute urticaria involves stopping the causative agent and treatment with systematic antihistamines.

Angioedema is a vascular reaction resulting in increased permeability and fluid leakage, leading to oedema of the deep dermis, subcutaneous tissue or submucosal areas. It has a lower incidence than urticaria. The tongue, lips, eyelids or genitalia are generally affected and the oedema may be either unilateral or symmetrical. Angioedema of the upper respiratory tract can result in serious acute respiratory distress, airway obstruction and death. This serious reaction should always be reported to the CSM if drug therapy is a possible cause.

Angioedema is a recognised problem with all angiotensin converting enzyme inhibitors (ACE inhibitors). The estimated incidence is 0.2 percent in Caucasians but may be higher in other racial groups. In most cases, the reaction has occurred in the first week after starting therapy, often within hours of the initial dose. However, in some cases it has developed after prolonged therapy of up to several years. The mechanism is poorly understood. Drug-induced angioedema is usually medicated by immunological factors. With ACE inhibitors, it has been postulated that bradykinin. ACE inhabitors should be withdrawn immediately in any patient who presents with angioedema and an appropriate drug of a different class (not an angiotensin II antagonist) substituted. ACE inhibitors are contraindicated in patients with a history of idiopathic angioedema. Panel 3 shows drugs which may cause urticaria or angiodema.

PANEL 4: DRUGS THAT MAY CAUSE PSORIASIFORM ERUPTIONS OR EXACERBATE PSORIASIS

ACE inhibitors	Beta-blockers
Chloroquine and hydroxychloroquine	
Granulocyte colony stimulating factor (GCSF)	
Gold	Interferons
Lithium	NSAIDs
Tetracyclines	

PANEL 5: SOME DRUGS FREQUENTLY IMPLCATED IN VASCULITIS

Allopurinol	Ampicillin
Climetidine	Frusemide
Granulocyte colony stimulating factor (GCSF)	
Hydralazine	NSAIDs
Phenytoin	Propylthiouracil
Sulphonamides	Thiazides

PANEL 6: SOME DRUGS THAT MAY CAUSE ERYTHEMA MULTIFORME OR STEVENS JOHNSON SYNDROME

Barbiturates	Carbamazepine
Cimetidine	Co-trimoxazole
Chlorpropamide	Gold
Lamotrigine	NSAIDs
Penicillins	Phenothiazines
Phenytoin	
Rifampicin	
Sulphonamides	Tetracyclines
Thiazides	

ACNE

Some drugs can cause or exacerbate acne. The term acneiform is applied to drug eruptions that resemble acne vulgaris. The lesions are papulopustular but comedones are usually absent. Corticotrophin (ACTH), corticosteroids, androgens (in females), oral contraceptives, isoniazid and lithium are among the most frequenhtly implicated drugs.

PSORIASIS AND PSORIASIFORM-ERUPTIONS

Psoriasiform eruptions typically consist of erythematous plaques surmounted by large dry silvery scales. A number of drugs can induce psoriasis in patients with no previous history or can worsen pre-existing psoriasis, although many reports are anedotal and causality is unknown.

One fairly definite trigger is lithium which can unveil psoriasis in the susceptible or aggravate existing psoriasis. Several investigators have confirmed that interferon alfa may either induce or worsen psoriasis.

The lesions have been shown to improve on withdrawal of interferon and to recur on reintroduction or rechallenge. In patients with pre-existing psoriasis, symptoms usually developed within the first month of treatment but in those with no previous history they developed after at least two months treatment. Other interferons have also been implicated.

The effect of chloroquine and hydroxychloroquine on psoriasis is variable; in some studies, most patients treated noted no change in their condition while, in others, symptoms worsened in a large proportion of patients. It is clear that psoriasis may worsen in some patients and this may make treatment decisions difficult in certain situations. For example, chloroquine may not be an appropriate drug for antimalarial prophylaxis in a patient with psoriasis, depending on the risk of infection in the place to be visited. Care should be taken with the use of hydroxycholoroquine in patients with psoriatic arthropathy.

Over the past 20 years, skin eruptions have been described with numerous B-blockers. Practolol was withdrawn in the UK following a serious syndrome termed the oculomucocutaneous syndrome, featuring a psoriasiform rash, xerophthalmia due to lachrymal gland fibrosis, otitis media, sclerosing peritonitis and a lupus-like syndrome. The pathogenisis of this adverse effect remains unknown, but it appears to have been unique to practolol. Psoriasiform eruptions have since been reorted with cardioselective ad non-cardioselective betablockets. Ophthalmic preparations (eg, timolol) have also been implicated. Cross-reactivity has been noted among propranolol, exprenolol and atenolol. Beta-blockets may also transform psoriasis into pustular psoriasis or erythrodematous psoriasis. The time of onset of the reaction can vary between days to up to a year after initiation of therapy. The underlying mechanism is unknown but beta-blockets2 receptors are found in the epdermis. Psoriasis induced by beta blockers is reported to be resistant to antipsoriatic therapy until the beta-blocker has been stopped.

PURPURA

Purpura describes small cutaneous extravasations of blood. The main causes are thrombocytopenia, platelet dysfunction, or cutaneous

or vascular disease. Drug-induced skin eruptions occasionally feature purpura and purpura is the main feature in some cases. There is no reliable physical sign that helps to distinguish thrombocytopenic from non-thrombocytopenic purpura. Drugs commonly implicated in vascular purpura include aspirin, quinine, sulphonamides, atropine and penicillin.

VASCULITIS

Vasculatis resulsts inflammation and necrosis of blood vessel walls. Drugs are thought to cause about 10 percent of acute cutaneous vasculitis. The mechanism is believed to be immune complex mediated.

PANEL 7: SOME DRUGS THAT MAY CAUSE TOXIC EPIDERMAL NECROLYSIS

Allopurinol
Barbituarates
Carbamazepine
Gold
Griseofulvin
Lamotrigine
Nitrofurantoin
NSAIDs (especially oxicam derivatives)
Penicillins
Phenytoin
Salicylates
Sulphonamides
Tertacyclines

Vasculitis commonly presents with raise purpuric (purple) lesions on the legs. Urticarial lesions, ulcerated areas and haemorrhagic blisters may also be present. The lesions range in size from a pinpoint to several centimetres. Vasculitis typically developes seven to 21 days after the initiation of new drug. The skin lesions may persist for up to four weeks or longer and in some cases become yellow to brown upon healing. Systemic symptoms, such as malaise, arthralgia and fever, may be present. Drug-induced vasculitis may also involve other organs, including the heart, liver and kidneys.
Drug-induced vasculitis is difficult to diagnose. Other causes to eliminate include Henoch-Schonlein purpura in young patients, cryoglobulinaemia, polyarteritis nodosa, infection and collagen vascular disease. Management involves stopping the suspect drug promptly. Systemic corticosteriods may be of some benefit in severe reactions Panel 5 show drugs implicated in vasculitis.

ERYTHEMA MULTIFORME

Erythema multiforme (EM) is a cutaneous response triggered by various infections and drugs (See panel 6). As the name implies, it can present with a variety of patterns. The classic pattern affects the hands and feet more than the trunk. There may be blisters, papular lesions or erythematous areas. A characteristic lesion is one of concentric rings, variously described as target, iris or bullseye shaped.

Involvement of the mucosa is common, so the mouth, eyes and genitalia may be affected.

Infections are a more common cause of EM than drugs and many cases have been wrongly blamed on drugs. Erythema multiforme may be due to vaccination, a variety of topical medications, and some environmental substances (eg, nickel) . When the condition is suspected, all drugs especially those introduced within the past month, should be discontinued, since there is a risk of progression to Stevens Johnson syndrome or toxic epedermal necrolysis.

STEVENS JOHNSON SYNDROME

Stevens Johnson syndrome (SJS) comprises fever, malaise, myalgia, arthralgia, and extensive erythema multiforme of the trunk and face. It is frequently drug induced. There may be skin blistering and erosions covering less than 10 per cent of the body's surface area. This syndrome is distinct from toxic epidemal necrolysis (TEN) but there is a degree of overlap as severe forms of SJS can evolve into TEN and several drugs can produce both entities. The estimated incidence of SJS ranges between 1.2 and 6 per million population per year. In about 50 per cent of cases the cause is not known. The fatality rate is believed to be about 5 per cent.

A large number of drugs has been implicated as a cause f SJS. Penicillins, tetracyclines, sulphonamides and NSAIDs are among the most common. Patients with HIV infection seem to be at increased risk of developing SJS with co-trimoxazole. Drugs that may be responsible for the reaction should be stopped immediately. Management involves systemic corticosteroids, fluid replacement and antibiotics, if required. Drug rechallenge is never justified.

TOXIC EPIDERMAL NECROLYSIS

Toxic epidermal necrolysis (TEN), or Lyell's syndrome, is a rare variety of erythema with acute epithelial necrosis affecting all areas of the skin. The estimated incidence ranges from 0.4 to 1.2 per million population per year. It has a high associated mortality of about 30 per cent. In TEN, sheet-like skin erosion affects more than 10 per cent of the body surface and there is severe involvement of the mucous membranes (oropharynx, eyes and genitalia). The main cause in adults is drugs. Patients with HIV infection, systemic lupus erythematosus and bone marrow transplant recipients seem to be predisposed to this disorder. Elderly patients and those with extensive TEN have a worse prognosis. Drug-induced TEN is rare in children, in whom the diagnosis must be distinguished from staphylococcal "scalded skin syndrome."

TEN presents with a prodromal period of fever, conjunctivitis, pharyngitis, pruritus and, occasionally, difficulty in urination. These symptoms generally last two to three days and can resemble an upper respiratory tract infection. The burning or painful skin rash generally begins on the face or upper trunk and is characterised by poorly defined erythematous or dark coloured macules, irregular target-like bullae, or diffuse ill-defined erythema. The affected skin may develop flaccid bullaie or may detach irregularly, sometimes in large sheets. The lesions generally progress and extend in waves over a three to four day period, but can progress rapidly in a few hours, or more slowly. In most cases, mucosal lesions are present, particularly of the buccal mucosa, with the ocular and genital mucosa affected less often. The consequences of such a massive loss of epidermis include dehydration, increased energy expenditure, and local or systemic infection such as septicaemia. In severe cases, other organ systems can be involved: hepatocellular damage, pneumonia, nephritis and myocardial damage may occur. Skin sloughing can extend into the oesophagus and bronchial tree.

The mechanisms responsible for TEN are unknown although a hypersensitivity-immunological basis is suspected. A TEN-like eruption has occurred in patients with a graft-versus-host reaction after bone marrow transplant.

Identification of the causative drug is often difficult. In general, most drugs causing TEN have been given the previous one to three weeks. A drug is unlikely to be the cause if it was first given in the preceding 24 hours or if it has been taken for more than three weeks. However, phenytoin-induced TEN can occur at any time between two and eight weeks after initiation of therapy and may progress despite discontinuation of the drug.

There is some debate about where this serious condition should be managed. It has been suggested that management in a specialist burn units is preferred. Treatment involves the careful protection of exposed dermis and eroded mucosal surfaces, managing fluid and electrolyte balance, nutritional support, and close monitoring for evidence of infection. Antibiotic therapy should be reserved for treatment rather than given prophylactically. The place of systemic corticosteroids is controversia.

The Committee on Safety of Medicines has recently warned about the risk of serious skin reactions with the antiepileptic lamotrigine. About 1 in 1,000 adults develop these reactions, including Stevens Johnson syndrome and toxic epidermal necrolysis. Children appear to be at increased risk and the frequency of these problems may be as high as 1 in 300 to 1 in 100. Factors associated with an increased risk of skin reactions indoses, more rapid dose escalation than recommended, and concomitant use of valproate. Most of these problems have developed within eight weeks of starting lamotrigine and resolved upon withdrawal but deaths have occurred.

PANEL 8: SOME DRUGS THAT MAY CAUSE PEMPHIGUS-LIKE ERUTIONS

Captopril
Enalapril
Flupenthixol
Interleukin-2
Frusemide
Penicillins
Penicillamine
Sulphasalazine

PANEL 9: SOME DRUGS ASSOCIATED WITH PHOTOSENSITIVITY

Frequent:
Amiodarone
NSAIDsPhenothiazines(particularly chlorpromazine)
Retinoids
Sulphonamides
Tetracyclines (particularly demeclocycline)
Thiazides

Less frequent:
Antidepressants (tricylic, MAOIs)
Carbamazepine
Griseofulvin
Quinolones
Quinine
Sulphonylureas

PEMPHIGUS-LIKE ERUPTIONS

Idiopathic pemphigus and bullous pemphigoid are autoimmune disorders. Idiopathic pemphigus typically features superficial blisters, although sometimes erythema, crusting signs. Idiopathic bullous pemphigoid is characterised by large blisters developing on an erythematous base. A number of drugs, most of which contain a thiol (or sulphydryl) group in their molecular structure, has been implicated in causing a disorder closely resembling these idiopathic conditions (Panel 8). Cicatricical pemphigoid is a rare variant in which mouth ulcers, eye problems and other complications may develop, with subsequent scarring.

The drug-induced disorder has a broad spectrum of clinical presentation comprising widely scattered large, firm, bullae, clasical but fewer lesions, scarring plaques, an erthema multiforme-like picture and a pemphigus-like picture. In general, affected patients are younger than those with idiopathic disease. The drug-induced variant can feature clinical characteristics of both pemphigus and pemphigoid. The mechanism is unknown; both immune and toxic mechanisms have been proposed.
The entire clinical spectrum of pemphigus has been reported in association with penicillamine. As many as 7 per cent of patients taking the drug for more than six months develop a pemphigus-like eruption.

This is thought to be a cutaneous manifestation of the autoimmunogenic properties of the drug. Evidence suggests that the penicil-lamine-induced variant of pemphigus is essentially the same as the ediopathic condition. The disease usually improves when penicillamine is stopped but may persist for many years and recur on rechallenge.

PHOTOSENSITIVITY

Photosensitivity denotes a reaction occurring when a photosensitising agent in or on the skin reacts to normally harmless doses of ultraviolet or visible light. It can be caused by topical or systemic drugs (see Panel 9). Drug-induced photosensitivity is classified as either phototoxic or photoallergic.

Phototoxic reactions

Phototoxic reactions are common and can be produced in most individuals given a high enough dose of drug and sufficient light exposure. The eruption is usually evident within 5-20 hours of exposure and resembles an exaggerated sunburn with erthema, oedema, blistering, weeping and desquamation. The rash is confined to areas exposed to light. Hyperpigmentation may remain after other features have subsided. Patients taking potent phtosensitising agents should be warned of the problem and counselled on the need to avoid direct sunlight and to use sunblocks.

Amiodarone therapy is associated with a 30-50 per cent incidence of photosensitivity. Symptoms develop within two hours of sun exposure as a burning sensation followed by erythema. A minority of affected patients develop a slate-grey pigmentation on light exposed areas. Light sensitivity may persist for up to four months after the drug is stopped. Cutaneous pigmentation slowly fades after amiodarone is stopped but may persist for months to years. The problem is related to both the dosage and duration of drug therapy. Skin cells and cells of other organs in affected patients have been found to contain myelin-like lysosomal structures and membrane-bound granules. This generalised derangement of lysosomal storage may also be the basis for other adverse affects of amiodarone such as interstitial alveolitis, acute hepatitis and disturbed thyroid function.

Chlorpromazine may cause a phototoxic response when given in high dose. The reaction is characterised by a burning, painful erythema within minutes of exposure to sunlight, either directly or through window panes. Erythema may persist for more than 24 hors. Occasionally, a golden-brown or slate-grey pigmentation, predominantly of exposed sites, may be seen. Photoallergy is less common than phototoxicity and may occur following exposure to chlorpromazine powder.

Photoallergic reactions Photoallergic reactions occur in predisposed individual who have been previously sensitised. There is a latent period during which sensitisation occurs and the reaction generally develops within 24 hours of re-exposure. Unlike phototoxic reactions, the reaction may spread beyond irradiated areas. Most systemic drugs causing photoallergy also cause phototoxicity.

These reactions may occur as a result of local photocontact dermatitis to a topical photoallergen or a result of systemic drug therapy.

PANEL 10: SOME DRUGS THAT MAY CAUSE LICHENOID ERUPTIONS

Antimalarials	Beta-blockers
Captopril	Gold
Interferon alfa	Lithium
Methyldopa	NSAIDs
Penicillamine	Sulphonylureas

LICHENOID DRUG ERUPTIONS

Lichenoid drug eruptions (LDE) are so called because of their resemblance to idiopathic lichen planus. The first drugs reported to cause lichenoid skin reactions were arsenicals used in the treatment of syphilis. Several causative drugs are now known (Panel 10) although LDE is quite rare in comparison with other drug-induced skin reactions. The lesions can be described as small, shiny, polygonal papules, sometimes with charcteristic white lines known as Wickham's striae. They are usually itchy but they can be asymptomatic. The surrounding skin is completely normal. LDE can rarely affect the buccal mucosa; a characteristic white lace pattern may be present.

Lichenoid drug eruptions tend to be extensive and may be linked with, or develop into, an exfoliative dermatitis. LDE can also result from contact dermatitis in photo-graphic workers who handle certain phenylenediamines.

The clinical course of LDE has been investigated in many studies. The mechanism is thought to have an immunological basis. The time to onset of the reaction ranges from weeks to months after initiation of therapy. In most patients the symptoms cleared spontaneously within a few weeks of drug withdrawal. In prolonged or severe cases, topical or systemic corticosteroids may be used.●

DRUG-INDUCED SEXUAL DYSFUNCTION AND INFERTILITY

By Fiona Maclean, Msc, MRPharmaS, and Anne Lee, Mpbil, MRPharmS

The issue of sexual health, once regarded as a taboo subject, has been widely debated recently, provoked by the introduction of sildenafil, the first licensed oral treatment for make erectile dysfunction. It is now generally accepted that good sexual health is an important aspect of physical well-being and the possibility that drug therapy can cause sexual dysfunction is increasingly recognised. Although sexual dysfunction is not life threatening, it can have a major impact on personal relationships, quality of life and the ability to conceive. It is also an important factor in non-compliance; studies have confirmed that many patients with hypertension, depression and schizophrenia discontinue their medication because of sexual side effect.

Patient information leaflets may alert patients to the possibility that their sexual function may be affected. Pharmacists should have some knowledge of the types of problem that can occur in case questions arise. This article reviews the most frequently reported drug-induced sexual problems, including infertility.

The overall incidence of drug-induced sexual dysfunction is difficult to quantify. Patients are often unwilling to raise issue of sexual health with health professionals, leading to under-reporting of problems. In addition, many diseases can affect sexual function, making it difficult to establish casualty with a drug rather than concurrent illness. Antihypertensive medication, for example, is associated with erectile dysfunction and is often prescribed for hypertension in patients with diabetes, with itself may cause impotence. Other factors that can influence sexual function in men and women are age, alcohol consumption, smoking, drugs of abuse, over-the-counter medicines and exposure to environmental or occupational toxins. Most of the published literature relates to the adverse effects of drugs on male sexual function. It is more difficult to assess these effects in women and this aspect of drug safety has seldom been considered in clinical studies. The effects of environmental exposures and drugs of abuse will not be considered here.

Sexual dysfunction as a consequence of drug therapy has been reported with a range of drugs, notably antihypertensives, antipsychotics and antidepressats. Yellow card reports to the Committee of Safety of Medicines (CSM) involving reproductive dysfunction constitute a small proportion (generally less than 5 percent) of the total received. Serious reactions in this category include infertility, congenital abnormalities and some pregnancy complications.

CASE STUDY

Dr. M. a consultant psychiatrist, contacts the drug information centre about one of his patients. Mr. J is a 42-year-old man with depression. He showed a good response to fluoxetine during a previous episode about three years ago. However, he stopped treatment abruptly when he noticed that he had difficulties with erection and ejaculation. Mr. J. has now told the psychiatrist that he would rather be depressed than take another drug that will ruin his sex life.

Dr. M, is aware that problems like this have been described with most antidepressants. He would like to know if there is any evidence that another SSRI or one of the newer antidepressants, would be less likely than fluoxetine to cause these problems.

How common is sexual dysfunction with SSRIs? Are both men and women affected?

The exact incidence of these problems is unknown. The reported frequency ranges between 2 and 75 per cent but data from controlled clinical studies are lacking. It is likely that at least 20 per cent of patients will experience problems. The reported frequency is usually higher in men, who complain of decreased libido, delayed ejaculation, erectile difficulty or anorgasmia. There is also evidence that women may experience loss of libido or orgasm dysfunction.

Would another SSRI or a newer antidepressant be less likely than fluoxetine to cause problems?

Of the SSRIs, there are limited data to suggest that paroxetine may be associated with an increased rate of sexual difficulties compared with fluoxetine, fluvoxamine and sertraline. It has been suggested that nefazodone and mirtazapine are associated with a low incidence of sexual effects but this requires confirmation.

If problems do develop might they remit during continued treatment?

Here have been reports of tolerance to sexual side effects developing, sometimes after months of treatment. If the antidepressant is affective it may be worth continuing it for a period of time to see whether the problem resolves, if this is acceptable to the patient and their partner. Some patients may

find that the effect diminishes but does not disappear entirely.

How else could this problem be managed? Would sildenafil be of benefit?

The preferred approach is to find a medication that is effective without causing sexual adverse effects. These problems are generally dose related so it is important to ensure that the minimum affective dose is given. In a patient who experiences problems it is not clear whether switching from one SSRI to another is helpful but it may be tried.

There are reports of a "drug holiday" being used to allow patients to time sexual intercourse with a medication-free period. However, this is not a very practical option and can only be tried with short half-life drugs.

Sildenafil is of benefit in erectile failure but there is limited evidence of efficacy in drug-induced sexual dysfunction. A number of specific treatment strategies have been reported to be effective in reversing SSRI-induced sexual dysfunction, including cyproheptadine (an antihistamine with serotonin blocking properties), yohimbine (a pre-synaptic alpha-blocker), amantadine, buspirone, granisetron and gingko biloba. Adding a medication to treat the adverse effect of another should always be avoided if possible because of the potential for additional adverse effects and drug interactions.

INFERTILITY

Infertility is one element of a spectrum of reproductive disorders that includes miscarriage, congenital abnormality, premature delivery and still birth. Infertility – defined as the failure to conceive after two years of unprotected intercourse – is fairly common, affecting about 15 percent of all couples at some time during their reproductive lives. It is generally only detected when a couple is actively trying to conceive. It can be difficult to draw firm conclusions about trends in infertility rates but the high number of patients currently attending fertility clinics suggests a growing problem.

Causes of infertility in women include failure of ovulation, tubal damage, endometriosis and hostile cervical mucus. In men, sperm defects, coital factors such as impotence or retrograde ejaculation, and hypogonadism may be implicated. In as many as 30 percent of cases, a cause cannot be found. Drugs and other toxins may be reponsible in a small proportion of cases, but, in general, the effects of drugs on fertility have been poorly studied.

The activity of the gonads (testes or ovaries) is regulated by the pituitary gonadotrophins, follicle stimulating hormone (FSH) and luteinising hormone (LH). Secretion of both hormones is controlled by gonadotrophin-releasing hormone (GnRH) from the hypothalamus. FSH regulates the development of Sertoli cells (which are involved in sperm maturation) in the testes and the Graafian follicle in females. LH controls formation of the corpus luteum in females and testosterone production by the Leydig cells in males. Both FSH and LH regulate oestrogen production and ovulation. Decreased amounts of FSH and / or LH reaching the testes can inhibit spermatogenesis.

PANEL 1: SOME DURGS THAT MAY CAUSE PRIMARY INFERTILITY

Alkylating agents (eg, chlorambucil, cyclophosphamide, melphalan)
Anabolic steroids
Colchicine
Diethylstilbestrol
Methotrexate
NSAIDs (females)
Procarbazine
Sulphasalazine (male)
Vincristine

Primary drug-induced infertility results from a direct toxic effect of the drug on the gonads or an indirect effect on pituitary gonadotrophin secretion (see Panel 1). Secondary drug-induced infertility results from drug effects on erection, libido or performance which may compromise the ability to conceive.

Cytotoxic chemotherapy can cause infertility by a direct effect on the gonads. The effects differ in men, women and children and depend on the patients' stage in reproductive life at the time of treatment. The dose and duration of drug exposure are also important. The potential effect of chemotherapy on reproductive function is an important consideration in cancer treatment, particularly of young patients. Now that a number of cancers are curable, the long-term effects of chemotherapy on fertility may influence the choice of therapy. Men may be offered sperm banking before treatment is begun but for many reasons this may not be possible or successful. As cryopreservation of female ova is not yet established, women may be faced with the prospect of premature menopause and/ or drug-induced infertility.

Alkylating agents are highly toxic to the testes. Cyclophosphamide and chlorambucil have been most extensively studied. The extent of gonadal damage depends on the dose and duration of treatment. Typically there is a progressive decline in sperm numbers, leading to azoospermia (absence of sperm) within several months which may be irreversible. Damage might be avoided if low doses are used. There is often partial recovery of spermatogenesis after cyclophosphamide treatment and with chlorambucil recovery can occur even after many years.

Methotrexate is thought to be less toxic that the alkylating agents but it still causes a reduction in sperm count. Reversible reductions in sperm count have been reported with the use of low doses of methotrexate in treatment of psoriasis. Vincristine and cisplatin have been reported to cause azoospermia.

In general, combination chemotherapy, at least in males, appears to produce persistent effects on reproductive function than single agent treatment.

It is more difficult to determine how chemotherapy affects female reproductive function as there is no direct way of monitoring toxic effects on the ovaries. Gonadal damage is often manifest by amenorrohoea, low oestrogen levels, and increased concentrations of FSH and LH, which resemble the hormonal changes seen at menopause. As in men, alkylating agents appear to be the most toxic. Primary ovarian failure has been reported with both melphalan and cyclophosphamide.

Sulphasalzine was reported to cause oligospermia (subnormal concentration of sperm) and infertility in men with inflammatory bowel disease 20 years ago. The effects on sperm become apparent within two months of starting treatment. Sperm motility is reduced, abnormal forms develop and sperm density is decreased. These effects on sperm function are probably due to the sulphapyridine component of sulphasalzine; slow acetyloators of the drug are more likely to be affected. Return to normal fertility has been reported when treatment was changed to mesalazine.

Diethylstilbestrol (DES), a synthetic oestrogen given to pregnant women between 1940 and 1970 to prevent threatened and recurrent abortion, is known to cause a number of reproductive tract abnormalities in the offspring of exposed women. These effects include clear-cell adenocarcinoma of the vagina, anatomical abnormalities of the uterus, and increased risk of ectopic pregnancy, miscarriage and premature delivery. Fertility rates appear to be reduced in the daughters but not in sons of exposed women.

Anovulation and amenorrhoea About 30 per cent of infertile women have anovulatory infertility. They may present with amenorrhoe (primary or secondary), oligomenorrhoea (infrequent or irregular periods) or occasionally with regular menstrual cycles but low or undetectable serum progesterone concentrations in the putative luteal phase. Secondary amenorrhoea is defined as the absence of menstruation for at least six months in a woman with a previously normal and regular menses. Hyperprolactinaemia is a common finding in women with amenorrhoea; occasionally this is drug-induced.

Drugs known to increase prolactin include methyldopa, metoclopramide, cimetidine, phenothiazines and oestrogens. Amenorrhoea is also associated with high dose corticosteroids, danazol and isoniazid.

PANEL 2: SOME DRUGS THAT MAY CAUSE ERECTILE DYSFUNCTION

Anti-androgens (eg, finasteride)
Anticholinergics
Antidepressants (tricyclics, MAOIs, selective serotonin reuptake inhibitors)
Benzodiazepines
Beta-blockers
Carbamazepine
Cimetidine
Digoxin
Finasteride
Methyldopa
Meoclopramide
Omeprazole
Phenothiazines
Phenytoin
Prazosin
Spironolactone
Thiazide diuretics

There has in the past been concern about a high incidence of amenorrhoea shortly after stopping combined oral contraceptives. However, studies have shown that the incidence of amenorrhoea is no greater that in the general population and that subsequent fertility is probably not impaired by previous use of oral contraceptives.

Spironolactone has been reported to cause amenorrhoea at daily doses of 100-200mg. Normal mentrual periods usually return within two months of spironolactone being stopped. The mechanism is believed to involve inhibition of didydrotestosterone binding to androgen receptors.

Evidence is accumulating that non-steroidal anti-inflammatory drugs (NSAIDs) taken in the middle of the menstrual cycle may inhibit ovulation. It has been suggested that the NSAID prevents rupture of the ovarian follicle which has developed normally. Progesterone levels measured in the second half of the menstrual cycle may be compatible with ovulation having occurred, which can obscure the diagnosis.

This problem has been reported with indomethacin, diclofenac and naproxen. NSAIDs should preferably be avoided around the time of ovulation in women trying to conceive and should be withdrawn in women undergoing investigation of infertility.

SEXUAL DYSFUNCTION

Sexual function may be divided into three categories reflecting the sexual response cycle: (1) libido or sexual desire; (2) arousal, including erectile function in men and lubrication in women; and (3) release (orgasm in women and ejaculation in men). Drug can affect one or more areas of the response cycle.

Understanding of the sexual response remains incomplete but there is evidence of dopaminergic, adrenergic, muscarinic and serotonergic involvement. In general dopamine increases sexual behaviour and serotonin inhibits it. Libido is influenced by reproductive hormones and the

emotional and physical health of the individual. Testosterone is necessary for normal sexual arousal, probably in both men and women and in the men testosterone deficiency is associated with impotence.

ERECTILE DYSFUNCTION AND EJACULATORY DISORDERS

Erectile dysfunction, or impotence, is the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. It is the most common form of male sexual dysfunction with a prevalence of up to 10 per cent across all ages, rising to over 50 per cent in men between 50 and 70 year old. The aetiology is often vascular but other contributory factors include drug therapy, endocrine disease and neurologic dysfunction.

Erectile dysfunction often occurs with diabetes, heart disease, hypertension and peripheral vascular disease. It may also be consequence of spinal cord injuries and pelvic or perineal radiotherapy or surgery. Smoking and alcohol intake are important contributing factors.

Male sexual function depends on the co-ordination of neurogenic, hormonal and psychological mechanism and disruption on one or more of these may result in erection dysfunction. The penile blood vessels and smooth muscle receive both sympathetic and parasympathetic innervation and erection is primarily a parasympathetic function. In the flaccid state the smooth muscle is contracted, preventing inflow of blood. Parasympathetic nerve stimuli, mediated by nitric oxide, relax the smooth muscle of the arterioles in the corpora cavernosa, allowing blood to flow rapidly into the penis. Venos outflow from the penis is reduced, blood is trapped within the corpora cavernosa, and rigid erection ensues.

About 25 per cent of cases of erectile dysfunction are believed to be drug-induced. The classes of drugs most frequent implicated are antihypertensives, antidepressants, antipsychotics and anti-epileptics (see Panel 2).

Ejaculation describes the expulsion of seminal fluid from the posterior urethra. This is achieved via stimulation of alpha-adrenergic receptors, leading to contracting of the smooth muscle of the prostate, seminal vesicles and vas deferens.

Disorders of ejaculation comprise ejaculatory failure and retrograde ejaculation in which semen passes into the bladder. A number of drugs have been implicated in these disorders.

Antihypertensives. The prevalence of both erectile dysfunction and ejaculatory disorders in significantly greater in untreated hypertensive men than in match normotensive controls, so caution is needed when assessing whether medication is likely to be the cause of such problems. Most demiological studies addressing this issue were carried out over 10 years ago when the types of drugs used did not reflect those in use today. More recent studies confirm that the rate of erectile dysfunction depends on class of antihypertensive. The effects of treatment on quality of life are particularly important in the management of hypertension, which can require lifelong therapy despite being asymptomatic. Evidence suggests that many hypertensive patients experiencing sexual side effect will stop taking their medication.

High rates of erectile dysfunction and ejaculatory failure are associated with the older adrenergic blockers reserpine and guanethidine, which are no longer used. Clonidine and methyldopa have also caused loss of libido, erectile dysfunction and ejaculatory failure. The alpha-adrenergic blockers indoramin and prazosin can cause ejaculatory failure and retrograde ejaculation.

The incidence of sexual dysfunction in men taking diuretics is between two and six times higher than in men taking placebo. Thiazides may cause reduced libido, erectile dysfunction and problems of ejaculation. The underlying mechanism as thiazides lack significant hormonal, autonomic or central nervous system effects but a direct on smooth muscle is thought to be responsible.

Erectile dysfunction is well documented with propranolol and can occur with other beta-blockers. The problem is more likely with lipid soluble beta-blockers but has also been reported with atenolol and with ophthalmic timolol. Reduced perfusion pressure caused by a drop in blood pressure or a direct effect on smooth muscle may be responsible.

Calcium channel blockers seem to cause fewer problems with sexual function than diuretics or beta-blockers although there are several published case reports or erectile dysfunction.

Erectile dysfunction does not seem to be a problem with angiotensin coverting enzyme (ACE) inhibitors

Psychotropic drugs. As sexual dysfunction is a common feature of psychiatric illness, particularly depression, it can be difficult to assess the relative contribution of the disease and drug therapy. Both antidepressants and antipsychotics have recognised adverse effects on sexual function in men and women.

Erectile dysfunction has been described with all classes of antidepressant. Numerous case reports have implicated tricyclic antidepressants (TCAs) but the association has not been confirmed in the few published controlled trials.

There is consistent evidence that serotonergic antidepressants (eg, selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors (MAOIs) and clomipramine) are associated with high rates of decreased libido, ejaculatory disturbance, delayed orgasm and anorgasmia. Serotonin appears to have a mainly inhibitory effect on sexual function. The mechanism of orgasm has not been confirmed but it is thought to be regulated by a balance of cholinergic and adrenergic influences and that serotonin receptor stimulation inhibits adrenergically mediated ejaculation.

Evidence that SSRIs cause sexual dysfunction is accumulating as their use increasese. The reported incidence varies widely, mainly because of differences in methodology between studies, but is probably at least 20 per cent. Problems may occur with all SSRIs. Delayed orgasm or ejaculation appears to be the most frequent problem and this has been observed in controlled studies. As a consequence of this effect, the SSRIs are now used in the treatment of premature ejaculation.

MAOIs can also cause delayed ejaculation. The phenothiazines, particularly thioridzine, have caused changes in ejaculation (no ejaculate or a reduced volume) and pain on orgasm. Chlorpromazine is also associated with dose-related ejaculatory failure. Newer antipsychotics, such as olanzapine, may be less likely to cause these problems.

Priapism Priapism is a prolonged penile erection which is usually unrelated to sexual stimulation. The problem occurs when the regulatory mechanisms which initiate and maintain penile flaccidity are disturbed and venous drainage from the corpora cavernosa is obstructed. It is a medical emergency requiring immediate treatment to prevent fibrosis or even gangrene. Management involves the aspiration of blood and administration of a vasoconstrictor sympathomimetic such as phenylephrine.

Drug therapy is an important cause of priapism, accounting for up to 40 per cent of cases (see Panel 3). Alpha-adrenoceptor antagonism is the most likely mechanism; constriction of the blood vessels supplying erectile tissue is prevented and detumescence does not occur.

Prazosin is the drug most frequently associated with priapism. Among psychotropic drugs, the phenothiazines and the antidepressant trazodone are most commonly implicated. Trazodone-induced priapism may affect patients at any age and is most likely to occur in the first month of treatment. Priapism has also been attributed to hydralazine, nifedipine, anticoagulants and risperidone.

Drugs given by instracavernosal injection in the treatment of erectile dysfunction (eg, papaverine, phenotolamine, alprostadil) may cause priapism and patients should be warned of this and advised to seek prompt medical attention should it occur.

PANEL 3: SOME DRUGS THAT MAY CAUSE PRIAPISM

Anticoagulants	Haloperidol
Hydralazine	Nifedipine
Papaverine	Phenothiazines
Phentolamine	Prazosin
Risperidone	Trazodone

FEMALE ORGASM DYSFUNCTION

In women, sexual dysfunction has not been thoroughly investigated and the underlying mechanisms are not fully understood. Most reported problems relate to orgasm dysfunction, reduced vaginal lubrication or loss of libido. Female orgasm involves involuntary rhythmic vaginal and pelvic muscle contractions; it can be assumed that the neurovascular control is similar to that in males. Thioridazine has been known since 1961 to inhibit ejaculation in men but it was not until 20 years later that the first report of inhibition of female orgasm was published.

Failure to achieve orgasm (anorgasmia) is one of the most common sexual adverse effects of psychotropic drugs in women. This problem has been described with SSRIs. Delayed orgasm or anorgasmia has been reported with MAOIs, TCAs, clozpine and risperidone. The antihypertensives clonidine and methyldopa have also been linked with anorgasmia (see Panel 4). Multiple spontaneous orgasms have been described in women treated with fluoxetine. There have also been occasional case reports of spontaneous orgasm induced by yawning caused by clomipramine and by fluoxetine.

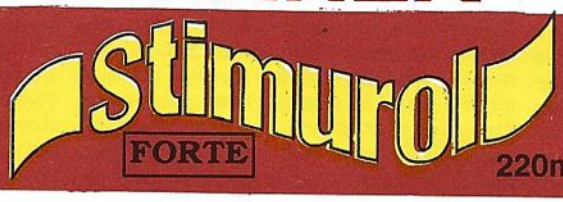
ALTERED LIBIDO

Loss of libido or sexual desire is frequently attributed to medication in both men and women. For example, all drugs causing central nervous system depression can potentially decrease libido. In women, loss of libido is the commonest reported form of sexual dysfunction; it is extremely difficult to quantify and manage. Changes in desire may be due to illness (e.g., gynaecological disorders causing pain on intercourse), stress or fatigue, or may be drug-induced. In controlled studies women have rarely been questioned about the effect of medication on sexual function and therefore most reports of altered libido are anecdotal or case reports.

Several anthypertensives, including clonidine and methyldopa, reduce female libido. Studies of both men and women taking methyldopa report an incidence of decreased libido ranging from 7 to 14 per cent. Spironolactone has anti-androgenic effects and is clearly linked with decrease libido. Propranolol, thiazide diuretis and calcium antagonists are believed to have mild effect (if any) while captoril appears to have no effect.

Continue on page 41

DANNEX



PROPERTIES

Stimurol is a formulation which possesses the ideal pharmacological response to the clinical problem of anorexia, both organic and psychological.
Cyproheptadine acts selectively on the hypothalamic centre of the appetite, starting up the neurovegetative mechanism thereby diminishing the "fullness threshold".
Lysine, which is an important aminoacid in metabolism has been added, and its action is augmented by the presence of the B-group vitamins which are well known for their energizing properties.

INDICATIONS

Anorexia of all types (both in children and adults)
Constitutional thinness.
Antiallergic - antipruritic

DOSAGE AND ADMINISTRATION:

1. Children: Syrup - 1-7 years half teaspoonful of 5ml twice daily before meals.
   7-12 years one teaspoonful of 5ml thrice daily before meals.
2. Adults: Syrup - Two teaspoonful of 5ml thrice daily before meals.
   Capsule - One capsule thrice daily before meals.
3. If and when drowsiness occurs, it is a good sign for computing the dosage; it is even desirable for drowsiness to occur slightly in nervous children because their psychic condition improves simultaneously. Any drowsiness, however, tends to disappear a few days after treatment has begun.
4. The effects of treatment are usually observed between 4 and 10 days after administration is initiated. Treatment can be administered for periods of one or two months with rest periods of 15 days to 1 month, without any undesirable side effects having been noticed nor any alteration of the humoral constants.

CONTRAINDICATIONS : None
SIDE EFFECTS: : May cause drowsiness. If affected do not drive or operate machinery.
Avoid alcoholic drinks.

PRODUCED BY
DANNEX LIMITED
P.O. BOX 5258, ACCRA–NORTH
GHANA

Psychotoropic drugs affect sexual desire in men and women in several possible mechanism, including sedation, effects on central or peripheral neutrotransmitters, or effects on hormones (e.g. prolactin). Antidepressants have been reported to decrease libido, possibly as a consequence of an indirect effect on dopamine; the incidence in men and women may be as high as 40 per cent.

In general, rate of sexual dysfunction appear to be greater with the SSRUs, followed by MAOIs then TCAs. Rates of sexual dysfunction appear to be similar for all the SSIRs and it is known if switching between them will diminish sexual side effects.

Case reports of decreased libido with anxiolytics have been published; centrally-mediated sedation and muscle relaxation are thought to be responsible.

Cimetidine has been reported to cause loss of libido, possibly because of its anti-androgen activity. This is likely to be dose-related. The problem is not seen with ranitidine.

The influence of testosterone on libido is well recognised and any drug that reduced serum testosterone may lead to a loss of sexual desire. In men, this includes drugs such as oestrogens, antiandrogens and gonadorelin analogues.

There are preliminary date linking protease inhibitors with loss of libido and also with erectile dysfunction and problems with ejaculation.

Increased sexual desire is a rare adverse effect. Trazodone has been reported to increase libido in both men and women, possibly by decreasing prolactin levels or by increasing dopamine. Levodopa has caused hypersexuality in men with Parkinson's disease. The reversible inhibitor of monoamine oxidase A, moclobemide, has been reported to increase sexual desire in some patients.

MANAGEMENT

The management of drug-induced sexual dysfunction can be difficult. Occasionally these problems may remit spontaneously over time. In some situation it may be possible to change therapy to a drug in another class which is less likely to cause problems, e.g. changing from a thiazide to an ACE inhibitor in hypertension. There may not always be an effective or tolerated alternative, however. Other possible potions may include dose reduction, delaying dosing until after sexual intercourse, or advocating "drug holidays." Pharmacoligical management of drug-induced sexual dysfunction with agents such as cyproheptadine or sildenafil is seldom indicated (see case study).

Sexual dysfunction due to medication is relatively uncommon and probably not an issue that the pharmacist will be consulted about very often. If approached by a patient or partner about the possibility that a sexual problem may be drug-related, a sympathetic and non-judgmental attitude should be adopted. The pharmacist may be able to give some general guidance about the likelihood that a particular drug therapy is involved. However, there are complex and sensitive issues surrounding sexual dysfunction and in most cases, if not every case, the individual should be advised to discuss the matter with his or GP.

PANEL 4: SOME DRUGS THAT MAY AFFECT FEMALE SEXUAL FUNCTION

Antidepressants (tricyclics, MAOIs, selective serotonin reuptake inhibitors)

Benzodiazepines	Cimitidine
Clonidine	Gonadoreline analogues
Methyldopa	Oestrogens
Propranolol	Spironolactone
Thiazide diuretics	Trazodone

A REVIEW OF MEDICATION USE IN PREGNANCY

By Katherine Ferrara Koffer, B.S. Pharm.D.

Through pharmaceutical expertise, pharmacists can accomplish their primary goal in healthcare – to enhance the care that is provided by a patient's primary caregiver. Many over the counter (OTC) medications, such as caffeine, alcohol, and nicotine, are widely available. Because of this easy access, a few laypersons perceive the dangers involved with the use of these medications. The frequency of drug use among pregnant women is alarming, despite the propensity of such practice to result in various problems for the fetus. It is vital that pharmacist educate women in their childbearing years about he risks and benefits of all drugs, especially those that are available without a prescription. This article will facilitate the provision of appropriate information that is essential for a healthy pregnancy.

FETAL DEVELOPMENT

Pregnancy begins with the fertilization of the egg, normally during or immediately after ovulation (usually 14 to 15 days after the onset of menses). The ovulatory or fertilization age calculates the age of the fetus relative to the time of ovulation, yet few use this nomenclature. When determining delivery dates, most clinicians use the more common, albeit the less technically correct, menstrual or gestational age. Gestational age assumes the normal pregnancy to be 40 weeks (approximately nine and one-third calendar months) from the first day of the last menstrual period. In this article, all dates provided are relative to gestational age.

The assignment of trimesters is commonplace to pregnancy because many of the milestones of pregnancy, as well as many obstetrical problems, are encountered specifically in one of these three periods. The first trimester includes weeks 1-12, the second includes weeks 13 through 24, and the third includes weeks 25 to term, normally 40 weeks.

By the end of the first 10 weeks, all the major organs as well as the circulatory, neural, and skeletal systems have begun their synthesis. At this point in pregnancy, the effects of teratogens are especially dramatic.

Some assume that the placenta, which is fully functional by the end of the first trimester, serves as a protective barriers to the fetus. In reality, during the last two trimesters, birth defects may arise as a direct result of medication consumption by the mother. The placenta is an organ of metabolic interchange between the fetus and the mother. It does provide some selective transportation, but the placenta is not impermeable. Although the extent of fetal exposure varies depending on drug concentrations in the mother, the ability of the fetus to metabolize and detoxify the substance, and other variables, exposure of a substance to a mother translates into exposure of that substance to the fetus.

LEARNING OBJECTIVES

After successfully completing this article, the pharmacist will be able to:

1. List and define the fetal risk categories and the limitations involved in using these categories.
2. Explain why dietary supplementation with vitamins, particularly folic acid, is necessary during pregnancy.
3. List the warning signs of problems during pregnancy.
4. Explain why early diagnosis of pregnancy is crucial.

CASE 1

A patient request a refill for her acne prescription (doxycline). While purchasing a home pregnancy test. Upon questioning, she informs you that she doubts that she is pregnant, but her menstrual period is 2 weeks late. What information should you give her?

Because a woman may experience denial or vague symptoms (ie, nausea and fatigue), one missed menstrual period may not seem significant. Diagnosis of pregnancy may easily be delayed until after successive missed periods when anatomical changes are more suggestive of pregnancy. If pregnancy is recognized during the first week after the first missed menstrual cycle, the woman is already 5 weeks pregnant.

Any woman purchasing a home ovulation predictor or pregnancy test should be counseled about the detrimental effects of drugs. This patient should be advised to contact an obstetrician to schedule a prenatal examination if the result of the pregnancy test is positive. Because she may not see the obstetrician immediately, it is appropriate for the pharmacist to telephone the prescribing physician to request a safer alternative to doxycycline for this patient during the interim. This patient should be educated about the effects of all types of drugs, including OTC medications, during the very early weeks of pregnancy.

TABLE 1: RISK FACTORS FOR FETAL EXPOSURE

CATEGORY A: Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester, and no evidence suggests a risk in later trimesters. The possibility of fetal harm appears to be remote.

CATEGORY B: Animal reproduction studies have not shown a fetal risk, but no controlled studies have been done in pregnant women; or animal reproduction studies have shown an adverse effect other than a decrease in fertility that was not confirmed in controlled studies in women in the first trimester of pregnancy, and no evidence suggests a risk in the later trimester.

CATEGORY C: Studies in animals have shown teratogenic, embryocidal, or other adverse effects on the fetus, and no controlled studies have been done in women; or studies in women or animals are not available. Drugs in this category should only be given if the potential benefit justifies the potential risk to the fetus.

CATEGORY D: Positive evidence has shown human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk.

CATEGORY X: Studies in animals or humans have shown fetal abnormalities; and/or evidence of fetal risk exists based on human experience. The risk for the use of this drug is pregnant women clearly outweighs any possible benefit. Drugs in this category are contraindicated in women who are, or may become, pregnant.

DRUGS IN PREGNANCY

When medicating a pregnant woman, it is crucial to recognize that at no point during the pregnancy is the fetus immune to toxins. Because of organ genesis, the fetus is especially sensitive to toxins during the first trimester. The thalidomide disaster of the 1960s provides a horrific reminder. At that time, thalidomide was prescribed during early pregnancy to combat morning sickness. Approxi-

mately one-third of the fetuses exposed to this drug *in utero* were born with phocomelia, a severe deformity of long bones. The ultimate tragedy was that thousands of babies were born without limbs before this problem was linked to thalidomide.

The effects of drug exposure *in utero* are not limited to dramatic anatomical defects present at birth. Certain functional, sensory, and behavioral difficulties have been associated with fetal drug exposure at various stages of pregnancy. The use of drugs at any stage of pregnancy may increase the risk for spontatneous abortion, growth impairment, and other more subtle defects that may not be detected until later in life.

In some instances (ie, hypertension, hypothyroidism, diabetes, asthma, infections), the use of a pharmacologic agent is essential to ensure the health of the mother. Ideally, the drug used should be effective for the given indication and safe for both the mother and the fetus. Although all drugs must be shown to be safe and effective to receive FDA-approval, teratogenicity data of new drugs are commonly lacking. In fact, it is not feasible or ethical to conduct large scale, controlled studies with potentially teratogenic drugs to document the safety of an agent. Moreover, the results of such a study may not prove to be conclusive for decades. Animal research is helpful, but it too has limitations.

In 1984, the FDA published fetal risk factors to assist in identifying the level of risk certain prescription drugs impart to a fetus. Definitions for identified risk categories are shown in Table 1. The category of the drug (A, B, C, D, or X) can be located in the precaution section of the prescribing information for that drug. This system is often useful for providing a quick reference to the teratogenicity of particular drugs, but the weaknesses of using this system as a sole reference must be recognized (Table 2). These risk factors may oversimplify very complex information. Also, the assignment of risk factors is not required for OTC medications or vitamins (vitamins are considered by the FDA to be foods, not drugs).

When considering the use of a drug in a patient who is, or may be, pregnant, the following points should be noted:

1. No pharmacologic agent should be used unless it is absolutely necessary. Elements of risk versus benefit must be considered.
2. Category B drugs are generally regarded as being safe if used appropriately and in therapeutic doses. Chronic use should be avoided unless this treatment is absolutely essential to the health of the mother.
3. Category C drugs are probably safe if used as directed. Because of a lack of consensus regarding safety, the pharmacist should contact the patient's obstetrician before recommending an OTC product in this category.
4. OTC medications listed in category D should not be recommended to a patient. If a prescription drug in this category is prescribed to a pregnant patient, a call to the prescribing physician is warranted, and an alternative medication may be suggested.
5. Category X drugs should never be dispensed.
6. When an appropriate drug is prescribed, every attempt should be made to reduce any fear that patient may have about taking that drug during pregnancy.

CASE 2

A woman who is 3 months pregnant and suffering from a urinary tract infection enters the pharmacy with a prescription for amoxicillin 250mg TID x 10 day. She is concerned that the drug may be harmful to her baby. How should you counsel her?

A precautionary statement in the prescribing information for amoxicillin states, "Safety for use in pregnancy has not been established." Because amoxicillin was approved before the FDA assignment of fetal risk factors, the manufacturer is not required to provide one. For such drugs, or for any questionable drug, it is prudent to use another reference. Drugs in Pregnancy and Lactation by Briggs, Freeman, and Yaffe provides a comprehensive list of drugs, and the authors assign fetal risk factors according to pertinent studies. If the manufacturer has already assigned a letter appear in this text. This text also provides summaries of pertinent information for each drug listed as well as references. As with any text, the most current recommendations may not be presented.

In the aforementioned text, amoxicillin is in category B. Further reading describes amoxicillin as being safe and effective for use during pregnancy. This patient should be assured that this drug has been used routinely in pregnant women, and its use has not been associated with any adverse effects on the fetus.

Pregnant women often suffer from various relatively minor ailments, ranging from morning sickness to constipation, provoking a high degree of self-medication. Pharmacists can direct pregnant women to appropriate remedies and safeguard against improper use of the medications. In general, OTC medications should be reserved until after more conservative, non-drug treatments have been tried. Selected OTC medications and their respective risk categories are listed in Table 3.

ANTIEMETICS

Nausea may or may not occur in the morning ("morning sickness"), and it may in fact worsen at the end of the day. For most women, this common symptom of pregnancy subsides after the first trimester. Unfortunately, no effective OTC remedies exist to treat nausea. Non-pharmacologic treatments, such as eating crackers or small frequent meals, will often provide equally effective relief as the OTC product dimenhydrinate. The effectiveness of both these treatments in minimal, but the non-pharmacologic method involves no risk to the mother or the fetus.

ANALGESICS

Many products contains aspirin both alone and in combination with other medications. In general, the use of aspirin should be avoided throughout pregnancy. High doses of aspirin have been associated with newborn and maternal hemorrhage, increased perinatal mortality, impaired perinatal growth, and other birth defects. If ingested near term, aspirin can prolong pregnancy and labor. Additionally, aspirin use late in pregnancy can effect the closure of the ductus arteriosus. If this fetal heart vessel does not close postnatally, surgery may be required.

Nonsteroidal anti inflammatory drugs (NSAIDS) have not yet been shown to be harmful to the fetus if used during the early stages of pregnancy. These agents should not be used in the third trimester because consequences similar to those encountered with aspirin use may result.

Acetaminophen is generally believed to be safe throughout pregnancy. In most cases, acetaminophen is the drug of choice in pregnant women when an analgesic or antipyretic is indicated.

ANTACIDS

Heartburn is a common occurrence during the various stages of pregnancy. Its severity may be decreased by avoiding large meals and late night snacks. Pharmacologically, low dose antacids may be used short term. Calcium carbonate products may be preferable because in addition to being effective antacids, they also provide additional calcium that is needed during pregnancy.

Alginic acid products are a suitable alternative to treat heartburn in pregnant women. Sodium bicarbonate should not be used due to the risk of sodium overload. Additionally, aluminum salts should be avoided in pregnant women because of their tendency to cause constipation.

TABLE 3. SELECT OTC DRUGS AND FETAL RISK FACTORS

A: FOLIC ACID

B: ACETAMINOPHEN
PSEUDOEPHEDRINE
CHLORPHENIRAMINE
PHYRILAMINE
DIMENHYDRINATE [M]
SENNA
IBUPROFEN [D]
SIMETHICONE

C: ASPIRIN[F]
NIACIN [G]
BROMPHENIRAMINE [M]
RIBOFLAVIN
DOCUSATE CALCIUM [F]
THIAMINE
DOCUSATE POTASSIUM[F]
VITAMINS A[B], B_{12}, C AND D[C]
OCUSATE SODIUM [F]
MINERAL OIL[G]

M = RISK FACTOR DESIGNATED BY MANUFACTURER OF PRODUCT *(ALL OTHER DESIGNATED BY THE AUTHORS OF DRUG IN PREGNANCY AND LACTATION.*

A = RISK FACTOR C IF USED IN AMOUNTS EXCEEDING RDA.

B = RISK FACTOR X IF USED IN AMOUNTS EXCEEDING RDA.

C = RISK FACTOR D IF USED IN AMOUNTS EXCEEDING RDA.

D = RISK FACTOR D IF USED IN THIRD TRIMESTER.

E = RISK FACTOR D IF USED IN FULL DOSE IN THIRD TRIMESTER.

F = CHRONIC USE OF 150-200 MG/D HAS BEEN ASSOCIATED WITH HYPOMAGNESEMIA IN THE NEONATE.

G. = CHRONIC USE MAY DECREAE ABSORPTION OF FAT SOLUBLE VITAMINS.

Continue on page 45

COUGH, COLD AND ALLERGY PREPARATIONS

Because most available cough and cold products are combination products, it is difficult to select one that is appropriate for a pregnant woman. As with any medications, if uncertainty exists about the acceptability of the product, the patient's obstetrician should be consulted. Also, most liquid cough and cold preparations contain some percentage of alcohol and should be avoided because of the risk of fetal alcohol syndrome.

If an antihistamine is indicated, shlorpheniramine is a reasonable choice. It is important to note that all antihistamines should be avoided during the last 2 weeks of pregnancy because of the link between antihistamine use and retrolateral fibroplasia, an abnormal increase of noncancerous fibrous tissue.

Unfortunately, little data exists concerning the use of many OTC decongestants and cough suppressants during pregnancy. For relief of nasal congestion, pregnant women can try a saline nasal spray during the day and a humidifier during the night.

LAXATIVES

Constipation is another common problem during pregnancy. Increasing fluids and fiber along with mild exercise under supervision of the patient's physician may help, but many patients often prefer to use a laxative. Bulk laxatives are the safest for pregnant patients. Those that contain artificial sweeteners should be avoided. Stool softeners should also be avoided unless used as directed by a physician. Stimulant laxatives in oral or rectal form have been reported to stimulate pre-term labor and should not be recommended.

TABLE 4: WARNING SIGNS OF PROBLEMS DURING PREGNANCY

1. ANY VAGINAL BLEEDING
2. SWELLING OF THE FACE OR FINGERS
3. SEVERE OR CONTINUOUS HEADACHE
4. ABDOMINAL PAIN
5. PERSISTENT VOMITING
6. CHILLS OR FEVER
7. DYSURIA
8. ESCAPE OF FLUID FROM THE VAGINA
9. MARKED CHANGED IN THE FRE QUENCY OR INTENSITY OF FETAL MOVEMENT

CASE 3

A pregnant woman in comes to the pharmacy counter to purchase a bottle of aspirin for a slight fever and some aches. What information should you share with her?

Aspirin is not a safe choice for this patient. More alarming, is that she is febrile and has not contacted her physician. Any pregnant woman presenting with any of the warning signs listed in Table 4 should not self-medicate. Instead, this patients should contact her obsterician immediately for an evaluation.

VITAMINS

Along with caloric intake, most dietary vitamin allowances for pregnant women rise because of the development and growth of the fetus. This increases the potential risk for the mother to develop vitamin deficiencies and associated complications including birth defects such as neural tube defects (NTSs), cleft palate, impaired growth, and phthalmic defects.

It has been observed that the administration of 0.4 mg of folic acid daily 1 month before conception and in the early weeks of pregnancy decreases the risk for NTDs, including spina bifida. Because more than 50% of all pregnancies are unplanned, the FDA has suggested an increase in the recommended intake of folic acid to 0.4 mg/d for all women of child bearing age. Women with a history of NTDs may benefit from the administration of 4.0mg of folic acid daily under the direction of a physician.

Preparations that contain 1 mg of folic acid require a prescription because high amounts of folic acid may mask a vitamin b12 deficiency and should only be used under a physician's supervision. Unfortunately, by the time a woman receives a prenatal folic acid prescription, she is often at least 5 weeks pregnant and past the time when the administration of folic acid would be most beneficial. Pharmacists are in a key position to educate women who are considering pregnancy about the benefits of 0.4mg folic acid daily (an OTC dosage).

Although folic acid currently appears to be the most important vitamin for reducing birth defects, is beneficial to receive adequate amounts of all vitamins during pregnancy. Thus, most obstetricians prescribe prenatal vitamin supplementation during the prenatal period. Ideally, a vitamin administered to pregnant woman should contain 100% of the current Recommended Dietary Allowance (RD) for that vitamin.

Patients should be told to avoid any high potency vitamin therapy unless specifically prescribed for deficiency. Teratogenic effects have been noted with the excess use of fasoluble vitamine (A, D, E and K).

CASE 4

After initial visit with her obstetrician, a woman who is 9 weeks pregnant presents you with a prescription for prenatal vitamins. After examining the bottle, she inquires whether these vitamins are safe for her to take during pregnancy, given that they "aren't really natural." She insists that she will be meeting her nutritional requirements through her diet because she will be "eating for two." What information should you pass on to her?

The myth that pregnant women should "eat for two" does not guarantee that the mother will receive adequate nutrition and will probably lead to excessive weight gain. A pregnant woman's caloric intake should increase by approximately 300 calories per day. Total weight gain during most pregnancies should be at least 20 pounds, but restricting a pregnant patient to an exact weight is unreasonable and may, in fact, be harmful. Failure of a pregnant woman to gain an adequate amount of weight during her pregnancy has been associated with low birth weight infants. Ideally, weight gain for an expectant mother who was well nourished and of normal weight before pregnancy should be approximately 25 to 30 pounds than are gradually obtained during the course of pregnancy.

This patient should be advised to eat a balanced diet with a daily increase of approximately 300 calories per day. Her weight gain will be monitored during her regular prenatal visits with obstetrician. Unfortunately, for this patient to have received the benefits of folic acid administration, supplementation should have been recommended before conception through early pregnancy. The pharmacist should also assure the patient that organic vitamins offer no advantages over the synthetic vitamins recommended by her doctor.

MINERALS

Most prenatal formulations do not contain 100% of the RDA for all minerals. Thus, additional supplementation may be needed for some patients. Calcium tablets may be prescribed if the patient's diet does not provide adequate calcium. Additional iron supplementation may be needed for women already iron deficient or for those who are pregnant with multiple fetuses. When extra calcium or iron is required, the need is greater in the latter portion of pregnancy when the fetal demands are greater. Therefore, if necessary, these mineral supplements may be avoided in the early stages of pregnancy when stomach upset is common.

RECREATIONAL DRUGS

Social or recreational drugs (i.e. caffeine, nicotine, alcohol) have no benefit with regard to the health of a pregnant woman and have varying degrees of risk to the fetus. Most studies have determined that, when consumed in small quantities, caffeine imposes a minimal risk on the fetus. In general, the amount of caffeine considered to be acceptable is less than 150 mg/d. Thus, one cup of caffeinated coffee (10 mg caffeine) or equivalent amounts of nonherbal tea (35 mg of caffeine per cup) or cola (50 mg of caffeine per 8 oz.) could safely be consumed daily. The consumption of greater amounts of caffeine has been associated with an increased incidence of miscarriage. Decreased fertility has also been associated with an increased fetal breathing rate; however, the significance of this finding has not yet been established.

The effects of cigarette smoking during pregnancy on the child include low birth weight and decreased head circumference. Cigarette smoking has also been linked to an increase in perinatal deaths. The concurrent use of caffeine and nicotine appears to increase the risk for the aforementioned effects. No safe limits have been established for nicotine used during pregnancy.

One of the most common and most preventable birth defects is fetal alcohol syndrome (FAS). This syndrome results in various facial, cardiac, and limb malformations along with impaired growth of the fetus, and lower IQ scores. If a woman refuses to abstain from drinking alcohol during her pregnancy, intake should be limited to less than 30mL of absolute alcohol daily. This recommendation was made by the American Council on Science and Health, but a safe level of alcohol consumption during pregnancy has not been determined. Alcohol should be avoided during pregnancy, especially during the first trimester.

It is the pharmacist's responsibility to remain current on relevant topics concerning teratogenicity and related issues and to effectively communicate this information to patients. By becoming involved in the education of prospective mothers, the pharmacist can aid in promoting the goal of prenatal care – a physically and emotionally healthy mother and child.

Continue on page 47

Freedom with Froben

- Relieves pain
- Reduces inflammation
- Offers good tolerability
- Satisfies patients over the long term
- Over 1 billion patient-days of treatment

Prescribing Information Presentation: White, sugar coated tablets, each containing either 50 or, 100mg of flurbiprofen. Uses: Froben is indicated in the treatment of rheumatoid disease, osteoarthrosis and ankylosing spondylitis. Dosage: Tablets 150 to 200mg daily in divided doses. In patients with severe symptoms or disease of recent origin, or during acute exacerbations, the total daily dose may be increased to 300mg in divided doses. Contra indications, Warnings etc: Froben should not be given to patients with peptic ulceration and inflammatory bowel disease, or to patients with a history of asthma or who have experienced bronchospasm or other hypersensitivity-type reactions with other anti-inflammatory agents. The safety of Froben during pregnancy or lactation has not been established. In animal experiments, no teratogenic effects were demonstrated but parturition was delayed and prolonged. Froben may prolong bleeding time and cause fluid retention. Use with caution where renal function is impaired. Side effects: Dyspepsia, heartburn and headache are the commonest encountered. Gastrointestinal haemorrhage, diarrhoea, mouth ulcers, peptic ulceration and skin rashes have been reported. Very rarely, cholestatic jaundice and blood dyscrasias have been reported but a direct causal relationship has not been established. Drug interactions: The effects of anticoagulants may be increased and oral diuretics decreased. Treatment of overdosage: Gastric lavage and, if necessary, correction of serum electrolytes. There is no specific antidote.

References: 1. Chalmers, T.M., et al, Brit J Clin Pract (1980), Suppl 9,3 · 2. Frame, J., Brit J Clin Pract (1986), 40, (11), 463 · 3. Benvenuti, C., Int J Tiss Reac (1983), V 61. 4. Data on file (1989), The Boots Company PLC

LOCAL DISTRIBUTORS:
NAMCO LIMITED

Further information is available from The Boots Company PLC, Nottingham NG2 3AA, England.

Flurbiprofen
Froben 100

EXAMINATION

1. When the pregnancy is calculated from the first day of the last menstrual period, the following terminology is correct:
   a. gestational age
   b. menstrual age
   c. ovulatory age
   d. fertilization age
   e. a and b

2. The period of time when organ genesis occurs is between weeks:
   a. 1 – 2
   b. 4 – 10
   c. 4 – 20
   d. 1 – 40
   e. 10 – 40

3. The placenta is fully functional by the end of weeks:
   a. 1 –2
   b. 1 – 12
   c. 13 – 24
   d. [illegible]
   e. [illegible] – 40

4. The crucial point in pregnancy when feratogens are most likely to cause anatomic birth defects is:
   a. the first trimester
   b. the second trimester
   c. the third trimester
   d. during labor
   e. not important

5. The effects of caffeine and nicotine during pregnancy:
   a. have not been established
   b. are not significant
   c. are significant only when alcohol is ingested
   d. are increased when used concurrently
   e. none of the above

6. Which of the following is not a warning sign that should be promptly reported to a physician?
   a. vaginal bleeding
   b. persistent vomiting
   c. chills or fever
   d. morning sickness
   e. abdominal pain

7. "Eating for two" is:
   a. an effective way to obtain of the necessary vitamins needed during pregnancy
   b. unhealthy, because a pregnant woman should never gain more than 20 pounds
   c. a great way to gain unnecessary weight
   d. does not ensure that the RDA of vitamins and minerals will be met
   e. c and d

8. Which of the following statements are true concerning folic acid administration?
   a. If received in adequate amounts during the weeks 10 to 40, the risk for NTDs is reduced.
   b. Administration of 4 mg one month prior to pregnancy is recommended for all women of child bearing age.
   c. Administration of 0.4mg one month prior to pregnancy and in the first weeks of pregnancy is recommended for all women of child bearing age.
   d. High amounts may mask a vitamin B12 deficiency.
   e. c and d

9. Many prenatal vitamins contain 1 mg of folic acid, this is:
   a. necessary to reduce the risk of NTDs
   b. is in excess of the amount recommended to reduce NTDs in women with no prior history.
   c. A toxic amount and has been associated with birth defects
   d. The reason some vitamin formulation require a prescription
   e. b and d

10. A vitamin administered to a pregnant woman should contain what percentage of the RDA for that vitamin?
   a. 35%
   b. 50%
   c. 75%
   d. 90%
   e. 100%

11. The placenta:
   a. is impermeable
   b. provides selective transportation
   c. provides metabolic interchange between mother and fetus
   d. b and c
   e. all of the above

12. Early diagnosis of pregnancy is crucial:
   a. because organogenesis occurs in the first trimester
   b. even though organogenesis does not occur until the second trimester
   c. even though organogenesis does not occur until the third trimester
   d. a and c
   e. b and c

13. A pregnant woman with a fever should be advised to:
   a. take aspirin
   b. take acetaminophen
   c. immediately phone her physician
   d. not take any medication
   e. tell her physician about the fever at her next scheduled visit

14. Teratogens:
   a. may produce anatomic malformations
   b. may cause effects not noticed until later in life
   c. do not cross the placenta after the first trimester
   d. a and b
   e. a and c

15. Drugs in pregnancy:
   a. are never indicated
   b. are never indicated during the first trimester
   c. should be used only when the benefit to the mother outweighs the risk to the fetus
   d. should only be used if in category A
   e. c and d

16. The FDA fetal risk category that represents a drug that is contraindicated in pregnancy is:
   a. A
   b. C
   c. D
   d. E
   e. X

17. The FDA fetal risk category that is used when inadequate information is available is:
   a. A
   b. C
   c. D
   d. E
   e. X

18. The limitations of the use of fetal risk factors include:
   a. Drug marketed before 1984 are not required to have a letter rating.
   b. OTC drugs are not included.
   c. Vitamins are not included.
   d. The letter ratings tend to over simplify very complex information.
   e. All of the above.

19. The following statements are true, EXCEPT:
   a. Excess vitamin A is not constraindicated for use during pregnancy.
   b. No safe limits exist for nicotine or alcohol use.
   c. Stimulant laxatives may induce pre-term labor.
   d. Bulk laxatives are safest for pregnant patients.
   e. Acetaminophen is a safer alternative to aspirin during pregnancy.

20. Medications containing what amount of folic acid require a prescription?
   a. .01 mg
   b. .04 mg
   c. .10 mg
   d. 1.0 mg
   e. 0.4 mg


Decongestant capsules
Karvol
Clears blocked up noses with the natural vapours of pine, cinnamon and menthol.
Decongestant capsules
Karvol
Clears blocked up noses with the natural vapours of pine, cinnamon and menthol.
10 Capsules
Decongestant capsules
Karvol
10 Capsules
Decongestant capsules
Karyo
Clears blocked up noses with the natural vapours of pine
LOCAL DISTRIBUTORS:
NAMCO LIMITED

Ciplox

Ciprofloxacin

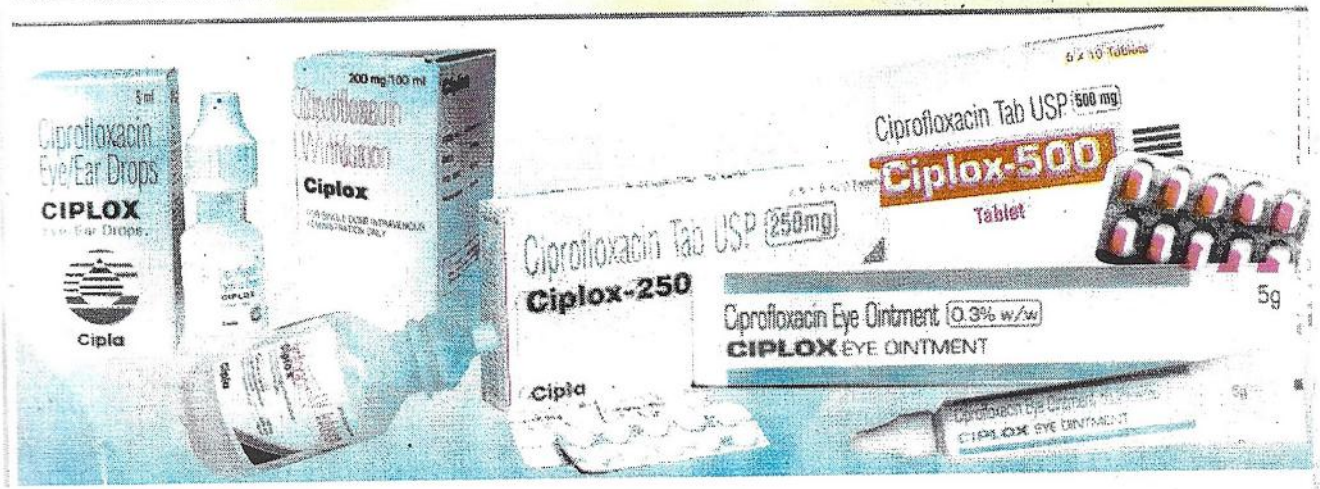
the cost-effective broad spectrum antibacterial

- Faster recovery
- Easy, twice daily oral administration
- Reduced hospital stay and cost
- Sequential IV and oral therapy for select patients
- Unmatched economy
- Added option of EYE/EAR presentations

100% CONFIDENCE

DOSAGE GUIDELINES

Type of Infection	Oral Dosage	Intravenous Dosage
Respiratory Tract	500 - 750 mg twice daily	200 mg twice daily
Bone and Joint, Skin/Soft tissue	500 - 750 mg twice daily	
Urinary Tract	250 - 500 mg twice daily	100 - 200 mg twice daily
Infectious Diarrhoea	250 - 500 mg twice daily	
Enteric Fever (Typhoid)	500 - 750 mg twice daily for 7 - 14 days	
Gonorrhoea	250 mg single dose	100 mg single dose
Non-gonococcal urethritis	750 mg twice daily	
Chancroid	500 mg twice daily	
Other infections	500 - 750 mg twice daily	200 mg twice daily
Patients with Renal Impairment	Half of the recommended dose	



Service In Medicine

HEAD OFFICE
TAIFA (Mile 9 Nsawam Road) P. O. Box 5260, Accra-North, Ghana.
Cable: Danafco, Accra
Tel: 21-400126 Telex: 2129 Fax: 021-400127, 021-228241

BRANCHES:
* Accra Regional Office, Lucas House, 6 Ring Road West,
Accra North, P. O. Box 5260, Tel: 021-228221, Fax: 228241.
* Takoradi, P. O. Box 12, Old Cape Coast Rd. Tel: 031-23732.
*Hohoe, P. O. Box 135, Tel: 0935-2088

* Kumasi, P. O. Box 1703, Asumfo Road, Tel: 051-22823
* Koforidua, P. O. Box 294, Tel: 081-222762
* Tamale, P. O. Box 900, Tel: 071-22678.

KNOWN AND TRUSTED IN MEDICINE OVER FOUR DECADES