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Working with the patient

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The pharmacist is the undisputed drug expert. Pharmacists possess an in depth knowledge of drug use, their therapeutic effects and undesired effects. The ever increasing amount of medicines available both through doctor's prescription and those directly available to the consumer are providing the possibility of better care for the patient. However, the potential for drug-related morbidity is also increasing.

Pharmacists' active intervention to ensure appropriate drug use is therefore imperative. In order to achieve this goal, pharmacists need to form a relationship both with the prescribers and with the consumers of medicines.

Pharmacists work exceptionally well in a team with other healthcare professionals for the benefit of the patient. The perception of other healthcare professionals as to what the pharmacist 'can do' or 'should do' may, at first, prove to be a barrier to pharmacists' acceptance by the team. However, once in the team, it becomes evident that the pharmacist's in depth knowledge of drugs makes

him/her indispensable for the optimum management of the patient. The formation of this type of relationship is facilitated by the fact that as healthcare professionals both pharmacists and doctors 'speak the same language' thus communication barriers are likely to be overcome.

Establishing a relationship/partnership with the patient/consumer of medicines is necessary to ensure the safe and effective use of drugs. Patients have a desire to be involved in and informed about their own health and about the medicines they use. It is rather disappointing that although pharmacists are the professionals with the best knowledge

about drugs, studies show that pharmacists are rarely the primary source of drug information for the patient/medicine consumer.

The first point to consider is whether the pharmacist can communicate with patients to transfer the desired information. Can pharmacists counsel patients about their medicines? Do pharmacists possess the appropriate skills to do this? Are these skills that simply develop over time, with experience or do they need to be taught?

Prof. Marja Airaksinen and her team have been working on these issues for the past ten years. Her paper entitled 'The role of communication skills in developing patient-centered practice in community pharmacies' published in this edition of the *Chronic*ill*, highlights problems associated with pharmacists' communication skills.

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It seems that while patients give a clear indication that they would like more information about their medication, pharmacists are unable to communicate this information. While pharmacists have grown accustomed to asking patients questions regarding the use of medicines they do not seem altogether comfortable with answering their questions.

From this and other work published by Prof. Airaksinen and her team, it is evident that pharmacists and undergraduate pharmacy students need appropriate training in communication skills.

The teaching of communication skills to pharmacists needs to be

urgently addressed. Unless these skills are developed, pharmacists are unable to build a relationship with the patient and effectively communicate their knowledge of drugs. Working with the patient to form a collaborative relationship requires not only the willingness of both patient and pharmacist to form such a relationship, but also requires pharmacists to effectively tap into their reservoir of knowledge and truly deliver a professional counselling service.

The 13th International Social Pharmacy Workshop will serve as a forum for the exchange of resources in this field. Prof. Airaksinen will be

joined in Malta, by other experts, to network and enhance international cooperation. Also present at the meeting will be delegates from EuroPharm Forum from the World Health Organisation. EuroPharm Forum was responsible for the campaign 'Questions to ask about your medicines' which led to the identification of communication problems between pharmacists and patients.

I would like to take this opportunity to officially welcome all the delegates to The 13th International Social Pharmacy Workshop and wish everybody a memorable scientific and social experience.

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Multidisciplinary professional interaction

lipservice to interprofessional relations or an effective approach to patient care?

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Modern healthcare provision has resulted in increasing demands with respect to the time that needs to be dedicated by busy professionals to continuing professional development and to the maintenance of quality of care. Implementation of evidence-based practice ensures that standards are met but individuals cannot possibly be expected to constantly keep up with the explosion of knowledge which is a pre-requisite to this. A multidisciplinary team acting cohesively however can make significant advances in optimizing the treatment of disease in all its aspects.

Whereas the medical and the nursing professions have interacted in patient care for many years, it is only relatively recently that doctors and pharmacists have begun to work closely together in a clinical setting and on a day to day basis.

In the hospital environment, the

clinical pharmacist plays a crucial role in tendering advice, and monitoring drug prescription and administration. Patient-based discussions regarding indications, dosage and administration serve an educational purpose and are part of good management. The explanation of times and means of

administration to patients, the screening of treatment charts and lists of medications for drugs that can potentially interact, provoking discussions about the optimal drugs to be used, including safeguarding antibiotic use and pointing out abuse, reporting adverse drug reactions, ensuring the proper maintenance of ward stocks both in terms of quantities and with due attention to expiry dates as well as topping up of drugs on the emergency trolleys all fall within the remit of clinical pharmacists. Regular review of practices and patient management by clinicians and pharmacists will maintain standards of care and trigger initiatives, establish guidelines and promote safe practice in a busy hospital setting.

In a community setting, the pharmacist plays a front-line role. In addition to interacting with clinicians as outlined above, there is direct patient contact with the need to answer queries and guide the patient. Furthermore, in instances where patients encounter results in the raising of issues which need clarification, then it is usually the pharmacist who refers patients back to the doctor for reassessment. Identification and discussion of potential side effects and adverse drug reactions in community practice remains the area where pharmacists can intervene, reassure the patient and, when necessary, counsel the patient to seek medical help. Vigilance is also essential to counteract the age-old habit of seeking over the counter remedies for potentially serious medical complaints.

With the revamping of healthcare service provision both clinicians and pharmacists are increasingly called upon to exercise an administrative and managerial role. Cost benefit analysis of the implementation of certain treatment recommendations including effects on patient outcomes and demands on service providers have become an essential part of the decision making process especially in national health service set-ups such as the one in Malta. Working in an advisory capacity to regulatory units both locally and now within the

framework of the European Union will cause an increasing demand on the time of healthcare professionals both in the medical and pharmaceutical professions.

In the research environment, the ongoing battle against disease provides healthcare professionals working in an academic and industrial setting with the possibility of developing and analyzing new medications from production to delivery and the possibility of assessing the efficacy of different preparations under different conditions and in different patient populations. Follow up studies on the use of certain drugs and outcomes in different populations have brought home the realization that the hereditary and genetic factors play an important role in the response to treatment. Hence drug development and delivery to patients has now acquired both national and international implications. Auditing has become crucial in ensuring quality of care and both clinicians and pharmacists can contribute effectively to the auditing process and to improvements in patient care that can arise as a result of the auditing process.

Ultimately clinicians and pharmacists form two distinct groups of healthcare professionals with differing remits but with one significant overriding concern, namely patient-oriented medical care and patient safety. Indeed their roles overlap and together, significant advances can be made in providing safe and effective medical care within the financial constraints existing in any healthcare system. For both professions, the ability to make their voice heard and to air their concerns is vital to ensure that financial considerations do not compromise healthcare provision in the community and individual patient safety. Given the economic realities that have to be faced by different countries, certain recommendations made by healthcare professionals may prove unpopular with administrators but unless put forward, decision-making processes may be inadequate and generate further unnecessary expenditure with disastrous outcomes.

To err is human but the guiding principle of clinical risk management should remain prevention; a principle which if followed, can be a significant burden on healthcare systems but if neglected, negates the professionalism and dedication required by the different disciplines.

The role of communication skills developing patient-centred practice in community pharmacies

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Patient-centred drug therapy that is based on partnerships in medicine taking has become a “golden standard” in healthcare.^{1,2} This has also challenged community pharmacists to reconfigure their service provision to meet the requirement of concordance and patient autonomy. But what does patient-centred practice mean for community pharmacies?

Introduction

How can pharmacists develop competency and skills needed in a new approach to the patient? The aim of this article is to discuss the role of communication skills in this process.

Background information for this paper will be provided from two Finnish national joint programmes. These programmes lasted for a period of 10 years (1993-2003) and were aimed at promoting professional pharmacy services with a special focus on patient information. Both programmes have attempted to implement a dynamic, long-lasting process leading to a permanent change in patient counselling behaviours, including

patients' active involvement and two-way communication. Both have also attempted to set up local agreements and guidelines on patient counselling.

The first one, 'Questions to Ask About Your Medicines', QaM Campaign was started by an initiative of the WHO EuroPharm Forum (www.who.dk/europharm) and ran for three years in 1993-1996.^{3,4} The QaM was started with a public awareness campaign,³ followed by a project identifying problems people have with their medicines at home. As the process showed lack of professional competency of pharmacists, the third phase focused on developing tools for pharmacists to improve patient

counselling practices. This was intensively continued by the program TIPPA during 2000-2003 that is currently under final evaluation (The abbreviation TIPPA stands for Customised Information for the Benefit of the Patient from the Community Pharmacy). TIPPA was the first massive program in Finland that actively involved all the key stakeholders in pharmacy, including Ministry of Social Affairs and Health and the major third party payer in redesigning community pharmacy services.

Old myths - still dominating the medication counselling behaviour?

Quality communication between the community pharmacist and the patient has been regarded as self-evident among the profession. It is typical to say that "Of course pharmacists interact with patients throughout their practice". The work in pharmacy is regarded as expert work requiring good communication skills. Still, little attention has been paid on developing competency in this field.

Our experiences in Finland show that even though attention was paid, it is hard to achieve a change in counselling behaviours. The following authentic conversation between a pharmacist and a customer was audio-taped during a pseudo customer study conducted annually in 60 Finnish community pharmacies during TIPPA to assess progress in implementation of concordance-based patient counselling behaviours. The total number of pseudo customer visits was 240 per follow up (altogether 960 visits). One of the pseudo customers came to pick up a sympatomimetic inhaler with a new prescription:

Pharmacist: Here is your medicine. Are you familiar with this product?

Customer: No, I am not.

Pharmacist: Did the doctor tell you how to use this medicine?

Customer: No, he didn't.

Pharmacist: Should I then open the package and show you?

Customer: I don't know.

Pharmacist: At least read the leaflet inserted in the package. Are you going to pay by cash?

This typical real-life pharmacist-customer interaction shows the level of competency acquired so far in communication with the patient. This example is derived from Finnish data but it could be derived from any other country. If we read the conversation we can see that the customer is giving the pharmacist a clear indication of his need for information but the pharmacist is not able to communicate accordingly. It seems that the pharmacist has learnt to ask questions but does not know how to make use of the information provided by the customer. This can be seen throughout the discussion: customer indicates that this is a new medication, and the doctor did not indicate how to use it but the pharmacist does not respond to his information. Finally, the pharmacist puts the customer in a difficult situation by asking him to decide whether to show him details about the use of the medicine, the medicine being an inhaled sympatomimetic. This type of behaviour goes against the evidence that laymen trust professionals and want them to decide what information to disclose. The laymen feel they do not know medicines and treatments well enough to take decisions regarding medicine use. This leads to illusion of competence.⁵ It means that patients are satisfied with the information provided even though they have not received any as they trust the competency of the expert.

This following audiotaped pseudo customer visit was related to self-medication. The customer asked for two medicines by a brand name, one being a ketoprofen product and the other a ranitidine product. Thus, there was potential for iatrogenic effects.

Customer: Hi, I would like to buy a pack of ketoprofen.

Pharmacist: 8 or 15 tablets?

Customer: The bigger one. And then a pack of ranitidine.

Pharmacist: A tablet to swallow or dissolve in water?

Customer: Ordinary tablets.

Pharmacist: Would you like to have anything else?

Customer: Nothing else.

Pharmacist: It comes to 11 euros and 20 cents.

In this case, the advice of the pharmacist was focused on product facts: which package size - 8 or 15 tablets - and what kind of tablets the customer wants. There is not a word about the symptoms and appropriate choice of the medication, risk assessment, or about instructions on how to use the medicines, or even suggesting a change of the painkiller to a less harmful one for a patient with stomach symptoms.

These two examples show that the value of the pharmacist's advice for the outcome of the therapy is limited. Pharmacists seem to have learnt to ask some questions repetitively without meaning and are unable to fulfil their duty to counsel, but they have not internalised their role as supporter of therapy. The pharmacist is not supporting self-management that is based on understanding the disease and its treatment. If we use this as a criterion for good quality communication, both of these pharmacists failed the test.

In the very best scenarios, pharmacists demonstrated patients inhaling techniques or asked some questions about symptoms when the patient intended to self-medicate, but they rarely showed systematic counselling patterns starting with needs assessment, selection of content accordingly, customising the content by different communication techniques and finally, concluding by assuring understanding. Neither did they show any outcome orientation.

These scripts reflect that old traditions still dominate pharmacist-customer interaction. Pharmacists seem to still have the attitude of selling medicines instead of selling treatments and this is influencing their behaviour. Pharmacists should instruct patients about the use of their medicines and provide medicine-related services which they believe will benefit their patients. Their relationship is paternalistic and asymmetrical, i.e. the pharmacist is 'in control'. They have a drug-centred way of thinking and the transfer of information is monologue-based. Assessment of symptoms is missing most often, reducing evidence-based decision-making for the treatment resulting in decreased value for the patient.

The communication behaviour of the pharmacists seems to be determined by beliefs and myths that are transferred from one generation of practitioners to another.⁶ Pharmacists believe that customers do not want information, especially when they pick up refills, customers are passive, we should not disturb them by transferring facts about medicines. Pharmacists also believe that it is not possible to learn communication skills. They feel it is like an inherited feature: some pharmacists are good communicators by nature and some are not.

Where do these myths and beliefs originate? According to our experience in Finland, it is because most of the practitioners lack training in communication and patient counselling skills.^{6,7} The systematic training of patient counselling skills started in the mid-1990's among basic students, and in 2000 among practitioners along with TIPPA. The data collected during TIPPA shows that practitioners lack the understanding of principles of two-way communication and the role of the patient in self-managed treatment. This negatively influenced their performance even though feedback from them showed that they were motivated to make a change.

Teaching practitioners a new approach to communication with the patient

It is crucial to teach practitioners a new approach to communication with the patient.^{6,7} The patient is an active medicine user, an active partner in communication with whom pharmacists are expected to establish a professional relationship based on trust, open communication and mutual decision-making. These principles are also mentioned as prerequisites for performing pharmaceutical care services, e.g., by the FIP statements.^{8,9,10} The pharmacist should also have an understanding of his role in the multidisciplinary team supporting the patient and the flow of information to the patient from different sources with an emphasis placed on electronic information.

How can new patient-centered scripts be developed? According to our

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experience in Finland and experiences in other countries, an extensive learning process is needed at the pharmacy level that involves individual pharmacists to develop personal competency; the whole working society needs to change the communication culture; pharmacy owners need to incorporate professional services into the vision and business strategy of the pharmacy; local consumers need to be encouraged to take an active role in self-management; and other healthcare providers need to agree on the new roles in multidisciplinary teams.^{7,11,12}

According to our experiences, practitioners need practical guidelines and resources based on concordance in acquiring a new practice. They also need to learn how to process in-house guidelines, i.e., some kind of protocols or standard operating procedures to reconstruct their communication patterns and produce repetitive quality. These mutual decisions within the working society of what to tell to the patient about the treatment can be taken at the general level. However, more and more pharmacies have been processing treatment-based guidelines for the patient groups who visit the pharmacy most often. Processing in-house guidelines was promoted by the Association of Finnish Pharmacies in 2002 with detailed instructions for implementing the switch of emergency hormonal contraception (EHC) to self-medication. The switch was historical in that the authorities obliged pharmacists to take increased responsibility of the proper use of EHC medicines than in previous switches with other OTCs, although duty to counsel has been covering OTCs as well as prescription medicines since 1983 in Finland. This indicates that authorities are increasingly recognising the pharmacist's competency and ability to work for health policy goals.

Long-term development plans are needed in pharmacies

Pharmacists require systematic and planned training, or even coaching to make use of new tools.^{7,11,12} To make this happen in Finland, each pharmacy has been encouraged to develop a long-term action plan that takes into account local conditions by applying principles of strategic planning. The recommended period for this action plan has been set at two years to make a permanent change. Pharmacies have also been encouraged to incorporate patient-counselling-specific feedback measures into their quality management systems.

For the development plan, current practices need to be evaluated in a wider perspective than the customer-pharmacist interaction in order to implement good quality patient information. The three key dimensions crucial in this respect are (1) understanding the needs of the customers; (2) modifying service processes, including resources and facilities to integrate counselling, and (3) developing competency of the personnel.

Developing training courses on communication skills

During TIPPA, we have realised the urgent need to train practitioners in counselling skills. The basic students need to be taught principles of patient-oriented counselling to adapt that approach from the very beginning. Practitioners need to be supported to change their routines and adapt new behaviour patterns.

The effective learning process needs to focus on principles of two-way communication, patient-orientation and concordance, self-evaluation and personal development, collective learning, strategic planning and quality assurance.

The learning process needs to be systematic and horizontally designed, that is, based on constructive and experimental learning.¹³ It needs to be started with an introduction to medication counselling as a process e.g., by using the USP Guidelines or some other instrument to facilitate detailed analysis of performance. It is also important to integrate theory and practice.

The learning methods should consist of a mixture of labs, lectures, seminars, group-work, self-study and role-plays. We have found role-plays and socio-drama especially useful. They help in processing a picture of patient needs and in rehearsing own skills and scripts. Learning can be intensified by using real patients as standardised patients.

International cooperation is needed

Internationally, there are still challenges to overcome in organising training in communication skills. The availability of courses, especially long-term courses that will involve the entire working society is limited. There is also a lack of training materials, as well as competent tutors and teachers. There is a need for international cooperation in developing training. Initiatives have already been taken to establish a forum for sharing resources. This will be discussed in the 13th International Social Pharmacy Workshop in Malta in July 2004. The conference will gather together more than 100 researchers and teachers in Social Pharmacy all over the world. Also the FIP Pharmacy Information Section will be organizing a two-day pre-congress training related to Medicines Information to Support Concordance in New Orleans in September 3-4, 2004. The deadline for registration is August 15 (preliminary program available on the Internet: www.fip.org).

***The Malta College of Pharmacy Practice
would like to congratulate the Antibiotic Team
at St Luke's Hospital on their recent excellent publication
of the Antimicrobial Prescribing Guidelines.***

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Warfarin

from rat poison to oral anticoagulant

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Keywords: warfarin, anticoagulant, indications, dosing, monitoring

Warfarin is now the most widely used long term oral anticoagulant. Due to the narrow therapeutic index and the complexity associated with warfarin therapy, a sound knowledge of the drug is required. This review is aimed at providing some basic concepts on warfarin in use and takes on a UK perspective.

History

The discovery of warfarin was centred around Canada and the US in the early 20th century when sweet clover was planted to feed the cattle. However, as reported in 1921-22 by veterinary pathologist Dr Frank Schofield, improperly cured sweet clover brought a disease to cows characterised by relentless,

spontaneous bleeding.¹ In 1940, Campbell and Link isolated the substance dicoumarol that was patented in 1941 for use as a rat poison. However, this was too weak a poison and continued research developed a derivative, patented as warfarin (Wisconsin Alumni Research Foundation + arin to indicate coumarin). Following an attempted suicide by a navy recruit in 1951,

clinicians identified warfarin as an anticoagulant and it was clinically introduced in 1952 becoming commercially available in 1954.^{1,2,3}

Worldwide the use of warfarin is increasing due to:

- the increasing number of indications
- the increasing elderly population^{4,5}

Breaking this down to a more localised example in Scotland, since January 1998, the number of warfarin prescriptions dispensed has increased annually from 7 to 11% (Jan 1998 - Dec 2001).⁶ Internationally, the increase in use of warfarin and the high risk associated with use of the drug have prompted guideline development. National UK guidelines (also adopted by the BNF) have been issued by the British Society of Haematology in 1998 and SIGN 36 tackling antithrombotic therapy was published in March 1999.^{4,5,7}

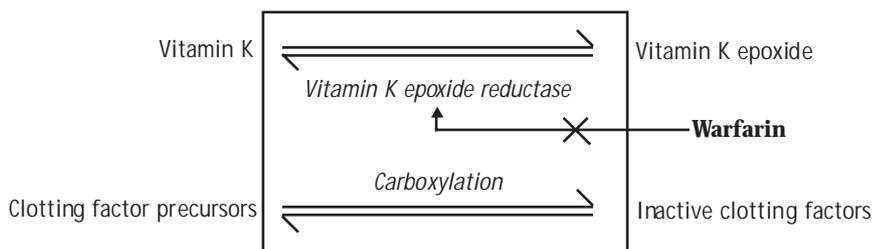
Mechanism of action

Warfarin is a Vitamin K antagonist and consequently inhibits Vitamin K-dependent clotting factors (factors II, VII, IX and X) by inhibiting the enzyme Vitamin K epoxide reductase. This is required for the conversion of clotting factor precursors into inactive clotting factors in the bloodstream. This is summarised in Figure 1.⁶

The inhibition of Vitamin K epoxide reductase by warfarin results in an accumulation of Vitamin K epoxide reducing the effective concentration of Vitamin K and shifting the equation towards the clotting factor precursors. Therefore there is a reduced amount of inactive clotting factors available in the circulation.⁹

Warfarin takes about 50 hours to start exerting its full action since Factor II has the longest half life of 50 hours. Protein C and S, which are naturally occurring anticoagulants, are also Vitamin K dependent and during initiation of treatment there is a possibility of development of a hypercoagulable state where the body's own anticoagulants are British

Figure 1: Schematic representation of the action of warfarin



Oxidation of Vitamin K to Vitamin K epoxide is coupled to the carboxylation of clotting factor precursors to inactive clotting factors. The regeneration of Vitamin K is accomplished by the action of vitamin K epoxide reductase on Vitamin K epoxide. The inhibition of Vitamin K epoxide reductase by warfarin results in reduced concentrations of Vitamin K, and a consequent reduction in the carboxylation of clotting factor precursors to inactive clotting factors.

depressed and warfarin has not yet produced a clinical response. This:

- is a problem in patients with hereditary or acquired deficiencies of protein C and S and may result in skin necrosis
- explains why overlap treatment with heparin is required in acute clinical conditions such as Deep Vein Thrombosis (DVT).⁶

Monitoring

There is no linear correlation between the dose of warfarin and its anticoagulant effect. Besides, various factors may cause inter- and intra-individual variation in response to a warfarin dose. It is therefore necessary to monitor the effect of warfarin and this is done through measurement of prothrombin time (PT).^{6,9}

The PT is the time taken for a sample of platelets to clot following addition of calcium and tissue thromboplastin, an enzyme from blood platelets that converts prothrombin into thrombin. This is usually about 12 seconds in a non-anticoagulated individual. Thromboplastins are not standardised among manufacturers or between batches. In an attempt to standardise results, the World Health Organisation (WHO) developed a system where thromboplastin is compared to an international reference thromboplastin in order to assign an International Sensitivity Index (ISI).

This is used to convert the PT time to the International Normalised Ratio (INR) for a patient and this is the standard of practice.^{6,9}

$$\text{INR} = \frac{[\text{PT patient}]^{\text{ISI}}}{[\text{PT mean normal}]}$$

Current recommendations for intensity of the most commonly accepted indications are summarised in Table 1. Current guidelines recommend that a target INR be designated for a particular indication rather than a range. An INR within 0.5 units of the target would generally be satisfactory in clinical practice.^{4,5} In most settings an INR of 2.5 is the target with higher intensity anticoagulation used in valve replacement and conditions of thrombotic recurrence.

Management of warfarin dosing

Prior to initiation of warfarin therapy, essential baseline investigations include a full blood count including platelets, urea and electrolytes, PT and liver function tests.^{6,7} Various protocols are available for the induction of warfarin anticoagulation. The most commonly used method is the Fennerty induction dosing which employs initial doses of 10mg with consequent dosing adjustments depending on the patient's INR.^{4,5,7,10} Such a regimen is suitable for the induction of in-patients where rapid anticoagulation is required and where

daily INR monitoring is feasible. It provides a predicted maintenance dose on day 4.¹⁰ However, efforts have been made to establish less intense regimens for starting off warfarin which may be especially useful in less acute indications such as anticoagulation due to chronic atrial fibrillation. These may be a safer alternative in elderly patients where a Fennerty regimen may be too severe or where initial daily monitoring is not appropriate. The Tait method employs a 5mg dose from day 1 to day 4 and INR monitoring and dose adjustments on day 5 and day 8. Dose at day 8 predicts the actual maintenance dose.¹¹ An alternative regimen, established by Oates et al starts the patient at 2mg daily with an INR check on day 8. The dose is adjusted accordingly and the patient returns weekly until the INR is stable (usually defined as the first of two INR results at least 7 days apart which are within target with no dose alteration). This method allows prediction of warfarin dose after two weeks of treatment.¹² Overall, both methods have been shown to result in fewer INRs >4.0. There are few protocols that provide guidance for dosing adjustments during the maintenance phase. The more useful regimens recommend dose adjustments as a percentage change in dose.¹³ Dose adjustments should take into consideration individual patient factors such as age, nutritional status, comorbid conditions and any change in drug treatment. Various computer assisted aids have been devised to take variables into consideration to aid in dosing adjustment. A Cochrane review has concluded that computerised prescribing of dosage improved prescribing. This included shorter times to achieve therapeutic control, a reduction in toxic drug levels and incidence of adverse drug reactions and a reduction in the length of hospital stay.¹⁴ Guidance on recall periods during maintenance therapy recommend a maximum recall time of 12 weeks once INR is stable and provided no new factor has arisen (apart from patients with prosthetic valves where a maximum recall of 6 weeks is recommended).^{5,7} In a document on anti-coagulation monitoring, the

Medical Association has produced evidence-based criteria for the frequency of monitoring that may be adopted in clinical practice.¹⁵

This review presents an overview of

the development, mechanism of action and clinical use of warfarin. Such a basic knowledge is essential to ensure safe and effective use of the drug. Due to the complexity associated with

warfarin therapy, safe use requires an understanding of factors affecting response to warfarin including drug interactions and comorbid states. The latter will be the focus of a second review article.

Table 1: Most common indications for warfarin use. All recommendations are related to warfarin use in adult males and adult non-pregnant females^{4,5,8}

Indication	Target INR	Duration
<i>Venous Thromboembolism</i>		
Isolated DVT – calf vein with no risk factors ^a in nonsurgical patients	2.5	3 months
First event PE/proximal vein thrombosis with no risk factors	2.5	6 months
Recurrence of PE OFF warfarin		
a) Two episodes of idiopathic DVT	2.5	Long term
b) Repeated provoked DVT	2.5	6 months or until risk factors resolve
Recurrence of PE ON warfarin	3.5	Long term or until risk factors resolve
Post-op calf vein thrombosis without persistent risk factors	2.5	6 weeks
Post-op calf vein thrombosis with persistent risk factors	2.5	Long term or until risk factors resolve
Recurrence of DVT OFF warfarin		
a) Two episodes of idiopathic DVT	2.5	Long term or until risk factors resolve
b) Repeated provoked DVT	2.5	6 months
Recurrence of DVT ON warfarin	3.5	Long term or until risk factors resolve
<i>Nonvalvular (Non-rheumatic AF)</i>		
Continuous or paroxysmal AF with at least one risk factor to develop thromboembolism ^b	2.5	Long term
AF associated with	2.5	
a) clinical thyrotoxicosis		a) Till controlled
b) intracardiac thrombus		b) As recommended by cardiologist
c) non-cerebral thromboembolism		c) Long term
d) congenital heart disease		d) Long term
Elective cardioversion	2.5	3 weeks before 4 weeks after
<i>AF associated with valvular disease (Rheumatic)</i>		
Rheumatic mitral valve disease ± atrial fibrillation	2.5	Long term
<i>Heart Valve Disease</i>		
Mitral valve prolapse, mitral annular calcification, aortic valve disease + previous systemic embolism or AF	2.5	Long term
<i>Heart Valve Prostheses</i>		
Mechanical heart valves	3.5	Long term
Bioprosthetic heart valves		
After implant surgery	2.5	3 months or as per guidance from cardiac unit
+ associated risk factors ^c	2.5	Long term

- a) Cancer, thrombophilia, (antithrombin III deficiency, Protein C and S deficiency, antiphospholipid syndrome, chronic infection, inflammatory bowel disease, nephrotic syndrome, pulmonary hypertension)
- b) Other risk factors: Advancing age (>65 years), history of hypertension, diabetes, heart failure, left ventricular dysfunction, previous ischaemic stroke or TIA, history of thromboembolism. The risk/benefit of warfarin needs to be determined for every individual patient above 75 years of age and needs to be reassessed annually particularly in this age group
- c) Risk factors: atrial fibrillation, history of systemic embolism, evidence of left atrial thrombus at surgery, persistent left atrial enlargement, or persistent heart failure

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Equity and solidarity in healthcare

a patient-centred pharmaceutical model

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Keywords: equity, solidarity, resources, healthcare,
community pharmacists, patient-centred,

The perceived application of the principles of Equity and Solidarity in healthcare has been amply debated over the years, nationally and internationally, particularly in the context of the allocation of resources. It is a consideration of grave concern to various stakeholders. It is significant, that at this moment in time, a time of change, opportunities and challenges, both nationally and globally, are addressed from a bioethical dimension, with a pharmaceutical perspective and a patient - centered focus. In this ambit the pharmaceutical model to counter inequality of access to pharmaceutical services is presented.

Introduction

In one of his renowned drawings, Homo Vitruviano (Fig. 1), Leonardo Da Vinci may be said to have placed Man at the centre of the Universe. The Creator Himself placed Adam (and Eve) above all other creations. One might be also tempted to add, therefore, that healthcare should be patient-centred and that this should be a moot point.

Malta's healthcare

Malta's healthcare is delivered by two completely separate systems, public and private. The public or national health system is traditionally based on a paternalistic welfare state model, based on the principles of Equity, Justice and Solidarity (Table 1).

The terms 'free healthcare', 'free medicines', 'free medical treatment' are

an integral part of our vernacular! But, over recent years, an intensifying debate has developed at various levels, locally and globally, on

- the sustainability of such a model,
- the extent of solidarity,
- the equity of access to care,
- equity in accessed care.

In this ambit, one cannot overlook the importance of the ethical consideration of the Allocation of Resources in healthcare at various levels. In the bioethical domain, management of resources must be based on equity. The entire population should have access to the necessary health services with particular regard being given to those who have specific needs - the disabled, the elderly, indeed, all the weaker members of the community. Health Professionals themselves have a(n) (bio)ethical obligation to exercise the principle of Human Solidarity in extending their help to the weaker members of society.

Moreover, contributing to the needs of people should not be provider-centered but should, in turn, be based on the Principle of Subsidiarity, whereby decisions are taken as close to patients as possible, so that with suitable support, taking into consideration their values, conscience and beliefs, they can make decisions about their health, in a spirit of concentration with their healthcare provider.

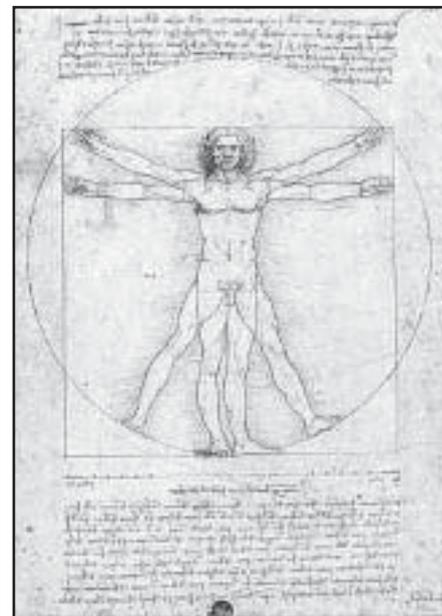


Figure 1: Leonardo da Vinci, Homo Vitruviano

The challenges brought about by new knowledge - the explosion of information following the decoding of the human genome is a case in point - innovative expensive medicines and interventions, new technologies, an aging population (demographic changes) emerging unhealthy lifestyles (e.g., explosion of teenage female smokers) environmental factors, increasing patient awareness, and patient expectations call for developments in the healthcare sector. These necessitate the adaptation of new strategies so that society will have access to health services that are comprehensive, efficient, effective and affordable. Inherent to the provision of quality healthcare that is sustainable are the principles of equity and justice and partnerships with all stakeholders.

A pharmaceutical patient-centered model of equity and solidarity in primary healthcare

The dimension of the issue of the allocation of resources includes the macro-level decisions taken by governments, insurance companies and other major healthcare funders.

In Malta, the bulk falls on Government, together with the private sector, which is separate and distinct but which may be considered to be complementary to the public system with hospitals and doctors' clinics and a network of 204 pharmacies, many of which are pharmacy-clinics providing to a certain extent still untapped synergies in the interest of patient-centered clinical pharmaceutical services.

Pharmacists' private practice in the community has always focused on the establishment of a good patient-pharmacist relationship, which is fundamental to the provision of patient focused pharmaceutical services. However, those patients who receive their pharmaceutical services through the public health system are being deprived of such a service because the public system is a barrier to the development of personalised services in an area where direct pharmacist-patient contact is essential. This is ethically and morally wrong, since it is

tantamount to inequity in access to services, which are necessary to attain positive outcomes of medicines usage and a better quality of life.

Thus people should have the equitable right to access to the services of a pharmacist, basing on the principle of social justice.

This is the main objective of the Malta Chamber of Pharmacists in insisting with successive Administrations to implement a "Pharmacist of Your Choice" scheme by decentralising the distribution of national health service medicines to the pharmacy/pharmacist of the patients' choice so that patients choose their private community pharmacy and pharmacist, not only on the basis of convenience in the location but significantly on the basis of the nature and quality of professional services that are delivered by the pharmacist.

This premise is based on the principle that "Freedom is essential to make choices" which can be considered to be derived from Kant's introduction of the concept of personal autonomy: that people, being free human beings are free to think, and free to act (in matters of morality).¹ Moreover, an individual's autonomy is a value that can be considered as basic - an individual's right to freedom to exist, to act, to think and to communicate.²

Our Society is organised as a state, and democracy can be organised as a system of parliamentary democracy. Thus, through the common interests of all individuals, democracy will result in a form of solidarity. Values that are considered as "essential" in today's western society are the individual's autonomy, democracy and solidarity, and justice. Indeed, healthcare as a common good is strongly connected to democracy. On the other hand, disease is one of the conditions that threatens autonomy. Thus, a compromise between autonomy and general interest is a

reasonable objective to avoid a climate of anarchy. An interesting premise is Rorty's,³ who explained that a certain level of solidarity guarantees a society that is stable enough to secure individual safety and prosperity. In fact, the public agreement about this is translated in a democratic political system, which forces by a majority vote every citizen to comply with this system. The result is a constant and dynamic tension between what Rorty calls the private and public domain.

In this bioethical scenario, the Pharmaceutical Profession has proposed the establishment of a public-private partnership between private community pharmacists and Government, whereby the distribution of National Health Service medicines (under the Social Security Act) from the government 'bereg' (postal system) and the health centre pharmacies is decentralized to be dispensed from the network of private community pharmacies of the patient's choice. This should entail the phasing out of the 'bereg'/postal system where patient and carers are deprived of any contact with their pharmacist.

It is also an excellent opportunity for the optimal use of healthcare resources through better involvement of private community pharmacists, whose expertise and services are at present underutilized. Thus, the implementation of such a system would "free" such highly trained human resources in the public health sector to use in the development of clinical pharmacy services in the hospital setting, thus improving patient care and outcomes. Moreover, the scheme is envisaged to require the re-evaluation of the entitlement criteria, with the exclusion of certain items under the "pink card" classification, in favour of a better service in other areas, such as extension to cover other chronic diseases under the 'Schedule V' criteria.

Table 1: Glossary

EQUITY	fairness, justice, and fairness in the adjustment of conflicting interests
SOLIDARITY	unity of fellowship arising from common responsibilities and interests and characterized by, or involving community of responsibilities and interests

One must distinguish between 'patients' wishes' and 'patients' needs'.

Árnason⁴ addressed the Rawlsian/Daniels arguments on justice in healthcare. With regard to the "principle of individual responsibility", it was argued that it is not a social obligation to provide health services which arise out of individual preferences and are not necessary to restore a person's functioning; while, in the context of the present paper, it would be more relevant to support the "principle of medical need", whereby, the Rawlsian/Daniels arguments revolve around the premise that it is more important to prevent, cure, or compensate for those disease conditions which involve curtailment of an individual's share of the normal opportunity range than to treat those conditions that affect it less.

Indeed, the present system does not satisfy patients' needs and requires revisiting insofar as it limits access to innovative, expensive medicines, in line with international trends for the treatment of diseases and conditions, based on proven efficacy (evidence-based), safety, cost effectiveness and improvement of the quality of life. More consideration should be shown to the prevalence of disease and conditions in Malta, and the consequences of non-treatment. In this regard, the support that government gives to those with ill-health should not be "rationed" to control expenditure on:

- innovative, expensive medicines for the treatment of those few patients with terminal or debilitating disease; and,
- treatments which can prevent serious health repercussions that can translate into expensive, invasive hospital-based treatments later on in life and a negative impact on patients' quality of life.

Rather, government should express a firmer commitment to solidarity and enable patients in their state of vulnerability to have access to medicines that not only add months or years to their life but also improve their well being.⁵

In this context, one cannot but re-emphasize the important and decisive roles that are played by continuously updated formularies, national and local,

and prescribing protocols. These are important tools to secure 'quality of outcome' intended as an optimised predictable, and uniform outcome of a specified intervention. In pharmacotherapy, it implies that a specific disease indication or problem is treated according to principles of 'evidence-based medicine'.⁶ Pharmacists and Doctors as healthcare professionals cooperate to compile, and update regularly, protocols, and groups of protocols to set-up formularies. These contribute to the practice of rational drug use, which must not be allowed to become restrictive but educational, being continuously monitored and evaluated with attention not only to e.g., consumption and expenditure, but also to e.g., efficacy and safety.⁷ Indeed, they should respect patients as individuals. The protocols should be communicated to the professional domain in a clear and unambiguous way and to society, where the decision takers have the responsibility to oversee the total field of request for public interference into the individual's life and to communicate their view to the people. The individual must recognise his ambiguous role in society, his different qualities and responsibilities, as this is fundamental to the acceptance of the daily consequences of any decisions concerning healthcare at the personal level.⁶

One such forum could be a national drugs and therapeutics committee which should include representatives of stakeholders, including, patients and professional associations, at the decision-taking level, introducing incentives for rational prescribing and dispensing and accountability; and to be able to evaluate requests for the introduction of new medicines and inclusion of new indications taking into consideration scientific evidence obtained from the maximum possible number of sources and not to restrict oneself to one sole institution.⁷

The pharmacy/pharmacist of the patient's choice

The primary objectives⁸ for the implementation of a system whereby the 'national health service' medicines are dispensed together with associated care services by the pharmacist of the patients' choice are summarized in Table 2.

Studies have consistently shown that there is strong support by the public for the decentralization of these services to the private community pharmacies in the towns and villages in Malta. Significantly, a body of knowledge is also building up, nationally¹⁰ and internationally, whereby research revealed evidence that pharmaceutical services in community settings make a positive

Table 2: The pharmacy/pharmacist of the patient's choice – objectives

- to ensure equitable access by the public to the expertise of pharmacists in medicines management and care services;
- to promote concordance to patients' treatment ensuring, not only compliance to medication but also empowering patients' responsibility of their own health⁹ and the rational use of medicines and other health resources;
- to contribute to the improvement of medicines management and to discourage the indiscriminate use of medicines, decreasing misadventures due to abuse;
- to eventually decrease hospitalization of patients as a result of drug misadventure and inadequate control of their condition;
- to develop the professional service of pharmacists in the community, upgrading the professional standards in the service of society;
- to develop seamless and continuous care between primary and secondary healthcare structures at the interface between public and private pharmaceutical care services.

impact on patient outcomes (e.g., clinical, humanistic, economic).¹¹

Patients, pharmacists and society: partners in healthcare

Patients are key partners in healthcare. Their needs are the leading principle in care-ethics.¹² Community pharmacists can empower them to take a more active role in their own healthcare, to take on responsibilities

to pursue healthy lifestyles, become more knowledgeable about their condition and their treatment, and to participate in decisions, and cooperate in accepted therapeutic regimes which should have the objective of restoring the maximum achievable autonomy.

The proposed "Pharmacist of your Choice" model is a public-private partnership initiative between the community pharmacists and 'society' intended as people, i.e., patients and other healthcare professionals, and

government. It would consolidate the role of the pharmacist as the gatekeeper to avoid negative outcomes of pharmacotherapy and the promotion of health. In the present circumstances, this is expected to receive an increasing public endorsement. Such a focus on patients together with the social imperative to provide medicines and care are deeply held convictions of our society, which are, in turn, ingrained in the principles of solidarity and equity in healthcare.

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Drugs in renal failure

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When prescribing a drug for a patient with renal failure, many issues must be considered before giving any advice or recommending any dosage changes in such a condition. This is one of the problems tackled by medicine information pharmacists. A drug may behave differently in a patient with renal dysfunction from a patient with normal function. This article helps to highlight some of the basic principles that we need to keep in mind when dealing with information about drugs in renal disease.

Renal failure is a condition in which many factors are involved in altering a drug's pharmacokinetics, inducing changes in the absorption of the drug, plasma protein binding, volume of distribution, excretion, drug sensitivity and tissue distribution. Thus when prescribing a drug in such a condition, one must keep some basic principles in mind.

Acute renal failure may be defined as the cessation of renal excretory function within a period of hours or days, accompanied by a rise in serum urea and creatinine. It may be accompanied by a fall in urine output, presenting itself as anuria or oliguria. The causes of acute renal failure may be classified as pre-renal, renal and post-renal damage.

Pre-renal damage occurs when the

kidneys are deprived of blood flow. Drugs can cause this type of damage by compromising the circulation and hence decreasing renal perfusion. Volume depletion resulting from aggressive diuretic therapy or from major gastrointestinal losses caused by drug-induced diarrhoea and/or vomiting can compromise renal function.¹ Renal damage may be subdivided into vascular, glomerular, tubular, and interstitial damage. Post-renal damage occurs when there is blockage to urinary outflow, for example, in prosthetic hypertrophy.

Drugs may be the cause of any of these processes leading to renal failure. Analgesic nephropathy is a form of renal disease in which there is often renal papillary necrosis and a history of analgesic administration. Analgesic combinations seem to increase the risk of developing chronic tubular interstitial disease and papillary necrosis.¹ Table 1 gives examples of such drugs.

Chronic renal disease occurs as a result of primary renal disease or a renal complication of another disease, for example diabetes mellitus. As the kidney function declines, the regulatory capacity of the kidney fails and uraemic complications occur affecting most systems of the body.²

1. Patients with renal disease are prone to the anaemia that may result from uraemia and reduced erythropoietin production. Uraemia increases the risk of GI bleeding.
2. Another complication is that as renal function decreases, phosphate filtration in kidney is reduced, leading to high phosphate levels (which causes itching). The latter results in low plasma calcium. A lack of active vitamin D causes reduction in calcium absorption from the gut and also results in low plasma calcium. Low calcium levels stimulate PTH secretion thus releasing calcium from bones causing renal osteodystrophy.

Table 1: Drugs affecting renal function¹

	Pre-renal disease	Drugs causing crystalluria	Analgesic nephropathy	Drugs causing glomerulonephritis	Tubulotoxic drugs	Drugs causing interstitial nephritis
Acetazolamide		X				
Aciclovir					X	
Allopurinol				X		X
Aminoglycosides					X	
Aminosalicylates						X
Amphotericin					X	
Antihypertensives	X					
Bumetanide, Furosemide						X
Caffeine			X			
Cephalosporins						X
Ciclosporin A					X	
Cimetidine						X
Cisplatin					X	
Cotrimoxazole						X
Diuretics	X					
Gold				X		X
Halothane				X		
Hydralazine				X		
Ifosfamide					X	
Indinavir		X				
Interferon						X
Isoniazid						X
Laxatives	X					
Lithium					X	X
Mannitol					X	
Mercaptopurine		X				
Methotrexate		X				
Nitrofurantoin		X				
NSAIDs	X			X	X	X
Paracetamol			X		X	
Penicillin				X		X
Pentamidine		X				
Phenytoin						X
Probenecid				X		
Quinidine				X		
Quinolones						X
Rifampicin				X		X
Salicylates			X			
Sulphonamides		X				X
Tacrolimus					X	
Thiazides				X		X
Vancomycin					X	
Vasoconstrictors	X					
Vitamin C		X				

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Information technology has become the fulcrum of communication and information dissemination in the scientific world. The internet highway is now the lifeline of scientific information interchange and is set to continue to expand in the future.

The website of the Malta College of Pharmacy Practice (MCP) was launched in June 2003, and constitutes a major information portal for the College. Besides providing visitors with information regarding the aims, structure, membership options and accreditation systems of the College, the site also provides surfers with up-to-date information regarding continuing professional development activities, MCP publications and future activities. Current and past issues of *The Chronic*ill* are available for download free of charge, while the Links pages provide internet shortcuts to various academic and professional

organisations as well as pharmacy-related knowledgebases, discussion groups, online books and journals. The site also provides email contact information for each member of the MCP council, and visitors are invited to submit any questions or comments to the relevant council members.

MCP is also currently hosting the official website of the forthcoming 13th International Social Pharmacy Workshop to be held in Malta between the 19-23 July 2004. Full registration and payment instructions together with the full programme, main speaker profiles and contact information are presented. These pages are being

continually updated as new information becomes available.

Plans are currently underway for new features to be added to the MCP website. A members-only area comprising an MCP noticeboard, continuing professional development documents download area, a pharmacy practice discussion forum and a contact email directory of members who specifically wish to be included are envisaged.

MCP welcomes any suggestions for new material to be included in the website, and readers are invited to email any comments to info@mcppnet.org.

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3. Oedema results from sodium and water retention. Low serum albumin is common in renal patients and can contribute to fluid retention.
4. The kidney's role in monitoring the correct ionic, osmotic, pH and fluid balance is disturbed and control of potassium levels deteriorates. Hyperkalaemia can cause muscle weakness, arrhythmias and cardiac arrest.
5. Acidosis results from hydrogen ion accumulation manifesting itself as decreased bicarbonate levels.
6. Restless legs, pruritus (due to high phosphate levels or uraemia), nausea (accumulation of toxins) are other complications.

The use of drugs in patients with reduced renal failure can cause problems.

1. The failure to excrete a drug or its metabolites may produce toxicity. Most systemically administered drugs are eliminated at least partly by the kidney, even if it is only a tiny proportion of the administered dose. However for some drugs, the kidney is the major site of elimination of unchanged drug and these are particularly liable to require careful dose adjustment in renal dysfunction to prevent accumulation. Examples of such drugs include aciclovir, cefotaxime, ciprofloxacin, digoxin, electrolytes, fluconazole, gentamicin, lithium, meropenem, pamidronate, methotrexate and vancomycin.³
2. There are drugs with therapeutic activity at least partly dependent upon metabolites that are excreted unchanged by the kidney.³ An examples of such a drug is allopurinol, whose therapeutic activity depends on the metabolite oxipurinol, the latter being excreted unchanged by the kidney.³
3. Nephrotoxic drugs must be avoided.
4. Sensitivity to some drugs is increased even if elimination is unimpaired. Uraemic patients are more susceptible to drug effects, for example an increased CNS-

depressant effect due to increased permeability of blood brain barrier.³

5. Gastrointestinal disturbances are very common and prescribing antacids must be done with caution.⁴
6. Some drugs may cease to be effective when renal failure is reduced. In the presence of oedema and ascites, there is an increased apparent volume of distribution of highly water-soluble drugs. Higher doses may be needed. Conversely dehydration or muscle wasting may result in unexpectedly high plasma concentrations of drug.³ Thus since oedema is a result of sodium and water retention, the sodium content of drugs must be checked before prescribing the drug.
7. Highly protein-bound drugs must be used with caution. This is because plasma protein binding is decreased in uraemia due to decreased plasma albumin levels allowing more free drug available at the site of action but a shorter half-life since more free drug can be metabolized and/or excreted.³

Besides the problems mentioned, some precautions must also be kept in mind.

1. If even mild renal impairment is considered likely on clinical grounds, renal function should be checked before prescribing any drug that requires dose modification.
2. Before starting a drug for a patient who is on dialysis, it must be checked whether the drug is dialysed or not. Sometimes doses may need to be titrated.
3. Renal function generally declines with age and many elderly patients have a glomerular filtration rate (GFR) of less than 50mL/min, which because of reduced muscle mass, may not be reflected by an elevated creatinine. Thus one can assume mild renal impairment in the elderly.⁵

Consequently, when choosing a drug for a renally impaired patient, one must also keep the above points in mind together with the complications that arise in chronic renal failure.

Principles of dosage adjustment

For toxic drugs with a small safety margin, dosage regimens based on glomerular filtration rate should be used. For those drugs where both efficacy and toxicity are closely related to plasma concentrations, the recommended regimens should be seen only as a guide to initial treatment; subsequent treatment must be adjusted according to clinical response and plasma concentration.

The total daily maintenance dose may need to be reduced and this is done by either reducing the size of the dose itself or by increasing the dosage interval. For some drugs, if the size of the maintenance dose is reduced, it will be important to give a loading dose if an immediate effect is required. When a patient is given a regular dose, it takes more than five times the half-life to achieve steady state plasma concentrations. The plasma half-life of drugs excreted by the kidney is prolonged in renal failure and so the reduced dose may take many days to achieve a therapeutic plasma concentration. The loading dose should usually be the same size as the initial dose of a patient with normal renal function.⁶

Calculating creatinine clearance

The severity of renal impairment is expressed in terms of glomerular filtration rate and is usually measured by the creatinine clearance. The equation generally quoted to calculate creatinine clearance is the Cockcroft & Gault equation and uses serum creatinine. Using serum creatinine to calculate creatinine clearance assumes that renal function and serum creatinine are stable.

$$CrCl = F \times (140 - \text{age}) \times (\text{weight in Kg}) / \text{plasma creatinine (micromol/L)}^{3,4}$$

where F = 1.04 in females and 1.23 in males.

In cases of obesity, oedematous patients and patients with ascites, the ideal body weight must be used. The equation cannot be used in children, pregnancy, marked catabolism or rapidly changing renal function,

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while in patients with muscle wasting diseases, use of the equation will lead to an overestimation of the creatinine clearance.

Drug dosing in renal replacement therapies

When prescribing a drug for a patient on a renal replacement therapy, one must be aware of the factors involved which will affect the clearance of the drug and whether a drug is actually dialysed or not. The summary of product characteristics, which is the detailed product information supplied by the drug marketing authorization holder, usually contains details of dosage regimens according to the type of replacement therapy the patient is

on. Clearance of the drug may be affected by factors such as drug characteristics and dialysis characteristics. Highly protein bound drugs and very large molecules are less likely to be removed. Dialysis solutions are aqueous so water-soluble drugs are preferentially eliminated. Lipid-soluble drugs tend to have larger volumes of distribution and so concentrations in plasma are comparatively small.³ Dialysis characteristics such as flow rate, composition of dialysate, type of dialyser membrane and duration of procedure all affect drug removal.⁷

No renal replacement therapy is as effective as the normal kidney, so the doses used will never be larger than those recommended in normal renal

function. Drugs usually excreted by the kidney are usually dialysed, and vice versa, although there are some anomalies.³ If a patient is on haemodialysis, it should be aimed towards administering the drugs after any session of dialysis since they may be removed before they even have time to act fully.

In conclusion, one must first gather the relevant information about the patient including weight of patient, medical condition, medications, replacement therapy, serum creatinine levels. A full picture of the patient's condition is important so as not to overlook any factors that may influence one's decision in choosing a drug or altering its dose.

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The AD/HD Family Support Group

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Attention Deficit Hyperactivity Disorder is still a diagnosis which raises many questions. Is it a bona fide diagnosis or not?

Its history can be traced back to 1916 in research carried out by Dr. Arthur Still on asthmatic children. Today it is known that there are three sub-types of AD/HD and researchers such as Prof. Russell Barkley (University of Massachusetts, USA) and Dr. Sam Goldstein (University of Massachusetts, USA) say that it is not primarily a problem of attention, but more a problem of developmental delay in the area of self-regulation. People with AD/HD know what they should do but they fail to do it.

It may be easy to brush off the symptoms as individually occurring problems, but when they prevent the normal development and acceptance of the child by his peers, they become as important as any other health-related problem.

The AD/HD Family Support Group has an extensive Resource Library covering all aspects of AD/HD. The literature is suitable for members of all the involved professions, parents, children with AD/HD as well as their siblings. Besides books, audio tapes and video tapes are also available and many information leaflets are provided free of charge.

Past activities of the Group include the organisation of visits to Malta by psychiatrist Dr. Veira Bailey (Maudsley Hospital, University of London) and Dr. Dianne Zaccheo, who runs a Family Clinic in London, and most recently a Seminar by Dr. Loretta Giorcelli, from Australia who is a consultant specialist in the disability and inclusion field in schools across Eastern Asia, America and England.

The Group also organises In-Service Training courses for schools and delivers talks at various venues, including the University of Malta and Parent-Teacher Association meetings. At the request of member parents, we also offer to communicate with the teachers of their AD/HD-affected child.

The Support Group disseminates information regarding the latest research and new medication to members and acts as a pressure Group in any area considered to be of importance to families and sufferers of AD/HD.

The Group meets regularly on the second Friday of every month at the premises in Msida, at 6.30 p.m. These meetings help group members realise that they are not alone and the moral support they give each other is of the utmost benefit. The meetings are open to all interested individuals, and not only to parents. Children with AD/HD have their meeting with a Personal and Social Development teacher who organises games and activities to help them consolidate the skills where they are having problems. A new addition to our Group meetings is a siblings' group; this also meets at the same time on the same day.

Parents suffer twice from this disability, once because of having a child with a disability and secondly because of the lack of awareness and appreciation of the condition, its manifestation and handling.

The address of the Support Group is: Paulmar, Oscar Zammit Street, Msida. The telephone (+356 2123 3749) is serviced by an answering machine and any messages are dealt with as promptly as possible. The office is open to visitors and the library may be used on Friday mornings between 10.00am and 12.30pm. However, if necessary, alternative arrangements for library viewing can be made by prior telephone arrangement.



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The scaly scalp

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Keywords: scalp dermatoses, psoriasis, eczema, tinea capitis

A popular atlas of dermatology lists more than 35 diseases which commonly affect the scalp.¹ Scaling is a prominent feature of several of them. Clearly, a comprehensive review is not possible within the compass of this article. Instead, attention will be focused on some relatively common conditions, which the community pharmacist may be called upon to recognize and treat. The discussion includes advice concerning diagnoses, pitfalls, over-the-counter (OTC) remedies, and when to refer.

Cradle cap

Cradle Cap is the vulgar name for infantile seborrhoeic eczema. The cause is unknown. The baby's scalp becomes pink and scaly, and greasy yellow crusts may also form. The rash may spread to the face and flexures of the ears, armpits, and groin. Rarely, it could become generalized, but never dangerous. The lesions are not itchy,

and they disappear with or without treatment after a few weeks. The condition is not infectious, and it does not lead to adult seborrhoeic eczema². The scales of cradle cap can be removed by rubbing with an emollient, such as almond oil, followed by a mild detergent shampoo. Alternatively, 0.5% salicylic acid in a cream base may be employed as a mild keratolytic. The

regular use of salicylic acid over a wide area should be avoided in babies because it carries the risk of salicylism due to systemic absorption. Infants with widespread eczema should be referred for medical examination. A prudent pharmacist would not dispense topical steroids on his/her own initiative in this type of situation.

Ringworm of the scalp

Ringworm of the scalp is technically known as tinea capitis. This is an infection of the scalp hairs by one of a number of dermatophyte fungi some of which habitually live on animals or in the soil, while others spread from one human being to another in epidemic fashion. In Malta, the commonest organism is *Microsporum canis*,³ which is a species of animal ringworm commonly found on stray kittens. Children are the usual victims. There are patches of redness, scaling and, most important, hair loss in the scalp. Contact with furry animals (kittens, rabbits, goats), multiple cases in a family, and concomitant ringworm on the body are useful aids to diagnosis. A boggy swelling (kerion) may develop in neglected or mistreated cases, and this could lead to permanent hair loss due to scarring in the area. Tinea capitis requires careful systemic treatment to prevent such complications. Suspected cases should consequently be referred immediately for specialist care. The use of topical anti-fungal preparations at this stage may pre-empt an accurate mycological diagnosis.



Figure 1: Tinea Capitis (Ducray archives)

Dandruff and adult seborrhoeic eczema

Seborrhoeic eczema affects approximately 5% of adults. It is even commoner in Parkinson's disease, and in HIV/AIDS where it may be the presenting complaint. Our understanding of seborrhoeic eczema turned full circle over the years. In the 19th century Sabouraud implicated *Pityrosporum ovale* after he observed it in the scales. However, this yeast is also present as a commensal in normal skin, and interest dwindled when it was determined that seborrhoeic eczema responds to topical steroids which, if anything, should make the putative 'infection' worse. Interest revived with the introduction of ketoconazole. This antifungal agent clears seborrhoeic eczema, albeit temporarily, administered orally. Furthermore, the association with HIV/AIDS could be related to overgrowth of *P. ovale* due to immunosuppression. Nowadays pityrosporicidal additives are included in many shampoos and other formulations intended for the anti-dandruff market, common dandruff being generally regarded as a mild variety of seborrhoeic eczema. Often, the diagnosis of seborrhoeic eczema can be made visually upon presentation because the erythema and flaking on the scalp, eyebrows and nasolabial folds plus dandruff deposited on the shoulders are so embarrassingly obvious. Leading questions concerning covert patches in the praesternum, interscapular area, and possibly flexures may convince the client that he or she (seborrhoeic eczema is commoner in men) has come to the right establishment. Dandruff and seborrhoeic eczema are likely to persist, with improvement in the summer. In the winter, the face should be protected from desiccating winds. Common dandruff should respond to shampoos containing selenium, zinc pyrithione, tar, or 2% ketoconazole in difficult cases. The pharmacist can improve the chances of success by explaining the correct mode of application, for poor technique may

account for treatment failure. Some modern facial moisturizers incorporate piroctone olamine or similar anti-fungal agents which may safely be used in the long-term control of facial seborrhoeic eczema. Another non-steroidal anti-seborrhoeic facial preparation contains 5% lithium succinate, but this is not yet available on the local market. On the face, seborrhoeic eczema must be distinguished from rosacea which requires appropriate treatment. In the scalp, seborrhoeic eczema may overlap with psoriasis which is more difficult to treat. In other areas of the body, dermatological referral may be indicated to exclude ringworm, candidiasis, erythrasma, psoriasis, or other disorders of keratinization which mimic seborrhoeic eczema.

Psoriasis

Psoriasis affects approximately 2-3% of the general population.⁴ It is the paradigm for chronicity in dermatology, so much so that in Malta severe psoriasis is listed among the diseases which entitle patients to free treatment on Schedule V Part 2 arrangements. The frequency and chronicity of psoriasis are just two of the many aspects which make it so important in terms of personal hardship⁵ and economic costs to the community.⁶ The Psoriasis Association of Malta is a useful source of information on the local scene.⁷ Immunological derangements are implicated in the aetiology of psoriasis but the fundamental cause remains mysterious, and so symptomatic remedies abound.

The scientific rationale is to reduce the rate of epidermal cell turnover which is accelerated in the plaques and which, in the scalp, is responsible for the well-defined raised areas of salmon redness and heaped-up silvery scales which feel like a ploughed field when running the fingers through the hair. There is no hair loss except in an unusual variant called Pityriasis amiantacea which affects children and in which asbestos-like scales (hence the name) cling to the hair shafts. There is a genetic predisposition to



Figure 2: Scalp Psoriasis (Ducray archives)

psoriasis, and the presence of confirmed disease in forebears is a useful pointer to diagnosis. Other possible important factors in the outbreak of psoriasis are streptococcal infections, stress, intercurrent illnesses, operations, physical accidents, and drugs - particularly anti-malarials and lithium. Patients may develop tell-tale changes in the finger nails consisting of pits or areas where the nail plate no longer sticks to the underlying bed (onycholysis). These nail changes are further clues to diagnosis. Spontaneous remission of psoriasis is common in the summer, and ultraviolet therapy on an outpatient basis is a very useful alternative for treatment of patches on the body and which is available all the year round. Private use of domestic ultraviolet sources should not be encouraged because of the risk of sunburn in the short term and skin cancer in the long run. Emollients are useful OTC adjuncts in the control of dryness, scaling and irritation. Regular use of emollients may reduce the need for prescription medications like topical steroids. There are several proprietary formulations on the market. Some are oily and designed to be dispersed in the bath water. Others produce a lather and are meant to be used as substitutes for soap. Several are oil in water emulsions intended to be applied directly to the skin. The pharmacist should help the client to understand the product clearly, thus preventing it from being put to the wrong use. A number of OTC emollients incorporate

urea and lactic acid which help the epidermis to retain moisture. Others contain 2% salicylic acid or 5-15% alpha-hydroxy acids (AHAs) which help desquamation. Tar may also be included as an emollient ingredient. Crude tars are chemical mixtures obtained from the destructive distillation of organic material. They have soothing and keratolytic properties, which have been exploited for the treatment of psoriasis long before their ability to reduce epidermal cell turnover was proven. Crude tars stain and smell. Refinement improves acceptability but reduces efficacy. Extemporaneous coal tar formulations are still an important standby in the hospital treatment of psoriasis. For a very long time coal tar has also been used in a wide variety of proprietary OTC products including soaps, shampoos, lotions, creams and ointments, but its use in cosmetic products is currently viewed with some anxiety due to its carcinogenic potential.⁸ Tar obtained from

bituminous schists (fossilized fish) is not carcinogenic, and upmarket "parapharmacy" products containing them (in combination with some of the other ingredients mentioned previously) have recently hit the local market. Another interesting therapeutic adjunct which has become available locally is the mineral salts from the Dead Sea.⁹ The anti-psoriatic benefits of the Dead Sea climate have been experienced by many European holidaymakers. The export of these minerals from the area is an attempt to reproduce just one of the components of the therapeutic regimen at home. Very severe psoriasis may need addressing with systemic anti-metabolites, retinoids, or immunomodulating drugs, and dermatological consultation is clearly imperative here. In addition up to 10% of patients may suffer from associated arthritic symptoms which may require attention by a rheumatologist. The natural history of psoriasis is notoriously unpredictable and isolated interludes of

spontaneous remission may be interspersed with frustrating episodes of relapse.

Conclusion

Scaliness of the scalp is a relatively common complaint. It can be a nuisance, especially if associated with embarrassing pruritus. There are many possible causes, and specialist consultation may occasionally be required to put the problem in its proper perspective. As explained, a scaly scalp may be part of a more widespread dermatosis, which requires a holistic approach to management. This article focused upon those relatively common situations where a community pharmacist could play an important role in providing primary care or in instigating medical referral. Spatial constraints imposed a thumbnail sketch approach. Hopefully the reader will be stimulated to fill in some of the details by looking up the references provided below.

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Errata corrigé

The Editorial Board apologizes for the following two errors which inadvertently appeared in the article entitled "The Concept of Social Pharmacy" published in the Summer 2003 issue of the *Chronic*ill*:

p.12: The email address of Prof. EW Sørensen should read 'ews@dfh.dk' instead of 'ews@dfk.dk'

p.15: Column 4 of Row 3, Table I (Dominating Method) should read 'Qualitative' instead of 'Quantitative'

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3. Blaxter P. Social health and class inequalities. In: Carter C, Peel J, editors. *Equalities and Inequalities in Health*. 2nd ed. London: Academic Press; 1976.

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