



Pharmaco Logical

The Newsletter of the Rational Drug Use Directorate
Ministry of Health, Sultanate of Oman

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In this edition there is a strong emphasis on pharmaceutical research work carried out in the Sultanate. We are delighted to publish a major contribution from pharmacists at the Royal Hospital who have carried out excellent work relating to Angiotensin Receptor Blockers (ARBs) and the rational prescribing of these valuable medicines.

Figure 1: A recent DRDU workshop for MOGPs



This is the fifth edition of the Pharmaco Logical newsletter so that means it is in its third year now! Hard to believe I know. Welcome everyone.

Contributors to this issue

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I understand that the distribution is getting better but could still be improved. Some of the remoter parts of our health system are still not receiving their copies on time. We are hoping that this

edition might appear on the Yahoo News Group “rduoman”. If you are lucky enough to have an internet connection and have not signed up yet I advise you to surf your way over to



and you can join. Just put in a search for “rduoman” (without the quotes). There is already some interesting material up for discussion. I use the term “discussion” loosely because at the moment it tends to be monologue and only rarely dialogue. Either myself or Dr Hassan Al Lawaty have been the only contributors so far. At the moment the number of members are few and there has been no feedback or input from the membership. The airwaves are eerily silent! As I have said before the group will only flourish if people contribute so please feel free to write in with your suggestions and comments. Unless we know what you like or are interested in we cannot hope to improve the group. In addition to the discussion there have been some very useful links posted which cover many different aspects of pharmacy and medicine.

Recent discussion topics include:

- Irrational practices – personal experiences.
- Glue used in surgery
- Illicit drugs

Some of the material is reproduced here in greater depth.

Public Education in Appropriate Drug Use

Dr. Ahmed Abdo-Rabbo

While prescribers and dispensers play an essential role in the choice of medicines, the role of the consumer is equally important. Public knowledge, attitudes, and perceptions regarding the use of medicines influence the decision to seek health care, the choice of provider, the use of medicines and the success of treatment.

Therefore public information and education in appropriate use of medicines is essential and is considered by the WHO to be the key element in any National Drug Policy.

The needs for public education at a general level are to give people better understanding of the beliefs and potential danger of drug use and at a specific level to tackle particularly serious problems of misuse and to organize campaigns for specific drug use problem e.g. the wiser use of specific drugs.

There are several drug use problems in the community, including problems of overuse, under-use and inappropriate use of medicines. These problems may give rise to serious health and economic consequences for individuals and community.

Unfortunately, there are very few documented descriptions of drug use problems in the community. Also little efforts has been made to change irrational drug use in the community and to alter the behaviour of consumers.

The Directorate of Rational Use of Drugs effectively conducted a number of public education activities on appropriate drug use. The aims of these activities were as follows:

- Identify different drug use problems in the community.
- Provide individuals and communities with unbiased information.
- Improve knowledge, attitude and practices in order to use drugs in an appropriate, safe and judicious way.

The activities which have been conducted on promoting rational drug use in the community are as follows:

- Development of plans for promoting appropriate drug use by public.
- Collecting information already available about drug use problems in the community to provide guidelines for future activities.
- Conducting (still on going) a survey on patients' knowledge, attitude and practice towards drug use to provide data on common drug use problems in the community and prioritize the problem(s) to be addressed in public education campaigns.
- Development of educational and training materials on rational drug use in the community for both public and health workers.
- Conducting one day seminar on certain aspects on rational drug use for health workers and health supporting groups from Wilayat Bausher.
- Training of health educators as trainers in promoting appropriate drug use in the community in North and South Sharqiya Regions and Muscat Governorate.
- Presenting lectures on promoting RUD in the community to female teachers, women and school children in Wilayat Bausher as well as school children in Wilayat Muttrah and staff in different ministries.

Drug Interactions. Part 1

It seems that everyone wants or needs to know more about this very important subject nowadays. Whenever our directorate evaluates a workshop or course the predominant feedback is a request for more information on “Drug Interactions”. In the coming months we shall try to give some useful information to you in small sections.

Drug Interactions may be desired or undesired, beneficial or harmful. They are deliberately sought when drugs are given together e.g. in tuberculosis or hypertension. In these cases the benefits to the patient may be increased as the two drugs may be additive or synergistic. In other cases the interaction is unintentional and results in some adverse effect on the patient. Clinically important interactions come about with drugs which have a steep dose-response curve and a narrow therapeutic index. Drugs which fall into this class include: oral anticoagulants, cardiac glycosides, anti-dysrhythmics, sympathomimetics, anti-hypertensives, anticancer drugs, antiepileptics, oral hypoglycaemics. **If two drugs treat the same condition then they are highly likely to interact.**

Mechanisms of Interaction:

1. **Pharmacodynamic interactions.** Both drugs act on the target site of clinical effect, exerting synergism, potentiation or antagonism. The drugs may act on the same or different receptors or processes.

e.g.

- alcohol and diazepam - mania and sedation
- morphine and naloxone - reverses the narcotic effect
- rifampicin and isoniazid - increased anti TB action

2. **Pharmacokinetic interactions.** The drugs interact remotely from the target site to alter plasma

(and other tissue) concentrations so that the amount of drug at the target site of clinical effect is altered.

e.g.

- enzyme induction - rifampicin and warfarin
- competition for plasma protein binding sites - aspirin and warfarin

Interactions can result in **antagonism** or **synergism**

Antagonism occurs when the action of one drug opposes another.

Possibly by opposing pharmacological effects e.g. histamine/adrenaline (physiological antagonism) or they may compete reversibly for the same receptor e.g. morphine/naloxone (competitive antagonism)

Synergism can be additive (e.g. bethanidine plus bendrofluazide) or greater than additive i.e. potentiated (e.g. trimethoprim and sulphamethoxazole). Nifedipine & diltiazem

Another way to think of the major classification of drug interactions is as follows:

Pharmacodynamic interactions refer to each drug's mechanism of action at the cellular level.

Pharmacokinetic interactions involve an alteration in a drug's absorption, distribution, metabolism or excretion (ADME).

Types of Interaction

The three most clinically important types of interaction involve:

Drug – Drug,

Drug – Food,

Drug – Laboratory test

Common Interactions

The most common types of interactions are drug – drug interactions and the most common mechanism usually leading to harmful effects is pharmacokinetic particularly with regard to drug metabolism.

To be continued.....

A Study on the Prescribing of Valsartan in Out-patient Clinics at the Royal Hospital

Fatma Al-Raisi, Zaher Al-Salmi, Ahmed Al-Harbi, Ali Al-Rawahi, Hamed Al-Naamani,

Introduction

Like Angiotensin Converting Enzyme inhibitors (ACEi), Angiotensin-II Receptor Blockers (ARBs) modulate the activity of the renin-angiotensin system by blocking angiotensin II type 1 (AT₁) receptors. Angiotensin II is a potent vasoconstrictor, and it stimulates the renal cortex to release aldosterone, which increases blood pressure by increasing retention of sodium and water in the kidney.¹

ACE inhibitors, and ARBs, have a key role in the treatment of common co-morbid conditions in patients with hypertension (HTN). They are associated with significant reductions in cardiovascular (CV) morbidity and mortality whether they are used as first-line therapy or in combination with other agents. Clinical evidence exists to recommend ACE inhibitors in patients with heart failure (HF), myocardial infarction (MI), high risk coronary heart disease (CHD), diabetes, chronic kidney disease, and recurrent stroke prevention. Evidence for the use of ARBs exists only for HF, diabetes, and chronic kidney disease. The results of the numerous clinical studies have established the reno-protective properties of renin-angiotensin-aldosterone inhibitors, therefore both ACE inhibitors and ARBs provide benefit in patients with diabetes by slowing the progression of renal disease. However ACE-inhibitors have been used as first-line agent in many randomized controlled trials comparing them with other antihypertensive drugs. Their efficacy in the presence of other co-morbidities and their safety in long-term treatment is well established. Therefore,

ARB is clearly indicated when the patient cannot tolerate an ACE inhibitor.¹⁻¹³

Medicines use review (MUR) showed that valsartan, which is the only ARB available at Royal Hospital (RH) at the time of the study, lies within the top twenty most expensive drugs in 2004 (O.R. 48,000), and in 2005 (O.R. 55,000).³ According to evidence based literature, ARBs are clearly indicated as a second line therapy when patients cannot tolerate an ACE inhibitor for HTN, HF, and post MI. Also, in view of the subsequent increase in the cost of Valsartan, and the lack of local guidelines/protocols to guide the use of such expensive drugs, it appears that there is a need to explore the current status of valsartan prescribing in Royal hospital.

In recent years, Ministry of Health strategy has concentrated on cost-effective medications. This study developed to fulfill the need for evaluating the ongoing system for improving the quality of drug use in RH. This study is a medicines use evaluation (MUE) which aims to describe the pattern of prescribing valsartan in Royal hospital. Comparison to international guidelines should highlight the need of developing local standard practice, which will ensure safe, effective, and economic use of medications in Royal hospital.

Aim and objectives:

The main objectives were to review the available international guidelines and to evaluate the adherence to these guidelines in prescribing valsartan in the outpatient setting at the Royal Hospital. Further objectives included identifying the rationale behind changing from ACEi to ARB for an approved indication and to make recommendations to improve the current practice of prescribing (valsartan) at the Royal Hospital.

Methods:Study criteria

All patients treated at the Royal Hospital, who are diagnosed with hypertension, HF, post MI and Diabetes related nephropathy should be prescribed valsartan as a second line therapy as an alternative to ACEi if not tolerated.

Study design

A retrospective study, conducted at the outpatient pharmacy setting, at the Royal Hospital in Oman between 15th May 2006 to 30th June 2006.

Inclusion and exclusion criteria :

The study included all adult patients who have been prescribed valsartan at the outpatient clinics at the Royal Hospital during the study period. We then excluded paediatrics and inpatient discharged patients.

Literature and guideline review

Literature search and review of well known international guidelines concerning the usage of Valsartan took place. Some guidelines reviewed are listed below:

1. British hypertension society
2. SIGN guidelines (hypertension, primary and secondary prevention and left ventricular systolic dysfunction LVSD)
3. NICE guideline (hypertension, heart failure)
4. ACC/AHA 2005 Guideline

Data collection

A data collection form was designed to standardise data collection. Please see table 1

Table 1

Patients demographics: (age, sex)

Co-morbidities and concomitant medications

Indication for valsartan

Whether patients were previously on ACEi or not or are on combination

If yes, what are the reasons behind shifting

If no, why not

Laboratory results relevant to use of valsartan

Adverse drug reactions (ADRs) if any

Finally, the cost of valsartan tablets per month for the included patients

A patient's electronic notes were reviewed and the data collection form was filled with the information required for the study.

A pilot study was conducted for 20 patients to see if there was any weaknesses in the data collection sheet.

Results:Demographics

The data were subjected to descriptive statistical analysis.

The study included 120 patients among which 11 were excluded because of duplication of prescriptions. Finally, 109 patients were included in the study during the study period. Of the 109 remaining patients, 54 (49.5%) were male and 55 (50.5%) were female with mean age of 55.8 years (SD=14.2).

Most of the prescriptions included in the study were prescribed from the cardiology clinics 55 (50.5%), followed by 38 (34.9%) from internal medicines clinics and 16 prescriptions (14.7%) from the nephrology clinic.

Co-morbidities

Most patients had significant co-morbidities. The most common co-morbidities recorded are as listed in the table 2 below:

Table 2

Most common co-morbidities of the studied patients	n	%
Hypertension	86	78.9
Diabetes Mellitus (DM)	43	39.4
Hyperlipidaemia	23	21
Heart failure (HF)	19	17.4
Chronic kidney disease	19	17.4
Myocardial Infarction (MI)	13	11.9
Angina	9	8.3

The patients were on an average of 5.9 medications per each prescription (SD = 2.5) with a maximum of 12 medications per prescription and minimum of 1 medication.

Indication of valsartan in studied patients

Most of the patients were prescribed valsartan for its FDA approved indication. 62% were on valsartan for hypertension, and 17% were prescribed valsartan for heart failure. Please see table 3.

Table 3

Indication	n	%
Hypertension	78	62
Heart failure	22	17
Proteinuria	12	9
DM related nephropathy	13	10
ISH	1	1
No indication	1	1

Among the 109 patients, 59 (54%) patients were previously initiated on an ACEi among which 48 (81%) were stopped due to different reasons. In 21% (n=10) ACEi was stopped because the patients developed side effects mainly cough and were shifted to valsartan. In 6% (n=3) of the patients the reason behind stopping ACEi was given as ineffectiveness of ACEi, while in 73% (n=35) there was no explanation why ACEi were stopped and valsartan initiated.

On the other hand 50 (46%) patients were commenced on valsartan and were not on any ACEi

previously. Among those who were not on an ACEi earlier, the reason given in one case was that an ACEi was not first choice as the patient was being treated with valsartan for isolated systolic hypertension (ISH). In 98% (n=49) of the patients there was no clear documentation to justify the use of valsartan without first trying an ACEi.

Laboratory monitoring (Urea and Electrolyte) U&E

Although the drug evaluated in this study had laboratory testing recommended in clinical guidelines, we observed wide variation in testing rates. 42% (n=46) of the patients were having their U&E done regularly (i.e. defined as every 3-6 months). In 36% (n=39) of the patients the laboratory monitoring was done sometimes, which is once a year. 16% (n=17) of the patients rarely got their U&E done (i.e. less than 1 a year). 6% (n=7) of the patients never had U&E done during the treatment period of valsartan.

ADRs associated with valsartan

This study revealed that only 7.6% (n=8) of patients seem to have ADR while in 93% (n=101) of patients there was no documented ADR in the notes. The ADRs detected in this study were not reported ADRs, these ADRs were only detected during the study period through the electronic notes of the patients. Among the 8 (7.6%) patients who were experiencing ADRs with valsartan, 5 (4.6%) patients were having hyperkalaemia (elevated serum potassium levels), one (1%) patient suffered from abdominal pain and 2 (2%) patients were complaining of headache.

Other findings of the study included estimating the cost of valsartan and comparing it to a standard ACEi used in the study setting. The cost of valsartan 80mg was compared to lisinopril 10mg

both in standard therapeutic doses. The cost was calculated for 109 patients for 1 year. Estimated average cost per prescription of valsartan was R.O. 9.3 per month.

Cost of ACEi (lisinopril 10mg)

Price / tab (0.013 R.O.) x 2 tab x 30days x 109 patients = 85.02 R.O. x 12 months = **1,020.24 R.O.**

Cost of ARB (valsartan 80mg)

Price / tab (0.200 R.O.) x 2 tab x 30 days x 109 patients = 1,308 R.O. x 12 months = **15,696 R.O.**

Cost difference ~**14,676 R.O.**

Discussion:

The results revealed that almost half of the study patients (54%, n=59) were initially on an ACEi prior to commencing valsartan. Of the 59 patients, 19% (n=11) were prescribed valsartan in combination with an ACEi for proteinuria.

Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines, recommend the use of ACEi and ARBs for diabetic kidney disease and non-diabetic kidney disease, as they lower BP, reduce proteinuria by 35-40%, slow progression of kidney disease and likely reduce CVD risk.

However, there is weak evidence that combined therapy is preferred (one large study of non-diabetic kidney disease, showed that combined therapy was more effective than either alone in slowing the decline in GFR but still additional studies required to support the combination. Most of the guideline recommends using one class rather than using them both)²⁰

Among the patients who were on ACEi 81% (n=48) found to be shifted to valsartan after discontinuation of their ACEi because of various reasons given. 21% (n=10) of the patients developed side effects from their ACEi (mainly cough) which required stopping the ACEi and

commencing valsartan, whereas, in 3 patients (6%) the documentations showed that ACEi was ineffective thus stopped and shifted to valsartan. In 73% (n=35) there was no clear explanation given as to why these patient were shifted to valsartan.

In (heart outcomes prevention evaluation) HOPE Tips reported that cough affected 14.3% of the patient and in 4% required discontinuation of ACEi.²¹ In our study shifting to valsartan because of cough was justified although there might be other reasons of cough which must be ruled out before labelling it as a side effect of ACEi.

Meta-analysis of ARB studies showed that there is no superiority of ARBs over ACEi in patients with heart failure.²² **(Valsartan In Acute myocardial infarction)** VALIANT trial concluded that valsartan was well tolerated and was as effective as captopril in patients with acute MI complicated with HF or LVSD.²³

This study also showed that 46% (n=50) were commenced on valsartan without first being on an ACEi, among which one patient was treated with valsartan for ISH. Valsartan appears to be effective for controlling ISH and had a better tolerability profile than amlodipine among ISH patients in the Val-Syst trial.²⁴ The rest of the 50 (n=49, 98%) patients were initiated on valsartan without giving any reasons of not trying an ACEi before commencing treatment with ARBs.

Living in an era of evidence based medicine (EBM), in which clinical guidelines are available in all specialties worldwide, a question is raised "Whether we need local guidelines or just to rely on the available international guidelines?"

The study has demonstrated the need to develop local guidelines to ensure safe and cost-effective prescribing of medications however, further studies

required to highlight the need for developing guidelines.

Conclusion:

The study was conducted at the Royal Hospital to evaluate the pattern of prescribing valsartan as a response of increased consumption over a relative short period. The study has shown that irrational prescribing of valsartan which has been elucidated by the study was attributed to the lack of local guideline or to the non-adherence to the available international guidelines. In general, prescribing according to the guidelines and rational drug use is necessary for saving the limited resources. Developing local guidelines was one of the main proposals of the study.

Acknowledgement:

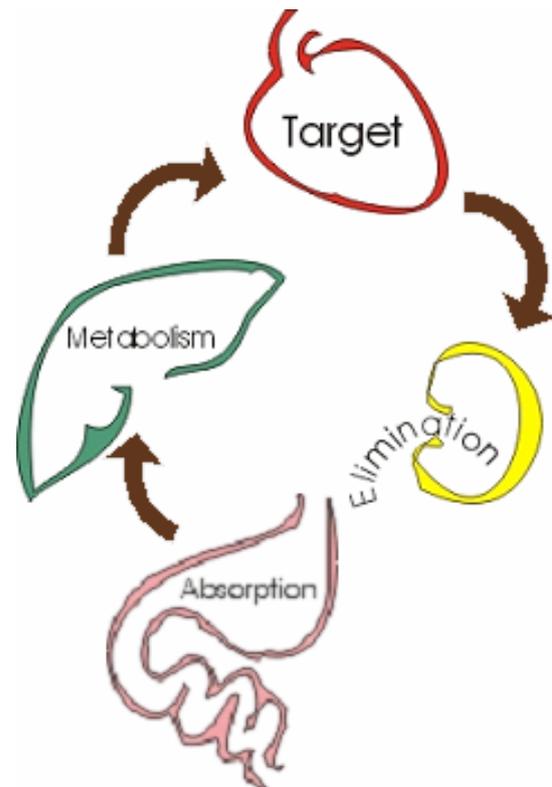
Thanks to pharmacist Jehan Al-Fannah, senior clinical pharmacist, head of clinical pharmacy department at Royal Hospital for all her support and valuable comments through out the study period.

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Sites of drug interaction within the body



A recent training of trainers workshop on rational prescribing for MOGPs held in Muscat

WHAT ARE THE ELEMENTS & GOALS OF DRUG MONITORING?

■ **Elements of drug monitoring**

- Quality: product defect
- Efficacy: lack or insufficient effect
- Safety: adverse drug reactions (ADRS)
- Rationality: drug utilization patterns

■ **Goals of drug monitoring**

- The rational and safe use of medicines
- The assessment and communication of the risks and benefits of drugs on the market
- Educating and informing patients

HOW TO RECOGNIZE ADRs?

- Ensure patient compliance
- Verify the onset of the ADR
- Determine the time interval
- Evaluate after dose reduction drug discontinuing and re-administering
- Analyse alternative causes other than the drug (prescribed and non- prescribed)
- Verify the incidence of similar reaction in the past to the same drug or similar one
- Verify the nature of the problem (check the relation with drug pharmacology and use your personal experience and relevant up-to-date literature)
- Report any suspected ADRs

INFORMATION CAPSULES

**By: Dr. Ahmed Abdo-Rabbo
Ph. Manal Al-Ansari**

WHAT TO WRITE IN ADRs REPORT?

1- Patient information

(name, age or DOB, sex, weight, nationality)

2- Suspected drug(s) information

(name, strength, dosage form, dose, route, start/stop dates, indication for use, lot. number, expiry date, source of the drug)

3- Suspected reaction(s)

(description, result of investigations and tests, start and termination date, outcomes)

4- Other medicines used (if any)

including self-medication (name, dose, route, start/ stop dates)

5- Report information (confidential)

(name, address, tel. no., date, specialty and occupation)

For more details see the yellow pages in the ONF

HOW TO PREVENT ADRs?

- Never use a drug unless there is a clear indication for its use
- Prescribe as few drugs as possible
- Use drugs with which you are familiar if possible
- Ask if the patient is already taking other drugs
- Only use drugs in pregnancy if it is absolutely necessary
- Ask if the patient had previous reactions
- Genetic factors should be considered
- Carefully explain dosage regimen to patients and give clear instructions
- Advise patient on food and drinks not to be taken

Test Yourself

Here are some questions from recent MOGP examinations:

1. Oral contraceptive pills should be started on day 5 of the menstrual cycle (T / F)
2. Most patients can use multi-dose inhalers (MDI) easily (T / F)
3. Corticosteroid MDI are also known as “relievers” in asthma therapy (T / F)
4. Regular liver function tests should be carried out on all patients on statins (T / F)
5. Glucagon is excreted by the liver parenchymal cells (T / F)
6. Glucagon injection can be given by any route s/c, im or iv (T / F)
7. SSRIs are more effective antidepressants than the older tricyclic drugs (T / F)
8. In the combination drug Co-amoxiclav the clavulanic acid component also acts as an antibiotic (T / F)
9. A patient on amoxicillin who develops a maculopapular rash is allergic to penicillin (T / F)
10. β -Blockers can be used in the third trimester of pregnancy (T / F)
11. Metolazone is a potassium sparing diuretic (T / F)
12. Prednisolone should be avoided in breast feeding (T / F)
13. Prednisolone can be stopped abruptly in a patient on a short course of treatment using less than 40mg per day (T / F)
14. Acarbose increases the sensitivity of insulin receptors to circulating insulin (T / F)

Answers:
1.F,2.F,3.F,4.T,5.F,6.T,7.F,8.F,9.F,10.T,11.F,12.F,13.T,14.F

Irrationality in Practice. 1

I would like to draw your attention to an irrational practice I experienced the other day as a "real patient" and I wondered if anyone had any thoughts or comments on this. I get monthly medication at a primary health care centre. Like most "chronic" patients I get other things from time to time such as analgesics, antibiotics, etc. The prescriber asked about my continuing therapy and how things were going. When I went to the pharmacy I was surprised to receive my correct medication plus other medication which I did not need as I had either stopped using it or already had enough. I do realise the prescriber was busy and I was in a hurry so perhaps the conversation never got round to other medicines or such issues. However, it occurs to me that there is a basic flaw in the computerised prescribing system. There has to be a means of discriminating between continuing medicines and occasional or one-off meds. I am only one patient out of many thousands so you can imagine the quantity of waste that must occur from day to day if this practice is common. Many patients will just take everything at the window without much checking (especially if there is a queue) and probably will not return the surplus. Everybody likes to save medicines for a "rainy day". So how should we solve this issue? Changing the computer software would be ideal but it could take a long time.

Irrationality in practice 2

Most health workers would agree that the labelling of dispensed medicines is a very weak area in the Sultanate. It is a very important area as incorrect labelling or instructions can result in improper use and abuse by the patient. It could even lead to the harm of the patient or another family member.

It is a difficult issue to generalise because of language and literacy. However, there is one labelling practice that needs to be addressed quickly. It involves the use of trade names vs generic names. It seems to be the norm here for health professionals to talk and think of medicines predominantly by the trade name or brand name. This is probably due to skilful marketing or advertising by the drug companies. Also, many of our health workers come from different backgrounds and have varied training.

What happens is that a patient receives a medicine which is usually a strip that is placed in a plastic outer envelope. The assistant pharmacist will then write on the drug name - predominantly the brand name although it is slowly improving in the last five years. The actual medicine in the envelope however, is unlikely to be the brand that is written on the bag and it will usually be a generic with a different brand name.

For example: the bag is written with "Tenormin®", inside the medicine strip shows the other brand name, say "Normoten®" and then in tiny letters the true generic name "Atenolol" might appear.

Is anybody confused yet? As a pharmacist I am confused so what about the poor patient? Proper machine printed labelling would help to prevent this but then language and literacy becomes an issue.

There are improvements taking place at this time and eventually it is hoped that all facilities will have label printing facilities like a few of our major hospitals and polyclinics do. It is hoped that the new labels will be printed in Arabic and/or other suitable language and perhaps have pictorial symbols to assist those patients who cannot read.

Breaking News

Online BNF (www.bnf.org) will no longer be available for reference in Oman from April 1 2007. In line with many other scientific journals and specialist pages the BNF on-line will become a subscription only service. Only a handful of developing countries will continue to get free access. There will still be some basic information available on the site and users will have to assess this for themselves. The same restrictions will apply to the new electronic Children's BNF .

Perhaps the MoH will be able to negotiate a special deal for all government health workers as is available for Micromedex (available now) and Cochrane Library (coming soon)



For more information on any article or for submission of suggestions or future articles please contact:

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