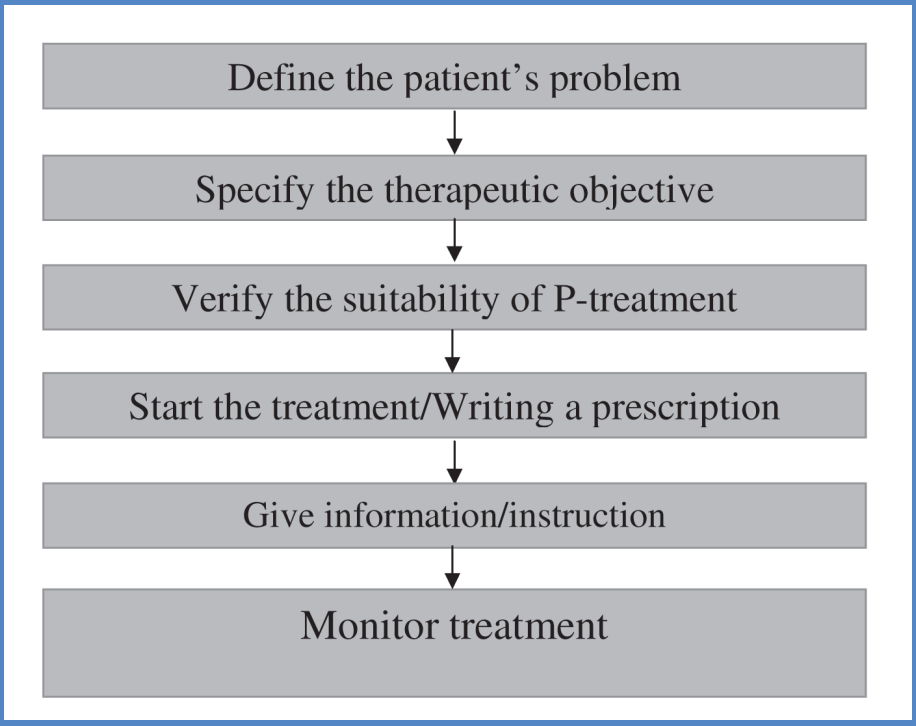
Manual for Medicines Good Prescribing Practice



Second Edition
May, 2012

Food, Medicine and Healthcare Administration and Control Authority (FMHACA) of Ethiopia

Food, Medicine and Healthcare Administration
and Control Authority of Ethiopia

Printed by:-www.masterprintingpressplc.com

Table of Contents

Acknowledgement....ii
List of Abbreviations....iii
Preface....v

Introduction....1
1.1 Background....1
1.2. Objectives....6

2. Principles of Rational Prescribing....7
3. Treatment....12
3.1. The concept of P-treatment and P-medicines....12
3.2 Guideline for selection of P-medicines....13
3.3 Treatment with P (personal) - medicines....15

4. Medicines Information....28
4.1 Provision of Medicine information to patients....28
5.Treatment Monitoring....32
6.Medicines Information....35
6.1.Updating Medicine Information....35
6.2. Sources of Medicine Information....35

Annex-1 Standard Prescription Paper....38
Annex-2 Adverse Drug Event Reporting Form....40
References....42
List of Consultative Workshops Participants....43

Acknowledgement

The Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia would like to extend its gratitude to USAID Funded Project,Systems for Improved Access to Pharmaceuticals and Services (SIAPS) for technical and financial support associated with the execution of the consultative workshop and printing of this manual for Medicines good prescribing practice . The Authority would also like to thank all participants of the workshop for their valuable contribution.

List of Abbreviations

ACE: Acetylcholinesterase

ADR: Adverse Drug Reaction

ART: Antiretroviral Therapy

AZT: Zidovudine

BID: Bis In Die (Latin) - meaning Two Times Daily

CNS: Central Nervous System

CSF: CerebroSpinal Fluid

EML: Essential Medicine List

EFV: Efavirenz

FMHACA: Food, Medicine and Healthcare Administration and Control Authority

FMOH: Federal Ministry of Health

GI: Gastrointestinal

GPP: Good Prescribing Practice

HIV/AIDS: Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

ICE: Information Communication Education

INN: International Non-proprietary Name

3TC: Lamivudine

LIME: List of Medicines for Ethiopia

Mitte: Mitte (Latin)-meaning Send

NSAID: Nonsteroidal Anti-inflammatoryDrug

NVP: Nevirapine

OTC: Over-The- Counter

PUD: Peptic Ulcer Disease

PO: Per Os (Latin) -meaning by mouth

STG: Standard Treatment Guideline

TID: Ter In Die (Latin) - meaning Three Times a Day

WHO: World Health Organization

Preface

Provision of promotive, preventive, curative and rehabilitative health services require regular availability of relevant medicines and their proper use; including proper diagnosis of health problems, prescribing and dispensing to patients. Guides and manuals for proper clinical practices are among those tools which assist in achieving the goals in the health service. And, a good prescribing manual is meant to guide through the process of prescribing and hence promote the rational use of medicines in Ethiopia.

The Manual for Medicines Good Prescribing Practice is hereby revised for the first time in light of the constantly changing knowledge and ideas about medicines and by taking in to consideration the recent reform in the health sector. It is designed in such a way to complement the standards and guidelines prepared in accordance to the new three-tier healthcare delivery system.The manual contains six main chapters.

The introduction deals with some of the positive trends and deficiencies observed over time in the prescribing practice in Ethiopia. These were based on review of relevant local literature.

The second part of this manual deals with what is generally accepted components and requirements of a good prescribing practice, principles of rational prescribing.

The third part of the manual comprises the major portion of the manual which introduce important concept of P-(personal) treatment, P- (personal) medicine and guidelines for selection and use of P (personal) -medicines in the treatment of individual patients with relevant examples and illustrations.

The fourth and fifth part of the manual, briefly describes provision of information to patient and Treatment monitoring respectively

The last part of the manual deals with the need and resources for updating medicine related information. The manual also contains annexes such as standard prescription paper, ADR report format and References at the end of the document.

Yehulu Denekew, Director Genenral

Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Addis Ababa, 2012

1.Introduction

Introduction

1.1 Background

Medicines are an essential component of health care delivery. When used rationally, they produce the desired effect of improving patients' ailments. Their irrational use on the other hand leads to prolongation of the illness, development of adverse effects, and unnecessary expense.

The rational use of medicines in the biomedical context in terms of rational prescribing practices should meet certain criteria, which are listed below:

- Appropriate indication in terms of the rationale of medicine use practices based entirely on medical considerations.
- Appropriate medicine in terms of selection based on efficacy; safety, suitability and taking into account cost considerations.
- Appropriate patient, to avoid the existence of contraindication and minimizing the chances of reactions.
- Appropriate dose in terms of administration and duration of treatment.
- Appropriate information and appropriate monitoring.

The terms "inappropriate" and "irrational" use were often used in association to the use of medicines when no therapy is indicated, the use of wrong medicines for specific conditions requiring medicine therapy, the use of medicines with doubtful efficacy, the use of medicines for uncertain safety status, use of correct medicines with incorrect route of administration, dosage, or duration[1].

In Ethiopia, several efforts have been made to promote the rational use of medicines. Among these, the publication of essential and national medicine list for Ethiopia, and the introduction of the Standard Treatment Guidelines (STG) are the most notable. As a result of such relentless efforts, some positive trends in the prescribing practice have been observed over time.

A survey which was undertaken in May-June, 2006 described the current treatment practices of hospitals. The method used was a cross sectional descriptive drug use indicator study covering both prescribing and dispensing practices on rational use of medicines.

Using standard indicators, data were collected for the availability of key essential medicines and rational use of medicines. All the regions and city administrations were included in the survey.

The study units comprised of governmental hospitals under RHB, which were from three different levels, i.e. regional, zonal and district. All the eleven regions and city administrations were included in the survey and from each survey region about 50% of the governmental hospitals were studied. Even though data collectors from the 40 selected hospitals were trained, results of the study from Kebridehar hospitals was not received, thus reducing the sample size to 39.

Although there have been tremendous improvement in the pharmaceutical sector over the past years, there is still the need to emphasize the setting up of appropriate systems to monitor the rational use of medicines regularly. Greater efforts should be directed at drug management practices in public drug outlets to improve their efficiency.

Data obtained from this survey show that availability of essential medicines in governmental hospitals is more than 80%.

There is a general tendency to over-prescribe medicines especially antibiotics. A national median of 65% patients received antibiotics. Irrational dispensing was also demonstrated – only an average of 19.92% of the drugs dispensed was adequately labelled. And only 12.18% of the respondents understood how to take their medicines [1].

Another study that looked into ; "patterns of drug utilization in inpatient department, Jimma hospital south west Ethiopia" concluded that: Inappropriate use of drugs is a problem even in a teaching hospital and continuing medical education on the management of widespread diseases is mandatory to reduce the risk of inappropriate use of drugs.

Result from the study showed weight record for 48 % (21) of paediatric patients who were admitted during the study period was not found. Although age and body surface area are used to compute drug dose in children, weight is frequently used to calculate paediatric dose of commonly used antimicrobials. Failure to take weight may lead to incorrect dose calculation, which is harmful to the patient.

This study showed that 24 % (59) of the prescription orders lack clear indications. Hence, relevant clinical evaluation and diagnostic investigations should be done before prescribing drugs to minimize unnecessary cost to the patient and to the country as well. Sixty five percent (161) of the order lack information concerning dose, which in turn could lead to under or over treatment of the patients.

Significant number of prescriptions lack information regarding the methods of drug administration, the interval of administration and the duration of treatment. These malpractices could result administration of drugs in the wrong route, unwanted shorter or longer interval of drug administration and incorrect duration of treatment.

Seven drugs (maximum) and 2.9 drugs on average were prescribed for paediatric patients during their hospital stay. Relatively higher results have been obtained in a study conducted in Gonder, Bahir Dar and Debre Tabor hospital, however a total of 158, 197, and 177 medical records were reviewed in Gonder, Bahir Dar and Debre Tabor hospitals respectively. Using less number of drugs is associated with good compliance, and relatively few side effects.

Antimicrobials in general and penicillin's in particular were the most frequently prescribed drugs in both departments. The prescription pattern closely related to the admission diagnosis. A similar result was obtained in a study conducted in Gonder, Bahir Dar and Debre Tabor Hospitals. Penicillin, chloramphenicol and TB 450 were the most widely prescribed drugs in Gonder, Bahir Dar and Debre Tabor Hospitals [2].

For instance, a survey of 115 health professionals (doctors, health officers, pharmacists, nurses and druggists) working in 12 health institutions in Addis Ababa, regarding their "Knowledge and application of national and essential medicine lists", documented the following findings [3]; Of the 115 respondents, 89 (77.4%) defined national and essential medicine lists correctly and 103 (89.6%) expressed that the essential and national medicine lists helped them to avoid unnecessary use of brand medicines. The importance of this study is, that publication of important documents like the LME, or STG, is not an end by itself. It can only be useful when the concerned health professionals have adequate knowledge about it and are committed to its application.

Data from a study done in Jimma hospital on prescription pattern also demonstrated that 95% of the medicines prescribed were those in the essential medicines list, and 75% of the prescriptions were for generic medicines [4].

The use of International Non Proprietary Names (INN) or generic names of medicines in prescribing is an essential component of good prescribing practice. This is because generic medicines are less costly, an important factor in our country, and for a generic prescription any suitable product can be dispensed hence avoiding delay while looking for a specific brand.

In the above cited studies in addition to this encouraging trend of generic prescribing, a low average number of medicines, and low cost per prescription were among the positive trends noted.

Although the commendable efforts of the Food, Medicine and Healthcare Administration and Control Authority and relevant professional schools and associations, have produced some good results, there are indications that the rational use of medicines in Ethiopia is far from satisfactory.

Results from the following studies illustrate some of the common problems of irrational medicine use in Ethiopia. A baseline survey conducted in 8 hospitals in southern Ethiopia looked in to the prescription pattern and factors that influence prescribing behavior [5]. This study concluded that irrational prescribing (in the form of high average number of medicines per encounter, high percentage of injections, high percentage antibiotic prescribing) is highly prevalent in the studied region. It also noted that prescribing behavior in over 60% of the respondents is influenced by factors like peer-norms, lack of medicine information, work load, etc rather than sound scientific evidence. These factors were given as the cause of the observed irrational medicine use.

A retrospective study on the prescription patterns of analgesics in 13 rural and regional hospital demonstrated that analgesics were prescribed almost for every patient in the study hospitals, showing that there was no a clear therapeutic guideline for prescribing analgesics [6].

Adherence of patients to a treatment program is necessary for the success of the program. Non-adherence or non compliance results from factors related to the medicine, the patient, the prescriber and the environment. One important prescriber factor leading to non-compliance is not giving the patient adequate information regarding his illness or the importance, effect, and adverse effects of the treatment. Result of a study illustrated that great majority of our patients are not given such essential information. In this study, out of 200 patients from four hospitals in Addis Ababa, asked whether they were given information about their medications, only 5.5% were informed about medicine-medicine interaction,

7% About adverse effect of the medicine, and only 9.5% were given information about contraindication of the medicine they were given[7].

The above cited examples probably show only the tip of the ice-berg regarding the problem of irrational prescribing. However, appraisal of such local data is essential in formulating remedial strategies.

As part of the strategies to solve problems related to medicine use, the FMHACA regularly prepares and distributes STG, LME, EDL, Medicine formulary and IEC material such as educational brochures and manuals (including this manual).

1.2. Objectives

To help prescribers in Ethiopia to critically look into their current prescribing behavior

- Encourage rational prescribing that is based on sound scientific evidence, conforms to international standards and local guidelines.
- Encourage all prescribers to develop a list of P-medicines (Personal medicines) so that they will have a thorough knowledge of the effects, adverse effects, medicine-medicine interactions, food-medicine interaction, and contraindications of the limited medicines in their P-medicine lists.
- Motivate prescribers to develop and maintain a behavior of regularly updating medicine information through all possible means

2. Principles of Rational Prescribing

Good Prescribing Practice (GPP) is prescribing the right medicine for the right patient, in the right dosage of the right formulation and for the right length of time. GPP also includes not prescribing any medicine at all if no need. It requires detailed knowledge of the pathophysiology of the disease and clinical pharmacology of the medicine.

Requirements for Good Prescribing Practice include:

1. One needs to assess the benefit-to-risk ratio of prescribing by considering:

I. Seriousness of the problem to be treated/appropriateness for the individual

II. Optimal use of the medicine with respect to: Therapeutic aspects

- The safety of the medicine
- Possible contraindications
- Medicine/medicine interactions
- Medicine/food interactions and
- Treatment duplication

e.g., phenylbutazone, commonly used in the treatment of osteoarthritis in the past, because of its high risk -to- benefit ratio, is currently replaced with safer medicines.

- Assessment of benefit-to-risk ratio may not always be easy. The following examples show this problem:
- The benefit of adding digoxin to a diuretic and vasodilator vis-à-vis the risk of its toxicity in the treatment of congestive cardiac failure. This might depend on the cause of the heart failure, patient compliance, renal function and ease of monitoring of plasma digoxin concentration.
- the benefit from a course of antibiotic in treating urinary tract infection in two months pregnant as compared to the risk of treatment to the fetus. Here the risk of teratogenesis needs to be compared to the risk of renal damage to the mother as a result of untreated infection.

2. Justification for medicine therapy

One has to justify the need for treatment before prescribing. Example of unjustified prescribing:

- Prescribing broad spectrum antibiotics for all patients with dysentery (May not be justified as the risk of antibiotic associated colitis will be increased, and the disease is usually self limited)

3. Once treatment is justified, to decide which particular medicine to use, the prescriber goes through the process of:

I. Selecting the therapeutic class; e.g.,

- antibiotics for infection (simple case);
- cardiac glycosides/vasodilators/diuretics for congestive heart failure (complicated case)

II. Selecting group of medicines within the class; the choice of antibiotics depends on

- sensitivities,
- site of infection,
- feature of patients such as contraindications
- availability and affordability

III. Selecting a particular medicine in the group; e.g. amoxycillin, among the penicillins

One may choose a medicine in favour of another based on different factors, such as:

- Pharmacokinetics
  - ☛ absorption; e.g., Cimetidine better absorbed than Rantidine
  - ☛ distribution; e.g. Fluconazole widely distribute throughout the body with good penetration into cerebrospinal fluid (CSF), eye, peritoneal fluid, sputum, skin and urine.
  - ☛ biotransformation; e.g., avoid opioids in liver disease for they are

extensively metabolized by the liver

- ☛ Excretion; e.g., avoid aminoglycosides in case of renal impairement.
- Pharmacodynamics: Efficacy could be the basis for the choice.
- Therapeutic effect such as:

☛ features of the disease; e.g.,choice of penicillin or cotrimoxazole for a patient with bronchopneumonia as the likely organism is pneumococcus or H-influenza; aspirin or paracetamol for mild pain and morphine for severe pain

- ☛ coexisting disease: e.g.,
  - thiazides for hypertension with ventricular failure;
  - beta blockers for hypertension with angina
- ☛ avoidance of adverse effects: e.g.,
  - short acting benzodiazepines (temazepam) preferred to long acting (nitrazepam);
  - Erythromycin for patients hypersensitive to penicillin
- ☛ avoidance of contraindications: e.g., avoid aspirin in a patient on warfarin treatment
- ☛ Patient compliance: e.g., 2g metronidazole as a single dose is preferable than 500mg twice daily for 7 days in the treatment of urogenital trichomoniasis.

4. Route of administration: e.g.,

- Crystalline penicillin is given by intravenous route for severe infections; Intramuscular benzathine penicillin monthly or oral penicillin daily can be given for rheumatic fever prophylaxis.
- Beta agonists like salbutamol are given through nebulizers or inhalers in acute asthmatic attack for fast action.

5. Formulations: e.g.,

- Oral formulations include tablets, capsules, granules, elixirs, suspension; injection formulations include lyophilized powders, solution.

- For chronic rheumatic disease, prescribe enteric-coated formulation in order to reduce GI irritation

6. Dosage regime (dose), frequency, timing of administration: the following need to be considered

- Pharmacokinetic variability: medicine with poor absorption, prescribe larger dose or prescribe another medicine/route.
- Pharmacodynamic variability: medicine with less effect, prescribe larger dose within therapeutic range.
- Characteristics of the patient: tailor the dose according to body weight, age and other factors while prescribing.
- Characteristic of the disease: e.g., dose of codeine used to suppress cough is lower than that required to relieve pain.
- Choosing a dosage regimen by
  - ☛ referring to a reliable source of information
  - ☛ considering dose related toxicity
  - ☛ deciding the initial dose: start with low dose and increase gradually
  - ☛ (ACE inhibitors, levodopa); for some medicines to increase the dose
  - ☛ may be necessary because of tolerance (opiates); sometimes
  - ☛ starting with a loading dose before giving a maintenance dose is
  - ☛ required (digoxin); in some cases to start with high dose and reduce
  - ☛ gradually might be required (corticosteroids)
  - ☛ Considering kinetic factors which may alter dosage requirements:
  - ☛ e.g., impaired renal function
  - ☛ Considering dose response relationship for the patients: e.g., higher
  - ☛ dose of insulin for ketoacidosis, and lower dose of antipsychotic
  - ☛ medicines in treatment naive patients
  - ☛ Considering other patient characteristics like age, sex weight, etc
- Frequency of medicine administration:

- ☛ usually fixed for a given formulation;
- ☛ sometimes may be altered (e.g., splitting the dose of spironolactone in two to avoid GI irritation), e.g. frequency of nitroglycerin administration depends on the frequency of symptoms

• Timing of medicine administration: The following are examples where timing is very important

- ☛ To minimize ADR: e.g. tricyclic antidepressants to avoid dry mouth and drowsiness better to take it at bed time; potent diuretics better be given in the morning to avoid disturbance during the night
- ☛ Timing of symptoms: e.g., anginal attack, use of antacids
- ☛ Timing in relation to meals: penicillin to be administered before meal; aspirin to be administered with meal

7. Course of treatment

• Depends on the nature of the disease or symptom: e.g., a single dose of aspirin for headache; Insulin for chronic therapy; treatment with H2 blockers require six weeks as healing occurs within this period, but longer periods of nightly administration may be required to prevent recurrence.

• Duration of treatment of infection depends on:

- ☛ The infecting organisms
- ☛ Site of infection
- ☛ Type of antibiotics
- ☛ Dosage of antibiotics
- ☛ Response to treatment

3. Treatment

3.1. The concept of P-treatment and P-medicines

As a prescriber you may see many patients per day, many of whom need treatment with a medicine. How do you manage to choose the right medicine for each patient in a relatively short time? By using P-medicines!

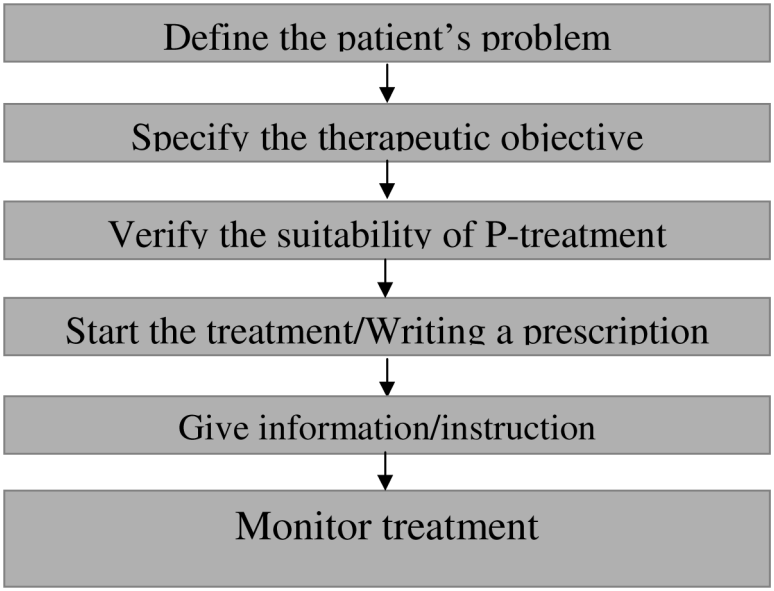
The first step in rational treatment is defining the patient's problem, which is making a correct diagnosis. Once a diagnosis is made, one has to specify his/her therapeutic objective, what the prescriber wants to achieve with the treatment to be applied. Based on the therapeutic objective, one chooses a treatment of proven efficacy, safety, suitability and affordable cost from different alternatives.

In choosing your treatment it is important to remember that not all health problems need treatment with medicines. The treatment may consist only of giving patients' advice and information about their illness, non-medicine therapy, treatment with medicine, or a combination of these. For every diagnosis you make, the treatment plan you choose will be your P (personal)-treatment. When for a certain diagnosis your P-treatment consists of medicine treatment, you have got to choose a medicine(s), on the basis of efficacy, safety, suitability, cost and availability. This will be your P - (personal) medicine. P-medicines are the medicines you have chosen to prescribe regularly, and with which you have become familiar. They are your priority choice for given indications.

P-medicines are list of medicines every prescriber got to choose for a particular problem based on the National Essential Medicines list and the Standard Treatment Guideline (STG) for Ethiopia. The prescriber, by choosing P-medicines which he/she prescribes regularly, becomes familiar with their effects and side effects. The P-medicine concept is more than just the name of a pharmacological substance; it also includes the dosage form, dosage schedule and duration of treatment. There

is a difference between P-medicines and P-treatment. The key point is that not all diseases need to be treated with a medicine. Not every P-treatment includes a P-medicine!

In general, there are six major steps to be performed in the prescribing cycle during the rational prescribing process.



3.2 Guideline for selection of P-medicines

In selecting p-medicines, the prescriber needs to consider the following:

1. Defining the diagnosis

Selecting a P-medicine is choosing a medicine for a common condition, not for individual patients. To select P-medicines for a given condition, considering the pathophysiology of the disease is important. Knowledge of the pathophysiology of the disease helps identify the possible site of action and the maximum therapeutic effect of the medicine to be used.

2. Specifying the therapeutic objectives

It is very useful to define exactly what you want to achieve with a medicine, for Example, to decrease the diastolic blood pressure to a certain level, to cure an infectious disease, or to suppress feelings of anxiety. Always remember that the pathophysiology determines the possible site of action of your medicine and the maximum therapeutic effect that you can achieve. The better you define your therapeutic objective, the easier it is to select your P-medicine.

3. Making an inventory of effective groups of medicines through

- Linking the therapeutic objectives to various medicines
- Considering efficacy as the first criterion for selection
- Looking at groups of medicines rather than individual medicines
- All medicines with the same mechanism and similar molecular structure belong to one group, e.g., benzodiazepines, ß-blockers. Most active substances in a group share a common stem in their generic name, e.g., diazepam, lorazepam

4. Choosing effective group of medicines according to the following criteria;

- Efficacy
  - ☛ To be effective the medicine has to reach a minimum plasma concentration
  - ☛ Kinetics of the medicine should be considered
- Safety
  - ☛ Possible side and toxic effects should be considered
  - ☛ Incidence and severity of potential side effects must as well be considered
- Suitability
- Convenient dosage forms, frequency of administration, route of administration, potency and other kinetic data should be considered to determine suitability
- Cost of treatment
  - ☛ The cost of treatment is always an important criterion for all countries. It

will be even more important in economically disadvantaged countries.

- ☛ The total cost of treatment, i.e., medicine cost, hospital cost and other costs required for the whole course of therapy, should be considered.

5. Selecting the P-medicine: Selecting P-medicines requires several processes

- Selection of the medicine based on the four criteria mentioned above.
- Selection of the dosage form based on the kinetics of the medicine
- Selection of standard dosage schedule based on clinical investigations
- Selection of standard duration of treatment based on the pathophysiology and prognosis of the disease

3.3 Treatment with P (personal) - medicines

Once P-medicines are selected for a given condition, one has to verify the suitability of the P-medicine to each patient. Not all the P-medicines could be convenient to every patient. Then one has to consider several steps for the process of choosing the best P-medicine for a given patient. These steps are described as follows using case examples:

Cases Examples on treatment with P-medicines

Step-1 Defining patient's diagnosis.

The first step in treatment with a P-medicine is to define the problem of a given patient. The following cases describe patients who mainly presented with complaints of cough but further clinical assessment and some laboratory tests disclosed that they all have cough for quite a different medical problems.

Case 1: Ato Tola is 54 years old male patient. Complains of a severe sore throat. No general Symptoms, no fever, slight redness in the throat; no other findings.

Case 2: W/t Almaz is 23 years old patient. Complains of a sore throat but is also very tired and has enlarged lymph nodes in her neck. Slight fever. She has come for the results of last week's laboratory tests.

Case 3: Abebech is a student, 19 years. Complains of a sore throat. Slight redness

of the throat; but no fever and no other findings. She is a little shy and has never consulted you before for such a minor complaint.

Case 4: Man 43 years. Complains of a sore throat. Slight redness of the throat; no fever and no other findings. Medical record mentions that he suffers from chronic diarrhoea.

Discussion of cases:

Case 1: The sore throat of case 1 probably results from a minor viral infection. Perhaps

he is afraid of a more serious disease (throat cancer?). He needs reassurance and advice, not medicines. He does not need antibiotics, because they will not cure a viral infection.

Case 2: Her blood test reveals that she is HIV positive. Her problem is completely different from the previous case, as the sore throat is a symptom of underlying disease.

Case 3: You noticed that she was rather shy and remembered that she had never consulted you before for such a minor complaint. You ask her gently what the real trouble is, and after some hesitation she tells you that she is 3 months overdue. Her real concern had nothing to do with her throat.

Case 4: In this case, information from the patient's medical record is essential for a correct understanding of the problem. His sore throat is probably caused by the loperamide he takes for his chronic diarrhea. This medicine may produce reduced salivation and dry mouth as a side effect. Routine treatment of a sore throat would not have solved his problem. You may have to investigate the reason for his chronic diarrhea, and consider AIDS.

These examples show that a single complaint may be related to different specific diagnosis.

Step-2 Therapeutic Objective

The second step in the selection of a P medicine is to specify the therapeutic Objective based on the diagnosis. This refers to what we want to achieve with the treatment. This could be illustrated by using the following examples.

Case 5: Girl, 4 years, slightly undernourished. Watery diarrhoea without vomiting for three days. She has not urinated for 24 hours. On examination she has no fever (36.8oC), but a rapid pulse and low elasticity of the skin.

Case 6: Woman student, 19 years. Complains of a sore throat. Slight redness of the throat, no other findings. After some hesitation she tells you that she is three months overdue. On examination, she is three months pregnant.

Case 7: Man, 44 years. Sleeplessness during six months, and comes for a refill of diazepam tablets, 5 mg, 1 tablet before sleeping. He wants 60 tablets.

Discussion of cases (5-7):

Case 5 (Diarrhoea): In this patient the diarrhoea is probably caused by a viral infection, as it is watery (not slimy or bloody) and there is no fever. She has signs of dehydration

(Listlessness, little urine and decreased skin turgor). This dehydration is the most worrying problem, as she is already slightly undernourished. The therapeutic objective in this case is therefore (1) to prevent further dehydration and (2) to rehydrate. Note: to cure the infection! Antibiotics would be ineffective anyway.

Case 6 (pregnancy): In case 6 you will have recognized case 3 who complained of a sore throat while her real problem was the suspected pregnancy. You will not solve her problem by prescribing something for her throat. The therapeutic objective depends on her attitude towards the pregnancy and she will probably need counseling more than anything else. The therapeutic objective is then to assist her to plan for the future. This will probably not involve medicine treatment

for her sore throat. Moreover, the fact that she is in early pregnancy should stop you from prescribing any medicine at all, unless it is absolutely essential.

Case 7 (sleeplessness): In case 7 the problem is not which medicines to prescribe, but how to stop prescribing them. Diazepam is not indicated for long term treatment of sleeplessness as tolerance quickly develops. It should only be used for short periods, when strictly necessary. The therapeutic objective in this case is not to treat the patient's sleeplessness but to avoid a possible dependence on diazepam.

This could be achieved through a gradual and carefully monitored lowering of the dose to diminish withdrawal symptoms, coupled with more appropriate behavioral techniques for insomnia, which should lead to eventual cessation of the medicine.

Step-3: Verifying suitability

It is not always possible to assume that the first medicine of choice will be suitable for every patient. Therefore, one has to verify the convenience of the P-medicine for that particular patient. One can start by looking up his/her P-medicines, and check for the suitability of the medicine, dosage form, dosage schedule and duration of treatment in view of effectiveness (indication and convenience of the dosage form), and safety (contraindications and possible interactions).

I. Medicine and Dosage forms

Though P-medicines are selected primarily on the basis of efficacy and safety, one has to verify that the selected P-medicine and the standard dose are suitable for an individual patient. The efficacy of a medicine can be reduced by a concomitantly taken medicine that reduces its bioavailability.

The safety of a medicine for a particular patient depends on contraindications and interactions. Always consider whether a given medicine is contraindicated, particularly, in high-risk groups and patients with high risk factors. High-risk

groups include pregnant women, lactating mothers, children and the elderly. High-risk factors include liver disease, renal failure, hypersensitivity reactions and concomitant diseases. Contraindications are determined by the characteristic of the patient (high risk patients) and the mechanism of action of the medicine. Interactions occur between the medicine and other concomitantly administered substances including drinks and food.

Verifying the suitability of the P-medicine based on the medicine and dosage form can be illustrated using the following examples:

Case 8: A 25 years old patient who has been on short course anti-TB therapy for the last 4 weeks came for re-valuation. He was also found to have HIV infection with a CD4 count of 50cells/mm3. He was subsequently put on HAART using AZT, 3TC and NVP regimen.

Case 9: A 2 years old boy has presented with complaints of cough and fever. He was diagnosed to have acute Lower respiratory tract infection (ALRI). One of your P-medicines for such condition is doxycycline.

Case 10: Ato Tolosa is a 45 years old mechanic living in Jimma. He is a known case of asthma for which he uses salbutamol inhaler .He was recently diagnosed to have hypertension (BP 150/110 mmHg) and he is put on Atenolol 50mg twice per day. (Note that Atenolol is your P medicine for the treatment of hypertension).

Discussion of cases (8-10):

Case 8: Nevirapine is one of the first line ARV medicines in the treatment of HIV in Ethiopia. However it is not suitable to be used for patients who are taking Rifampicin containing anti-TB medicine regimen. This is because of increased risk for medicine induced hepatitis. Therefore although Nevirapine is one of the P-medicine for ART in this country, it is not suitable to be used in this particular patient. Other NNRTI like EFV could be used instead.

Case 9: Doxycycline could be selected as the P-medicine for the treatment of

acute Lower respiratory tract infection (ALRI) but it is not generally suitable for younger children as it would cause discoloration of the teeth and may also interact with milk. Hence it is not suitable to treat bacterial infection in younger children. Other alternative P-medicine like cotrimoxazole or Amoxacillin could be used.

Case 10: Atenolol is one of the preferred medicines for the treatment of hypertension in-patients below 50 years of age and it is very convenient. However, like other beta-blockers, its main side effect is broncho-constriction so that it is relatively contra-indicated in asthmatic patients. If the hypertension is not severe, atenolol can still be prescribed in low dose (£ 50 mg/day). Otherwise, in severe cases, one should switch to the second P-medicine selected.

II. Dosage Schedules

A dosage schedule should be convenient, i.e., simple. For example 2 tablets a day is more convenient than one tablet two times a day. Complex dosage schedules reduce patient compliance leading to a decrease in effectiveness.

The dosage schedule can be adjusted by changing the dose or frequency of administration or both. Changing the daily dose changes the mean plasma concentration, while changing the frequency of administration defines the fluctuation in plasma. For example, twice daily administration of 100 mg will give the same mean plasma concentration as that of 50 mg four times daily, but with more fluctuations in plasma level. The minimum fluctuation can be achieved by administering 200 mg in 24 hours by a continuous infusion. Before one decides to reduce either the dose or the frequency, one should consider the nature of the medicine whether high peak plasma concentration is required to be effective as in the case of antibiotics. If high peak concentration is required for effectiveness of the medicine, the frequency should be reduced not the dose. On the other hand, increasing the dose increases both the mean plasma levels and fluctuations. The safest way to prevent fluctuation is to increase the frequency. Some medicines

such as some antiepileptic medicines, tricyclic antidepressants and alpha blockers, might be started treatment with a slowly rising dosage schedule.

Verifying the suitability of the P-medicine based on the dosage schedule can be illustrated using the following examples:

Case 11: Abraham complains of mild, intermittent crampy abdominal pain associated with diarrhoea. Stool examination showed Giardia Lamblia Trophozoites. He was given metronidazole 500 mg 3 times a day for 5 days. Two days later he returned reporting nausea and abdominal discomfort each time he takes the medicine, hence is unable to continue treatment.

Case 12: Ayalew is a 35 years taxi driver came for the treatment his genital herpes. He says these painful lesions were coming almost every month for the last one year. He was prescribed acyclovir 200mg 4 times per day for long term suppression,

Discussion of cases:

Case 11: Giardiasis can be effectively treated with a single dose of 2 gm Tinidazole and obviously would have been less of trouble.

Case12: This patient needs to take acyclovir continuously to suppress recurrence of his ulcers. A twice daily dose of 400mg or even a once daily dose of 800 mg will be a more convenient schedule for this busy taxi driver.

III. Duration of Treatment

Another issue is to verify whether the standard duration of treatment is suitable for a given patient, in terms of efficacy, safety and cost. Longer duration of treatment than needed might result in unnecessary adverse effects, medicine dependence, inconvenience to the patients, wastage of the scarce resources, etc. Shorter duration of treatment than required also results in ineffectiveness and unnecessary wastage

of resources for ineffective treatment. Verifying the suitability of a P-medicine based on the duration of treatment is illustrated using the following examples:

Case 13: A 25 years old woman comes with complaints of generalized body weakness and easy fatigability. Physical examination is unremarkable except the presence of slight pallor. Her Haemoglobin result is not known. She is prescribed ferrous sulphate 100-mg tablets, to take 1 tablet three times daily for 10 days.

Case 14: A 50 years old accountant comes for a refill. He was given prescription to buy Diazepam, a total of 60 tablets. He was advised to continue taking the medicine one tablet before sleeping as previously.

Discussion of cases:

Case 13: In this patient, prescription is given without a clear therapeutic objective. If anaemia was considered as a cause of her body weakness, the haemoglobin should have been measured and if the diagnosis of iron deficiency anaemia is confirmed iron should have been given for several weeks and months with regular haemoglobin measurements rather than being prescribed only for ten days.

Case 14: Giving out psychoactive medicines for a longer period without adequate supervision is not rational. The medical record of this patient actually reveals that he had taken his refill just 02 weeks ago. With further questioning, he admitted that he has been taking 5-mg tablets q.i.d since recently. This kind of treatment would of course leads to severe dependency and could also be quite expensive appropriate corrective measures have to be taken in time instead of keeping on prescribing the refills.

Step-4 writing a prescription:

A prescription is an important therapeutic transaction between the prescriber and medicine consumer through a dispenser, It is a written order of the prescriber for one or more medication, and instructs the dispenser how to prepare and dispense medicines and the patient how to use them.

A prescriber is a health professional who makes the diagnosis and orders medicine(s) to patients. All prescribers are not at the same professional level.

Classes of prescription

1. Pre-compounded prescription, prescribing readymade dosage forms
2. compounded (extemporaneous) prescription, prescribing medicines to be prepared by the dispenser as per the instruction of the prescriber

Requirements for a prescription

- Should be written on a standard prescription blank
- Should be written in ink
- Should be legible
- Should be written in generics, as brands could be expensive, promotional and do not give freedom to the dispenser to dispense the most affordable one.
- Should be clear, not ambiguous
- Should be written in English with some Latin abbreviations
- The quantity of ingredients should be expressed in metric system

Content of prescription paper

According to Guidelines for the control of use of prescription paper (Jan, 2004), published by the Drug Administration and Control Authority of Ethiopia, the content of any prescription paper should include the following information:

1. Serial number and area code.
2. Name, level and address of the health institution.
3. Full name, age, weight, sex, card number and address of the patient.
4. Type of diagnosis or International classification of disease (ICD) code number.
5. Name, strength, dosage form, treatment duration and dose of the medicine.
6. If the medicine is to be compounded, the type of ingredients needed how to

prepare it, and directions on how to use it.

7. If the medicine is refillable directions for refill.
8. Prescriber's name, qualification, registration number, and signature and the date on which prescription is written.
9. Dispenser's name, qualification, registration number, and signature and the date on which the prescription is filled.
10. Summarized directions to be followed by prescribers and dispensers. (See Annex-1)

Examples on prescription writing

Case 15: A 25 years old man diagnosed to have Typhoid fever. The P medicine is Chloramphenicol.

Case 16: A 2 years old boy, weighing 12-kg is diagnosed to have acute otitis media. The P medicine is Cotrimoxazole.

Case 17: A 5 years old boy, pneumonia with greenish sputum. The P-medicine is amoxicillin syrup.

Case 15:

PRESCRIPTION PAPER **Code.00001**

Institution name Black Lion hospital Tel.No. 0111511211

Patient's full Name: Eyob Tessema

Sex: _M __ Age: 25__Weight: --------Card No.334995

Address: Region 14 Town A.A Sub-city Arada

Kebele 17 House No.1002

Diagnosis (ICD code No.) typhoid fever Date: 12/06 /2003

Medicine name, strength, dosage form, dose, Frequency,Duration Quantity, How to use & other information	Price (dispenser use only)
R_x 1. Chloramphenicol 250 mg capsule # 112 sig. 2 capsules every 6 hourly p.o for 14 days.	
2. Paracetamol 500 mg tablets # 20 Sig. two tablets every 6 hourly, p.r.n	

Prescriber's *Dispenser's*

Full Name : Balcha Degefu _____

Qualification:Internist_____

Registration: 0127/95_____

Signature: _____

For case 16:

PRESCRIPTION PAPER **Code.00002**

Institution name: Betezata hospital Tel.No. 0115515068

Patient's full Name: Abeba Lemma

Sex: _F __ Age: 2__Weight: --------Card No.165349

Address: Region 14 Town A.A Sub-city bole

Kebele 10 House No.005

Diagnosis (ICD code No.) Acute otitis media Date: 15/06 /2003

Medicine name, strength, dosage form, dose, Frequency, duration Quantity, How to use & other information	Price (dispenser use only)
R_x 1. Cotrimoxazole 240mg/5 ml suspension # 1 bottle sig. 1 tea spoon every 12 hourly p.o	

Prescriber's *Dispenser's*

Full Name: Balcha Degefu _____

Qualification: GP_____

Registration: 1847/93_____

Signature: _____

For case 17:

PRESCRIPTION PAPER Code.00003

Institution name: Betezata hospital Tel.No. 0115515068

Patient's full Name: Abush Abebe

Sex: _M __ Age: 5__Weight: --------Card No. 146359

Address: Region 14 Town A.A___ Sub-city bole___

Kebele 12 House No.1102____

Diagnosis (ICD code No.) Pneumonia Date: 13/06 /2003

Medicine name, strength, dosage form, dose, Frequency, duration Quantity, How to use & other information	Price (dispenser use only)
R_x 1. Cotrimoxazole 240mg/5 ml suspension # 1 bottle sig. 1 tea spoon every 12 hourly p.o	

Prescriber's *Dispenser's*

Full Name: Balcha Degefu _____

Qualification: GP_____

Registration: 1847/93_____

Signature:_____

4. Medicines Information

4.1 Provision of Medicine information to patients

Many patients do not take the prescribed medicines correctly or regularly or do not take them at all for the following reasons:

- Complicated dosage schedule
- The medicines not perceived as effective
- Disappearance of symptoms
- Occurrence of side effects.
- Pill burden
- Inadequate information

Patient non-compliance may not have serious consequences for medicines with long plasma half lives, but effectiveness will highly be compromised with medicines having short plasma half lives.

Patient compliance may be improved by

- Prescribing a carefully selected P-medicine: Creating a good prescriber-patient relationship, established through respect for the patients feeling and idea, thereby making the patient treatment partner
- Providing the necessary information: The information should provide the knowledge to accept and follow treatment, and to acquire the necessary skills to take the medicine as prescribed. The information should be given clearly in a language the patient understands, and should be checked whether the patient has understood the information correctly by letting him/her to repeat it in his/her own word.

The minimum information that should be provided to patients include:

- Therapeutic effects
  - ☛ the role of the medicine

- ☛ disappearance of symptoms
- ☛ onset of action
- ☛ consequences of stopping the medicine or using it incorrectly

• Instructions
- ☛ dose of the medicine
- ☛ route of medicine administration
- ☛ time of medicine administration
- ☛ frequency of medicine administration
- ☛ duration of medicine administration
- ☛ medicine storage conditions

• Side effects
- ☛ types of the side effects
- ☛ ways of recognizing the side effects
- ☛ duration of the side effects
- ☛ seriousness of the side effects
- ☛ actions to be taken

• Precautions
- ☛ drug-drug interaction
- ☛ drug-disease interaction
- ☛ Food-medicine interaction
- ☛ maximum dose
- ☛ the need for full treatment course

• Contraindication
- ☛ History of hypersensitivity
- ☛ Pregnancy
- ☛ Age

• Future consultations
- ☛ date of next appointment if needed

- ☛ circumstances in which coming earlier is needed

- Clarity of the information
  - ☛ Re-checking whether the information is understood
  - ☛ allowing patients to ask some more questions

It is the responsibility of the prescriber to make sure that the treatment plan is understood and accepted by the patient. This responsibility should not be left to the dispenser only.

Examples Concerning Provision of Information to patients

Case 17: Alemu is a 40 years old teacher who has stage IV HIV/AIDS. He is just been started on ART with the following regimen: AZT, 3TC and EFV.

Case 18: Workinesh is a 35 years old athlete from Addis Ababa. She is diagnosed to have peptic ulcer, for which she is given Cimetidine 400mg tablet to be taken twice a day for four weeks.

Illustration

Case 17: HIV is a chronic viral infection that leads to severe immune deficiency, which will ultimately leads to death if left untreated. There is no cure for HIV yet but there are nowadays very effective medicines, which suppresses multiplication of the virus. This results in boosting the immunity of the patient and ultimately prevents the occurrence of life threatening opportunistic Infections and hence prolongs survival. The treatment is however complex and it has to be taken lifelong. Therefore there is a significant risk that many patients may not take their medicine as prescribed. Hence adequate and appropriate information should be given to such patients as follows:

- The medicine suppresses multiplication of the virus and results in boosting immunity.
- Takes one tablet of each AZT 300mg, 3TC 150mg twice a day and EFV 600mg at night for two weeks.

- To take their medicines daily exactly as prescribed and not stop taking the medicines unless otherwise instructed to do so
- Advise your patients to follow a regular time for their medicine administration
- Warn patients for common side effects of the medicines. For instance, AZT may lead to profound anaemia and some GI upset. EFV is often associated with some CNS side effects ranging from simple sleep disturbance to frank psychosis. Reassure them that most of these side effects will disappear after a couple of weeks. However in those patients with severe symptoms, they should be advised to report early.
- Patient also should be advised not to drink alcohol, chew chat, smoke cigarette and have unprotected sex
- Underline the importance of having a regular follow up. This will help the treating physician not only to evaluate patient's response to treatment but will also enable him/her to monitor for medicine side effects.
- Avoid fatty meal for EFV.

Case 18: In this case the patient should be informed that:

- The medicine reduces the acidity of the gastric contents and relief the pain
- Takes one tablets twice a day for about 4 weeks
- The patient will begin to feel better after taking the medication but it takes a longer time to get cured
- Cimetidine may cause mild diarrhoea, otherwise doesn't have serious side effects
- In addition to medicine therapy, she should also try to take non-medicine measures like avoiding smoking .She should also be advised to refrain from taking medicines such as Aspirin, NSAID and alcohol as these will reduce the chance of cure of the PUD.
- Emphasize on the importance of having a regular follow up in the future

5. Treatment Monitoring

Treatment monitoring is required to determine whether the treatment has been successful or additional action is needed. To do this the prescriber should maintain contact with the patient and gather information on whether the treatment was effective or not, and whether side effects occurred or not. This can be achieved through either of the following ways.

- Passive monitoring- the prescriber explains to the patient to report back if the treatment is not effective, inconvenient or significant side effect occurs.
- Active monitoring- in which the prescriber makes an appointment with the patient to determine how effective the treatment has been and whether side effects developed. How soon the prescriber would like to see the patient after administration of the treatment and how frequently follow up visits will depend on type of illness, the duration of treatment, and the maximum quantity of medicines to prescribe.

If the disease is cured, the treatment can be stopped. If not cured or chronic, the treatment can be continued provided it is effective and there are no side effects. If serious side effects occur, the selected medicine and its dosage schedule should be reconsidered and whether the patient took the treatment correctly or not should be checked.

If the treatment has not been effective; the diagnosis, the prescribed medicine(s), the dose, the duration, the instruction given to the patient, patient compliance and the monitoring process should all be reconsidered.

Examples concerning treatment monitoring and the importance of a follow up visit.

Case 19: Captain Tesfaye is a 35 years old pilot who was diagnosed to have pneumonia and has just finished a course of antibiotic treatment with Amoxicillin 500mg three times a day for one week. He is a known smoker for over 20 years.

When he returned back for a follow – up, he was rather sick with additional complaints of fever and body weakness. He has started producing copious amount of purulent sputum mixed with blood.

Case 20: Yimer is a 28 years old farmer who was diagnosed to have pulmonary TB some 04 months ago and took anti-TB medication for the first 03 months. When he came a month later, he admitted to his prescriber that he had not been taking the anti-TB medicine since the last one month, as he felt perfectly healthy.

Case 21: Ato Tofic is a 60 years old merchant from Harar, who is a known case of type II diabetes with secondary failure. He has been taking Lenti insulin 30 IU in the morning and 20 IU in the evening .How ever during the recent follow up, the patient has noted frequent fainting attacks and palpitation although he takes his meal and medications as usual. His fasting blood sugars (FBS) were all below 50-mg% whenever he has these symptoms. All these have occurred after he began to notice intermittent leg and facial swellings.

Case 22: Azeb is a 25 years old known HIV patient who have been put on ART for the last 02 months. She has been taking AZT, 3TC and NVP. She was doing fine until the last 2 weeks when she started to feel very weak and easily tired.

Discussion of cases (17-20):

Case 19: This patient seems to have developed one of the local complications of pneumonia. A control Chest x-rays shows multiple lung abscesses. He has to be admitted and put on high dose parenteral antibiotics for a couple of weeks. If no improvement, review the diagnosis, drug, dose and duration of the treatment.

Case 20: One of the challenges of patients who are put on prolonged therapy is to continue taking their medication when they do not have any complaint. That is exactly what happened to this patient! Actually most of the TB symptoms will disappear within 02 months of the start of effective treatment. However the

treatment still has to be continued for about 6-8 months in order to achieve cure and prevent development of medicine resistance. We should always explain this to patients at the start of treatment and need to encourage them to complete their treatment during subsequent follow-ups.

Case 21: This patient seems to have frequent hypoglycemic symptoms. Prior to the developments of these symptoms, he gave history of leg and facial swellings. . Such history is very much suggestive of development of diabetic nephropathy with some degree of renal failure. This may lead to reduced rate of insulin excretion. This has to be confirmed with appropriate Lab. investigation and the dose of insulin has to be adjusted accordingly.

Case 22: Further evaluation of this patient has revealed that she has developed marked anaemia with haemoglobin of 4gm %. Anaemia is one of the common complications of AZT and this is probably what is happening in this patient. Therefore the AZT has to be discontinued and be replaced by other medicines like 3TC. Patient also requires blood transfusion.

6. Medicines Information

6.1. Updating medicine information

As knowledge about medicines is changing, new medicines are being developed. Some medicines known to be effective and safe in the past may not be as effective or safe as more information about the medicines is gathered. Hence, updating knowledge on every medicine we are bound to use is indispensable for good prescribing practice. In most health institutions in Ethiopia, medicine information resources are scarce. A concerted effort should be made by all concerned to alleviate this problem. Ultimately, it is the responsibility of every prescriber to equip himself/herself with the necessary information for a safe practice.

So prescribers should try to update themselves through whatever means available to them.

6.2. Sources of medicine information

Although basic information about medicines is obtained through training in clinical medicine profession, additional knowledge can be gained from various sources. These sources of medicine information can be classified into primary, secondary and tertiary.

Primary sources: provide new medicine information mainly based on research in journals. Such sources include health journals such as the Ethiopian Medical Journal, the Ethiopian pharmaceutical Journal, the Ethiopian Journal of Health Development, Lancet, and others. It is important to assess the reputability of the journal and time of publication.

Secondary sources: provide reviews of articles that appear in primary sources. Examples include medicine information bulletins, adverse medicine reaction bulletin, hospital formularies, etc.

Tertiary sources: include standard reference books such as British National Formulary, basic and clinical pharmacology, medical dictionary, Ethiopian national drug formulary, etc. The selection of a particular source of information

depends on the type of information required. Tertiary sources are used prior to secondary or primary sources as they provide a broad overview of particular subject area. It should also be remembered that standard books are published at longer time intervals than journals.

Listed below are some of the sources to look for medicine information. Such sources include:

- Standard treatment guidelines
  - ☛ Are disease centered
  - ☛ Provide clinical information on medicines
- Medicine formularies
  - ☛ Are medicine centered
  - ☛ Provide information on a list of pharmaceutical products
- Can be national or institutional
- Pharmacology books
  - ☛ Provide information on basic or clinical pharmacology
  - ☛ Books revised frequently provide up-to-date information
- Medicine bulletins
  - ☛ Provide unbiased information
  - ☛ Select topic of national importance
  - ☛ Published frequently
- Health Journals
  - ☛ Provide important new information on medicines
- Medicine information centers/ services
  - ☛ are accessible to all health professionals
  - ☛ provide recent information on medicines
- Verbal communication
  - ☛ informal way of getting recent information on medicines from medicine specialists

- Pharmaceutical industries
  - ☛ may provide biased information
  - ☛ the information might be promotional
  - ☛ disseminate information through medical representatives or direct mailing to prescribers
- Internet
  - ☛ Easily accessible information
  - ☛ Provides more recent information

The various medicine information sources have been outlined. Possible information sources will vary according to country and the prescribers own personal situation. The prescriber's job is to decide how best to keep up-to date, by making a list of all the possible resources to which he/she has access. Try to find at least one of the following: (1) medical journals; (2) medicine bulletins; (3) pharmacology or clinical reference books; (4) medicine and therapeutic committees or consultants. Although the primary source of prescribing information in daily clinical work should be a personal formulary, sometimes difficult problems may be faced, which calls for an additional source of information. This could be a pharmacology or clinical reference book, a medicine bulletin, consultants (pharmacist, specialist, colleagues), or a formulary. The limitations of commercial information have been clearly described. If you decide, nevertheless, that it has a role to play, always ask for copies of the published references on efficacy and safety. Even before reading these, the quality of the journals in which they appear will be a strong indication of the likely quality of the study. The prescriber should know that the majority of newly marketed medicines do not represent true therapeutic advances; they are very similar in chemical composition and action to other products on the market. The difference is usually in price. Seeing medical representatives can be useful to learn what is new, but the information should always be verified and compared with impartial, comparative sources.

Annex-1 Standard prescription paper

PRESCRIPTION PAPER Code_____

Institution Name: _____Tel. No… ……
Patient's full Name: _____
Sex: ___ Age:___ Weight: _____ Card No. _____
Region: _____Town _____ Woreda_____Kebele _____
House No. ____ Tel. No: _____☐ Inpatient ☐ Outpatient
Diagnosis, if not ICD _____

Drug Name, Strength, Dosage Form, Dose, Frequency, Duration, Quantity, How to use & other information	Price (dispensers use only)
℞	
Total Price	

Prescriber's Dispenser's

Full name _____ _____
Qualification _____ _____
Registration #_____ _____
Signature _____ _____
Date: _____ _____

See overleaf

Please Note the Following Information

1. **Prescriptions:**
   - are valid only if it has the seal of the health institution
   - filled and blank are legal documents, treat them as fixed assets
   - written and verbal information to the client complement one another
2. **The prescriber:**
   - drug treatment is only one of the treatment options
   - write the prescription correctly and legibly
   - diagnosis and other parts of the prescription have to be complete
   - abbreviations are NOT recommended
   - please accept prescription verification call from the dispenser
3. **The Dispenser:**
   - check legality of the prescription
   - check completeness and accuracies before dispensing
   - check for whom the medicine is being dispensed: actual client o care taker
   - if in doubt about the contents of the prescription; verify with the prescriber
   - containers used for packaging must be appropriate for the product
   - labels of drugs should be clear, legible and indelible
   - drugs should be dispensed with appropriate information and counseling
   - keep filled prescriptions at least for 2 years
4. **Minimum drug label information** should include the following:
   - Patient name
   - Generic name, strength and dosage form of the medicine
   - Dose, Frequency and Duration of use of the medicines
   - Quantity of the medicine dispensed
   - How to take or administer the medicine?
   - Storage condition

Annex-2 Adverse Drug Event Reporting Form

Food Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)
Adverse Drug Event reporting form

Patient Name (abbreviation)	Card No	Age, Date of birth	Sex	Weight	Height
Ethnic group		Substance of abuse			

Information on suspected drug/vaccine **S=suspected drug** **C=concomitantly used drugs**

Drug name(write all information including brand name batch no and manufacturer	S/C	Dose/dosage form, route, frequency	Date drug taking was started (D/M/Y)	Date drug reaction started (D/M/Y)	Date drug taking was stopped (D/M/Y)	Indication (Reason for drug use)

Adverse drug event description(include all available laboratory test results)

Reaction necessitated:	Reaction subsided after D/C of suspected drug?
Discontinuation of drug/s □ YES □ No	□ YES □ No □ Information not available
Hospitalization prolonged □ YES □ No	Reaction reappeared after restart of suspected drug?
	□ YES □ No □ Information not available

Treatment of reaction:

Outcome: □ Died due to the adverse event □ Died, drug may be contributory □ Not yet recovered
□ Recovered without sequelae □ Recovered with squelae □ Unknown

Squelae:

Relevant medical conditions such as allergies, renal disease, liver disease, other chronic diseases, pregnancy etc

Reported by: Name	Profession:	Email address:	Telephone
Name of health institution:			Date

Product quality problem: Color change, separating of components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling, etc (Write if anything different than given above)

Drug trade name	Batch No	Registration no	Dosage form and strength	Size /type of package

For office use only

Received on:	Registration no:

Key: D/M/Y ; Date /Month/Year D/C: Discontinue treatment Y:YES N:NO

መጀመሪያ እዚህ ላይ እጠፍ

First fold here.

This ADE reporting form was prepared by FMHACA in collaboration with MSH/SPS and financial support from USAID

ቀጥሎ እዚህ ላይ እጠፍ

Next fold here.

what to report

All suspected reactions to drugs
Unknown or unexpected reactions
Serious adverse drug reactions
Unexpected therapeutic effects
All suspected drug interactions
Product quality problems
Treatment failures
Medication errors

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

From ----------

የጉዳይ መስጫ አገልግሎት ፈቃድ ቁጥር HQ2
Business Reply Service License No HQ2

Postage prepaid

Food, Medicine and Health care Administration
And Control Authority of Ethiopia

Food, Medicine and Health Care Administration and Control Authority
Regulatory Information Development and Dissemination Team
P.O.Box 5681 Tel.0115-523142
Addis Ababa, Ethiopia

References

1. DACA, Rational Drug use study, 2006

2. Amare Mengistu(MD). Patterns of drug utilization in inpatient departments, Jimma hospital south west Ethiopia. Ethiop. J. Health Dev. 2005: 15(2): 139-145.

3. Tewodros Leka, Yohannes Jorge. Survey of the knowledge and application of essential and national medicine lists among health professionals in Addis Ababa. Ethiop .J .Health Dev: 1990; 4(1): 31-34

4. Mohammed Abdullah, Testate Shivered. Patterns of prescription in Jimmy Hospital: Ethiop. J. Health. Dev. 1997;11(3):263-267

5. Dawit Dilbeto, Sleek Gobi, Shiferaw Teklemariam. A base line survey on prescribing indicators and factors influencing prescribing in Southern Ethiopia, Ethiop. J. Health Dev. 1998;12(2):87-93

6. Tewodros Leka, Mohammed Abadir. Prescription pattern of analgesic medicines in 13 rural & regional hospitals of Ethiopia. Ethiop. J. Health Dev. 1990;4(1): 21-29

7. Daniel Zewde, Yohannes Jorge, Tsige Gebre-Mariam. A preliminary assessment of outpatient counseling in four referral hospitals of Addis Ababa. Ethiop. Pharm. J. 1999; 17: 44-51

List of Consultative Workshops Participants

S/N	Full Name	Name of Organization	Profession
1	Mesret Ephram	Ethiopian Druggists Association	Druggist
2	Kelali Mehari	Defense University	Pharmacist
3	Mengistab W/Aregay	FMHACA	Pharmacist
4	Yanatan Taye	Axum Pharmacy	Pharmacist
5	Israel H/Gorgis (D/r)	MCM Hospital	Internist
6	Misikir Ambaye (D/r)	Mekele University	Medical Doctor
7	Fikru Worku	Ethiopian Pharmacy Association	Pharmacist
8	Aida Arefayne	FMHACA	Pharmacist
9	Tekelu G/Hiwot	Mekele University	Pharmacist
10	Dr Dreje Alemayhu (D/r)	Ghandi Memorial Hospital	Gynecologist
11	Yosef Wakwoya	MSH/SPS	Pharmacist
12	Getahun Aschalew	MCM Hospital	Pharmacist
13	Girma Ayalew	Betezata Hospital	Pharmacist
14	Tigist Fessaha (D/r)	Black Lion Hospital	Medical Doctor
15	Kidanemariam G/Michael	FMHACA	Pharmacist
16	Shimels Dejene (D/r)	Black Lion Hospital	Medical Doctor
17	Etagegnehu Mamo (S/r)	Ethiopian Nursing Association	Nurse
18	Tizita Refera	Amanuel Mental Specialized Hospital	Pharmacist
19	Asrat Eregena	Ghandi Memorial Hospital	Pharmacist
20	Yeneneh Getachew (D/r)	Ethiopian Medical Association	Medical Doctor
21	Mekonnen Afework	Axum Pharmacy No -4	Pharmacist

22	Mamo Engdayehu	FMHACA	Pharmacist
23	Mekbib Lalensa	Jimma University Specialized Hospital	Pharmacist
24	Samuel Asfaha	Medco Biomedical College	Pharmacist
25	Asfaw Regassa	Oromia Regional Health Bureau	Pharmacist
26	Lealem Sisay	Amanuel Mental Specialized Hospital	Pharmacist
27	Elias Geremew	MSH/ SPS	Pharmacist
28	Endalkachew Admassu	Gondar University	Pharmacist
29	Balemlay Tilahun	Rift Valley University College, Adama Camps	Pharmacist
30	Fitsum Abraha	Tsion Pharmacy	Pharmacist
31	Mohamd Hajihyder Ali (D/r)	Amanuel Mental Specialized Hospital	Consultant Psychiatrist
32	Netsanet Behabtu	FMHACA	Pharmacist
33	Solomon Getnet	Addis Ababa Health Bureau	Pharmacist
34	Kebede Abera	Addis Ababa University, School of Pharmacy	Pharmacist
35	Tenaw Andualem	MSH/ SPS	Pharmacist
36	Kibrnesh Bezu	Axum Pharmacy	Pharmacist
37	Andamlak Dinku	Kenema No.2 Pharmacy	Pharmacist
38	Asnakech Alemu	FMHACA	Pharmacist
39	Yonas Yilma (D/r)	Gondar University	Surgeon