Hospital Medicines & Therapeutic Committees

A Practical Guide to Their Establishment

Produced By:
Directorate of Pharmacy Services
Ministry of Health and Child Welfare
June 2012
Reviewers: Members of the NMTPAC

Borok Margaret  Mujuru Hilda
Chakanyuka Christine C.  Mushavi Angela
Hove Ropafadzai  Nyatsambo Collen.
Kasule Jonathan  Ndhlovu Chiratidzo E.
Khoza Star
Moyo Sifiso  Sifeku Florah N.
Mudzimu Forward  Wellington Maureen
Mushayi Givemore  Vuragu Davison N.
Tsitsi-Mutasa Apollo  Mudzura-Samkange Emma

Editors
Forward Mudzimu and Sifiso Moyo

Copyright © Directorate of Pharmacy Services, Ministry of Health and Child Welfare, June 2012
Printed by World Health Organisation with Humanitarian Aid Department of the European Commission (formerly: European Community Humanitarian Aid Office) ECHO funds
# Acknowledgments

We are grateful to those people currently involved in the programme for sharing their experiences as well as best practices and thus contributing to these guidelines. We do acknowledge the contributions made by these participants at the Adaptation Meeting (Harare, 02 June 2012)

<table>
<thead>
<tr>
<th>Name</th>
<th>Position/Role</th>
<th>Organization/Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alex Matonhodze</td>
<td>PPM Midlands</td>
<td>Fungai Makwabarara DNO</td>
</tr>
<tr>
<td>Angelbetter Mahlangu</td>
<td>Mat North</td>
<td>G.J Matandiritsha Pharmacist Mat South</td>
</tr>
<tr>
<td>Arthur P. Sanyanga</td>
<td>MOHCW DPS</td>
<td>George Chinomona Logistics Officer</td>
</tr>
<tr>
<td>Blessing Mudzudzu</td>
<td>MOHCW</td>
<td>Givemore Mushayi Pharmacist Pharmaceutical Manufacturers Association</td>
</tr>
<tr>
<td>Boniface Machingauta</td>
<td>PPM Mash East</td>
<td>Lee Nkala MOHCW Head Office</td>
</tr>
<tr>
<td>C. Ndlovu Matron</td>
<td>Beitbridge Hospital</td>
<td>Lincoln Charimari Dr WHO</td>
</tr>
<tr>
<td>Chiratidzo E. Ndlovu</td>
<td>UZCHS/NMTPAC</td>
<td>Margaret Butau Assistant Director Service Delivery ZNFPC</td>
</tr>
<tr>
<td>Cynthia Kungumoni</td>
<td>UNICEF</td>
<td>Marian Fadzi DNO Mash East</td>
</tr>
<tr>
<td>D.N Vuragu Chief</td>
<td>Pharmacist Parirenyatwa</td>
<td>Masimba Dube City Health Bulawayo</td>
</tr>
<tr>
<td>Edson Muchemwa</td>
<td>DPS/Logistics Unit</td>
<td>Mbuya Muaka Kapepula PPM Masvingo</td>
</tr>
<tr>
<td>Edward Makondo</td>
<td>MOHCW</td>
<td>Memory Chitera RGN</td>
</tr>
<tr>
<td>Emma Mudzura-Samkange</td>
<td>MCAZ</td>
<td>Michael Xhinzete CHN MOHCW Mash Central</td>
</tr>
<tr>
<td>Eustace B. Zhou</td>
<td>Logistics Unit</td>
<td>Millicent Chinembiri PPM Mash West</td>
</tr>
<tr>
<td>Florence Chingwena</td>
<td>Chief Pharmacist Harare City Health</td>
<td>Misheck Ndlovu MOHCW DPS</td>
</tr>
<tr>
<td>Florence Thondhlana</td>
<td>Pharmacy Technician PMD Manicaland</td>
<td>Miltcilda R. Takaza EMLO</td>
</tr>
<tr>
<td>Forward Mudzimu</td>
<td>MOHCW HQ</td>
<td>Molly C. Madziwa Matron Mutare Provincial Hospital</td>
</tr>
<tr>
<td>Alex Matonhodze</td>
<td>PPM Midlands</td>
<td>Nicholas Fidze Pharmacy Technician MSF Holland</td>
</tr>
<tr>
<td>Angelbetter Mahlangu</td>
<td>Mat North</td>
<td>Panganayi Chivese PPM Mash Central</td>
</tr>
<tr>
<td>Arthur P. Sanyanga</td>
<td>MOHCW DPS</td>
<td>Portia Manangazira Dr MOHCW HQ</td>
</tr>
<tr>
<td>Blessing Mudzudzu</td>
<td>MOHCW</td>
<td>Regina N. Kanyemba Principal Tutor Parirenyatwa Group of Hospitals</td>
</tr>
<tr>
<td>Boniface Machingauta</td>
<td>PPM Mash East</td>
<td>Ropafadzai Hove MOHCW HQ</td>
</tr>
<tr>
<td>C. Ndlovu Matron</td>
<td>Beitbridge Hospital</td>
<td>Ruth Rimai MOHCW HQ</td>
</tr>
<tr>
<td>Chiratidzo E. Ndlovu</td>
<td>UZCHS/NMTPAC</td>
<td>Silethile Moyo BCC/HSD SIC Bulawayo</td>
</tr>
<tr>
<td>Cynthia Kungumoni</td>
<td>UNICEF</td>
<td>Siifiso Moyo MOHCW DPS</td>
</tr>
<tr>
<td>D.N Vuragu Chief</td>
<td>Pharmacist Parirenyatwa</td>
<td>Stanley Midzi Dr WHO</td>
</tr>
<tr>
<td>Edson Muchemwa</td>
<td>DPS/Logistics Unit</td>
<td>Tembinkosi Ncomazi Dr Medical Team Leader MSF Holland</td>
</tr>
<tr>
<td>Edward Makondo</td>
<td>MOHCW</td>
<td>Tendai Mudenge PPM Mat North</td>
</tr>
<tr>
<td>Emma Mudzura-Samkange</td>
<td>MCAZ</td>
<td>Teresiah Shumba DNO Midlands</td>
</tr>
<tr>
<td>Eustace B. Zhou</td>
<td>Logistics Unit</td>
<td>Tichatyei A. Mhazo MOHCW DPS</td>
</tr>
<tr>
<td>Florence Chingwena</td>
<td>Chief Pharmacist Harare City Health</td>
<td>Tinei Chitsike John Snow Inc.</td>
</tr>
<tr>
<td>Florence Thondhlana</td>
<td>Pharmacy Technician PMD Manicaland</td>
<td>Tsungai Chiwara Logsistscs Unit</td>
</tr>
<tr>
<td>Forward Mudzimu</td>
<td>MOHCW HQ</td>
<td>Molly C. Madziwa Matron Mutare Provincial Hospital</td>
</tr>
</tbody>
</table>
The contributions by the members of the Subcommittee for Establishment and Organisation of MTCs in Zimbabwe, their names listed below, are acknowledged. It is their draft document that enabled the production of these guidelines.

<table>
<thead>
<tr>
<th>Cephas Dzuda</th>
<th>Norman Nyazema</th>
<th>Bothwell Mbuwaysango</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jona Chieza</td>
<td>Evans Maketo</td>
<td>Farai Chinyanganya</td>
</tr>
<tr>
<td>David Simbanegavi</td>
<td>Felistus Sifeku</td>
<td>James Hakim</td>
</tr>
<tr>
<td>Isidore Pazvakavambwa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Thank you!**

Mrs R.F. Hove  
Director of Pharmacy Services

Dr. C. E. Ndhlouv  
NMTPAC Chairperson
# CONTENTS

Acknowledgments ..........................................................................................................................3
Contents ...........................................................................................................................................5
Acronyms and abbreviations ...........................................................................................................6
1. Introduction ..................................................................................................................................7
2. Background ....................................................................................................................................8
3. Justification for HMTCs ..............................................................................................................10
4. Getting started ............................................................................................................................11
   4.1 Addressing the problem ...........................................................................................................11
   4.2 Stepwise approach to starting a HMTC where none exists ....................................................12
   4.3 Revitalizing non-functioning HMTCs ....................................................................................15
   4.4 Using this manual to solve problems ....................................................................................15
5. What Should HMTC Do? ...........................................................................................................18
   5.1 Model Terms of Reference for HMTCs in Zimbabwe ............................................................18
   5.2 Activities ................................................................................................................................19
6. Organisation of HMTCs ..............................................................................................................20
   6.1 Membership ............................................................................................................................20
   6.2 How Often Should They Meet? .............................................................................................21
7. How Should HMTCs Function? ...................................................................................................22
   7.1 Selecting Essential Medicines ...............................................................................................22
   7.2 Adding Medicines to the List ................................................................................................22
   7.3 ABC Analysis ........................................................................................................................23
   7.4 Therapeutic Category Analysis .............................................................................................23
   7.5 Educational Activities on Rational Medicine Use .................................................................24
   7.6 Regulating Medicine Representatives ..................................................................................26
   7.7 Generic Substitution Policy ....................................................................................................26
   7.8 Medication Error Reporting .................................................................................................27
   7.9 Adverse Medicine Reaction Monitoring ...............................................................................28
   7.10 Medicine Utilization Review (MUR) ..................................................................................29
   7.11 Intervention Selection and Design .......................................................................................31
   7.12 Intervention Evaluation .......................................................................................................31
8. Data Sources for Monitoring ......................................................................................................33
9. Budgeting for HMTC Activities ..................................................................................................35
10. Reporting of HMTC Activities ..................................................................................................36
11. Sources of Support for HMTCs ..................................................................................................37
Annex 1: Model Terms of Reference for HMTCs in Zimbabwe ......................................................38
Annex 3: Example of a declaration of interest form .......................................................................41
Annex 4: Application for Addition to Hospital Essential Medicines List .........................................42
   Application for Addition to Hospital Essential Medicines List ...................................................42
Annex 5: ADR Forms .......................................................................................................................43
Annex 5: PRODUCT DEFECT Forms ..........................................................................................44
List of References ............................................................................................................................45
**ACRONYMS AND ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTs</td>
<td>Artemeter Lumefantrine Combinations</td>
</tr>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>CAJM</td>
<td>Central African Journal of Medicine</td>
</tr>
<tr>
<td>DaTIS</td>
<td>Drugs and Toxicology Information Service</td>
</tr>
<tr>
<td>DPS</td>
<td>Directorate of Pharmacy Services</td>
</tr>
<tr>
<td>EDLIZ</td>
<td>Essential Medicine List of Zimbabwe</td>
</tr>
<tr>
<td>GMO</td>
<td>Government Medical Officer</td>
</tr>
<tr>
<td>Hb</td>
<td>Haemoglobin</td>
</tr>
<tr>
<td>HMTC</td>
<td>Hospital Medicines and Therapeutics Committees</td>
</tr>
<tr>
<td>INRUD</td>
<td>International Network on Rational Use of Drugs</td>
</tr>
<tr>
<td>MCAZ</td>
<td>Medicines Control Authority of Zimbabwe</td>
</tr>
<tr>
<td>MOHCW</td>
<td>Ministry of Health and Child Welfare</td>
</tr>
<tr>
<td>MTC</td>
<td>Medicines and Therapeutics Committees</td>
</tr>
<tr>
<td>MUE</td>
<td>Medicine Use Evaluation</td>
</tr>
<tr>
<td>MUR</td>
<td>Medicine Use Review study</td>
</tr>
<tr>
<td>NDP</td>
<td>National Drug Policy</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicine Policy</td>
</tr>
<tr>
<td>NMTPAC</td>
<td>National Medicine &amp; Therapeutics Policy Advisory Committee</td>
</tr>
<tr>
<td>PEDLIZ</td>
<td>Proposed Essential Drug List for Zimbabwe</td>
</tr>
<tr>
<td>SRN</td>
<td>State Registered Nurse</td>
</tr>
<tr>
<td>STGs</td>
<td>Standard Treatment Guidelines</td>
</tr>
<tr>
<td>UZ</td>
<td>University of Zimbabwe</td>
</tr>
<tr>
<td>VEN</td>
<td>Vital, Essential and Necessary Medicines</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>ZEDAP</td>
<td>Zimbabwe Essential Drugs Action Programme</td>
</tr>
<tr>
<td>ZNMP</td>
<td>Zimbabwe National Medicines Policy</td>
</tr>
</tbody>
</table>
1. INTRODUCTION

IN EVERY HOSPITAL, MEDICINES & MEDICAL SUPPLIES ARE CRITICAL TO THE DELIVERY OF SERVICES. However, the availability of medicines in the hospital depends not only on good supplies but also on their efficient use through rational prescribing and dispensing practices. Several approaches have been tried to improve the management and use of medicines in various health settings. In a hospital setting, Medicine and Therapeutics Committees (MTCs) are thought to be effective in ensuring that medicines are used in a safe, appropriate and cost-effective manner. In developed countries such as Australia and the USA, HMTCs have proven to be effective in improving prescribing, dispensing, and resource allocation & management. Such Medicine and Therapeutics Committees have used a combination of several strategies including formulating and implementing medicine use policies and guidelines as well as educational approaches appropriate to their setting.

In developing countries, not much is known about the existence and operations of HMTCs. In these countries, only a few hospitals might have the organizational and technical capability to take on the comprehensive functions of HMTCs. The majority of hospitals in the developing world will have a heavy workload and limited human and financial resources. With the exception of central hospitals and a few privately owned ones, most hospitals in Zimbabwe experience this limited human, financial and technical capacity. Most of these hospitals will have up to five doctors, only one or no pharmacist at all, a number of nurses, medical records officer and perhaps a laboratory technician. Accordingly, these hospitals should not try to do everything but choose only those functions that are relevant and possible in their circumstances. This manual is intended to assist these hospitals in establishing and organizing their own HMTCs, but the staff at the hospital will need to choose among the various functions that the HMTC could support, and focus on the most important and realisable goals.

Summary
Inappropriate use of medicines wastes resources and seriously undermines the quality of patient care. A Medicines and Therapeutics Committee (MTC) can significantly improve medicine use and reduce costs in hospitals and other health care facilities in the following ways:
• providing advice on all aspects of medicine management
• developing medicine policies
• evaluating and selecting medicines for the formulary list
• developing (or adapting) and implementing standard treatment guidelines
• assessing medicine use to identify problems
• conducting interventions to improve medicine use
• managing adverse medicine reactions and medication errors
• informing all staff members

Inappropriate use of medicines wastes resources and seriously undermines the quality of patient care. A Medicines and Therapeutics Committee (MTC) can significantly improve medicine use and reduce costs in hospitals and other health care facilities in the following ways:
2. Background

At independence in 1980, Zimbabwe adopted the primary healthcare approach as a guiding principle in the delivery of health services to the people. As part of that national strategy, a Proposed Essential Drug List for Zimbabwe (PEDLIZ) was produced in 1981, followed 4 years later in 1985 by the first Essential Drugs List (EDLIZ) that included standard treatment guidelines (STGs). To ensure rational use of the medicines, the Zimbabwe Essential Drugs Action Programme (ZEDAP) developed and implemented in-service training programmes mainly targeting primary health care staff. Many different disease-specific case management modules for such conditions as diarrhoea, ARI and STDs were used together with EDLIZ to train staff in rational medicine use. For more than a decade, ZEDAP has undertaken many primary care activities resulting in significant improvement in the use of medicines at clinics and rural health centres. In all this, the hospitals were neglected, with the result that most hospital staff considered EDLIZ and its accompanying treatment guidelines to be only for primary care health workers. In 1992, a number of local doctors and pharmacists attended an international course on rational medicine use organised by INRUD and held in Zimbabwe. Since then, ZEDAP through the National Medicine & Therapeutics Policy Advisory Committee (NMTPAC) has organised a number of similar courses for doctors and pharmacists.

A comprehensive National Drug Policy (NDP) document was launched in 1998, and this document has since been revised and updated in 2011. In line with the NDP, a pilot project was started to stimulate the development of active and effective HMTCs in Zimbabwe.
Excerpts from the 2011 Zimbabwe National Medicines Policy

1. The Ministry of Health and Child Welfare (MOH&CW) will support the NMTPAC by providing appropriate terms of reference and a working budget. The Committee will assist with the development of policies in the field of medicines generally, advancement of medicinal treatment, rational use of medicines and the implementation of the ZNMP.

2. The NMTPAC will be composed of experts from the principal areas of medicine and pharmacy and representing different levels of the health care system. The committee will be entitled to co-opt other members as and when required and will consult widely with interested groups including those in the private sector and at consumer level.

3. Recognizing the need for Medicines and Therapeutic Committees in order to promote the rational use of medicines in health care institutions, the MOH&CW will work towards the establishment of such committees in district, provincial and central hospitals. The committees will be composed of senior administrative staff, pharmacy personnel, doctors, nurses, laboratory staff and co-opted members when indicated.

4. The MOH&CW will issue guidelines for the formation and functioning of Hospital Medicines and Therapeutic Committees. The NMTPAC will co-ordinate and advise on the work of the committees. Among their other duties, these committees will be responsible for determining the number, the range and quantity of EDLIZ-listed medicines to be available in the health facility and for guiding health workers in the rational use of medicines and the use of the STG. The committees will further monitor the use of medicines in their institutions and draw up hospital formularies. The MOH&CW, acting through the NMTPAC, will be responsible for monitoring and evaluating their activities. Institutional health workers will be encouraged to participate in the collaborative management of medicine use in their institutions and in developing rational practices.

Evidently, the now National Medicine Policy (NMP) has not only established the place and role of HMTCs in Zimbabwe, but also provided the policy framework for HMTC activities.

This edition of HMTCs manual has been produced as a result of a highly consultative process and represents both the practical nature of the input from health care workers and the changing nature of medicine especially over the recent years. The NMTPAC is a standing committee that reviews the therapeutic guidelines in EDLIZ on a continual basis, and always looks forward to feedback from the providers of health care in Zimbabwe. Contact the NMTPAC through Directorate of Pharmacy Services on dps@dps.co.zw with your comments.
3. Justification for HMTCs

Developing countries spend 20 – 40% of their health budget on medicines. In 2012, the Ministry of Health and Child Welfare Zimbabwe MoH budget has allocations of $14,453,000 for medical supplies and services (4.18% of the entire health budget) on medicines and surgical supplies. Increasing costs and lack of resources often result in public health systems being unable to procure sufficient medicines to meet patient demand. Despite this, medicines are often managed and used inefficiently and irrationally. In Harare Central Hospital for instance, blood and blood products accounted for 1/3 of the monthly allocation for medicines. Faced with ever-increasing costs and a capped budget, hospitals must find ways to continue to offer effective but affordable care.

These spiraling costs have been attributed to unregulated prices, poor procurement procedures and inefficient distribution mechanisms. However, medicines are often prescribed, dispensed and used inefficiently. When choosing between medicines, clinicians often consider only efficacy and are not aware of the most cost-effective treatment regimen. On their part dispensers, often give generous quantities of certain medications, for example analgesics or more expensive dosage forms such as paediatric suspensions where tablets could do. Patient non-adherence to medical advice is another source of waste. In a recent campaign to urge the community to return unwanted medicines, three tonnes of medicines were collected in only six months by pharmacies in the Hunter Valley area in Australia (Goodman and Lazzarini 1995). This reflects inefficient use of an expensive resource leading to unnecessary costs.

Apart from cost, this inefficient use of medicines also affects the safety and quality of therapeutic care. Inefficient use of medicines affects the safety and quality of therapeutic care and wastes resources. According to WHO (1985):

Rational medicine use requires that the patients receive medicines appropriate to their clinical needs in doses that meet their individual requirements (right dose, right intervals and right duration). These medicines must be of acceptable quality, and available and affordable, at the lowest cost to patients and the community.

When medicine use is not in accordance with this definition, it is often associated with undesirable health and or economic outcomes. Therapeutic poisoning is one such undesirable but often preventable outcome.

A study at a Melbourne teaching hospital in Australia demonstrated that 5.7% of admissions were medicine related and of these, 26% were caused by prescribing factors, 27% by patient non-adherence and 47% due to adverse medicine reactions (Dartnell et al 1996). With antibiotics, the consequence of inappropriate use is the increased frequency and spread of resistant bacterial strains (Chetley 1993).

The inability to treat common infections with the antibiotic of choice can be costly or even disastrous. With scarce resources and an increasing demand for quality care, how can hospitals ensure that available resources are used efficiently for effective and affordable treatments? The hospital must develop and implement strategies for selection and quality use of medicines.
Summary

HMTCs can nearly always be started or their functioning improved by demonstrating a medicine use problem to all the major stakeholders and senior prescribers and then planning with them what to do about it. The plan should include:

- measuring the problem quantitatively
- investigating the problem qualitatively to understand underlying reasons for the problem
- developing and implementing an intervention to correct the problem
- measuring the medicine use problem again in order to evaluate the intervention.

The problem of a HMTC not functioning can be dealt with in the same way. Firstly, the aspects that are not working need to be defined, secondly, the reasons that this is so investigated and finally, an appropriate intervention developed and implemented.

Getting a HMTC started will require a strategy based on:
- local conditions
- local data
- starting small and scaling up
- choosing a problem that can easily be addressed
- transparent decision-making
- political and administrative support.

This cannot happen without doctors, pharmacists and nurses and financial managers coming into a partnership to negotiate the best balance between cost and quality. Again, this cannot be done by Head Office, it must be done by hospital staff getting together to address their own problems.

4. GETTING STARTED

4.1 ADDRESSING THE PROBLEM

A HMTC must deal with many issues but it cannot do so all at the same time, especially in the beginning. The way to get started will depend on the varying circumstances and context in different countries, health-care systems and hospitals. Many countries do not have HMTCs in their hospitals or facilities. In other countries where HMTCs do exist, many of them do not function properly.

Any process of change requires, first, that someone realizes the need for change. In the context of HMTCs, the first step is for you, the reader, to realize that irrational medicine use is a problem and that a HMTC may provide a framework for solving the problem in your own environment. Thereafter, your job is to convince others of the need to address the problem of irrational medicine use and to work with them in finding the solutions through a HMTC. This chapter is designed to help you get started and shows how to use this manual in the process. Three areas are covered:

- how to start a HMTC where none exists
- how to improve the functioning of an existing HMTC
- how to use this manual in solving problems related to medicines and therapeutics.
4.2 Stepwise approach to starting a HMTC where none exists

STEP 1 Do your groundwork
Starting a HMTC will require the undertaking of a lot of advocacy. For this advocacy to be successful, there need to have gathered sufficient evidence. Consider:

• Are there any data on medicine use problems? If so, collect them.
• Do senior staff (doctors, pharmacists, nurses) think there are problems, and if so what are they? Reported problems might include:
  — prescription of too many medicines
  — overuse of antibiotics or injections
  — medication errors
  — medicines not working
  — poor quality medicines
  — adverse drug reactions
  — frequent medicine stock-outs due to insufficient budget
  — frequent medicine stock-outs due to poor supply system
  — medicines not on the formulary list
  — prescribers not following the formulary list

• Which problem do staff feel is the most serious?
• How do staff think these problems, and especially the most serious one, should be addressed?
• Of the most serious problems, which one could be addressed most easily?

STEP 2 Gain a friend in authority
Take the findings of the initial groundwork to the most senior medical authority that you can find, and discuss what he or she thinks. Present any data that may have collected and discuss how it might negatively affect patient outcome and/or increase the hospital (or health facility) budget. Discuss how improved use of medicines could lead to improved patient outcomes and/or decreased costs. Plan a course of action with this senior medical person. This course of action may include:

• meeting with all medical staff to identify a problem to investigate, or
• initial investigation of a medicine use problem to discuss later with medical staff.

STEP 3 Meet all the senior staff and stakeholders
With the approval of senior management, meet all senior health staff to discuss medicine use problems. In the initial meeting one may:

• present the findings of your groundwork
• present any extra medicine use data, for example ABC analysis, that you may have done, following your meeting with the most senior medical authority.

Then:
• If all agree that medicine use problems are a serious issue, ask them how they wish to address it — this is the first opportunity to discuss having a HMTC.
• If they do not agree that medicine use problems are serious enough to warrant a HMTC, get agreement from them to investigate a medicine use problem of their choice. If prescribers are involved at the start of a project to investigate a medicine use problem, they are more likely to accept the results. In any case, certain detailed investigations such as medicine use evaluation (MUE) cannot be done without the cooperation and
participation of senior physicians. It is wise to choose one of the simpler problems for which one can see a solution rather than a more complex problem which has no easy answer. There is need for this first investigation to be a success so that it can be used later to advocate for having a HMTC.

STEP 4 Measure your medicine use problem
Measuring a specific problem in detail is your first step to improving medicine use. What you will investigate will depend on what the agreed problem is. One possible approach that may address problems of the formulary list, stock-outs and overuse might consist of the following steps:

• involve all the senior staff in a VEN analysis to identify vital, essential and necessary medicines.
• conduct an ABC analysis to identify which medicines consume most of the budget (A medicines).
• compare the VEN and ABC analyses to see whether any non-essential medicines are in the high cost/consumption A category.

STEP 5 Present your findings and plan next steps with your stakeholders
Present the results of your investigation to all the stakeholders. During the presentation, you can mention how much time it took and thank all those who helped or participated. Assuming some medicine use problems are identified, discuss with the group:

• what they think of the findings; try to get a consensus from them on which are the most important problems
• how to address the medicine use problems identified – this is the second opportunity to discuss having a HMTC
• a plan for a more detailed investigation of the medicine use problem chosen in order to find out how best to rectify the problem.

Whether or not the group agrees to discuss having a HMTC, do not lose the momentum in trying to promote more rational use of medicines. After VEN/ABC analysis the next step is to discuss with the group the nature of the problem, its size, why it exists and what to do about it. If the causes are well understood and agreed, then solutions can be found by the group. If not, then the group should agree to a process of more detailed investigation.

Even though the stakeholders’ meeting is not a HMTC meeting, it presents an opportunity to give people the idea of how a HMTC might function. Thus, minutes should be recorded. It may be necessary to write up a small proposal for conducting any agreed medicine use investigation and submit it to the hospital or regional administrative authority, requesting funds and human resources. The involvement of the senior prescribers and stakeholders from the meeting will lead to greater cooperation and acceptance of the findings and also understanding of the work involved.
STEP 6 Undertake a detailed medicine use investigation

The type of study will depend on what the medicine use problem is and the type of facility. It may be necessary to write up a small proposal and circulate it to the members of the stakeholder/prescriber group and the hospital administration before conducting the study.

Make sure you cover the issues of human resources and finance to conduct the investigation.

Extra staff may need to be hired, or at least existing staff excused from certain activities in order to do the study.

In a hospital, a MUE of one or two medicines may be done, choosing a medicine according to whether it:

- has the highest value
- has serious side-effects
- is non-essential
- has more consumption than expected from morbidity patterns.

In primary health-care facilities, an indicator study may be more appropriate. In both cases, some qualitative investigation is needed to find out the reasons underlying the prescribing behaviour. The final choice of which type of investigation to do should be that of the group.

STEP 7 Present your detailed findings and plan an intervention

Present the results of your detailed investigation to all the stakeholders in a meeting and also by report to the hospital administration. During the presentation, you can mention how much time it took and thank all those who helped or participated. Discuss and agree with the senior prescribers and stakeholders in the group a plan of action which may include:

- a targeted intervention based on the detailed study findings
- initiating a formulary process or other general means to improve medicine use – this is your third opportunity to discuss having a HMTC.

STEP 8 Implement and evaluate an intervention to correct the problem

Implement the intervention and evaluate it by measuring the medicine use problem before and after implementation. Interventions may be educational, managerial or regulatory and should be implemented with the full cooperation and participation of the senior prescribers and stakeholders. Measure also the cost of the intervention and the savings in terms of less medicine used as hospital administrators are likely to be more supportive in the future if they see that your measures have saved money. The type of interventions used will depend on the nature of medicine use problem identified and investigated.

STEP 9 Present the results of your intervention to senior prescribers

The final step of any intervention study is to present the findings to the interested stakeholders – prescribers and senior management. In fact, if the senior prescribers have been fully involved, they will already know the results and be keen to spread them to all other prescribers. During this dissemination, the following need to be emphasized:

- the benefits – improved health care for patients and reduced costs for the hospital or health facilities
• the need for time and resources to achieve an improved result
• The need for a sustainable mechanism to conduct such work – this is your fourth opportunity to discuss having a HMTC.

STEP 10 Plan the start of a HMTC
If the above process has been followed, it is very likely that you will already have started planning a HMTC. If not, a successful intervention may gain the support you need to do so.
By now, your senior friend in authority, whom you have kept fully involved in the process, should be sufficiently motivated to help in the establishment of a HMTC. Terms of reference, membership and methods of working need to be agreed by the senior physicians and management. A successful HMTC is an active one. Therefore, the cycle of changing medicine use problems should be continued, addressing one medicine problem at a time.

4.3 Revitalizing non-functioning HMTCs
Many HMTCs do not function. The way to address this is very similar to starting up a HMTC from scratch. Often HMTCs do not function because there is:

• lack of awareness of medicine use problems or interest to address these problems
• lack of awareness of what a HMTC could do to address medicine use problems
• lack of time or reward for members to undertake any HMTC activities
• no mandate or support from senior authority.
Just as with changing medicine use problems, the first step is to quantify the problem and understand why it exists. Only after this can solutions be found. Therefore, if staff is unaware of medicine use problems, demonstrate the problems and their underlying causes.
If HMTC members are not active, find out why. Perhaps HMTC members are not given sufficient reward for their effort and you need to find suitable incentives – this will mean gaining the support of the senior administration. Perhaps HMTC members have a conflict of interest and do not want to be active. In such a case, you would need to gain senior support for introducing regulations concerning conflict of interest in HMTC members. Finding such support is likely to require evidence of medicine misuse, for example the unnecessary cost of using a more expensive branded product which is no more effective or safe than a cheaper alternative.

If a HMTC has ceased to function because a specific issue cannot be resolved, for example a decision about a formulary medicine, investigate whether all the appropriate steps had been taken. If not, tackle the problem again following an agreed set of steps. If all the correct steps had been followed, or could not be followed because of reasons beyond your control, then leave this problem and choose a simpler one to solve first. Resolve the simpler problems before tackling the more complex ones.

4.4 Using this manual to solve problems
The goal of a HMTC is to ensure that patients are provided with the best possible quality of therapeutic care. Every country and health institution in the world has problems of medicine use. Thus, a HMTC should always be looking for medicine use problems and then trying to solve them. If we do not look for problems we will not find them, but that does not mean they do not exist. Figure 4.1 shows the role of the HMTC in maintaining quality of care.
There will be no one solution or starting point for every hospital MTC. What you do will depend on your local circumstances. The activities of a HMTC should be problem-based.

Figure 4.1 The HMTC and quality of care

Establishing standards
(1) Formulary list criteria & process
(2) Standard treatment guidelines
(3) Evaluating medicines
(4) Medicine use evaluation criteria

Interventions to correct medicine problems & achieve standards
(1) Interventions to promote rational medicine use
(2) Interventions to prevent medication errors quality problems stock-outs and ADRs

Regular medicine use assessment
(1) Aggregate methods
(2) Indicator studies
(3) Medicine use evaluation
(4) Regular review of reports of medication errors and ADRs

Investigation of reported problems
(1) Investigation of: outbreaks of medication errors, medicine quality problems, medicine non-availability and ADRs
(2) Qualitative investigation why a medicine use problem exists

HMTC’s role in ensuring quality of therapeutic care
always looking for problems and finding solutions.

It is not the role of the HMTC to take over the function of any department. The membership of the HMTC should be drawn from the various departments and their expertise used to ensure that all aspects of medicine management and use are performed to a high level in a coordinated manner.

In conclusion, getting a HMTC started or making it more functional will require a strategy based on:
• local conditions
• local data
• starting small and then scaling up
• choosing a problem that can easily be addressed
• transparent decision-making
• political and administrative support.

There is nearly always something we can do to get started. Patients deserve all our effort to ensure that they receive medicines appropriate to their clinical needs in doses that meet their individual requirements.
5. What Should HMTC Do?

The HMTC should have its own terms of reference which spell out the committee’s place in the organisational structure of the hospital, its goals, objectives, scope of authority and responsibilities. In the Zimbabwe pilot, hospitals developed their terms of reference at a workshop at the beginning of the project (Manyemba et al 1998. Report of the first workshop to establish MTCs in Zimbabwe).

5.1 Model Terms of Reference for HMTCs in Zimbabwe

**Name**
Hospital Medicine and Therapeutics Committee of …………………………………………………………………………………………… Hospital.

**Status**
The HMTC is a standing hospital committee responsible, through its chairman, to the hospital executive.

**Chairman**
The hospital executive shall appoint the Medical Superintendent or a senior doctor to chair the committee.

**Secretary**
The committee secretary is usually the pharmacist. In hospitals without a pharmacist, the hospital executive can appoint the pharmacy technician or any other member of the committee to be secretary.

**Members**
The hospital executive appoints the other committee members on a representational basis and also to take advantage of the available human resources in the hospital and community.

**Goals**
The overall goal of the HMTC is to ensure that patients are provided with the best possible cost-effective and quality of care through determining what medicines will be available, at what cost, and how they will be used.

- Improved health and economic outcomes of hospital care particularly those related to medicine use.
- Rational and cost-effective medicine use through collaborative medicine management involving all health workers.

**Objectives**
The committee will be responsible for defining its own specific objectives on an annual basis. Each committee can do that by reviewing the following objectives and choosing what they want to work on.

- To formulate and implement policies for selection and use of medicines.
- To develop and manage a hospital essential medicines list.
- To develop and implement consistent standard treatment guidelines.
- To carry out medicine utilization reviews in the hospital.
- To provide prescribers with objective medicine information.
- To monitor and analyze expenditure on medicines.
- To carry out educational and other activities aimed at improving medicine use by prescribers, dispensers and patients in the hospital.
- To monitor and report adverse medicine reactions to the Medicines Control Authority of Zimbabwe (MCAZ).
- To monitor medication errors and act to prevent their recurrence.
- To regulate operations of the pharmaceutical industry in the hospital.

5.2 Activities
To meet these objectives, the committee must plan and carry out certain activities that may include:

- Drawing up and circulating criteria for selection of medicines into the hospital essential medicines list from EDLIZ. Clinical efficacy and cost of therapy are two key criteria, but others may be considered.
- Appointing individual members within or outside the committee to develop standard treatment guidelines for the main diseases in the hospital. The committee must approve these guidelines.
- Developing protocols and defining level of use for particular items such as blood, antibiotics and high cost medicines.
- Presenting medicine consumption and cost information by ward or by consultant monthly or quarterly.
- Designing interventions (educational, managerial, and regulatory) to correct specific medicine use problem.
- Evaluating the impact of interventions.
6. ORGANISATION OF HMTCs

6.1 MEMBERSHIP

Committee membership should facilitate the building of partnerships between all stakeholders, including consumers. Typically, membership comprises administrators, doctors, pharmacists, nurses and consumers. Studies in the USA and Australia and experience from Zimbabwe suggest that the choice of chairman is critical to the committee’s credibility and effectiveness. The chairman must be someone who is perceived as competent in therapeutics and enjoys the respect of his/her colleagues. In most cases, this individual is a senior doctor in the hospital. If the Superintendent possesses these qualities, he/she is the ideal choice since the office already has authority in the hospital.

Summary
The committee secretary ensures implementation, follow-up and feedback on the committee’s decisions, preparation of meeting agenda and background materials for consideration by the committee. The secretary must be able to devote sufficient time to this work in between meetings. The hospital (chief) pharmacist is a natural choice for this position as he or she has great interest in and is appropriately skilled to deal with medicine-related issues. However, staff turnover among hospital pharmacists in Zimbabwe is very high and for continuity, another member of the pharmacy department such as a pharmacy technician should also be a member of the committee.

Other committee members may include:

- representatives of each clinical division in the hospital
- a clinical pharmacologist

Summary
In order for a HMTC to function it should have a multidisciplinary, transparent approach, technical competence and an official mandate. It is essential to define and document:

- the membership of the HMTC, including the chairperson and secretary, and criteria for membership
- the goals, objectives and functions of the HMTC
- how the HMTC will operate and its terms of reference
- the funding sources identified
- the mandate – HMTCs will not work without senior administrative support
- the relationship of the HMTC with other subcommittees for specific areas of work
- a process for self-assessment and evaluation.
- an administrator
- a microbiologist or laboratory technologist
- a nurse,
- medical records officer
- a consumer

In Australia, consumer representatives ranged from a retired judge, a psychiatric patient, member of a pensioners association, a volunteer hospital worker and a poisons information pharmacist.

Consumer representation is a relatively recent development not yet widely practised. The consumer or consumer advocate is looked upon to bring a societal view to the committee.

### 6.2 How Often Should They Meet?

The committee should meet regularly, at least monthly with each meeting not exceeding one hour and half.

In Boston USA, the timing (morning and lunchtime) and provision of food during meetings was found to be a strong incentive for regular attendance.

The secretary should ensure that:

- Items of agenda, any background material and minutes of the previous meeting are circulated in sufficient time for members to prepare for the meeting.
- All proceedings of the meeting are recorded accurately, showing the matter discussed, the decision taken, the person to action that decision and the time frame for implementing the decision.
- Decisions of the committee are followed up in between meetings.
7. How Should HMTCs Function?

It is neither possible nor desirable for the HMTC to try to do everything. The committee must choose priority activities in which to invest time and human resources.

7.1 Selecting Essential Medicines

For instance, selecting essential medicines for the hospital could be the first major activity for the committee. This can be divided into manageable parts such as inpatient and outpatient lists. The inpatient list can still be further divided into separate wards stock for the surgical, medical, paediatric emergency and maternity wards. Alternatively, the committee can look at each therapeutic class and choose the best 2 or 3 in terms of efficacy and cost of a treatment course. In this whole process, the committee must maintain communication with and ask for input from the relevant ward staff.

7.2 Adding Medicines to the List

The committee must develop guidelines for the management and periodic review of the list to ensure availability of a range of medicines sufficient to cover conditions treated at the hospital while at the same time avoiding duplication. These should include procedures for adding a new medicine to the list or simply obtaining a non-listed medicine either to initiate or continue therapy in hospital. All applications to add medicines to the list must be made on the official application form (see Annexure 4: Application for Addition to Hospital Essential Medicines List). Individual doctors making the application must get the endorsement of their head of department before forwarding the application to the HMTC. It is useful for the committee to have two sets of criteria. One set of criteria would be for consideration of new treatments for conditions hitherto not amenable to medicine therapy or treatments representing major improvements in survival and quality of life and another for treatments representing minor improvements in therapy compared to existing listed medicines. For new treatments or major improvements, the committee should consider among other factors:

- The efficacy and safety of the medicine.
- Whether the hospital has the necessary clinical expertise to use the medicine and what role specialists should play to regulate therapy.
- An estimation of the cost (and potential savings) to the hospital should the medicine be introduced. These should include costs of the medicine itself, hospitalisation and investigation.
- The availability of the medicine on the market.

As for medicines representing minor improvements in therapy, the committee should consider at least the following:

- Whether the medicine is superior to existing ones in terms of efficacy, safety, or convenience of dosing/administration.
- How it will affect the budget compared to already listed medicines.

Apart from additions to the list, the committee will also need to consider requests for non-listed medicines to cover special circumstances such as non-response or contraindications to available medicines. Doctors may also request a non-listed medicine to continue therapy for a patient who had been stabilised on a non-listed medicine before admission to hospital where changing to another medicine is considered detrimental. The pharmacy must keep a register of all non-listed medicine requests indicating the name of the requesting doctor, the name and quantity of the medicine and
the indication for which the medicine was requested. When compiled at the end of the year, this information helps the committee decide whether or not to add the medicine onto the list.

7.3 ABC Analysis
ABC analysis and therapeutic category analysis (MDS-3 Managing Access to Medicines & Health Technologies) are powerful tools that you can use to manage the essential medicines list.

An ABC analysis can:

- Reveal high usage items for which there are lower-cost alternatives on the list or available on the market.
- Identify purchases for items not on the hospital essential medicines list.

You can apply ABC analysis to medicine consumption data over a year or shorter time or even to a particular tender or set of tenders. A detailed description of the actual steps is given in MDS-3 Managing Access to Medicines & Health Technologies. In summary:

- List items consumed or purchased and enter the unit cost of each item. To account for changes in price over time, calculate the average unit cost.
- Enter the number of units purchased or consumed.
- Calculate the value of consumption by multiplying the unit cost by the number of units consumed for each item. The total value of consumption is the sum of item values.
- Calculate the percentage of total value for each item by dividing the value of each item by the total value. Express your percentage to two decimal places.
- Rearrange the list by ranking the items by value of consumption or percentage value of consumption (either gives the same result) in descending order.
- Calculate the cumulative percentage value by adding from the top the percentage value of consumption of the next item down the list.
- Categorise your items into A, those few items accounting for 75 – 80% of total value; B, those items which take up the next 15 –20% and C, the bulk of items which only account for the remaining 5 – 10% of value. Typically, class A items constitute 10 – 20% of all items, with class B items constituting another 10 – 20% and the remaining 60- 80% being in category C.

7.4 Therapeutic Category Analysis
Building on the ABC analysis, therapeutic category analysis can:

- Help the committee choose the most cost-effective medicines within a therapeutic class and to choose alternatives for therapeutic substitution.
- Indicate potential inappropriate use if used together with information on the morbidity pattern.
- Identify medicines that are overused or whose consumption is not unaccounted for by the number of cases of a particular disease for example quinine and malaria.

With Therapeutic Category Analysis you can easily identify therapeutic categories that account for the highest consumption and greatest expenditures. MDS-3 Managing Access to Medicines & Health Technologies gives details of both the summary and detailed analyses. The procedure is similar to ABC analysis:
Do the first three steps of ABC analysis to produce a list of all items by volume and value of consumption.

Assign a therapeutic category to each medicine using the WHO Model List of Essential Medicines or the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System for example.

Rearrange the list into therapeutic categories and sum the percentage value of items in each category.

Like in ABC analysis, a small number of high-cost therapeutic categories account for most of the expenditure. You can perform a more detailed analysis of the identified high-cost categories to identify more cost-effective therapeutic alternatives.

7.5 Educational Activities on Rational Medicine Use

Within the hospital there are a number of people who either prescribe or dispense medicines. The committee should define who should be the target of educational activities and what should be the key messages transferred. Possible target groups could be SRNs working in Outpatients, newly appointed GMOs, or people who do dispensing. The target messages might be to take temperatures before diagnosing malaria, using chloramphenicol instead of ciprofloxacin, or asking patients to repeat back their instructions after they have received their medicines. Every educational activity should have defined objectives. An example would be “By the end of training the dispensing assistant would be able to ensure that each patient dispensed understands the instructions as to how to take the medicines.” The committee should review and approve the educational activities, which should have clear time limits. Different educational activities have been tried to change prescribing or dispensing behaviours. These are well described in MDS-3 Managing Access to Medicines & Health Technologies. Some that might be tried include:

Printed Materials.

By themselves printed materials are unlikely to be effective.

The materials could be posters, desk pads, newsletters, and journal articles or articles written by pharmacy staff or DaTIS publications. However, when these are combined with more interactive teaching methods the effect may be increased.

All training should be evaluated to assure that the messages have been understood; by assessing knowledge change and that the training has been effective by assessing changes in performance.

Large Group Meetings.

These can be effective if they are well prepared targeted, use interactive methods and provide a clear message as to what change is expected.

For example a lecture on antimicrobial resistance in which staff sits in rows of chairs and listen to a lecturer talk about bacteriostatic or bactericidal medicines for an hour is likely to have minimal effect.

A more successful approach might occur if the facilitator introduces the topic of antimicrobial resistance by saying “Last month we had a patient Mr Komiti whom many of
you nursed. As you know he finally died after we had tried so many different antibiotics. We now have the lab results showing his infection was resistant to every antibiotic. I want you to discuss in groups why you think his infection was resistant to so many antibiotics and what could be done to prevent such an event."

After the discussion it would be important to summarise the discussions and leave participants with clear messages as to what should be done. Visual aids should be carefully prepared as people learn in different ways.

**Small Group Meetings.**

These are usually more effective in that they can be held at the worksite for shorter periods of time. Again careful preparation is needed, with a clear message and an ability to evaluate the impact of the training. Wherever possible the teaching should be problem based where staff is asked to identify their problems and then in discussion the material prepared can be used.

Reinforcement is far easier with small group teaching. In practice in hospitals it may be possible to group staff for an hour over tea either in the morning or afternoon on a regular basis e.g. weekly to discuss particular medicine issues. Visual aids are also important but may be in the form of print material that can be used as the basis for discussion.

**Individual Teaching.**

Teaching individuals may be time consuming but is very effective. Medicine representatives are the best at doing this.

In 15 minutes a medicine representative can persuade a doctor to change his practice. They do this by being charming (good communication skills), having only one or two key messages to convey, providing attractive visual aids or memory aids (colourful pamphlets or notepads, desk calendars, engraved pens etc).

They also use the names of opinion leaders to support claims, and always follow up visits with a reinforcement visit. It is perfectly possible for pharmacists or members of the HMTC to use the same approach. In a recent study of supervision at health centres two visits by pharmacists or pharmacy technicians were shown to be effective in improving medicine use. The trainers in this approach used modern communication techniques to convey their messages.

**Nurses.**

In many hospitals, nurses make many of the decisions about which medicines are prescribed. In some cases they do this directly, for example in outpatients, but they often do it indirectly. Doctors learn to listen to SRN's advice and when a senior nurse says to a doctor "I think this patient needs such-and-such", he usually follows her advice. If the ward sisters could be encouraged to monitor how well a doctor follows EDLIZ prescribing in hospitals could only improve.

But for this to happen, nurses need to be exposed to EDLIZ in an effective way. Nurses tend to be practical in outlook and thus teaching around problems is more likely to be effective.
Opinion Leaders.

In all health systems there are opinion leaders. These are the people junior staff go to for advice. It may be the professor or the senior consultant but it is often not. In a teaching hospital it may be a registrar, but it may be an experienced SRN in outpatients or an effective pharmacist or a junior doctor who is known to be “smart”. Identifying the opinion leaders is important and relatively easy.

By asking, as medicine representatives do, “Who would you send a relative to if they had problem X?” or “When you need advice about Y who do you ask?” Once the committee has identified who the opinion leaders are it may be a good idea to invite them to join the committee and it may be useful to target individual teaching at them.

There are other educational approaches that may be used but in all cases, a target audience should be identified, key messages developed and the process and impact of education should be evaluated. If you want to read more about educational methods to improve medicine use see MDS-3 Managing Access to Medicines & Health Technologies

7.6 Regulating Medicine Representatives

This may be a problem in larger hospitals, particularly where doctors have active private practices. Medicine representatives sometimes bring new information into hospitals and act as sources of information for doctors. However they are primarily salesmen interested in promoting a medicine sold by their company. The committee may choose from different options to regulate access of medicine representatives in the hospital. They may choose to ban them entirely, which can be counter-productive as the representatives then approach doctors outside the hospital. One option used in other countries is that of equal time presentations. In this approach representatives are required to submit their materials in advance. The hospital pharmacist or a clinical pharmacologist if there is one in the hospital actively reviews the materials. Then a meeting is arranged at which the rep is invited to present his information and then equal time is given to the pharmacist or clinical pharmacologist to comment on the materials and the presentation. Then the meeting can be opened for questions and discussion. By debating the merits of a new medicine it is possible for prescribers to gain a balanced perspective on the medicine. If this approach cannot be used finding ways to regulate the time taken by medicine representatives should be established. MDS-3 Managing Access to Medicines & Health Technologies

7.7 Generic Substitution Policy

Generic substitution can be defined as the dispensing of a product that is generically equivalent to the prescribed product, with the same active ingredients in the same dosage form, and identical in strength, concentration and route of administration. Considering the range of generic products available on the market and the significant difference in the price of brands compared to generics, generic substitution is clearly an efficient use of resources and can result in significant savings in the medicine budget. Zimbabwe’s public health sector already has a generic prescribing policy which previous ZEDAP surveys has shown to be working quite well at primary health care level. To
augment this generic prescribing policy, your HMTC must formulate, disseminate and implement a generic substitution policy.

For example, your committee may stipulate that the pharmacy may supply the generic equivalent of any medicine ordered, unless the prescriber has specifically endorsed on the prescription that there shall be no substitution for the specified brand product. When a generic equivalent is dispensed, the patient must be informed.

As in the formulation of any policy, it is advisable to seek the active involvement of all those to be affected by the policy. Some of the criticism against generic prescribing and substitution arises from doubts about the bioequivalence of generics. It is important to acknowledge clinically important bioavailability problems with generic products where these exist. Fortunately, these cases are the exception rather than norm, and examples include digoxin, chloroquine, aminophylline, glycerol trinitrate etc. MDS-3 Managing Access to Medicines & Health Technologies. DaTIS, MCAZ and the Department of Pharmacy, UZ can help when in doubt about the appropriateness of generic substitution in a particular case.

7.8 Medication Error Reporting

Errors can occur in the prescribing and administration of medicines to patient. One of the committee’s functions is to monitor and report on the occurrence of medication errors in order to avoid possible adverse consequences or their recurrence. The following is a list of some of the possible errors that you should monitor in your hospital:

Medicine given to the wrong patient

- Wrong medicine or IV fluid administered
- Wrong dose or strength given
- Wrong route of administration
- Wrong rate of administration
- Wrong time or frequency of administration
- Potentially interacting medicines prescribed or administered

Having a pharmacist or nurse or another doctor review the prescription before the medicines are administered can prevent some of these errors. Whenever an error is identified, it must be documented and the prescriber or nurse administering the medication informed. All errors should be compiled and a report presented to the full HMTC monthly. It is important to do this in a non-confrontational manner without mentioning names of the doctor, nurse or pharmacist responsible for the errors, see example below.
Medication Errors Report for September 2010

<table>
<thead>
<tr>
<th>Type</th>
<th>Ward</th>
<th>Brief Description</th>
<th>Reporter</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>C6</td>
<td>Heparin 15000u/100ml given instead of 10000u/100ml</td>
<td>Nurse</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>B4</td>
<td>Ofloxacin 200mg tablet given instead of 400mg tablet</td>
<td>Doctor</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>A4</td>
<td>Theophylline 5mg/kg loading dose given instead of 6mg/kg</td>
<td>P’cist</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>A2</td>
<td>Amoxycillin given 4 times instead of 3 times daily</td>
<td>Nurse</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>C1</td>
<td>Frusemide prescribed q4h but given q6h</td>
<td>Nurse</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>B3</td>
<td>KCl prescribed q8h but charted 1000hrs, 1600hrs &amp; 2100hrs</td>
<td>P’cist</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>A4</td>
<td>Chlorpromazine given instead of chlorpropamide</td>
<td>P’cist</td>
<td></td>
</tr>
</tbody>
</table>

Key: A = wrong dose or strength; B = wrong time or frequency; C = wrong medicine

7.9 Adverse Medicine Reaction Monitoring

The monitoring and reporting of adverse medicine reactions (ADRs) is often ignored. The Adverse Medicine Reaction and Medicines Review Committee of the Medicines Control Authority of Zimbabwe (MCAZ) encourages you to report all suspected adverse reactions to medicines and medicinal products. This is because “the reporting of a seemingly insignificant or common adverse reaction or side effect may help pinpoint a more widespread prescribing problem”. Apart from being a health hazard, ADRs may contribute to increased health care costs if serious enough to require treatment.

It is therefore important for your hospital to encourage ADR monitoring and reporting especially to new medicines whose safety has only been evaluated in pre-marketing clinical trials. ADR monitoring and reporting is an important aspect of post-marketing surveillance which contributes to better understanding of the medicine’s safety and effectiveness in the real world of practice as opposed to pre-marketing clinical trials which are conducted in a highly selected small population.

Your HMTC should encourage all health workers to bring to its attention any cases of suspected therapeutic failure, any adverse effect of changing between brand and generic products, adverse effects of herbal and traditional and adverse reactions to vaccines. The MCAZ specifies medicines of particular interest in its Medicine Information Bulletin, which is distributed free to most health professionals in Zimbabwe. Remember you do not have to know the pharmacology of an adverse effect or reaction to report it, your suspicion is enough. These reactions should be documented as soon as possible using ADR reporting forms available among the green pages at the back of EDLIZ. To enable timely reports, the committee must ensure that reporting forms are easily available in
such departments as casualty, out patients, theatre, all wards and the pharmacy. You may find it easier to compile all reports and send them to the MCAZ once a month rather than as and when a reaction occurs.

### 7.10 Medicine Utilization Review (MUR)

This is an important function for the HMTC to oversee. Members of the committee may do the work or they may oversee what is done. The purpose of MUR is to identify a problem that may be either a medicine or a condition, set criteria (standards) for how the medicine should be used or the condition treated. Then case notes are reviewed to see who are following the standards and then these results are fed back to the prescribers. When they see the results, the prescribers may criticise the standards or may change their own practices. Developing the standards and collecting the information about prescribing practices may be a lot of work but usually the results are very dramatic. It may be possible to involve visiting medical students or pre-registration pharmacists in collecting and analysing the data. A detailed description of MUR is included in MDS-3 Managing Access to Medicines & Health Technologies. As part of the pilot test for establishing Pharmacy and Therapeutic Committees in Zimbabwe MUR activities have been undertaken in some hospitals. Examples from these hospitals will be used in the description below of MUR.

**Step 1: Establish responsibility for the MUR Process**

This is usually the HMTC committee, but it may be allocated to a subcommittee. In case, the full HMTC committee should be involved in deciding on the problem to be addressed, in reviewing the criteria used and when the results are presented.

**Step 2: Establish the Scope for each Study**

A MUR study may focus on a medicine or a condition. Selecting which condition or medicine to study may be difficult, as there are often so many problems worth addressing. But to help you choose; you may wish to look at the ABC analysis of medicine consumption to see which are the medicines on which you are spending a lot of money on; either because they are expensive or they are used a lot. For a condition, you may choose one which it often treated incorrectly, or where better treatment choices exist, or where outcomes of bad therapy are serious. You may wish to make a matrix to help you choose. At Bindura Hospital the staff chose to review how blood was used. At Wankie and Mutare the problem selected was that antibiotic prophylaxis for Caesarean sections and at Bonda the use of amoxycillin for paediatric pneumonia.

**Step 3: Establish Criteria or Indicators for how the medicine should be used or the condition treated.**

The criteria would usually define which patients should and should not receive the medicine. For example children with a respiratory rate of less than 40/min, or with malaria or amoebic dysentery would not receive an antibiotic. Other criteria might be that all pregnant women should receive ferrous sulphate, patients with an Hb of more than 5g should not receive a transfusion unless they are about to undergo surgery. Other criteria might depend on laboratory findings such as no ciprofloxacin without culture evidence of resistance. Whatever the criteria selected, it must be easy to measure and it must be
agreed. Often the criteria will be copied from EDLIZ or Ministry circulars but they MUST be published and circulated because often prescribers have not paid attention to what is in EDLIZ. Criteria may also apply to dispensing e.g. criteria could be: After every dispensing episode patients will be asked if they have any questions or be asked to repeat back the dispensing instructions.

**Step 4: Collect and organise data**

Data collection forms can be developed which are simple tally sheets, observational checklists or simple questionnaires. Only a few items of data should be collected for each MUR study. The sources of data most usually are patients' notes but they may be observational checklists, dispensing records, laboratory reports or dispensing registers. It is important not to collect too much data and to collect only data directly related to problem being studied. If the report is going to be made by prescriber or by ward it is useful to organise the data forms by prescriber or ward.

**Step 5: Analyse the data**

To analyse the data it is usually necessary to create simple tables often sorted by the most important indicator. For example if the dispensing criteria were “Every patient should be asked to repeat back the dispensing instructions and should be asked if they had any questions” the table might look like the one below:

<table>
<thead>
<tr>
<th>DISPENSER</th>
<th>Asked patient to repeat back instructions</th>
<th>Asked patient if any questions</th>
<th>Dispensing Time (sec)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benchmark</td>
<td>100%</td>
<td>100%</td>
<td>Undefined</td>
</tr>
<tr>
<td>Nurse A</td>
<td>62%</td>
<td>44%</td>
<td>93</td>
</tr>
<tr>
<td>Pharm Tech B</td>
<td>78%</td>
<td>38%</td>
<td>110</td>
</tr>
<tr>
<td>Ambulance Driver C</td>
<td>0%</td>
<td>56%</td>
<td>65</td>
</tr>
<tr>
<td>Average</td>
<td>46.6%</td>
<td>46%</td>
<td>89.3</td>
</tr>
</tbody>
</table>

**Step 6: Develop Conclusions**

The HMTC committee would review the results and decide what needs to be done. Normally the individuals involved would be fed back the results of all persons audited. In some situations this may cause problems and a list sorted by a key indicator would be prepared and the top three names would be left exposed and the rest of the names would be blacked out except for the individual receiving the form. See the example below. In this example, Dr Big Shot would receive this result form.

<table>
<thead>
<tr>
<th>% Generic Prescribing by Consultant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Able</td>
</tr>
<tr>
<td>Dr Best</td>
</tr>
<tr>
<td>Dr Competent</td>
</tr>
<tr>
<td>Dr Big Shot</td>
</tr>
<tr>
<td>Average</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Using this method Dr Big Shot can see how he rates but nobody else will know which may protect his feelings. Drs Able, Best and Competent would usually not mind their names being published as they have done well and will try to do better in the future. Once the results are fed back, staff is likely to attack the criteria used to assess performance. If this happens the committee may wish to review the criteria, publish new criteria including the objections and repeat the audit. This time the objectors are more likely to change to meet the criteria.

**Step 7: Make Recommendations**
The committee may recommend changes based on the audit. They may suggest training e.g. for the ambulance driver or dispenser, they may want to investigate further the reasons for the behaviour, maybe the prescribers do not know the generic names, or they may want to change procedures, e.g. take the ambulance driver out of the dispensary.

**Step 8: Take Action**
The action of the committee may be to feed back the results, provide training, change procedures or any combination of actions. HMTC members may need to involve others in taking action to effect changes.

**Step 9: Follow Up**
It is important to follow up the actions decided on in Step 8. If the actions were taken, was there an improvement in performance? This may require another audit. Usually no problem should be subject to more than two audits. However, common problems such as dispensing communication may be revisited at a later time when the results can be compared.

### 7.11 Intervention Selection and Design
While MUR is a form of intervention other interventions may be undertaken. A wide range of methods to promote rational prescribing or improve dispensing is described. These interventions are usually categorised into:

- Educational
- Managerial
- Regulatory

Each method can be effective with effort. All interventions require that the reasons for the problem behaviour be clearly understood. Educational interventions are appropriate when there is a knowledge problem. Managerial interventions such as audit and feedback are usually effective but may require a lot of work. Regulatory interventions such as restricting access to certain medicines such as ciprofloxacin may be effective but may also have unintended side effects such as an increase in the use of ceftriaxone. Whichever intervention method is selected, there should be an evaluation component.

### 7.12 Intervention Evaluation
Evaluating interventions in a hospital can be difficult. The essence of valuation is having a control group. This would be a number of people or facilities that would not be subject
to the intervention or be affected by the intervention. This is difficult in a hospital setting, as it is unlikely that there will be many other hospitals that could be used as controls. Also people in the same hospital, even if they work on different wards, are likely to be affected by the intervention even if this is informal. The best way to evaluate a hospital-based intervention is by the use of time-series evaluation ideally with a control group. In this method a limited number of indicator variables (e.g. IM and IV chloroquine use) is collected monthly before the intervention and after the intervention. Ideally at least 6 time points before and six time points after the intervention should be used. The results can be entered on to a table but ideally should be plotted on a graph to show the changes. Examples of a table and chart are shown below. Whenever an evaluation is done it is important to present and publish the results. The UZ Research day is a good opportunity to share the results with people from other hospitals and units. The Directorate of Pharmacy services would want to receive copies of any reports of interventions undertaken.

**Dummy Table of Time Series Evaluation of ACT Use for Malaria at St Albert’s Hospital**

<table>
<thead>
<tr>
<th>Month</th>
<th>Jan 09</th>
<th>Feb 09</th>
<th>Mar 09</th>
<th>Apr 09</th>
<th>May 09</th>
<th>Jun 09</th>
<th>Jan 10</th>
<th>Feb 10</th>
<th>Mar 10</th>
<th>Apr 10</th>
<th>May 10</th>
<th>Jun 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>% IM Quinine</td>
<td>8</td>
<td>12</td>
<td>9</td>
<td>13</td>
<td>7</td>
<td>11</td>
<td>84</td>
<td>91</td>
<td>87</td>
<td>78</td>
<td>89</td>
<td>91</td>
</tr>
<tr>
<td>% IV Quinine</td>
<td>92</td>
<td>88</td>
<td>91</td>
<td>87</td>
<td>93</td>
<td>89</td>
<td>16</td>
<td>9</td>
<td>13</td>
<td>22</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>% Mortality</td>
<td>4.5</td>
<td>6</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>8</td>
<td>4</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>4.5</td>
<td>5</td>
</tr>
<tr>
<td>Average LOS (Days)</td>
<td>7</td>
<td>9</td>
<td>7.6</td>
<td>8.1</td>
<td>9.3</td>
<td>8.25</td>
<td>7.4</td>
<td>7.7</td>
<td>8.2</td>
<td>6.8</td>
<td>9.7</td>
<td>6.8</td>
</tr>
<tr>
<td>Average Coma Time (Hrs)</td>
<td>34</td>
<td>44</td>
<td>29</td>
<td>32.3</td>
<td>27.4</td>
<td>25</td>
<td>27.7</td>
<td>23</td>
<td>31.9</td>
<td>27.3</td>
<td>38.4</td>
<td>29.6</td>
</tr>
</tbody>
</table>

**IM and IV Quinine Use for Cerebral Malaria**

![Graph showing IM and IV Quinine Use for Cerebral Malaria](image)
8. DATA SOURCES FOR MONITORING

Finding data for monitoring the effect of the work of the PTC is relatively easy. There are many sources of information about medicine use that exist in any hospital. The strengths and weaknesses of each reviewed below.

- Stock Records (either stock cards or stock books). These are often very useful. They are easy to access, usually accurate and provide immediate data on medicine consumption. They are particularly useful when a medicine is used for a single indication and when there is an aim to shift from one medicine to another. If the HMTC wanted to reduce paracetamol consumption and increase aspirin consumption the consumption of these medicines as a monthly ratio would be a useful measure. The problem with this source of data is that often medicines are used for multiple indications and it may not be possible to determine the effect of a change in guideline.

- Dispensing Registers. These are particularly useful if the diagnosis is recorded. Even without diagnosis these register may give an indication of what medicines are given in combination, the rate of antibiotic, or injection use and the average number of medicines.

- Prescriptions. Again if diagnoses are recorded this data is more useful. The records may provide data on average prescribing for males and females, different age groups, prescribing by individual prescriber or group of prescribers.

- Pharmacy registers of special medicines. Often hospital pharmacies keep a register of medicines sent to wards on a named patient basis. At Harare hospital this register showed that many of these entries were for IV Metronidazole, a very expensive medicine. By using this register it was possible to identify which consultants liked to prescribe this medicine.

- Patient Case Notes. These are often the first source of data consulted but they may be a lot of work to extract useful data. Sometimes it may be difficult to find the needed records. Then the records may be incomplete or you cannot read the writing. Do not forget to read the nurses notes, if they are in the file. They are often more comprehensive, easier to read and may report details such as patient discomfort etc.

- Laboratory Registers. These may be useful in identifying which case notes to draw from the records office. If for example you want to study Blood slide proven malaria you may be better off using the laboratory register than the discharge register to identify cases.

- Admission and Discharge Registers. These may be useful in identifying cases for further study. Unfortunately though sometimes the clerks are forced to fill in discharge diagnoses because one has not been filled in the notes and the clerk’s guess may not be accurate.

- Receipts from the accounts office. At one mission hospital in Malawi, the medicine names are written on the receipt for payment. By looking at the carbon copies it was possible to determine exactly what medicines had been sold to patients.

From this list of sources it should be obvious that there are many different sources of data for evaluating the effects of interventions. With experience it should be possible to decide which source provides the most reliable and easy to access data. For more
information about investigating medicine use see MDS-3 Managing Access to Medicines & Health Technologies
9. **Budgeting for HMTC Activities**

HMTC activities must be supported by a budget drawn up against a plan of action at the beginning of the year. You should consider staff time costs, meeting costs (food, secretarial and duplication), MUR data collection costs, intervention costs, and reporting costs.

- Staff time costs are to cover a small sitting allowance for members who are not employed by the hospital such as private practitioners and consumer representatives.
- Meeting costs must cover food served during meetings, secretarial services and duplication of minutes and any other background reading materials.
- Data collection for MUR is often very involving and may have to be done by staff outside the normal working hours. It may be better to fix a payment rate per record collected/reviewed rather than time taken.
- If you plan to have an intervention, then you should budget for it to cover all activities to do with implementation and evaluation of the intervention. These may include fees for an outside speaker, production of printed materials and data collection for evaluation.
- Reporting costs should cover the production and dissemination of all reports by the HMTC quarterly and annually.
10. REPORTING OF HMTC ACTIVITIES

The HMTC should report on its activities to the hospital executive, the district and provincial health executives, and the ministry’s Department of Pharmacy Services at least once a year. You may find it better to produce quarterly reports which can then be compiled into an annual report. In addition, the UZ Medical School Annual Research Day and the Central African Journal of Medicine (CAJM) provide excellent opportunities for presentation and publication of MUR and intervention studies conducted at your hospital. Publication of results in the CAJM is a particularly important way of disseminating useful information to other HMTCs and all health professionals in Zimbabwe.

Self-assessment and evaluation of the HMTC are very important if performance and impact are to be improved. The organizational development and performance of the HMTC should be monitored continuously and documented, especially if the HMTC expects the hospital management to provide continuing funds. Some indicators that can be used in HMTC self-assessment are shown in box alongside. These indicators are considered to be core parameters that should be used. However, the HMTC can develop other indicators and measures that will suit its purpose. Most important is for the indicators to be used in evaluating the impact of the HMTC. In this way, the HMTC may see if it is achieving its goals and objectives and justify the continued support of the hospital management.

Indicators to assess HMTC performance and impact
Is there a HMTC document that indicates its terms of reference, including its goals, objectives, functions and membership?
• Is the HMTC in the organizational chart of the hospital?
• Is a budget allotted to HMTC functions?
• Does the HMTC have established criteria and authority concerning medicine selection?
  — How many medicines are there in the hospital formulary?
  — Are there documented criteria for addition to and deletion from the list and requests for the use of non-formulary medicines?
  — What percentage of prescribed medicines belong to the hospital formulary?
• Has the HMTC been active in the development and implementation of STGs?
  — Has the hospital developed/adopted its own STGs?
  — Have medicine utilization studies been performed to assess adherence to STGs?
• Has the HMTC organized educational activities about medicines?
  — Have there been any organized training and lectures for health-care staff?
  — Is there an established library accessible to staff?
  — Is there continuing medical education?
11. SOURCES OF SUPPORT FOR HMTCs

The Department of Pharmacy Services in the Ministry of Health has overall responsibility in the implementation and evaluation of national medicine policy. As such, the Department together with the NMTPAC will assist hospitals to organise HMTCs. Support is available in the form of expert advice, reference materials and identifying other sources of support.

Every year, the UZ Pharmacy School supervises research projects for final year students. Hospitals should interest final year students with such useful projects as ABC and therapeutic category analyses, in and Outpatient prescribing surveys or interrupted time series analyses of the level and pattern of consumption of particular medicines of interest. The department also runs a Drug and Toxicology Information Service (DaTIS) which provides medicine and poisons information to health professionals. They have a pharmacist or pharmacologist on duty (or on call during silent hours) to attend to any queries about medicines or poisons. Queries can be submitted through post, telephone, fax or e-mail.

The Blair Research Laboratory can assist with proposal development as well as designing and implementing health systems research while WHO Africa Region and Geneva can assist with funding in addition to standard manuals on medicine utilisation studies and an assortment of relevant literature.
ANNEX 1: MODEL TERMS OF REFERENCE FOR HMTCS IN ZIMBABWE

Model Terms of Reference for HMTCs in Zimbabwe

Name
Hospital Medicine and Therapeutics Committee of ..........................................................
............................................................................................................Hospital.

Status
The HMTC is a standing hospital committee responsible, through its chairman, to the hospital executive.

Chairman
The hospital executive shall appoint the Medical Superintendent or a senior doctor to chair the committee.

Secretary
The committee secretary is usually the pharmacist. In hospitals without a pharmacist, the hospital executive can appoint the pharmacy technician or any other member of the committee to be secretary.

Members
The hospital executive appoints the other committee members on a representational basis and also to take advantage of the available human resources in the hospital and community.

Goals
The overall goal of the HMTC is to ensure that patients are provided with the best possible cost-effective and quality of care through determining what medicines will be available, at what cost, and how they will be used.

- Improved health and economic outcomes of hospital care particularly those related to medicine use.
- Rational and cost-effective medicine use through collaborative medicine management involving all health workers.

Objectives
The committee will be responsible for defining its own specific objectives on an annual basis. Each committee can do that by reviewing the following objectives and choosing what they want to work on.

- To formulate and implement policies for selection and use of medicines.
- To develop and manage a hospital essential medicines list.
- To develop and implement consistent standard treatment guidelines.
- To carry out medicine utilization reviews in the hospital.
- To provide prescribers with objective medicine information.
- To monitor and analyze expenditure on medicines.
- To carry out educational and other activities aimed at improving medicine use by prescribers, dispensers and patients in the hospital.
- To monitor and report adverse medicine reactions to the Medicines Control Authority of Zimbabwe (MCAZ).
- To monitor medication errors and act to prevent their recurrence.
- To regulate operations of the pharmaceutical industry in the hospital.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Central Hospitals</th>
<th>Provincial Hospitals</th>
<th>Mission hospitals</th>
<th>Private hospital</th>
<th>Av. Value</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Harare</td>
<td>Mpilo</td>
<td>Bindura</td>
<td>Gweru</td>
<td>Mutare</td>
<td>St Albert's</td>
<td>Bonda</td>
</tr>
<tr>
<td>N</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Av. # Days</td>
<td>5.87</td>
<td>8.71</td>
<td>3.8</td>
<td>5.6</td>
<td>9.4</td>
<td>7.32</td>
<td>6.3</td>
</tr>
<tr>
<td>Av. # Medicines</td>
<td>3.25</td>
<td>2.71</td>
<td>3.46</td>
<td>3.6</td>
<td>1.5</td>
<td>4.12</td>
<td>2.3</td>
</tr>
<tr>
<td>Medicines/IP Day</td>
<td>0.55</td>
<td>0.31</td>
<td>0.91</td>
<td>0.64</td>
<td>0.16</td>
<td>0.56</td>
<td>0.37</td>
</tr>
<tr>
<td>Av. # Generics</td>
<td>2.67</td>
<td>2.56</td>
<td>2.75</td>
<td>2.71</td>
<td>1.2</td>
<td>3.61</td>
<td>1.4</td>
</tr>
<tr>
<td>Generics/IP Day</td>
<td>0.45</td>
<td>0.29</td>
<td>0.72</td>
<td>0.48</td>
<td>0.13</td>
<td>0.49</td>
<td>0.22</td>
</tr>
<tr>
<td>Av. % Generics</td>
<td>82</td>
<td>94</td>
<td>79</td>
<td>75</td>
<td>80</td>
<td>88</td>
<td>61</td>
</tr>
<tr>
<td>Av. # Antibiotics</td>
<td>1.63</td>
<td>1.44</td>
<td>1.12</td>
<td>0.96</td>
<td>0.63</td>
<td>0.94</td>
<td>0.6</td>
</tr>
<tr>
<td>Antibiotics/IP Day</td>
<td>0.28</td>
<td>0.17</td>
<td>0.29</td>
<td>0.17</td>
<td>0.07</td>
<td>0.13</td>
<td>0.10</td>
</tr>
<tr>
<td>Av. % Antibiotics</td>
<td>50</td>
<td>53</td>
<td>32</td>
<td>27</td>
<td>42</td>
<td>23</td>
<td>26</td>
</tr>
<tr>
<td>Av. # Injections</td>
<td>1.21</td>
<td>0.74</td>
<td>1.28</td>
<td>0.73</td>
<td>0.2</td>
<td>0.56</td>
<td>0.5</td>
</tr>
<tr>
<td>Injections/IP Day</td>
<td>0.21</td>
<td>0.08</td>
<td>0.34</td>
<td>0.13</td>
<td>0.02</td>
<td>0.08</td>
<td>0.08</td>
</tr>
<tr>
<td>Av. % Injections</td>
<td>37</td>
<td>27</td>
<td>37</td>
<td>20</td>
<td>13</td>
<td>14</td>
<td>22</td>
</tr>
<tr>
<td>Av. Medicine Cost ($)</td>
<td>462.39</td>
<td>107.44</td>
<td>54.22</td>
<td>149.85</td>
<td>587.00</td>
<td></td>
<td>587.0</td>
</tr>
<tr>
<td>Cost/IP Day ($)</td>
<td>78.77</td>
<td>12.34</td>
<td>14.27</td>
<td>26.76</td>
<td>94.22</td>
<td>33.03</td>
<td>94.2</td>
</tr>
</tbody>
</table>

### Notes

1. Wankie Hospital (now called Hwange Colliery Hospital) used private sector medicine prices. All other facilities used Government Medical Stores prices. Averages exclude Hwange costs.

2. At Bonda, abbreviations were not considered generic while at other hospitals they were.

3. Harare Central Hospital used medicine prices from Parirenyatwa Group of Hospitals which are close to private sector prices. Harare Hospital costs are therefore more comparable to Wankie Hospital that to other hospitals.
ANNEX 3: EXAMPLE OF A DECLARATION OF INTEREST FORM

DECLARATION OF INTEREST FORM

Name ………………………………………………………………… Position …………………………………………………

Have you, or anyone in your family, any financial or other interest in any pharmaceutical manufacturer or supplier, and which may constitute a real, potential or apparent conflict of interest?
Please tick: ☐ Yes ☐ No

Have you had, during the past 4 years, any employment or other professional relationship with any organization that is a pharmaceutical manufacturer or supplier or represents such organizations?
Please tick: ☐ Yes ☐ No

If you answered ‘yes’ to either question, please give details in the box below.

<table>
<thead>
<tr>
<th>Type of interest, for example patents, shares, employment association, payment*</th>
<th>Name of commercial entity</th>
<th>Belongs to you your family or work unit?</th>
<th>Current interest? or year that interest ceased</th>
</tr>
</thead>
</table>

* Amounts do not have to be declared

Is there anything else that could affect, or be perceived to affect, your objectivity or independence in carrying out your duties in the HMTC?

I hereby declare that the disclosed information is correct and that no other situation of real, potential, or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances.

Signature …………………………… Date ……………………………

Types of financial or other interests

• Any payment for performance of work or research or educational grants during the past four years by any commercial entity that has an interest in the HMTC’s work.
• Current proprietary interest in a substance, technology or process (for example ownership of a patent), being considered by the HMTC or otherwise related to the HMTC’s work.
• Current financial interest (for example shares, bonds) in a commercial entity with an interest in the HMTC’s meetings or work. Share holdings through general mutual funds etc., where the person has no control over the selection of shares, are exempt.
• Any employment, consultancy, directorship, or other position during the past 4 years or presently under negotiation, whether paid or not, in any commercial entity (for example a pharmaceutical company) that has an interest in the HMTC’s work.
Annex 4: Application for Addition to Hospital Essential Medicines List

Application for Addition to Hospital Essential Medicines List
(To be filled in by applicant)

<table>
<thead>
<tr>
<th>Generic name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name and supplier</td>
<td></td>
</tr>
<tr>
<td>Unit cost</td>
<td></td>
</tr>
<tr>
<td>Is this medicine on EDLIZ</td>
<td></td>
</tr>
<tr>
<td>Therapeutic class</td>
<td></td>
</tr>
<tr>
<td>Proposed indications for use</td>
<td></td>
</tr>
<tr>
<td>Principal mode(s) of action</td>
<td></td>
</tr>
<tr>
<td>Major adverse effects &amp; medicine interactions</td>
<td></td>
</tr>
<tr>
<td>Precautions and contraindications</td>
<td></td>
</tr>
<tr>
<td>Prescribing restrictions e.g. “specialist only”</td>
<td></td>
</tr>
<tr>
<td>Please attach prescribing guidelines</td>
<td></td>
</tr>
<tr>
<td>Estimated number of patients/year</td>
<td></td>
</tr>
<tr>
<td>Average dose &amp; frequency</td>
<td></td>
</tr>
<tr>
<td>Average duration of therapy</td>
<td></td>
</tr>
<tr>
<td>List medicines already approved for same indication</td>
<td></td>
</tr>
<tr>
<td>List medicine(s) to be replaced by requested medicine</td>
<td></td>
</tr>
<tr>
<td>Estimated annual expenditure on medicine</td>
<td></td>
</tr>
<tr>
<td>Advantages over listed alternative(s). Please attach references.</td>
<td></td>
</tr>
</tbody>
</table>
### Report of a Suspected Adverse Drug Reaction

**Patient Details (to allow linkage with other reports)**

<table>
<thead>
<tr>
<th>Family Name:</th>
<th>OR Patient Clinic/Hospital Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forename(s):</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth:</th>
<th>Weight</th>
<th>Sex:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M/F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age:</th>
<th>kg</th>
</tr>
</thead>
</table>

**Adverse Reaction**

<table>
<thead>
<tr>
<th>Date of onset:</th>
<th>Duration:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Less than one hour</td>
</tr>
<tr>
<td></td>
<td>Days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Description:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Outcome:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovered</td>
</tr>
<tr>
<td>Not yet recovered</td>
</tr>
</tbody>
</table>

**Suspected Medicine(s)**

<table>
<thead>
<tr>
<th>Medicine:</th>
<th>Generic Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Brand Name:</td>
</tr>
</tbody>
</table>

**Indication medicine was given for:**

**Daily dose/route:**

<table>
<thead>
<tr>
<th>Date begun:</th>
<th>Date stopped:</th>
</tr>
</thead>
</table>

**Concomitant (Other) medicines taken & Dates/period taken:**

<table>
<thead>
<tr>
<th>Name of medicine:</th>
<th>Date started:</th>
<th>Date stopped:</th>
</tr>
</thead>
</table>

**Laboratory test results**

**Reported by**

<table>
<thead>
<tr>
<th>Family Name:</th>
<th>Forename(s):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Status:</th>
<th>Doctor</th>
<th>Pharmacist/Pharmacy Technician</th>
<th>Nurse</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Address:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
</table>

**Send to:**
The Director-General Medicines Control Authority in Zimbabwe 106 Baines Avenue, P O Box 10599, Harare
Fax:+263-4-736980, email:mcaz@mcaz.co.zw, website:www.mcaz.co.zw
### Annex 5: PRODUCT DEFECT Forms

**Medicines Control Authority of Zimbabwe**

**PVF 05**

**REPORT ON MEDICINAL (PHARMACEUTICAL) PRODUCT DEFECT OR PROBLEM**

To be completed by Pharmacists, Pharmacy Technicians, Medical Practitioners, Nurses, Veterinary Surgeons and other Distributors of Medicines.

<table>
<thead>
<tr>
<th>1. Product Name (Brand and Generic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Description of the Device</td>
</tr>
<tr>
<td>3. Intended Use</td>
</tr>
<tr>
<td>4. Size/Type of Container</td>
</tr>
<tr>
<td>5. Registration No.</td>
</tr>
<tr>
<td>6. Batch Number</td>
</tr>
<tr>
<td>7. Expiry Date</td>
</tr>
<tr>
<td>8. Name and Address of Manufacturer</td>
</tr>
<tr>
<td>9. Name and Title of Reporter</td>
</tr>
<tr>
<td>10. Your Practice Location and Address of Hospital, Clinic, Retail Store etc.</td>
</tr>
<tr>
<td>11. Phone Number</td>
</tr>
<tr>
<td>12. Date Problem Occurred or Observed</td>
</tr>
<tr>
<td>13. If requested will the actual product involved be available for examination by MCAZ?</td>
</tr>
<tr>
<td><strong>YES</strong></td>
</tr>
<tr>
<td><strong>NO</strong></td>
</tr>
<tr>
<td>14. Signature of Reporter</td>
</tr>
<tr>
<td>15. Date</td>
</tr>
<tr>
<td>16. Defects/Problem Noted or Suspected (see +j below)</td>
</tr>
</tbody>
</table>

### NATURE OF DEFECT OR PROBLEM

- a) Presence of foreign material
- b) Unusual odor
- c) Colour changes
- d) Fungal growth
- e) Suspected contamination
- i) Presence of moulds, fungi, bacterial, discoloration etc.
- g) Wrong label, wrong packaging, wrong strength
- h) Lack of therapeutic response
- i) Unsuitable dose
- j) Other (specify)

**Return To:**
The Director-General
Medicines Control Authority of Zimbabwe
100 Baines Avenue
P O Box 10139
Harare
Fax: 784981 Tel: 784981 Ext. 5
E-mail: mcaz@medicinesline.co.zw

Rev 0, November 2009

Page 1 of 1
LIST OF REFERENCES


Royal North Shore Hospital Drug Committee. Policy and procedures, 1995. Sydney Australia


Westmead Hospital Drug Committee Terms of Reference and Policy Statement. 1996. Australia