Training manual for pharmacists and lab technicians on NCD management

Access to Medicines Project, Institute of Public Health, Bangalore

In partnership with
Tumkur district health and family welfare unit and
District NCD cell, Tumkur
Acknowledgements

This manual is part of the intervention of a research project titled “Improving equitable access to quality generic medicines for patients with NCD in Tumkur, India.” The authors are most grateful to the district health and family welfare officer, Tumkur for his continuous support and guidance throughout the development of this manual. We thank the district NCD officer for contributing to the development of this manual and enriching its content with his inputs.

Citation: Manoj K Pati, Bhanuprakash, Praveen Aivalli, Maya Annie Elias, Mune Gowda, and NS Prashanth. Training manual for pharmacists and lab technicians on NCD management, Access to Medicine study, Institute of Public Health, May 2014.


All reasonable precautions have been taken by the Institute of Public Health, Bangalore and the ATM team to verify the information contained in this manual. However, this material which is used in the training stands without warranty of any kind either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the Institute of Public Health, Bangalore or its partners be liable for damages arising from its use.
**Contents**

**Message** ........................................................................................................................................... 5

**Preface** ............................................................................................................................................. 8

*Objective of the training* ......................................................................................................................... 8

**Chapter 1: Introduction** ..................................................................................................................... 10

**Box 3: Key messages** ........................................................................................................................ 10

1.1 : Introduction ................................................................................................................................... 10
1.2 : Diabetes and Hypertension ............................................................................................................ 11
1.2.1 : Definitions ................................................................................................................................. 11
1.2.2 : Magnitude of the problem ......................................................................................................... 13
1.3 Risk factors for hypertension and diabetes. .................................................................................... 16
1.4 : ATM Project ..................................................................................................................................... 16

**Chapter 2: National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke** ........................................................................................................ 18

2.1 Objectives of NPCDCS ...................................................................................................................... 19
2.2 Strategies ........................................................................................................................................... 19

**Chapter 3: Role and responsibilities of pharmacists in diabetes and hypertension management at PHC** ........................................................................................................................................ 22

3.1 Role and responsibilities of pharmacists at PHC .......................................................................... 22
3.2 How to use Essential Medicines List (EML) ..................................................................................... 23
3.3 Role of Pharmacists and lab technicians in diabetes and hypertension treatment .............. 24
3.4 Counseling for people who have Hypertension and Diabetes ...................................................... 24

**Chapter 4 : Good pharmaceutical practices and lab maintenance** .................................................. 25

4.1 Drug procurement and Storage ........................................................................................................ 25
4.1.1 Introduction .................................................................................................................................... 25
4.1.2 Strategic objectives of a good pharmaceutical procurement ...................................................... 27
4.1.3 Principles of procurement ............................................................................................................ 27
4.1.4 Tender processing : Example from Tamil Nadu Medical Services Corporation(TNMSC) model ............................... 30
4.1.5 Self life and stability of drugs ....................................................................................................... 32
4.2 Medicines Good storage practices .................................................................................................. 32
4.2.1 Storage areas ................................................................................................................................. 33
4.2.2 Storage conditions and stock control .......................................................................................... 34
4.3 Efficient management of drugs : ..................................................................................................... 35
4.4 Ensuring drug availability ................................................................. 36
4.4.1 Material management ................................................................. 36
4.4.2 Analysis and control of pharmaceutical cost ................................. 39
4.5 Lab Readiness ............................................................................. 43
4.6 Good drug dispensing practice ....................................................... 43
4.7 Some useful information for lab technicians on diagnosis and measurement of hypertension ................................. 44
4.8 Some useful information for lab technicians on diagnosis and measurement of diabetes ........................................... 45

Chapter 5: Rational use of medicines .................................................. 47
5.1 Introduction ................................................................................. 47
5.2 Generic medicine ......................................................................... 47
5.3 Rational use of medication ............................................................. 48
5.4 Consequences of irrational medicine use ...................................... 48
5.5 How to promote rational use of medicines ..................................... 49

References .......................................................... ............................... 50

Suggested Reading .......................................................... .......................... 52
Messages

The Institute of Public Health has embarked on a very important task. Diabetes and hypertension are increasingly affecting rural and urban populations alike and are seen as one of the major disease transitions of our century. However, primary health care and community health services have traditionally been designed for the needs of mothers and children: they have achieved a great deal in decreasing maternal and child mortality and providing appropriate pre- and post-natal as well as child care. Given this huge mission, it is only normal that medical officers and health practitioners operating at PHCs and CHCs are not always equipped to deal with chronic conditions such as diabetes and hypertension. The training program developed by IHP will hopefully contribute to bridge this gap and this training manual will provide the necessary tools to face this new challenge.

Indeed, managing diabetes and hypertension requires a combination of skills, associating prevention and counselling with adequate diagnosis capacity and medical treatment. Moreover, utilization of health services by patients with chronic diseases should not be seen as a succession of isolated events independent one from another: the continuum of care is important and should seek to engage the patient as an actor of its own health and well-being. The Alliance for Health Policy and Systems Research is very proud to support this research program on access to medicines for diabetes and hypertension in Tumkur, and we are delighted to see that beyond the objectives of health systems research, this programme will also contribute to training medical officers on management of these diseases at community level.

-Message from Maryam Bigdeli

WHO Alliance for Health Policy and Systems Research
In developing counties like India till now preference was given for controlling communicable diseases, with discovery and availability of effective quality medicines and health system strengthening have played effective role in controlling the communicable disease burden. With that we have succeeded in controlling the communicable diseases. In contrast to that non communicable diseases burden and its complications are constantly increasing, change in society, industrialization, urbanization, environmental pollution, population explosion, physical, and mental stress along with that life style modification, increased bad habits, unlimited unhealthy food, physical inactivity and sedentary life styles have resulted in increasing the burden of non communicable diseases. Horrifying fact about NCDs is that all these NCDs are long standing diseases which require continuous treatment and are costly to afford, mortality and morbidity are increasing due to failure in treatment. NCDs like cancer, diabetes, cardiac disease, hypertension, stroke, respiratory problems, physiological conditions, accidents and their adverse effects statistics are as follows.

- More than half of deaths (30 to 59 years) are due to NCDs.
- Cardio vascular diseases contribute to high mortality and morbidity by 2020.
- There are 25 lack existing cancer patients, 5 lack new patients every year.
- 40 million diabetics at present the number is likely to increase 70 million by 2025
- Indians die five to ten years earlier because of diabetes, hypertension and CVDs when compared to western people.

Though the statistics are very dangerous, luckiest thing is that the solutions and easy ways are in our hand itself. Knowledge, awareness adoption of minimum discipline, keeping away from bad habits, life style modifications and reclamation can control lion’s share of problems, which is the happiest thing to know.

Based on all these facts, to control NCDs central government in association with state government has come up with ambitious programme called NPCDCS, the programme is about motivating the above said factors at community level and to find out the symptoms and the disease at primary health care level. In such a programme activities of nongovernmental organization and health organisations hand holding for the success of the programme is welcoming fact, it’s also shows the burden of the disease in the society. If it reaches all layers of the community person become physically mentally socially economically strong and become invaluable property of the country. It is our wish with all your cooperation let this goal to be achieved.

Dr.T.N.Purushottam

District NCD officer, Tumkur
I am happy to note that the Institute of Public Health is bringing out a training manual on management of diabetes mellitus and hypertension for pharmacists and lab technicians. This is a very important need for our government health system as these patients usually seek care at government PHCs and CHCs. Such a training programme will ensure that these patients receive rational therapy.

However, along with rational therapy, the medical officers also need to ensure that the required medicines are available in their facilities. There are enough studies which clearly show that most patients with diabetes or hypertension cannot afford to purchase the medicines regularly from private pharmacies. So they default in the treatment, thereby increasing their chances of suffering from unnecessary morbidity and mortality. To prevent this, the government and especially the medical officers need to ensure that adequate medicines are available in the PHCs and CHCs. Today, with NRHM, this is not difficult as all one has to do is include the costs of the extra medicines into the annual PIP.

Other than ensuring the availability of medicines and rational therapy, one must also remember to create awareness among the patients and the community about these two diseases. While traditional methods of IEC such as wall paintings and posters maybe effective, it is seen that individual face to face counselling is an effective form of creating awareness among the patients. So it is important that medical officers not just prescribe medicines, but also spend some time with these patients and talk to them about their illness. While this may be difficult in a busy outpatient clinic, one can use existing resources, e.g. the counsellor from the ICTC centre, or a nurse or pharmacist who is a good communicator. The important point is that one should give the patient enough time to understand the enormity of the disease and the lifestyle changes that she/he has to make to manage the disease.

Today, PHCs are seen as MCH centres, meant only for the women and children. Successful treatment of NCDs will help in reviving the image of the PHC as a centre that provides good primary health care and will increase the credibility of the facility and the staff that work in this facility.

Let us join hands to manage this important problem that faces our community.

Yours sincerely,

Dr. N. Devadasan MBBS, MPH, PhD
Director,
Institute of Public Health,
Bangalore
Preface

This training manual will serve as a basic tool for building capacity of pharmacists and lab technicians on NCD management at primary health care level. This manual consists of information on the burden of non-communicable diseases (mainly diabetes and hypertension), the risk factors, diagnosis and the role of pharmacists and lab technicians in NCD management. The manual also contain general information on salient features of efficient drug management, use of essential drug list, drug procurement and storage and good drug dispensing practices.

This manual is a part of a set of three manuals prepared under the Access to Medicines project supported by WHO Alliance for Health Policy and Systems Research (WHO-Alliance). The manual is produced by Institute of Public Health, Bangalore (IPH) in partnership with the Karnataka Health Systems Resource Centre, Bangalore (KSHSRC) and the Tumkur district health and family welfare unit. The newly launched district NCD cell under the National Programme for prevention and control of cancer, diabetes and cardiovascular diseases and Stroke (NPCDCS) provided guidance in the preparation of the document.

The document is expected to accompany a package of community-level and health services level interventions under the WHO-Alliance Access to Medicines Project (ATM project; see later in the manual for details of ATM project). Under this project, a health systems research study is being implemented in Tumkur district in order to improve equitable access to quality generic medicines for people with non-communicable diseases in three talukas of Tumkur district.

Objective of the training

The main objectives of this training programme are as follows:

1. Sensitise the pharmacists and PHC staff about the rising burden of NCDs and the state-of-the-art in public health literature on the response to this rising NCD burden
2. Provide an overview of diagnosis and drug management for Diabetes and Hypertension at primary health care drawing from different models of drug management.
3. Discuss the implementation of various interventions to improve care for patients with NCDs at government PHCs
4. Coordinate with medical officers at their PHC and other health workers (staff nurse, ANMs and AHSAs) for providing counseling, follow-up and patient-centered care for NCDs at government PHCs.
5. To improve drug indenting and procurement practices for improving availability of drugs for NCDs at PHC.
6. To train pharmacists on good dispensing practices.
7. To train lab technicians on laboratory readiness practices for diabetes and hypertension.

In the training programme, some of the following topics will be discussed in detail.

1) Prevention and control of NCDs
2) Early Detection of NCDs
3) Capacity Building of health systems to tackle NCDs.
4) Good drug procurement, distribution and dispensing practices at primary care level.
5) Dedicating one day per month for managing patients with NCD (NCD clinics) and
using patient-held medical records for improving continuity of care for NCDs
6) Importance of counselling about lifestyle changes during drug dispensing.
7) Use of Standard Treatment Guideline (STG) and Essential Drug List (EDL) to ensure rational therapy.

The ATM project is receiving a lot of support from the district health team and the state health department. We sincerely thank them for their support and encouragement. We look forward to working with the health managers, doctors, health workers and the people of Tumkur in finding creative solutions to counter the rising burden of NCDs.

Access to medicines team
Institute of Public Health, Bangalore
Chapter 1: Introduction

Box 3: Key messages

- NCDs have a serious negative impact on human development in social and economic realms; NCDs will lead to poverty by reducing productivity.
- NCDs impede the progress towards the MDGs. Creates a significant burden on health and government and growing economic on the country economics.
- Worldwide 382 million people have diabetes in 2013; by 2035 this will rise to 592 million.
- The number of people with type 2 diabetes is increasing in every country.
- 80% of people with diabetes live in low- and middle-income countries.
- The greatest number of people with diabetes is between 40 and 59 years of age.
- Healthy diet, regular physical activity, maintaining a normal body weight and avoiding tobacco use can prevent or delay the onset of type 2 diabetes.


1.1: Introduction

Non-communicable diseases (NCDs) are chronic diseases, which include cardiovascular diseases, diabetes, stroke, most forms of cancers and injuries. Such diseases mainly result from lifestyle related factors such as unhealthy diet, lack of physical activity and tobacco use. Globally, the increase in NCDs has been attributed to increase in average lifespan, coupled with lifestyle changes as result of urbanization and socio-cultural changes.

Non-communicable diseases (NCDs) now account for the lion’s share of global morbidity and mortality. Much of the burden is falling on developing countries, whose relatively recent adoption of new health behaviors and lifestyle choices has led to increased prevalence of risk factors for NCDs. At the same time, developing countries also hold the greatest burden of infectious disease, and the rapid increase of NCDs has left countries with under-resourced health care systems to deal with a double burden. NCDs account for half of all the deaths in the age group 30-59 years in India. Of these, nearly one-third are due to cardiovascular diseases. It was estimated that, by 2020, cardiovascular diseases (like hypertension) would be the largest cause of disability and death, as a proportion of all deaths in India. Also, Indians succumb to diabetes, hypertension and heart attacks nearly 5-10 years earlier than their western counterparts and in their most productive years. This leads to considerable loss of productive person years in India.
The good news is that making simple changes in lifestyle could prevent these diseases. There are several national and international guidelines on NCD management; not all of them can be automatically applied in low-resource or primary health care settings. The WHO global status report on non-communicable diseases 2010 highlights the need for countries to integrate NCD prevention and management into primary health care even in low resource settings.

The focus of the ongoing Access to Medicine (ATM) project by Institute of Public Health, Bangalore, (See later section 1.5) is to reorient existing knowledge so that one can effectively implement the programme of NCD prevention and control at the PHC level in Karnataka. Under this project, we have identified and developed essential package of cost-effective interventions in order to manage the needs of most of the diabetes and hypertension patients at the level of primary health care. This is crucial as the health expenditure on the poor would be the least if good quality medicines and treatment could be provided to them at the nearest government primary health centre.

1.2 : Diabetes and Hypertension

1.2.1 : Definitions

*What is Diabetes Mellitus?*

Diabetes Mellitus is a disease in which a person has high blood sugar, either because the body does not produce enough hormones called insulin, or because cells do not respond to the insulin that is produced. The symptoms of high blood sugar levels are frequent urination, increased thirst, and increased hunger. This is a disease that slowly develops and stays there for life long. Diabetes without any control for it’s risk factors and management may lead to serious complications. Commonly the disease is associated with sedentary life style although at times it affects individuals through hereditary route.

There are three main type of diabetes.³

1. **Type 1 diabetes** used to be called juvenile-onset diabetes. It is usually caused by an auto-immune reaction where the body’s defence system attacks the cells that produce insulin. The reason this occurs is not fully understood. People with type 1 diabetes produce very little or no insulin. The disease may affect people of any age, but usually develops in children or young adults. People with this form of diabetes need injections of insulin every day in order to control the levels of glucose in their blood. If people with type 1 diabetes do not have access to insulin, they will die.

2. **Type 2 diabetes** used to be called non-insulin dependent diabetes or adult-onset diabetes, and accounts for at least 90% of all cases of diabetes. It is characterised by insulin resistance and relative insulin deficiency, either or both of which may be present at the time diabetes is diagnosed. The diagnosis of type 2 diabetes can occur at any age. Type 2 diabetes may remain undetected for many years and the diagnosis is often made when a complication appears or a routine blood or urine glucose test is done. It is often, but not always, associated with overweight or obesity, which itself can cause insulin resistance and lead to high blood glucose levels. People with type 2 diabetes can often initially manage their condition through

³ International Diabetes Federation. Available at : http://www.idf.org/types-diabetes
exercise and diet. However, over time most people will require oral drugs and or insulin.

Both type 1 and type 2 diabetes are serious. There is no such thing as mild diabetes.

3. **Gestational diabetes (GDM)** is a form of diabetes consisting of high blood glucose levels during pregnancy. It develops in one in 25 pregnancies worldwide and is associated with complications to both mother and baby. GDM usually disappears after pregnancy but women with GDM and their children are at an increased risk of developing type 2 diabetes later in life. Approximately half of women with a history of GDM go on to develop type 2 diabetes within five to ten years after delivery.

Other specific types of diabetes also exist.

**What is Hypertension?**

**High Blood Pressure (HBP)** or hypertension is a disease condition in which a person has persistent abnormal elevation of the pressure within the arteries which deliver blood to the entire body. This requires the heart to work harder than normal to circulate blood through the blood vessels which increase load on heart.

Hypertension is often called “The silent killer” because most people do not even realise that they have hypertension. A person with high blood pressure may usually have no symptoms of the condition at all, so regular check-ups are most important. Hypertension is rarely accompanied by any symptoms, and its identification is usually through screening, or when seeking healthcare for an unrelated problem. Some people with high blood pressure report sweating, headache, as well as light headedness. These symptoms however are more likely to be related to anxiety than the high blood pressure itself. Hypertension in adults (>18 yrs) is defined as systolic blood pressure (SBP) of 140 mm of Hg or greater and/or diastolic blood pressure (DBP) of 90 mm of Hg or greater, based on the average of two or more properly measured, seated BP readings on each of two or more visits. Based on the etiology it is classified into following types.

**Types**

1. **Primary/essential**: Primary or "essential" hypertension has no known cause, however many of the above said lifestyle factors are associated with this condition. This constitutes majority of the high blood pressure in the world today. (90-95%)

2. **Secondary**: Secondary hypertension is caused by some other medical conditions/problem or the use of certain medications. Secondary hypertension is seen only in very few individuals in the community. The causes of secondary hypertension include: kidney diseases: reno-vascular disease and chronic renal disease, endocrine disorders: hyperthyroidism, cushing’s syndrome and pheochromocytoma, sleep disorders, coarctation of the aorta and non specificaorto-arteritis. Some of these causes are often curable, and many others treatable.

3. **Isolated systolic hypertension** : A systolic pressure > 160 mm of Hg with diastolic pressure <90 mm of Hg . Most commonly found in elderly individuals due to vascular compliance.
Table 1: Classification of blood pressure for adults. <sup>b</sup>

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>Systolic blood pressure (mm of Hg)</th>
<th>Diastolic blood pressure (mm of Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120 and</td>
<td>&lt;80</td>
</tr>
<tr>
<td>High-borderline</td>
<td>120-139 or</td>
<td>80-89</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>140-159 or</td>
<td>90-99</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>&gt;160 or</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>

1.2.2: Magnitude of the problem

a. World statistics.

Table 2: Top five countries for number of people with diabetes (20-79 years), 2013

<table>
<thead>
<tr>
<th>S No.</th>
<th>Countries/territories</th>
<th>Millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>India</td>
<td>65.1</td>
</tr>
<tr>
<td>2</td>
<td>Bangladesh</td>
<td>5.1</td>
</tr>
<tr>
<td>3</td>
<td>Sri Lanka</td>
<td>1.1</td>
</tr>
<tr>
<td>4</td>
<td>Nepal</td>
<td>0.7</td>
</tr>
<tr>
<td>5</td>
<td>Mauritius</td>
<td>0.1</td>
</tr>
</tbody>
</table>

(Source: Regional fact sheet, SEAR, IDF diabetes atlas, sixth edition, 2013)

b. Figure 1-SEAR- Deaths by diabetes in South East Asia Region, 2013.

(Source: Regional fact sheet, SEAR, IDF diabetes atlas, sixth edition, 2013)

b. India

Table 3: Country statistics-India.

<table>
<thead>
<tr>
<th>Country Name</th>
<th>Region</th>
<th>Total NCD deaths('000s)</th>
<th>NCD deaths under age 70 (percent of all NCD deaths)</th>
<th>Age-standardized death</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Males</td>
<td>Females</td>
<td>Males</td>
</tr>
<tr>
<td>India</td>
<td>SEAR</td>
<td>2967.6</td>
<td>2273.8</td>
<td>61.8</td>
</tr>
</tbody>
</table>


<sup>b</sup> Standard treatment guidelines of select conditions, hypertension, Armed Forces Medical College in collaboration with MOHFW, Govt of India and WHO, India. Available at: http://nrhm.gov.in/nhm/nrhm/guidelines/nrhm-guidelines/standard-treatment-guidelines.html.
Figure 2: Proportion of global NCD deaths under the age of 70, by cause of death, 2008.


**India**

During the year 2005, NCD accounted for 53% of all the deaths in the age group 30-59 years in India. Of these, 29% were due to cardiovascular diseases; It is estimated that, by 2020, cardiovascular disease will be the largest cause of disability and death, as a proportion of all deaths in India. In 2003 alone, in India, there were approximately 30 million people suffering from coronary heart disease. Diabetes which is a major risk factor for chronic disease on its own causes increased death and disability. According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India is currently around 40.9 million and is expected to rise to 69.9 million by 2025, unless urgent preventive steps are taken. Similarly, 118 million people were estimated to have high blood pressure in the year 2000 which is expected to go up to 213 million in 2025.

Around 118 million people were estimated to have hypertension currently in India, which is expected to go up to 213 million in 2025. Not only this, Indians succumb to diabetes, hypertension and heart attacks 5-10 years earlier than their western counterparts and in their most productive years. This leads to considerable loss of productive man years in India. It has been estimated that, by the year 2030, India will lose approximately 17.9 million potentially productive years which is higher than the expected combined loss in China, Russia, USA, Portugal and Brazil. Another estimate is that the economic loss will be as high as 237 billion dollars by the year 2015.

Development of diabetes and heart attacks at an early age is not largely because of environmental causes but majorly due to low consumption of fresh fruits and vegetables.
along with other unhealthy diet, increasing use of tobacco, and higher prevalence of sedentary life-style.

The prevalence of hypertension ranges from 10% to 43% in different sub regions and age groups in Karnataka. Study done in coastal Karnataka in 2006-07 showed that the, prevalence of hypertension among the people aged 30 years was 43.3% and out of them, only half knew that they were hypertensive and 20.2% were newly detected during the study13. A study done among the information technology professionals in Bengaluru found that the prevalence of hypertension among them was 31%, in predominately young population14. A community based study in 2010 for assessing the prevalence of hypertension in rural areas found the prevalence of hypertension to be 19.1%15. The prevalence of type 2 diabetes ranges from 3.77% to 16%. One study in 2005 done in rural population aged above 25 years in Karnataka found that the prevalence of diabetes was 3.77%16.

To prevent and contain the projected increase in the burden of non-communicable diseases, Ministry of Health and Family Welfare, Government of India, has launched the (Refer: Section II) National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) on 4th January 2008 on a pilot basis. Now it is being expanded as it has moved from pilot phase. Government of Karnataka has introduced NPCDCS in five districts as pilot study.¹⁶⁶

study title: Improving equitable access to quality generic medicines for patients with NCD in Tumkur, India.

1.3 Risk factors for hypertension and diabetes.

Table 4: Risk Factors

<table>
<thead>
<tr>
<th>Behavioral Risk Factors</th>
<th>Physiological Risk Factors</th>
<th>Iatrogenic Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dis-continue intake of diabetes and hypertension drugs</td>
<td>High intake of sodium (salt)</td>
<td>High intake of insulin</td>
</tr>
<tr>
<td>Harmful consumption of alcohol</td>
<td>Low intake of calcium, potassium</td>
<td></td>
</tr>
<tr>
<td>Tobacco smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inactivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The healthy diet</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.4: ATM Project

ATM is a health systems research study which aims to understand the health system factors that are necessary to enable access to good quality generic drugs for rural NCD patients in Tumkur, India.
The study includes seven phases covering the 36 months duration. Major activities involve a baseline survey intervention at community level and finally an end line survey. The study includes only research on diabetes and hypertension as a medium to study NCDs. The baseline survey includes a community assessment of household utilisation of medicines for treatment of NCDs, source of medicines for treatment of NCDs, expenditure on treatment for NCD patients etc. It also includes survey at PHCs and private pharmacies on their prescribing behaviour at facility, average consultation time per NCD patient at PHC, patient satisfaction with respect to consultation time, stock-out of essential drugs for NCD treatment at facility, average rate of NCD patients by facility (proportion of patients with NCD obtaining treatment at government facility), regularity of follow-up visits etc.

The intervention will be carried out in two settings. That is one will focus on strengthening community participation arrangements for NCD care which include formation of PHC level NCD patient groups, generating awareness on NCD care in community and patient groups through multiple awareness building channels and finally facilitating message of importance of NCD care in VHSC and PHC level ARS meetings. The second type of intervention is strengthening health service delivery for NCD care which include capacity building of medical officers, pharmacists and ANMs at PHC level on managing and indenting drugs at the PHC pharmacy, instituting paper-based medical records for patients with NCD to ensure continuity of care, rational treatment for NCD using standard treatment guidelines, conducting a NCD day etc.

The end line survey will reassess the same factors involved in baseline survey after the intervention.
Chapter 2: National Programme for Prevention & Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke

Box 7: Key Messages

- A national programme (NPCDCS) was launched by the Government of India in order to systematically respond to the rising burden of NCDs.

- NPCDCS will integrate its efforts within the existing health services and the NRHM framework.

- The key strategies of NPCDCS are prevention through behavioural change, early diagnosis, effective and rational treatment, capacity-building of human resources and surveillance, monitoring and evaluation.

- PHCs have a key role in implementing several key components of NPCDCS.

Government of India is supporting the efforts of the state by providing technical and financial support through National Program for Prevention and Control of Cancer, Diabetes, CVD and Stroke (NPCDCS) since 4th January 2008. The NPCDCS addresses management of Cancer, Diabetes, CVDs and Stroke. The strategies have been integrated at different levels as far as possible for optimal utilization of the resources. According to this program, the activities at state, districts, CHC and Sub Center level have been planned under the programme and will be closely monitored through NCD cell (proposed to be created) at different levels. The NPCDCS aims at integration of NCD interventions in the NRHM framework for optimization of available resources and provision of seamless services to the patients as also for ensuring long-term sustainability of interventions.

Its plan of action draws upon the Global NCD action plan. Objectives of Global NCD action plan are as follows.

1. To raise the priority accorded to non-communicable disease in development work at global and national levels, and to integrate prevention and control of such diseases into policies across all government departments.

2. To establish and strengthen national policies and plans for the prevention and control of non-communicable diseases.

3. To promote interventions to reduce the main shared modifiable risk factors for Non-communicable diseases: tobacco use, unhealthy diets, physical inactivity and harmful use of alcohol.

4. To promote research for the prevention and control of non-communicable diseases.

5. To promote partnerships for the prevention and control of non-communicable diseases.

6. To monitor non-communicable diseases and their determinants and evaluate...

---

This chapter is largely based on information from the operational guidelines, National Programme for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS), Directorate General of Health Services Ministry of Health & Family welfare, Government Of India.
progress at the national, regional and global levels.

7. The activities at State, Districts, CHC and Sub Centre level have been planned under the programme and will be closely monitored through NCD cell at different levels.
8. Aims at integration of NCD interventions in the NRHM framework for optimization of scarce resources and provision of seamless services to the end customer / patients as also for ensuring long term sustainability of interventions.
9. The institutionalization of NPCDCS at district level within the District Health Society, sharing administrative and financial structure of NRHM becomes a crucial programme strategy for NPCDCS.
10. Pilot programme was launched on 4th January 2008 in 7 states covering one district each.
11. The NCD cell at various levels: Ensure implementation and supervision of the programme activities related to health promotion, early diagnosis, treatment and referral, and further facilitates partnership with laboratories for early diagnosis in the private sector.
12. It will attempt to create a wider knowledge base in the community for effective prevention, detection, referrals and treatment strategies through convergence with the ongoing interventions of National Rural Health Mission (NRHM), National Tobacco Control Programme (NTCP), and National Programme for Health Care of Elderly (NPHCE) etc. and build a strong monitoring and evaluation system through the public health infrastructure.

2.1 Objectives of NPCDCS

1) Prevent and control common NCDs through behaviour and life style changes.
2) Provide early diagnosis and management of common NCDs.
3) Build capacity at various levels of health care for prevention, diagnosis and treatment of common NCDs.
4) Train human resource within the public health setup viz doctors, paramedics and nursing staff to cope with the increasing burden of NCDs.
5) Establish and develop capacity for palliative & rehabilitative care.

2.2 Strategies

1) Prevention through behaviour change.
2) Early Diagnosis.
3) Treatment.
4) Capacity building of human resource.
5) Surveillance, Monitoring & Evaluation.
1) **Prevention through behavior change**

The major risk factors to cancer, hypertension, obesity, diabetes and cardiovascular diseases are unhealthy diet, physical inactivity, stress and consumption of tobacco & alcohol.

Attempts will be made to prevent these risk factors by creating general awareness about the Non Communicable Diseases (NCD) and promotion of healthy life style habits among the community. Such interventions will be done through the peripheral health functionaries and NGOs.

Approaches such as mass media, community education and interpersonal communication will be used for behavior change focusing on the following five messages:

- increased intake of healthy foods
- increased physical activity through sports, exercise, etc.
- avoidance of tobacco and alcohol;
- stress management
- warning signs of cancer etc.

Interpersonal communication will be carried out through ASHAs/ AWWs/ SHGs/ Youth clubs, Panchayat members etc. for which education material will be developed at central / State level to facilitate IEC/ BCC activities

Targeted intervention programmes will be designed to bring awareness in schools and workplaces.

2. **Early Diagnosis**

Strategy for early diagnosis of chronic non-communicable diseases will consist of opportunistic screening of persons above the age of 30 years at the point of primary contact with any health care facility, be it the village, CHC, District hospital, tertiary care hospital etc.

Opportunistic screening will have in built components of mass awareness creation, self screening and trained health care providers. Such screening involves simple clinical examination comprising of relevant questions and easily conducted physical measurements (such as history of tobacco consumption and measurement of blood pressure etc.) to identify those individuals who are at a high risk of developing diabetes and CVD, warranting further investigation/ action. The investigations which may not be carried out in the health facilities can be outsourced.

3. **Treatment**

“NCD clinic” will be established at CHC and District Hospital (NCD here refers to Cancer Diabetes, Hypertension, Cardiovascular diseases and Stroke) where comprehensive examination of patients referred by lower health facility /Health Worker as well as of those reporting directly will be conducted for ruling out complications or advanced stages of common NCDs. Screening, diagnosis and management (including diet counseling, Lifestyle management) and home based care will be the key functions.
4. **Capacity building of human resource**

Health personnel at various levels will be trained for health promotion, prevention, early detection and management by a team of trainers at identified Training Institutes/Centres. These Training Institutes/Centres will be identified by the State in consultation with the Centre.
Pharmacists and lab technicians play crucial roles in diabetes and hypertension management at PHC. Their major responsibilities are:

- To ensure timely and effective drug procurement of drugs for Diabetes and Hypertension.
- To ensure optimal drug distribution based on needs and guidelines by analyzing drug costs.
- To ensure good drug dispensing practices.
- To provide necessary counselling to patients about prevention and control of diabetes and hypertension.

### Daily/Weekly

- Drug storage
- Monitor storage conditions.
- Clean receiving, storage, packing and dispatching areas.
- Sweep or scrub floors.
- Remove garbage.
- Clean bins, shelves, and cupboards, if needed.
- Ensure adequate ventilation, environmental control and cooling.
- Ensure that products are protected from direct sunlight, rain water and moisture.
- Monitor store security and safety.
- Check the store roof for leaks, especially during the rainy season and during or after a storm.
- Monitor product quality (visually inspect commodities and check expiry dates).
- Ensure that products are stacked correctly (Are the cartons below being crushed?)
- Update stock records and maintain files.
- If rotational counting, conduct physical inventory and update stock keeping records.
- Monitor stock levels, stock quantities and safety of stocks.
- Place emergency order (as needed, using local guidelines).
- Update back-up file for computerized inventory control records.
- Update bin cards.
- Separate expired stocks and move to secure area.

---

**Box 8: Key Messages**

3. 1 Role and responsibilities of pharmacists at PHC

Chapter 3: Role and responsibilities of pharmacists in diabetes and hypertension management at PHC
Monthly:-

• Conduct physical inventory or cycle count and update stock keeping records.
• Run generator to ensure the system is working correctly; check the level of fuel, if needed.
• Check for signs of rodents, insects or roof leaks.
• Inspect the structure of the storage facility for damage, including the walls, floors, roofs, Windows and doors.
• Irrational use

Quarterly (Every three months):-

• Conduct physical inventory or cycle count and update stock keeping records.
• Use established procedures to dispose of expired or damaged products.
• Visually inspect fire extinguishers to ensure that pressures are maintained and Extinguishers are ready for use.

Tasks according to reorder interval and reporting schedule (Usually monthly or quarterly)

• Assess stock situation.
• Complete and submit requisition form (indent or “pull” system).
• Determine issue quantity and issue products (“push” systems)
• Receive products.
• Store products using correct procedures: rearrange commodities to facilitate the first-to-expire, first-out (FEFO) policy.
• Complete required reporting and documentation.
• Every 6 months; -
• Conduct fire drills and fire safety procedures.
• Inspect trees near the medical store and cut down trees with weak branches.

Every 12 months: -

• Service fire extinguishers and smoke detectors.
• Conduct complete physical inventory and update stock keeping records.
• Reassess maximum/minimum stock levels and adjust if needed.

3.2 How to use Essential Medicines List (EML)
The main objective of the “EML” is to satisfy the priority health needs of the community. From this it is to be ensured that all medicines required for treating priority diseases like diabetes and hypertension among people are available at all health care facilities and dispensed to patients in desired quantity, dosage form and strength at all times.
3.3 Role of Pharmacists and lab technicians in diabetes and hypertension treatment

1. To ensure timely and effective drug procurement of drugs for Diabetes and Hypertension.
2. To ensure optimal drug distribution based on needs and guidelines.
3. To ensure good drug dispensing practices.
4. To ensure proper storage and quality of drugs.
5. To keep buffer stocks/emergency stocks of medications for diabetes and hypertension.

3.4 Counseling for people who have Hypertension and Diabetes

- Develop the habit of taking meals at regular intervals.
- Reduce salt and sugar intake.
- Exercise regularly and reduce weight.
- Get blood pressure checked regularly and if high, consult doctor and follow the advice.
- Don’t stop or change medication on your own or advice of friends.
- Take the advice of doctor for regular tests e.g. kidney function, eye checkup, foot checkup etc.
Pharmaceutical procurement is a complex process.

Little experience in responding to market situations and absence of a comprehensive procurement policy are major causes for procurement failure in many developing countries.

A procurement policy should aim to achieve strategic objectives of good pharmaceutical procurement and should be guided by its principles.

Pharmaceutical agencies should adopt good storage practices.

Efficient management of drugs supply ensures sustainable access to and availability of essential medicines in public.

Ensuring optimal drug availability at any given point is a key pharmaceutical function.

Good dispensing practices ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, with clear instructions.

4.1 Drug procurement and Storage

4.1.1 Introduction

Pharmaceutical procurement is a complex process which involves many steps agencies, ministries and manufacturers. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market. Market constraints differ from country to country. Public sector drug procurement must take place in the context of both the local pharmaceutical market and the international market. In many countries public health officials have limited experience in designing an optimal procurement system to fit their market context. An increasing number of countries have moved, or are moving, away from a pharmaceutical procurement and distribution system which is totally operated by the public sector, and are investigating various options for involving the private sector in order to enhance public health. A recent MSH/WHO publication explores various models which exist. Each of the models discussed in that book has advantages and disadvantages, and each presents a different challenge to effective procurement management. There are many steps in the procurement process. No matter what model is used to manage the procurement and distribution system, efficient procedures should be in place: to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to lack of access to appropriate drugs and to waste. In many public supply systems,

---

This chapter draws significantly from, World Health Organization, and UNICEF. "Operational principles for good pharmaceutical procurement." (1999).
breakdowns regularly occur at multiple points in this process. If there is an appearance of special influence on the selection of products and suppliers or if the procurement process is not managed in an efficient and transparent manner, interest among suppliers in competing for procurement contracts decreases, leading to fewer choices and higher prices for drugs. If the procurement system cannot guarantee access to funds at the time they are needed, drug shortages and procurement inefficiencies are inevitable. Government funds for procurement are, in some countries, released irregularly during the financial year. In some countries government regulations specify that funds must be spent in the year for which they are allocated or be returned to the treasury; this compounds the problem. Where this combination exists it compromises procurement planning and execution. Limited or irregular funding which leads to delays in payments worsens procurement problems as suppliers deny credit or insist on advance payments.

A degree of financial autonomy for the health system, while providing flexibility, requires proper accountability and efficient management.

Pharmaceutical procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists’ expertise all along the pharmaceutical procurement chain.

Box 10: Summary of main pharmaceutical procurement related problems
- Inadequate rules, regulations and structures.
- Public sector staff with little experience in responding to market situations.
- Absence of effective planning and procurement strategy.
- Government funding which is insufficient and/or released irregularly.
- Donor agencies with conflicting procurement regulations.
- Fragmented drug procurement at provincial or district level.
- Lack of unbiased market information.
- Lack of trained procurement staff.

Pharmaceutical procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists’ expertise all along the pharmaceutical procurement chain.
4.1.2 Strategic objectives of a good pharmaceutical procurement

1. **Procure the most cost-effective drugs in the right quantities**
   The first strategic objective is that all organizations responsible for procurement, whether they are public, private non-profit or private for-profit, should develop an essential drugs list to make sure that only the most cost-effective drugs are purchased. Procedures must also be in place that accurately estimate procurement quantities in order to ensure continuous access to the products selected without accumulating excess stock.

2. **Select reliable suppliers of high-quality products**
   The second objective is that reliable suppliers of high-quality products must be (pre-)selected, and that active quality assurance programmes involving both surveillance and testing must be implemented.

3. **Ensure timely delivery**
   The third strategic objective is that the procurement and distribution systems must ensure timely delivery of appropriate quantities to central or provincial stores and adequate distribution to health facilities where the products are needed.

4. **Achieve the lowest possible total cost**
   The fourth objective is that the procurement and distribution systems must achieve the lowest possible total cost, considering four main components:
   
   a) The actual purchase price of drugs.
   b) Hidden costs due to poor product quality, poor supplier performance or short shelf-life.
   c) Inventory holding costs at various levels of the supply system.
   d) Operating costs and capital loss by management and administration of the procurement and distribution system.

**Box 11: Four strategic objectives of pharmaceutical procurement**

1. Procure the most cost-effective drugs in the right quantities
2. Select reliable suppliers of high-quality products
3. Ensure timely delivery
4. Achieve the lowest possible total cost

**4.1.3 Principles of procurement**

1. **Efficient and Transparent Management**
   Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.
A number of key procurement functions typically require different expertise and should be separated. Examples include:

- **Drug selection**, which should be done by a national formulary or essential drugs list (EDL) committee. Where such a committee does not exist an ad hoc committee should be set up for this purpose.
- **Quantification of drug requirements**, which should have inputs from the medical stores and/or from district or health facility managers in decentralized systems. However, the procurement office should draw up the final procurement list.
- **Product specifications**, which should be prepared by a standing committee or an ad hoc technical committee.
- **Pre-selection of suppliers**, which should be done by a broad-based procurement committee composed of managers and technical staff, including quality assurance experts.
- **Adjudication of tenders**, which should be reserved for the procurement committee or tenders board. Procurement office staff can make technical recommendations but should not have a vote in the contract decision.

Pharmaceutical procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists’ expertise all along the pharmaceutical procurement chain.

**2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.**

Fairness and the perception of fairness are essential to attract the best suppliers and achieve the best prices. When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair. There may be accusations of unfair influences. Whether true or not, such charges are damaging and suppliers, health care providers and the public lose confidence in the system. Unsuccessful suppliers may feel that they have no chance of winning and consequently withdraw from future tenders. As the pool of potential suppliers decreases to a small set, price competition decreases and Procurement prices become much higher than necessary.

**Practical aspects**

The tender procedures should be transparent. Formal written procedures should be developed and be followed throughout the tender, and explicit criteria should be used to make procurement decisions. Broad-based committees should have the sole authority to make contract awards. Tender adjudication should be done properly and the award of contracts and issuing of orders should be completed within the shortest period of time possible. Information on the tender process and results should be public, to the extent permitted by law. At the very least, both bidders and health personnel should have access to information on the successful suppliers and the prices for all winning contracts.
3. **Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.**

In order to ensure that drugs are available where and when they are needed, drug procurement must be carefully planned. Planners should consider factors such as access to suppliers; funding availability and timing; the number of levels in the logistics system; constraints of time and resources affecting procurement functions such as drug selection, quantification, tendering and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport.

**Practical aspects**

A reliable management information system (MIS) is one of the most important elements in planning and managing procurement. Lack of a functioning MIS or the inability to use it appropriately is a key cause of programme failure. The MIS should track the status of each order and payment, and compile the information required for supplier monitoring, as discussed in Operational Principle 11. It is important that the MIS also tracks the number of orders placed, payments made, quantities actually purchased compared with estimates, purchases from all contract suppliers, and drug purchases from non-contract suppliers. In all but the smallest procurement systems, the procurement information system should be computerized in such a way as to facilitate tracking and reporting on performance by suppliers and by the health system.

The procurement office should be required to report regularly on key procurement performance indicators, selected by senior managers. Some standard indicators include the planned versus actual items and quantities purchased; prices obtained versus average international prices; average supplier lead-time and service level; percentage of key drugs in stock at various levels of the supply system; and report on stock-outs.

At least once a year the procurement unit should undergo an audit, either internal or external, to verify procurement office accounting records. The auditor should issue a statutory audit report in accordance with the legal regulations of the jurisdiction and in addition should issue a detailed *Letter of Comment* to the management of the organization and to the appropriate public supervisory body.

4. **Drug Selection and Quantification**

**Public sector procurement should be limited to an essential drugs list or national/local formulary list.**

No public or private health care system in the world can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure. A nationally developed formulary or selection based on the essential drugs concept has been used in both industrialized and developing countries' health systems for more than twenty years. This allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or national list allows for concentrating on a limited number of products. Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs.
**Practical aspects**

Some public and private health systems strictly limit procurement to drugs listed on an essential drugs list. However, in most cases some mechanism exists to address special needs, allowing the occasional procurement of non-list drugs after approval by senior officials.

5. **Procurement and tender documents should list drugs by their generic name.**

The INN (*International Nonproprietary Name*) is widely accepted as the standard for describing drugs on a procurement list or tender request. Although this is most obviously applicable when purchasing drugs which are available from multiple sources, generic description should also be used when purchasing single source products. When purchasing products which present potential problems with pharmaceutical equivalence or bioequivalence the procurement request should specify the quality standards but not mention specific brands.

**Practical aspects**

This does not mean that brand-name suppliers should be barred from tender participation; they may offer the most cost-effective product, and in fact may offer more competitive prices for certain branded drugs than generic competitors. However, all drugs supplied to the public health system should be properly labelled in accordance with standards laid down by law (or in accordance with labelling instructions), including the INN featured prominently in addition to the brand name that may be on the label.

4.1.4 **Tender processing : Example from Tamil Nadu Medical Services Corporation (TNMSC) model**

The designated drug committee to finalize the list of items (Essential Drug List) and quantity. This list is consolidated as per pharmacopeia standards and by analysing last year purchase & utilisation.

Then they open tender advertisements in :-

§ National Dailies.

§Websites

§Trade Journal like Pharma pulse.

§Letters to Drugs Controllers & Pharma Association Issue and receipt of Tender Documents Tender Cover “A” opening

Then tender Committee receives tender documents followed by the scrutinizing team inspection of the manufacturing premises of new suppliers in case of drugs evaluation of surgical/sutures samples by experts.
Salient features of Cover “A” opening –

- Licence for the product quoted.
- Minimum three years market standing for the drug issued by the licensing authority.
- Minimum turn over of Rs. 35 lakhs.
- Non conviction certificate for three years.
- GMP certificate.

Salient features of Cover “B” opening-

- Printed format for quoting the landed price excluding Sales Tax.
- Printed format to furnish the break up details of landed price
- The tenderer is strictly prohibited to change /alter specification or unit size in the printed format
- The rate per unit(landed price)will be the criteria for determining the L1 rate
- The manufacturing capacity for each item for effecting supplies to the warehouses within 60 days shall be given in the printed format
- The above details of rates and capacity shall be given in computer floppy

Fig 3 : Diagram depicting procurement of drugs at TNMSC.
The drug committee discuss and decide about the drugs to be purchased.

As procurement, proper storage of medicines is extremely important. It ensures drug lasts until it expiry. It also helps to prevent accident.  

**Box 12: Guidelines for proper drug storage**

- Solid medicines like capsules, tablets may be kept in a dry and cool place away from sunlight.
- Store household medicines preferably in transparent plastic containers.
- Dry powder after mixing with water should be stored in the refrigerator without freezing.
- Maintain a proper cold chain for vaccines.
- Do not keep medicines on the floor.
- Keep medicines away from the reach of children.
- Keep lids of medicines bottles tight to prevent entry of insects or dust or moisture.
- Check intravenous fluids in sunlight for fungus prior to infusion.

**Box 13: Signs of improper storage**

- Change of color or smell.
- The medicines sticks with the package.
- Label is destroyed.
- Expiry date is not legible.
- Unusual particulate matters inside that does not dissolve after shaking.

**4.1.5 Shelf life and stability of drugs**

“Shelf-life” of a drug refers to the prior to it’s expiry date up to when, the medicines may be stored for usage. Expiry date of any medicine denotes the period of its efficacy provided all stipulated conditions of storage are maintained. Once the date mentioned over the label expires it is taken for granted that the efficacy of the said medicines not only lost but also there is every possibility that due to chemical degradation a toxic and harmful product may be produced. Sometimes, the detection of degradation is physically manifested by change of color, taste, smell or inseparable sticking with package material.

**4.2 Medicines Good storage practices**

Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process. For additional guidance relating to the general principles of storage of pharmaceutical products, refer to the WHO guide to good storage practices for pharmaceuticals.

---

This sub chapter draws significantly from WHO good distribution practices for pharmaceutical products (2010).
4.2.1 Storage areas

Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely commercial 249 and non-commercial products, products in quarantine, and released, rejected, returned or recalled products as well as those suspected to be counterfeits.

Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

Storage areas should be clean and free from accumulated waste and vermin. Organizations in charge of distribution must ensure that premises and storage areas are cleaned regularly. There should also be a written programme for pest control. The pest control agents used should be safe and there should be no risk of contamination of pharmaceutical products.

There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.

Receiving and dispatch bays should protect pharmaceutical products from the weather. Receiving areas should be designed and equipped to allow incoming containers of pharmaceutical products to be cleaned, if necessary, before storage.

Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel.

Any system replacing physical quarantine should provide equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.

Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned should be appropriately identified.

Unless there is an appropriate alternative system to prevent the unintentional or unauthorized use of quarantined, rejected, returned, recalled or suspected counterfeit pharmaceutical products, separate storage areas should be assigned for their temporary storage until a decision as to their future has been made.

Radioactive materials, narcotics and other hazardous, sensitive and/or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids and solids and pressurized gases) should be
stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.

Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

A system should be in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

Broken or damaged items should be withdrawn from usable stock and stored separately. Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

4.2.2 Storage conditions and stock control

Storage and handling conditions should comply with applicable national and local regulations.

Storage conditions for pharmaceutical products should be in compliance with the recommendations of the manufacturer.

Facilities should be available for the storage of all pharmaceutical products under appropriate conditions (e.g. environmentally controlled when necessary). Records should be maintained of these conditions if they are critical for the maintenance of the characteristics of the pharmaceutical product stored.

Records of temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year, or as required by national legislation.

Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

Equipment used for monitoring of storage conditions should also be calibrated at defined intervals.

Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at defined intervals.

Stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mix-ups, incorrect issues and receipts, thefts and/or misappropriations of pharmaceutical products. Documentation relating to the investigation should be kept for a predetermined period.
4.3 Efficient management of drugs:
Efficient management of drugs supply ensures sustainable access to and availability of essential medicines in public.

Efficient management saves money and improves performance in following ways:

(1) Avoiding purchasing of unnecessary medicines:-

It is most important that each health care unit should carefully select those medicines that are required in their own unit to treat maximum priority diseases. It acts as a check point to a large extent & facilitates purchasing only those medicines that are needed.

(2) Reducing stock-out days:-

Every health care unit should order the required quantity of medicines by using scientific & reliable estimation. It leads to the availability of medicines in accurate time interval. It has been seen that many health care units fail in accurate estimation of the medicines as a result of which “shortage of medicines occurs”.

(3) Reducing irregular supply of medicines:-

Medicine supply reaching at any health care unit should mainly depend upon its distribution process. Efficient distribution process should be achieved by designing an effective network of storage facilities & transport facilities. Keeping in view the geographical layout of the health care unit, it is essential to work out an appropriate roadmap and strategy for delivery of medicines at all places.

(4) Avoiding Storage of expired medicines:-

By adopting “ Good Store Keeping Practices (GSKP) “, medical stores & pharmacies have reduced their wastage and streamlined the availability of medicines in the health care units.

(5) Improving dispensing process:-

Dispensing is a major step taken by the dispenser & patients. The dispenser (Pharmacist or compounder) dispenses the medicines to the patients, prescribed to him/ her by the prescriber. The dispenser should realize that patients themselves should not choose their medicines but should be asked to take all the prescribed medicines. Therefore, it is a major role of the dispenser to educate the patients about each prescribed medicines and dispense the desired quantity of medicines to the patients.
4.4 Ensuring drug availability

4.4.1 Material management

At PHC or CHC level major materials include drugs, contraceptives, laboratory chemicals, equipments and vehicles.

Following are the components of the materials management -

1. Estimation of the demand.
2. Indenting and purchasing
3. Procurement and storage
4. Issue from store for use
5. Maintenance of registers

Table 5 : Material management -description of Top 10 items by ABC analysis.

<table>
<thead>
<tr>
<th>Items</th>
<th>Name</th>
<th>% of total budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3(A)</td>
<td>Tab Ciprofloxin 250 mg</td>
<td>10.7</td>
</tr>
<tr>
<td></td>
<td>Cap Ampicillin 250 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cap Omeprazole 10 mg</td>
<td></td>
</tr>
<tr>
<td>4-5(B)</td>
<td>Cap Tetracycline 250 mg</td>
<td>6.8</td>
</tr>
<tr>
<td></td>
<td>Tab Cotrimoxazole</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dextrose 5%</td>
<td></td>
</tr>
<tr>
<td>7-10(C )</td>
<td>Tab Baralgan</td>
<td>6.8</td>
</tr>
<tr>
<td></td>
<td>Cap Raricap</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tab Desferol</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>24.3</td>
</tr>
</tbody>
</table>

This section significantly draws from management manual for medical officers, SN Manjunath.
VED analysis is better than ABC analysis.

**Table 6 : Example of VED analysis.**

<table>
<thead>
<tr>
<th>Category of drugs</th>
<th>No. of drugs</th>
<th>% of total drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>V : Vital</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>E : Essential</td>
<td>26</td>
<td>32</td>
</tr>
<tr>
<td>D : Desirable</td>
<td>38</td>
<td>47</td>
</tr>
<tr>
<td>Total</td>
<td>81</td>
<td>100</td>
</tr>
</tbody>
</table>

Here in VED analysis importance is given to vital category which can be increased further. The desirable category is not just to possess but the proportion can be brought down.

**FSN Analysis –**

This implies classification of drugs into three categories.

F: Fast moving drugs. (Most utilized)

S: Slow moving drugs .

N: Non moving drugs.

The grouping can be done similar to VED analysis. Non-moving drugs need not be indented at all.

**Box 14 : A practical example for estimating vaccine requirement –**

The estimation depends on – Number of beneficiaries, Number of doses of each vaccine, Wastage multiplication factor .

Illustration – PHC population = 30000 (Approx), Birth Rate= 30/1000

Estimated no. of births =900; Estimated no. of pregnancies = Estimated no. of births+ (10% of estimated no. of births)= 900+90=990.

Each pregnant women needs two doses of TT.

Hence TT doses required would be equals to 1980. (990x2)
### Fig 4: Photos of some improper pharmaceutical storage practices. (Source: Performance Audit report Comptroller of audit chapter 2, 2013)
4.4.2 Analysis and control of pharmaceutical cost

The selection, procurement, distribution and proper utilization of medicines are as crucial components of any disease control programme as these are for NCD control programme in any country, while these are the major responsibilities of a pharmacist at a primary health care set up, it is utmost important for him to adopt and ensure good indenting (selection and procurement) practices and continuous availability of drugs for NCDs. He should also be competent enough to analyze and control cost while indenting for drugs.

Sources of medicines -

Public sector procurement should be limited to an essential drugs list or national/local formulary list. The sources are from government supply, DHAP and ARS stock at district level to purchase drugs.

Box 15: Tools to analyse costs

<table>
<thead>
<tr>
<th>Total cost analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td>VEN analysis.</td>
</tr>
<tr>
<td>ABC analysis.</td>
</tr>
<tr>
<td>Therapeutic category analysis.</td>
</tr>
<tr>
<td>Price comparision analysis.</td>
</tr>
<tr>
<td>Lead time analysis.</td>
</tr>
</tbody>
</table>

Of these two categories are important method for cost control in drug indenting. That are the VEN analysis and ABC analysis.

Box 16: The VEN system of analyzing cost

The VEN system categorises pharmaceuticals by their relative public health value. Developed in Sri Lanka for the first time, it is useful in setting purchasing priorities, determining safety stock levels and pharmaceutical sales price and dividing staff activities.

The categories in the original system are vital (V), essential (E) and non essential (N). Some health systems find a two category system more useful than the three tiered VEN. For example, The categories might be V & N, differentiating between those medicines that must always be in stock and other not so priority medicines.

The classification of medicines should not be a one-time exercise. As the national essential medicines list is updated and as public health priorities change, the VEN or VN categories should be reviewed and updated. Any new medicines added to the list should be...
categorized appropriately and category assignments for older medicines should be reviewed and changed if needed.

**Box 17 : Application of VEN analysis**

Application of VEN analysis –

- ✓ Selection : Assigning priorities in medicine selection especially when funds are short.
- ✓ Procurement : Assigning priorities again.
- ✓ Order monitoring : Orders of V & N should be monitored closely and shortages reported
- ✓ Safety stock : safety stock should be higher for vital and essential items.

---

**Fig 5 : The VEN Analysis System.**
**ABC Analysis**

ABC analysis examines the annual consumption of medicines and expenditures for procurement dividing the medicines consumed into three categories.

---

**Class A**
- Includes 10-20% of items.
- Accounts for 75-80% of expenditures.

**Class B**
- Includes 10-20% of items.
- Accounts for 15-20% of expenditure.

**Class C**
- Includes 60-80% of items.
- Accounts 5-10% of expenditure.

---

**Figure 6 : ABC analysis of medicines.**

**ABC analysis can be used in the following circumstances.**

- Measure the degree to which actual consumption reflects public health needs and morbidity.
- Reduce inventory levels and costs by arranging for more frequent purchase or delivery of smaller quantities of class A items.
- Seek major cost reductions by finding lower prices on class A items where savings will be more noticeable.
- Assign import and inventory control staff to ensure that large orders of class A items are handled expeditiously.
Fig 7: The ABC system of drug cost analysis.
4.5 Lab Readiness
It is utmost important for lab technicians as well as respective medical officers to oversee quality functioning of their PHC lab facilities. Equipment to measure diabetes and hypertension should be readily available in a fully functional mode at any given point of time. They should ensure waste disposal practices placed appropriately.

4.6 Good drug dispensing practice
*Need of the hour is to improve the quality of advice being given to patients.* Good dispensing practices ensure that an effective form of the correct medicine is delivered to the right patient, in the correct dosage and quantity, with clear instructions, and in a package that maintains the potency of the medicine. Dispensing includes all the activities that occur between the time of the prescription is presented and the time of the medicine or other prescribed items are issued to the patient. Dispensing must be performed accurately and should be done in an orderly manner, with disciplined use of effective procedures. Care should be taken to read labels accurately. The dispenser must count and measure carefully and guard against contamination of medicines.

*Practicing a standard dispensing procedure*

- Receive and validate the prescription.
- Understand and interpret the prescription.
- Prepare and label items for issue.
- Make a final check /
- Record action taken.
- Issue medicines to patients with clear instructions and advice.

Pharmacists or staff members who dispense must be trained in the knowledge, skills, and practices necessary to dispense the range of medicines prescribed at the facility. Ensuring patients understanding of how to take their medicines is a primary responsibility of the dispensers. Dispensers should check understanding by asking each patient to repeat instructions.

The ultimate goal of the training should be to make available the right drugs that is administered in right dose, at right time, for right duration at an affordable cost to the common people of Rural Karnataka normal as well as in emergencies should be the ultimate aim of the training.
Step 1.
Rest the arm of the person on table so that the elbow of the person is parallel to heart. Wrap the blood pressure cuff around the arm slightly above the crease of the forearm and pump the blood pressure cuff up to 160. The metal attachment on the side of the pump allows you to inflate and deflate the cuff.

Step 2.
Listen for two different sounds with the stethoscope as you slowly deflate the cuff. The first sound will be strong and the second sound lighter. At the start of each new sound, look at the reading on the cuff to see the numbers with the first and stronger sound representing the top systolic number and the second, softer sound is representing the diastolic number.

Step 3.
Repeat the blood pressure reading. Results will vary from arm to arm. Ideal blood pressure is 120/80. Take three or four readings and average the...

Table 7: Criteria for diagnosing the hypertension

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic Blood Pressure (Top number)</th>
<th>Diastolic Blood Pressure (Bottom number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Less than 120 mm Hg</td>
<td>Less than 80 mm Hg</td>
</tr>
<tr>
<td>Pre-hypertension</td>
<td>120-139 mm Hg</td>
<td>80-89 mm Hg</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 1</td>
<td>140-159 mm Hg</td>
<td>90-99 mm Hg</td>
</tr>
<tr>
<td>Stage 2</td>
<td>160 mm Hg higher</td>
<td>100 mm Hg higher</td>
</tr>
</tbody>
</table>
4.8 Some useful information for Lab technicians on diagnosis and measurement of diabetes

Table 8: Criteria for diagnosing Diabetes

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Fasting Glucose (Mg/dl)</th>
<th>2-hour Post-Glucose* (Mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>&gt;=126</td>
<td>&gt;=200</td>
</tr>
<tr>
<td>Impaired Glucose Tolerance</td>
<td>&lt; 110</td>
<td>&gt;140 to &lt;200</td>
</tr>
<tr>
<td>Impaired Fasting Glucose</td>
<td>&gt;=110 to &lt;126</td>
<td></td>
</tr>
</tbody>
</table>

*A 2-hour postprandial blood sugar test measures blood glucose exactly 2 hours after eating a meal.
Hypertension and Diabetes Mellitus are caused by a set of shared risk factors namely, unhealthy diet (low fruit and vegetable intake), physical inactivity and tobacco use.
Expenditure on medicines accounts for a major proportion of health costs in developing countries. More than 50% of all medicines are prescribed, dispensed or sold inappropriately, and half of all patients fail to take medicines correctly. The overuse, underuse or misuse of medicines harms people and wastes resources. More than 50% of all countries do not implement basic policies to promote rational use of medicines. In developing countries, less than 40% of patients in the public sector and 30% in the private sector are treated according to clinical guidelines. A combination of health-care provider education and supervision, consumer education, and an adequate medicines supply is effective in improving the use of medicines, while any of these interventions alone has limited impact. (Source: Available at http://www.who.int/mediacentre/factsheets/fs338/en/, accessed on 11 April 2014)

5.1 Introduction
Expenditure on medicines accounts for a major proportion of health costs in developing countries. This means that access to treatment is heavily dependent on the availability of affordable medicines. It is estimated that one-third of the developing world's people are unable to receive or purchase essential medicines on a regular basis. In India, the situation is not different. Irrespective of the place of care (government or private), the patient often ends up purchasing medicines from private pharmacies. One most common reason for this is the lack of continuous supply of medicines in the government healthcare facilities. Private pharmacies usually stock branded medicines, which often costs 3-4 times more than their unbranded generic counterparts. This raises the health expenditure for families, more so in the case of NCDs where the patient has to take regular medication on a long-term basis. It is estimated that around 70% of out of pocket expenditure in India are on medications. One way to improve the affordability is to prescribe generic version of medicines.

5.2 Generic medicine
Generic medicine can be defined as "a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use". A generic drug is identical or bioequivalent to a brand name drug in all the above mentioned aspects. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name. Generic drugs are frequently as effective as, but much cheaper than brand-name drugs. A

---

h This chapter draws significantly from Standard Treatment Guidelines for Primary Healthcare Facilities (2012) published by SIGN, CDMU & EPN.
brand name is a name given to a drug by the manufacturer. The use of the name is reserved exclusively for its owner. For example, paracetamol is a chemical ingredient found in many of brand-name painkillers, but is also sold as a generic drug (not under a brand name).

5.3 Rational use of medication

Irrational use of medicines is a major public health issue. WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately. Also, half of all patients fail to take the prescribed medicines correctly. The overuse, underuse or misuse of medicines results in wastage of scarce resources and further limits access to medicines. Examples of irrational use of medicines include:

- Use of too many medicines per patient ("polypharmacy")
- Inappropriate use of antimicrobials often in inadequate dosage, for non-bacterial infections.
- Over-use of injections when oral formulations would be more appropriate
- Failure to prescribe in accordance with clinical guidelines
- Inappropriate self-medication, often of prescription-only medicines.
- Non-adherence to dosing regimes.

5.4 Consequences of irrational medicine use

1. Antimicrobial resistance: Overuse of antibiotics increases antimicrobial resistance and medicines may not be effective against infectious disease

2. Adverse drug reactions and medication errors: Harmful reactions to medicines caused by wrong use, or allergic reactions to medicines can lead to increased illness, suffering and death.

3. Lost resources: Between 10–40% of national health budget is spent on medicines. Out-of-pocket purchases of medicines can cause severe financial hardship to individuals and their families.
4. Eroded patient confidence- Exacerbated by the overuse of limited medicines, drugs may be often out of stock or at unaffordable prices and as result erode patient confidence.

5.5 How to promote rational use of medicines
There are many ways to promote rational use of medicines among the providers and the patients. Problem-based training in pharmacotherapy and prescribing has to be stressed in the undergraduate medical curricula. Also it has to be made a part of the continuing medical education of doctors. Financial and/or other incentives leading to improper prescriptions have to be eliminated. Regulatory mechanisms have to be improved to ensure ethical prescription practices. Adequate funding should be there to ensure the availability of medicines. Public education about medicines has to be improved.
References

17. Guide materials for medical store management training, Community Development Medicinal Unit (CDMU).
18. Scientific storage, chapter-2, A training manual on rational use of medicines , Community Development Medicinal Unit (CDMU).


22. Role of health assistants in prevention and management of non-communicable diseases (with a focus on hypertension, diabetes mellitus and cervical cancer), Public Health Foundation of India, Sponsored and funded by Government of Karnataka. (Sep 2013)


Suggested Reading

1. The operational guidelines, National Programme for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS), Directorate General of Health Services Ministry of Health & Family welfare, Government Of India
4. A training manual on rational use of medicines, Community Development Medicinal Unit (CDMU).