STANDARD TREATMENT GUIDELINES
AND
ESSENTIAL DRUGS LIST
FOR
SOUTH AFRICA

HOSPITAL LEVEL
PAEDIATRICS

2006 EDITION
NOTE:
The information presented in these guidelines conforms to current medical, nursing and pharmaceutical practice. It is provided in good faith. Contributors and editors cannot be held responsible for errors, individual responses to drugs and other consequences.

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FOREWORD

It is the vision of the National Department of Health to ensure that every citizen has access to good quality and affordable health care, including the access to medicines.

The goal of the National Drug Policy is to ensure an adequate and reliable supply of safe and efficacious medicines of acceptable quality in the most cost-effective manner to all citizens of South Africa. Resources are not unlimited and the appropriate management and use of drugs has often been underestimated and is increasingly being identified as a critical component of an efficient health care system. Thus affordability is a key element in ensuring access.

The National Department of Health through the Cluster: Pharmaceutical Policy and Planning has reviewed the Standard Treatment Guidelines and Essential Drugs List at hospital level for adults and paediatrics. These provide a vital tool to guide prescribers, particularly doctors working in district and regional hospitals.

More attention has been given to address healthy lifestyles, mental health conditions, neonatal conditions, palliative care and to strengthen the implementation of the Department’s Comprehensive HIV and AIDS Prevention, Care, Management and Treatment Plan. More in depth emphasis has been placed on the review of the endocrine, hypertension, infections and tuberculosis chapters. Evidence-based decision-making has been strengthened in the selection of drug entities.

The National EDL Committee has endeavoured to consult widely with colleagues within the Department, Provincial Pharmacy and Therapeutic Committees, universities, experts in different specialities, relevant societies and other stakeholders. I would like to take this opportunity to thank the National Essential Drugs List Committee, the Expert Review groups and all those who have contributed for their dedication and hard work. Congratulations to all role players on this achievement.

I hope this edition of the Standard Treatment Guidelines and Essential Drugs List for Hospital Level will guide you daily in treating all patients optimally.

DR MANTO TSHABALALA-MSIMANG
MINISTER OF HEALTH
INTRODUCTION

The Department of Health is committed to providing quality and affordable healthcare including access to medicines to all citizens in South Africa. This is a challenging task in our health care system.

One of the goals of the National Drug Policy is to develop the full potential of drugs to improve the health status of South Africans within the available resources. The second edition of the Standard Treatment Guidelines (STGs) and Essential Drugs List (EDL) at Hospital Level for adults and paediatrics is a vehicle for the implementation of the National Drug Policy. Legislation has been adapted to address issues of affordability and improved access to medicines.

Advocacy and training are vital elements for the successful utilisation of the Hospital Level STGs and EDL. The concepts of evidence based selection of medicines and cost-effective treatment protocols need to be included in the training of doctors, pharmacists, nurses and other health care professionals. Pharmacovigilance remains an important aspect of ensuring the safety of medicines used. A reporting form in this regard is included in the book. The inclusions of the ICD-10 codes for conditions should facilitate analysis, peer review, billing etc.

The Hospital Level STGs and EDL are aimed for use at District and Regional Hospitals. Formularies remain the responsibility of Provincial Pharmacy and Therapeutics Committees. The Hospital Level STGs and EDL should be used as guidelines to develop these formularies. Updating the STGs and EDL is an ongoing process. Suggestions for improvement will be welcomed and considered.

The intention of the STGs and EDL is to strengthen priority health interventions. The implementation of the Department’s Comprehensive HIV and AIDS Care, Management and Treatment Plan is encapsulated in this edition, particularly with regard to the use of antiretrovirals and treatment of opportunistic infections.

It should not be forgotten that patients must take full responsibility for their own health, including adherence to prescribed treatment and lifestyle changes.

I wish to record a special word of appreciation to the chairpersons of the expert groups, the groups themselves and all other contributors to this edition of the STGs and EDL.

Mr. T.D. Mseleku
Director-General: Health
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It is impossible to name all who have played a part in producing this edition. The treatment
guidelines and essential drugs list which appears in this book have been compiled after a
lengthy consultative process. They include recommendations and advice from numerous
individuals and groups including professional societies, expert committees, medical schools
and secondary and tertiary hospitals.

We offer sincere thanks to those who contributed appropriate information and comments
and to the members of the National Essential Drugs List Committee.

We are especially grateful to Prof PM Jeena the chairperson and members of the Paediatric
Expert Committee for their dedication and hard work and Prof DF Wittenberg for his technical
and editorial support.

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THE ESSENTIAL DRUGS CONCEPT

The WHO describes Essential medicines as those that satisfy the priority health care needs of the population. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Effective health care requires a judicious balance between preventive and curative services. A crucial and often deficient element in curative services is an adequate supply of appropriate medicines. In the health objectives of the National Drug Policy, the government of South Africa clearly outlines its commitment to ensuring availability and accessibility of medicines for all people. These are as follows:

- To ensure the availability and accessibility of essential medicines to all citizens.
- To ensure the safety, efficacy and quality of drugs.
- To ensure good prescribing and dispensing practices.
- To promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information.
- To promote the concept of individual responsibility for health, preventive care and informed decision-making.

Achieving these objectives requires a comprehensive strategy that not only includes improved supply and distribution, but also appropriate and extensive human resource development. The implementation of an Essential Drugs Programme (EDP) forms an integral part of this strategy, with continued rationalisation of the variety of medicines available in the public sector as a first priority. The private sector is encouraged to use these guidelines and drug list wherever appropriate.

The criteria for the selection of essential drugs in South Africa were based on the WHO guidelines for drawing up a national EDL. They include the following:

- any drug included must meet the needs of the majority of the population
- sufficient proven scientific data regarding effectiveness must be available
- any drug included in the EDL should have a substantial safety and risk/benefit ratio
- all products must be of an acceptable quality, and must be tested on a continuous basis
- the aim, as a rule, is to include only products containing single pharmacologically active ingredients
- combination products, as an exception, will be included where patient compliance becomes an important factor, or two pharmacologically active ingredients are synergistically active in a product
- products will be listed according to their generic names only
- where drugs are clinically equally effective, the drugs will be compared using the following:
  - the best cost advantage
  - the best researched
  - the best pharmacokinetic properties
  - the best patient compliance
  - the most reliable local manufacturer
THE ESSENTIAL DRUG CONCEPT

- a request for a new product to be included on the EDL must be supported by scientific data and appropriate references on its advantages and benefits over an existing product.

The implementation of the concept of essential drugs is intended to be flexible and adaptable to many different situations. It remains a national responsibility to determine which medicines are regarded as essential.

It should be noted that the Essential Drugs List (EDL) reflects only the minimum requirements for facilities. In keeping with the objectives of the National Drug Policy, provincial and local Pharmacy and Therapeutics Committees should provide additional drugs from the Hospital level EDL based on the services offered and the competency of the staff at each facility.
HOW TO USE THIS BOOK

It is important that you become familiar with the contents and layout of the book to use the standard treatment guidelines effectively.

Where relevant this book is consistent with the Standard Treatment Guidelines for Primary Health Care, Integrated Management of Childhood Illness Strategy (IMCI) and other National Programme treatment guidelines.

The ICD-10 number, included with the conditions, refers to an international classification method used when describing certain diseases and conditions. A brief description and diagnostic clinical, radiological and laboratory tests are included to assist the medical officer to make a diagnosis. These guidelines also make provision for referral of children with more complex and uncommon conditions to facilities with the resources for further investigation and management.

It is important to remember that the recommended treatments provided in this book are guidelines only and are based on the assumption that prescribers are competent to handle patients' health conditions presented at their facilities.

The treatment guidelines are presented in chapters according to the organ systems of the body. In order to find the relevant sections in the book easily, use the indices at the back of the book. These have been divided into indices of disease conditions and drugs. Some of the drugs listed are only examples of a therapeutic class. In such cases the Provincial Pharmacy and Therapeutics Committees (PTCs) will decide on their drug of choice within that therapeutic class.

All suspected adverse drug reactions must be reported. In this book, only the common adverse effects have been mentioned. Information on the reporting of adverse drug reactions is provided in the section Guidelines for Adverse Drug Reaction Reporting. The purpose of ADR reporting is to reduce the risks associated with the use of drugs and ultimately improve patient care.

Potentially toxic drugs, drugs with narrow therapeutic indices and those with variable pharmacokinetics should be monitored regularly to optimise dosing, obtain maximum therapeutic effect, limit toxicity and assess compliance. The section on Patient Education in Chronic Conditions aims to assist health workers improve patient compliance and health generally.

As most paediatric doses are given as mg/kg all children must be accurately weighed at each consultation. All doses of drugs in children should be calculated to take into account their size and are based either on weight or body surface area. Modifications of dosage according to organ maturity should also be taken into account. In resource poor settings where a scale is not available, the following formula (though inaccurate in wasting or obesity) may be a useful guide:
Weight (kg) = (age (years) x 7) + 4.

Body surface area (m²) = \( \sqrt{\frac{\text{height (cm)} \times \text{weight (kg)}}{3600}} \)

A number of drugs are not registered for paediatric use. None-the-less it is common practice to use such drugs in children where norms for such use have been established, and where adequate alternatives are not available. This is termed “off label” use. The responsibility for adverse outcomes associated with such practices lies with the prescriber.

Comments that aim to improve these treatment guidelines will be appreciated. The submission form and guidelines for completing the form are included in the book. Motivations will only be accepted from the Provincial PTC. Comments from persons and institutions outside the public service should be sent to:

The Essential Drugs Programme
Pharmaceutical Programmes and Planning
Department of Health
Private Bag X828
Pretoria
0001

PRESCRIPTION WRITING

Drugs should be prescribed only when they are necessary for treatments following clear diagnosis. Not all patients or conditions need prescriptions for drug. In certain conditions simple advice and non-drug treatment may be more suitable.

In all cases carefully consider the expected benefit of a prescribed medication against potential risks. This is important during pregnancy where the risk to both mother and foetus must be considered.

All prescriptions should:
- be written legibly in ink by the prescriber with the full name and address of the patient, and signed with the date on the prescription form
- specify the age and weight of the patient in the case of children
- have contact details of the prescriber e.g. name and telephone number

In all prescription writing the following should be noted:
- the name of the drug or preparation should be written in full using the generic name and
- no abbreviations should be used due to the risk of misinterpretation.
- Avoid unnecessary use of decimal points and only use where decimal points are unavoidable. A zero should be written in front of the decimal point where there is no other figure, e.g. 2 mg not 2.0 mg or 0.5 mL and not .5 mL