STANDARD TREATMENT GUIDELINES

A manual for medical therapeutics

5th Edition

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Editors
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Foreword

With great sense of satisfaction and pleasure, I am writing this foreword for the Fifth Edition of Standard Treatment Guidelines. Promoting Rational Use of Medicines is the raison d'etre of the Delhi Society for Promotion of Rational Use of Drugs (the Society). Since its inception in 1996, the Society has been developing tools for promoting Rational Use of Medicines, like amongst other things, development of (i) Essential Medicines List, (ii) Formulary and (iii) Standard Treatment Guidelines and assisting various State Governments in their implementation.

The first edition of the Standard Treatment Guidelines was brought out in 2002. Since then, DSPRUD has been regularly updating these guidelines to match with the therapeutic advances and is now in its fifth edition (2018). Since 2002, we have brought out several special editions of the Standard Treatment Guidelines, namely States of Rajasthan (two editions – first in 2006 and the second in 2012), Uttarakhand (2007), Haryana (2013) and Delhi (2014).

Increasingly, there is a greater acceptance from the community of clinicians to accept the STGs as a ready and convenient reference in their practice of medicine.

The editors – Dr. Sangeeta Sharma and Dr. G.R. Sethi – deserve our sincere appreciation for their sustained and painstaking efforts in bringing out this new edition.

We pay tribute to Professor Ranjit Roy Chaudhury and Professor Usha Gupta. Both were founders of DSPRUD for their immense contributions in fulfilling the objectives of DSPRUD.

R. Parameswar
President
Delhi Society for Promotion of Rational Use of Drugs

Preface

One of the most consistent findings in health services research is the gap between the best practice and the actual clinical practice. The best practices are not always implemented in care delivery, leading to huge variation in clinical practices. Standard Treatment Guidelines (STGs) have emerged as a very powerful tool to facilitate the application of research evidence into clinical practice and for promotion of rational use of medicines. STGs also serve as an important vehicle in assisting the doctor in decision making and providing the best treatment options for his/her patients. Healthcare professionals may have difficulties in keeping up to-date with the overwhelming and fast growing volume of new scientific evidence for good clinical practice, especially in resource poor settings. Sometimes, clinicians may be uncertain about which treatment options to use when research results or advice from experts are conflicting.

We thoroughly enjoy the creative journey of developing and updating the guidelines every 2-3 years for clinicians beyond business to propagate the science of drug safety and quality care for the cause of patient safety. We earnestly believe that it is the strong size of our readership with six special editions, four general editions and several reprints that has continuously motivated us to develop and update treatment guidelines based on strong evidence throughout these 15 years with the same level of enthusiasm we had when the first edition of the book was released in 2002. This edition of STGs has incorporated several changes by taking cognizance of therapeutic advances in the field and recommendations given in national disease control programmes such as TB, HIV, malaria, dengue, kala azar as well as asthma, migraine, hypertension, diabetes, stroke, acute kidney injury, chronic kidney disease and urinary tract infections; in addition, 18 priority diseases have been added such as sickle cell anaemia, thalassaemia, lung abscess, urethral injuries, retention of urine, adrenal insufficiency, Cushing's syndrome, sudden painless loss of vision, orofacial infections, potentially malignant oral lesions, myasthenia gravis, etc. Section on trauma has been rewritten to include first-aid, pre-hospital and in-hospital care of trauma patients etc. This edition has provided an algorithmic approach to treatment in many chapters, thus making the book more reader friendly, up to date and comprehensive and providing step-wise treatment along with criteria for assessment of response to therapy since step-down therapy is equally important step-up on stabilization of the patient's condition. The chapter on skin diseases has lot many pictures included to facilitate diagnosis of skin lesions.

These guidelines seek to summarise the treatment of patients presenting with priority diseases, however, need to be balanced with other information and in the context of each individual patient. The recommendations neither encroach on clinical flexibility nor replace clinical judgment, which must be tailored to the particular needs of each clinical situation. The unique feature of the book is the Patient Education section for each disease section

which is meant to empower the patients and the doctors equally so that they are in a better position to take informed decisions.

This book serves as a ready reference for healthcare providers and supply management staff. We hope that this updated edition would be useful to the clinicians in providing a standardized care to patients, reducing inappropriate variation in practice, thereby improving patient safety and patient outcomes and promoting cost-effective and quality care.

We would like to place on record the support we received from all contributors and reviewers who lent their time and expertise towards the preparation and review, and suggestions from readers are welcome. Suggestions can be sent by email at dsprud2005@yahoo.com.

We pay tribute to both Professor Ranjit Roy Chaudhury and Professor Usha Gupta for their immense contributions to not only bring out this publication but also for their vision and contribution in health and giving shape and substance to fulfill the objectives of DSPRUD.

Sangeeta Sharma
G R Sethi

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GUIDELINES DEVELOPMENT METHODOLOGY

Need for Standard Treatment Guidelines (STGs)

This book is an attempt to give guidelines/protocols for management of common/priority diseases, to deliver best quality of care and for promotion of rational use of medicines by reducing inappropriate clinical variation in practice and discouraging ineffective—or potentially harmful—interventions. These guidelines especially assist the clinicians in making decisions when they may be uncertain about which treatment options to use when research results or advices from experts are conflicting. Also it aims to provide invaluable assistance to all practitioners, especially those with lower skill levels for critical appraisal of research findings, yet remain up to date for good clinical practice.

Methodology used

High-quality guidelines are used internationally to inform and improve quality care for respective diseases produced by various organizations, including national agencies, intergovernmental organizations and professional bodies or specialist medical societies. The process of developing de-novo guidelines though is well defined but is more complex than is generally recognized. Considering the diverse nature of India, its population size and socio-cultural characteristics, and health care being a state subject, it is required that each state develops its own guidelines depending on its morbidity pattern and local requirements. Developing STGs for each state afresh may be an expensive waste of time, effort and money as the process of development is complicated and lengthy. Further if guidelines are not developed properly reflecting existing inappropriate practices, it carries a risk due to supply of wrong information to prescribers, thus doing more harm than good since expertise to interpret scientific evidence may not be available at the local level. Also STGs may generate considerable differences of opinion among prescribers, and managing consensus is difficult and time consuming carrying a potential danger of non-completion of the project, as in our experience only a few of the STGs were completed and updated from time to time and widely accepted. Hence for successful guidelines there is a need for sufficient resources in terms of time and people with a wide range of skills, including expert clinicians, health service researchers and financial support. The end product is a starting point for performance improvement.

For crafting a valid and action-ready product, Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) developed STGs for about 330 priority diseases using the existing guidelines as a starting point. The guidelines were identified by a computerized search of the national guideline clearing house, MEDLINE database (peer-reviewed medical literature) as well as guidelines produced by the national professional societies. Retrieved documents were considered guidelines if they met the definition of a guideline as proposed by the Institute of Medicine (IOM). While examining the existing guidelines, quality assessment was done using an Appraisal of Guidelines for Research and Evaluation (AGREE) tool. We excluded articles on diagnostic criteria or technical standards, guidelines on research methods, review articles and any secondary publications of the guideline.

These guidelines present current context-specific clinical recommendations by adopting and adapting available good quality guidelines to suit the local needs for treatment keeping in view the feasibility issues such as time, skills, staff and equipment necessary for the healthcare providers to implement them. Wherever adaptation was required for the Indian context, conditional recommendations were made balancing pragmatism with developmental rigor. Since conclusive evidence exists for relatively few healthcare problems, deriving recommendations solely in areas of strong evidence would lead to a guideline of limited scope or applicability as patients have to be treated holistically. The evidence also needs to be interpreted into a clinical, public health, policy or payment context. Therefore, wherever no guideline could be identified that contains evidence from high-quality studies or were inconclusive or do not answer a particular question, recommendations were based upon a consensus opinion by experienced clinicians based on their vast clinical observations. Adequate discussion of the evidence or its absence while developing the recommendations in the guideline was ensured. Strengths of the STG development process were a participatory approach involving end-users and a sufficiently large group of doctors from different disciplines from various levels of health care.

This publication is designed as a summary to serve as a ready reckoner for busy clinicians by using carefully summarized scientific data in an easy-to-understand format. The recommendations in this document though are evidence-based, they do not reference the supporting published studies nor list classes of recommendation or levels of evidence for each recommendation; however, key source references from where recommendations have been drawn are listed at the end of the section. References on strong evidence and on original data were preferred. Anecdotal data or individual's preferences were not considered. There may be limitations in this approach, especially when recommendations are needed for a particular clinical problem on which scant or no original data is available, particularly in the Indian context. In such cases, it was necessary to rely on less-qualified references with a low grading or expert consensus. The principles embodied in the guidelines are to help to define 'good' practice and ultimately lead to better standards of care for patients, even if they do not meet all standards of the guideline development process simultaneously.

Cost is a consideration while selecting recommendations on various treatment options and drug choices; however, explicit cost-effectiveness analyses were not conducted.

This special edition is an update of the previous document developed by DSPRUD in 2015 which has been subjected to wide review by almost 150 reviewers till date. It is felt because of the extensive peer review process, these guidelines could most legitimately be held accountable to methodological criteria.

Disclosures and management of conflicts of interest. Everyone who was intellectually involved in the project (i.e. considered for guideline authorship) had no conflict of interest.

Scope and target audience. Given the large number of potential areas, some priority setting is needed to select an area for guideline development. These guidelines seek to summarize the treatment of patients presenting with priority diseases. The diseases for inclusion in the guidelines were prioritized keeping in mind the following and were finalized by a dialogue among clinicians and the potential users:

- Major causes of morbidity and mortality for a given population
- Uncertainty about the appropriateness of healthcare processes as evidenced by a wide variation in clinical practice and service delivery
- Evidence that they are effective in improving patient outcomes
- The need to conserve resources in providing care

The target audience or groups include both healthcare professionals and service providers from all levels of health care from primary to tertiary care. These guidelines cater to all age groups and patient populations in major specialities. Although conditions at health facilities may vary from health facility to health facility, we have used the premise that facilities appropriate to the level of health care exist. In case appropriate facilities in terms of adequate trained personnel or infrastructure are not available, this document still aims to serve as an aid to the treating physician to stabilize the patient and take timely action for referral to a higher level facility.

These guidelines attempt to meet the needs of most patients in most circumstances and make suggestions intended to apply to an average patient in each group. However, these do not focus on atypical presentation or exceptional cases. It is assumed that the patient has been fully evaluated, diagnosis has been made and all co-morbidities disorders and other medical factors that may affect the diagnosis or treatment of the patient have been identified. Although guidelines provide a preferred approach to the diagnostic, therapeutic and preventive aspects of care, they do not address details related to diagnosis of a particular disease, surgical intervention or physical therapy, assuming that the clinician using these guidelines is familiar with assessment and diagnostic issues.

Treatment of the patient involves a holistic approach and requires the expertise of the treating physician in formulating a treatment plan. Since patients differ greatly in their presentation, treatment preference and history of response to previous treatment, and tolerance for different side effects, first-line recommendations in the guidelines may not be appropriate in all circumstances; therefore, several alternatives or choices have been suggested to meet the individual patient's requirements. The ultimate judgment regarding care of a particular patient must be made by the clinician in light of all the

circumstances presented by that patient. As a result, sometimes situations may arise for which deviations from these guidelines may be appropriate.

FORMAT OF THE BOOK

Chapters. The book is divided into 20 chapters. The first two chapters deal with general diseases and emergencies which may be common to all specialties. The aim is to provide complete step-wise management of the commonly encountered diseases and emergency cases with clear instructions for referral (when, where and how) to a higher centre with facilities for appropriate management. The rest of the chapters deal with common diseases in each specialty, namely medicine, ENT, eye, skin, obstetrics and gynaecology, psychiatry, orthopaedics, surgery, paediatrics and dentistry. There is a separate paediatric section which describes treatment of diseases which are specifically encountered in this age group or requires specific monitoring. For other diseases, the doses or special requirements of the paediatric patients are described in the respective sections.

Generally, the text is given in telegraphic language and the rationale for a particular choice of drug or modality of treatment is not mentioned. Details of a treatment are described at one place only and if a particular treatment needed is mentioned at several places, e.g. fever, shock, pain relief, then in that case details are given in one section with a note 'for details, see relevant section'.

Sections. The format of guidelines is such that it gives only few salient features of the disease and important diagnostic tests followed by non-pharmacological and pharmacological treatment. Non-pharmacological treatment, being an important aspect, has been described very clearly. Pharmacological treatment includes instructions on drug use, special precautions and warnings related to therapy. Assessment of response to therapy and key assessment indicators (signs/symptoms, investigations, etc.) with the monitoring interval are also incorporated. The guidelines mention the aim of therapy and in the case of no response to the preferred treatment, step-up therapy or referral to a higher centre with appropriate facilities for care is recommended. Also mention step-down therapy wherever relevant.

Selection of medicines. Medicines have been selected from the National Essential Medicines List as far as possible, based on balanced criteria of efficacy, safety, suitability, availability and cost.

Drugs are mentioned in generic names only. Combination drugs are not included in the treatment except for some topical preparation, e.g. in eye, ENT and skin preparations. These combinations were selected on the basis of appropriate ingredients and availability in the market.

Several choices/options are provided to provide flexibility to the prescribers. Wherever drug choices are given for the treatment of a disease, they are listed in order of their preference. However, when several equi-efficacious alternatives are available, choices are limited to 2-3 choices to facilitate supply management. The guidelines specifically differentiate between step-up and combination therapy. Drug choices are demarcated by 'Or'. If several drugs are required concomitantly for treatment, they are

mentioned as 1, 2, 3 and so on. Only drugs with the best available evidence in support are listed in the text.

Use of a particular drug, if not supported by a good acceptable level of evidence or is obsolete but still prescribed, is not listed in the text. Drug dose is given as a range and wherever required in per kilogram dose with maximum tolerated dose. The frequency, route and special precautions are mentioned very clearly.

Step-up and step-down therapy. Substantial high costs are associated with unnecessary medications and failure to step down after achieving control and continuing patients on unnecessary medicines. Step-down (a staged reduction in the dose and agents) is as important as step-up therapy.

This document describes modification of treatment after assessment of the response step-up and step-down. This document differentiates between step-up and combination therapy. For example, in hypertension the 'steps' begin with one of the ACE inhibitors, ARB, diuretic or beta blocker for patients with mild hypertension to a combination, if BP not is not controlled; hydralazine, prazosin, minoxidil, nitroprusside for hypertensive crisis/emergencies and step-down (a staged reduction in dose or agents) once blood pressure is controlled.

Empowerment of providers and patients. A special feature of the guidelines is a '***section on patient education***' since no treatment is complete without a good communication with the patient. This includes in details the aims to empower the patient by providing information about the nature and duration of the illness, prognosis and natural course of the disease, preventive measures, duration of therapy and follow-up with precautions and important side effects which might interfere with the treatment.

The relative explosion in the volume and complexity of research data has made it increasingly difficult for healthcare professionals to assimilate new important findings into daily practice and communication with the patients and families about crucial information necessary for patients' care. On one hand there is an ever growing need for patients and families to have more information about, and involvement in, care decisions whereas on the other hand today's health care environment makes good communication among patients, families, and caregivers harder and harder to achieve because of less consultation time, complexity of medical care and meagre resources.

We have relied on expert opinion precisely because we are asking crucial questions that are not very well answered in the literature. One thing that the history of medicine teaches us is that expert opinion at any given time can be very wrong. Accumulating research will ultimately reveal better and clearer answers. Clinicians should therefore stay abreast of the literature for developments. We will continue to revise the guidelines periodically based on new research information and on reassessment of expert opinion to keep them up to date.

No set of guidelines can ever improve practice if read just once. These guidelines are meant to be used in an ongoing way, since each patient's status and phases of illness will require different interventions at different times. We believe the guideline recommendations will reinforce your best judgment when you are in a familiar territory and help you with new suggestions when you are in a quandary.

The Concept of Essential Medicines

Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations. Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines (including improved quality of prescribed medicines) and more cost-effective use of health resources.

The lists of essential medicines closely relate to guidelines for clinical healthcare practice, which are used for the training and supervision of health professionals. Lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations and local medicine production.

Selection criteria

The choice of essential medicines depends on several factors, including the public health relevance, and sound and adequate data on the *efficacy, safety, suitability and comparative cost-effectiveness of available treatments*. Stability of a dosage form/pharmaceutical preparation in various conditions, the need for special diagnostic or treatment facilities and pharmacokinetic properties are also considered in selecting medicines for treatment, if appropriate.

Most essential medicines should be formulated as single compounds. Fixed-ratio combination products are selected only when the combination has a proven advantage in therapeutic effect, safety or compliance over single compounds administered separately.

In cost comparisons between medicines, the cost of the total treatment, and not just the unit cost of the medicine, is considered. Cost and cost-effectiveness comparisons may be made among alternative treatments within the same therapeutic group, but generally should not be made across therapeutic categories (e.g. between treatment of tuberculosis and treatment of malaria). The patent status of a medicine is not considered in selecting medicines for the List. Other factors which are also considered include local demography and pattern of disease, treatment facilities, training and experience of the

available personnel, local availability of individual pharmaceutical products, financial resources and environmental factors.

Quality of products

Priority is given to ensuring that available medicines have been made according to good manufacturing practices and are of assured quality. It is recommended that medicines be purchased from known manufacturers, their duly accredited agents or recognized international agencies known to apply high standards in selecting their suppliers.

STANDARD TREATMENT GUIDELINES

The terms *standard treatment guidelines*, *treatment protocols* and *prescribing policies* are all used to indicate systematically developed statements to help practitioners or prescribers make decisions about appropriate treatments for specific clinical conditions. Treatment guidelines exist for different levels of health care, ranging from general prescribing guidelines for rural areas to detailed protocols for tertiary healthcare centres.

Advantages

Standard guidelines benefit health officials, supply management staff, healthcare providers and patients. Their development is a good opportunity to integrate the technical advices of different disease programmes into an overall training programme. Treatment guidelines should be used as the basis for undergraduate medical and paramedical training, for in-service training, for supervision and for medical audit to assess and compare quality of care. For Health Care Managers, it provides expert consensus on most effective, economical treatment for a specific setting and gives opportunity to the healthcare providers to concentrate on correct diagnosis. For patients, it offers and encourages adherence to treatment through consistency among prescribers, provision of most cost-effective treatments, improvement in availability of drugs and better treatment outcome.

Key features

Simplicity. The number of health problems is limited and for each health problem a few key diagnostic criteria are listed. Drug and dosage information is clear and concise.

Credibility. Guidelines developed by the most respected clinicians in the country and revisions based on actual experience.

Use of the same standard for all levels of health care. Doctors and other healthcare providers use the same standard treatment as it is a referral criterion which differs, and the first-choice treatment for a patient depends on the patient's diagnosis and condition – not on the prescriber.

Provision of standards to drug supply. Most importantly, drug supply should be matched to the recommended treatments and drugs on the list of essential drugs.

Regular updating. As bacterial resistance patterns change or other factors alter therapeutic preferences, the standards are revised to reflect current recommendations.

RATIONAL PRESCRIBING AND PRESCRIPTION WRITING

Once a patient with a clinical problem has been evaluated and a diagnosis has been reached, the practitioner can often select from a variety of therapeutic approaches. Medication, surgery, psychiatric treatment, physical therapy, health education, counselling, further consultation and no therapy are some of the options available. Of these options, drug therapy is by far the most commonly chosen. Drugs should only be prescribed when they are necessary, and in all cases the benefit of administering the medicine should be considered in relation to the risks involved. Bad prescribing habits lead to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient and higher cost. Like any other process in medicine, writing a prescription should be based on a series of rational steps. The following steps will help to remind the prescriber of the rational approach to therapeutics:

1. **Define the patient's problem.** Whenever possible, making the right diagnosis is based on integrating many pieces of information: the complaint as described by the patient, a detailed history, physical examination, laboratory tests, X-rays and other investigations. This will help in rational prescribing, always bearing in mind that diseases are evolutionary processes.
2. **Specify the therapeutic objective.** Doctors must clearly state their therapeutic objectives based on the pathophysiology underlying the clinical situation. Very often, physicians select more than one therapeutic goal for each patient.
3. **Selecting therapeutic strategies.** The selected strategy should be agreed with the patient; this agreement on outcome, and how it may be achieved, is termed *concordance*. The selected treatment can be non-pharmacological and/or pharmacological; it also needs to take into account the total cost of all therapeutic options.

Non-pharmacological treatment

It is very important to bear in mind that the patient does not always need a drug for treatment of the condition. Very often, health problems can be resolved by a change in lifestyle or diet, use of physiotherapy or exercise, provision of adequate psychological support and other non-pharmacological treatments; these have the same importance as a prescription drug and instructions must be written, explained and monitored in the same way.

Pharmacological treatment

i. **Selecting the correct group of drug.** Knowledge about the pathophysiology involved in the clinical situation of each patient and the pharmacodynamics of the chosen group of drugs are two of the fundamental principles for rational therapeutics.
ii. **Selecting the drug from the chosen group.** The selection process must consider benefit/risk/cost information. This step is based on evidence about the maximal clinical benefit of the drug for a given indication (efficacy) with the minimum production of adverse effects (safety). In cost comparisons between

drugs, the cost of the total treatment and not just the unit cost of the drug must be considered.

iii. **Verifying the suitability of the chosen pharmaceutical treatment for each patient.** The prescriber must check whether the active substance chosen, its dosage form, standard dosage schedule and standard duration of treatment are suitable for each patient. Drug treatment should be individualized to the needs of each patient.

iv. **Prescription writing.** The prescription is the link between the prescriber, the pharmacist (or dispenser) and the patient, and it is a medicolegal document. While a prescription can be written on any piece of paper (as long as all of the legal elements are present), it usually takes a specific form. This item is covered in more detail in the following section.

v. **Giving information, instructions and warning.** This step is important to ensure patient adherence and is covered in detail in the following section.

vi. **Monitoring treatment.** Evaluation of the follow-up and the outcome of treatment to allow the stopping of it (if the patient's problem is solved) or to reformulate it when necessary. Also, this step gives rise to important information about the effects of drugs contributing to building up the body of knowledge of pharmacovigilance, needed to promote the rational use of drugs.

PRESCRIPTION WRITING

A prescription is an instruction from a prescriber to a dispenser. All prescriptions orders should be legible, unambiguous, dated (and time in the case of chart order) and signed clearly for optimal communication between prescriber, pharmacist and nurse. A good prescription or chart order should contain sufficient information to permit the pharmacist or nurse to discover possible errors before the drug is dispensed or administered. The prescriber is not always a doctor but can also be a paramedical worker, such as a medical assistant, a midwife or a nurse. The dispenser is not always a pharmacist, but can be a pharmacy technician, an assistant or a nurse. The following guidelines will help to ensure that prescriptions are correctly interpreted and leave no doubt about the intention of the prescriber.

Prescription form

The most important requirement is that the prescription be clear. It should be legible and indicate precisely what should be given. The local language is preferred.

The following details should be shown on the form:

i. The prescriber's name, address and telephone number. This will allow either the patient or the dispenser to contact the prescriber for any clarification or potential problem with the prescription.

ii. Specific areas for filling in details about the patient including name, address and age.

iii. Date of the prescription.

iv. Name, form, strength of the drug and duration of treatment. The International Nonproprietary name of the drug should always be used. If there is a specific reason to

prescribe a special brand, the trade name can be added. The pharmaceutical form (e.g. 'tablet', 'oral solution', 'eye ointment') should also be stated.

v. ***Directions***

Although directions for use are no longer written in Latin, many Latin apothecary abbreviations are still in use. Knowledge of these abbreviations (Table 1) is essential for the dispensing pharmacist and often useful for the prescriber.

Directions specifying the route, dose and frequency should be clear and explicit; use of phrases such as 'take as directed' or 'take as before' should be avoided.

For preparations which are to be taken on an 'as required' basis, the minimum dose interval should be stated together with, where relevant, the maximum daily dose. It is good practice to qualify such prescriptions with the purpose of the medication (e.g. 'every 6 hours as required for pain' or 'at night as required to sleep').

It is a good practice to explain the directions to the patient; these directions should then be reinforced by the label on the medicinal product and possibly by appropriate counselling by the dispenser.

Quantity to be dispensed

The quantity of the medicinal product to be supplied should be stated such that it is not confused with either the strength of the product or the dosage directions. Alternatively, the length of the treatment course may be stated (e.g. 'for 5 days'). Whenever possible, the quantity should be adjusted to match the pack sizes available.

For liquid preparations, the quantity should be stated in millilitres (abbreviated as 'ml') or litres (abbreviated as 'L', since the letter 'l' could be confused with the figure '1').

Table 1. Commonly used Latin apothecary abbreviations and their explanations.

Abbreviation	Explanation	Abbreviation	Explanation
ac	before	qd	every day
bid	twice a day	qh, q1h	every hour
dil	dilute	qid	four times a day
Disp, dis	dispense	Qs	sufficient quantity
gr	grain	Rx	take
gtt	drops	sos	if needed
hs	at bedtime	stat	at once
OD	right eye	Tbsp, T	tablespoon (always write out '15 ml')
prn	when needed	tid	three times a day
q	every	tsp	teaspoon (always write out '5 ml')
Qam, om	every morning	U	units (always write out 'units')

The abbreviation 'OD' should be used (if at all) only to mean 'the right eye'; it has been used for 'every day' and has caused inappropriate administration of drugs into the eye.

Narcotics and controlled substances

The prescribing of a medicinal product that is liable to abuse requires special attention and may be subject to specific statutory requirements. Practitioners may need to be authorized to prescribe controlled substances; in such cases, it might be necessary to indicate details of the authority on the prescription.

In particular, the strength, directions and the quantity of the controlled substance to be dispensed should be stated clearly, with all quantities written in words as well as in figures to prevent alteration. Other details such as patient particulars and date should also be filled in carefully to avoid alteration and unauthorized refills.

MEDICATION ERRORS' REPORTING, ANALYSIS AND STRATEGIES FOR PREVENTION

Every step in patient care involves a potential for error and some degree of risk to patient safety. Errors in ambulatory and ICU prescribing are a major public health problem. On average, more than one medication error each day is expected. The complexity of the modern healthcare systems presents a unique challenge in delivering care of the required quality in a safe environment across a large organization. Reducing or eliminating harm to patients is the real key to patient safety. Medication error can occur in the process of ordering, transcribing, dispensing, administering and monitoring of medication. A medication error may or may not result in an actual adverse drug event.

Who is at most risk?

1. Polypharmacy and irrational use of medicines: Polypharmacy is the largest risk factor, which on one hand increases the chance of adverse drug reactions and on the other hand makes it vulnerable to medication errors.
2. Look-Alike, Sound-Alike (LASA) combinations: The existence of confusing drug names is one of the most common causes of medication error and is of concern worldwide. This includes confusion between non-proprietary names and proprietary (brand or trademarked) names. Many drug names look or sound like other drug names, e.g. Daonil (Glibenclamide), Duodil (chlorzoxazone) and Diovol (antacid). Contributing further to this confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labelling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments prior to approving new product names. In this situation, errors are best avoided by noting the indication for the drug in the body of the prescription, e.g. 'Daonil (Glibenclamide), for diabetes'.
3. Use of abbreviations for drug names: Acronyms such as ASA (aspirin), 5-ASA(5-Aminosalicylic acid), PCM (paracetamol), CPM (chlorpheniramine), CPZ (chlorpromazine), CBZ (Carbamazepine), THP (Trihexyphenidyl) and TFP (Trifluoperazine), etc., again are an important source of errors. Moreover, prescription is a medicolegal document, and these acronyms are not standard abbreviations used by

all and may be interpreted differently, e.g. MS (Magnesium sulphate Or Morphine Sulphate). Full drug name should be written out.

4. Use of error-prone abbreviations, symbols and dose designations (Table 2).
5. Errors due to Mixups: between 'l' and the number '1'; 'O' & '0,'; 'Z' & '2,'; '1' & '7.' For example, Q1d can easily be mistaken for QID leading to four times the dose and hand-written 'U' could easily be interpreted as '0 or 4'. Therefore, always write 'Unit'.

Table 2. Error-prone abbreviations, symbols and dose designations.

Abbr	Intended meaning	Misinterpretation	Abbr	Intended meaning	Misinterpretation
@	at	2	1.0 ml	1 ml	10 ml
+	Plus/and	4	.5 mg	0.5 mg	5 mg
^{0}	hour	0 ($q2^0$ seen as q 20)	100000 units	100,000	1000000
IJ	injection	IV	U or u	Unit	0/4
IU	International units	IV	X3d	For 3 days	3 doses
OD	Once daily	Right eye	q1d	daily	4 times daily
10 mg		1 if written poorly	qhs	Nightly at bed time	Qhr or every hour

Avoid decimals whenever possible. Do not write naked or trailing decimal ('.5' or '1.0'). If unavoidable, a zero should be written in front of the decimal point (e.g. '0.5').

Give space between drug and strength as no space between drug and strength may be misread (e.g. Tegretol300 mg can be misread as Tegretol 1300 mg).

Do NOT use symbols/abbreviations

- The symbols '>' and '<'
- Do not abbreviate 'microgram' and 'nanogram' since the abbreviated form 'µg' is very easily misread as 'mg', a 1000-fold overdose. The strength of the drug should be stated in standard units using abbreviations that are consistent with the System Internationale (SI).
- Do not abbreviate 'units' as U since handwritten abbreviated form ('U') is very easily misread as '0 or 4'.
- Use of non-standard abbreviations 'D/C' for discontinue/discharge/death certificate, 'TCA' for to come again, 'CST' for continue same treatment, or discontinue 1, 2, 5, rest to continue, etc.

6. **Patients receiving high-alert medications:** High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are clearly more devastating to patients, e.g. concentrated electrolytes, neuromuscular blocking agents, adrenergic agents, insulin, heparin, warfarin, narcotics etc.

Drugs more likely to be involved in serious medication errors are:

- Adrenergic agonists (e.g. epinephrine, phenylephrine, norepinephrine)
- IV adrenergic antagonists (e.g. propranolol, metoprolol, labetalol)
- Antithrombotic agents and Anticoagulants including warfarin, low-molecular-weight heparin, IV unfractionated heparin, Factor Xa inhibitors (fondaparinux), direct thrombin inhibitors (e.g. argatroban, lepirudin, bivalirudin), thrombolytics (e.g. alteplase, reteplase, tenecteplase) and glycoprotein IIb/IIIa inhibitors (e.g. eptifibatide)
- Chemotherapeutic agents
- Chloral hydrate/midazolam
- Dextrose, hypertonic, 20% or greater, Concentrated electrolytes
- Hypoglycaemic agents and Insulin
- Inotropic medications, IV (e.g. digoxin, milrinone)
- Anaesthetic agents, general, inhaled and IV (e.g. propofol, ketamine)
- Neuromuscular blocking agents (e.g. succinylcholine, rocuronium, vecuronium)
- Opiates IV, transdermal, and oral (including liquid concentrates, immediate and sustained-release formulations)
- Theophylline
- Radio-contrast agents IV

7. **Patients receiving high-risk medicines:** These are medicines that present a high risk when administered by the wrong route or when other system errors occur and are involved in a high percentage of medication errors/sentinel events/high risk for abuse, error or other adverse outcomes, e.g. medications with a low therapeutic index (lithium, digoxin, phenytoin, carbamazepine, valproic acid, phenobarbitone), controlled substances, psychotherapeutic medications and look-alike, sound-alike (LASA) medicines.

Patient Safety Solutions

- Optimize the medication process
- Simplify – understanding of roles and routines
- Reduce reliance on memory
- Medication reconciliation
- Identify and prepare a list of high alert, high risk and LASA for your hospital or practice and display prominently at all clinical care locations. This list is used to determine which medications require special safeguards to reduce the risk of errors. This may include strategies such as separate storage at different locations
- Eliminate LASA or limit the number of dosage forms
- Develop a policy for verbal orders
- Employing independent double-checks when necessary, etc., improving access to information about these drugs
- Control or limiting access to high-alert medications, using auxiliary labels and automated alerts, standardizing the order, e.g. no issue of concentrated electrolytes to in-patient care units except operation theatres or ICUs

- Utilizing technology such as computerized physician order entry (CPOE) and clinical decision support, error proofing and bar code technology
- Oversight and error interception

Safety event reporting and learning

A good way to learn from medication errors is to establish a voluntary reporting system for adverse events (both sentinel events and near-misses) which provides data that leads to improved patient safety. There is generally under-reporting and what is reported is often the tip of the iceberg.

In order to create learning systems, sufficient attention must be given to analyzing and understanding the causes of errors (critical incident analysis) – whether or not the event actually leads to a bad outcome. This critical incident analysis examines adverse events to understand where the system broke down, why the incident occurred and the circumstances surrounding the incident.

Feedback and dissemination of information creates an awareness of errors that occur in the system and help in improve system design to reduce or eliminate medication errors. Healthcare organizations and health professionals should be encouraged to participate in voluntary reporting systems as an important component of their commitment to patient safety.

Building safer health systems: from blame to opportunity

The common reaction when errors happen is to blame and shame and punish individuals (e.g. firing or suing them). The problem with patient safety is not bad professionals in health care, but bad systems that need to be made safer. Blaming is not an effective way to prevent recurrence except in some cases (e.g. reckless behaviour/deliberate negligence).

It is unlikely that errors happen due to a single act by a healthcare provider and blaming an individual does not address the underlying risk factors. Analyze and understand the causes of errors in order to create learning systems and improve patient safety.

Abbreviations Used

General

ABG = arterial blood gas
AFB = acid-fast bacilli
AFP = acute flaccid paralysis
APH = antepartum haemorrhage
ART = antiretroviral therapy
ASOM = acute suppurative otitis media
ATT = antitubercular therapy
BP = blood pressure
CBC = complete blood count
CCF = congestive cardiac failure
CNS = central nervous system
COAD = chronic obstructive airway diseases
CPAP = continuous positive airway pressure
CPR = cardiopulmonary resuscitation
CSF = cerebrospinal fluid
CSOM = chronic suppurative otitis media
CVP = central venous pressure
DUB = dysfunctional uterine bleeding
EEG = electroencephalogram
ERCP = endoscopic retrograde cholangio-pancreatography
FNAC = fine needle aspiration cytology
GERD = gastroesophageal reflux disease
GIT = gastrointestinal tract
Hct = haematocrit
HR = heart rate
INR = international normalized ratio
JVP = jugular venous pressure
KFT = kidney function test
LFT = liver function test
MCH = maternal-child health
MTP = medical termination of pregnancy
Mo/mth = month
NSAIDs = nonsteroidal anti-inflammatory drugs
OCD = obsessive compulsive disorder
ORS = oral rehydration salts
ORT = oral rehydration therapy
PEEP = peak end expiratory pressure
PCR = polymerase chain reaction
PCWP = pulmonary capillary wedge pressure
PEFR = peak expiratory flow rate
PFT = pulmonary function test
PID = pelvic inflammatory disease
PPH = postpartum haemorrhage
PMS = premenstrual syndrome

PUO = pyrexia of unknown origin
RAP = recurrent abdominal pain
RBBB = right bundal branch block
RBC = red blood cell
RR = species
STD = sexually transmitted disease
USG = ultrasonogram
WBC = white blood cells
Wt = weight

Units

µg/mcg = microgram
g = gram
IU = international units
kg = kilogram
mg = milligram
min = minutes
h = hours

Routes

IM = intramuscular
IV = intravenous
PO = per oral
PR = per rectum
PV = per vaginum
SC = subcutaneous