

Standard Treatment Guidelines in Primary Healthcare Practice

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ABSTRACT

In India, healthcare delivery is implemented at primary, secondary and tertiary levels. Of these, primary health care is the essential health care and is the first point of care for the public across the country. The primary health care system caters to nearly 70% of the population by treating about 90% of the common and locally prevailing problems. One of the integral elements of primary health care is provision of essential medicines, which should be available at all times in adequate amounts in appropriate dosage forms and at an affordable cost. It has an important bearing on the medical, economical and social outcomes of the healthcare delivery system. This situation mandates the need for rational use of medicines by standardizing the treatment of commonly occurring illness at the primary health care level. Standard Treatment Guidelines (STGs) have been in vogue in India only since recent times and is gaining popularity among practitioners. STGs have many advantages for the patients, healthcare providers, drug manufacturers and marketing agencies, and above all, the policy makers and the legislative system of the country. The drawback in STGs lies in the difficulties in implementation on a large scale. With due efforts to prioritize the health needs, comprehensive coverage of national health programs involving all the stakeholders including professional organizations, undergraduate medical curriculum planners and medical practitioners, STGs can be implemented effectively and thereby we can ensure a quality health care at the primary care level at an affordable cost as part of the now redefined Universal Health Coverage. This article is intended as a guide to understand the concept of STGs, prepared with the aim of capacity building for medical professionals in rationally treating patients in their day-to-day clinical practice.

Keywords: Essential medicines, rational use of medicines, standard treatments

Introduction

The healthcare delivery in India is carried out through a network of primary, secondary and tertiary care centers. Primary health care caters to nearly 70% of the population and is concentrated on the rural, hilly and tribal areas of the country. As per the Alma-Ata declaration of 1978, appropriate treatment of commonly occurring diseases and injuries and provision of essential drugs are the two vital components of primary healthcare concept.^[1]

As per the WHO Expert Committee, essential drugs are those drugs that satisfy the healthcare needs of the majority of the population; they should therefore, be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford.^[2] It is found that there are more than

60,000 drug formulations available in the Indian drug market.^[3] However, 90% of the commonly prevalent diseases can be treated with about 10% of drugs available. There are medical, economic, social, and administrative advantages in popularizing the concept of essential drugs.^[4]

The concept of rational use of drugs means reasonable or sensible use of drugs and is defined as appropriate use of drugs, when it is really needed, in appropriate strength, dosage, and duration, which will have a beneficial effect on the individual. "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community." (WHO 1985)^[5] Requirements for rational use of drugs will be fulfilled, if the process of prescribing is appropriately followed, like defining the patients problems (diagnosis), defining effective and safe treatment, selecting appropriate drugs, dosage, and duration, writing a good prescription, giving patients adequate information,

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and planning to evaluate [monitor] treatment responses.^[6] Bad prescribing practices leads to ineffective and unsafe treatment, exacerbation or prolongation of illness, distress and harm to the patient at a higher cost.

Undergraduate medical education in India is oriented toward training of medical students to undertake the responsibilities of a primary healthcare physician. Clinical training for medical students often focuses on diagnostic, rather than therapeutic skills. They are not often taught how to properly prescribe a drug for their patient's benefit and also the advantages of essential medicines and rational use of medicines.^[7]

In recent times Governments are giving more emphasize on propagating the concept of Essential Medicines and Rational Use of Medicines, by various means. The concept of Standard Treatment Guidelines (STGs) for commonly occurring illnesses treatable at primary healthcare level is gaining acceptance in improving the quality and uniformity of medical care. Its popularization and acceptance will help medical practitioners to plan and prescribe medicines appropriately and rationally to treat or cure the illnesses with minimum expenses and minimum use of medicines.

Primary Health Care

As per our constitution, health has been declared a fundamental human right. This implies that the State has a responsibility for the health of its people. Therefore, health care is a public right and it is the responsibility of the governments to provide this care to all people in equal measure. In this regard, the health services are designed to meet the health needs of the community through the use of available knowledge and resources. The healthcare system in India has undergone several changes in its core structure starting from provision of 'comprehensive health care' as per recommendations of Bhole Committee in 1946, to provision of 'basic health services' in 1965 as per UNICEF/WHO joint health policy, to provision of 'primary health care' as per Alma-Ata declaration in 1978. It is now fully realized that the best way to provide health care to the population is through primary health care and the social policy was formulated to build up health systems based on primary health care toward the objective of Health for All by 2000 A.D. Accordingly, primary health care was defined as *"the essential health care made universally accessible to individuals and acceptable to them, through their full participation and at a cost the community and country can afford"*.^[8]

Primary health care stands on four pillared principles namely equitable distribution, community participation, inter-sectoral coordination and appropriate technology. The implementation of primary health care is carried out through eight service elements which cover the essential components of health care services. This concept has been redefined today as Universal Health Coverage. The goal of Universal Health Coverage is to ensure that all people get affordable, accountable and appropriate health services of assured quality they need without suffering financial

hardships. While a key element of primary health care is provision of essential medicines, an important aspect of realizing universal coverage is providing access to essential medicines, vaccines and medical technologies.^[9,10] In all, it has been widely accepted that availability, accessibility and affordability of essential medicines is a main component of a healthcare system.

Standard clinical guidelines

In developed countries like the United States of America, Europe and the United Kingdom, the concept of Clinical Guidelines has been in vogue for years. Clinical guidelines have been developed based on the clinical diagnostic criteria, therapeutic practice guidelines and guidelines for management of diseases. Clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions and are based on the best available evidence and helps healthcare professionals in their work, but they do not replace their knowledge and skills. Good clinical guidelines aim to improve the quality of healthcare and they can change the process of healthcare and improve people's chances of getting as well as possible.^[11]

An analysis of a random sample of clinical practice guidelines as prescribed by the American Institute of Medicine Standards and archived on the NGC website demonstrated poor compliance with Institute of Medicine standards, with little if any improvement over the past two decades indicating a failure of clinical practices guidelines in the US when compared to the NICE Clinical guidelines in UK.^[12] So the Standard Clinical Guidelines practiced in countries like the NHS in UK, is a greater challenge for our existing system to implement at present. In India, the clinical guidelines do exist and are based on National Health Programs which provide clear guidelines for diagnosis, treatment and therapeutic guidelines for individual diseases addressed by the programs. Thus, creating awareness about Standard Treatment Guidelines and its implementation is the first priority in streamlining the primary healthcare delivery system in our country at present.

Standard treatment guidelines

Essential medicines are those that satisfy the priority health needs of a population. They are selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost effectiveness. The implementation of the concept of essential medicines is intended to be flexible and adaptable to specific situations and provision of these essential medicines has been recognized as an important responsibility of the country.^[13] While on one hand, provision of essential medicines has its own demands and challenges, the other major challenge is the rationale behind the use of these essential medicines. In order to achieve this, STGs have been formulated to minimize the erroneous use of these essential medicines.

Standard Treatment Guidelines have existed for as long as the art of healing has existed. Traditional healers developed

their standard set of cures and passed them from generation to generation by word of mouth or in writings. In modern medicine, there is a definite thinking that there may be more than one treatment modality available for many medical conditions. This leads to confusion and, in many cases, incorrect choice of treatment. STGs also known as standard treatment schedules, standard treatment protocols, therapeutic guidelines, and so forth list the preferred drug and non-drug treatments for common health problems experienced by people in a specific health system.^[14]

Formulation of STGs is a necessity for countries like India, whereby maximum number of patients derives benefit from the scarce available resources. STGs in India have been developed for various diseases and ailments by clinical and professional bodies for the treatment in their respective areas. The Ministry of Health and Family Welfare Government of India and WHO Country Office, India, in consultation with Heads of Departments of various specialties in Armed Forces Medical College, Pune, came out with a comprehensive STG for the Primary and Secondary level of care, based on nearly 35 conditions as per the National Health Programs.^[14]

The Government of Tamil Nadu Health System Project (TNHSP) has also published 'A Handbook on Standard Treatment Guidelines: A Manual for Medical Practitioners', which is a profile of thematic presentation of various medical conditions and existing treatment modalities practiced worldwide. It is a systematically developed method to assist Medical Practitioners and other healthcare providers in making decisions for specific clinical episodes and its use will contribute significantly in attaining Total Quality Management in healthcare.^[15] Similarly the Governments of Chhattisgarh, Odisha, Pondicherry, etc., also developed their own version of STG's for their medical officers. Standard treatments are currently in use in parts of the United States, Europe, Latin America, Asia, Africa and the Western Pacific.

Implementation of the STGs and Essential Medicines List is still a major challenge in most of the countries. The inefficient use of resources has a negative impact on equitable access to essential medicines, and therefore on the quality of care. All healthcare providers are encouraged to use the STGs and Essential Medicines List to attain economic efficiencies in terms of optimizing available resources and the rational use of medicines.^[16]

The development and implementation of STGs is a necessary task in a country like India, where there are numerous treatment options available. In such situations, physicians use their own knowledge base, training, and preconceived ideas on the treatment rationale for each patient. Frequently, this is effective and reasonable and results in optimal care. However, it carries a potential risk of dangerous medical care, resulting in poor and adverse outcomes for the patient. Therefore, development of STGs is an important strategy for improving drug use in

the health care system as they are a valuable resource in the management of drug therapy.

Definition

Standard Treatment Guideline has been defined as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances.^[17]

Guidelines must be consistent with national formularies and guidelines and STGs should as a general rule:

- Use the fewest drugs necessary to treat the medical condition
- Choose cost-effective treatment
- Use formulary drugs (from local and national formularies)
- Give first-, second-, and third-line drugs when appropriate
- Provide dose and duration, contraindications and side effects.

Advantages of standard treatment guidelines

STGs offer a number of potential advantages for the patients, health providers, supply managers and health policy makers. The potential benefits of introducing standard treatments include the following.^[17]

For patients

- Consistency among prescribers reduced confusion and increased compliance
- Most effective treatments prescribed
- Improved access to drugs, if drugs are prescribed only when needed
- Minimize adverse drug reactions and other drug related complications.

For providers

- Gives expert consensus on most effective, economical treatment for a specific setting
- Provider can concentrate on correct diagnosis
- Provide a standard to assess quality of care
- Provide a simple basis for monitoring and supervision
- Minimizes liabilities of the health care provider.

For supply management staff

- Performance standard for drug supply, there should be sufficient quantities of drugs available for the most commonly treated problems at the different levels of the health system
- Facilitates pre-packaging of course-of-therapy quantities of commonly prescribed items for common conditions
- Drug demand more predictable, so forecasting more reliable
- Enables effective maintenance of inventory control.

For health policy makers

- Provide a method to control costs by using drug funds more efficiently
- Serve as a basis to assess and compare quality of care
- Development and implementation of a single set of standard treatments can be a vehicle for integrating special programs, at the primary health care facilities

e.g. Diarrheal diseases control, ARI control, tuberculosis control, malaria control, etc

- Enable to achieve a regulatory control over illicit/spurious/counterfeit drugs at all levels
- Minimize legal issues over procurement/marketing of life-saving drugs.

Standard treatments focus the thinking on critical aspects of the therapeutic process like

- Careful identification of signs and symptoms
- Correct diagnosis
- Effective patient counseling on proper use of drugs or non-drug treatments that will truly benefit the patient.

Disadvantages of STG's

Disadvantages of treatment guidelines do exist, but seldom are they proven to have any serious effects on overall patient outcomes.

- Inaccurate or incomplete guidelines will provide the wrong information for providers and therefore do more harm than good. Guidelines may not be based on the most reliable information
- Updating guidelines is difficult and time-consuming and must be done on a regular schedule or they will become obsolete very quickly
- Guidelines have been referred to as “cook book” medicine. They provide information to treat the population, but not necessarily the individual patient
- Guidelines provide a false sense of security, i.e. many providers will limit their evaluation of a particular patient as soon as it fits into a particular standard treatment.

When looking at the risk-benefit of a guideline, most authorities agree that the benefits of a guideline far outweigh any risks or disadvantages. STGs are disease-oriented while formulary manuals are very much drug-oriented documents. These two documents provide the very essence of the Therapeutic Committee's efforts to provide rational drug therapy.

Key features of standard treatment guidelines for use in primary health care practice

Standard treatment exists for common illnesses of children, common illness of adults and obstetrics and gynecology. The existence of these treatments has reportedly had a major impact on the consistency, effectiveness and economy of prescribing. Key features of the standard treatments include:

- **Simplicity:** The number of health problems is limited. For each health problem, a few key clinical diagnostic criteria are listed. Finally, drugs and dosage information is clear and concise
- **Credibility:** The treatments are initially developed for patients by the most eminent clinicians. Revisions based on actual experience will further add to the credibility
- **Same standard for all levels:** The first choice of treatment of a patient depends on the patients' diagnosis and condition.

The referral criteria may differ. Doctors and other health care providers can use the same standard treatment. If a patient attends a primary level or secondary level or tertiary level hospital, with a common condition the treatment will be exactly the same

- **Drug supply based on standards:** The STGs are coordinated with the supply of drugs
- **Pre-service training:** Standard treatment manuals are introduced and distributed during pre-service training and their use becomes habit
- **Regular updates:** A change or alteration in the therapeutic preferences are incorporated and updated, the standards should be revised to reflect current recommendations
- **Pocket manuals:** The standard treatments are published as small, durable pocket manuals, which makes them convenient to carry and use.

The following important considerations need to be taken into account in the development of standard treatment guidelines

- Target priority conditions
- Based on local disease factors
- Coordination with special programs
- Use fewest drugs necessary
- Choose cost-effective treatments
- Use essential drug list drugs only
- Invoke eminent clinicians
- Consider patient perspective.

In the interest of therapeutic and economic efficiency, standard treatments should target those conditions which contribute the most in terms of morbidity and mortality patterns. In terms of selection of health problems, standard treatments fall into one of the three categories.

- **Individual:** A standard treatment is prepared for only one problem or set of problems, (e.g. only diarrheal diseases, only ARI or only Malaria)
- **Selective:** Standard treatments are prepared for a small number of high priority problems, for example a package of treatment for diarrheal diseases, ARI, ante-natal care, malaria, tuberculosis, etc
- **Comprehensive:** STGs are ideally prepared for 30, 50, 100 or even more common health problems. When published, such standard treatment for the common health problems will be comprehensive and easy to practice and will be useful in terms of efficiency and in considerable reduction in the cost of treatment as well.

The STGs together with the essential drug list and the drug formulary will help to rationalize medical practice. There is an urgent need to protect the population from irrational and hazardous therapy. Often unnecessary drugs and injections are given to patients merely to satisfy a wrong perception of health and health care. Educating people and health professionals about the hazards of irrational curative care is another necessity of our

times. Rationalizing clinical health care also reduces costs for the public health system and makes the system more effective for the same level of expenditure.

Recommendations

- As a first step, the STGs for the diseases coming under India's National Health Programmes should be compulsorily included in our Primary health care practice
- The commonly occurring irrational drugs use today is due the lack of emphasis given to the concepts of essential medicines and rational use of medicines in our medical curriculum. Undergraduate medical education should focus more on good prescribing practices and rational use of medicines, which will have long-term beneficial effects
- Every effort should be expended to publish STGs and the drug formulary manuals, and have them readily available for all practitioners, and update them on a regular basis to ensure accuracy of the information provided
- Involvement of professional associations to encourage their members in helping to make evidence based rational prescription of drugs may improve the attitude of those using STGs in their day to day practice^[18]
- The importance of following STGs by private medical practitioners, who are working as family physicians or primary care physicians or general practitioners, should be popularized by regular CME's
- The STGs must be backed with sufficient monitoring and surveillance systems intended to measure the outcomes in terms of cure rates and compliances. Moreover sufficient audit systems must be in place to ensure accountability of the system of STG.

By carrying out the above-mentioned tasks, we can ensure that a rationale in the primary health care with respect to practice of treatment and prescription use is achieved at a large scale. This will have a wider reach in providing quality and consistent medical care to the majority of the needy population in our country both in the public and private healthcare delivery system.

Conclusions

The use of STGs is a time-honored system that works well and improves patient outcomes. The STGs are prepared as a tool to assist and guide doctors, pharmacists, dispensers, and other healthcare staff who prescribe at primary care facilities in providing quality care to patients. The guidelines list the preferred treatments for common health problems experienced by people in the health system. The guidelines are designed to be used as a guide to treatment choices and as a reference book to help in the overall management of patients and are meant for use at all levels within the health system, both public and private.^[17]

STGs are one of the most important concepts in providing rational medicines use. These guidelines have been shown to provide valuable guidance to practitioners at all levels, especially those with minimal training. Guidelines need to be

prepared with the ultimate goal of providing a protocol for the health care system to follow that will produce improved patient care and outcomes. In India, expertise in developing and implementing STGs exists only in certain pockets of health sector i.e. either for specific diseases or for specific States, but these were never shared or reviewed and discussed at a common platform. Implementation of STGs in primary health care practice calls for a cooperation between all sectors of health care providers and a coordinated effort to make it available at the level of point of care. Provision of STGs will make the farfetched dream of universal health coverage a reality in times to come.

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