Barriers and facilitators to development of standard treatment guidelines in India

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ABSTRACT
This paper describes 15 years’ experience of the development process of the first set of comprehensive standard treatment guidelines (STGs) for India and their adoption or adaptation by various state governments. The aim is to shorten the learning curve for those embarking on a similar exercise, given the key role of high-quality STGs that are accepted by the clinical community in furthering universal health coverage. The main overall obstacles to STG development are: (i) weak understanding of the concept; (ii) lack of time, enthusiasm and availability of local expertise; and (iii) managing consensus between specialists and generalists. Major concerns to prescribers are: encroachment on professional autonomy, loss of treating the patient as an individual and applying the same standards at all levels of health care. Processes to address these challenges are described. At the policy level, major threats to successful completion and focused implementation are: frequent changes in governance, shifts in priorities and discontinuity. In the authors’ experience, compared with each state developing their own STGs afresh, adaptation of pre-existing valid guidelines after an active adaptation process involving local clinical leaders is not only simpler and quicker but also establishes local ownership and facilitates acceptance of a quality document. Executive orders and in-service sensitization programmes to introduce STGs further enhance their adoption in clinical practice.

Key words: Evidence-based guidelines, essential medicines, standard treatment guidelines (STGs), rational use of medicines

INTRODUCTION
The provision of quality health care for all has been a recent key challenge for the Government of India. The health sector in India is disorganized to a large extent and reliant on inequitable, regressive financing by way of out-of-pocket expenditure, which can reduce household spending on basic necessities.1 In order to provide assured and equitable access to health-care services, the Steering Committee of the 12th Five Year Plan (2012–2017) proposed universal health care (UHC).2 However, entitlement-based UHC arrangements covering outpatient, inpatient and emergency treatment for every citizen may result in cost escalation unless measures such as routine application of standard treatment guidelines (STGs) and use of generic medicines are rigorously implemented.

There has been a concerted effort by the Ministry of Health, Government of India, and some more proactive state governments to introduce STGs to address this challenge. Delhi was the first Indian state to adopt a comprehensive rational drug policy in 1994.3 The various components of this policy were implemented through the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD), a nongovernmental organization (NGO), during 1996–2004. The programme considerably improved the availability of medicines in public hospitals.4,6

Rising health-care costs, variations in clinical practice among providers and hospitals, and difficulties faced by prescribers in keeping up to date with the overwhelming and fast-growing volume of new scientific evidence, especially in resource-poor settings, have increased interest in STGs.7 Irrational medicine use is responsible not only for escalating health-care costs but also for adverse health outcomes; thus, successful implementation of STGs reduces inappropriate variation in practice and also improves patient safety and quality of care.8–12
However, the large number of sometimes conflicting or poor-quality clinical practice guidelines being produced by individuals, professional organizations, insurers and others has led to concerns about quality, although some successful approaches to developing STGs have been well documented. The development of STGs is complex and lengthy, and writing guidelines is not without risk; there is always the threat of nonacceptance by the clinicians. Due to considerable differences of opinion among prescribers, managing consensus is difficult and time consuming. Hence the production of successful guidelines needs strong development, editorial and project-management processes, together with a keen eye for detail.

As part of the comprehensive rational drug policy described above, DSPRUD developed the first set of comprehensive STGs for India. Standard Treatment Guidelines – a manual for medical therapeutics was first published in 2002 with financial support from the World Health Organization (WHO), via the WHO-INDIA Essential Drugs Programme. The second and third editions were published in 2005 and 2009, respectively. The current, fourth, edition was published in 2015 and provides guidance on treatment approach for more than 320 priority diseases, from primary to tertiary care. These STGs have now been extensively reviewed and adopted by several state governments.

This paper describes 15 years of first-hand experience of development, dissemination, implementation and evaluation of the guidelines; sharing this experience may shorten the learning curve for those embarking on a similar exercise. The aim is to discuss barriers, facilitators, issues and concerns crucial to acceptance among prescribers during development and adaptation in other states, and implementation issues for policy-makers and managers.

Process of development of the STGs

Figure 1 summarizes the development of the STGs. The process was a great challenge, particularly in a state such as Delhi, which has several academic centres of excellence and a diverse health-care infrastructure ranging from quaternary care to perurban dispensaries in the public sector, in addition to nonqualified private practitioners. Work was formally initiated in 2000 with the selection of priority diseases on the basis of morbidity patterns and national programmes, as well as diseases with high potential for inappropriate treatment. A core group was mandated to develop treatment protocols and referral guidance starting with first aid and progressing through the continuum of primary, secondary and tertiary care. Development of the first edition took two years. Key features of the STGs are shown in Box 1.

During the two years following the launch, the publication was distributed, work on linking and matching with drug supplies was done and feedback was collected. The scepticism that this project would never be completed or reach the intended users was dispelled by ensuring time-bound completion and providing a personal copy of the guidelines to each doctor registered with Delhi Medical Council instead of via bulk delivery to the Department of Health and Family Welfare. The medicines included in the STGs were matched with those on the Delhi Essential Medicines List (EML), and medicines that were recommended in the STGs were included in the EML (that is, medicines listed in the EML but not in the STGs were deleted from the EML). The revised EML was then used as a basis for procurement and supply of essential medicines in the state of Delhi.

Application of lessons learnt and use of a structured approach meant that subsequent revisions took only around six months. To date, the guidelines have been peer reviewed by more than 150 experts in a range of states.

The successive editions of the STGs have been widely accepted, since: (i) they have been developed by a representative multidisciplinary group and extensively peer reviewed; (ii) recommendations are based on evidence or, if evidence at the required level is not available, a consensus of expert opinion; (iii) they identify problem areas in daily care; and (iv) clinicians are alerted to ineffective, dangerous and wasteful practices. The recommendations are made on the basis of capacity appropriate to the level of the health facility. Where appropriate capacity in terms of adequately trained personnel or infrastructure is not available, the guidelines provides advice to the treating physician to stabilize the patient and take timely action for referral to a higher-level facility. The guidelines also clearly identify situations where immediate referral to a tertiary care centre is required. The regularity with which the guidelines have been updated to reflect current recommendations and actual experience have further added to their credibility and acceptance. Although the first edition was developed with assistance from WHO, subsequent editions have been produced in association with a publishing house and nominally priced to cover incidental costs and ensure a nationwide network for distribution, thereby ensuring sustainability and widespread availability.

Box 1. Key features of Standard Treatment Guidelines – a manual for medical therapeutics

Contains about 20 chapters covering all major specialties. More than 325 priority diseases covered. Key features of content for each disease include:

- Salient features and diagnostic tests
- Nonpharmacological and pharmacological treatment
- Drugs referred to by generic names in order of preference
- Drug selection based on criteria of efficacy, safety, suitability and cost
- Treatment goals, step-up/step-down therapy or criteria for referral, key assessment indicators and monitoring intervals
- Patient-education section – nature, duration of illness, prognosis, preventive measures, duration of therapy, follow-up, drug precautions and side-effects
- Key references
The experience of working on this series of STGs has provided a wealth of insight into the barriers and facilitating factors to successful development and acceptance among prescribers; these are summarized below.

### Barriers and facilitating factors to STG development and acceptance

#### Allaying practitioners’ concerns about the role of guidelines

Contributors and critics raised several concerns during the development process. The chief concerns were: (i) misuse by non-qualified practitioners; (ii) the legal liabilities or protections offered by this type of document; (iii) the danger that STGs would lead to so-called cookbook medicine; and (iv) doctors' loss of prescribing autonomy. The concerns were allayed by interactive rounds of discussions with experienced, respected clinicians using examples from real-life settings.

As non-qualified practitioners were beyond our jurisdiction, it was decided that guidelines should clearly provide details of the first aid and red-flag signs so that, at the least, timely referral to a proper health facility may be arranged by these practitioners. Regarding so-called cookbook medicine, it was emphasized that the role of the STGs is not to order or direct patient management. Rather, STGs minimize the chances of variation in treatment such that the clinician can concentrate on the diagnosis itself without expending time and energy identifying the best treatment approach.

Concerns about legal liability were allayed by explaining that they are guidelines, not law, and clinicians should be in a position to explain why STGs were not followed in a given situation. A major debate was on how there could be a same standard of treatment at all health-care levels; this notion was especially unacceptable to specialists as they felt they were offering an added level of expertise to the management of a patient who had already been seen by a doctor at a lower level. Through repeated dialogue, they were convinced that it is referral criteria that differ rather than the first-choice treatment for a patient, since choice of medicines depends on the patient’s diagnosis and condition, and not on the seniority of the prescriber or level of the health facility.

#### Target audience for the guidelines

Another concern raised was whether the intended STG users would be doctors from only public hospitals, or private practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well. The proposal to address particularly junior doctors and private practitioners was more than welcomed by practitioners as well.

About 68% of doctors found that guidelines matched their own prescribing but some consultants had residual concerns that, with STGs, their professional autonomy was lost and, since not all cases have a typical presentation, the concept of patient individuality is lost. However, such concerns among doctors are common and most can be resolved if due care is taken to provide flexibility of drug choices and to conduct in-service programmes to introduce STGs.

Our own experience further endorses that the development process is important for acceptance of the end-product. The most common reason for lack of credibility and nonimplementation of STGs is an a priori failure to involve a wide range of experts and established institutions in the development process.

#### Writing process and precision of language used in guidelines

Flexibility was needed when setting deadlines for contributors who, although motivated, had difficulty combining work on the guidelines with their busy schedules. Several contributors found that the best approach to adhering to the schedule was to allocate a time and place away from routine work.

Clinical behaviour is more likely to change if guidelines are precise, simple and reader friendly. To ensure uniformity throughout the STGs, certain rules were framed, and standard abbreviations and definitive recommendations were given. Words such as “may” were avoided as were instructions that could be interpreted in different ways. For example an instruction such as “give slowly” was made more precise to, for example, “give over 5 minutes”. Similar clarity was used to describe factors such as length of treatment or the recommended interval between two tests.

A patient-education section was included to empower both patient and doctor, as time constraints can limit clinicians’ ability to provide brief, relevant information about the course of an illness, prognosis, early identification of red-flag signs and follow-up. Details, such as the incidence of different conditions, which may be of general interest but are not required for decision-making, were omitted. Condensing all relevant information into a brief format was difficult for contributors and writing the patient-education sections was the most challenging.

#### Participatory and consensus-building approaches to guideline development

The strengths of the STG development process were the participatory approach involving end-users and a sufficiently large group of doctors from different disciplines and various levels of health care. The large number of experts involved also...
made consensus management and time-scheduling difficult. Since team coordinators themselves co-opted contributors, this helped to establish good communication among the groups and also facilitated consensus building. Furthermore, the time spent in repeated meetings and consultations with a large number of experts and professional associations did a great deal to promote the team approach by resolving queries/doubts and difference of opinion, particularly when the desired level of evidence was not available.

Arriving at a consensus is difficult to manage and time consuming. There is also a danger of introducing inaccurate guidelines by including treatment choices that reflect common existing practices rather than best practice, thus providing wrong information to prescribers. The greatest risks are that an inappropriate action may result from an error in the guideline, misinterpretation of a guideline or use of a guideline that is inappropriate for an individual situation. Clinical errors may occur as a result of ambiguity in the guidelines; hence the need for robust editorial processes.

Time-bound following of a consistent format with a diverse range of contributors, not all of whom were sensitized to requirements of guidelines development, was difficult. A strong editorial process is a key component to the development of quality guidelines and includes: (i) liaising with authors; (ii) associated correspondence/documentation with appropriate specialists; (iii) editing and proofreading to ensure that there are no errors; and (iv) liaising with the printer to ensure adherence to production schedules. Experiences similar to ours have been reported by Woolf et al. and McMaster et al. Our observations also concur with the finding of Woolf et al. that use of editors whose area of work is not primarily in the specialist area being covered is useful to circumvent assumption of knowledge.

Guidelines or essential medicines list – which comes first?

Policy-makers face the dilemma of deciding whether STGs or an EML should be developed first. In our experience, having an EML in place first saves time and delivers initial gains by improving availability and accessibility to essential medicines by setting-up/streamlining systems for procurement. In parallel, the adaptation process for the STGs can be initiated and completed within a short time and matched with EML without losing momentum caused by extraneous factors such as changes in governance or a shift in priorities. Finally, guidelines cannot be effectively used unless linked with essential medicines supplies.

Raising awareness of guidelines and measuring impact

Since dissemination of guidelines alone does not change practitioners’ behaviour, we used a multifaceted approach to raise awareness of the STGs. The programme of activities included news reports of the official launch in leading daily newspapers and The Lancet, educating patients, endorsement by clinical groups, book reviews and training programmes that focused especially on interns to increase awareness and acceptance of guidelines. However, to achieve a sustainable impact on prescribing practices, in-service training of doctors, supervision and medical audit are required.

Observations on adoption or adaptation of STGs

When considering developing STGs, policy-makers have the opportunity to develop their own new guidance or use existing guidance, either by adopting it as a whole or adapting it to their needs. New, locally produced STGs that involve end-users may have better potential acceptability than so-called imported guidance, but developing STGs afresh for each location may be an expensive waste of time, effort and money, particularly if they are not developed correctly. In addition, in cases where individual institutional departments have developed guidelines, they often have idiosyncrasies, inconsistent formats, lack an evidence base and are not regularly reviewed. More importantly, there is a potential danger of noncompletion of projects.

In our experience, there are only a few other initiatives to develop STGs in India that have been completed, regularly revised and widely accepted. Lack of awareness of the concept and availability of expertise locally were major obstacles, as was prescribers’ insistence on inclusion of outdated practices, and or of drugs by brand names of unproven efficacy. Moreover, it was observed that guideline review groups often lacked time, enthusiasm, resources and skills to gather and scrutinize every piece of evidence, particularly in relation to editorial responsibilities. These difficulties have also been reported by others. Adoption and adaptation of Standard Treatment Guidelines – a manual for medical therapeutics is summarized in Figure 1. The Government of Gujarat adopted the second edition of these STGs with a message from the State Minister of Health in 2004. The governments of Rajasthan (in 2006), Uttarakhand (in 2007), Haryana (in 2013) and Delhi (in 2014) adapted the STGs after peer review by local experts and provided a personal copy to all practising doctors in the public sector. The peer review process was led by the authors from DSPRUD. Rajasthan published a revised adapted edition in 2012. A few states – Karnataka, Maharashtra, Chhattisgarh, Himachal Pradesh and Uttar Pradesh – successfully developed their own independent STGs. However, these publications were either targeted at primary care alone or focused only on certain diseases; in addition, the sections on treatment were less comprehensive and none has been updated since the first edition. One state decided to develop its own guidelines but these were never published for various reasons: lack of motivation and committed core group, time constraints and, most importantly, a change in governance and shift of priorities.

In our experience, adoption/adaptation of valid pre-existing guidelines not only saves time, effort and money but also ensures that there is a good-quality document in place after an active adaptation process. Since adapting/adopting guidelines saved time and money, health systems could focus their efforts and resources on effective implementation activities such as linking with procurement sources and monitoring prescribing patterns. Although there are disadvantages to this approach, such as lack of local resource creation, there are substantial advantages in terms of success rate.
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With adaptation/adoption, good acceptance among clinicians can be achieved, especially through active participation of local clinical leaders and allowing local clinical input by practitioners. Active local participation helped overturn the beliefs of doctors accustomed to outdated practices and boosted appreciation of the importance of consistency of care and the difference between a textbook and guidelines. Another advantage of adoption/adaptation is that one need not repeat the same mistakes again.

The adaptation process in the various states revealed that the main changes required were the addition of a few more priority diseases, while only a few changes in the treatment protocols were needed. Adaptation also saved money as it covered only the printing and logistics costs, and the editorial team/contributors were not compensated for their intellectual input; when developing fresh STGs, sufficient resources are needed to reimburse all contributors, in addition to the costs of printing, dissemination and training. The creation of the state’s own STGs, with its own book cover design, created a sense of ownership. An executive order from the government and an in-service sensitization programme introducing STGs further facilitated adoption of guidelines in clinical practice.
CONCLUSION

Good–quality STGs are critical to promoting rational use of medicines and have great potential to improve patient care. Robust STG development is best undertaken across a network of motivated and cooperating contributors. However, successful guideline development requires dedicated resources and a well–defined process, along with a strong editorial team. Regular updates to reflect current recommendations and actual clinical experience add to the credibility and acceptance of the guidelines. Local adaptation/adoptions of pre-existing valid guidelines makes the process easier and quicker and fosters a good sense of ownership and acceptance among doctors. Since adaptation/adoptions of pre-existing guidance saves time and money, policy-makers can focus resources on activities to change practitioners’ behaviour, such as pre-service/in-service sensitisation programmes, endorsement by opinion leaders/professional organizations, prescription monitoring and feedback.

REFERENCES


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