Attributes of Standard Treatment Guidelines in Clinical Settings and Public Health Facilities in India

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Abstract

Background: Standard Treatment Guidelines (STGs) are time-tested tool to improve healthcare quality and patient safety. This study was done to review the available guidelines and assess their essential attributes using AGREE reporting checklist 2016. Methods: Publications from PubMed, World Health Organization, Global Health Regional Libraries, Index Medicus, Google, Google Scholar, and insurers, state/central government portals were searched. Results: In total, 241 STGs met the inclusion criteria. A range of developers with a varying focus and priorities developed these guidelines (government mostly under national programs 134 (56%); professional associations 67 (28%), academic/research institutions 36 (15%); international agencies 4 (2%)). The government-led guidelines focused on program operations (mainly infections, maternal, and childcare), whereas insurers focused on surgical procedures for protection against fraudulent intentions for claims. The available STGs varied largely in terms of development process rigor, end-user involvement, updation, applicability, etc.; 12% guidelines developed documented GRADE criteria for evidence. Most guidelines focused on the primary care, and only 27 and 7% included treatment at tertiary and secondary levels, respectively, focused on general practitioners. Conclusion: There is a need for coordinated, and collaborative efforts to generate evidence-based guidelines, facilitate periodic revisions, standardized development process, and the standards for monitoring embedded in the guidelines. A single designated authority for the standard treatment guidelines development and a central web-based repository with free access for clinicians/users will ensure wide access to quality guidelines enhancing acceptance and stewardship.

Keywords: India, public health, quality of care, standard treatment guidelines, universal health coverage

Introduction

Quality of care (QoC) is multidimensional and encompasses structural attributes (availability of supplies, adequate human resources, infrastructure) and the processes through which care is rendered. Globally, health systems strengthening efforts have recognized the importance of the quality paradigm in attaining Universal Health Coverage (UHC). Poor QoC is associated with poor outcomes, increased healthcare cost due to ineffective, and harmful management. Poor-QoC is a bigger barrier in reducing mortality than insufficient access, as 60% deaths occur from conditions amenable to healthcare but remain unaddressed. For good QoC to improve outcomes, all dimensions of quality including adherence to Standard Treatment Guidelines (STGs) should be measured besides processes and pathways. Janani Suraksha Yojana, a conditional cash incentive program for institutional births, though increased institutional deliveries but did not result in commensurate reduction in maternal or newborn mortality. Addressing QoC is particularly pertinent for advancing toward UHC and has attained greater relevance in context of Ayushman Bharat -Pradhan Mantri Jan Arogya Yojana (AB-PMJAY). The insurance schemes contribute to improved healthcare access, but irrational medicine use results in open-ended cost escalation unless measures like STGs and essential generic medicines are rigorously implemented.

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Large numbers of STGs are being produced by individuals, professional organizations, government/insurers, etc. Multiple, overlapping, and possibly conflicting practice guidelines recommended by different panels raise concerns about the guideline quality, which can befuddle clinicians and lead them toward inappropriate prescribing. If guidelines are to improve the QoC, they must be credible, to inspire confidence in prospective users. Developing STGs that enlighten service providers is an exceptionally challenging task requiring diverse skills ranging from the scientific evidence critical appraisal to the management of decision making to the presentation of complex information in easily understandable useful forms.

Certain attributes determine guideline acceptability and uptake. Validity of recommendations ranks as the most critical attribute, a key element of which is based on evidence. Other critical attributes are source organization’s credibility, and accountability, a key element of which is a conflict disclosure. Since guidelines by themselves do not lead to behavioral change among service providers, development process becomes an important determinant for their acceptance.

In India, several STGs are available for different diseases/conditions, levels of care, and cadres of healthcare providers, but the product quality varies. The Appraisal of Guidelines, Research and Evaluation (AGREE) II checklist, a generic tool for the assessment of the methodological quality of guidelines, is used internationally for evaluating the essential components of the practice guidelines. This review aimed to assess the extent of coverage of diseases by the guidelines available in India and to assess their attributes produced by various developers and make policy recommendations for health system development and patient safety.

**Materials and Methods**

The study reviewed all available technical resources of the stated sub thematic areas in the country published year 2000 onwards. The data for review was collected during a period of December 2016-February 2017 using AGREE II reporting checklist.

**Search strategy and data sources:** Databases searched included Medline through PubMed, World Health Organization, Global Health Regional Libraries, Global Index Medicus, Google, and Google Scholar using a snowball approach. As STGs in India are also published on central or state government and insurers portals, Ministry of Health and Family Welfare (MoHFW), National Health Mission (NHM), Medical Council, and key professional bodies’ websites were also searched.

**Keywords:** “Standard treatment guidelines”; “guideline”; “protocol”; “standard operating procedures”; “treatment guidelines”; “operational guidelines” and “standard treatment protocols”; “clinical guideline” OR clinical practice” AND India initially without limits followed by AND Medical Subject Headings (MeSH) terms and controlled vocabulary. Further, abstracts and reference lists of the guidelines were searched to identify other guidelines.

**Eligibility Criteria:** A complete list of all STGs in India, released after 01 January 2000, was prepared. To avoid duplications, the most recent versions of available STGs in English, focusing on health problems encountered at different levels of care or for specific diseases or symptom-based approach were considered.

**Exclusion criteria:** Guidelines for the Indian system of medicine were developed by individual authors with no affiliation to professional bodies/groups or without full text; developed prior to January 1, 2000 without revision in the last 10 years; or operational or program management guidelines or guidelines published in local language.

**Data Extraction:** A data extraction form was developed based on the assessment framework with indicators organized under the following domains: scope and purpose, stakeholder involvement, development rigor, presentation clarity, applicability, and editorial independence. Two trained researchers independently read and analyze each STG using AGREE reporting checklist 2016 and systematically extracted data into separate forms; these forms were then compared and any differences in assessment were verified with original texts and discussed with a third researcher to arrive at a consensus. The separate extraction forms were merged into a single extraction form and used for the interpretation of results.

**Results**

Out of the 241 STGs, 134 (56%) were developed by central/state governments, 67 (28%) by professional associations, 36 (15%) by academic institutions, and 4 (2%) by international agencies. Disease conditions addressed by STGs were classified into four groups: (i) communicable diseases and maternal, perinatal, and child health conditions, 104 (43.15%), (ii) noncommunicable diseases (NCDs) and injuries, 98 (40.66%), (ii) injuries and critical care, 8 (3.32%), and (iii) other diseases, 20 (8.30%) [Table 1]. STGs were further stratified into comprehensive, individual, and selective depending on the approach and scope [Table 2]. Table 3 depicts the guideline attributes by different developers.

**Scope and purpose:** Out of 241 guidelines, only 11 (4.6%) including 10 guidelines developed/adopted by State governments were comprehensive/consolidated (i.e., provided guidance on most common diseases for all levels of healthcare). A few states adopted/adapted already existing valid comprehensive guidelines developed by DSPRUD or others developed de novo.

Out of total STGs, 145 (60.2%) covered individual topics (epilepsy, rheumatic fever etc.). Similarly, a proportion of all STGs, 85 (35.2%) were selective in the scope, i.e., focused on the system (neonatal, respiratory, maternal diseases, genitourinary or gastrointestinal) or healthcare level. Out of 241, 58 (24%) guidelines were on infectious diseases followed by neonatal care 25 (10%), 17 (7%) neuropsychiatric illnesses, and 15 (6%)
Among STGs for NCDs and injuries, the largest group focused on neuropsychiatric conditions, 17 (7%), followed by diabetes mellitus, 15 (6%), malignant neoplasm, 14 (5.8%), and genitourinary diseases, 11 (4.6%). Guidelines developed under Clinical Establishments Act (CEA) 2010 focused on selective conditions on critical care, general surgery, orthopedics, ENT, and pediatrics.

Maternal and child health 11 (4.5%) guidelines covered different aspects of maternal conditions, obstetric emergencies, ectopic pregnancies, caesarean sections, preconception care, etc. Under injuries burns, trauma, and poisoning guidelines, only one on arsenic poisoning was available. Others group covered diseases such as sexual violence, skin diseases, and snakebite.

As regards guideline focus of the developers (government, professional organizations, institutions), government’s contribution was the most on national programs, i.e., infectious disease, neonatal and maternal diseases, nutritional deficiencies followed by diabetes, neuropsychiatry (mental health and epilepsy) diseases, malignancy. Other developers, in addition, produced NCDs guidelines resulting in multiplicity for some diseases such as diabetes mellitus (15), ischemic heart disease (8), chronic obstructive pulmonary disease (3), neonatal preterm birth (27), lower respiratory infections (5), neonatal encephalopathy (4), diarrheal diseases (9), tuberculosis (9), trauma/road injuries, and emergency care-related (7). Professional organizations developed guidelines for unaddressed high-prevalence high-morbidity causes in children such as asthma, epilepsy, rheumatic fever, tuberculosis, and snakebite. Government, a few professional organizations as well as one institution developed national guideline applicable for all healthcare levels and published on their official journal/website.

Purpose: The overall objective(s) were described in 81 (38.6%). Multiple reasons attributed were high prevalence 58 (24.0%), improving diagnosis/management 34 (14%), and reducing clinical variation 24 (10%), whereas 20 (8%) were developed to fulfill regulatory requirement under the CEA or in response to epidemics (HINI, Zika, avian influenza, Japanese Encephalitis in 10 (4.1%). The guidelines to handle sexual violence were developed in response to a legal direction.

Stakeholder involvement: Groups involved in development and views of target population were sought by only 43 (17.8%), as per descriptions available in the guidelines reviewed.

### Table 1: Coverage and scope of the guidelines developed by different agencies

| Category                        | Government (n=134) | Professional association (n=67) | Institutional (n=36) | International (n=4) | Total (n=241) |
|---------------------------------|-------------------|--------------------------------|---------------------|-------------------|--------------|
|                                 | %                 | %                              | %                   | %                 | %            |
| Communicable and MCH            | 58 (43.28%)       | 24 (35.82%)                    | 20 (55.56%)         | 2 (50.00%)        | 104 (43.15%) |
| Noncommunicable diseases (NCD)  | 42 (31.34%)       | 41 (61.69%)                    | 13 (36.11%)         | 2 (50.00%)        | 98 (40.66%)  |
| Comprehensive                   | 10 (7.46%)        | 1 (1.49%)                      | -                   | -                 | 11 (4.56%)   |
| Other diseases/conditions       | 18 (13.43%)       | 1 (1.49%)                      | 1 (2.78%)           | -                 | 20 (8.30%)   |
| Injuries and critical care      | 6 (4.48%)         | -                              | 2 (5.56%)           | -                 | 8 (3.32%)    |
Majority 198 (82.2%) either did not seek patient/public preferences or did not specify their engagement in such development process. The target users were not explicitly defined in half the guidelines 118 (51.8%) and 37 (15%) did not specify population or level of healthcare provision. Among those which defined, the target users were general practitioners, 96 (40%), and specialists in 9 (3.8%). Most guidelines focused on the primary care and only 27% and 7% included treatment at tertiary and secondary level respectively.

Development Rigor: Only 61 (25.30%) described the development process and only 4 (2%) explicitly mentioned the evidence search method. The majority guidelines (professional and institutional) mentioned that decision was arrived by consensus or were formulated as summary discussions from different working group meetings. Although about a third of guidelines described methods for formulating the recommendations and consideration of health benefits, side effects, and risks, but criteria for selecting evidence, their strengths, and limitations and the link between the recommendations and the supporting evidence were not described in any of the guidelines or were externally reviewed. Only 38 (15.7%) guidelines were either revised or had a scheduled revision plan. Only 10 (4.1%) provided procedure for updating the guideline.

Presentation clarity: Key recommendations were identifiable in 209 (86.7%) of the guidelines and recommendations were presented clearly in 192 (79.7%) of such guidelines. The different options for management were also presented in 183 (75.9%) guidelines. All STGs described the health condition of interest and case definition and most linked the disease to the exact ICD code.

Applicability: Only 96 (39.8%) guidelines provided advice and/or tools on how the recommendations can be put into practice. Only a few 25 (10.3%) mentioned facilitators and barriers to its application. Only 73 (30.2%) guidelines including all international guidelines provided resource implications/treatment cost. A few 19 (7.8%) guidelines developed by government under the national programs, namely, TB, AIDS, Family Planning, NCD, and health systems project provided monitoring/evaluation audit criteria. A total of 145 (60.1%) STGs provided supporting materials, mostly, by all international, institutional, and professional associations.

Editorial independence: Name of the guideline developer was mentioned in all and majority were developed by the government 134 (56.0%) followed by professional organizations 67 (27.8%), institutions 36 (14.9%), and international agency 4 (1.6%). However, explicit funding source or statement that funding body did not influence the contents of the guidelines was not documented. Very few 10 (4.1%) guidelines explicitly documented no conflict of interest.

Discussion

The present study reviewed attributes of the guidelines available in India using an international validated AGREE checklist and studied focus and priorities of the different guideline developers.[18] Multiple guidelines by different developers are available for some specific group of diseases/conditions; however, these varied in scope and target users. Koli et al., used a modified criterion[19] and did not evaluate the guideline attributes, as in case of guidelines, process is more important than the product.[20-21]

Statement of principal findings

Most STGs covered individual topics (epilepsy, rheumatic fever, etc.) or were selective (either for the healthcare level or system or disease such as neonates or maternal diseases, nutritional problems or emergencies. Most government-led guidelines mentioned high prevalence, high mortality and morbidity, the lack of relevant treatment protocols in the Indian context, and low resource settings as the trigger for developing guidelines. Guidelines developed under national programs, regulations (CEA), and insurance schemes acted as a driver for national guidelines, whereas external accreditation programs served as a driver for institutional guidelines.

Despite availability of many guidelines, the range and scope of coverage was limited (covered ~40% of the most prevalent diseases contributing to highest morbidity and mortality rates). There is an excess versus access paradox with guideline multiplicity concentrating on select diseases by different guidelines developers, on one hand, and paucity of guidance for other conditions/diseases with high mortality and high prevalence such as poisoning. Guidelines multiplicity besides duplication marks ambiguities in the recommendations confusing users since there is no single authority to determine if a particular STG represents the best practice. Some guidelines were written with a narrower scope for super-specialty/quaternary care (diabetic retinopathy, diabetic macular edema, bypass surgery, etc.). A comprehensive
| Attribute                                                                 | Government $n=134$ (55.60%) | Professional organization $n=67$ (27.80%) | Institutional $n=36$ (14.94%) | International organization $n=4$ (1.66%) | Total $n=241$ (100%) |
|--------------------------------------------------------------------------|-----------------------------|----------------------------------|--------------------------------|----------------------------------|----------------------|
| Comprehensive                                                             | 10 (7.46%)                  | 1 (1.49%)                        | -                              | -                                | 11 (4.56%)           |
| Individual                                                                | 59 (44.02%)                 | 55 (82.08%)                      | 27 (75%)                      | 4 (100%)                        | 145 (60.16%)         |
| Selective                                                                 | 65 (48.50%)                 | 11 (2.7%)                        | 9 (25%)                        | -                                | 85 (35.26%)          |
| **Domain 1: Scope and Purpose**                                           |                             |                                  |                                |                                  |                      |
| The overall objective(s) of the guideline is (are) specifically described | 65 (48.51%)                 | 9 (25%)                          | 9. (25%)                       | 4 (100%)                        | 81 (38.61%)          |
| The health question(s) covered by the guideline is (are) specifically described | 65 (48.51%)                 | 9 (25%)                          | 9. (25%)                       | 4 (100%)                        | 81 (38.61%)          |
| The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described | 65 (48.51%)                 | 9 (25%)                          | 9. (25%)                       | 4 (100%)                        | 81 (38.61%)          |
| **Domain 2: Stakeholder involvement**                                     |                             |                                  |                                |                                  |                      |
| Stakeholder involvement described: groups involved in development         | 24 (17.91%)                 | 18 (26.86%)                      | -                              | 2 (50%)                         | 43 (17.84%)          |
| Views of target population sought: end users involved in STG development, target users defined, piloting of STG among users done | 24 (17.91%)                 | 18 (26.86%)                      | -                              | 2 (50%)                         | 43 (17.84%)          |
| Target users defined                                                      | 58 (43.28%)                 | 31 (55.36%)                      | 27 (79.41%)                    | 2 (50%)                         | 118 (51.75%)         |
| **Domain 3: Rigour of development process**                               |                             |                                  |                                |                                  |                      |
| Systematic methods were used to search for evidence                       | 10 (7.5%)                   | 42 (62.7%)                       | 1 (33.3%)                      | 4 (100%)                        | 61 (25.3%)           |
| The criteria for selecting evidence are clearly defined                   | -                           | -                                | -                              | -                                | -                    |
| The strengths and limitations of the body of evidences are clearly described | -                           | -                                | -                              | -                                | -                    |
| The methods for formulating the recommendations are clearly described    | 10 (7.5%)                   | 42 (62.7%)                       | 1 (33.3%)                      | 4 (100%)                        | 61 (25.3%)           |
| The health benefits, side effects, and risks have been considered in formulating the recommendations | 10 (7.5%)                   | 42 (62.7%)                       | 1 (33.3%)                      | 4 (100%)                        | 61 (25.3%)           |
| There is an explicit link between the recommendations and the supporting evidence | -                           | -                                | -                              | -                                | -                    |
| The guidelines has been externally reviewed by experts prior to publication | 5 (3.73%)                   | 4 (5.97%)                        | -                              | 1 (25%)                         | 10 (4.1%)            |
| A procedure for updating the guideline is provided                        | 10 (7.46%)                  | 9 (13.43%)                       | -                              | 1 (25%)                         | 38 (15.7%)           |
| If there were any revisions or proposed scheduled revisions               |                             |                                  |                                |                                  |                      |
| **Domain 4 Clarity of presentation**                                      |                             |                                  |                                |                                  |                      |
| The recommendations are specific and unambiguous                          | 90 (67.16%)                 | 64 (95.52%)                      | 34 (94.44%)                    | 4 (100%)                        | 192 (79.67%)         |
| The different options for management of the condition or health issue are clearly presented | 101 (75.37%)                | 49 (73.13%)                      | 31 (86.11%)                    | 2 (50%)                         | 183 (75.93%)         |
| Key recommendations are identifiable                                      | 106 (79.1%)                 | 66 (98.5%)                       | 2 (66.6%)                      | 4 (100%)                        | 209 (86.7%)          |
| **Domain 5 Applicability**                                               |                             |                                  |                                |                                  |                      |
| The guideline provides advice and/or tools on how the recommendations can be put into practice | 18 (13.4%)                  | 47 (70.1%)                       | -                              | 4 (100%)                        | 96 (39.8%)           |
| The guideline describes/mentions facilitators and barriers to its application | 02 (1.4%)                   | 19 (28.3%)                       | 1 (33.3%)                      | 3 (75%)                         | 25 (10.3%)           |
| The potential resource implications of applying the recommendations have been considered | 32 (23.8%)                  | 32 (47.7%)                       | 2 (66.6%)                      | 4 (100%)                        | 73 (30.2%)           |
| Monitoring and evaluation audit criteria defined                          | 15 (11.1%)                  | 1 (1.49%)                        | 1 (33.3%)                      | 2 (50%)                         | 19 (7.88%)           |
| Availability of supporting materials, like algorithms, job-aids, decision instruments/charts, pocket-guides, etc. | 74 (55.2%)                  | 36 (53.7%)                       | 1 (33.3%)                      | 4 (100%)                        | 145 (60.1%)          |
| **Domain 6 Editorial independence**                                       |                             |                                  |                                |                                  |                      |
| The views of the funding body have not influenced the content of the guidelines | 5 (3.73%)                   | 4 (5.97%)                        | -                              | 1 (25%)                         | 10 (4.1%)            |
| Conflicts of interest declaration by guideline development group members  | -                           | -                                | -                              | -                                | -                    |
The STGs reviewed had a notable lack of impact on the quality of clinical care, remains a challenge. The internationally accepted GRADE criteria, while others (primarily academic/research institutions). Some STGs used and outlined methods for formulating recommendations nor comparable. Only a few STGs stated quality of evidence and their health benefits versus risks. In most cases, the yardsticks used for evidence evaluation were not similar, nor comparable. Only a few STGs stated quality of evidence and outlined methods for formulating recommendations (primarily academic/research institutions). Some STGs used the internationally accepted GRADE criteria, while others used combinations of criteria to assess evidence applicability and its strength.

In the absence of a specific mandate or an organization specializing in the development process most guidelines reviewed were not updated, a critical attribute for their wider adoption and uptake in clinical practice. Outdated recommendations may perpetuate outdated practices which in turn not only confuse the clinicians but also managers may unfairly judge the QoC based on these invalid and outdated guidelines. Previous studies have reported their experiences highlighting barriers in developing de-novo guidelines and their use in Indian setting due to lengthy, complicated process and lack of skills for critical appraisal of evidence.[10,20,21]

Though most developers identified key recommendations clearly, they did not explicitly document the criteria for selecting evidence, method of formulating the recommendations, and their health benefits versus risks. In most cases, the yardsticks used for evidence evaluation were not similar, nor comparable. Only a few STGs stated quality of evidence and outlined methods for formulating recommendations (primarily academic/research institutions). Some STGs used the internationally accepted GRADE criteria, while others used combinations of criteria to assess evidence applicability and its strength.

Monitoring the guideline implementation, particularly its impact on the quality of clinical care, remains a challenge. The guidelines developed to serve different purposes such as insurers developed guidelines for protection against adverse selection/fraud or cost containment, thus, were more oriented toward procedures/processes (preauthorization to minimize fraudulent claims, reimbursement, and empanelment), whereas healthcare systems’ objective was to improve operational efficiency or optimizing resource utilization and clinicians looked for explicit recommendations particularly for protection from medico-legal protection and malpractice litigation. [22]

For guidelines to change behavior and improve patient outcomes, regular audit for guideline adherence is required, but very few guidelines provided monitoring and evaluation criteria. Even in STGs where aspects of monitoring are mentioned, mechanisms for reporting are not specified. None of the available STGs linked provider performance to guideline adherence. Without proper implementation, the financial and human resources expended in the development process are wasted; therefore, monitoring and audit standards should be inbuilt into the development process. Another aspect hindering uptake in clinical practice is the structure/format of the document. STGs which are designed as voluminous (detailed background information, methodology, consensus management, etc.), with less emphasis on concrete or implementable steps, are less target user friendly at a primary level. A comprehensive ready reckoner or a quick reference guide providing stepwise treatment for various levels of healthcare would be more appropriate for the general practitioners. [23] The STGs reviewed had a notable lack of involvement of stakeholders and end users in the development process. No guidelines are complete if not written with patients’ perspective in mind as addressing patient needs or unmet needs or areas of uncertainty can impact guidelines uptake.

Present study underscores the need for coordinated, collaborative efforts to generate evidence-based guidelines, periodic revisions, standardized development process, and standards for monitoring embedded in the guidelines. All these can be achieved by a designated guideline developer who could focus on their effective dissemination and implementation in clinical practice. A central web-based repository can improve access to all valid STGs. Guidelines attributes such as stepwise treatment according to healthcare level would further facilitate their adoption, auditing, and assessing healthcare workers’ training needs.

Conclusions

STGs available in India have been produced by multiple developers with guideline multiplicity on one hand and paucity for some diseases; vary in terms of development rigor, content/presentation, end-user involvement, applicability; and were not updated regularly. For good quality valid product, guideline development process standardization and a system for regular updation are paramount. A designated guideline authority would not only save resources and efforts but also allow expansion of scope and focus on improving outcomes. As India scales up efforts for UHC, central repository will
ensure that wide access to quality guidelines will enhance stewardship, acceptance, and their uptake in clinical practice.

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Conflicts of interest
There are no conflicts of interest.

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