STANDARD TREATMENT GUIDELINES

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

NHSRC

METHODS BOOK

AUGUST 2017

Ministry of Health & Family Welfare
Government of India

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BACKGROUND

Standard Treatment Guidelines, some also termed as clinical guidelines and clinical protocols are component of health services provisioning to ensure evidence based medicine and quality of care. At health system level it helps in planning and costing of services. Standards Treatment Guidelines also become important tool for monitoring and authorising procedure in a public funded health insurance schemes. With this quality control, regulatory and planning functions standard treatment guidelines become indispensable tools both for public and private service providers.

Understanding its importance, Ministry of Health & Family welfare commissioned a Taskforce on Standard Treatment Guidelines comprised of eminent clinicians and representations from important stakeholders such as ICMR, DGHS , FICCI, civil society organizations and academic institutions. NHSRC was designated as secretariat for this taskforce. The objective of this taskforce was to collate and review the existing standards treatment guidelines as well as identify the procedures/ conditions where fresh development of Standard treatment Guidelines is required. Taskforce was also mandated to suggest principles / protocols by which guidelines are reviewed and updated. Taskforce was also asked to update the exiting guidelines and companion documents aimed at treating doctors, insurance program teams, patients and clinical reviewers/ medical auditors. The existing guidelines were collated by taskforce secretariat and put for review of taskforce members. During the brainstorming it came out that we do not have consensus and comprehensive framework and protocols for reviewing and updating the guidelines in Indian context. It was agreed that first taskforce will develop the process and protocols, and take some disease conditions as demonstration project where this methodology can be tested and further evolved. As the outcome of the process, taskforce will deliver certain model standard treatment guidelines and as well as

a methodology guidebook for developing standard treatment guidelines. Task force also agreed to give recommendations for developing a sustainable institutional framework for Guidelines development and review in India as update and this is a long term continues work and will require a more formal structure. Further 10 clinical subgroups were constituted to develop standard treatment guidelines on agreed methodology. In last two years taskforce had 7 rounds of consultation apart from numerous meetings of clinical subgroups and internal review group to develop these STGs and Methodology. Following are the Key finding and recommendations.

Current Scenario

Standard Treatment Guidelines are not a new concept for Indian Health system. Multiple agencies have developed standard treatment guidelines in India with varying objectives and target audiences. These Guidelines also vary in rigour of development and evidence based approach. Several divisions and sections of MoHFW, GoI develops standard treatment guidelines on topics related to their work. These include technical guidelines by program divisions eg. RMNCHA, Non Communicable Disease Control Programs and disease control programs. In addition Clinical Establishment Act has developed detailed treatment guidelines on 21 clinical specialties ranging from Medicine to organ transplant. In addition State Health departments have also developed Standard Treatment Guidelines for their respective states. These guidelines are usually printed and distributed to public health facilities. Apart from government, professional associations such as Indian Academy of Pediatrics (IAP), National Neonatology Forum (NNF), The Federation of Obstetric & Gynecological Societies of India (FOGSI), Association of Physician in India (API), Indian Society of Nephrology (ISN) etc. develops their own clinical guidelines targeted for both private and public healthcare providers. Certain NGOs have also come up with standard treatment guidelines eg. Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) has published its own set of STGs. Apart from Indian sources, guidelines from international sources such as National Institute of Health & Care Excellence (NICE) United Kingdom), World Health Organization (WHO) and international professional agencies ie. American Heart Association (AHA) & Royal College of Obstetricians and Gynecologist (RCOG) etc. Are often referred by Indian doctors. Information Technology based clinical decision support system such as 'Up-to-date' has also become popular with physicians. It is evident from above discussion that guidelines from multiple sources are available in India. Following are the major issues.

1. There is no agreed format on STG. Multiple agencies develop guidelines in different format and structures.
2. Most of these guidelines are adopted from international guidelines or expert consensus. The reference to source guidelines is usually missing. Guidelines seldom mentions the process of development of guidelines.
3. Strength of evidence is usually missing while mentioning the recommendations, which is a basic requirement of evidence based medicine.
4. Government health department usually print voluminous STGs which are circulated in to government hospitals. Use of these guidelines in clinical practice is quite low.
5. There is no robust mechanism to restrict any vested interest especially by pharma and biomedical equipment firms to influence guideline recommendations. Many of the guidelines developed by professional associations are fully or partially funded by pharma companies. In absence of a robust mechanism to declare conflict of interest even government agencies are prone to get influenced unknowingly by pharma companies and lobbyists.
6. Guidelines usually do not factor in cost to benefit considerations. Many of the recommendations are copied from international guidelines without knowing their cost implications. In low resources setting such India with limited government spending and poor purchasing capacity of individuals, it is imperative to factor in cost considerations while giving recommendations. This especially becomes important for government funded public health & insurance schemes as a costly alternative may swell the government budget.
7. There is no mechanism of periodic review and update of the guidelines.

As evident that guidelines are being developed by multiple agencies using multiple methodology and funding sources. There is inherent risk of vested interest to creep in. If not regulated this may lead to confusion in clinical practitioners and variation quality of care.

International Scenario

This is not a unique situation for India. Clinical guidelines are developed by multiple agencies across the world. Though many countries with evolved health systems have a dedicated agency to screen the guidelines for quality and evidence and approve them for use in their country. Eg. USA has a National Guideline Clearinghouse under Department

of Health & Human Sciences, which scrutinizes the available guidelines and authorize the guidelines which meet their minimum criteria. Similarly in United Kingdom NICE supports NHS (National Health Services) in developing, reviewing and updating the clinical guidelines. NICE also develops implementation tools such as clinical protocols & quality standards upload on its website for dissemination. In Australia this task is done by National Health and Medical Research council. Usually these agencies upload the approved guidelines on a designated web portal for use of clinician or common public. There are international groups such as "Guidelines International Network (G-I-N) which coordinates guidelines syntheses, appraisal and update in member countries. Cochrane Library is another organization that keeps repository of evidence based guidelines usually based on systematic review of randomize control trials.

How guidelines are developed

The guidelines are developed across globe using either of three methods :

1. **Evidence Synthesis (De novo Guidelines) –** This is most sophisticated way of developing guidelines. This requires evidence synthesis on pre defined clinical questions using by systematic review of primary research. Recommendations are formulated based on finding of evidence synthesis and graded as per strength of evidence. This methodology is advocated by World Health Organization. Many other reputed agencies including NICE (UK) develop clinical guidelines using the same methodology with some variations. The rigour of this methodology ensures that only recommendations with strong evidences are reflected in guidelines. Though it's the best way of developing the guidelines, this requires plenty of resources in terms of time and money. NICE, UK usually takes 1.5- 2 years in developing one such guideline.

2. **Adopting the existing guidelines –**This is quite common in Indian scenario where international guidelines from reputed institutions are adopted as Indian guidelines. Sometime adopted guidelines are further adopted to produce guidelines by multiple users. A close scrutiny of standard treatment guidelines in many states would reveal that these have been adopted from a single Indian source, which itself can be further traced to some other international guideline. Usually these guidelines do not search for original source and evidence, so it is difficult to trail the strength and origin of evidence. The time, efforts and financial resources required for developing such guidelines are limited.

3. **Guidelines by expert consensus –** This is subjective but popular way of developing guidelines. Here a small group of clinicians/ academicians collaborate to draft recommendations based on their clinical experience and expert opinion. Though these guidelines are considered as low quality, these become the only feasible option where good quality primary research is either not available in local context. This is still a popular option where systemic synthesis of evidences is not possible because of paucity of resources or primary research.

   With above discussion it is clear that there is no single agency, criteria or approach to develop standard treatment guidelines in India. With India's emerging health sectors and increasing role of insurance sector in financing healthcare , it is imperative to have a robust structure and process for developing, appraising , authorizing and updating clinical guidelines.

STG DEVELOPMENT APPROACH FOR INDIA

The issues discussed above and options available for developing guidelines were discussed in detail during several rounds of STG taskforce meetings. It became evident that no single approach perfectly matches our requirement. Best way of developing guidelines would have been through evidence synthesis. But we do not have adequate primary research done in Indian context. Conducting systematic reviews of already known evidences from other countries will yield similar recommendations and will be a non value adding activity. This will also consume substantial resources and time. One advantage with adoption approach is that it saves time and effort by reproducing the already synthesized recommendations. If the process of adoption can be made robust by ensuring only quality source guidelines meeting certain parameters, this can be optimal way of developing guidelines in short time. These parameters would consist of rigour of development of source guidelines as well as applicability of the source recommendations in Indian context. AGREE II (Appraisal of Guidelines Research & Evaluation) is a globally accepted criterion for assessing the quality of guidelines used by reputed organizations globally. Recommendations not meeting the Indian context should be either validated by a systematic review of primary research in Indian context. If primary research is not available, recommendations based on expert opinion can be given. The recommendation which deviates from source guidelines would be termed as 'adapted' recommendations. Where ever cost is a consideration, a cost effectiveness analysis can be done before finalizing the recommendations. This 'Hybrid' approach takes best of all three existing

approaches and optimize the guidelines development process so that evidence based guidelines in Indian context can be developed in short time within limited financial resources.

Process of Development – Once 'How' guidelines should be developed was finalized, taskforce worked on process of developing the guidelines. This includes What Guidelines Should be Developed: 'Who should be members of guidelines development team, what should be the structure format of guidelines', what should be the process of internal and peer review and commissioning of guidelines.

STG writing group - Taskforce decided to work on limited no. of guidelines in the first phase. 10 clinical specialty subgroups were formed with each group initially to focus one disease condition. To make guideline group multidisciplinary each group was directed to recruit members from diverse background apart from domain experts. This includes allied health workers (Nursing/Paramedic/Rehabilitation), Physician, private practitioners, primary care doctors, public health/ health system experts, methodology experts and patients or patients right organization. In each the senior most expert was usually designated as facilitator. Each member was asked to declare any conflict of interest on a standardized format and records are kept with Taskforce secretariat. Writing group members were trained for the guideline development methodology in a two day workshop with technical support of NICE, UK. Each subgroup was allocated some financial resources by NHSRC for conducting subgroup meetings and covering other incidental cost.

Topic Selection Process – Each subgroup was requested to propose 5 disease conditions of their respective clinical specialty. These disease conditions were prioritized on a criteria based on burden of disease, non availability of Indian guidelines and policy importance. The disease conditions on which MoHFW already have issued guidelines were excluded. Total 14 disease condition was selected for the first phase.

Guideline Development – Guidelines were developed using agreed 'Hybrid' methodology adopting/adapting guidelines as explained above. Scope of Guidelines was defined before starting the search for guidelines. As a strategy reputed repositories of guidelines such National Guideline Clearinghouse and NICE were searched for existing guidelines as these have been already screened for quality. For guidelines from other sources a screening of guidelines against AGREE II tool was done before considering them for adoption/adaption.

Documentation – Once the recommendations were finalized (Adopted or Adapted) following documents were developed.

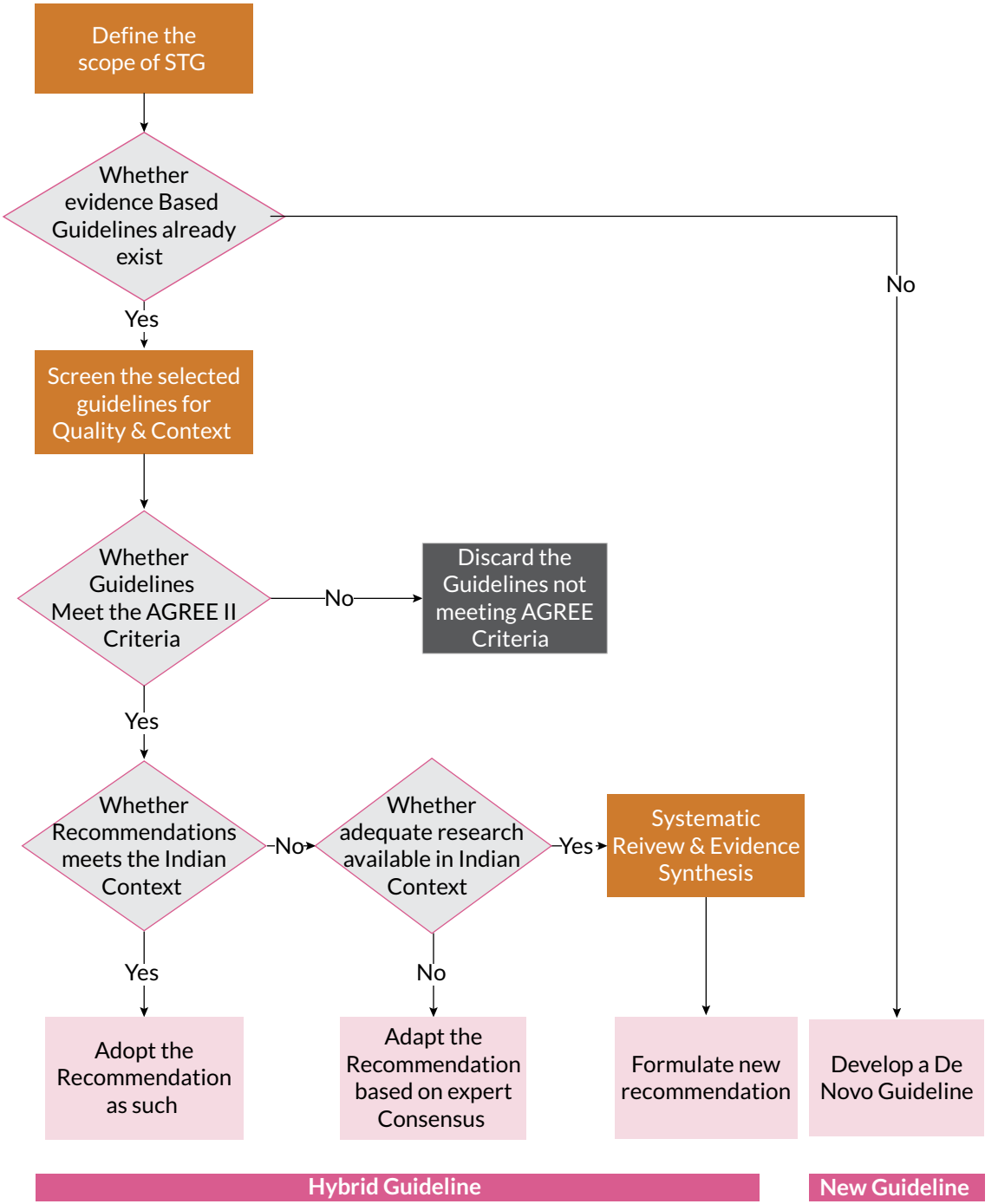
Full Background document- Contains the detailed recommendations along with reference to source guidelines. Document also describes the process of development of guideline, details of writing group members, and decision taken on adopting or adapting on specific recommendations.

Quick Reference Guide- A concise version of full document consists of key recommendations and clinical pathways more targeted for frontline clinicians.

Apart from these, implementation tools such as Quality Standards, Patient Information Sheet and Formulary were also developed for each set of guidelines.

Review Process- All the documents went through three tier review process. First Internal review was done by a designated internal harmonization group. This group reviewed the document for consistency and adherence to agreed methodology. Once the internal review suggestions were incorporated documents were submitted to DGHS for external review, who in turn appointed prominent expert for external review of the documents. Finally documents were uploaded on MoHFW and NHM website for one month for open consultation and comments from public. Finally revised documents were submitted to MoHFW for final approval and commissioning.

The entire process is explained in the previous diagram.


Define the scope of STG
Whether evidence Based Guidelines already exist
No
Yes
Screen the selected guidelines for Quality & Context
Whether Guidelines Meet the AGREE II Criteria
No
Discard the Guidelines not meeting AGREE Criteria
Yes
Whether Recommendations meets the Indian Context
No
Whether adequate research available in Indian Context
Yes
Systematic Reivew & Evidence Synthesis
Yes
No
Adopt the Recommendation as such
Adapt the Recommendation based on expert Consensus
Formulate new recommendation
Develop a De Novo Guideline
Hybrid Guideline
New Guideline

OVERVIEW OF PROCESS

The purpose of this manual is to guide the users develop high quality guidelines within the limits of resources that we have and the paucity of time that we work on. Also, it seems logical to take advantage/build on the existing guidelines, and undertake literature search only for areas where nothing contextual/up to date work is available.

This time saving, resource utilizing methodology which makes the best of both worlds has been named as the hybrid methodology. This implies that both the adapt/adopt and the de novo approach would be used in conjunction to produce high quality guideline. For the areas where guidelines produced in one setting are available for the health question in consideration, they would be adapted/adopted for use in a different cultural and organizational setting. The process has been designed to ensure that the adapted guideline not only addresses specific health questions relevant to the context of use but also is suited to the needs, priorities, legislation, policies and resources in the targeted settings. The transparent and explicit reporting of the adaptation process followed will enhance the validity and quality of the adapted guideline.

In case, the selected review question is not answered by any of the existing guidelines, it would require a denovo literature review to develop recommendations. It should be ensured that the best available evidence is used to guide the recommendations in the guideline. To ensure this, the evidence is selected and quality assessed using clear and appropriate methods.

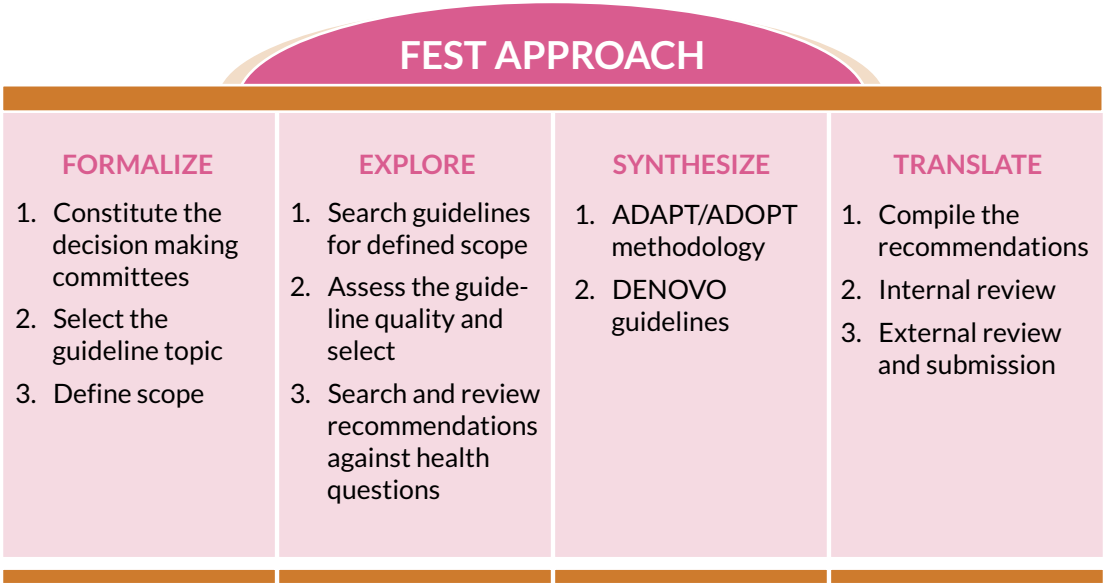
This hybrid approach consists of 4 phases, each with its set of modules. This can be acronymised as "**FEST**":

1. **Formalize:** Outlines the necessary tasks to be completed before guideline search begins such as constituting a guideline development group and formulating clinical questions.

2. **EXPLORE:** Assists users through the process of searching for and retrieving guidelines, assessing the consistency of evidence and the guideline quality.
3. **Synthesize:** Decision making around adaptation/adoption/denovo methods and selecting the appropriate approach.
4. **TRANSLATE:** Involves translating evidences into recommendations. Also guides the user through the process of obtaining feedback on the document from stakeholders impacted by the guideline, establishing a process of review and updating of the adapted guideline and creating a final document.

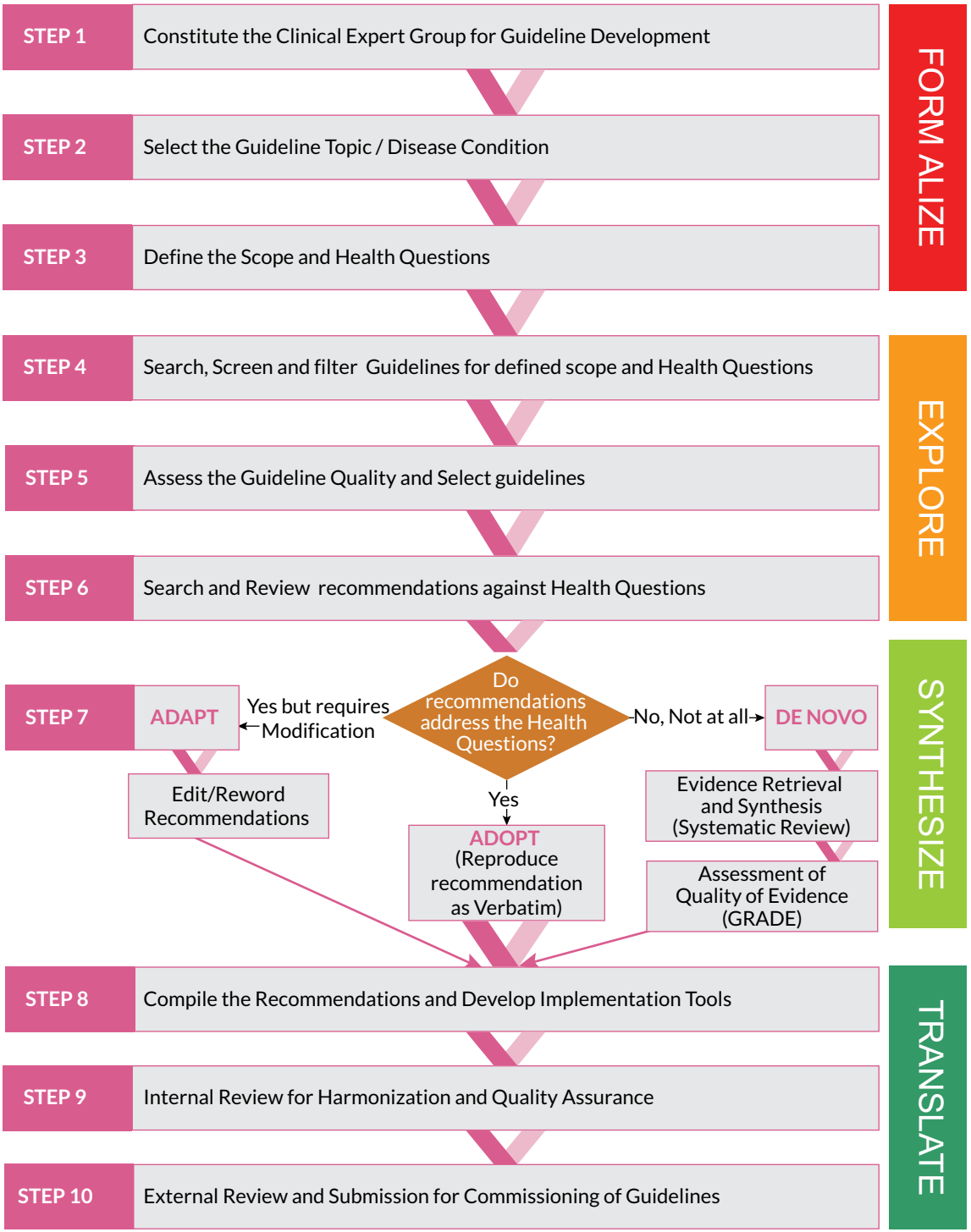
For a clearer understanding it can also be depicted as in the Fig 1 below.

FIG 1: THE FEST APPROACH



This manual would now take you through and explain all of these steps in detail. Each module includes several steps, products and deliverables, skills and organizational requirements and tools.

Below is a flowchart, that shows the step by step path that would be followed in developing the STG's using the HYBRID methodology.


STEP 1
Constitute the Clinical Expert Group for Guideline Development
STEP 2
Select the Guideline Topic / Disease Condition
STEP 3
Define the Scope and Health Questions
FORM ALIZE
STEP 4
Search, Screen and filter Guidelines for defined scope and Health Questions
STEP 5
Assess the Guideline Quality and Select guidelines
STEP 6
Search and Review recommendations against Health Questions
EXPLORE
STEP 7
ADAPT
Yes but requires Modification
Do recommendations address the Health Questions?
No, Not at all
DE NOVO
Edit/Reword Recommendations
Yes
ADOPT (Reproduce recommendation as Verbatim)
Evidence Retrieval and Synthesis (Systematic Review)
Assessment of Quality of Evidence (GRADE)
SYNTHESIZE
STEP 8
Compile the Recommendations and Develop Implementation Tools
STEP 9
Internal Review for Harmonization and Quality Assurance
STEP 10
External Review and Submission for Commissioning of Guidelines
TRANSLATE

PHASE 1: PREPARE

1. Constitute the Decision making committees

2. Select the guideline topic

3. Define scope

CONSTITUTE THE DECISION MAKING COMMITTEES AND GUIDELINE DEVELOPMENT GROUP

The entire process of guideline development lies with the various stakeholders ranging from commissioning agency, domain experts, method experts, target groups and program managers who with their mutual coordination, discussions, support in various capacities, deliver quality evidence based guidelines. To develop clarity, four groups are proposed with clear description of roles and responsibilities of the members of the group. This chapter deals with the "PEOPLE" and group dynamics aspect of the guidelines development eg. Who are involved, how are they selected, and what do they do etc.

THE COMMISSIONING BODY (MINISTRY OF HEALTH AND FAMILY WELFARE, MOHFW)

For the guidelines to be developed there ought to be a commissioning body that would fund the guideline as well as own the guideline once it is developed. For example, Ministry of Health and Family Welfare, GOI or counterpart state health department acts as a commissioning body.

ROLE

The key role of the commissioning body in this context can be tabulated as follows:

KEY TASKS	• Provide administrative support for guideline development
	• Select members of the STG task force and the clinical subgroups
	• Collect and assess disclosures of interest and manage conflicts
	• Organize STG task force meetings, consultation meetings with external stakeholders
	• Approves the scope of the STG
	• Oversee peer review, review comments and revise the draft guideline as appropriate
	• Approves (signs off) the final STG and confirms that the correct process has been followed for its development.
	• Oversee publication and dissemination of the guideline.

GUIDELINE DEVELOPMENT AGENCY/ STG TASK FORCE

This is made up of external experts whose central task is to develop evidence based recommendations. This group should be established early in the guideline development process.

The members of the task force are not commissioned and do not receive any financial compensation other than for direct expenses associated with their work on the guideline. The responsible technical officer may develop terms of reference so potential task force members clearly understand their roles and responsibilities before committing themselves. Currently NHSRC works a secretariat for STG taskforce.

COMPOSITION

Potential members of the task force are identified by the commissioning body (Ministry) and selected to encompass the technical skills, diverse perspectives and geographic representation needed. The group should be small enough for effective group interaction and decision-making, but large enough to ensure that all relevant expertise and perspectives are represented. A group of 10 to 20 is usually feasible and effective. The task force is usually headed by the Member Secretary. The roles and responsibilities of Member Secretary are given in box below.

MEMBER SECRETARY	• Calls for and organizes meetings
	• Co opt new members, as and when required from various stakeholders
	• Create specialty groups and mentor other members
	• Provide Administrative and Financial support to the members
	• Support the harmonization group
	• Facilitate documentation of STG's
	• Review revised STG's
	• Submit the STG's to Govt. for consultation in public domain
	• Share the comments and suggestions received from experts and public with the specialty groups.
	• Submit the Final STG document to MOHFW for approval

ROLE: The role of the STG task force is to:

KEY TASKS	• Select topics for STG
	• Prepares the process for existing guideline adaption/adoption or development of denovo STG's
	• Guide the STG development committee on the development of the STG scope and provides ongoing guidance to STG development committee during the entire process of STG development.

THE INTERNAL HARMONIZATION GROUP

This group consists of members from the STG task force as well ad hoc domain experts. The strength of the group is usually 10-15 members. The group acts as a peer review group who review the guideline before it goes in for the public consultation.

THE STG DEVELOPMENT GROUP

This group contains the technical expertise on the guideline topic under consideration and is mainly responsible for penning down the guideline.

COMPOSITION

The STG development group is multidisciplinary and composed of subject matter experts, primary healthcare practitioners, private practitioners, experts from nursing background, patient representatives, public health specialists, representatives from NGOs, and other experts/people can be roped in depending on the topic under consideration. The aim is to have a diverse group. The decision on the members is usually taken by the NHSRC in consultation with the STG task force.

The STG Development Group has the following representations:

A. The Facilitator

B. Healthcare and other professionals (both specialists in the topic and generalists): This includes doctors, nurses, and other health professionals allied to medicine (e.g. physiotherapist, nutritionists) whenever relevant. Representation from both public and private sector is recommended.

C. Rapporteur(Writing team)

D. Health System Specialist

E. Methodology expert

F. Technical coordinator from Quality Assurance division of NHSRC, with technical knowledge onappraisal of evidence and development of STGs.

G. Health Economist

H. Representatives from NGO's, Professional bodies

I. Patient and family members

Additional technical members are assigned or added by NHSRC if new clinical/ review questions or De Novo STGs are planned.

Representatives from hospital administration and/ or insurers may also be included the STG clinical sub group if relevant.

For some STG topics, it may be important for the STG clinical sub group to include an epidemiologist with knowledge of the subject.

Ideally, STG clinical sub group members should be drawn from different parts of India (because STGs apply to all Indian States) but this will be influenced by the expertise available.

Gender representations should also be considered to avoid biases in gender related issues.

A. THE FACILITATOR

The selection of the facilitator of the STG development committee is a key decision. The STG task force usually selects the facilitator, but the choice should generally be agreed upon by members of the committee. The facilitator should be an expert in facilitating groups that reach decisions based on consensus; be experienced at critically appraising and interpreting evidence and developing evidence-informed recommendations; and have no financial interests related to the guideline's topic. Although the facilitator should have a general knowledge of the topic of the guideline, no one with strong views about the interventions under consideration should chair the committee. The facilitator should

have experience engaging in consensus-based processes involving people with different opinions. The facilitator can be a guideline methodologist with expertise in evidence synthesis and in formulating recommendations based on evidence.

The role of the facilitator is:

KEY TASKS	• Writes the STG scope with help from NHSRC and the STGTask Force.
	• The Chair and/ or program manager provides induction/ orientation session to STG clinical sub group members during the first STG subgroup meeting.
	• Prepares the work plan which outlines the various activities, timelines, division of work etc. for development of STGs (adapted/ de novo).
	• Selects guideline recommendations from existing guidelines that adhere to international guideline development criteria and decides whether they can be adopted entirely or whether individual recommendations from 1 or more selected guidelines need to be adopted or adapted.
	• If key clinical issues identified for India in the scope are not covered by existing guidelines, defines the new review questions that will guide the search for evidence, assesses & synthesizes the evidence, discusses the evidence, translates the evidence into broad conclusions and develops the guideline recommendations for new clinical questions
	• If de novo guidelines are being developed, drafts all the new clinical questions and uses same methodology as described above for new review questions.
	• Reviews the draft implementation tools like the quick reference guide, the patient version and quality standards.
	• Provides clinical direction to NHSRC staff designated to write the STG document and implementation tools.
	• Responds to comments received during peer review make consensus for necessary changes to the STG.

B. HEALTHCARE PROFESSIONAL MEMBERS

Healthcare professional members of the STG clinical sub group should represent the perspective(s) of the healthcare professionals (and other professionals where relevant) involved in the care of patients affected by the guideline topic. They are on the STG clinical sub group as healthcare professionals with appropriate knowledge and skills; detailed research expertise is not necessary but a basic understanding of evidence based medicine and priority setting is essential. They are not expected to represent the views of their professional organizations.

The list of professions represented in the STG clinical sub group is agreed as part of the document developed by the technical team in NHSRC after consultation with the STG task force. The roles and responsibilities of the healthcare professional members of the STG clinical sub group are shown below:

KEY TASKS	• Review existing guidelines which are developed according to defined criteria and ensure that they are relevant to the topic. The guidelines are compiled by the NHSRC technical team before the first STG meeting.
	• Decide whether recommendations from any of the existing guidelines can be adopted in verbatim or whether individual recommendations from one or more guidelines can be adopted/adapted. Suggest new wording in case adaption is required.
	• With other members of the STG clinical sub group, consider implementation issues arising from recommendations.
	• Decide whether all the key clinical issues in the scope are addressed in the selected existing guidelines or whether new clinical/ review questions are required.
	• Guide the technical team in framing new review questions if key clinical issues in the scope are not addressed in existing guidelines or if de novo guidelines are being developed. They use their background knowledge and experience on the guideline topic to provide guidance to the technical members carrying out systematic reviews and economic analyses for new review questions. They also approve the review protocols for new clinical questions with other members of the STG Development Group.
	• Contribute constructively to meetings and have good communication and team-working skills; this should include a commitment to the needs of patients and their families. With other members of the STG clinical sub group, they should agree to the minutes of STG clinical sub group meetings.
	They are not routinely expected to: • Search the literature • Perform systematic review

C. RAPPORTEUR(WRITING TEAM)

The writing team actually pens down the guideline. This consists of the members of the STG development committee. A clearly written guideline and a well-documented process

are critical to the final clearance and usability of the guideline, so the writing team needs to be involved in the planning and development stages, attend committee meetings, and work closely with the task force and the facilitator.

D. HEALTH SYSTEM SPECIALIST

This is an expert from the public health background. Who looks into the guideline from a public health perspective and provide insights on the feasibility of the guideline. He/She also have an important role to play in predicting the implementation issues in the guideline.

E. TECHNICAL COORDINATOR

The technical coordinator should have the techno-managerial skills. He/She should have technical knowledge on the development of STG's and appraisal of evidence.

The technical coordinator oversees and facilitates the whole process and organizes the STG clinical sub group meeting in consultation with the Chair. He/she is appointed/ assigned by the commissioning body to provide administrative and technical support the STG clinical sub group and also liaises with the STG Task Force. In addition to administrative responsibilities, the technical coordinator has technical skills relevant to STG development.

Note: The STG clinical sub group can seek advice from the technical team which is common to many or all the clinical sub groups if there are queries related to technical issues like appraisal of evidence or cost-effectiveness.

If new clinical/ review questions or de novo STGs are planned, additional technical members are included in the clinical sub group. These members can be from NHSRC, Indian Universities or Centres of excellence. These will consist of an information specialist, a lead systematic reviewer and a health economist and these members will be voting members of the STG clinical sub group.

F. METHODOLOGY EXPERT

The methodology expert is usually appointed if new review questions that require a systematic review are present in the STG. He/She identifies the relevant literature that is used to answer the review questions developed by the STG development Committee.

The role of methodology expert involves:

- Contributing to the development of the scope and review of existing STG's.
- Setting of review questions
- Designing and testing population and study design search filters.
- Contributing to discussions among the technical team and in STG development committee meetings as required, including deciding whether a search is needed and gathering key terms and synonyms.
- Identifying which databases should be searched
- Drafting, refining and executing search strategies
- Creating databases of the search results using reference management software (including removing duplicates), in preparation for filtering by a systemic reviewer
- Maintain audit trails, including keeping a log of search results, rationales and strategies.

In addition, the information specialist advises on issues such as copyright and licenses, archiving and record management.

G. HEALTH ECONOMIST

An economist can be an important contributor to STG development group (SDG). if resource-related issues are at play in the formulation of recommendations. This SDG member can advise on matters of economic efficiency, such as cost–effectiveness, and on any other resource implications of the interventions under consideration. The economist can also advise on how to search for and interpret relevant economic data and the evidence on resource use. The Health Care Financing division of NHSRC would be consulted in all matters related to this context.

H. REPRESENTATIVES FROM NGO'S, PROFESSIONAL BODIES

Professional bodies like IMA,IAP may also have their representatives in the group. This makes them take ownership of the guidelines .

I. PATIENT AND FAMILY MEMBERS

All Committees have at least 2 lay members with experience or knowledge of issues that are important to people using services, family members and carers, and the community

affected by the guideline. This helps to ensure that the guideline is relevant to people affected by the recommendations and acknowledges general or specific preferences and choice.

Lay members usually have direct experience of the condition, services or topic being covered by the guideline – as a patient, service user, carer or family member, or as a member or an officer of a lay stakeholder organization or support group. However, they do not represent the views of any particular organization.

PLANNING AN EFFECTIVE MEETING

The Committee is multidisciplinary and its members bring with them different beliefs, values and experience, also they come from different geographies. Getting them together for a face to face meeting, therefore entails lot of resources in terms of time and money. So, it is essential to plan the meeting beforehand so that it is fruitful in all aspects.Each member should have an equal opportunity to contribute to the development of guideline, and should receive any additional support they need to do this.

During meetings, the facilitator must ensure that group members can present their viewpoints and that all relevant issues are discussed in a respectful and efficient manner. In addition, the facilitator should keep the group focused on the agenda; reflect on and summarize the opinions of the group members; raise issues that could inform the decision process; and manage the group so as to achieve consensus. The facilitator and co facilitator should not impose their own opinions on the group; however they may put forth their views in a purely personal capacity.

All the proceedings of the meeting should be duly recorded and shared with all the members of the group within a week.

CONFLICT OF INTEREST

- A conflict of interest is an important potential source of bias and results in diminished credibility in the development of guidelines. “A conflict of interest is any interest that may **affect** or reasonably be **perceived to affect** the expert’s **objectivity** & **independence** in providing advice.

All Committee members and anyone who gives direct input into the guideline must declare any potential conflicts of interest.

Types of conflict of Interest:

1. Financial interests
2. Non financial personal interests
3. Institutional interests
4. Academic or intellectual interests

They can be illustrated as below:

Intellectual Interests	Finanacial Interests	Institutional interests
• Prior publication of a study/ systematic review that is part of the evidence base under consideration; • Prior public declaration of a firm opinion or position, as in public testimony or in an editorial in a journal; or • Professional or personal affiliation with an organization advocating for products related to the subject	• Personal financial gain such as paid work, consulting income or honoraria and travel stipends support for research, including direct monetary contributions or donations of equipment, laboratory space, etc.; • Proprietary interests and patents; • Grants, fellowships or other financial support to the individual or to their institution; and • Stock shares or bonds in a commercial entity	• Publicity of one's institution

Box : Types of conflicts of interest.

Declaration of interests

All the STG group members and anyone who gives direct input into the guideline must declare any potential conflicts of interest. For the STG task force and the STG development committee, this happens on application for committee membership. Any relevant interests, or changes to interests, should also be declared publicly at the start of each Committee meeting. Before each meeting, any potential conflicts

of interest are considered by the **facilitator and senior members of the guideline development committee.** Any decisions to exclude a person from all or part of a meeting should be documented. Any changes to a member's declaration of interests should be recorded in the minutes of the meeting. Declarations of interests are published with the final guideline.

An overview of the process is given in the box below:

Overview of the process for identifying, managing and reporting secondary interests

1. All potential external contributors to guideline development fill the standard declaration of interests form before invitations to participate in a STG development committee or attend a meeting are finalized and before contracts are issued. Potential contributors should submit a curriculum vitae also.
2. The Member Secretary, in consultation with the STG task force, assesses the declaration of interests and curriculum vitae and determines if a conflict of interest exists.
3. Conflicts of interest are assessed for severity (risk of adversely affecting the guideline development process) and a management plan is formulated.
4. At each committee meeting, declarations of interests are summarized and presented, with the opportunity for members to update and/or amend their declaration. The management strategy for each member with a conflict of interest is also presented.
5. A summary of all disclosed interests and the management plan for any conflict of interest are reported in the final guideline document.

The format used for declaration of interests from the committee members is attached in the annexure 1.

PHASE 1: PREPARE

1. Constitute the Decision Making Committees
2. **Select the guideline topic**
3. Define Scope

SELECT THE GUIDELINE TOPIC

Once the clinical expert group is formed, the next step in the **Prepare** phase is to select the guideline topic. In some cases, the need for a guideline on a particular topic will already have been identified. In other cases, a group may need to select a topic. The list of potential topics for STGs is prepared by the STG task force in consultation with the commissioning body and clinical and policy networks. This chapter provides general guidelines for prioritizing the topic of the STG. This could be a guiding tool but it is advised that the developers use their discretion and consider their specific needs in addition to the guidance available here.

Following is a list of criteria which can be to prioritize and decide the topic for framing the guidelines:

1. POLICY IMPORTANCE : The selected topic:
• Not relevant to any specified government health policy • Relevant to specified government health policies
2. PREVALENCE: The selected topic is:
• Rare disease (Affects <5 people/10,000 population in India) • Disease with potential to become more common (Affects between 5-100 people/10,000 population in India) • Disease with potential to become an epidemic (Affects>100 people/10,000 population in India)
3. DISEASE LEADING TO SIGNIFICANT MORBIDITY OR DISABILITY
• Disease causes low or no mortality or disability • Disease can cause intermediate mortality or disability • Disease can cause high mortality or disability

4. NEED : The selected topic has
• Updated guidelines/Resource material exist • Some guidelines/Resource material (not up to date) available • No guideline/resource material exists
5. VARIATIONS IN CLINICAL PRACTICE: The selected topic has:
• No published or anecdotal evidence of variation in practice • Ancedotal evidence of variation in practice but no published evidence • Published evidence of variation in practice
6. ESTIMATED RESOURCE IMPACT: The selected topic has:
• Expected to have significant resource/cost implications • Expected to be cost neutral/low cost • Expected to be cost saving
7. TIMELINES OR URGENCY: The selected topic has:
• No time issues/urgency • Need to be timely • Is urgent/pressing need

PHASE 1: PREPARE

1. Constitute the Decision Making Committees
2. Select the guideline topic
3. **Define Scope**

DEFINE SCOPE

Scoping is the process of defining what a guideline will and will not include. It is the first step to creating any guideline. It is a sort of framework in which STG development process will take place.

The purpose of scoping the guideline is:

- To ensure that key clinical issues are covered by STG
- Set the boundaries of the development work and provide a clear framework to enable the work to stay within the priorities agreed with NHSRC and to be conducted within the specified time period.
- Compilation of existing guidelines relevant to the scope of the STG topic
- To see if new clinical or review questions need to be developed and guide their development.

The scope sets the boundary that ensures the work stays within the defined field of interest and informs any relevant quality standard. It briefly describes the epidemiology relevant to the disease or condition, and defines the following:

- The Population that will and will not be covered for example, age groups and people with certain types of disease.
- The Interventions and treatments to be included and excluded-for example, diagnostic tests, surgical treatments, medical and psychological therapies, rehabilitation and lifestyle advice. It is important that the scope is as specific as possible about the interventions the guideline is intended to cover.
- The expected Outcome including patient outcomes (e.g. improved disease free survival, improved quality of life); improved system outcomes(e.g. decrease in

practice variations); and/or public health outcomes (e.g. a decrease in cervical cancer incidence).

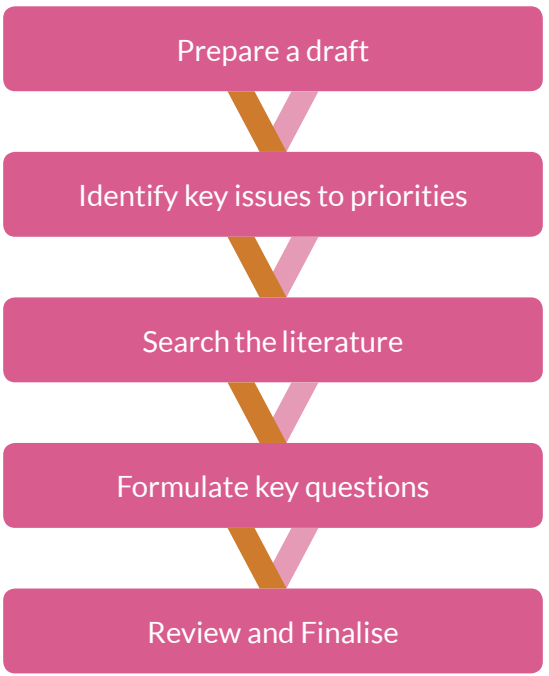
- The Healthcare setting and context in which the guideline is to be implemented- for example primary, secondary or tertiary care.

The title of the guideline (as given in the scope) should accurately reflect the content of the scope and needs to be considered very carefully.

The process of defining the scope is an important step in the STG development process as it will then guide the framing of review questions and hence evidence search and recommendations. It should be ensured that the scoping is such that the guideline focuses on key areas needing policy advice and at the same time is of manageable size, capable of being executed in the allocated time frame and with the available resources.

STEPS FOR SCOPING THE GUIDELINE

The flowchart below represents the steps in developing the scope:



STEP 1: Prepare a draft

Draft a potential scope for the topic under consideration and a list of potential priority topics.

The scope is drafted by the facilitator of the guideline development group in consultation with other members of the group.

STEP 2: Identify key issues to prioritise

This determines the breadth and depth of work. It is not feasible to include everything. Including areas which need policy changes, significant interventions are desired and are feasible. Focusing on areas where some inequity, controversy or uncertainty exists would help.

ISSUES RELATING TO INTERVENTIONS

- Antispasmodics for the management of IBS (irritable bowel syndrome)
- Antibiotics for preventing wound infection in women who have had an elective caesarean section
- Decision aids in prostate cancer

ISSUES RELATING TO DIAGNOSIS

- CT for identifying patients with lung cancer who are suitable for curative surgery
- Diagnosis and management of Headaches in young people and adults

STEP 3: Search the literature

At this stage, a preliminary search of the literature of the literature should be undertaken to identify potential existing guidelines, systemic reviews, economic evaluations etc. The search should not be too exhaustive since proper literature search will happen later.

Some of the suggested sources for literature search are given below. Detailed list is given in annexure 2.

- Cochrane database of systemic reviews-CDSR 9 (Cochrane review)
- National Guideline clearinghouse(US) http://www.guideline.gov/
- NICE website: http://www.NICE.org.uk
- MEDLINE
- National Library for health
- Websites of relevant professional bodies and associations that may have produced guidelines or reports.

STEP 4: Formulate key questions:

Use the topic list to formulate the key questions to be answered in the guideline. These questions will guide the search for evidence and are best developed using the "population, intervention, comparator and outcome" (PICO) format.

STEP 5: Review and finalize:

Once the scope is finalized, the facilitator will circulate it amongst the members of the guideline development committee and the STG task force. If any changes are suggested by the members, they are discussed and applied. Once there is consensus among the members, the scopeis finalized.

Once the scope recommended by the guideline development committee has been approved and signed off by the commissioning body, the guideline development committee should not make any changes without consulting the commissioning body.

Annexure 3 illustrates a sample scope prepared for the guideline on Hypertension.

PHASE 2: EXPLORE

1. **Search guidelines for defined scope**
2. Assess the guideline quality and select
3. Search and review recommendations against health questions

SEARCH GUIDELINES FOR DEFINED SCOPE

Based on the key questions defined in the scope, a search strategy is developed and followed. Inclusion and exclusion criteria, the year of development, language, and the guideline development group should be determined beforehand. These predefined criteria should guide the search and a methodology expert can be a useful resource to help with designing the strategy. A reasonably comprehensive search for guidelines should be undertaken to identify most relevant guidelines.

Various search sources are available on the web where a comprehensive search for the relevant guidelines can be done. Since guidelines may not be published in the journals and not indexed in bibliographic databases, the search can start in the US National Guideline Clearinghouse (www.guideline.gov), NICE website, WHO website and Uptodate. Even country specific databases can be looked into. In addition, the websites of organizations developing guidelines and of relevant specialty societies should also be consulted. A list of these sources is available for reference in annexure 2.

In addition internet search engines such as Google, Yahoo can also be used to locate guidelines. As with the other searches, the inclusion and the exclusion criteria for the internet search should be well defined.

An additional search should be conducted to identify any other relevant documents such as recent systematic reviews or health technology assessment reports published since the preparation of the retrieved guidelines. This documentation might be used to confirm whether an update is necessary or/and to fill in gaps not covered by the retrieved guidelines.

It is recommended to tabulate the search results in a table mentioning:

- Developing authors/organization
- Date of publication, posting and release
- Country/language of publication
- Dates of the search used by the source guideline developer.
- Reasons for selecting/not selecting the guideline.

Annexure 4 gives a template of this table.

Below is a snapshot of recently published guideline on diabetic foot, showing search results in tabulated form.

Guidelines available	Selected/Not Selected	Rationale
Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini MSJM, Kravitz SR, et al. Surgery Diabetic Foot Disorders : A Clinical Practice Guideline (206 revision) Diabetic Foot Disorders : The Journal of foot and ankle surgery. 2006;45(5):1-66	Not selected, though this guidleline was well constructed, since it was about a decade old.	
International Working Group on the Diabetic Foot (IWGDF) 2015-Prevention and Management of Foot	Selected	GRADE compatible and very well structured guideline available on the

A preliminary assessment of the health questions covered by the review guidelines should be carried out to eliminate those that are clearly not relevant to the defined key questions. In case where the existing guidelines do not cover all the required health topics, some denovo work may be required. Also, looking for systematic reviews, health technology assessment reports, or current research articles would enable them to write their own recommendations for those areas where no recommendations exist.

PHASE 2: EXPLORE

1. Search guidelines for defined scope
2. **Assess the guideline quality and select**
3. Search and review recommendations against health questions

ASSESS THE GUIDELINE QUALITY AND SELECT

The potential benefits of guidelines are only as good as the quality of the guidelines themselves. Appropriate methodologies and rigorous strategies in the guideline development process are important for the successful implementation of the resulting recommendations. The quality of guidelines can be extremely variable and some often fall short of basic standards.

The Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument was developed to address the issue of variability in guideline quality. To that end, the AGREE instrument is a tool that assesses the methodological rigor and transparency in which a guideline is developed. The original AGREE tool has been refined, which has resulted in the new AGREE II.

The purpose of the AGREE II tool is to provide a framework to:

1. Assess the quality of clinical practice guidelines;
2. Provide a methodological strategy for the development of guidelines; and
3. Inform what information and how information ought to be reported in guidelines.

The 23 items in the AGREE instrument assess the method used for developing the guideline and the quality of the reporting. The instrument does not assess the clinical content of the recommendations. The AGREE II replaces the original instrument as the preferred tool and can be used as part of an overall quality mandate aimed to improve health care. Although the AGREE instrument does not provide thresholds for acceptable or unacceptable guidelines based on quality, a comparison of rigor scores across guidelines can provide the group with information to guide the selection process.

HOW TO USE THE TOOL

The details of the tools, its usage, training exercise, AGREE inter-rater Agreement spreadsheet and AGREE score calculation is freely available on its website http://www.agreetrust.org/.

RATING PROCESS

It may be impractical from a resource or time perspective to have all panel members rate all of the guidelines. It is recommended that with respect to improving the reliability of AGREE instrument, each guideline should be appraised by at least two and preferably four appraisers.

All AGREE II items are rated on the following 7-point scale:

1 Strongly disagree	2	3	4	5	6	7 Strongly agree

Score of 1 (Strongly Disagree). A score of 1 should be given when there is no information that is relevant to the AGREE II item or if the concept is very poorly reported.

Score of 7 (Strongly Agree). A score of 7 should be given if the quality of reporting is exceptional and where the full criteria and considerations articulated in the User's Manual have been met.

Scores between 2 and 6. A score between 2 and 6 is assigned when the reporting of the AGREE II item does not meet the full criteria or considerations. A score is assigned depending on the completeness and quality of reporting. Scores increase as more criteria are met and considerations addressed.

HOW THE SCORES CAN BE USED

The AGREE scores provide a sense of quality of some aspects of the guideline and how well they were reported. They can be used as one element in the decision making process around whether or not to adapt a specific guideline. But, a poor AGREE score may not be sufficient in itself for eliminating a guideline.

As also stated earlier, although the domain scores are useful for comparing guidelines and will inform whether a guideline should be recommended for use, the Tool has not set minimum domain scores or patterns of scores across domains to differentiate between high quality and poor quality guidelines. These decisions should be made by the user and guided by the context in which AGREE II is being used.

The detailed AGREE tool is given in annexure 5.

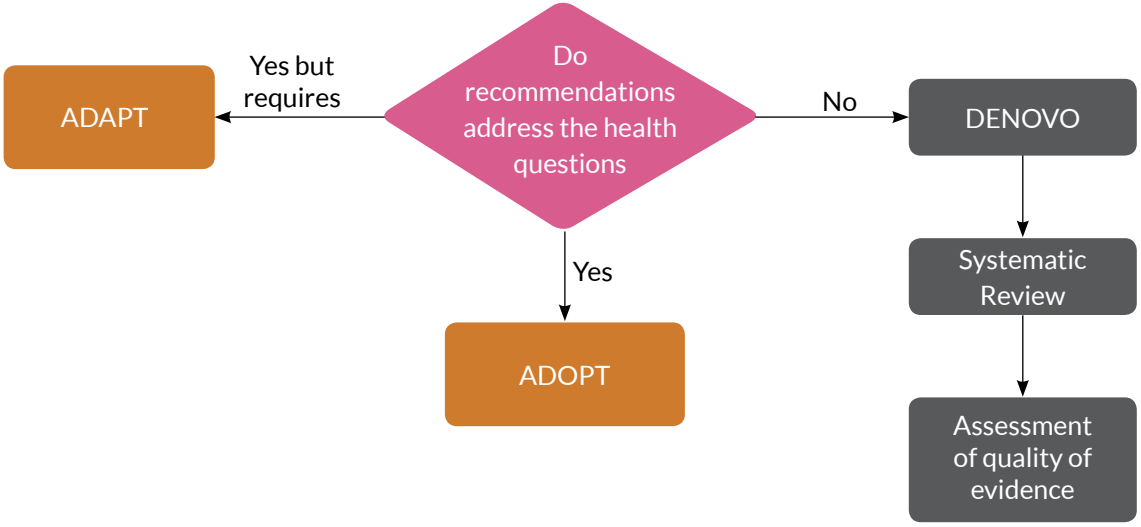
PHASE 3: SYNTHESIZE

1. **Search and review recommendations against health questions(ADAPT/ADOPT methodology)**
2. Developing DENOVO GUIDELINES
   a. Developing the review questions and planning literature review
   b. Evidence retrieval and synthesis
   c. Reviewing Research Evidence

SEARCH AND REVIEW RECOMMENDATIONS AGAINST HEALTH QUESTIONS

After the searched guidelines are validated, the next step is to examine the recommendations in the guideline with respect to the review questions in the scope. This is a decision making stage, where we need to choose one or all three of the below mentioned choices.

Modification



The facilitator of the guideline development group should assist the members in this decision making process. This is a meeting best held face to face. Good facilitation skills are needed by the chair to ensure that all members have an opportunity to present their views.

Decision making occurs around the following three options:

1. **ADOPT:** This will consist of taking the recommendations in the guideline as verbatim, without any changes.

   Below mentioned box illustrates some examples of recommendations which were taken as is (adopted):

Key Recommendation	Source	STG
Screening of hypertension should be done using an automated BP instrument or any other validated device, using a standardised BP measurement procedure.	NICE, European society of Cardiology guidelines	Hypertension
Evaluate a patient with diabetes and a foot ulcer for the presence of PAD. Determine, as part of this examination, ankle or pedal Doppler arterial waveforms; measure both ankle systolic pressure and systolic ankle brachial index (ABI). (Strong; Low).	IWGDF 2015 Guidance document	Diabetic foot

2. **ADAPT:** This entails making some changes to the recommendations as they get into the guideline. This could be a minor edit in order to ensure local compatibility with the country setting or adding precision to the verbatim to clarify the recommendation. The important point here is when adapting a recommendation; the evidence underpinning the recommendation remains intact.

   Below are some of the examples illustrating adaption of recommendations from source guideline. Also the justification behind adaption is mentioned in the comment section.

Key recommendation	Source guideline	Comment
All adults above the age of 18 years should undergo opportunistic screening for hypertension by healthcare providers at every point of contact with health services.	The USPSTF recommends screening for high blood pressure in adults aged 18 years or older.	Adapted. We added the component of opportunistic screening and screening by both physicians as well as non-physician staff.

Key recommendation	Source guideline	Comment
BP targets General population : <140/90 mm Hg in people under 80 years<150/90 mm Hg in people 80 years and over	The original recommendation is "aim for a target clinic BP below 140/90 in people aged less than 80 years with treated hypertension." And "Aim for a target clinic BP below 150/90 in people aged 80 years and over, with treated hypertension."	Adapted. Reworded.
For clinically uninfected wounds, do not collect a specimen for culture.	For clinically uninfected wounds, we recommend not collecting a specimen for culture (strong, low).	Rephrasing done for using active verb.
The diagnosis of alcohol dependence can be done using ICD-10 diagnostic criteria		Adapted. While some of the guidelines did not specify the process of reaching at a diagnosis of alcohol dependence, others recommended use of DSM. Since ICD- 10 is the WHO approved nosological system the same has been recommended for diagnosing

3. **DEVELOP A NEW REVIEW QUESTION:** If the selected guideline/s, do not cover one/many health question described in the scope, new review questions will have to be developed and a systematic review undertaken. When no other high quality guideline has addressed the question, this would require creating a denovo guideline. The process of developing a denovo guideline is elaborated in subsequent chapters. A guideline methodologist can support the process.

PHASE 3: SYNTHESIZE

1. Search and review recommendations against health questions(ADAPT/ADOPT methodology)
2. **Developing DENOVO GUIDELINES**
   a. **Developing the review questions and planning literature review**
   b. **Evidence retrieval and synthesis**
   c. **Reviewing Research Evidence**

DEVELOPING THE REVIEW QUESTIONS AND PLANNING LITERATURE REVIEW

Two situations where new review questions need to be developed are:

- When the existing source guidelines selected for adaption do not contain recommendations covering clinical areas that are of key importance to India and which are specified in the scope or the recommendations given in the source guideline are not appropriate in Indian context because of specific demographic factors or resource constraints.
- If after searching there are no high quality guidelines available on the topic of the STG for adaptation.

Review questions design the frame work in which the guideline development process will take place. They must be clearly defined and focused. These questions drive the evidence search and form the basis of recommendations; they should be carefully crafted and be precise.

Clinical issues identified in the scope, but not covered in the source guidelines selected for adaptation, are translated into review questions. This chapter describes how review questions are developed and agreed. It describes the different types of review question and provides examples. It also provides information on the different types of evidence and how to plan the evidence review.

NUMBER OF REVIEW QUESTIONS

The number of review questions for each guideline depends on the topic and the breadth of the scope. However, it is important that the total number of questions:

- Are manageable
- C an be covered in the time and with the resources available
- Provides sufficient focus for the guideline, and covers all areas outlined in the scope.

The number of review questions for each guideline will therefore vary depending on the topic and its complexity.

DEFINING THE SCOPE OF THE REVIEW QUESTION (BROAD VS NARROW)

The questions addressed by a review may have a broad or a narrow scope. Determining the scope of a review question is a decision dependent upon multiple factors including perspectives regarding a question's relevance and potential impact; supporting theoretical, biologic and epidemiological information; the potential generalizability and validity of answers to the questions; and available resources.

For example, a review might address a broad question regarding whether antiplatelet agents in general are effective in preventing all thrombotic events in humans. Alternatively, a review might address whether a particular antiplatelet agent, such as aspirin, is effective in decreasing the risks of a particular thrombotic event, stroke, in elderly persons with a previous history of stroke.

There are advantages and disadvantages of both keeping the review question broad/narrowed scope. It should be best judged by the STG committee and will vary on case to case basis.

DEVELOPING REVIEW QUESTIONS FROM THE SCOPE

The review question in an adapted STG should be developed from all the areas covered in the scope, but that are not addressed in existing guidelines. They should build on the key questions contained in the scope and will usually be in detail. Review questions for denovo STG's should address all areas covered in the scope, and should not introduce new areas not specified in the scope. They will, however, build on the key questions in the scope and will usually contain more detail.

Review questions are usually drafted by the STG development committee along with MOHFW/NHSRC technical team at a formal meeting which involves brainstorming and

discussions among members to ensure that appropriate review questions are identified, covering all the areas of the scope. This will essentially form the basis of the literature search. Sometimes the questions need refining once the evidence has been searched.

Review questions will fall under one of the two below mentioned categories:

BACKGROUND REVIEW QUESTIONS	FOREGROUND REVIEW QUESTIONS
Pertain to background information • Definition • Prevalence/burden • Etiology • Pathophysiology	Foreground questions • Form the basis for recommendations • PICO format 1. Population 2. Intervention 3. Control Outcome Examples: 1. In LBW infants (P), what is the effect of feeding mother's own milk (I) compared with feeding infant formula (C) on critical outcomes? 2. In LBW infants who cannot be fed mother's own milk (P), what is the effect of feeding donor human milk (I) compared with feeding infant formula (C)?

FORMULATING AND STRUCTURING REVIEW QUESTIONS

The review questions should be clear and focused. To ensure this, a structured format is generally used to develop the review question i.e. the PICO (Population, Intervention, Comparator, and Outcome) format. It is an acronym which can be variably used i.e.

The PICO format also provides a useful structure for delineating inclusion and exclusion criteria for the body of evidence and for formulating recommendations.

P: Population or group being targeted by the intervention/exposure.

I: Intervention or exposure under consideration.

C: Comparator is the alternatives to interventions being considered.

O: Outcomes to be considered to assess how well the treatment/intervention is working.

Population

This defines the group that is being targeted by the intervention or exposure or treatment under consideration. It is important to accurately define the members of the target population considering their demographic characteristics. Consider age, sex and other social, geographic and environmental characteristics that are of relevance to the guideline topic.

The healthcare setting of the guideline is also included here. Any sub populations to be covered should also be analyzed and defined e.g. pregnant women, HIV positive patients etc.

Intervention or Exposure

It may mean intervention, treatment or diagnostic modality being used. Defined broadly, it may mean anything from treatment, procedure, prognostic factor, risk factor etc under consideration. For interventions that are complex, consider which components are of greatest interest to the target audience of the guideline and how they might best be described. An "exposure" is any factor that can influence the risk of a given outcome.

Comparator

The comparator in a recommendation may be standard practice –including no specific treatment – or another intervention relevant to current practice. It defines the courses of action or exposures that stand as an alternative with which to compare to those in the guideline.

The most important comparators are generally those that are most closely related to current practice because they provide guideline developers with the information needed to formulate recommendations relevant toend-users' needs.

Outcomes

These imply the outcomes to be considered to understand which intervention was working well or people/patient preferences with respect to treatment. In general, reviews should include all outcomes that are likely to be meaningful to clinicians, patients (consumers), the general public, administrators and policy makers, but should not include outcomes reported in included studies if they are trivial or meaningless to decision makers. Outcomes may include survival (mortality), clinical events (e.g. strokes or myocardial infarction), patient-reported outcomes (e.g. symptoms, quality of life), adverse events, burdens (e.g. demands on

caregivers, frequency of tests, restrictions on lifestyle) and economic outcomes (e.g. cost and resource use). It is critical that outcomes used to assess adverse effects as well as outcomes used to assess beneficial effects are among those addressed by a review.

The purpose of any recommendation is to achieve a net benefit. Thus, selecting the most important outcomes is critical to producing a useful guideline. For this reason, it is essential to ask members of the Guideline development committee – which should contain end-users, implementers, patient representatives, policy-makers, technical experts and perhaps also other stakeholders – to identify the key outcomes that need to be considered in a guideline.

Selecting and rating outcomes:

Steps

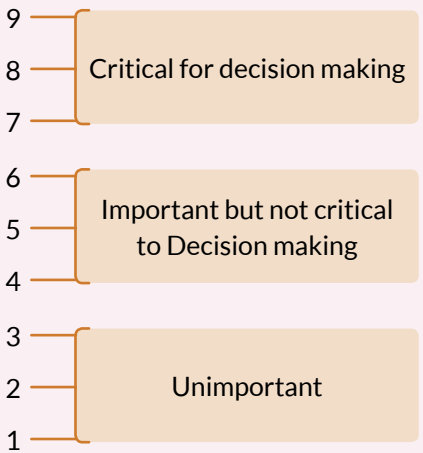
- Enlist the outcomes
- Rank them on a scale of 1-9
- Iterative approach
- Finalize critical outcomes (not more than 7)

Example:

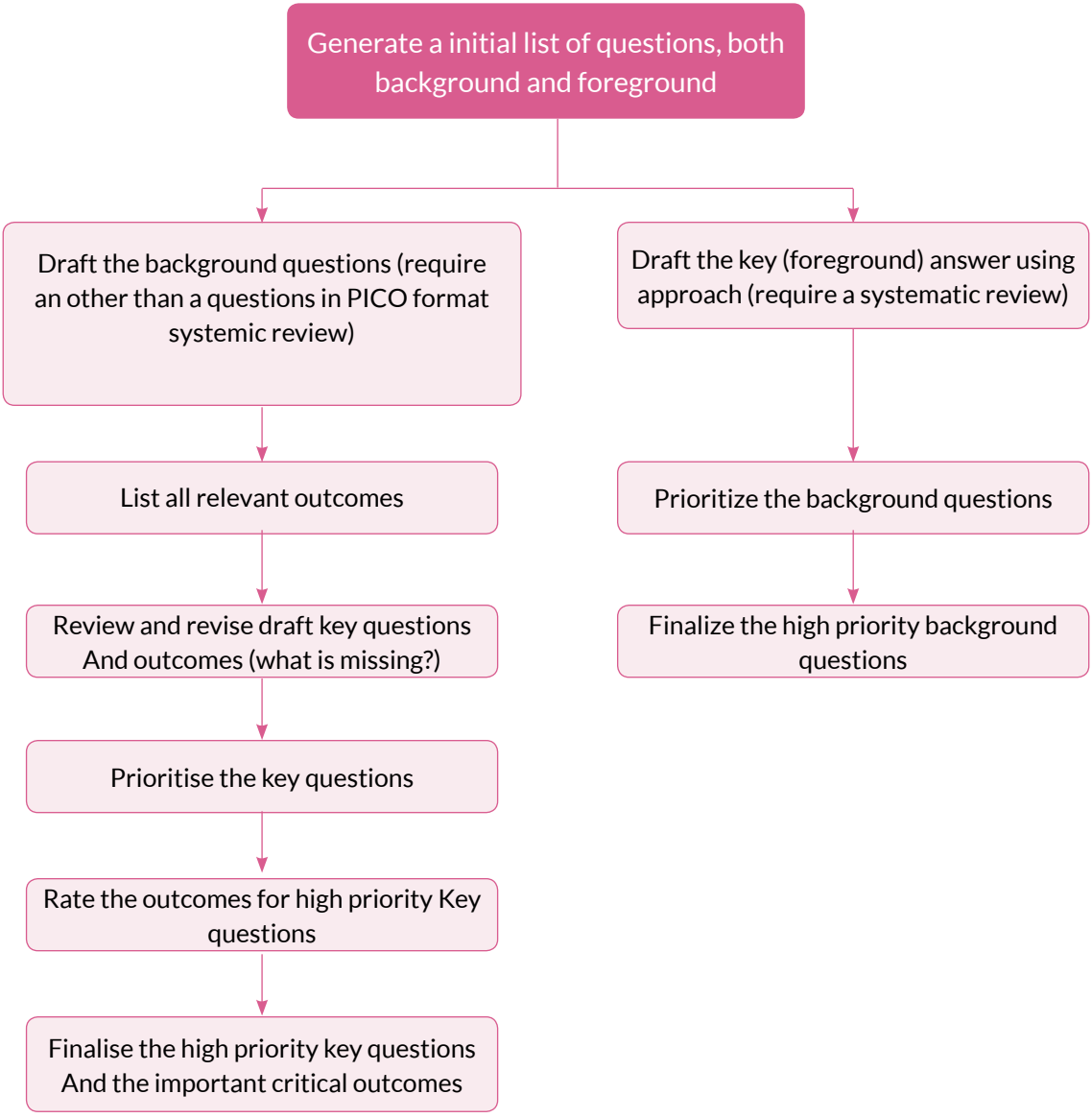
Key outcomes for LBW feeding:

1. Mortality
2. Severe morbidity
3. Neurodevelopment
4. Anthropometric status

Scale for Rating Outcomes:



Prioritizing key questions and outcomes



Below is the table that enlists the different types of key questions in PICO format for a better understanding:

Types of Key questions in PICO format

Type of key question	Syntax	Population	Intervention	Comparator	Outcomes	Example
Intervention efficacy	Among individuals with a certain disease or condition (P), how effective is a certain treatment or approach (I) in producing an outcome of benefit (O)?	What populations are of interest? Which sub populations?	What intervention, treatment or approach is being considered?	What is/are the main alternative treatment (s) or approach(es)?	What outcomes matter most to individuals affected by the disease or condition?	Among children with HIV (P), how effective is isoniazid prophylaxis (I) compared to no prophylaxis in preventing tuberculosis (O)
Diagnosis	Among patients with a certain condition (P), how accurate is a certain test (I)in diagnosing a given disease (O) compared with a reference standard (C)?	To which populations would the test be applicable? Which sub populations?	What test or strategy is being evaluated?	What is the comparison test, (often the reference standard or current diagnostic approaches)?	What is the diagnostic accuracy of the test or strategy for detecting the target condition (usually sensitivity, specificity, predictive value and related parameters)?	Among patients with acute chest pain (P), how accurate is an electro-cardiogram (I) in diagnosing acute myocardial infarction (O) compared to serum enzyme testing (C)?

Type of key question	Syntax	Population	Intervention	Comparator	Outcomes	Example
Risk or prognosis	Among patients with a certain disease (P), does a prognostic or risk factor (I), change the risk of a certain event (O) relative to baseline risk (C)?	What populations are of interest? Which sub populations?	What exposure is of interest? Which individual or environmental factors predict outcomes?	What is the baseline risk (the risk in the unexposed)?	What is the incidence or prevalence of the condition In the exposed?	Among patients with prostate cancer (P), do lumbar metastases (I), increase 5 year mortality (O) compared to no metastatic disease?
Resource con-siderations	What is the cost of intervention X in setting Y? What is the cost–effectiveness of intervention X in setting Y, for outcome Z?	What populations are of interest? Which sub populations?	What intervention, treatment or approach is being considered?	What is/are the main alternative treatments or approaches?	What is the cost of intervention X? Which outcome matters most to individuals affected by the disease or condition and would provide a metric for cost–effectiveness?	What is the cost (O) of latex-free gloves in West Africa (I) for use in managing persons in Ebola treatment units (P)? Is drug X (I) cost–effective in preventing death (O) from cardiovascular disease in adults with type 2 diabetes mellitus (P)?

EVIDENCE RETRIEVAL AND SYNTHESIS

This is an important step for developing recommendations for which no guidelines exist. All recommendations must be based on best available evidence. Systemic literature searches should be transparent, thorough and reproducible. This is essential to develop valid recommendations and high quality guidelines.

The suggested starting point to developing recommendations is the use of systematic reviews. Systematic reviews work on specific, objective and clearly focused key questions. They rely on explicit, transparent and reproducible methods. It includes a comprehensive and systematic search for all studies that meet the search criteria.

After scoping the proposed guideline and crafting the key questions, the next step in guideline development is to identify one or more systematic reviews to address each key question. It is not always necessary to commission a new systematic review. If one or more relevant, current and high-quality systematic reviews exist, these should be used. Updates, if needed, are usually less expensive and time-consuming than new reviews.

The first step to conducting a meaningful systematic review is developing a search protocol. Search protocols predefine how the evidence is identified and provide a basis for developing the search strategies. They should include the following elements; sources to be searched, plans to use any supplementary search techniques and limits to be applied to search.

STEPS IN DEVELOPING A SYSTEMATIC REVIEW

SOURCES TO SEARCH

Searches should include a mix of databases, websites and other sources depending on the subject of the review question and the type of information sought. For most searches

there will be key sources that should be prioritized for searching, and other potentially relevant sources that could be considered for searching. It is important to ensure adequate coverage of the relevant literature and to search a range of sources, but there should be a clear rationale for including sources, with only those likely to yield relevant results included. Searching the literature involves balance between sensitivity and precision. Methodology expert with specific expertise in bibliographic database searching related to systemic reviews is preferable.

The core databases are listed in table below. These should be searched for every review question. Additional subject specific databases and other sources may also need to be searched, depending on the subject area of the review question and the type of evidence sought.

Questiontype	Databases
Review questions about interventions, diagnosis, prognosis[a], patient experience and service delivery	**Core Databases** MEDLINE/MEDLINE In-Process Embase Cochrane Database of Systematic Reviews – CDSR (Cochrane Reviews)[b] Database of Abstracts of Reviews of Effects – DARE (Other Reviews)[c] Cochrane Central Register of Controlled Trials – CENTRAL (Clinical Trials)[b] Health Technology Assessment (HTA) database (Technology Assessments)[c] Subject-specific databases (this list is not exhaustive): **AMED (Allied and Complementary Medicine Database)** The Campbell Collaboration Library of Systematic Reviews CINAHL (Cumulative Index to Nursing and Allied Health Literature) ERIC (Education Resources Information Centre) PEDro (Physiotherapy Evidence Database) PsycINFO[d]

a CDSR and DARE do not need to be searched for questions about prognosis.

b Accessible via the Cochrane Library. Database names in parentheses are those used in the Cochrane Library. CENTRAL only needs to be searched when evidence from controlled trials is sought.

c Accessible as part of the Cochrane Library and via the Centre for Reviews and Dissemination (CRD). The CRD website hosts the most up-to-date version of the databases. Database names in parentheses are those used in the Cochrane Library.

d PsycINFO is searched as an additional core database for Mental Health.

An awareness of the strengths and weaknesses of each database is important when undertaking a systematic literature search. The different databases index different journals, use different subject headings, cover different time periods and provide different amounts of bibliographic information. For example, EMBASE is considered to be stronger than MEDLINE in its coverage of the pharmacology, toxicology, drug research and psychiatric literature, but contains only selected coverage of the dental and nursing literature. On the other hand, MEDLINE contains a much better developed collection of scope notes for its subject heading (MeSH) terms, which can assist development of the search strategy. There will be overlap in the records retrieved from the different databases for a particular review question; the extent of this overlap for MEDLINE and EMBASE is reported to range between 10 and 87% depending on the topic.

Other search sources

These may include National, regional and subject-specific databases which should be selected according to the topic of the review. Conference abstracts and other grey literature can be an important source of studies for inclusion in reviews. Reference lists in other reviews, guidelines, included (and excluded) studies and other related articles should be searched for additional studies. Ongoing trials should be identified and tracked for possible inclusion in reviews on completion. The list of such sources is given in annexure.

Supplementary search techniques

Supplementary search techniques should be used in addition to database searching when it is known, or reasonably likely, that relevant evidence is either not indexed in bibliographic databases and/or that it is difficult to retrieve from databases in a way that adequately balances sensitivity and precision. Supplementary search techniques might include forward and backward citation searching, journal hand-searches or contacting experts and stakeholders. Supplementary search techniques should follow the same principles of transparency and reproducibility as other search methods.

DEVELOPING SEARCH STRATEGIES

Review questions can be broken down into different concepts, which can be combined to devise a search strategy. For example, the PICO (population, intervention, comparator and outcome). It is important to consider which concepts to include in the strategy because some concepts may not be mentioned in the titles, abstracts or subject headings of a

database record. It is important to ensure that relevant studies are not missed as a result of an overly complex search structure.

When the relevant literature for a question is less well defined or indexed, a multi-stranded approach to searching may be more efficient. This involves developing several shorter search strategies (strands) with an emphasis on precision. Each strand should reflect one way in which the relevant literature may be described. The strands are then combined.

Review questions that overlap and can be grouped together should be identified for searching purposes. For example, questions with the same population may involve comparing several interventions. This should make it possible to carry out one search that covers all the interventions.

Identifying search terms

Search strategies should usually consist of a combination of subject headings and 'free-text' terms from the titles and abstracts of relevant studies. When identifying subject headings, variations in thesaurus and indexing terms for each database should be taken into account: for example, MeSH (Medical Subject Headings) in MEDLINE, Emtree in Embase. Not all search concepts will have a subject heading, so free-text terms should also be used. Free-text terms may include synonyms, acronyms and abbreviations, spelling variants, old and new terminology, brand and generic medicine names, and lay and medical terminology.

For example

- Synonyms: 'pressure sore' OR 'decubitus ulcer', etc;
- Related terms: 'brain' OR 'head', etc; and
- Variant spellings: 'tumour' OR 'tumor'.

Use of FILTERS

Validated search filters may be useful in limiting the number of records (i.e. increase precision). Filters are available for study designs and for specific databases. An example is the Cochrane Highly Sensitive Search Strategy for identifying randomized controlled trials in Medline. The use of filters requires caution, as each filter has limitations in terms of sensitivity and precision.

REFERENCE MANAGEMENT

Specially designed bibliographic or reference management software such as End Note, Pro Cite, Reference Manager and Ref Works is useful and relatively easy to use to keep track of references to and reports of studies. The choice of which software to use is likely to be influenced by what is available. Bibliographic software also facilitates storage of information about the methods and process of a search. For example, separate unused fields can be used to store information such as:

1) The name of the database or other source details from which a trial report was identified,

2) When and from where an article was ordered and the date of article receipt and

3) Whether the study associated with an article was included in or excluded from a review and, if excluded, the reasons for exclusion.

DOCUMENTING SEARCH STRATEGIES

The search process needs to be documented in enough detail throughout the process to ensure that it can be reported correctly in the review, to the extent that all the searches of all the databases are reproducible. The following information should be recorded for each search conducted during the STG development process:

- Details of the questions for which the search was conducted
- The names of the databases and the database host systems used
- Names of any other sources searched
- Search strategies for all sources, annotated to explain any decisions on included and excluded terms which are not self-explanatory
- Details of any supplementary searching undertaken, including the rationale
- Any limits or search filters applied to the search (for example, language, date, study design)

Rerunning Searches

Searches undertaken to identify evidence for each review question may be re-run to identify any further evidence that has been published since the search was last run. For example, searches

should be re-run if the evidence base changes quickly, or if there is reason to believe that substantial new evidence exists, or if the development time is longer than usual.

A decision to rerun the searches will be taken by the STG subgroup, in discussion with the review team and technical staff with a quality assurance role.

THE FINAL REPORT

The purpose of reviews is to facilitate healthcare decision making by the patients and the general public, clinicians, administrators and the policy makers. A clear statement of findings, a considered discussion and a clear presentation of the author's conclusion are important parts of the review.

The following are the key issues that can help people make better informed decisions and increase the usability of reviews:

- Information on all important outcomes, including adverse outcomes.
- The quality of the evidence for each of these outcomes, as it applies to specific populations, and specific interventions.
- Clarification of the manner in which particular values and preferences may bear on the balance of benefits, harms, burden and costs of the intervention.

REVIEWING RESEARCH EVIDENCE

Quality assessment is a critical stage in reviewing the evidence. It requires a systematic process of assessing bias through considering the appropriateness of the study design and the methods of the study. This chapter describes the steps involved in assessing the evidence gathered in the systematic review. Specifically, it explains how to quantify, for each key question (in PICO format), the risk of bias in the outcomes of the individual studies found; how to determine the quality of the evidence for each outcome relevant to decision-making across included studies and, finally, how to assess the quality of the evidence for all outcomes needed to formulate a recommendation. Critical thinking should be used to ensure that relevant biases are considered fully.

In the context of evidence syntheses, the GRADE working group defines the quality of the evidence as the "extent to which one can be confident that an estimate of the effect or association is correct".

NHSRC/MOHFW recommends the use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of a body of evidence, and to develop and report recommendations.

GRADE METHODOLOGY

GRADE is a system developed by an international working group for rating the quality of evidence in systematic reviews and guidelines; it can also be used to grade the strength of recommendations in guidelines. The key difference from other assessment systems is that GRADE rates the quality of evidence for a particular outcome across studies and does not rate the quality of individual studies.

In order to apply GRADE, the evidence must clearly specify the relevant setting, population, intervention, comparator(s) and outcomes.

Quality Assessment using GRADE Methodology

GRADE categorizes the quality of the evidence as high, moderate, low or very low. These quality ratings apply to the body of evidence for each outcome assessed for each key question and not to individual studies. A judgment on the risk of bias of each individual study included in the body of evidence is needed, however, to assess the quality domain of study limitations.

Quality Level	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very Low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

The GRADE approach to assessing the quality of evidence for intervention studies:
Five factors can lower the quality of the body of evidence for each outcome:
Study limitations (risk of bias) – the 'internal validity' of the evidence
Inconsistency – results for a given outcome are not similar across studies
Indirectness – the degree of differences between the population, intervention, comparator for the intervention and outcome of interest across studies
Imprecision (random error) – results are imprecise when studies include relatively few participants and few events and thus large uncertainty (i.e. wide confidence intervals) surrounds the estimate of effect
Publication bias – the degree of selective publication of studies.

Three factors can increase the quality of the evidence from observational studies
Dose–response gradient- presence may generate greater confidence in the findings of observational studies
Direction of plausible bias – results for a given outcome are not similar across studies
Magnitude of the effect – When a body of evidence from observational studies yields large or very large, precise and consistent estimates of the magnitude of a treatment or exposure effect, one can have greater confidence in the results

Below is an illustration of GRADE table:

Quality Assessment						No of Patients		Effect		Quality
No of studies	Design	Risk of bias	Incon-sistency	Indi-rectness	Imp-recision	Inter	Control	Relative (95% CI)	Absolute (95%CI)	
Outcome										

Determining overall quality of the evidence

NHSRC/MOHFW team reviews all the information from the systematic review and, if needed, reassesses and makes a final decision about which outcomes are critical and which ones are important in light of the recommendations that they aim to formulate. They assign an overall quality to the evidence, based on a combined rating of the quality of the evidence across all outcomes that are considered critical for answering the key question (i.e. for making a decision or a recommendation). SDG must determine the overall quality of the evidence across all the critical outcomes for each recommendation. Because quality of evidence is rated separately for each outcome, the quality frequently differs across outcomes. If the quality of the evidence is the same for all critical outcomes, then this is the level of quality that applies to all of the evidence supporting the answer to the key question. If the quality of the evidence differs across critical outcomes, the overall confidence in effect estimates cannot be higher than the lowest level of confidence in the effect estimates for an individual outcome. **Therefore, the lowest quality of the evidence for any single critical outcome determines the overall quality of the evidence.** The judgment about which outcomes are critical for decision-making may depend on the evidence. Although it happens rarely, the overall quality of the evidence is sometimes not based on the outcomes judged critical at the beginning of the guideline development process. There can be two reasons for this:

- An outcome turns out not to be critical for decision-making (e.g. a particular adverse event considered critical at the outset of the guideline development process turns out to be very infrequent and of questionable relevance to the intervention).
- If there is higher quality of evidence for some critical outcomes that is sufficient to support a recommendation, then there is no reason to downgrade the overall

quality of evidence because of lower quality for another critical outcome when the recommendation would not change.

GRADE pro software can be used to prepare the GRADE profiles. These are evidence profiles that contain a 'quality assessment' section that summarizes the quality of the evidence and a 'summary of findings' section that presents the outcome data for each critical and each important outcome. The 'summary of findings' section includes a limited description of the quality of the evidence and may be presented in the evidence review to help readers quickly understand the quality of the evidence base.

PRESENTING EVIDENCE

The following sections should be included in the evidence review:

- Summary of the evidence, including the 'summary of findings' section from the GRADE profile (if this improves readability and the GRADE system has been used).
- Evidence statements.
- Full GRADE profiles or links to the profiles in an appendix (if GRADE has been used).
- Evidence tables.

The evidence should usually be presented for each review question; however, alternative methods of presentation may be needed for some evidence reviews (for example, where review questions are closely linked and need to be interpreted together). In these cases, the principles of quality assessment, data extraction and presentation, and evidence statements should still apply.

Evidence tables

Evidence tables help to identify the similarities and differences between studies, including the key characteristics of the study population and interventions or outcome measures. This provides a basis for comparison.

Data from identified studies are extracted to standard templates for inclusion in evidence tables. The type of data and study information that should be included depends on the type of study and review question, and should be concise and consistently reported.

The types of information that could be included are:

- Bibliography (authors, date).
- Study aim, type (for example, randomised controlled trial, case–control study) and setting (for example, country).
- Funding details (if known).
- Population (for example, source, eligible and selected).
- Intervention, if applicable (for example, content, who delivers the intervention, duration, method, mode or timing of delivery).
- Comparator, if applicable (for example, content, intervener, duration, method, mode or timing of delivery).
- Method of allocation to study groups (if applicable).
- Outcomes (for example, primary and secondary and whether measures were objective, subjective or otherwise validated).
- Key findings (for example, effect sizes, confidence intervals, for all relevant outcomes, and where appropriate, other information such as numbers needed to treat and considerations of heterogeneity).
- Inadequately reported or missing data.
- Comments on quality, based on the quality assessment.

Summarising Evidence

A summary of the evidence should be produced. The content of this summary will depend on the type of question, the type of evidence included and whether GRADE is used. It should also identify and describe any gaps in the evidence.

They can be presented in two ways:

NARRATIVE SUMMARY	SUMMARY TABLES
The narrative summary places a study and its findings in context. It should highlight key factors influencing the results observed, interpret the results and give more detail than presented in the evidence tables.	If appropriate short summary tables (based on the 'summary of findings' section from the GRADE profile or the narrative summaries) should be included with the main findings (usually before an evidence statement) or in the appendices.

NARRATIVE SUMMARY	SUMMARY TABLES
Each narrative summary should include: • a brief description of the study design, methodology, population, setting and research questions or outcomes (if appropriate) for all relevant studies • a summary of the key findings • a summary of the quality ratings (expanding, as appropriate, on study strengths and weaknesses), applicability issues and any other relevant contextual points.	**These might:** • Summarize the information gleaned for different review questions • summarise the study types, populations, interventions, settings or outcomes for each study related to a particular review question • organise and summarise studies related to different outcomes.
If GRADE is used, the narrative summary needs only to be very brief and describe key features of the included studies and any other important information that is not included in the GRADE tables.	It is generally used when GRADE is not applied.

Evidence Statements

Evidence reviews for both qualitative and quantitative studies should include a narrative summary and GRADE tables where used, and should conclude with one or more supporting evidence statements.

The evidence statements should provide an aggregated summary of all of the relevant studies or analyses regardless of their findings. They should reflect the balance of the evidence, its strength (quality, quantity and consistency) and applicability. The evidence statements should summarise key aspects of the evidence but can also highlight where there is a lack of evidence (note that this is different to evidence for a lack of effect).

Evidence statements are structured and written to help Committees formulate and prioritise recommendations. They help Committees decide:

- Whether or not there is sufficient evidence (in terms of strength and applicability) to form a judgement.
- Whether (on balance) the evidence demonstrates that an intervention, approach or programme can be effective or is inconclusive.
- The typical size of effect (where there is one) and associated measure of uncertainty.
- Whether the evidence is applicable to people affected by the guideline and contexts covered by the guideline.
- Evidence statements should be included in the final guideline.

Structure and content of evidence statements

One or more evidence statements are prepared for each review question or subsidiary question. (Subsidiary questions may cover a type of intervention, specific population groups, a setting or an outcome.)

Each evidence statement should stand alone as an accessible, clear summary of key information used to support the recommendations. The guideline should ensure that the relationship between the recommendations and the supporting evidence statements is clear.

Evidence statements if GRADE is not used

Evidence statements should refer to the sources of evidence and their quality in brief descriptive terms and not just by acronyms. Each statement should also include summary information about the:

- Content of the intervention, if applicable (for example, what, how, where?).
- Population(s) and setting(s) (for example, country), if applicable.
- Outcome(s), the direction of effect (or correlation) and the size of effect (or correlation) if applicable.
- Strength of evidence (reflecting the appropriateness of the study design to answer the question and the quality, quantity and consistency of evidence).
- Applicability to the question, people affected by the guideline and setting.

PHASE 4: TRANSLATE

1. **Develop Recommendations**
2. Internal Review
3. External Review and Submission

DEVELOPING RECOMMENDATIONS

Once the evidence is identified and its quality assessed, next step is to synthesize recommendations out of these evidence. The guideline recommendations are the distillation of the STG task force's development work. They should be clear, understandable to the intended audience without reference to the evidence reviews, and based on the best available evidence.

This chapter describes the key stages in developing guideline recommendations:

Interpreting the evidence to make recommendations:

GRADE enlists a list of factors that must be considered to determine the strength and direction of evidence before translating them into recommendations. To formulate a recommendation, the STG task force considers each factor in turn and judges its importance and effect on the recommendation.

Factor	How the factor influences the direction and strength of a recommendation
Quality of the evidence	The quality of the evidence across is outcomes critical to decision-making & will inform the strength of the recommendation. The higher the quality of the evidence, the greater the likelihood of a strong recommendation.
Values and preferences	This describes the relative importance assigned to health outcomes by those affected by them; how such importance varies within and across populations; and whether this importance or variability is surrounded by uncertainty. The less uncertainty or variability there is about the values and preferences of people experiencing the critical or important outcomes, the greater the likelihood of a strong recommendation.
Balance of benefits and harms	This requires an evaluation of the absolute effects of both benefits and harms (or downsides) of the intervention and their importance. The greater the net benefit or net harm associated with an intervention or exposure, the greater the likelihood of a strong recommendation in favour or against the intervention.
Resource implications	This pertains to how resource-intense an intervention is, whether it is cost–effective and whether it offers any incremental benefit. The more advantageous or clearly disadvantageous the resource implications are, the greater the likelihood of a strong recommendation either for or against the intervention.
Priority of the problem	The problem's priority is determined by its importance and frequency (i.e. burden of disease, disease prevalence or baseline risk). The greater the importance of the problem, the greater the likelihood of a strong recommendation.
Equity and human rights	The greater the likelihood that the intervention will reduce inequities, improve equity or contribute to the realization of one or several human rights as defined under the international legal framework, the greater the likelihood of a strong recommendation.
Feasibility	The greater the feasibility of an option from the standpoint of all or most stakeholders, the greater the likelihood of a strong recommendation. Feasibility overlaps with values and preferences, resource considerations, existing infrastructures, equity, cultural norms, legal frameworks, and many other considerations.

Assessment and interpretation of the evidence to inform the guideline recommendations is at the heart of the work of the Committee. The Committee should also judge to what extent it will be possible to put the recommendations into practice. The Committee should consider the extent of change in practice that will be needed to implement a recommendation, staff training needs, policy levers and funding streams, and the possible

need for carefully controlled implementation with, for example, training programmes. This should be documented in the guideline and in any relevant resources which support implementation.

Insufficient evidence

If evidence of effectiveness for an intervention is either lacking or too weak for firm conclusions to be reached, the Committee has several options. It may make recommendations based on the limited evidence, using expert opinion; or make no recommendation; or it may recommend that the intervention is used only in the context of research.

THE STRENGTH OF THE RECOMMENDATION

The strength of a recommendation expresses the degree to which the SDG is confident in the balance between the desirable and undesirable consequences of implementing the recommendation.

STRONG RECOMMENDATION vs WEAK RECOMMENDATION	
When a SDG is very certain about this balance (i.e. the desirable consequences clearly outweigh the undesirable consequences), it issues a strong recommendation in favour of an intervention.	When it is uncertain about this balance, however, it issues a conditional (or "weak") recommendation.
e.g. For patients	
Most individuals in this situation would want the recommended course of action; only a small proportion would not. Formal decision aides are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Most individuals in this situation would want the suggested course of action, but many would not.
For clinicians	
Most individuals should receive the intervention. Adherence to the recommendation could be used as a quality criterion or performance indicator.	Different choices will be appropriate for individual patients, who will require assistance in arriving at a management decision consistent with his or her values and preferences. Decision aides may be useful in helping individuals make decisions consistent with their values and preferences.

WORDING THE RECOMMENDATIONS

Recommendations need to be clear and actionable, reflect the PICO format and contain an indication of their strength and of the quality of the evidence on which they are based. I is the part of the guideline that most people would read, so it should be unambiguous, clear and easy to translate into practice by the intended audience.

NICE recommends the use of following general principles while wording the guideline by the STG task force:

Focus on the action:

- Recommendations should begin with what needs to be done.
- Recommendations should be as specific as possible about the exact intervention being recommended and the group of people for whom it is recommended.
- Recommendations should use direct instructions wherever possible because they are clearer and easier to follow.

Box :Examples of guideline recommendations that start with a verb

- Record the person's blood pressure every 6 months.
- Advise pregnant women to limit their intake of oily fish to 2 portions a week.
- Encourage staff who regularly come into contact with people whose health and wellbeing could be at risk to provide them with a brief intervention.

Reflect the strength of the recommendation:

Some recommendations can be made with more certainty than others (see the section on strength of recommendations). This concept of the 'strength' of a recommendation should be reflected in the consistent wording of recommendations within and across guidelines. This is described earlier in the chapter.

NICE uses 'offer' (or similar wording such as 'measure', 'advise', 'commission' or 'refer') to reflect a strong recommendation, usually where there is clear evidence of benefit. NICE uses 'consider' to reflect a recommendation for which the evidence of benefit is less certain.

Include what readers need to know:

Recommendations should contain enough information to be understood without reference to the evidence or other supporting material, but at the same time, they should not include unnecessary details, because recommendations are more likely to be followed if they are clear and concise:

- Define any specialised terminology that is used in the recommendations. Avoid using abbreviations, if used define them at first mention, then in glossary.
- Define the intended audience for the recommendation.
- Define the population the setting of intervention to be delivered, if it is not obvious from the context
- Avoid trade names
- Include only one main action in each recommendation or bullet point.

Emphasise the involvement of people using services:

Recommendations should acknowledge the role of people who are directly affected by them. This can be done as:

- Use verbs such as 'offer' and 'discuss' in recommendations, rather than 'prescribe' or 'give'.
- 'Consider' is used for recommendations on interventions that could be used, and implies that more discussion with the person will be needed.
- Use 'people' (or 'patients', or 'people using services') rather than 'individuals', 'cases' or 'subjects'. Use 'people' rather than 'patients' for people with mental health problems or chronic conditions.

Use plain English and avoid jargon

- Using plain, consistent wording is an important part.
- Avoid vague words and phrases, such as 'may' and 'can', or general statements such as 'is recommended', 'is useful/helpful', 'is needed' and 'service options include'. Instead, use an active verb that tells readers what they should do, and indicates the strength of the recommendation.

Examples

- Instead of 'an intervention may be offered', say 'consider the intervention'.
- Instead of 'an intervention is recommended', say 'offer the intervention'.

Recommendations on medicines

- **Do not give dosages routinely:** Include dosage information only if there is evidence that a particular medicine is often prescribed at the wrong dosage, or there is clear evidence about the effectiveness of different dose levels.
- **Off-label use of licensed medicines:** Off-label use may be recommended if the clinical need cannot be met by a licensed product and there is sufficient evidence and/or experience of using the medicine to demonstrate its safety and efficacy to support this.

HIGHLIGHTING AREAS FOR FUTURE CONSIDERATION IN QUALITY STANDARD DEVELOPMENT

Where a linked quality standard is planned, the Committee may choose to discuss which recommendations might be suitable for consideration within the quality standard development process.

Recommendations that may be highlighted should:

- Be in areas in which there is evidence or consensus that there is variation in the delivery of care to people using services
- Focus on key requirements for high-quality care or service provision that are expected to contribute to improving the effectiveness, safety and experience of care or services
- Be measurable and therefore suitable for development as quality measures

FORMULATING RESEARCH RECOMMENDATIONS

The Committee is likely to identify areas in which there are uncertainties or in which robust evidence is lacking. Therefore the Committee should select key research recommendations

that are likely to inform future decision-making (based on a systematic assessment of gaps in the current evidence base) for inclusion in the guideline.

FORMULATING QUALITY STANDARDS

Where a linked quality standard is planned, the Committee may choose to discuss which recommendations might be suitable for consideration within the quality standard development process.

Recommendations that may be highlighted should:

- Be in areas in which there is evidence or consensus that there is variation in the delivery of care to people using services (in particular, aspects of care or services that are not widely provided and/or not considered to be standard practice, but that are feasible to provide).
- Focus on key requirements for high-quality care or service provision that are expected to contribute to improving the effectiveness, safety and experience of care or services.
- Be measurable and therefore suitable for development as quality measures.

Examples

Quality Standards for Hypertension Guideline:

- The blood pressure is measured opportunistically at any encounter with a health professional in all those over 18 years of age so that there is at least one recording every year.
- Those with raised cardiovascular risk factors in the community are offered blood pressure screening every 2 years.

Quality Standards for Alcohol dependence guideline:

- All patients reporting to health facility should be screened for presence of alcohol dependence.
- All patients reporting current alcohol use and scoring high on the screening tests or having problems due to alcohol use should be assessed for presence of alcohol dependence.

DEVELOPING RECOMMENDATION PATHWAYS

Pathways are flow diagrams showing step by step view of recommendations given. They are usually added at the end of the guideline as an annexure. They ease out understanding recommendations and also help user to understand the process flow of recommendations.

COMPILING THE NEW STG: BACKGROUND DOCUMENT & IMPLEMENTATION TOOLS

The final draft guideline consists of two documents:

I. The Background Document

II. Implementation tools

a) The Quick Reference Guide (QRG)

b) The Patient's Information Document

c) The Quality Standard

I. THE BACKGROUND DOCUMENT

This document includes details about how the STG was developed: the process by which key recommendations were chosen. It is aimed at peer reviewers and all those who are interested to understand how the STG was developed, including who was involved, the evidence (guidelines) underpinning the recommendations, how decisions were made. This document should provide sufficient information to demonstrate that the STG has been developed according to international criteria and is therefore of good quality. Its length varies according to the topic of the guideline and whether it is adapted/adopted.

II. IMPLEMENTATION TOOLS

a) The Quick Reference Guide (QRG)

Summarises the recommendations in an easy-to-use format aimed at healthcare providers (doctors, nurses) for use in practice.

The QRG is a practical resource to use on a day-to-day basis and includes all the recommendations. It presents the STG recommendations in a concise, easy-to-use format and utilizes a chart of a care pathway (represented in the form on an algorithm) containing the clinical decisions (recommendations) described in the STG. The decision points are represented by boxes linked by arrows.

The QRG should be uncluttered: boxes should be limited to those defining the clinical problem and those representing a clear decision point. Arrows should mostly flow from top to bottom. A logical sequence should be maintained so that each decision flows from the question that precedes it. It may be necessary to produce more than one care pathway if the recommendations cannot be summarised into a single chart.

If a care pathway is not appropriate, the recommendations may be summarised in other ways, including tables, boxes or flow charts showing the care pathway.

b) The Patient's Information Document

The Patient information document summarises the recommendations in the STG in everyday language, and is **aimed at patients, their families and carers, and the wider public.** It does not describe the condition or interventions in detail.

Please refer to annexure for a sample Patient's Information Document.

c) The Quality Standard

This is described above.

PHASE 4: TRANSLATE

1. Develop Recommendations
2. **Internal Review**
3. External Review and Submission

INTERNAL REVIEW

After the draft guidelines are in place, the next step will be consultation by the internal harmonization group. This group contains members who are subject experts as well as methodology experts. Thus, this would be a r view of content as well as the methodology of the guideline. As the name suggests, the guideline would be harmonized to the standard guideline methodology.

The commissioning body would commission this peer review. All reviewers are required to complete a declaration of interests form. Comments received from the peer reviewers should be discussed by the whole STG development committee. Comments from reviewers are responded as described below and are published in the background document of the STG under 'internal consultation/ peer review'.

All comments received from the peer reviewers are entered into a table in a word file containing the following information:

Peer reviewer – name of the peer reviewer that submitted the comments.

Section – this column can be used by the STG development committee to facilitate the identification of comments by section.

Comments – comments received from peer reviewers, which are entered unchanged.

Responses – blank column for the STG development committee to complete.

The STG development committee considers the comments received, and then responds to the comments. The following key points should be taken into account when responding to comments from peer reviewers.

Each comment must be acknowledged and answered as fully and as factually as possible. It is important to acknowledge that each point has been seen and has been understood. Some comments may be presented as general commentary, but they should still be acknowledged. If changes are made to the STG as a result of the comment, this must be made clear in the response. If no changes have been made, it should be made clear why not.

Responses and changes must be made with the agreement of the STG clinical sub group before publication, preferably through a STG clinical sub group meeting (the date for which should be agreed in advance to ensure that all STG clinical sub group members can attend). Any changes must be reflected in the background STG; an audit trail of changes needs to be maintained. Examples of responses to types of comments received during peer review of STGs are given below:

S. No.	Comment	Response
INTRODUCTION		
IHG	What population is recommended for targeted screening? If high risk population, request to define it and also document the evidence on which recommendation is based	The population groups at high risk are older adults (>50 - 60 years), persons with diabetes, obesity especially those with a higher abdominal circumference, current smokers, those with any cardiovascular disease, and those with family history of premature cardiovascular disease. Predictors for the presence of hypertension have been developed in Indian cohort studies and these risk scores are again based on age, current smoking, presence of abdominal obesity.
IHG	Salt intake recommendation to be corrected and uniform throughout the document.	We have mentioned a dietary intake of 6 gm. Salt per day for the general population, and have added a qualifier that this limit may be reconsidered in some patients who are engaged in heavy manual labour under hot climatic conditions, where substantial loss of salt in sweat may occur, as seen in some studies.

SCOPE OF HT GUIDELINE		
IHG	The choice of BP measuring device should be discussed with Health Technology Assessment and finalized.	India is committed to phasing out mercury and alternatives have to be considered. Electronic digital oscillometric devices are emerging as the clinical standard for BP measurement worldwide, and have proved to be accurate and robust. Aneroid sphygmomanometers need frequent calibration. Both mercury and aneroid sphygmo3manometers need an auscultation based measurement which may be less feasible for non-physician health staff.
LIST OF RECOMMENDATIONS		
IHG	Ambulatory BP/ HBP are the gold standard and may be possible in urban areas. Perhaps both recommendations can be put along with clearly stating that in the absence of ambulatory BP, clinic BP is recommended as an alternative.	Addressed

PHASE 4: TRANSLATE

1. Develop Recommendations
2. Internal Review
3. **External Review and Submission**

EXTERNAL REVIEW AND SUBMISSION

The final guideline, post the internal review, is put up for public consultation/online review. The comments received in a stipulated time frame are analysed by the STG development committee. Comments received after the deadline are not considered and are not responded to; in such cases the sender will be informed.

Post the consultation, three scenarios might arise:

1. No comments : In case, no comments are received in the time frame given, it is considered that there are no objections to the guideline content, hence it may be submitted to the commissioning body for approval.
2. Minor comments: If the comments are such that the do not significantly alter the technical content/recommendations in the guideline, they may be addressed by the STG development committee and the guideline submitted for approval.
3. Major comments: If after the consultation, the comments received challenge the recommendations in the guideline or the technical content of the guideline, they may require decision on changes in the guideline content. In such cases, a second consultation involving the STG development committee and other experts on the topic may be contemplated. The commissioning body will take the final call on need of such consultation.

The final guideline is submitted to the commissioning body for approval.

REVIEW OF NEW STG

The new STG will need to be reviewed regularly, e.g. every three years, to ensure it is up to date. The STG development committee/commissioning body may designate a person

responsible for the same . This would require redo of the original search performed to check if new guidelines are available for the topic.

Any decision to update a STG must balance the need to reflect changes in the evidence against the need for stability, because frequent changes to STG recommendations would make implementation difficult. Usually 3 years after publication, the STG is reviewed and a decision made on whether it needs to be updated.

ANNEXURES

ANNEXURE 1
FORM FOR DECLARATION OF INTEREST

Declaration of Interests Form

THE MINISTRY OF HEALTH & FAMILY WELFARE

DECLARATION OF INTERESTS

I have read and understood the National Health Systems Resource Center (NHSRC) Code of Practice on Declarations of Interests. I hereby declare the following interests in the healthcare industry and those organizations with whom the MoH&FW may have a contractual relationship, according to MoH&FW published Code.

Personal financial interest
Description (if you have no interests in this category, state 'None')
Non-personal financial interest (if you have no interests in this category, state 'None')
Description

Signature:.....

Name (please print):..... Date:.....

ANNEXURE 2

SOURCES FOR SYSTEMATIC REVIEWS AND HEALTH TECHNOLOGY ASSESSMENTS

Guideline Internet Sites	URL
National Guidelines Clearinghouse (NGC)	http://www.guideline.gov/
Guidelines International Network (G-I-N)	http://www.g-i-n.net/
Ontario Guidelines Advisory Committee (GAC) Recommended Clinical practice Guidelines	http://www.gacguidelines.ca/
Institute for Clinical Systems Improvement (ICSI)	http://www.icsi.org/knowledge/
National Institute for Clinical Evidence	https://www.nice.org.uk/page.aspx?o=ourguidance
New Zealand Guidelines Group	http://www.health.govt.nz/
Scottish Intercollegiate Guideline Network (SIGN)	http://www.sign.ac.uk/guidelines/index.html
Canadian Agency for Drugs and Technology in health	https://www.cadth.ca/
Canadian Medical Association Info base	http://mdm.ca/cpgsnew/cpgs/index.asp
The Cochrane Library	http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME
Food and Drug administration	http://www.fda.gov/cdger/guidance/index.htm
Centres for Review and Dissemination Health Technology Assessment Database	http://www.york.ac.uk/crd/#HTA
Directory of evidence based information websites	http://132.203.128.28/medecine/repertoire/repertoire.asp
Haute Autorite De Sante (HAS)	http://has-sante.fr/anaes/anaesparametrage.nsf/Page?ReadForm&
CHU de Rounen-Catalogue and Index des Sites Medicaux Francophones (CISMef)	http://doccismef.chu-rouen.fr/dc/#wt=true&q=recommandations professi
Bibliotheque Medicale AF Lemanissier	http://www.bmlweb.org/consensus.html

SOR-Standards, Options et Recommendations	http://www.unicancer.fr/?q=-sci/sor/index.htm
Registered Nurses of Ontorio	http://rnao.ca/
Agency for Quality in Medicine	http://www.aezq.de/
Finish Medical Society Duodecim	http://www.kaypahoito.fi
American Society of Clinical Oncology	http://www.asco.org/
Cancer Care Ontario Practice Guideline Initiative	https://cancercare.on.ca/
National Cancer Institute	http://www.cancer.gov/
National Comprehensive Cancer Network	https://www.nccn.org/
Agency Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS)	http://afssaps.sante.fr/

ANNEXURE 3
SAMPLE SCOPE FOR GUIDELINE ON HYPERTENSION

Section 4: Scope and Objective of the Guideline.

a) To increase detection of hypertension in adults in India using a systematic, primary care led approach based on standardised measurements of BP and their follow up.

b) To provide guidance on assessment of persons with hypertension appropriate to different levels of care in India.

c) To provide a structured , simplified and standardised treatment guideline for hypertension in adults in India, along with implementation tools (quick reference guide, quality standards, patient information leaflets)

d) To provide guidance on availability of a core list of medications in the public health system for treatment of hypertension.

e) To outline research issues related to hypertension in India.

Population

Groups that will be covered

a) Adults at risk of hypertension (18 years and older)

b) Adults with hypertension (18 years and older) with or without cardiovascular disease.

c) People with diabetes

d) People with severe hypertension or high blood pressure in emergency care settings.

Groups that will not be covered

a) Children and young people (younger than 18 years).

b) Pregnant women

c) Secondary causes of hypertension: For example, chronic kidney disease, endocrine causes of hypertension [Cushing's syndrome, pheochromocytoma] and renovascular hypertension. However clues to suspect of secondary causes of hypertension will be mentioned.

Healthcare setting

a) Community settings: These would be involved in promoting awareness of cardiovascular risk factors and their modification by a healthy lifestyle. Screening of hypertension at this level so through trained non-physician staff is a major point of emphasis in this guideline

b) Sub-centres: These would be involved in screening for hypertension, patient education and assessment, and follow up of diagnosed patients.

c) Primary health centres. These would be involved in diagnosis, patient education, assessment with simple laboratory tests, management and follow up of patients.

d) Community Health Centres: These would be involved in diagnosis, patient education, assessment by physician and biochemical investigations (including renal function and lipid profile), and management and follow up of patients.

e) District Hospitals, Medical Colleges: These would be involved in diagnosis, assessment, management of hypertension including those with severe/resistant hypertension.

Detection, diagnosis, assessment and clinical management of hypertension in India

Key clinical issues that will be covered in the guideline

A. **Screening for hypertension in adults in India**

   a) Age at screening

   b) Health care settings for screening and role of non-physician staff.

   c) BP devices for measurement: sphygmomanometers or oscillometric devices or aneroid devices

   d) Standardised BP measurement procedure and sources of error.

B. **Diagnosis of hypertension in India**

   a) Number of measurements required for diagnosis

   b) Classification of hypertension in India according to BP levels.

   c) Time frame for recheck and review of elevated BP readings in case of grade 1 and Grade 2 hypertension.

C. **Patient education and assessment of persons with hypertension in India:**

a) Education of the patient regarding nature of disease, its treatment, and the importance of adherence to treatment.

b) Assessment for target organ damage at different levels of care.

c) Assessment of associated clinical conditions at different levels of care

d) Assessment of cardiovascular risk at different levels of care.

e) Patient assessment to rule out secondary hypertension.

D. **Management of hypertension**

a) Initiation of treatment in different grades of hypertension.

b) Targets for BP control.

c) Classes of antihypertensive drugs and preferred choices.

d) Treatment regimens and strategies to achieve effective control of BP including optimisation of drug dosages and addition of other medications.

e) Treatment of hypertension associated with other conditions like diabetes, heart disease, cerebrovascular disease.

f) Reasons for poor response to therapy.

g) Integration of interventions to reduce global cardiovascular risk including cessation of tobacco use, antiplatelet therapy and lipid lowering therapy.

h) Improving adherence to therapy and systems for long term follow up of patients.

Clinical issues that will not be reviewed

Specialist management of secondary hypertension (that is, hypertension arising from other medical conditions).

Outcome and quality indicators

Outcomes

1. Fatal or non-fatal stroke.
2. Myocardial infarction
3. Heart failure and other cardiovascular deaths.

ANNEXURE 4

TABLE FOR SUMMARIZING GUIDELINE CHARACTERISTICS

Title	Publisher	Country, Language	Publication Date	End of Search Date	Comments

ANNEXURE 5
AGREE II-GLOBAL RATING SCALE (AGREE II-GRS) INSTRUMENT

Instructions

The AGREE II-GRS Instrument consists of 5 items assessing how well the guideline is reported. The AGREE II-GRS is a reasonable guideline assessment tool alternative to, AGREE II, especially when time and resources are limited.

Table 1: AGREE II-Global Rating Scale Item Descriptions provides information about the contents in each item category.

Table 1: AGREE II-Global Rating Scale Item Descriptions

Element	Description
Process of Development	Rate the quality of the development process. Consider: Were the appropriate stakeholders involved in the development of the guideline? Was the evidentiary base developed systematically? Were recommendations consistent with the literature? Was there consideration of alternatives, health benefits, harms, risks, and costs?
Presentation Style	Rate the quality of the guideline presentation style. Consider: Was the guideline well organized? Were the recommendations easy to find?
Completeness of Reporting Rate the quality of reporting. Consider: 1) The transparency and reproducibility of the guideline development process 2) The completeness of information to inform decision making.	
Clinical Validity Rate the quality of the guideline recommendations. Consider: Are the recommendations clinically sound? Are the recommendations appropriate for the intended patients?	
Overall Quality	Rate the overall quality of the guideline. Consider:
Your response to the above four items.	

ANNEXURE 6
SAMPLE PATIENT EDUCATION LEAFLET FOR HYPERTENSION

PATIENT INFORMATION LEAFLET

Hypertension or High Blood Pressure (BP)- Patient Information Leaflet

Why is high blood pressure called a silent killer? In the past most illnesses made us feel unwell. We know we are ill because we get symptoms like diarrhoea or fever or cough. We see the doctor to get help. But when we have high blood pressure there are no symptoms for many years. It's like a silent killer who comes quietly behind you and stabs you. High BP slowly damages the important blood vessels in our body without us knowing it. Later we can become suddenly very sick. Only then we know we had hypertension but it may be too late to treat it by then.

What is hypertension? The pressure of air in a bus tyre must not be too high or too low. If it is too high it may burst without warning. If the pressure of water in a hose is too high it may suddenly burst. In the same way our blood flows to different parts of the body in blood vessels. If the pressure in the blood vessels is too high the blood vessels will become damaged over time. We do not always know why some people get high blood pressure. In a few people there are reasons like kidney disease and alcohol overuse.

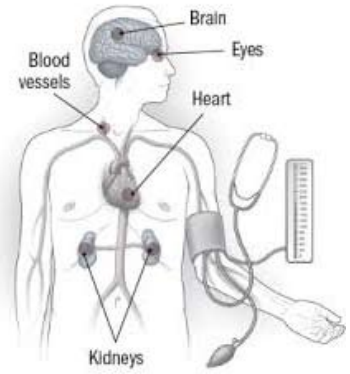
If hypertension causes no symptoms of disease at the start, how can we find hypertension early? The only way to check blood pressure is through blood pressure machines.

What is the normal blood pressure? Our heart is a pump that first fills with blood and then pumps it to the blood vessels. It then fills again and then pumps again. So blood pressure readings have 2 numbers. The first number or systolic BP is when the heart is pumping blood. The second number or diastolic BP is when it is filling. The normal blood pressure is 130 systolic and 80 diastolic and we write that as 130/80. Readings lower than 130/80 can be normal. However the

blood pressure of every person can vary from time to time. When we are exercising or worried it can increase. When we are resting it can be lower. So your blood pressure may need to be repeated s few times when you are resting if it was found to be high. Anyone who keeps having readings over 140/90 has high blood pressure.

What are the effects of high blood pressure on the body? If untreated high blood pressure damages the blood vessels to different parts of the body causing:

- Strokes- we get sudden paralysis or numbness of one side of the body or speech which may not get better.
- Heart attacks- sudden blockage of blood vessel in the heart can cause severe chest pain and sudden death.
- Kidney failure.
- Damage to vision and many other problems.
- **Sadly these problems may happen very suddenly without warning.**



When should I have my blood pressure checked? You should check your blood pressure even if you feel well because in the early stages it causes no symptoms. All those over 18 years should have the blood pressure checked every 2 years. If you are overweight, have diabetes, do little exercise, smoke, drink alcohol, or have family members with high blood pressure you should have it checked once a year. Your health centre nurse or health worker can check your BP. You do not need to see a doctor to check BP.

If I have high blood pressure what can I do to help it myself? There are several things you can do:

- Stop smoking: smoking markedly increases the damage caused by high blood pressure.
- If you already do not do hard work, do some exercise you enjoy doing that makes you a little short of breath for at least 30 minutes each day.
- If you are overweight reducing your weight by even 5 kg over 6 months can lower blood pressure.
- If you work hard and sweat a lot just avoid salty food. Otherwise reduce the salt you add in cooking by half.

- Avoid fatty food like oils or oily fried food, fatty meat (take off the fat before you cook goat or take the skin off chicken). Eat more vegetables and fish.
- Do not take excessive alcohol.
- Don't drink more than 2 glasses of coffee each day.

Do I need to take tablets? How long will I need to take these tablets? People with high blood pressure of 160/100 or higher and those for whom changing lifestyle does not work need tablets to lower blood pressure. Disease like pneumonia, typhoid can be cured by taking tablets for only a limited time. But blood pressure tablets do not cure the disease but control it only as long as you take them. It's like dying your hair which has turned grey as you get older. It will become black only as long as you keep dying it black! You must keep taking the tablets regularly and not stop them without asking your doctor. Most tablets can be taken once a day either in the morning or night. It should become a routine like brushing your teeth. Make sure you get more tablets before your last lot run out. **Remember that treating high BP will be one of the best things you can do to protect your health in the future. Treatment of hypertension may not help always make you feel better straight away.**

Will the tablets cause harm? Blood pressure tablets are usually very safe. If you do get side effects there are many different medications to choose from and the doctor will find one that suits you. The doctor may ask you take other medicines like aspirin and some tablets to lower your blood cholesterol which is a chemical in blood that can worsen the effects of high blood pressure.

How often do I need to see the doctor? Till your blood pressure is controlled the doctor may see you once a month. Once the blood pressure is controlled you only need to see the doctor once in 6 months. Continue your medications and you can see the doctor at any time if you have any worries over your treatment. **Remember- take your medications regularly. TOGETHER WE CAN STOP THE SILENT KILLER AND PREVENT UNNECESSARY SUDDEN DEATHS AND DISABILITY.**

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NOTE

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