HEALTH TECHNOLOGY ASSESSMENT IN INDIA

PROCESS MANUAL AND QUALITY CHECK GUIDELINES

FEBRUARY 2022

DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH & FAMILY WELFARE
INDIA

THE LOGO

The logo of Health Technology Assessment in India (HTAIn) is in the form of a shield which represents the protecting role of HTAIn towards its citizens as the Board shields the citizens from financial hardship arising out of health care seeking. The top of the shield is marked with Ashok Chakra, depicting the allegiance of HTAIn towards the constitutional values and the nation. Rod of Asclepius and symbol of Indian Rupee are placed side by side below the National Emblem, as while making a decision about cost- effectiveness of an intervention, HTAIn gives due consideration to both public health potential and costs associated with an intervention. "***सर्वे सन्तु निरामयाः।*** *(Sarve Santu Niramayah)*" is scripted in Devnagri script on a ribbon, which means "***Let All Be Healthy***', and expresses the devotion of HTAIn towards the values of Universal Health Care.

About the Document

This document is a guide for Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR), Ministry of Health & Family Welfare for use in the Health Technology Assessment (HTA) and all the Regional Resource Centres and Technical Partners established in different states across the country dedicated to assist informed health policy decision making in India. The process manual will outline the steps for conducting the HTA studies and quality control.

Website: www.htain.icmr.org.in

Twitter: HTAIn_DHR@DhrHtain

Contact:

Health Technology Assessment in India Secretariat,
Department of Health Research
1st Floor, Indian Red Cross Society Building,
1, Red Cross Road,
New Delhi - 110001.
Email ID: htain-dhr@nic.in/ kavitha.rajsekar@nic.in
Phone No: +91 11 23736085

List of Abbreviations

DHR: Department of Health Research

HTA: Health Technology Assessment

HTAIn: Health Technology Assessment in India

MoHFW: Ministry of Health & Family Welfare

PICO: Population, Intervention, Comparator, Outcome

Sec: Secretariat

TAC: Technical Appraisal Committee

TP: Technical Partner

Patrons

Professor Balram Bhargava
Secretary, DHR and Director General, ICMR

Smt. Anu Nagar
Joint Secretary, DHR

Compiled by

Dr. Kavitha Rajsekar
Scientist – E, DHR

Dr. Shankar Prinja
Additional Professor, School of Public Health, PGIMER, Chandigarh

Dr. Aamir Sohail
Health Policy Analyst, HTAIn Secretariat, DHR

Ms. Kirti Tyagi
Scientist C, HTAIn Secretariat, DHR

Contents **Page No.**

CHAPTER 1

HEALTH TECHNOLOGY ASSESSMENT IN INDIA (HTAIn)

1. INTRODUCTION

Health technology assessment (HTA) is widely used methodology internationally for optimization of resource allocation in health. It is a multidisciplinary process that gathers policy relevant evidence about the medical (clinical effectiveness), economic (cost effectiveness), social and ethical issues related to the use of a health intervention in a systematic, inclusive, transparent and robust manner to assist policy makers in decision making while formulating policies for incorporating or excluding health interventions from the health system.

Recognizing the importance of Health Technology Assessment (HTA) in healthcare decision making guided by considerations of scientific evidence on clinical effectiveness, cost effectiveness, social values and equity issues Government of India has set up an institutional structure called as "**Health Technology Assessment in India (HTAIn)"** under the Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW). HTAIn is entrusted with the responsibility to analyze evidences related to cost-effectiveness, clinical-effectiveness and equity issues regarding the deployment of health technologies viz. medicines, devices and health programmes by means of HTA in India, and in turn help in efficient use of the limited health budget and provide people access to quality healthcare at minimum cost.

1.1. Purpose of establishing HTAIn

The Government of India is committed to extend healthcare services to its 1.34 billion population as part of India's Universal Health Coverage (UHC) agenda. One of the most important challenges in India that warrant immediate attention is increasing catastrophic out of pocket expenditures (OOP) in healthcare. According to National Health Accounts Report 2017-18 Household's Out of Pocket Expenditure on health (OOPE) was 61% of total health expenditure (1). 2017 World Bank report estimated the OOP spending on healthcare in India to be as high as 62% (2). Extending adequate healthcare services to the population requires optimal utilization of existing resources to ensure that the greatest amount of health is bought for every rupee spent. National

Health Policy 2017 also proposes a responsive and strong regulatory framework so that challenges of quality of care, cost escalations and impediments to equity are addressed effectively. The main purpose of the HTAIn is to engage in explicit and evidence-based decision-making in health taking India towards universal health coverage. HTA will help to bridge the evidence-to-policy gap and ensure alignment of academic and policy interests through HTA towards the common goal of improving decision-making for health resource allocation to improve the health of the Indian population.

1.2. Objectives of HTAIn

The main objectives of HTAIn is **maximizing health, reducing Out of Pocket Expenditure (OOP)** and **minimizing inequality** in healthcare services. These objectives can be achieved by supporting the process of decision-making in health care at the Central and State level by providing reliable information based on scientific evidence, developing systems and mechanisms to assess new and existing health technologies by a transparent and inclusive process and appraising health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety. It will also ensure healthcare accessibility and usefulness to inform health policy. Dissemination of research findings and resulting policy decisions will educate and empower the public to make better informed decisions for health.

1.3. HTAIn Structure

HTAIn consists of – **(i) DHR In-house Secretariat, (ii) Technical Appraisal Committee (TAC), (iii) HTAIn Board and (iv) Regional Resource Centers/Hubs and Technical Partners (TP)** (Fig. 1). The secretariat coordinates between the Resource Centres, Technical Partner(s) (TP), Technical Appraisal Committee (TAC) and the Board.

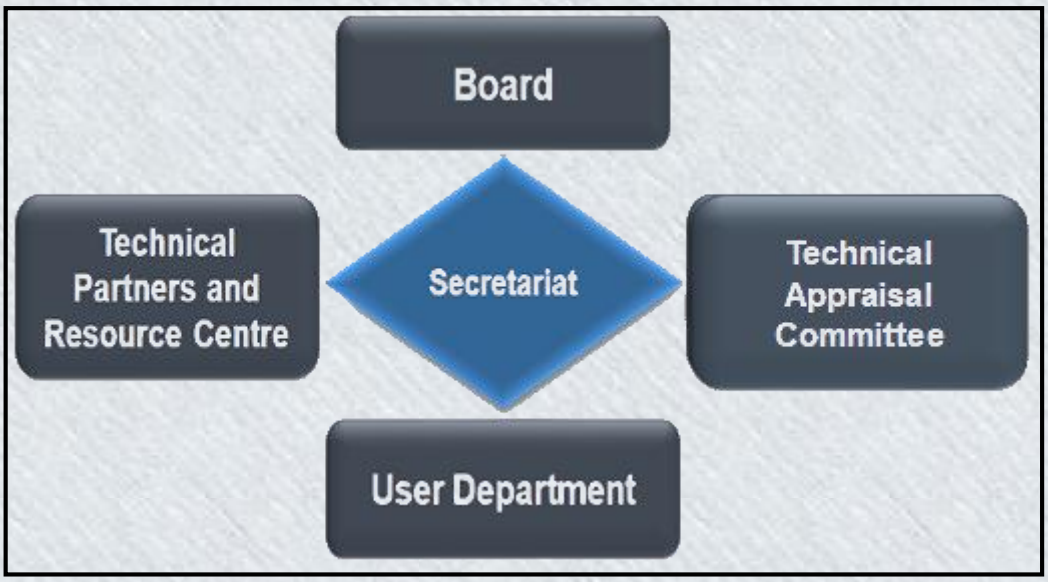

Figure 1: Organizational structure of HTAIn to conduct HTA

- ***User Department/ User Agency:*** User Department could be a Central and State Health Ministry or any Government Healthcare Provider or Agency that are directly or indirectly involved in the health sector in India. User Department gives topics of study to HTAIn and implement the recommendations of the completed studies.
- ***HTAIn Secretariat or Secretariat*:** HTAIn Sec. is a DHR-in-house body that coordinates between the User Department, TAC, Board, Regional Resource Centres and Technical Partners. It consists of Scientists, Economists, Health Policy Analyst, Financial Consultants, Project Manager, Data Entry Operators and Multi-Tasking Staffs. Secretariat conducts all the TAC, Stakeholders Consultation and Board meetings in DHR. It also coordinates between Resource Centres and Technical Partners during topic allocation, follow ups, monitoring the studies allocated to them, financial and technical support wherever required. Secretariat ensures the proposals and Outcome Reports are in proper format and it ensures transparency at all stages of HTA by consultation and regular updates. Besides that, the Secretariat can also take up any topic to conduct HTA in certain conditions.
- ***Technical Appraisal Committee (TAC):*** TAC is a multidisciplinary body that consists of experts from different backgrounds such as Clinicians, Researchers, Economists, Social Scientists, Policy Experts etc. headed by an eminent person. There could be some co-opted members or subject experts in the TAC depending upon the topic of study. The TAC is the first approving body of HTAIn. It appraises the HTA study at different stages mainly after proposal

development and the outcome of the study. TAC not only review the study thoroughly from the research question(s), objective(s), methodological details, outcomes, policy recommendations etc. but also help to better formulate these aspects wherever required and ensure the quality of the studies.

- ***HTAIn Board:*** Board is the highest decision-making body of HTAIn consisting of Policy-Makers, Bureaucrats and Experts from different Government Bodies (Central as well as States) etc. Board appraises the recommendations of the studies from TAC and takes the final decision before sending the recommendations to the User Department for implementation. If required, the Board may seek clarification on any aspect of the study and suggest modifications depending upon the technicalities or feasibility of implementation. The Board may also look into the gaps in evidence and instruct for further research in that area.
- ***Technical Partners and Regional Resource Centres/ Hubs:*** **Technical Partners** are Central/ State Government Institutes that conduct the HTA studies of HTAIn. They have been identified with regards to their capacities, expertise and previous experience in the area of HTA. Technical partners allocated with the topics depending on their core competence. They formulate a study proposal that contains the study details along with the manpower, funds and timeline required for the study and undertake the study after due approval from Technical Appraisal Committee. **Regional Resource Centres** are also institutes of Central/ State Government but they act as an extended arm of Secretariat that besides conducting the HTA studies have additional tasks of liaising and coordinating with the State Governments Health Officials they are situated in (and/ Or in vicinity), sensitize them about HTA, provide training wherever required and ask them for relevant topics for HTA. Regional Resource Centres are also identified on the basis of their capacities, expertise and previous experience in the area of HTA Or, in collaboration with the State Governments in their identified institutes. Some of the Technical Partners may also be upgraded to Resource Centres after completed at least three good quality studies with the approval of competent authority. Resource Centres act as a bridge between Central and State Governments health agencies for smooth functioning and make efficient use of HTA at national as well as state level. The Resource Centres also ensures

uniformity/ consistency of methodologies/ processes documented by HTAIn Secretariat in its Process Manual. There is a dedicated team of Scientists, Economists, Field Worker, Data Entry Operator etc. and an annual budget for Regional Resource Centres. If there is a requirement of additional manpower or funds for a particular study, it may be provided on the basis of proper justification and after the approval of TAC. Currently there are 10 Technical Partners and 16 Regional Resource Centres in different parts of the country (Fig. 2).

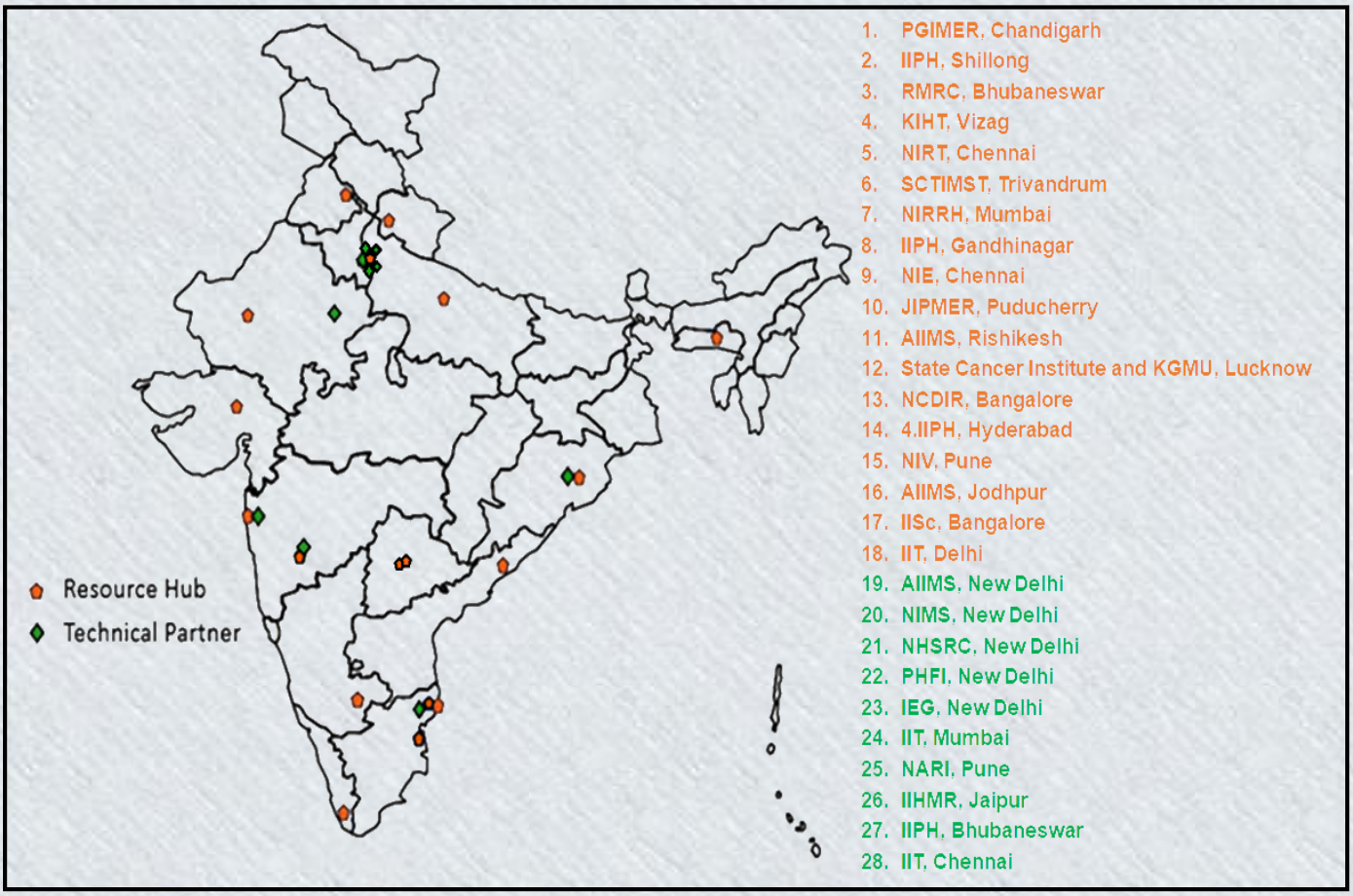

Figure 2: HTAIn Regional Resource Centres and Technical Partners

Regional Resource Centres

1. **Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh -** PGIMER liaise and coordinate with the State Govt. of Punjab, Haryana, Jammu & Kashmir and Himachal Pradesh.

2. **All India Institute of Medical Sciences, Rishikesh –** AIIMS, Rishikesh coordinates with the State Government of Uttarakhand.
3. **All India Institute of Medical Science, Jodhpur –** AIIMS, Jodhpur coordinates with the State Government of Rajasthan.
4. **State Cancer Institute and KGMU, Lucknow –** They coordinate with the State Government of Uttar Pradesh.
5. **Indian Institute of Public Health, Shillong –** IIPH, Shillong coordinates with the seven sister states of North-East Region.
6. **Indian Institute of Public Health, Gandhinagar –** IIPH, Gandhinagar coordinates with the State Government of Gujarat.
7. **Regional Medical Research Center, Bhubaneswar –** RMRC, Bhubaneswar coordinates with the State Government of Odisha.
8. **National Institute for Research in Reproductive Health (NIRRH), Mumbai** – NIRRH, Mumbai coordinates with the State Govt. of Maharashtra,
9. **National Institute of Virology (NIV), Pune –** NIV, Pune also coordinates with the State Government of Maharashtra.
10. **National Centre for Disease Informatics and Research (NCDIR), Bengaluru –** NCDIR coordinates with the State Government of Karnataka.
11. **Kalam Institute of Health Technology (KIHT), Vizag –** KIHT, Vizag coordinates with the State Government of Andhra Pradesh.
12. **Indian Institute of Public Health (IIPH), Hyderabad –** IIPH, Hyderabad coordinates with the State Government of Telangana.
13. **National Institute of Epidemiology (NIE), Chennai –** NIE, Chennai coordinates with the State Government of Tamil Nadu.
14. **National Institute for Research in Tuberculosis (NIRT), Chennai** – NIRT, Chennai coordinates with the State Government of Tamil Nadu.
15. **Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry –** JIPMER, Puducherry also coordinates with the State Government of Tamil Nadu.

16. **Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum**: SCTIMST, Trivandrum coordinates with the State Government of Kerala.

Technical Partners:

The following 10 institutes have been identified so far as Technical Partners of HTAIn in different parts of the country and processes is underway to identify more technical partners due to influx of large number of study topics from State and Central Governments:

1. **All India Institute of Medical Sciences (AIIMS), New Delhi.**
2. **National Institute of Medical Statistics (NIMS), New Delhi**
3. **National Health Systems Resource Centre (NHSRC), New Delhi**
4. **Public Health Foundation of India (PHFI), New Delhi**
5. **Institute of Economic Growth (IEG), New Delhi**
6. **Indian Institute of Health Management Research (IIHMR), Jaipur**
7. **Indian Institute of Technology (IIT), Mumbai**
8. **National AIDS Research Institute (NARI), Pune**
9. **Indian Institute of Public Health (IIPH), Bhubaneswar**
10. **Indian Institute of Technology (IIT), Chennai**

1.4. Overview of Functioning

The User Department gives a topic for assessment to the HTAIn Secretariat that are prioritized by the Secretariat and allocated to the suitable Technical Partners/ Resource Centers for them to come up with a study proposal and present it to the TAC. Once approved by TAC the TP/RRHs may conduct the HTA and after the completion the outcome reports is again presented to the TAC again and after approval by TAC the report along with the policy recommendations are forwarded to the Board for final approval. After the Board's approval, the Outcome Report along with Policy Recommendations is handed over to the User Department for its implementation and the outcome report is uploaded on the HTAIn website for the feedback. Proposal and results are also shared with relevant stakeholders for their comments and feedback either through Stakeholders Consultation Meeting or via email.

1.5. Funding

HTAIn receives its funding from Government of India, Ministry of Health & Family Welfare, Department of Health Research. HTAIn does not directly or indirectly receives any financial support from any profit making organizations or institutes funded by profit making organizations.

CHAPTER 2

HTAIn PROCESS AND FUNCTIONING

2. KEY PHASES OF HTAIn PROCESS

Key phases of HTAIn process is shown in Fig. 3. It includes Topic Selection, Technical Partner/ Resource Centers identification, Proposal Development, Research and Analysis, Appraisal of Evidences, Approval by Board and Implementation by the User Department.

Figure 3: Key Phases of the HTAIn Process

2.1 Topic Selection and Prioritization: Topics are provided by the User Department as per their requirement with a clear Policy and Research Question. Topics are selected and prioritized on the basis of given set of prioritization criteria or Indicators (Table 1) i.e. Size of population affected, Severity of disease, data availability, clinical effectiveness, economic impact on households and health sector emergency etc.

2.2. Topic Prioritization Criteria

Topic prioritisation considers health benefit, impact on health-related Government policy, impact on health resources, clinical practice variation, and whether DHR can add value by issuing guidance on the given health technology by conducting a formal HTA decision. Prioritisation can be carried out by considering the following criteria -

1. **Population size**- The larger the population affected, the more important a technology is for evaluation.
2. **Disease severity** - Severity of condition impacts on importance of evaluation, takes into account, life expectancy, how far the individual is away from perfect health and health states that incur social stigma.
3. **Potential therapeutic benefit** - Extent to which a new technology claims measurable therapeutic benefit over currently available treatments.
4. **Economic impact -** Impact on household expenditure as a consequence of providing health intervention to a family member with consideration of catastrophic illness or health catastrophe.
5. **Availability and relevance of evidence** - Availability and relevance of evidence for conducting HTA.
6. **Health policy priority** - The level of priority of diseases/health problems and proposed interventions. Public or political demand can also influence the priority setting.

Table 1. Topic selection and prioritization criteria: Definition, scoring Criteria, and parameter information

S. No.	Indicators	Definition	Parameter	Scoring	Data source
1	Size of population affected by disease	Number of people affected by the disease or health problem that is treated or prevented by the proposed intervention among Indian population at a specified time:	Incidence or Prevalence	5= >50% total population affected 4= 25% total population affected 3= 10% population affected 2 = 5% 1 = 0 – 5%	• National Vertical program (e.g. NPCDCS) • ICMR database • ICMR registries • WHO Fact sheet • NHFS
2	Burden of disease in terms of DALY	Severity of disease or health problem that is treated or prevented by the proposed intervention by considering BoD of disease/health problems. The more severe of disease or health problem the higher rank in the leading cause list of BoD.	Ranking in Burden of Disease:	Condition-specific DALY / Total DALY to calculate % contribution to total DALY. 5 = >5% 4 = 3-5% 3 = 1-3% 2 = .5 to 1% 1 = <.5%	• Local studies on BOD in India • Estimation of BoD of India in the Global Burden of Disease Study (IHME Global Burden of Disease study) • IHME Burden of disease specific DALY indicators (e.g. cancer, diabetes etc) • DALY estimates from international sources
3	Effectiveness of available intervention	*For treatment/ rehabilitation:* Capacity of the proposed intervention to treat or rehabilitate the patients from the disease and its impact on the patients' QOL	The clinical benefit of the proposed intervention and improvement in QOL	5= Cure 4= Prolong life and major improvement in QOL 3= prolong life and minor improvement in QOL 2= major improvement in QOL 1 = minor improvement in QOL	• National Vertical program data (e.g. National dialysis program) • Literature review • Consultation/Opinions of relevant stakeholders in Indian context

S. No.	Indicators	Definition	Parameter	Scoring	Data source
		2. For screening/ diagnostic: Accuracy (specificity and sensitivity) of the proposed intervention to screen or diagnose the disease of the patients and the expected outcome beyond the screening or diagnostic	Accuracy of the intervention and whether the screened disease could be cured	5= accuracy 80% and screened disease could be cured 4 = accuracy 60%– 80% and screened disease could be cured 3 = accuracy 80% but screened disease could not be cured 2 = accuracy 60%– 80% and screened disease could not be cured or accuracy 60% and screened disease could be cured 1 = accuracy 60% and screened disease could be cured	• National Vertical program data (e.g. National dialysis program) • Literature review • Consultation/Opinions of relevant stakeholders in Indian context
		3. For Prevention: Risk reduction or preventive capacity provided by the proposed intervention to the population	Effectiveness of the intervention to prevent the disease	5 = > 90% 4 = 81% – 90% 3 = 71% – 80% 2 = 61% – 70% 1 = ≤ 60%	• National Vertical program data (e.g. National dialysis program) • Literature review • Consultation/Opinions of relevant stakeholders in Indian context
4	Economic impact on household expenditure	Impact on household expenditure as a consequence of providing health intervention to a family member with consideration of catastrophic illness or health catastrophe	Level of economic impact on household expenditure of disease/health problems' treatment cost	5 = Very great impact toward HH expenditure 4 = Great impact toward HH expenditure 3 = Moderate impacts toward HH expenditure 2 = Minor impact toward HH 1= No impact toward HH expenditure	• Literature review • Expert consultation • household surveys, NHSSO

S. No.	Indicators	Definition	Parameter	Scoring	Data source
5	Availability and relevance of evidence for conducting HTA	Availability and relevance of evidence for conducting HTA	Level of availability and relevance of evidence for conducting HTA – information including	5 = Available and relevant 4 = Somewhat available and relevant 3 = Limited availability and relevance 2 = Indefinite/Unclear 1 = Unavailable and/or irrelevant	• Literature review • Expert consultation
6	Health sector priority and policy objective	The level of priority of diseases/health problems and proposed interventions/ Frequency of nomination	The urgency of diseases/health problems and proposed interventions	5 = High urgency 4 = Medium urgency 3 = Low urgency 2 = Indefinite 1 = No urgency	• Legal document review • Consultation/ Opinions of policy makers • Check policy briefing documents and media reports • Budget announcements

2.3. Technical Partner/ Resource Identification: Once the topics are selected a potential Technical Partner/ Resource Centre is identified by the Secretariat, depending upon their area of expertise, capacity and previous experience, to take up that topic to conduct HTA study. TAC can also suggest a suitable technical partner/ resource centre for a particular topic allocation.

2.4. Proposal Development: Technical Partner/ Resource Centre is asked to develop a formal HTA proposal that contains the Policy Question, Research Question, Aims and Objectives, PICO, Methodological Details, Expected Outcomes, Budget Impact, Budget and Timeline etc. During the proposal development the team needs to do the preliminary work on the topic in order to look for the availability of enough data. The proposal is presented in the Technical Appraisal Committee Meeting and reviewed thoroughly by the members and subject experts. TAC may approve the proposal or provide comments/ suggestions and ask the for clarification/ revision in the proposal wherever required. Once approved by the TAC, funds are sanctioned to the TP/RRC to conduct the HTA study.

2.5. Research and Analysis: After the TAC approval the Technical Partner/ Resource Centre start doing the research and analysis that included evidence synthesis for clinical effectiveness and cost effectiveness **mainly from published literatures/ secondary data sources** like Medline, Cochrane, OVID and other national/ international/ Government data sources. In case of new drug/ devices when there is a scarcity of data TP/ RRC may go for primary data collection with the approval of TAC or drop the study during proposal development stage.

The evidence synthesis includes Systematic/ Rapid Review, meta-analysis, data extraction etc. and the analysis include running the simulation models, calculating the ICERS and Budget Impact Analysis etc. The analysis should also consider the equity issues for the accessibility and affordability.

2.6. Appraisal of evidences: Once the study is complete the Outcome Report along with the recommendations is presented to the TAC for appraisal. TAC (including subject experts) review the proposal thoroughly and it may approve the report or

provide comments/ suggestions and ask the for clarification/ revision in the proposal wherever required.

2.7. Approval by the HTAIn Board: Once approved by the TAC the Outcome Report is forwarded to the Board along with Policy Recommendations for final decision. The Board may approve the recommendations or provide comments/ suggestions and ask for clarification/ revision wherever required.

2.8. Implementation by the User Department: The outcome report and recommendations approved by Board are handed over to the respective User Department who provided the topics for HTA for implementation.

The final Outcome Reports are also discussed with the Stakeholder for their feedback and the report along with all the Meeting Minutes are uploaded on the HTAIn website for widespread dissemination and further feedbacks. Fig. 4 outlines the overall process flow of HTAIn and concerned departments responsible for carrying out various steps involved.

2.9. Different Phases of HTA Studies

1) Selection and Prioritization of Topic

Objective: To identify topic(s) that are agreed on by the User Department and HTAIn as relevant and worthwhile for assessment.

Activities

- The HTAIn secretariat will request formal submission of topics from user departments.
- The secretariat and/ Or TAC will review the submitted list of topics and prioritize according to prioritization criteria (discussed above).
- The list of HTA topics finalized may be discussed with the TAC and allocated to suitable Technical Partners/ Resource Centers. Fig. 5 shows various steps involved in topic selection and prioritization of topics.

Topic Selection timelines: The schematic diagram (Fig. 6) shows the timeline of topic selection and prioritization.

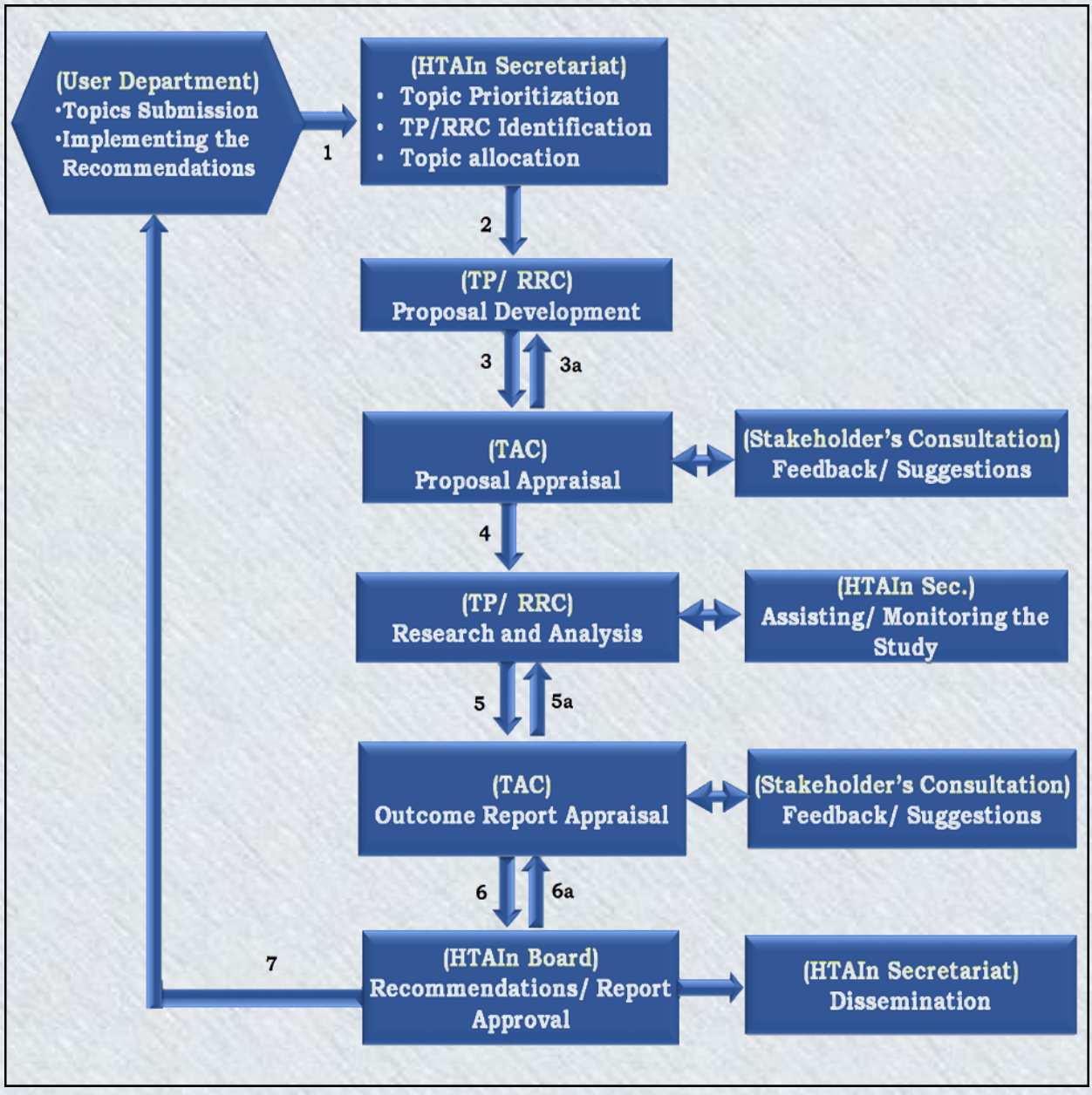

Figure 4: HTAIn Process flow

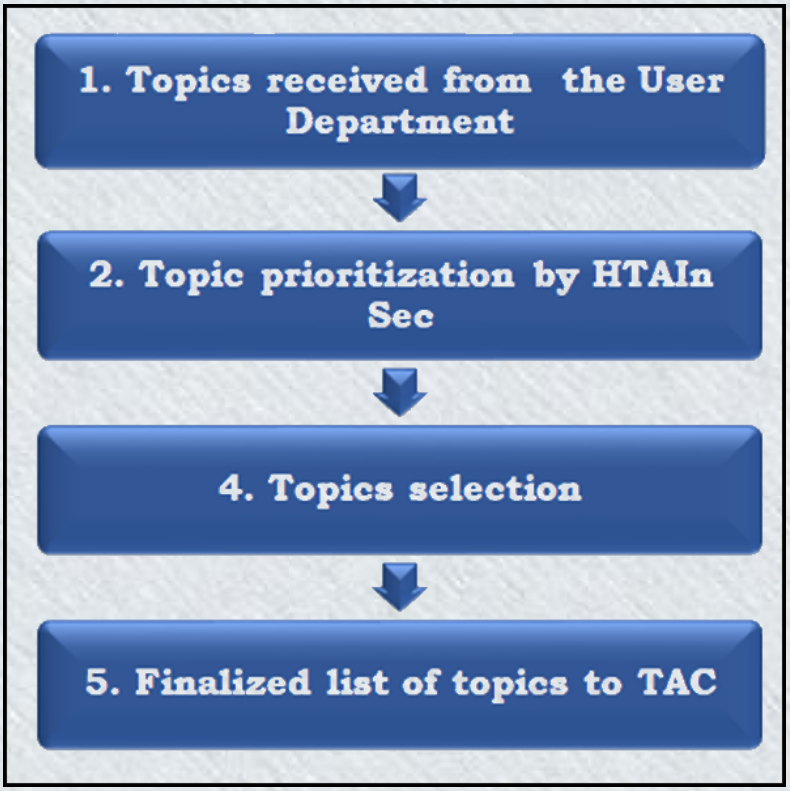

Figure 5. Topic Selection Activities

2) Technical Partner/ Resource Centre Consultation

Objective: To identify the potential technical partner(s)/ Resource Centre(s) and allocate the topic(s) for HTA analysis based on a consultative process.

Activities:

- HTAIn Secretariat identifies the TP/ RRC and may seek guidance from the TAC in their identification.
- HTAIn Sec. will inform the TP/ RRC about the selected topics through email or formal letter.
- After agreement of topics between secretariat and TP the TP will submit a proposal to carry out HTA on the selected topic in a prescribed format.
- Secretariat will review the proposal according to the methods manual/ reference case for initial screening and proposals and the proposal will be sent to the technical appraisal committee (TAC) for evaluation at least one week before the TAC meeting.
- TP/RRC will present the proposal before TAC in the TAC meeting conducted by the Secretariat in DHR.

- If the TAC provide any comment(s)/ suggestion(s) on the proposal, then it is sent back to HTAIn Sec. with comments and the TP/ RRC is asked to address those comments/ modification and present the proposal again in TAC till it gets approved.

Note: Depending on the skills, expertise, and time constraints of each organization, multiple Technical Partners/ Resource Centres may be required to collaborate on a given HTA analysis. For example, a TP/ RRC with expertise in systematic review may undertake this component of the analyses to determine clinical effectiveness, while another technical partner with expertise in economic evaluation will undertake this part of the analysis and so on.

3) Proposal Development:

Objectives: To draft the HTA proposal by the technical partner/ resource centre on the given topic and ensuring the TAC and stakeholders views are taken into consideration.

Activities:

- Once topics are allocated to the TP they are asked to draft a HTA proposal and submit to the Sec.
- Secretariat will evaluate the proposal whether it is in the prescribed format (discussed below)
- Proposal should be structured in the prescribed format that contains:
  - **a)** Key Policy Question(s) that need(s) to be addressed by the User Department.
  - **b)** Research Question(s), Aims and Objectives based upon the Policy Questions)
  - **c)** Scope of the study clearly outlining the PICO i.e. Population, Intervention, Comparator(s) and Outcome.
  - **d)** Methodological Detail according to the Methods Manual/ Reference Case for economic evaluation.
  - **e)** The proposal for HTA may also consider transferability of data from sources outside India wherever it is appropriate (e.g. if data is not available in the Indian context and it is available for a country with similar socio-demography).

f) Introduction and Literature Review:

- Availability of data to inform all components of analysis i.e. epidemiological population information, service use, cost, clinical efficacy and safety of the intervention(s) and comparator(s).
- Availability of existing health economic models that could be adapted for the Indian health system.
- Availability of similar studies in other settings or to identify any concerns about the introduction or use of particular health interventions or technologies.

g) Conflict of interest among the authors/ contributors, if any.

h) Details of manpower and funds required and the funding agency.

i) Timeline of the study.

j) References

- Once the draft proposal has been developed, the TP/RRC submits it to the Secretariat that reviews the proposal and forward it to the TAC for appraisal.
- The draft proposal is presented by the TP/RRC in front of the TAC in the first TAC Meeting.
- If any comment/ query/ correction or modification is suggested by the TAC then TP/RRC needs to defend those comments and revise the proposal if needed and present it again in the next TAC meeting. The cycle continues till the proposal is approved by the TAC.
- Once approved by the TAC proposal is presented before the stakeholders for their comments and feedback in the Stakeholder Consultation Meeting.
- After incorporating the feedback and comments of TAC and stakeholders the final version of the proposal is submitted to the Secretariat and the TP/RRC is instructed to conduct the HTA study.

Timeline for Proposal Development: The timeline for the proposal development may be one month from the date of allocation of the topic.

4) Research and Analysis

Objectives:

- To collect and collate all the data relevant to informing the analyses. This will include literature review, as well as direct evidence submission from appropriate experts (and perhaps unpublished data), Government data sources etc..
- To undertake a detailed economic evaluation of the allocated research topic(s) according to the methods outlined in the methods manual/ reference case to address the key question(s) of assessment.
- Address the equity issues, if any.
- To write a formal HTA report based on the results of the analysis.

Activities:

- Undertaking systematic review/ rapid review
  - According to the agreed Scope and PICO to inform meta-analysis of clinical benefit and other key outcomes, where appropriate.
  - If existing Systematic Review, Health Technology Assessments study and related models were identified during scoping – these should be reviewed against an internationally-recognized quality checklist (e.g. Drummond's, INAHTA, 2007 or R-AMSTAR Checklists)
  - For interventions that are not yet formally adopted within the health system, written submissions to request access to data should be made to any party that is known or suspected to have unpublished data relating to the intervention, including manufacturers and clinical or public health research institutions.
- Approval from ethical and scientific committee should be obtained, if required.
- Economic Evaluation (According to Methods annual):
  - Undertaking Cost Effective/ Cost Utility/ Cost Benefit Analysis as per the requirement
  - Analytic Modelling – Decision Tree or, Markov Modelling as per the requirement.
- If there is any equity issue regarding the feasibility of implementation, accessibility and usage of the healthcare intervention TP/ RRC needs to address

that with the best possible way so that the inequity with respect to the underprivileged population should be minimized.

- All inputs into the model should be conducted according to the methods and principles outlined in the Methods Manual/ Reference Case for economic evaluation.
- Secretariat will monitor the progress of HTA for quality and timeline assurance and to see if the HTA analysis is being done in a correct way according to the methods manual/ reference case and assist the TP(s)/ RRC(s) if required.
- Once the analysis is complete, outcome is submitted to the HTAIn secretariat with all related data for internal review and quality control.
- The secretariat will review the analysis and forward it to the TAC for appraisal at least a week before the TAC meeting.
- The TP/ RRC will present the outcome in front of the TAC in the TAC Meeting and address all queries raised by TAC. TP/ RRC needs to reconsider the outcomes if any major flaw is found by the TAC.
- Once approved by the TAC the results will be presented in front of the Board.
- Feedbacks and comments from stakeholders will also be taken into consideration.

Note: Evidence synthesis and formal assessment should be carried out in accordance with the HTA methods manual using the Indian reference case for economic evaluation.

Timeline for Research and Analysis: Pre-agreed timelines for delivery of project milestones should be followed by the TP/ Resource Centres. The timeline for research and analysis could be 6-12 months depending upon the availability of relevant data. Longer timeline should be justified properly before the TAC for approval. Secretariat should monitor the studies to ensure that all analyses are conducted in a timely manner according to methods manual and process guidelines.

5) Appraisal and Approval of Evidences

Objective: To make sure that the overall study is technically rigorous and followed the prescribed methods in the Methods Manual and to review the technical evidence along with equity considerations, if any, to arrive at policy-relevant recommendations.

Activities:

- The TAC reviews the policy question, research question, aims and objectives, methodologies, evidences, data, model, outcomes etc. of HTA studies mainly outcome reports submitted by the TP/ RRC prior to TAC meeting.
- If there are any major/ minor comments, clarifications or suggestions the TP/ RRC addresses them and if required the proposal/ outcome may be revised accordingly.
- Potential inequities associated with the HTA study related to the feasibility of implementation, accessibility or acceptability should be highlighted and addressed appropriately in order to reduce the inequities among underprivileged population.
- After approval from the TAC and feedbacks from the stakeholders the TP/ RRC/Secretariat prepares an evidence summary and policy brief of the outcomes report and submit it along with the detailed report and supplementary materials (if any), to the Board, in the HTAIn Board Meeting, for final approval.
- The Board may comment, seek clarification or modify the recommendations according to the feasibility of implementation. The TP/RRC or the TAC has to address the comments and suggestions made by the Board.

- **Policy brief** should be prepared for every topic outcome(s) following a standard format that will include the important feature of the study i.e. summary, significance, key findings, policy recommendations, limitations and uncertainties etc. These briefings should be decision-makers oriented including relevant results and recommendations addressing the policy question(s).
- A brief section at the end of the dissemination document should mention the list of funding agencies.

6) Dissemination and Implementation of Final Recommendations

Objective:

- To provide the Policy Recommendations along with the detailed outcome report to the User Department for implementation.

Activities to be carried out in this phase:

- The recommendations approved by the HTAIn Board is handed over to the User department formally to help them in decision-making and implementation.
- The secretariat may follow up the implementation process and keep a record of implemented studies
- Outcome report is also presented before the stakeholders and uploaded on the HTAIn website for feedback. Stakeholders are requested to furnish their views within a period of 15 days from the date of online publication of report.
- The TP/RRC may also publish the report/ policy brief in a peer reviewed journal or other media sources (print or electronic) so that it may reach to the wider audience such as policymakers, administrators, health professionals, industrialists, academicians, patients groups and citizens and become useful to them as well while making decisions in the healthcare.
- Outcome Reports may go for publication or media reporting only after the due approval of HTAIn Secretariat.
- Decision making and implementation of the policy is the role of the policy makers of the respective User Agencies. It is quite possible that the policy makers accept the Board recommendations as such or they may modify the recommendations depending upon their own intellect, feasibility of implementation and acceptability. The role of HTAIn is to assist the policy makers in decision making backed by evidences and rigorous research procedure.

Note: The timelines provided in different phases of the study may vary depending upon the topic and availability of data. A proper justification is required for the same.

CHAPTER 3

STAKEHOLDER'S ENGAGEMENT POLICY

3. INTRODUCTION

The quality, usefulness and legitimacy of HTA can be improved by open and consultative processes. The interested parties affected by a recommendation for a health intervention are called the stakeholders. Stakeholders are individuals, organizations or communities that are directly affected or, have a direct interest in the process and/or outcomes of a health technology assessment. Stakeholders in the HTA process could be:

- The User Department (e.g. RSBY or NPPA, NHM)
- Central Government and/or State Government Public health authorities
- Policy makers
- Healthcare organizations (e.g. Indian Medical Association)
- Insurance Providers
- Regulatory agencies
- Industrial associations (e.g. manufacturers, suppliers, wholesalers, distributors and retailers)
- Patients (patient organization, disease specific society or organization)
- Academics or Methodological experts
- Researchers
- Social groups (NGOs, Advocacy groups, Ethical groups etc.)

Stakeholders are distinct from the common public as they are impacted by the the process and/ or recommendations of an HTA. The impact can be on patient outcomes, service provision, income, or out of pocket expenditure. Therefore, their participation in HTA is both rational and likely to contribute to the quality and legitimacy of the process and outcomes. Stakeholders may provide valuable inputs on different aspects of HTA (epidemiology, grey literature, therapy, clinical efficacy and effectiveness, cost and budget impact) at different stages of the HTA.

3.1. Stakeholders Engagement

Globally, a range of measures are used to constructively engage multiple stakeholders throughout the HTA process. Stakeholder engagement is an iterative process of actively soliciting the knowledge, experience, value judgment of stakeholders identified to represent a broad range of direct interests in a particular issue.

Purpose:

The purpose of stakeholder engagement would be to identify relevant stakeholders and involve them in the ongoing study to obtain their views, ideas, data available with them or feedback on the data/information used in the study as well as any findings from the study.

Types of Engagement

Engagement with stakeholders could be at three levels:

i. **Information Gathering** – This involves participation of stakeholders in order to collect information regarding data available to them.
ii. **Consultation** – This involves the feedback from stakeholders on specific documents or findings and address them appropriately.
iii. **Participation** – This involves stakeholder's participation in certain study topics actively to ensure their concerns are understood and considered, and to give them some influence on and ownership of decisions such as to the User Department or other Government Agencies.

Depending on the nature of interest, expertise and relevance to the HTA study, different strategies of stakeholder engagement are employed. For example:

- User department participate throughout the study especially during framing the research question, aims and objectives. User Department along with other Government organizations are asked to participate for sharing the data available to them.
- Researchers and clinicians participate often during the course of study, for their expert opinions and guidance.

- Industries/ private organizations and NGOs may be consulted twice - one to discuss about the proposal and second when the outcome report is approved by the TAC or as required.
- NGOs can also be consulted periodically by HTAIn to discuss the social/ ethical aspects of the intervention and feasibility of implementation and/ or participate during the of implementation of the policy

3.2. Process of Stakeholders Engagement

1) Identification of stakeholders

The most important step in stakeholder engagement involves the identification of relevant stakeholders. Reasonable steps should be taken to identify topic-specific organizations with appropriate geographical coverage (e.g. state/ national organizations). Stakeholders could be an individual or a small group representing an organization having a mandate to speak on behalf of that organization such as CEO, President, Chairperson or Head of the Organization or someone nominated by an organization.

2) Stakeholder's Registration

All the interested parties are encouraged to register themselves online on the HTAIn website (in the HTAIn section) or, they may send a formal request to the secretariat for registration. This registry of stakeholders developed by HTAIn through online registration maybe used for identification of relevant stakeholders for specific HTA.

Activities during Stakeholder Engagement

- The HTAIn Sec. informs the relevant stakeholders about the topic(s) selected for study and organize a consultation meeting at HTAIn Sec. in close coordination with the Technical partner/ Resource Centre.
- TP/RRC present their proposal (approved by the TAC) to the stakeholders for their feedback/ views and the **same stakeholders** are again consulted for a second meeting, once the outcomes report of the study is approved by the TAC, to discuss the results and policy recommendations.

- The Stakeholder's meetings are chaired by a senior official of the Ministry of Health and Family Welfare or a renowned expert identified by the HTAIn secretariat.
- Stakeholders are asked to join hands to with HTAIn while conducting the study and fill the data gap and provide assistance, if needed.
- After the study is completed, the report of findings as well as key policy recommendations are also uploaded online and Stakeholders will be asked to furnish their feedback/ views within 15 days from the date of report uploading. Feedback may be submitted on the web portal or sent via email to htain-dhr@nic.in.
- Each attendee of the meeting must disclose their interest by signing a declaration of interest form provided by the HTAIn Secretariat.
- If required, a brief presentation may be shared with them about HTAIn, its structure, processes and importance of the stakeholders for sensitization.
- In conjunction to the consultative meetings, a participatory approach may be used with a subset of stakeholders like representatives of user departments, other Government agencies, relevant policymakers, clinicians or public health experts in the HTA topic in a **closed-room meeting** to get their feedback, suggestions and data.

Note: Record of discussion for every meeting (TAC, Stakeholder's and Board) are maintained and published online after approval from the chair.

CHAPTER 4

DECLARATION OF INTEREST POLICY

4. INTRODUCTION

A conflict of interest (COI) may arise when a person or organization involved in HTAIn have multiple interests, personal, professional, commercial or otherwise, in a particular HTA study. COI arises a risk of influence the study, its recommendation and hence the decision-making. COI may not always, in and of itself, be evidence of wrongdoing. However, it is important to manage all COI, in order to ensure that the recommendations of the HTAIn are perceived to be free from external influences and to uphold the principles of transparency and accountability.

4.1. Types of interests (Identifying the conflict)

i. ***Non-financial (Competition)*** **–** An interest other than financial interest such as reputation, career advancement, goodwill etc. that could directly/ indirectly influence the design, conduct, results or reporting of an HTA study including the outcomes and recommendations. These COI could be personal or non-personal.

- ***Non-financial personal interest:*** If a member of HTAIn, Stakeholders or associated committees (TAC/ TP/ Regional Resource Hubs/ Board) or their relatives may gain or appear to gain any career advancement, name or reputation.
- ***Non-financial non-personal:*** It may emerge if any HTAIn, Stakeholders or associated committees are a part of any firm or organization or having any social or political connections with anyone (close acquaintances) that may gain or appear to gain in terms of advancement of reputation, career or opportunities.

ii. ***Financial*** **–** A financial interest is anything of monetary value being or appear to gain by any of the HTAIn member or Stakeholders. It could directly and significantly affect the design, conduct, results, reporting and recommendation of an HTA study. It is again of two types: personal and non-personal.

- ***Financial personal:*** If a member of HTAIn and associated committees or his close relative(s) have or appears to have a direct financial benefit from any recommendation and affect the course of study, results and outcomes. If a

member or his/ her relative has received or plans to receive in future a financial benefit from a firm or a representative body related to the intervention under assessment during the last 2-3 years or any other product of service that is specific to an agenda item under consideration for HTA by HTAIn or associated committees, it will fall into financial personal COI.

- ***Financial non-personal:*** If a member of belongs to an institution, firm, association or company that gains or perceived to gain a direct financial benefit e.g. sponsorship, product manufacturing contracts, monetary funds to conduct research or production then the representative member of that institute falls into financial non-personal interest.

4.2. Objective

The objective of declaration of interest is to effectively identify, disclose and manage any interest, be it actual, potential or perceived, in order to protect the integrity of HTAIn and credibility of the recommendations made ensuring that, in principle, recommendations made by the HTAIn are free from any bias and external influences.

4.3. Scope of Declaration of Interest

The declaration of interest is applicable to all the HTAIn Members especially those who are directly involved in conducting the study or appraising the study or providing comments/ suggestions or approving the study at any stage such as Technical Partners, Regional Resource Centres, Technical Appraisal Committee, Co-opted members (Experts), Special invitees, Board and the Stakeholders. All of the above members should declare if there is any conflict of interest in any particular HTA study and if it is there, it should be managed appropriately.

4.4. Activities during declaration of interests

- A declaration of interest form should be prepared in a prescribed format and all the Members of TP/RRC, TAC, Board and Stakeholders are asked to declare their interests, if any.

- Regional Resource Hubs, TP, TAC, Special Invitees, Experts and Board members should fill the Declaration of Interest form provided by the Secretariat before conducting the study and comply with their mandate Terms of Reference.
- Stakeholders should also fill the Declaration of Interest form in the first stakeholder consultation meeting.
- The secretariat will make sure that all the members have filled the the declaration of interest form while collecting and documenting it.
- If any member does not declare their interest and it is revealed at any later stage, then their involvement in the HTAIn proceedings could be terminated and they might be subjected to legal liability.
- Secretariat will monitor the compliance of the members with this policy and might review this policy annually to ensure that the policy is operating effectively.

4.5. Managing the Conflict

As mentioned above, COI may not always, in and of itself, be evidence of wrongdoing. However, it is important to manage all COI, in order to ensure that the recommendations of the HTAIn are perceived to be free from external influences and to uphold the principles of transparency and accountability. While managing the COI the following need to be assessed carefully:

i. The seriousness of the conflict
ii. The range of all possible mitigation options.

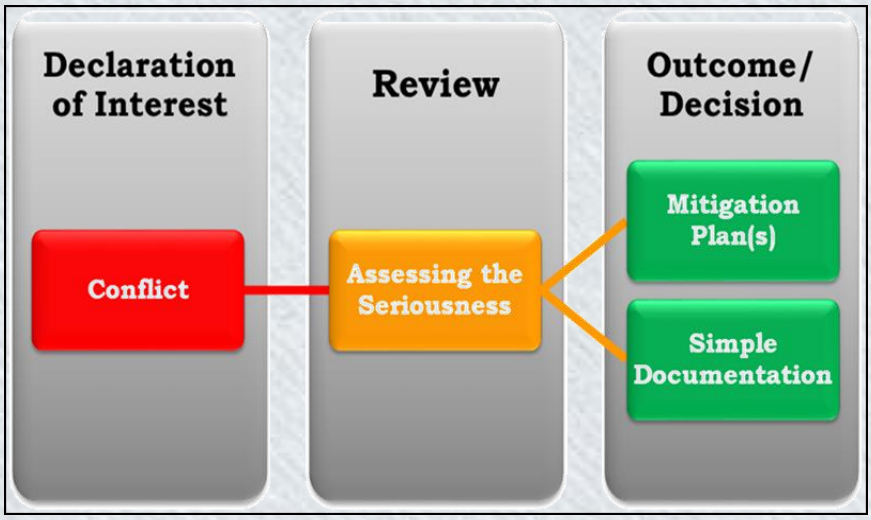

Figure 6: HTAIn Conflict of interest Process Overview

Seriousness of conflict is a question of degree. It involves a spectrum of directness and significance of the conflict. Several factors may need to be weighed in assessing the seriousness like:

i. The type of conflict (financial/ non-financial)
ii. The extent to which the conflict of interest could affect the proceedings.
iii. Whether the conflict will realistically impair the disclosing person's capacity to impartially participate in decision-making etc.

Conflict among Board/ Committee Members

If a conflict of interest is identified among TP/RRC, TAC or Board, the Secretariat will share it with the chair of the respective committee, withholding the name of the member having a potential conflict. The Chair will then call for Board/TAC members to discuss and decide upon whether the member with COI:

- May continue to participate fully in the meeting
- May participate in the discussion but not in the final decision making.
- May be transferred to another position.
- Be requested to not participate in the meeting at all.

The approval of any of the above action may require the agreement of at least a majority in the Board/ TAC who are present at the meeting (excluding any conflicted member/s).

Conflict among Board/ Committee Members

If any potential conflict is identified among the Resource Hubs/ Technical Partners the TAC will take a decision, on case to case basis, respectively as to how to handle the conflict such as re-assigning tasks or duties to another hub or technical partner or any other potential mitigating option, such as withholding the person with COI from getting involved in the study.

Notes:

- While, deciding which approach to take during the mitigation of conflict, the Chair and/ or members of the committee(s) will consider whether the conflict needs to be managed or simply documented depending upon its seriousness. The

- Secretariat will document if there is any conflict of interests and decisions taken regarding that conflict should be recorded in the minutes of meeting with name(s) of the member(s) redacted, if necessary.

CHAPTER 5

CONFIDENTIALITY OF DISCLOSURES AND COMPLIANCE WITH THE HTAIn POLICIES

5.1. Objective

The main purpose of maintaining confidentiality is to avoid the misuse of data, external influence in the study and hence, maintaining the credibility and reliability of processes and outcome. It also helps in data management and building trust among the members.

5.2. Activities

- An undertaking form is prepared in a prescribed format for data confidentiality and HTAIn policy compliance.
- All the committee members need to fill an undertaking that they will maintain the confidentiality of sensitive data, documents, proceedings, discussions and comply with HTAIn policies.
- Sensitive information and proceedings may not be open to public.
- Details of who will have access to the information discussed during the meeting should be disclosed prior to the meeting.
- If any confidentially breach or non-compliance with HTAIn policy is found the member's involvement in the processes may be terminated and they might be subjected to legal action.

CHAPTER 6

GUIDANCE MANUAL TO HTA-QUALITY ASSESSMENT CHECKLIST INDIA

6. Background

A study (Prinja et al.) reports that the average quality score for economic evaluations done in India is 65.1%. Out of 104 studies included in the analysis, only 16% had performed PSA, only 36% considered the fiscal implications of the intervention and just 40% of the studies considered generalizability of their findings.

Since the primary aim of HTA is to generate evidence to ensure and facilitate the process of informed healthcare decision making, it is important to standardize the processes pertaining to it. Therefore, it was decided to develop a standardized tool/checklist to assess the quality of HTA studies being conducted in India.

The primary objective is to develop a comprehensive tool that will capture all vital aspects of conducting an HTA study. This will enable to standardise the reporting as well as reviewing processes pertaining to HTA studies being conducted in India. Also, it would improve the quality of reporting practices thus ensuring transparency and clarity.

6.1. Purpose of the guidance manual

The guidance manual to the checklist aims to ease the process of filling out the checklist. It consists of the operational definitions of all the questions which are to be filled out by the author as well as reviewer. This will help the author and the reviewer to respond to the questions as expected.

6.2. Overview of the checklist

The checklist has been divided into two parts: a self-reporting section to be filled by the author and the other to be filled by the reviewer. The reviewer checklist has further been divided into two sections: to review the report/manuscript and the other to review the model.

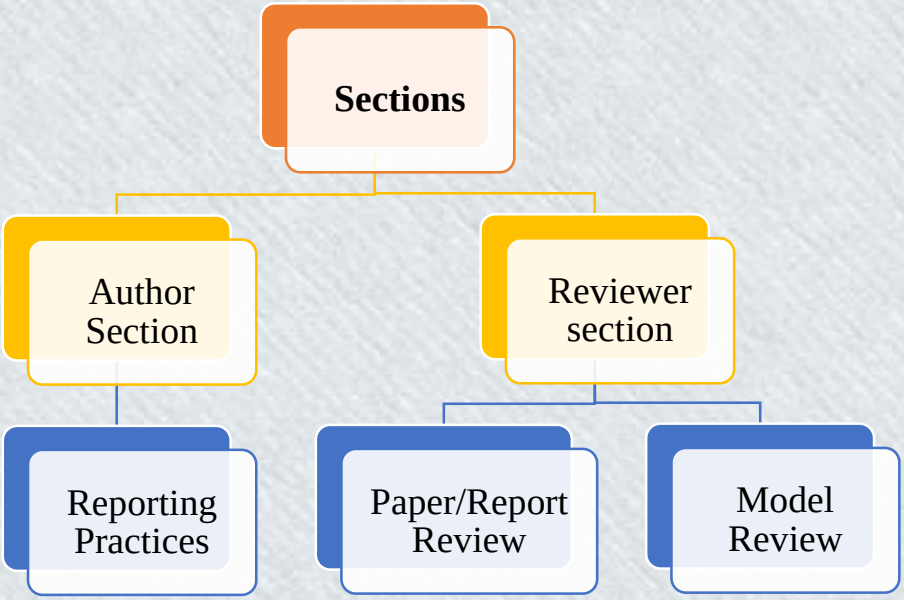

Figure 7: Framework of the checklist.

The author section of the checklist aims at obtaining a comprehensive description of the study from the author. This will not only ensure efficient reporting practices but will also form a guiding document for the reviewer to analyze the appropriateness of key aspects of an HTA study. Broad heads included in this checklist are: Basic information, rationale of the study, policy relevance, study description, study methods, reporting of model parameters, study results, discussion and conclusion.

The reviewer section of the checklist focuses on the quality aspect of the conducted study. The first part of this section, which is the report review, focuses on reviewing the information given in the report or manuscript. The domains included in this part are in concurrence with the author section: Basic information, study methods, study results, discussion, conclusion and references.

The second part constitutes the technical aspect of reviewing the model. This includes: basic information, model assumptions, functionality, model inputs, calculations, uncertainty analysis, model output and model validation. The model check and review will further improve the quality of the study in terms of technical proficiency.

Author section

The author section is a self-reporting format comprising of 8 domains.

The first domain, i.e, basic information, includes information regarding title of the study, year of the study and ethical approvals sought for the study. The title should reflect the study design, study setting, intervention, comparator and disease/program of concern. The second and third domains talk about the need for the study being conducted as well as its implications for policy making.

The next domain asks for a complete description of the analysis in terms of objectives, intervention, control, target population, study perspective, discount rate and time horizon. The fifth domain correspond to the study methods. This section asks about information pertaining to the choice of model, time horizon and perspective along with justification for the choice. Information pertaining to inclusion of various types of costs and estimation of health-related outcomes is included. This domain also seeks information pertaining to the analyses conducted in the study such as uncertainty analyses, Equity analysis, budget impact analysis and stakeholder analysis.

The next domain talks about assumptions made pertaining to various model parameter. The seventh domain pertains to reporting of the results of all types of analysis performed. The last section talks about validation of the results, statement of limitations and strengths followed by key conclusion and recommendations.

All the responses will be in the form of Yes, No, Not Applicable (NA), Not Reported (NR), page numbers, line numbers, figure/table numbers wherever appropriate.

Reviewer section: Report/manuscript review

The domains under this section are more or less similar to the above section. The difference is that this section talks about the appropriateness of choices made for the analysis conducted. The first domain is regarding appropriateness of basic information pertaining to the analysis. It includes questions such as whether the title

is appropriate or not; whether the abstract is complete or not; are the objectives stated clearly; are the intervention, comparator and target population described completely?

The next domain pertains to appropriateness of study methods. Following type questions are addressed in this domain: whether the choice of model is appropriate or not; what all costs have been included and their sources; appropriateness of these sources; sources of effectiveness estimates and its appropriateness; sources of quality of life estimates and appropriateness. The analysis part under this domain talks about the appropriate conduct of various types of analyses as listed in the author section as well. It also includes questions pertaining to the choice of discount rate and its appropriateness as well as animalization of costs.

The next domain refers to appropriateness of reporting results of all the analyses done in the study. For examples, the results of OWSA should be presented in the form of tornado, CEAC and CE plane are constructed for PSA. This section focuses on the quality of reporting the finding of the study so as to ease the interpretation of findings. The next domain focuses on the discussion and conclusion part. It includes points regarding, justification and validation of findings, generalizability, limitations of the analysis, implications from the policy perspective and recommendations.

The last and the fifth domain (References) seeks information about accounting for all the secondary sources of information mentioned in the text.

All the responses will be in the form of Yes, No, Not Applicable (NA), Not Reported (NR) as well as rating on a scale of 1 to 10. They type of response expected has been mentioned along with each question.

Reviewer section: Model review

This section consists of 8 domains which guide the reviewer to assess the model. The first domain refers to basic information which comprises of necessary information required to assist review of the model. It consists of key points like the type of platform used for building the model; availability of a model dictionary containing brief analysis description, index for different sheets, abbreviations, labels for different variables, tables and figures and references; proper labelling of sheets, tables and figures;

consistent naming convention throughout and a user friendly layout to efficiently review the model.

The next domain is regarding clear listing of model assumptions, tables and figures so as to facilitate the review process. The third domain pertains to model functionality which includes checks for macros, ranges and look up values, check for general error messages and any link to external sources. The fourth domain refers to model inputs which includes listing of all inputs under one sheet, checking for correctness of any conversion of parameters (ex: risk/ratios to probability), checking for proportion sums and mutually exclusive parameters.

The next domain pertains to calculations done in the model. It includes correct linking of different cells within as well as between sheets and the correct formulation of processes like discounting, annualization, QALY calculations and others. The sixth domain refers to checks pertaining to uncertainty analysis. It includes checking appropriateness of ranges listed for all parameters, proper linking of tables and graphs generated, functioning of macros, appropriateness of distributions assigned to parameters and their sources and appropriate presentation of results of various analyses. The seventh domain refers to the model output/summary. This section is reviewed to ensure appropriate linking of summary estimates, comprehensive description of results, appropriate linking and labelling of tables, figures and graphs.

The last domain talks about the validity of the model. This section seeks information on whether the outputs of the model are in concurrence with the existing scientific evidence available. For ex: Is the average life expectancy of the cohort in concurrence with the existing evidence on the same, is the average predicted survival from the model in concurrence with clinical evidence etc. This domain also talks about the validity of model in terms of effectiveness of intervention. For ex: Is the reduction in disease free episodes/ increase in average disease-free survival/ increase in average progression free survival/ decrease in mortality from the model in concurrence with the evidence from clinical effectiveness literature.

6.3. The Checklist

All these sections have been explained more comprehensively in the tables below.

Section I: Self Reporting by Author

S.No.	Section heads	Description
1.1	**Basic information**	
1.1.1	Title	Specifies the study design, study setting/geography, intervention/control, disease/program of concern
1.1.2	Study year	Please specify the year in which study was undertaken.
1.1.3	Ethical approvals (Yes=1, No=2, NA=3)	Please mention whether necessary ethical approval was sought.
1.2	**Need for the study**	
1.2.1	What is the current available evidence in this domain?	Summarize the existing knowledge regarding the topic under study and justify the need of the present study.
1.2.2	How will the present study additionally contribute towards evidence generation?	
1.3	**Policy relevance (3 bullet points)**	
1.3.1	Policy implications and novelty	Describe the relevance and implications of the study from policy perspective
1.4	**Study description**	
1.4.1	Specify the study objectives	
1.4.2	Specify:	For any section which has not been considered for the analysis, please mention "Not applicable"

a	Intervention	
b	Comparator	
c	Target population	
d	Time horizon	
e	Discount rate	
f	Study perspective	
1.5	**Study methods**	
1.5.1	***Choice of model***	
1.5.1.1	Decision tree=1, Markov model=2, Both=3	Pleasy specify the choice of model, whether a decision tree or a markov model or both were used for the study.
1.5.2	***Study perspective***	
1.5.2.1	Choice of study perspective (societal/provider/patient) and its justification	Please specify the perspective from which the study was undertaken. Whether only provider perspective or only patient's perspective or both were considered.
1.5.3	***Time horizon***	
1.5.3.1	Choice of time horizon and its justification	Please specify the choice of time horizon considered to capture all the benefits and costs.
1.5.4	***Costs included***	
1.5.4.1	Health system costs (Yes=1, No=2, NA=3)	

a	Costs associated with the intervention (drugs, vaccine, health technology)/Program costs:	
a.1	Start-up costs/scale up costs (Yes=1, No=2, NA=3)	Any capital investment: building, space, equipment, health worker trainings
a.2	Implementation/operational costs (Yes=1, No=2, NA=3)	Service delivery, monitoring and supervision, administration, support, IEC/BCC materials, personnel
b	Treatment costs (Yes=1, No=2, NA=3)	Cost of treatment at various levels of service delivery: primary/secondary/tertiary, drugs/diagnostic, hospitalisation, management of complication
1.5.4.2	Patient costs	
a	Direct costs (Yes=1, No=2, NA=3)	Medical (drugs, diagnostics, procedural, hospital charges) and Non-medical (transportation, boarding & lodging)
b	Indirect costs (Yes=1, No=2, NA=3)	Loss of wages, employment and less productivity due to morbidity
1.5.5	***Health benefits***	
1.5.5.1	Source: effectiveness estimates for intervention (Primary=1, Secondary=2, Both=3)	Specify the sources for effectiveness estimates. Whether primary data was collected or estimated from literature were considered.
1.5.5.2	Immediate/short term outcomes reported (Yes=1, No=2, NA=3)	
1.5.5.3	Long term outcomes reported (Yes=1, No=2, NA=3)	

1.5.5.4	Choice of utility measure (QALY=1, DALY=2)	
1.5.5.5	Source: QOL score (Primary=1, Secondary=2, Both=3, Expert opinion=4)	
1.5.6	***Analyses conducted***	
1.5.6.1	Uncertainty analysis	
a	OWSA (Yes=1, No=2)	
a.1	Threshold analysis (Yes=1, No=2)	
a.2	Scenario analysis (Yes=1, No=2)	
a.3	Subgroup analysis (Yes=1, No=2)	
a.4	Extreme case analysis (Yes=1, No=2)	
b	PSA (Yes=1, No=2)	
c	EVPI (Yes=1, No=2)	
1.5.6.2	Equity analysis (Yes=1, No=2)	
1.5.6.3	Budget impact analysis (Yes=1, No=2	
1.5.6.4	Stakeholder analysis (Yes=1, No=2)	
1.6	**Reporting of model parameters & their sources**	
1.6.1	Demographic parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.6.2	Epidemiologic parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.6.3	Coverage and utilisation parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.6.4	Risk parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.6.5	Transition probabilities (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source

1.6.6	Cost parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.6.7	Effectiveness parameters (Yes=1, No=2, NA=3)	Base value, uncertainty ranges and reference/source
1.7	**Study results**	
1.7.1	Cost (with uncertainty ranges):	
1.7.1.1	Intervention	
1.7.1.2	Comparator	
1.7.1.3	Incremental costs	
1.7.2	Health outcomes (with uncertainty ranges):	
1.7.2.1	Intervention	
1.7.2.2	Comparator	
1.7.2.3	Incremental outcomes	
1.7.3	Cost-effectiveness: ICER (with uncertainty ranges)	
1.7.4	Uncertainty analysis	
1.7.4.1	Univariate: Tornado (Yes=1, No=2, NA=3)	
1.7.4.2	Threshold analysis: Graph/table/text (Yes=1, No=2, NA=3)	
1.7.4.3	Subgroup analysis: Groupwise ICERs (Yes=1, No=2, NA=3)	
1.7.4.4	Scenario analysis: Scenario specific ICERs (Yes=1, No=2, NA=3)	
1.7.4.5	Extreme case analysis: Scenario specific ICERs (Yes=1, No=2, NA=3)	

1.7.4.6	PSA: Uncertainty limits (Yes=1, No=2, NA=3)	
1.7.4.7	PSA: CEAC (Yes=1, No=2, NA=3)	
1.7.4.8	PSA: CE Plane (Yes=1, No=2, NA=3)	
1.7.5	Equity analysis: ICER, Financial Risk Protection (Yes=1, No=2, NA=3)	
1.7.6	Budget impact analysis (Yes=1, No=2, NA=3)	
1.7.7	Stakeholder analysis (Yes=1, No=2, NA=3)	
1.8	**Discussion & Conclusion**	
1.8.1	Result validation	Comparison of findings with existing evidence and explain the possible reasons for difference in findings
1.8.2	Strength and limitations	
1.8.3	Key conclusion and recommendation	

Section II: Report/Manuscript Review by Reviewer

S.No.	Section heads	Description
2.1	**Basic information**	
2.1.1	Appropriateness of the title (Rate on a scale of 1 to 10)	Does the title appropriately justifies the objectives of the study? Specifies the study design, study setting/geography, intervention/control, disease/program of concern
2.1.2	Comment on the completeness of the	Rationale, study perspective, time horizon, intervention and comparator, choice of model

	abstract/summary given in the report (Rate on a scale of 1 to 10)	(static progression: cohort/population or dynamic transition), study results (ICERs with uncertainty ranges), study conclusion
2.1.3	Are the objective of the study stated clearly? (Rate on a scale of 1 to 10)	Complete justification of what is expected out of the study and its relation to existing evidence.
*2.1.4	Have the authors sought necessary ethical approval for the study? (Yes=1, No=2, NA=3)	Ethical approval sought from the concerned body. In case of patient involvement, informed consent
2.1.5	Description of intervention, comparator, study population and appropriateness. (Rate on a scale of 1 to 10)	Detailed description of intervention and comparator, appropriateness of justification for the choice of intervention and comparator. Description of characteristics of the study population and justification of why this population is relevant for the study. Any subgroups chosen ? justification for its choice. Comment on whether any relevant subgroup if it was not considered.
2.2	**Study methods**	
2.2.1	***Model structure & assumptions***	
2.2.1.1	Appropriateness of choice of model	
a	In case of decision model, does this model incorporate all possible ramifications. (Rate on a scale of 1 to 10)	Comment on whether the choice of model for the analysis was considered appropriate.

b	In case of markov model, comment on the biological plausibility of the model. (Rate on a scale of 1 to 10)	
2.2.1.2	Were the assumptions underlying the model described clearly? (Rate on a scale of 1 to 10)	Comment on whether all underlying assumptions were clearly mentioned in the report/manuscript.
2.2.2	***Costs***	
2.2.2.1	Are all the costs included in line with the study perspective? (Yes=1, No=2)	Check whether all costs considered were in concurrence with the perspective of the study.
2.2.2.2	Have all the associated costs been captured comprehensively? (Rate on a scale of 1 to 10)	
2.2.2.3	If primary data has been collected pertaining to costs, comment on the appropriateness of the methodology. (Rate on a scale of 1 to 10)	If primary data was collected, whether top down, bottom up or normative costing approach was considered.
2.2.2.4	If secondary sources have been used, are they justified? (Rate on a scale of 1 to 10)	
2.2.2.5	Are the conversion rates used for costs appropriate? (Yes=1, No=2, NR=3)	

2.2.3	***Effectiveness data***	
2.2.3.1	Source	
a	What was the source of effectiveness data?	
	(Primary data=1, Single study=2, Multiple studies=3, Existing systematic review=4, Systematic review=5, Systematic review & meta-analysis=6, Expert opinion=7)	
b	Was the source for effectiveness estimates considered appropriate ? (Yes=1, No=2)	
c	Please rate the appropriateness of effectiveness estimate derived (Rate on a scale of 1 to 10)	
2.2.3.2	Valuation	
a	Was the choice of immediate/short term outcomes chosen appropriate? (Yes=1, No=2, NA=3)	
b	Was the choice of long term outcomes chosen	

	appropriate? (Yes=1, No=2, NA=3)	
c	Was the choice of utility measure (QALY/DALY) appropriately justified? (Yes=1, No=2)	
d	If primary data was collected pertaining to QoL, comment whether the methodology was appropriate based on:	
d.1	Is the sample representative of the population group under study? (Yes=1, No=2)	
d.2	Is there likely to be a selection bias in recruitment of subjects? (Yes=1, No=2)	
d.3	Does the sample selection represent the heterogeneity comprehensively? (Rate on a scale of 1 to 10)	For ex: Age-sex composition, literacy level, locality (urban/rural), wealth status etc.
d.4	Along with the tool administration, was valuation also done? (Yes=1, No=2)	
d.5	If not, then how likely is the use of tariff values form other setting	

	generalisable to the population under study? (Rate on a scale of 1 to 10)	
e	If secondary source, was the choice appropriately justified? (Rate on a scale of 1 to 10)	
2.2.4	***Analysis***	
2.2.4.1	Discounting (Yes=1, No=2, NA=3, NR=4)	
a	Were all the future costs and outcomes discounted? (Yes=1, No=2, NA=3, NR=4)	
a.1	If yes, were all the future costs and outcomes discounted appropriately? (Rate on a scale from 1 to 10)	
b	Were all the past costs and outcomes discounted? (Yes=1, No=2, NA=3, NR=4)	
b.1	Were all the past costs and outcomes discounted appropriately (if applicable)? (Rate on a scale from 1 to 10)	Cost and outcomes are supposed to be discounted at rate of more than 1 in this case
2.2.4.2	Annualization	

a	Were the capital costs annualised appropriately? (Yes=1, No=2)	
2.2.4.3	Uncertainty analysis	
a	What type of uncertainty was identified?	
a.1	Methodological (Yes=1, No=2, NA=3, NR=4)	
a.2	Structural (Yes=1, No=2, NA=3, NR=4)	
a.3	Heterogeneity (Yes=1, No=2, NA=3, NR=4)	
a.4	Parameter (Yes=1, No=2, NA=3, NR=4)	
b	What type of analysis were conducted to handle uncertainty?	OWSA(threshold, scenario, subgroup, extreme case), PSA
b.1	Methodological uncertainty: Refence case	
	Was the method appropriate? (Rate on a scale of 1 to 10)	
b.2	Structural uncertainty: Scenario analysis	
	Was the method appropriate? (Rate on a scale of 1 to 10)	
b.3	Heterogeneity : Subgroup analysis	

	Was the method appropriate? (Rate on a scale of 1 to 10)	
b.4	Parameter uncertainty: PSA, Univariate	
b.4.1	Were distributions assigned to all the following parameters? :	
-	Probability distribution used for risk and epidemiologic parameters	Beta
-	Probability distribution for coverage and utilisation parameters	Uniform
-	Probability istribution for quality of life parameters and transition probabilities	Beta
-	Probability distribution for effectiveness parameters	Beta, Normal distribution is used for estimates derived from metanalysis
-	Probability distribution for cost parameters	Gamma/Lognormal
b.4.2	Were the distributions assigned to above parametes appropriate? (Rate on a scale of 1 to 10)	
b.4.3	Was the choice of WTP threshold appropriately justified? (Yes=1, No=2, NR=3)	
*2.2.4.4	EVPI	

	Was the analysis performed appropriately? (If Yes= Rate on a scale of 1 to 10)	
2.2.4.5	Equity analysis	
	Was the analysis performed appropriately? (If Yes= Rate on a scale of 1 to 10)	
2.2.4.6	Budget impact analysis	
	Was the analysis performed appropriately? (If Yes= Rate on a scale of 1 to 10)	
2.2.4.7	Stakeholder analysis	
	Was the analysis performed appropriately? (If Yes= Rate on a scale of 1 to 10)	
2.2.5	***Consistency of methods***	
	As per the review based on section 2.2, were the methods in concurrence with the HTA process manual of India? (Rate on a scale of 1 to 10)	
2.3	**Study results**	
2.3.1	Were all costs, outcomes, incremental gains and	Base value as well as confidence interval should be reported

	ICER(s) listed comprehensively? (Rate on a scale of 1 to 10)	
2.3.2	Uncertainty analysis	
2.3.2.1	OWSA (If applicable, rate on a scale of 1 to 10)	
a	Were the parameters identified to which ICER is most sensitive along with appropriate justification?	
b	Were the results represented in appropriate format?	Was a tornado generated?
c	Were the results of relevant subgroup analysis reported appropriately?	
d	Were the input parameters considered for threshold analysis appropriate?	
2.3.2.2	PSA	
	Were the results reported appropriately in the form of CEAC and CE plane? (Yes=1, No=2, NA=3)	CEAC,CE plane
*2.3.3	EVPI	
	Were the results reported appropriately? (Rate on a scale of 1 to 10)	
2.3.4	Equity analysis	

	Were the results reported appropriately? (Rate on a scale of 1 to 10)	ICER(Financial risk protection ratio)
2.3.5	Budget impact analysis	
	Were the results reported appropriately? (Rate on a scale of 1 to 10)	
2.3.6	Stakeholder analysis	
	Were the results reported appropriately? (Rate on a scale of 1 to 10)	
2.4	**Discussion and conclusion**	
2.4.1	Have the authors appropriately justified the findings of the study? (Rate on a scale of 1 to 10)	
2.4.2	Have the authors appropriately justified the difference in results as compared to that reported by the existing literature both in local as well as global context? (Rate on a scale of 1 to 10)	
2.4.3	Whether the authors have discussed the generalisability of the study findings ? (Rate on a scale of 1 to 10)	

2.4.4	Have the authors specified all the key limitations of the study? (Rate on a scale of 1 to 10)	
2.4.5	Is the study conclusion is in line with the objectives of the study? (Rate on a scale of 1 to 10)	
2.4.6	Does the study provide clear recommendations in regard to the policy perspective? (Rate on a scale of 1 to 10)	
2.5	**References**	
2.5.1	Do the authors appropriately account for all secondary source of information utilised for the analysis as well as mentioned in the text? (Rate on a scale of 1 to 10)	

Section III: Model Review by Reviewer

S.No.	Section heads	Description
3.1	**Basic information**	
3.1.1	Platform used for the model (Spreadsheet=1,	

	Treeage=2, Any other, specify=3)	
*3.1.2	Is an index/dictionary/menu provided in the model? (Yes=1, No=2, NA=3)	The purpose of model dictionary is to help understand the content of the model file.
*3.1.2.1	If yes, does the model dictionary include the following:	
a	A descriptive note of the analysis	
b	Index for all sheets with a brief description	
c	Abbreviations	
d	Labelling/description of variables	
e	Any direction/description for results	
f	Tables/figures (if any)	
g	References (if any)	
3.1.3	Have all the sheets been labelled appropriately? (Yes=1, No=2)	
3.1.4	Have all the figures and tables been labelled properly? (Yes=1, No=2)	
*3.1.5	Is the naming convention consistent across all the sheets ? (Yes=1, No=2)	
*3.1.6	Is the layout user friendly? (Rate on a scale of 1 to 10)	

***3.2**	**Model assumptions**	
3.2.1	Are all related model figures (markov model, decision tree) given? (Yes=1, No=2)	
3.2.2	Are all model related assumptions listed clearly in a separate sheet? (Yes=1, No=2)	
3.3	**Functionality**	
3.3.1	Is there a guiding sheet with an interface to navigate through the model? (Yes=1, No=2)	
3.3.1.1	If yes, check that the navigation buttons/drop down lists contain valid links. (Yes=1, No=2)	
3.3.2	Are all macros working properly? (Yes=1, No=2)	
3.3.3	Check that named ranges and 'look-ups' have valid, accurate cell references (Yes=1, No=2)	
3.3.4	Are there any links to external sources (Yes=1, No=2)	

3.3.5	Are there any general error messages in outputs (Yes=1, No=2)	Ex: circular references, invalid numeric values, unrecognised names…
3.4	**Model inputs**	
3.4.1	Are all model inputs/parameters listed in one sheet? (Yes=1, No=2)	
3.4.2	Check for the correctness if any conversions were required for parameter values:	
3.4.2.1	Rate/risk/ratio to probabilities (Yes=1, No=2)	
3.4.2.2	Inflation adjustments (Yes=1, No=2)	
3.4.2.3	Currency conversions (Yes=1, No=2)	
3.4.3	Check that mortality rates from life tables are transformed into probabilities. (Yes=1, No=2)	
3.4.4	Check that all proportions sum to 1 where appropriate. (Yes=1, No=2)	
3.4.5	Check for mutually exclusive parameters (x, 1-x) (Yes=1, No=2)	
3.4.6	Check whether upper and lower limits for all	Check for the base value consistently falls between upper and lower limits

	parameters have been listed along with the base values. (Yes=1, No=2)	
3.5	**Calculations**	
3.5.1	Linking	
3.5.1.1	Check for appropriate linking in between sheets (wherever applicable). (Yes=1, No=2)	
3.5.1.2	Confirm that the Markov Trace refers to the correct input in every cycle. (Yes=1, No=2)	
3.5.1.3	Confirm that cost formulas in Markov Trace refer to the right cells and are correctly executed. (Yes=1, No=2)	
3.5.1.4	Confirm that QALY and LY formulas in Markov Trace refer to the right cells. (Yes=1, No=2)	
3.5.1.5	Check that mortality rates from life tables are correctly brought in based on the characteristics of the cohort. (Yes=1, No=2)	When applying age-wise all cause mortality
3.5.2	Processes	

3.5.2.1	Are the discount rates for costs and outcomes applied correctly? (Yes=1, No=2)	
3.5.2.2	Were the capital costs annualised appropriately? (Yes=1, No=2)	
3.5.2.3	Does the total of all health states in every cycle adds up to the cohort/population size? (Yes=1, No=2)	Ex: if cohort size is 1 then the total should be 1.
3.5.2.4	Check that the hazard of death in the model doesn't fall below that of the general population/better off stage/less severe comparator. (Yes=1, No=2)	
3.5.2.5	Do the LYs become equal to QALYs when utility weights are set equal to 1? (Yes=1, No=2)	
3.6	**Uncertainty analysis**	
3.6.1	OWSA	
3.6.1.1	Check for the ranges for parameters should make sense. (Yes=1, No=2)	
*3.6.1.2	Was the OWSA macro running properly? (Yes=1, No=2)	

3.6.1.3	Is the direction of change in results as per expected? (Yes=1, No=2)	
3.6.1.4	Check for appropriate linking of data for generating tornado? (Yes=1, No=2)	
3.6.1.5	Was the threshold analysis done appropriately? (Rate on a scale of 1 to 10)	
3.6.1.6	Were the results of threshold analysis reported appropriately? (Rate on a scale of 1 to 10)	graphs/tables
3.6.2	Subgroup analysis	
*3.6.2.1	Is there any description/guide to subgroup analysis (Yes=1, No=2, NA=3)?	
*3.6.2.2	If yes, Does it give information on parameters for forming subgroups? (Yes=1, No=2)	
3.6.2.3	Are the results of subgroup analysis as expected? (Yes=1, No=2)	
3.6.2.4	When parameter values for both subgroups are set equal:	

a	Total LY and QALYs should be equal between arms (Yes=1, No=2)	
b	Total costs should be equal between arms (Yes=1, No=2)	
c	Total costs per health state should be equal between arms (Yes=1, No=2)	
3.6.2.5	Check for presentation of results of subgroup analysis (Rate on a scale of 1 to 10)	
3.6.3	PSA	
3.6.3.1	Check for appropriateness of distributions assigned to each parameter (Rate on a scale of 1 to 10)	
a	Probability distribution for risk and epidemiologic parameters	Beta
b	Probability distribution for coverage and utilisation parameters	Uniform
c	Probability distribution for quality of life parameters and transition probabilities	Beta
d	Probability distribution for effectiveness parameters	Beta, Normal distribution is used for estimates derived from metanalysis
e	Probability distribution for cost parameters	Gamma/Lognormal

3.6.3.2	Check for the proper functioning of PSA macro. (Yes=1, No=2)	
3.6.3.3	Are the graphs generated from the simulations linked appropriately? (Yes=1, No=2)	CEAC,CE plane
3.7	**Model summary**	
3.7.1	The summary should capture the following:	
3.7.1.1	Costs and outcomes for all interventions as well as comparator. (Yes=1, No=2)	Outcomes can be in the form of life years, QALY, infections averted, disease endpoints
3.7.1.2	Incremental outcomes and costs. (Yes=1, No=2)	
3.7.1.3	ICER(s). (Yes=1, No=2)	
3.7.1.4	Both discounted and undiscounted results should be presented. (Yes=1, No=2)	
3.7.1.5	Results of OWSA, PSA. (Yes=1, No=2)	Tornado, threshold analysis table/graph, CEAC, CE plane
3.7.2	Linking	
3.7.2.1	Check from where the summary estimates are being pulled into the results sheet and their correctness. (Yes=1, No=2)	
3.7.2.2	If there are any tables and figures, check that the data	

	has been linked correctly. (Yes=1, No=2)	
3.7.3	Consistency checks	
3.7.3.1	The undiscounted value should always be higher than discounted values. (Yes=1, No=2)	
3.7.3.2	If ICER is negative, check whether it is because of costs or outcomes	Though, it is not expected to have negative incremental outcomes as CEAs are conducted only if there is sufficient evidence for higher clinical effectiveness of the intervention under the study.
3.8	**Model Validity**	
3.8.1	Are the model outputs in concurrence with science and the data (Yes=1, No=2, NA=3):	
a	Disease incidence predicted by model: Counterfactual	Does the incidence predicted by the model matches the existing data on incidence
b	Average life expectancy (predicted by model): Counterfactual	Does the life expectancy predicted by the model match with the actual life expectancy
c	Survival predicted by model: Counterfactual	Is the predicted survival in concurrence with the clinical literature available
c.1	1 year	
c.2	2 years	
c.3	5 years	
c.4	10 years	
c.5	Lifetime	

d	Does the overall mortality in the cohort/population under study corroborates with the time horizon of the study ?	
e	Effectiveness: Intervention	
e.1	Reduction/Prevention of disease episodes	
e.2	Average Disease-free survival (DFS)	
e.3	Average Progression free survival (PFS)	
e.4	Mortality averted (%)	
e.5	Average life years gained	
f	Average lifetime risk reduction	
f.1	Mortality	
f.2	Developing disease	

Note: The authors and the reviewer will be provided with an Excel Sheet containing the above information for quality assessment.

BIBLIOGRAPHY

1. National Health Accounts | National Health Systems Resource Centre, MoHFW, Government of India [Internet]. [cited 2020 Aug 19]. Available from: http://nhsrcindia.org/category-detail/national-health-accounts/ODU=
2. Out-of-pocket expenditure (% of current health expenditure) | Data [Internet]. [cited 2020 Aug 19]. Available from: https://data.worldbank.org/indicator/SH.XPD.OOPC.CH.ZS

DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH & FAMILY WELFARE
INDIA
INDIAN RED CROSS SOCIETY BUILDING,
1-REDCROSS ROAD, NEW DELHI