

**Ministry of Health & Family Welfare
Department of Health Research**

Concept Note for establishing Medical Technology Assessment Board (MTAB) and institutionalizing HTA in India

1. Background:

a) Need for HTA in India:

The Government of India is committed to extend healthcare services to its 1.25 billion population as part of India's Universal Health Coverage (UHC) agenda. In 2014, the World Bank reported the out-of-pocket (OOP) spending on healthcare in India to be as high as 89%¹, and nearly 72% of the OOP expenditure is on medicines². The private healthcare sector is expensive and not amenable to quality control. The rising cost of healthcare has not been matched by a corresponding increase in the government healthcare budget. A finite health budget means that policy makers are faced with difficult decisions regarding prioritisation of health on a daily basis –for example, should the government pay for a National dialysis program, or drugs for management of chronic diseases like diabetes and hypertension? One woman with breast cancer may be treated with chemotherapy for the same cost as treating 20 lakh children for intestinal worms – how can policy-makers decide based on evidence which health condition and population to prioritise, and why? 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. Health Technology Assessment (HTA) is a widely used methodology internationally for optimization of resource allocation in health. HTA is a method of synthesis that considers evidence regarding clinical effectiveness, safety, and cost-effectiveness and, when broadly applied, includes social, ethical, and legal aspects of the use of health technologies. The word 'technology' can include interventions like drugs, devices, diagnostics, treatments, and vaccines.

b) International use of HTA for priority setting

HTA is widely used to inform healthcare resource allocation in numerous countries in Europe, Scandinavia, Asia, and Australasia. Nascent institutions are also being established in South East Asia, the West Pacific, South America and Africa. These countries utilize HTA for the purpose of informing content of health benefits packages, such as the universal health coverage program of Thailand, or the National Health Service (NHS) in the UK, and the essential medicines lists (NLEM) in low and middle income countries, such as Thailand, Indonesia, the Philippines, and Mozambique. In 2014, the World Health assembly adopted a resolution on use of HTA to ensure Universal Health Coverage.

¹ Out-of-pocket health expenditure (% of private expenditure on health). World Health Organization Global Health Expenditure database. 2014.

² Government of India. National Sample Survey Organization. Household consumption of various goods and services in India 2004–05. Vol I: major states and all India.

http://mospi.nic.in/rept%20%20pubn/ftest.asp?rept_id=509_P1&type=NSSO; April 2007. (Accessed Aug 2016).

c) Past activities towards establishment of MTAB at Department of Health Research (DHR):

The 12th 5 Year Plan for India designed by the then Planning Commission (NITI Aayog) states the need to take into account 'cost effectiveness studies to frame clinical treatment guidelines'. It's recommended that 'on the lines of the UK's National Institute of Clinical Excellence (NICE), DHR would develop expertise to assess available therapies and technologies for their cost-effectiveness and essentiality, and formulate and update, on a regular basis, the Standard Treatment Guidelines, and suggest inclusion of new drugs and vaccines into the public health system'. It further states 'The justification for housing the proposed institute outside the Department of Health, but within the Ministry, is to provide it an element of objectivity and independence from practitioners, and to avoid conflict of interest'³.

A commitment was made in the Parliament in response to a question raised that 'the need to establish such a board was discussed and recommended by 12th Plan Working Group on Health Research. Considering the recommendations, the Government recognized the urgent requirement of Medical Technology Board in India and therefore, has decided to set up the Medical Technology Assessment Board (MTAB) for evaluation and appropriateness and cost effectiveness of the available and new Health Technologies in India. The MTAB aims to encourage the process and finalize the development of standardized cost effective interventions that will reduce the cost and variations in patient care, expenditure on medical equipment in directly affecting the cost of patient care, overall cost of medical treatment, reduction in out of pocket expenditure of patients and streamline the medical reimbursement procedures'⁴.

The Parliamentary Standing Committee has also commented that 'DHR plans to focus on programmes aimed at making healthcare affordable for the poor / marginalized groups/ communities. The DHR will set up Technology Assessment Board consisting of economists, social scientists, public health professionals and other specialists (similar to the Offices of Health/Medical Technology Assessment systems in some countries) whereby new technologies can be scientifically assessed for cost efficacy before introduction / procurement for affordable health care'.⁵

The draft National Health Policy, 2015 has highlighted the importance of HTA by stating 'One important capacity with respect to introduction of new technologies and their uptake into public health programmes is health technology assessment. This new multidisciplinary domain, modeled on the work of the National Institute of Clinical Excellence in the UK, is required to ensure that technology choice is participatory and is guided by considerations of scientific evidence, safety, cost effectiveness considerations and social values. This approach is extended also to technology choice involved in the development of standard treatment guidelines and in public health programmes. The National Health Policy commits

³ Para 20.194, 12th 5-year plan (2012–2017), Social Sectors, Volume III.

⁴ Medical Technology Assessment Board, Unstarred question no-549, Rajya Sabha, answered on-10.12.2013, Ministry of Health & Family Welfare, Government of India.

⁵ Para 6.8, p.36, Parliament Standing Committee.

to the development of capacity in this areas and the use of this approach for making technology choices that impact on public health'.⁶

The Department of Health Research has convened an advisory committee to supervise the process of establishment of MTAB and an independent cell is being established at DHR to run the process.

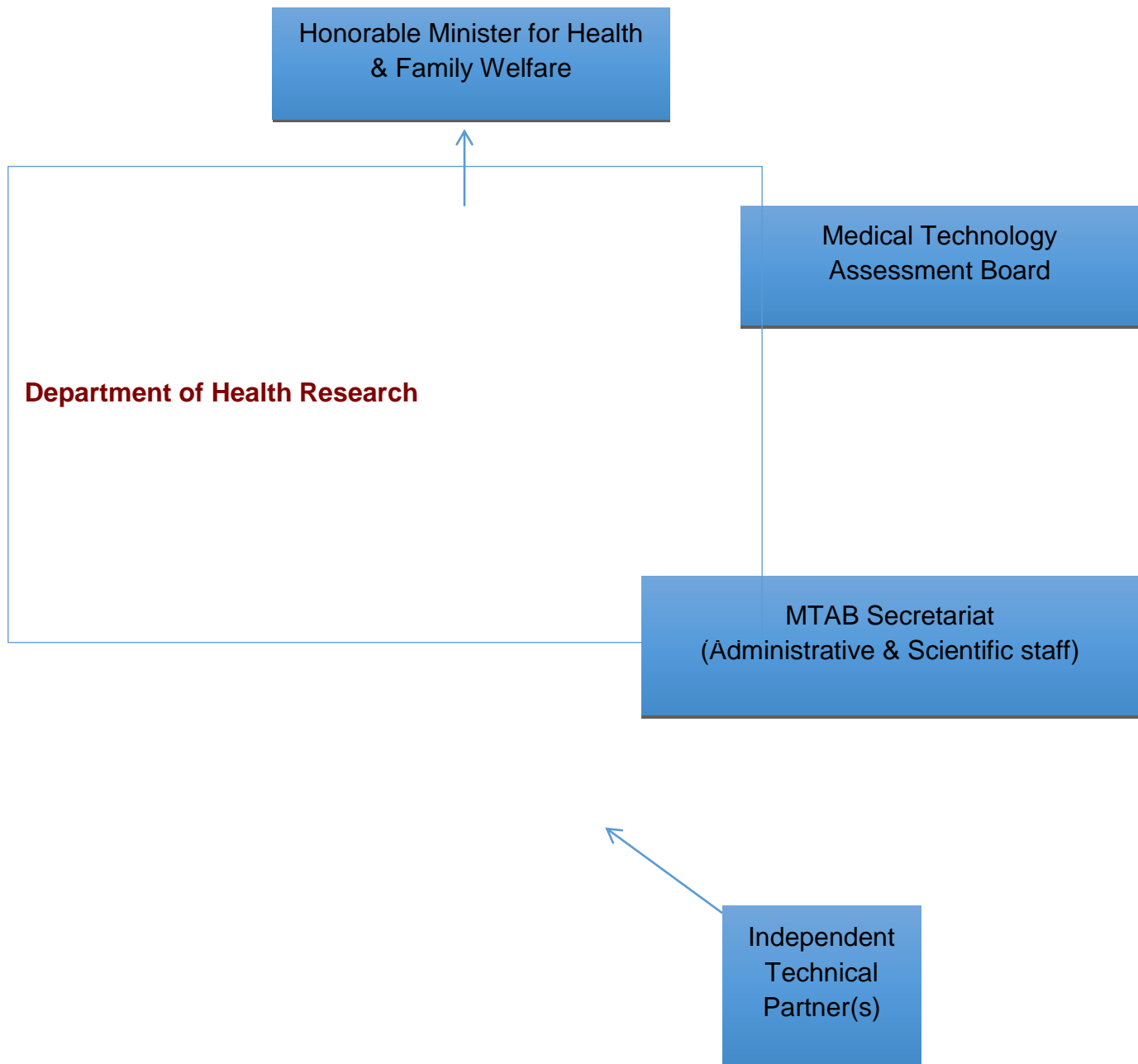
Recently, a three-day 'Health Technology Assessment (HTA) Stakeholders Consultative Workshop' was held from 25-27th July 2016, to identify existing HTA initiatives in India and raise awareness on the steps being taken by DHR towards the establishment of MTAB, for the institutionalization of HTA in India. It was jointly organised by the Department of Health Research (DHR), the Indian Council of Medical Research (ICMR), and the International Decision Support Initiative (iDSI). It was inaugurated in the august presence of the Honourable Ministers of State for Health & Family Welfare, Ms Anupriya Patel & Shri Faggan Singh Kulaste. Secretary Health & Family Welfare, Shri B.P. Sharma and the Director General Health Services, Dr Jagdish Prasad. Over 200 delegates attended the event and it had a very wide stakeholder participation ranging from policymakers (national & state level), researchers, representatives from public health insurance schemes, Dept. of Biotechnology, Armed Forces Medical Service, Drug Controller General of India, and engineers, economists, public and private healthcare providers, industry. The workshop provided an opportunity for key stakeholders within the field to share experiences and engage in rich discussion and debate regarding the context, need, function, structure, and future plans for this initiative. The Department of Health Research is now seeking to build a network of institutions identified with technical skills for conducting HTA, and to create a rich repository of knowledge leading to setting up of an efficient, credible, and effective MTAB.

2. Objectives of MTAB

- To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.
- Develop systems and mechanisms to assess new and existing health technologies by a transparent and inclusive processes.
- To appraise health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety
- To collect and analyse evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy
- Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health

⁶ Para 8.10. National Health Policy, 2015 draft, Ministry of Health & Family Welfare

3. Proposed Structure of Medical Technology Assessment board (MTAB) under Department of Health Research (DHR)



a) It is proposed broadly that the Medical Technology Assessment Board (MTAB) will be an advisory body under the Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW). It will submit its recommendations to the Honourable Minister for Health & Family Welfare, Government of India, for prioritizing health resources. Recommendations made by MTAB may be used to inform health services provided by the Government like the national health programs, the National Health Protection Scheme (formerly RSBY), the National List of Essential Medicines (NLEM), state-specific health insurance packages etc.

b) It is proposed that

- the MTAB secretariat will conduct a formal topic selection process periodically, whereby topics considered being of national and state importance will be prioritised according to a pre-defined criterion. (Ref. Annexure 1).
 - A collated list of topics will be submitted to MTAB for approval. Subsequently, the MTAB secretariat will allocate technical analysis on each prioritized topic to an Independent Technical Partner to undertake exhaustive 'assessment'.
 - MTAB will define the methods and processes for analyses, to which partner institutions must abide by when undertaking all analyses, and quality-assure the analysis once it has been completed.
 - Once the Independent Technical Partner has completed the analyses, a report of the findings will be submitted to the MTAB secretariat for review by MTAB.
- c) The MTAB will comprise eminent people from relevant fields, like public and private healthcare providers, academia, researchers, representatives from the MoHFW, civil society etc. The MTAB will consider the evidence and make a judgement on whether or not the technology should be considered as a clinically and cost effective use of National or State resources, or whether it should only be recommended for specific subgroups of patients. MTAB will submit its recommendations to the Honourable Minister for Health & Family Welfare for his consideration and acceptance.
- d) Establishment of MTAB is covered under the Research Governance mandate of DHR. Though necessary budget line for meeting expenditure already exists in the Demand for Grant of DHR, no financial provision has been made in the Budget Estimate for 2016-17. Requisite funds would be sought at RE stage or through re-appropriation of funds to meet current year's requirements for MTAB. Meanwhile, expenses on day-to-day activities like convening of meetings for MTAB, capacity building, etc can be met from the funds available under the head 'Secretariat Expenses' and detailed HTA Projects for gathering comprehensive knowledge about 'assessment processes' can be funded under the Grant-in-Aid Scheme.
- e) Partners will include NHSC and National Knowledge Platform.
- f) EFC will be developed in duet course.

4. Conclusions

HTA provides an important place in India's plan for Universal Health Coverage (UHC), and brings the country closer to achieving the UN Sustainable Development Goals (SDG's). The introduction of HTA by way of establishing MTAB will ensure more efficient allocation of resources for healthcare spending, and creation of an environment conducive to the introduction of new and existing cost effective interventions into the public health system of India, both at the Centre and State level. In order to effectively establish MTAB, there is a need to strengthen Indian institutions data collecting mechanisms and research

in the country. It will enable a strong governance mechanism to ensure that the decision making process is independent, transparent, evidence-based, and participatory.

Annexure 1.

Indicative criteria for topic selection (Ref: adapted from the Thai model for HTA topic selection)

- Number of people affected
- Disease/ health problem severity
- Effectiveness of technologies
- Variation in practice
- Financial impact to the households
- Equity/ ethical implications (affected by the poor and rare disease conditions)

Annexure 2. Outline of key components of Strategic Plan to establish MTAB

