# HITAP'S VISIT TO DEPARTMENT OF HEALTH RESEARCH (DHR) 27-30 JUNE, 2017 NEW DELHI, INDIA

HITAP International Unit (HIU)

# Abbreviations

| | |
|---|---|
| AIIMS | All India Institute of Medical Sciences |
| BMGF | Bill and Melinda Gates Foundation |
| CUA | Cost-utility analysis |
| DALY | Disability-adjusted life year |
| DHR | Department of Health Research |
| EQ-VAS | EuroQoL - Visual Analog Score |
| GDP | Gross Domestic Product |
| GoI | Government of India |
| HITAP | Health Intervention and Technology Assessment Program |
| HEWG | Health Economic Working Group |
| HTA | Health Technology Assessment |
| IC | Imperial College |
| iDSI | International Decision Support Initiative |
| IOL | Intraocular lens |
| MoHFW | Ministry of Health and Family Welfare |
| MoU | Memorandum of Understanding |
| MTAB | Medical Technology Assessment Board |
| NCD | Non-Communicable Diseases |
| NHSO | National Health Security Office |
| NHSRC | National Health Systems Resource Center |
| NICE | National Institute of Health Care and Excellence |
| NIRRH | National Institute for Research in Reproductive Health |
| NLEM | National List of Essential Medicines |
| NPPA | National Pharmaceutical Pricing Authority |
| OOP | Out-of-Pocket Expenditure |
| PGIMER | Post Graduate Institute of Medical Education and Research |
| PHFI | Public Health Foundation of India |
| QALY | Quality-adjusted life year |
| RSBY | Rashtriya Swasthya Bima Yojana |
| SCTIMST | Shree Chitra Tirunal Institute for Medical Sciences and Technology |
| TAC | Technical Appraisal Committee |
| TP | Technical Partners |
| UHC | Universal Health Coverage |
| VA | Visual Acuity |
| WHO | World Health Organization |

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# Executive Summary

India is setting up a priority setting unit called the Medical Technology Assessment Board (MTAB) under the Department of Health Research (DHR) in the Ministry of Health and Family Welfare (MoHFW), Government of India. The International Decision Support Initiative (iDSI) is working with DHR in its effort to institutionalise health technology assessment (HTA) in the country. As part of this work, a team comprising staff from HITAP and Mahidol University visited DHR in New Delhi on 27-30 June, 2017. Three core groups working on HTA in India participated in the meeting viz. DHR, PGIMER, Chandigarh, and a delegation from Kerala. The objective of the visit was to learn about MTAB's progress, to discuss and review the studies selected by each HTA team, to support their studies by sharing Thai experiences, to discuss how to conduct stakeholder meetings and to plan the next steps going forward.

On the first day of the visit, the team focused on discussing the progress from MTAB on its constitution and technical partners, process guidelines, stakeholder engagement and discussing on conflict of interest. The second day was more to discuss on how to plan a HTA study, discuss risk register assessment of studies led by each groups. The participants were divided into two groups, MTAB group and Kerala group. The third and fourth day saw the presence of Post Graduate Institute for Medical Education Research (PGIMER) team to discuss on the reference case and EQ-5D study in India. On the third day, the participants were again divided into 2 groups, one discussing on IOL study led by MTAB group and the PGIMER group to discuss the reference case. The last day was to fine-tune the research proposal on IOL, discuss the stakeholder consultation meeting, and conduct risk register assessment to identify potential risks associated with the study and solutions to overcome them.

In the end, it was planned that following this visit the MTAB group would revisit the proposal and refine the study protocol and methodology to finalize the proposal and present it to the Technical Advisory Committee (TAC) scheduled on 7th July and stakeholder consultation meeting scheduled on 27th July. It was decided that through regular teleconferences and emails, all developments will be updated between all parties to plan the work ahead. HITAP's next plan would be to visit DHR during the end of October to follow up on the progress and to provide support based on their progress to ensure the study runs smoothly and efficiently for the data analysis part.

# Introduction

Inadequate expenditure on healthcare by the public sector and high out-of-pocket expenditure leading to catastrophic payments on health that pushes the households to fall under poverty line are some of the characteristics of healthcare in India. These are a few of the many reasons as to why India is in need of increased health investment and given the limited resources available to the government, to make smart purchases for Universal Health Coverage (UHC). Health Technology Assessment (HTA) is a tool that can be used to determine which interventions should be prioritized so that rational and appropriate healthcare spending would maximize the health benefits in the country.

The Government of India's Department of Health Research (DHR), under the Ministry of Health and Family Welfare (MoHFW) is currently in the process of establishing a Medical Technology Assessment Board (MTAB) which will be a national level agency conducting HTA in India for medicines, vaccines, medical devices and insurance schemes. As part of the same effort, the International Decision Support Initiative (iDSI) received a grant from the Bill and Melinda Gates Foundation (BMGF) to support DHR to institutionalize HTA in India. This collaborative project runs from January 2017 to December 2019 and involves a close partnership between Imperial College (IC), the Health Intervention and Technology Assessment Program (HITAP), Mahidol University and partners in India, most notably DHR, the Post Graduate Institute of Medical Education and Research (PGIMER) and Shri Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST).

Prior to this visit, a six-day workshop co-organised by DHR, SCTIMST and iDSI was held on 8 -13 May 2017 in Kerala. The workshop aimed to build technical capacity of local partners including health economists and health professionals. Following this workshop, technical partners in the country were expected to initiate and conduct HTA studies as per protocols set by MTAB. Therefore, the visit to DHR was aimed to discuss and review the topics selected by each team, share Thai experiences on the chosen topic and discuss next steps. Four HITAP staff and two experts from Mahidol University participated in this meeting. Three core teams working on HTA were present during the meeting viz. DHR, PGIMER, Chandigarh, and a delegation from Kerala. The activities are summarised in the next section. The agenda and list of participants can be found in Appendix 1 and 2, respectively.

# Summary of the Visit

Over the four days, HITAP and Mahidol staff worked with colleagues from DHR, PGIMER and Kerala to discuss the process and infrastructure for HTA in the country as well as the scope of two HTA studies being conducted by DHR and the Kerala teams. Further, the PGIMER team presented the results of their study. These are described in the sections below:

## HTA process in India

### MTAB process manual

The MTAB team presented on the structure of HTA being developed in India. The MTAB board, Technical Appraisal Committee (TAC) and Technical Partners (TPs) are independent bodies and the Secretariat will act as a bridge between the various agencies. The user departments, which will supply the topics, are state governments and Ministry of Health departments. After the topic is selected, the TP is identified which develops a proposal for approval by the TAC. MTAB plans to have an online portal for the process. It is estimated that it will take 17 weeks to conduct assessment. It was noted that HTA methods are evolving. If data is not available, TPs may conduct primary studies. The other important stage is evidence appraisal and dissemination. The Secretariat will work with partners at each stage. The timeline may be decided on over time. MTAB has not yet involved stakeholders and comments will be solicited after the completion of the study. In Kerala, there is a different system as the HTA Committee will also have technical capacity.

It was noted that MTAB could work more similar to NICE model i.e prioritizing the topic and allocating the assessment work. The team needs to know whether the technical partners are willing to take up the study or not and needs to also consider financial and nonfinancial matters, taking into account how to ensure that they will commit to the work, how to ensure that the research will be ready for use by decision makers etc. MTAB shared that the topics are allocated to various units/departments based on their strengths. After allocation, proposal with the reference case will be submitted to TAC and then will be further communicated with the technical partners taking up those studies. Once MTAB completes a particular study, they can then support other studies. HITAP/Mahidol team shared Thai experience on Health Economic Working Group (HEWG) and HITAP is a secretariat. The group allocated topics to universities and gives grants to develop proposal. The assigned team may then consult various stakeholders. Those who proposed the topic must be invited to stakeholders who will have a say in the proposal. The timeline to submit the proposal to HEWG will then be 1-2 months. HITAP as secretariat then looks ta the proposal and guidelines. User groups will also be included in the proposal review. If approved, the grant will be given to them to conduct the study.

A list of fourteen topics has been received from user departments and assessed based on certain criteria. Of these, seven topics can be done either by MTAB by the TPs and for the additional seven topics, more information is needed. Some topics are a political priority but

not a priority for the TPs which leads to a mismatch. There is an option to take up state specific topics. However, funding is linked to following priorities and the TPs would need additional funding to cover these. A question was raised about how to conduct HTAs for epidemics which require time sensitive interventions. In such cases, one may work on these in advance in preparation. The seven priority topics and the TP are listed below:

- Intraocular lens (IOL) by MTAB
- Dialysis by Public Health Foundation Institute (PHFI)
- Breast cancer by National Health Systems Resource Centre (NHSRC)
- CAD stents has not yet been taken up/assigned to any TP
- Diabetes and Hypertension has not yet been taken up/assigned to any TP
- Hemoglobinometer by All India Institutes for Medical Sciences (AIIMS)
- Implants by National Institute for Research in Reproductive Health (NIRRH)

The Thai team asked how the process had been developed to which MTAB responded saying that it was based on a study visit to Thailand by the DHR team. The MTAB team referred to the HITAP and NICE processes. One key difference is that the topics will be prioritized by user departments. A TAC meeting will be held each month and the TPs will be responsible for the analysis. Regarding stakeholders, the Thai team noted that in Thailand, a range of stakeholders can propose topics. They had tried to involved patients, but found that this was difficult and it may be worth strengthening the patient groups as it is something they need. Out-of-pocket expenditure is high in India so it is important that end users are invited to participate in the process.

In Thailand, the research team organizes meeting with different groups to comment on the proposals, inviting experts from Royal Colleges. The MTAB is planning to post the proposal on the website. In lieu of a targeted approach, an online can be more open whereby anyone can comment, although the challenge will be about incorporating these comments at the initial and end stages. This, the MTAB team mentioned, has been planned and can use the approach of the National Health Systems Resource Centre (NHSRC) which has an innovation portal. This is a user-friendly platform. MTAB also plans to create a national registry for stakeholders online. This approach is different from Thailand where people are keen to interact, discuss and summarise information. Most stakeholders dislike HTA for example, doctors are not happy about exclusion of drugs, so it is important to involve all experts. It is also necessary to talk to the media. However, one should know that one cannot please everyone. A question was asked about the criteria for stakeholder selection. NICE for example has a guideline for stakeholder selection.

It is also important to have representatives from pharmaceutical companies at the stakeholder meetings. Industry representatives have already been visiting MTAB offices. One option suggested was to ask industry representatives to submit or publish their evidence. The HTA guideline is being developed and it is possible to ask pharmaceutical companies to do some topics and comply with the guidelines. In Thailand, there are two lists of topics: the high priority topics are done by academia whereas the low priority ones by

pharmaceutical companies. A question was asked whether there is any incentive for pharmaceutical companies to carry out this work to which the team responded that this mechanism allows companies to presents studies that would otherwise be excluded. This is optional and can also be by a consultancy. In such cases, pharmaceutical companies may fund the studies themselves. If funded by pharmaceuticals, it needs to follow the HTA guideline and presented to the HEWG. The topic needs to have been approved by the HEWG; then HEWG will review and forward it to the sub-committee. Pharmaceutical companies can also propose a topic, however for the National List of Essential Medicines (NLEM), pharmaceutical companies cannot propose topics and these from clinical experts. The HEWG evaluates the studies with comments from one external and one internal reviewer, who is a health economist. In India, the external reviewer function can be served by the TAC.

In terms of identifying stakeholders, HITAP shared that one should not identify like-minded stakeholders, there needs to be supporters as well as opposers to get different views on the study. Even if the stakeholders are not happy with the results, we should know that once the study is finished, what matters is its implementation or impact. Getting stakeholders involved in each and every step is a useful way of getting your study right. Stakeholder's engagement and varied opinions is very important for conducting any study. It creates a process to allow unhappy stakeholders to understand why there is any issue and can be discussed. Rather than inviting individuals, representatives from an invited group is preferred to avoid bias. In case if the stakeholders don't reach a consensus it's important to have a strong chair in the meeting to convince people. The time allocated to present needs to be carefully monitored and the number of people invited should also be not more than 10. In the beginning it's evident that it's hard to get stakeholders involved, but once the study has been used, later they might want to join. It is useful to involve stakeholders during proposal development because not only will they be able to identify potential data sources but also they might not have to spend too much time conducting primary data, they can depend on those big data resource centers willing to lend the data.

The stakeholders can be formed and grouped as supporters, high power to influence, low power to influence. Before getting them involved, asking them to sign a conflict of interest might be useful in the long run. HITAP shared that in Thailand, academic groups might act as a consultant. The meeting is usually for 3 hours in form of presentation, each presentation not exceeding 0.5 hours. The minutes of the meeting will be circulated and revising the proposal, within 2 weeks the proposal will be sent to all and accessible to lay people. Also, for the subsequent stakeholder meetings, it will be better if the same stakeholders are invited so that there won't be different opinions again. A formal invitation letters needs to be issued to the stakeholders making it attractive to gain their attention to the study, stating clear objective of the meeting, study background information etc. Management of conflict of interest was addressed in a presentation by the HITAP team highlighting the importance of the issue as well as sharing the process in Thailand. MTAB also wanted to know about the conflict of interest documents used in Thailand. While these documents are in Thai, the team

shared some of the main elements that need to be included in a form, by whom and when in the HTA process, with reference to the process in Thailand.

A point was raised about the process for contestability and what it means to reject or appeal the results. For this, it would be important to have a legal person on the team who knows how to handle issues or an appellate authority in DHR. A question was raised that not all the analyses will be doable by the TPs and if this is the case, whether industry or MTAB do the HTA instead. At the moment there is no mechanism for involving industry to conduct studies. The quality control mechanism is through the MoU signed between DHR and the TPs which will be cancelled in case of non-compliance. The outcomes will be published. Currently, the resource centres are being set up and funded by the Government of India and the TPs are hiring their own staff, which will have a skill mix.

There is a plan to develop a national repository of all the evidence, which will be housed in DHR. It is also important that all the steps being taken by the TP are documented and published so that they can help others. Also, it is important to archive all the cost-effectiveness studies in the national repository of economic evaluations. Another repository is being developed for data by one TP. These databases can be accessed by anyone and if not, make the abstract and link to paper available to the public. An India-specific reference case is being developed. Consultations are being undertaken and it will need to be approved by the Board.

Building HTA capacity can be challenging. For technical capacity, several routes were taken. An annual economic evaluation training is conducted in Thailand. Young staff were hired and paired with senior staff to gain on-the-job training. This allows staff to not only learn the theory but also practice. Mahidol University graduate students work on their thesis and submit their results to policy makers. Mahidol University has a graduate program in HTA. It would be helpful if MTAB/DHR bought Cochrane and Campbell licenses and extend these resources to all TPs. The Centre of Review Dissemination (CRD) is also a useful resource for conducting HTA. MTAB has organized trainings on systematic reviews. As part of its HTA infrastructure, method guidelines will be developed.

Another aspect of building capacity for HTA is that one needs to sensitise people on how HTA can help them. The limited knowledge of the policy makers in HTA is a challenge. It is important to communicate this in a simple way. It is also important to provide knowledge to experts including clinical experts. Bureaucrats and universities should also be targeted. The MTAB team will ensure that the newly appointed Board will also receive training.

The team advised on the upcoming activities and dates for MTAB:

Table 1: MTAB activity dates

| Activity | Date |
|---|---|
| MTAB to organize TAC meeting | 7th July |
| First stakeholder consultation meeting | 27th July |
| Second TAC meeting | 1st August |

# Infrastructure for HTA

## Reference case

Dr. Shankar Prinja presented on the Indian reference case for economic evaluation. As MTAB has been established for HTA institutionalization throughout India, we should understand that globally there exists non-uniform methodological variations for conducting an economic evaluation study, for which a reference case might be useful. At this moment, the challenges of institutionalizing HTA in India would be lack of availability of data on cost, epidemiological data, contextual environment, technical capacity, presence of multiple users/decision makers, technical partners, multiple interventions to be covered under HTA, mixed current evidences. For the measurement of costs, both household cost and healthcare costs needs to be taken into account. The way forward for overcoming challenges would be to incorporate the concept of cost effectiveness threshold derived from UK which is 17-23% of GDP per capita.

The reference case will be presented on TAC meeting being scheduled on 7th August to give overview of the reference case and the process. International experts can be used as that as technical partners to help review the comments given from the board. Dr. Miqdad Asaria quoted that reference case should include financial protection not only benefits. Extended cost effectiveness threshold analysis is not quite relevant in India as it's difficult to say how many people will benefit or are in loss.

## EQ-5D-5L study

There is currently no EQ-5D-5L value set for India although a questionnaire in Hindi is available although the translation needs to be checked. PGIMER also presented on their proposal to develop an EQ-5D-5L value set in India. This study aims to develop an EQ-5D-5L tariff value. The study will be included in this study representing the various geographic regions; these are Haryana, Uttar Pradesh, Gujarat, Tamil Nadu, West Bengal and Meghalaya. Data will be collected over four to five months in two districts in each of the six states in the sample. This study will be conducted together with six partner institutes. The presentation included details on training, translation, sampling strategies, technicalities etc. the age groups divided were 18-34, 35-64, >65. For data collection, background questions were asked with self-reported health questionnaire. A composite time trade off framework will be

used for the valuing the health states. The Thai team highlighted the importance of ensuring quality of the data is maintained. They suggested that the trainer needs to be properly trained so as to reduce wastage and the leader of the team needs to check with the interviewer on a regular basis. In Thailand, only a small proportion of the data needed to be discarded due to quality issues. Interviewers were trained three time and pilots were also conducted.

## Costing database

PGIMER is developing a health system cost database. The team discussed the components of expenditure being reviewed. The data has been collected from primary, secondary and tertiary health centres in the following states: the Punjab, Haryana and Himachal Pradesh. The second phase is part of a project on health financing and will cover the states of Tamil Nadu, Kerala, Uttar Pradesh and Orissa. There is also a plan to do costing of the northeastern states. The states have been selected based on infant mortality rate and GDP per capita. The primary healthcare system comprises sub-centres with assistant midwives only and primary health centres with a doctor and six beds. Secondary care is provided at community health centres which has 30 beds and district hospitals. Tertiary hospitals have not been included in any of the states except for the northeast where teaching hospitals have been included as data has already been collected for the primary healthcare centres. The main components covered are human resources and overhead costs. Services such as chemotherapy have been excluded since it is mostly out-of-pocket expenditure; only radiology is subsidized.

An economic perspective has been taken and a bottom up approach to collecting the data for the health system. Types of analyses include analyzing input costs, disease type. Human resources has been found to be the biggest component and is calculated by apportioning teaching time etc. Productivity losses have been estimated by using a human capital approach. The team has looked at unit costs and for in-patient costs, has accounted for per bed day cost. Standard errors have been included for all costs except in the case of tertiary care as only one facility was reviewed. Users may be able to use the information from the state most comparable to their own.

In Thailand, costing is done based on activities using the Standard Cost List which contains direct medical and direct non-medical costs. The latter includes transport to different types of health facilities, food and average time to the hospital as well as productivity losses. Transport costs may be further disaggregated into public and private costs. Direct medical costs include all services. In India, the HMIS system is geared towards capturing outcomes rather than costs and there is no patient level data available. For the purpose of modelling, one needs aggregate unit costs. For this purpose, one can use activity codes, which in Thailand can be taken from the National Health Security Office (NHSO). Prof. Arthorn Riewpaiboon, who developed the Standard Cost List for Thailand used a micro-costing approach. There is not much variation in costs among provinces in Thailand, only between he levels of care, which is captured in the Standard Cost List.

One limitation is that the multi-morbidity cost is not available. Further, information on costs cannot be accessed from university or tertiary hospitals as they are autonomous. The team has, however, conducted a costing study of the PGIMER hospital which can be useful while comparing costs of large hospitals. It was noted that the costs at hospitals are pooled at the outpatient level and cannot be disaggregated by division. Further, the data currently does not include information on diagnostics. This database can be built in an iterative manner and as more disaggregated data becomes available, it will be added to the database. Data from the northeast is relatively more disaggregated. One can make assumptions and model the costs at the tertiary levels using information from facilities at the secondary care level.

# HTA Studies

Participants were divided into groups, MTAB and Kerala, for two sets of activities. The first was a stakeholder mapping exercise which was designed to help the participants go through the process of stakeholder mapping and identify the key stakeholders in each area to invite in stakeholder consultation meetings, the type of inputs they require and their roles in the given project. These stakeholders were then grouped into by their stakes in the study and their power/influence. The second group activity entailed to plan HTA study, to understand/identify potential risks of the study via risk register assessment.

## Intraocular lens (IOL) study

The IOL study was selected as the first HTA study to be conducted by the MTAB Secretariat from among seven topics such as cardiovascular stents and dialysis. These topics were scored according to size of the population affected, severity of disease, availability of comparators in the health system, inequality of access, economic burden and policy relevance. The IOL study was found to be of particular interest to several users across the country, specifically, the National Programme for the Control of Blindness (NPCB), RSBY, NPPA and the Rajiv Gandhi Jeevandayee Arogya Yojana (now the Mahatma Jyotiba Phule Jan Arogya Yojana), a state level insurance scheme. By the time of the visit in June, the MTAB team had conducted background research and prepared a draft proposal for the IOL study.

Over the course of the four days of the visit, the teams discussed the scope of the study, preparation for the stakeholder consultation meeting and conducting the study. The HITAP team shared its experience of conducting a study on IOL in Thailand. Further, the team identified risks and mitigation measures for conducting the study in the form of a risk register and shared it with senior staff at DHR. These points are described below:

*Scope of the study*

Cataract prevalence in India is about 0.1-1% of total population of about 1.3 billion. 62.6% of total blindness is attributable to cataract in India and there is a high rate of cataract surgeries being performed in India. Perhaps more risk factors such as genetics and others are contributing to this. Dr. Yot shared Thai experiences on cataract surgeries in Thailand and also shared that analysis of unifocal vs multifocal could be problematic in practice. There

is big data gap i.e. there is no nationally representative data on the cost of cataract surgeries in India. And also there are very few costing studies, even if there are, they are outdated or restricted to only one facility. So this study could also set a protocol for NPPA for them to set the price. NPPA has been revising/fixing the price of scheduled medicines and some medical devices as well. Literature review should include how other countries sets the price for medical devices, how many margin profit will they allow, who is making price cap for other products in India etc. It was noted that NPPA has only recently started to include medical devices in the list. But the medical devices do not go through clinical effectiveness tests so NPPA doesn't know about its rational use in India. So NPPA may only look at products that deemed to be too much for the government to pay.

The MTAB team provide background information and the rationale for the IOL study through a presentation. It was noted that there was a high rate of cataract surgery in India which was about 4000 per million versus 1500 per million in Thailand. This could be because there may be more risk factors in India such as genetics. It was clarified that the number of surgeries was reliable. The team was advised to compare the rate per million by state and depict it in a map, if possible. In terms of policy, the NPCB was introduced in 1976 and cataract surgery became accessible to people in rural India. Description of the surgeries in India were provided such as manual small-incision cataract surgery (MSICS) being the most common type of surgery. A cost utility analysis (CUA) conducted by the Arvind Eye Institute found that 40% of patients used foldable lens. In this case, a sister organisations also produces the lens.

*Preparation for stakeholder meeting*

Some common points regarding organizing stakeholder consultation meetings were discussed. The importance of having a strong chair were highlighted. Prior to the meeting, the chair should be informed about the objectives and expected outcomes of the meeting. The stakeholders need to be informed about the process. The user departments such as RSBY who are responsible for managing and controlling cataract may be invited to speak for 10-15 minutes. The presentation for the research proposal should be circulated to participants before the meeting so that they have time to review. During the meeting, there should be an introduction of the participants. The presentation of the research proposal should be for about 20 mins and discussion should follow for at least two hours. The minutes of the meeting should be recorded, reviewed and approved after which they should be publicly available. This is a crucial input in the development of the proposal.

Points to be discussed at the stakeholder consultation meeting:

1. To confirm whether the value for money of cataract surgery has already been answered or not
2. To confirm if the use of silicon for rigid lens is out of Indian market or not. Also modified silicon is currently available in the Indian market or not

3. To ask about the data source of the prevalence/incidence of blindness due to cataract in India and the number of patients who has the access to cataract surgery
4. To confirm about the type of cataract surgery that are currently being performed in India

Policy questions:

There are two policy questions proposed by Rashtriya Swasthya Bima Yojana (RSBY) which is a social security and healthcare insurance scheme in India. The policy questions are as follows:

1. What type of lens including lens material should be recommended in the benefit package?
2. What are the costs of the cataract package i.e. including cataract surgery and the lens?

The third policy question is proposed by MTAB secretariat because currently there is no standard practice on determining the stages of cataract in India. The question is:

3. At what visual acuity should the cataract surgery be performed?

In order to answer the third policy question, research team should prepare the following three data:

1. Evidence to confirm that there is no eligibility criteria for cataract surgery in India
2. Data on the current practice to find out about the average visual acuity of patients who undertook cataract surgery.
3. The incidence of blindness due to cataract in order to prove whether the current practice performs well or not.

Research question:

1. Foldable and/or multifocal lens are good value for money in India
2. Different types of materials used for the same type of lens offer different safety and effectiveness profiles.
3. Health outcomes
4. The level of visual acuity that cataract surgery offers good value for money

*Conducting the study*

The data needs for the study were discussed. Individual data on cataract (1-2 hospitals) surgery from one or two hospitals to measure Visual Acuity (VA) needed to be collected. The team was to identify any statistical information about blinding cataract in India, preferably, information from the past two years. Quick reviews of the safety and clinical benefits of foldable and/or multifocal lens, comparison of different materials (modified silicon and acrylic) and any previous studies about cataract including unpublished report (e.g. report to

World Health Organization WHO 2020) were to be conducted. Further, given the dominance of outreach camps in performing cataract surgeries, it would be helpful to find the proportion of surgeries conducted through this modality.

A societal perspective would be used in this study. In order to derive a cost function for surgical interventions for cataract surgery, data on the following types of costs would need to be collected:

- Types of surgery: Manual Small Incision Cataract, Extra Capsular Cataract Extraction, PHAECO
- Types of facilities: primary, secondary and tertiary care center and outreach camps (eg. how many percentage of cataract surgery in outreach camps); if outreach camp is not significant, need not be taken into account
- Types of cities: Tier 1 (biggest city), Tier 2 (population more than 10 lakhs) and Tier 3 (population less than 10 lakhs)
- Type of facility: Public and private hospitals.

Using the above categories, five to seven settings could be selected. The data could be organized as per the following table:

Table 2: Template for data collection of lens types

| | | Secondary | | | Tertiary | | |
|---|---|---|---|---|---|---|---|
| Surgery | City | Tier 1 | Tier 2 | Tier 3 | Tier 1 | Tier 2 | Tier 3 |
| PHAECO | Public | | | | | | |
| | Private | | | | | | |
| MSIC | Public | | | | | | |
| | Private | | | | | | |
| ECCE | Public | | | | | | |
| | Private | | | | | | |

The market price of IOC lens (either material or lens), could be collected from manufacturers and retailers. One may need to send a formal letter to ask price of selling 100,000 to 1,000,000 lenses as well as their maximum capacity per year. Also request to submit the price and specification. The cost for hospitals may be collected from 5-7 settings, retrieve the cost of procurement and magnitude of procurement (big or small proportion). Finally, patients may be interviewed to get information on where they buy the lens and the cost of the lens.

For measuring health outcomes, the VA may be ascertained by asking doctors. QALYs can be generated by using EQ5D and VAS from different surgeries. Patients may be interviewed before surgery until 7 days. Classifications by visual acuity could be poor vision, vision impairment, and almost blindness. And after surgery which is 7 and 30 days after. A sample

of 20-30 patients may be interviewed for each type of surgery. The team may use the VA measure to answer who gets the priority for the surgery. To make this comparison, two groups of patients (poor vision, vision impairment, and almost blindness). There should be high variation in the VA of the sample and quota sampling could be applied in the hospitals. Similarly, the QALY gains could be observed for the different groups.

Areas of expertise related to conducting the study were identified. The chief skill sets required are evidence synthesis by using systematic reviews and meta-analysis, costing studying, price survey (including interview patient, cohort outcome measurement, and decision tree modelling.

*Risk registry*

The last task of the MTAB group was to draft a risk register assessment with the help from HITAP team to identify potential risks associated with the study.

Table 3: Risk Assessment of study on intraocular lens in India by MTAB HTA team

| **Rank** | **Risk** | **Root cause** | **Likelihood of the risk** | **Impact** | **Potential solutions** |
|---|---|---|---|---|---|
| 1. | Inadequate manpower to complete the study | • Contractual staff discontinuing the project | High | High | • Attachment of permanent staffs should be assigned as part of the team to complete the study<br>• Efforts to retain existing staff should be made |
| 2. | Lack of good quality data | • No database, no registry, no publication, no previous research<br>• No access to library journals | High | High | • MOU with academic institutes or ICMR to get account to access the library journals should be done<br>• Primary research/data collection should be done |

| Rank | Risk | Root cause | Likelihood of the risk | Impact | Potential solutions |
|---|---|---|---|---|---|
| | | | | | • Data can be obtained from experts/stakeholders consultation meeting<br>• Data from other settings can be used in the analysis<br>• HITAP/IC staff can help access the full papers |
| 3. | Inadequate infrastructure to complete the study | • No office, no meeting rooms<br>• No IT support (computer, internet access, telephone and printer) | High | High | • Procurement of IT facilities should be done<br>• Policy on working from home can be applied |
| 4. | Inadequate technical expertise/experience to complete the study | • HTA is a multidisciplinary research<br>• Limited timeline to complete the study<br>• MTAB is a newly established organization | High | Medium | • Dedicating resource and time for building capacity in research team<br>• Collaboration with internal and external partners on technical issues should be encouraged<br>• More flexible timeline to be |

| Rank | Risk | Root cause | Likelihood of the risk | Impact | Potential solutions |
|---|---|---|---|---|---|
| | | | | | able to accommodate capacity building activities |
| 5. | Stakeholders and users not supportive to the study and results | • Not good quality of study<br>• Conflict of interest<br>• Different expectations and perceptions to this study because this is the first HTA study in India | Medium | High | • High quality of study must be ensured<br>• Engagement of stakeholders and declaration of conflict<br>• Ensuring good communication about MTAB and its work<br>• HTA process and steps should be made in a more transparent manner |
| 6. | Change in leaders of DHR | • Uncertainties in policies/politics | Low | High | • No action can be done |

After the MTAB team finished with the detailed clear research proposal plan, the next step for them was to prepare a final version of the proposal to be presented at the TAC meeting on 7th July and the stakeholder consultation meeting on 27th July. It was agreed between all parties that HITAP team would visit to DHR next during the end of October to provide support based on their developments for proceeding with data analysis. Apart from that it was agreed that regular technical support will be provided via regular teleconferences, emails, sharing important documents on request in between.

# Next steps

The plan for the next steps can be found in the table below:

Table 6: Next steps of collaboration between HITAP and MTAB/DHR

| No | Activities | Dates |
|---|---|---|
| 1. | MTAB, Kerala teams to work on areas identified during the workshop as per timeline | July-October, 2017 |
| 2. | Regular teleconferences among all parties | Regularly, every two weeks |
| 3. | HITAP to visit DHR at the end of October | 23-31 October |
| 4. | Revise the proposal within one month. Team may request technical committee, HITAP, Imperial College team to review the proposal | 31 July |

# Appendices

# Appendix 1: Agenda of the visit

| Day 1 | | | |
|---|---|---|---|
| **Time** | **Session** | **Description** | **Person (s) Responsible** |
| 10.00-10.10 | Opening remarks | • Opening Remarks | • Mr V.K.Gauba |
| 10.15-10.45 | Introduction | • Presentation<br>• Topic Prioritisation of MTAB | • Dr Kavitha Rajsekar |
| 10.45-11.00 | | TEA BREAK | |
| 11.00-12.00 | Planning HTA studies | • Timelines<br>• Identify training needs<br>• Planning HTA Studies | • Dr. Usa Chaikledkaew |
| 12.00-12.30<br>12.30-13.00 | Process Guidelines | • Presentation<br>• Discussion | • Dr Aamir Sohail,MTAB |
| 13.00-14.00 | | Lunch | |
| 14.00-15.45 | Stakeholder Engagement | • Presentation<br>• Tools/Questionnaires(in English) used<br>• Exercise on stakeholder mapping | • Waranya Rattanavipapong |
| 15.45-16.00 | | TEA BREAK | |
| 16.00 – 17:00 | Management of Conflict of interest | • Presentation<br>• Processes and documents for managing conflict of interest with different stakeholders/ technical partners. | • Saudamini, Sneha, Waranya |
| **Day 2** | | | |
| 10.00 – 10:30 | Background of Proposal for HTA analysis of IOL | • Presentation | • MTAB |
| 10.30-11.30 | IOL STUDY from THAILAND- | • Presentation<br>• Exercises | • HITAP/MAHIDOL |
| 11.30-11.45 | | Tea Break | • |
| 11.45-13.00 | IOL STUDY from THAILAND- | • Presentation<br>• Exercises | • HITAP/MAHIDOL |
| 13.00-14.00 | | Lunch | |
| 14.00– 15:45 | Sensitivity Analysis of the Thai model of IOL | • Presentation<br>• Exercises | • Mahidol/HITAP |
| 15.45-16.00 | | TEA BREAK | |

| | | | |
|---|---|---|---|
| 16:00 – 17:00 | Policy Brief taking IOL as an example | • Presentation<br>• Sharing the template for policy briefs | • Saudamini, Sneha, Waranya |
| **Day 3** | | | |
| 10.00-11.00 | Cost Effectiveness threshold | • Presentation | • Dr. Montarat Thavorncharoensap |
| 11.00-11.15 | | Break | |
| 11.15-12.15 | Costing | • Presentation | • Dr. Yot Teerawattananon |
| 12.15-13.00 | Costing Database in India | • Presentation | • PGIMER |
| 13.00-14.00 | | LUNCH | |
| 14.00-14.45 | Tariff for Thailand | • Presentation | • Dr. Montarat Thavorncharoensap |
| 14.45-15.00 | | TEA BREAK | |
| 15.00-16.00 | Collection of EQ5D for particular studies,using IOL AS AN EXAMPLE | • Presentation<br>• Tools /Questionnaire for collection of EQ5D | • Dr. Montarat Thavorncharoensap) |
| 16.00-17.00 | EQ5D study in India | Presentation | • PGIMER |
| | | **DAY4** | |
| 10.00-11.00 | Priority Setting for healthcare in India | • Presentation<br>• Discussion | • PGIMER |
| 11.00-11.15 | | • Tea break | |
| 11.15-13.00 | Reference Case | • Presentation<br>• Discussion | • Dr Shankar Prinja ,PGIMER |
| 13.00-14.00 | | Lunch | |
| 14.00-15.00 | Project Management | • Discussion on recruitment, management, monitoring and appraisal of HTA conducting agencies/partners | • Mahidol/HITAP |
| 15.00-15.15 | | Tea Break | |
| 15.15-17.00 | Meeting with User departments | Meeting with User departments | Meeting with User departments |

# Appendix 2: List of workshop participants

| | Name | Organization |
|---|---|---|
| 1 | Shri Vijay Kumar Gauba | DHR |
| 2 | Dr. Kavitha Rajshekar | DHR |
| 3 | Dr. Shalu Jain | DHR |
| 4 | Dr. Oshima Sachin | DHR |
| 5 | Dr. | DHR |
| 6 | Mr. Aamir Sohail | DHR |
| 7 | Dr. Miadada Asaria | DHR/IC |
| 8 | Dr. Neethi Rao | DHR/IC |
| 9 | Dr. Shankar Prinja | PGIMER |
| 10 | Mr. Pankaj | PGIMER |
| 11 | Ms. Gunjeet Kaur | PGIMER |
| 12 | Ms. Deepshikha | PGIMER |
| 13 | Mr. | PGIMER |
| 14 | Mr. Biju George | Kerala team |
| 15 | Mr. Arun Nair | Kerala team |
| 16 | Mr. Anish | Kerala team |
| 17 | Dr. Usa Chaikledkaew | HEPTA (Mahidol University) |
| 18 | Dr. Montarat Thavorncharoensap | HEPTA (Mahidol University) |
| 19 | Dr. Yot Teerawattananon | HITAP |
| 20 | Ms. Waranya Rattanavipapong | HITAP |
| 21 | Ms. Saudamini Dabak | HITAP |
| 22 | Ms. Sneha Rajbhandari | HITAP |