Record of discussion of the Technical Appraisal Committee (TAC) Meeting held on August 1st, 2017 at 9.30 AM in the Conference Room, Department of Health Research (DHR) under the chairmanship of Dr. K.K. Talwar, former chairman of the Medical Council of India and former director, Post Graduate Institute of Medical Education and Research (PGIMER)

- 1. The 2nd TAC meeting was held on **August 1st, 2017 at 9.30 AM** in the Conference Room, DHR, 2nd Floor, IRCS Building, Red Cross Road, New Delhi, under the Chairmanship of Dr. K.K. Talwar, former chairman of the Medical Council of India and former director of Post Graduate Institute of Medical Education and Research (PGIMER). The purpose of this meeting was to discuss the
 - (i) Reference Case by Dr. Prinja, Associate Professor, School of Public Health, PGIMER),
 - (ii) Proposal for the Intra-ocular lens for the treatment of cataract by MTAB Secretariat.
 - (iii) Proposal for the Breast Cancer Screening by National Health Systems Resource Centre (NHSRC)
 - (iv) Proposal for the Hemoglobinometer for the diagnosis of anemia by All India Institute of Medical Sciences (AIIMS)

The meeting was held to discuss these topics with the experts and get their feedbacks.

Annexure-I contains the list of participants in the meeting.

- 2. Shri V.K. Gauba, Joint Secretary, DHR, MoHFW welcomed all the TAC members and discussed the background, agenda and purpose of this meeting. The topics taken by various technical partners (TP) were mentioned such as safety engineered syringes by PGIMER, IOL for cataracts by MTAB secretariat, screening for breast cancer by NHSRC and Haemoglobinometer by AIIMS. He requested Dr. Shankar Prinja to bring out main issues for reference case for a fruitful discussion. He requested members to sign the Declaration of Interest (DOI) form provided.
- 3. Dr. Kavitha Rajsekar, Scientist D, DHR, MoHFW presented the mandate of TAC and topic Prioritization criteria. Dr. Talwar, Chairman of TAC requested to look into the prioritization criteria once again because sometimes topic are demand driven.
- 4. Dr. Indrani Gupta, Professor, Institute of Economic Growth, suggested that NTAGI and MTAB should collaborate and work because NTAGI does somewhat similar activity for vaccines as MTAB is doing for other health technologies. Responding to that Mr. Muraleedaran from IIT Chennai suggested that vaccines NTAGI can play a complementary role and become a subset.

EQ-5D proposal as part of reference case

1. Dr. Shankar Prinja presented his costing study and EQ5D on project entitled "Indian Reference Case for Economic Evaluation: Valuation of health consequences". The presentation included a recollection of the previous TAC meeting i.e. the context, rationale, objective, methods for developing a reference case. He then suggested a debate on different methodologies to build a consensus and develop a possible guideline which would be flexible and evolve with time. He also recommended a utility based measure for health outcome i.e. QALY.

- The presentation covered mainly the costing studies where he emphasized upon the costing and quality of life for different states and suggested that measuring and valuing health effects should be generalizable across the diseases states
- Since there is no evidence system on cost available in India therefore, he focused on standardizing costing data base so that all studies can use the same structure. He showed an example of cost database from Thailand where cost menus are available and there is no need for costing studies and suggested to make similar kind of database for India.
- He also suggested that while costing Societal Perspective should be taken into account and instead of price, cost should be measured.
- 2. Prof. Indrani Gupta enquired whether this database would be national or regional because different states have different costs to which Dr. Prinja replied that he will be working on primary regional cost data. She also suggested to get this database updated periodically similar to NHS.
- 3. Dr. Shankar Prinja proposed a short term plan of 6 months in which unit costs could be extracted using existing studies and stratified as per delivery service. Medium term plan of next 1-2 years could be obtaining costs by disease and resources used that would be collected and disaggregated. Long term plan (2-5 years) could be obtaining a comprehensive data on resource use and cost of services. These plans will help in better coverage.
- 4. Dr. Muraleedaran mentioned that some work has already been done on costing covering Punjab, Himachal Pradesh, Odisha, Tamil Nadu, Haryana and Kerala. 90% data has already been collected and analyzed and this could be further developed. He also added that data from 190 sub centers, 41 Primary Healthcare, 21 secondary healthcare and 45 district hospitals were collected.
- 5. Dr. Sundaraman was concerned about the risk of under costing as non-functioning facilities are also out there. In some cases technicians are not there or they are underpaid that they don't provide proper service. These were the concerns that could cause much variation in costing. Dr. Muraleedaran responded that in these cases a benchmarking can be done and we can see whether average comparators can be used. Dr. Sundaraman suggested to get normative data, define average and then see the standard deviation from the average. Dr. Prinja added that an ideal way would be to have a standard treatment guidelines for costing as well.
- 6. Dr. Miqdad Asaria asked that is it sufficient to only look at public sector costs upon which Dr. Talwar responded that it could be done at 3 levels public, charitable (NGO), and private. Dr. Prinja said that Out of Pocket expenditure should be available for all sectors.
- 7. Prof. Rama Baru shared her experience about doing a costing study for the Ministry where huge variation were captured in private facilities.
- 8. Prof. Gupta suggested to take some time, step back, refine proposals and if there are a few different scenarios that need to be modelled, should do that and can conduct a sensitivity analysis to understand variability.

- 9. Prof. J V Peter inquired that whether services provided by NGO be a true reflection of actual costs upon which Prof. Rama Baru responded that there is too much heterogeneity in NGOs. We should identify truly non-profitable organizations to get actual costs.
- 10. Dr. Asaria mentioned that costing is done based upon who is the user department for example RSBY asked MTAB to look at packages for IOL and most of them will be done in private facilities. Upon which Prof. Talwar responded that packages often miss many costs so one should include all aspects of costing i.e. it should be a wholistic costing. Prof. Gupta again suggested that any proper costing study should include all costs. It is not good enough to miss out any cost.
- 11. Dr. Prinja said that at times, private sector cuts corners and as such the cost in public sector can come out as higher. This often happens at PGIMER e.g. in dialysis. Sometimes, private sector inefficiencies are very high. Also, pricing does not depend on a cost marker. Aravind Eye Hospital on another level is driven by having to maximize efficiency. Private sector ultimate goal is to generate revenue, on the other hand NGO/public sector hospitals will be to cover as many people as they could. Prices should be set by what the market can bear. Charge is based on how much each person can bear, not how much an intervention costs. There is a trade-off between price and demand so NGOs will work better for costing studies but for that we need to define inclusion criteria. Prof. Baru added that social cost should also be included.
- 12. Prof. Murleedharan suggested to have some expert groups for costing to make this process robust followed by the finalization of the Reference case.
- 13. Prof. Talwar reminded that Insurance companies who fix their reimbursement price must be getting their data from somewhere so we can get costing data from those insurance companies as well. We can create small group to deliberate and guide this study
- 14. Dr. Laura Downey from Imperial College mentioned that the mandate of MTAB is not to inform private spending but public spending to achieve the UHC goal and that will also take OOP spending into account through societal perspective and disaggregated costs. Even if there are private hospitals empanelled through RSBY should charge less costs to RSBY patients and can charge private patients if they are paying themselves. In this way taking into account private hospital service provision but not high private sector for profit costs.
- 15. Shri. Gauba said that if private sector is out of our studies MTAB need to justify their exclusion.
- 16. Dr. Prinja said that is wide variation in what public sector pays for a given service to be deliver. He then continued with his presentation and explains the purpose of the database i.e. to nominate costs to universally cover services, to advise on reimbursement costs or capture current practice.
- 17. Prof. Muraleedaran suggested that database should be used for estimating cost effectiveness.
- 18. Prof. Talwar recommended to constitute a small group to discuss these important issues and can be brought further to the next meeting.
- 19. Dr. Prinja. Continued with his second presentation about EQ5D mentioning about the Collaborative institutes in the states of Haryana, UP, West Bengal, Gujarat, Tamil Nadu and Meghalaya where IMR is taken as health status metric. He outlined the strategies to collect EQ5D.

- 20. Prof. Sundaraman asked whether income is not an important factor to which Dr. Prinja replied that income was taken into account while choosing the states and income or high assets have correlation with life quality and satisfaction.
- 21. Prof. Sundaraman was skeptical about asking people to trade off health in 10 years when it's not sure that they are going to live for 10 years. Dr. Prinja responded that it should be ensured because people are always making a trade-offs like one child for another, suicide or life, hospital for treatment or food.
- 22. Prof. Muraleedaran said that self-reporting is not a norm in India giving an example that Kerala people rated selves lower than those in Bihar. Dr. Asaria responded that sub groups in study could be designed to capture them in different ways. However, TAC need to understand key details i.e. what is best measure to capture health outcomes and quality of life which has not yet been done.
- 23. Prof. Baru shows her concerns about the conceptualization and importance of these process saying that there are many different perspectives and it seems like MTAB have already moved ahead.
- 24. Prof. Sundaraman also mentioned that TAC members should have been sent papers/ proposals 2 weeks earlier so that they had time to think and respond because these issues are technically dense and require thinking in advance. He added that if a methodology is standardizes it will last for a decade or at least 5 years, so it should get right from the beginning. He suggested to ensure the relevance of EQ5D for India and look at the questionnaires tool once again.
- 25. Prof. Gupta supported Dr. Sundaraman and said that members should: a) Be involved from beginning, and b) Given information in advance and suggested for a brainstorming session for an in-depth discussion for which one day meeting is not sufficient.
- 26. Prof. Muraleedaran emphasized that these are the bedrock for demand-driven studies that might be used for small, medium and long term so all the burden should not be put only on Shankar's shoulders but whole of MTAB should participate. This requires several rounds of meetings to make the processes robust.
- 27. Prof. Peter also said that it needs several days of deliberation in order to define what is cost effective.
- 28. Shri Gauba asked for suggestions and ways to take it forward to which Prof. Muraleedaran responded that there is a need to familiarize members with terms like EQ5D and outcome.
- 29. Prof. Sundaraman suggested to circulate proposals in advance and have one person present from those who have submitted the proposal and a person or two from TAC for the discussions. Then members can raise issue and circulate key questions. It should be shown clearly to the members that what being done instead of background methods already is been finalized. Key members of the TAC should be selected depending upon topics to lead on discussion from their side.
- 30. Prof. Gupta mentioned that this is something of national importance rather than a regular academic work so we must be very careful keeping in mind the implementation issues and since this is the first time in taking place in India doing so it is important to get it right. He supported Dr. Sundaraman that it should never be on one person's head but several institutes should come forward to support.
- 31. Dr. Rajsekar said that TAC members could play a role as peer reviewers for the proposal ensuring that the methodologies and parameters are correct and also assured that there will be small workshops for TAC members to understand key things about HTA and come up with Reference Case. Small

- subcommittee meetings can also be held to decide between different plans (A or B). After that they can undertake the review process. Eventually we will have a roadmap and then that proposal could be brought to TAC for final discussion and appraisal.
- 32. Shri Gauba said that the format of the process could be altered, if needed, to make it right and said that there will be a hub at PGIMER and collaboration with other institutes is not ruled out. He welcomed the input of others in the study, if needed.

Safety Engineered Syringes

- 1. After these discussions Dr. Prinja moved to his next presentation entitled "Cost-effectiveness of Safety Engineered Syringes (SES) for Therapeutic care in Punjab State and India" in which he outlined the background of the proposal, use of injections globally and in India, adverse outcome of unsafe injections followed by research questions, methodology, intervention, comparator, decision model, levels of stratification (OPD/ Public/ Private Providers/ Primary secondary tertiary etc.), Markov Model in different scenarios, transmission model, cost assessment, effectiveness assessment, inclusion/ exclusion criteria, search strategies, quality of evidences, expected outcome and policy implications. Dr. Prinja update that Up to 40% needles are re-used in India that contributes to HIV transmittion, Hep B and Hep C.
- 2. Prof. Gupta suggested that prophylaxis post needle stick injury should also be included upon which Dr. Prinja agreed.
- 3. Prof.J.V Peter suggested to include needle stick injury, accident and risk of transmission and efficiency of transmission.
- 4. Dr. Asaria pointed out that the study relates to Punjab only and Prof. Sundaraman suggested not to make it a generalization for India as will be dependent on state data.
- 5. Dr. Laura mentioned that the mandate came from NPPA which is national body so it might be a problem for them if they look at only state-level data.
- 6. Dr. Prinja expected to have preliminary results in 2-3 months upon which Dr. Downey suggested to have a stakeholder meeting before that to make sure that MTAB process guidelines standards are followed. Shri Gauba also agreed to have stakeholder meeting in DHR soon.

Screening for Breast Cancer

- 1. Dr. Mohammed Ameel from NHSRC presented their Proposal about the Screening for Breast Cancer outlining the
 - Objective to assess effectiveness and safety of various interventions available for breast cancer screening in India
 - Comparison of existing techniques such as ultrasonography, mammography and MRI, a new technology that has been submitted through National Innovation portal 'ibreast' and also of selfexamination
 - Decision tree compared screening vs. non-screening and then examining each type of screening
- 2. Prof. Gupta suggested that the frequency of screening should be dependent on risk category rather than just 3 and 5 years mentioned in the study. Dr. Sundaraman added that one of outcome should be once in 3 years or once in 5 years and also screening age should be taken into account. Dr. Ameel replied that

- screening at lower age will increase chances of false negative results and that will increase the cost and also the probability of cancer is also high above a certain age.
- 3. Dr. Downey suggested to ensure the management of breast cancer because it is neither cost effective to diagnose if not managing nor it is ethical if there are no plans for the treatment once it is diagnosed to which Dr. Ameel agreed to take it into account.
- 4. Prof. Sundaraman suggested to capture where these interventions are being delivered as this will have impact on cost.
- 5. Prof. Gupta suggested to incorporate non-cancerous lumps in the model as it is a false positive result and needs to be a part of the study.
- 6. Prof. Sundaraman pointed out that MRI is not a screening option as suggested in the proposal and also mammography should not be at diagnostic stage but the screening stage upon which Dr. Ameel agreed to change mammography to a first screening strategy.

Intraocular Lenses for cataract

- Dr. Shalu Jain, Presented IOL proposal entitled "Health Technology Assessment of intraocular lenses
 for treatment of age-related cataracts in India" outlining the background, epidemiology, various types of
 surgeries and various types of IOL available, outcome measures, equity issues, various blindness
 programs run by the MoHFW followed by policy questions, research questions, aim, objectives and
 PICOT.
- 2. Dr.Oshima Sachin took a lead on "Methodology for HTA of Intraocular Lenses for Age Related Cataract" and covered the contextual background of cataract in India, decision tree for cataract surgery, methodology (including search strategies, costing and cost effectiveness) and significance of the proposal.
- 3. Prof. Talwar commented that 1997 figures are not sufficient for Cost Effective Analysis for present study. And asked about the availability of latest data to which Dr. Praveen Vashisht, Opthalmologist from AIIMS, replied that a comprehensive study is required from various parts across India but right now much data is not available.
- 4. Prof. Talwar also asked why phacoemulsification taken only as a comparator to which Dr. Vashisht responded that at present mainly SCIS surgery (80%) and phacoemulsification (20%) is performed for cataract treatment but SCIS is cost effective as per clinical experience. Due to this very large difference there are variation in reimbursement by RSBY, this is the whole reason for doing HTA although it is complex but it is required to make sure which of the two is cost and clinically effective. Dr. Vashisht also mentioned that phacoemulsification is a costly machine and not readily available, whereas SCIS doesn't need any machine and is readily available so there are equity issues as well.
- 5. Prof. Talwar said that data collection might take long time so it should not be taken as of now upon which Shri Gauba replied that they are not doing the primary data collection but basing clinical efficacy on literature.

- 6. Dr. Kavitha supported the fact and said that data already have been identified and studied in depth. She further explained that Costing and cost effectiveness for IOL will be studied in depth and clinical efficacy will be reviewed from published data.
- 7. Prof. Talwar also pointed out that overall costing data cannot be taken from Aarvind Eye Care Hospital because it is a highly efficient model.
- 8. Dr. Sundaraman added that Aravind' Eye Care hospital manufactures their own lens rather than imported that also adds to the costs.
- 9. Prof. Sundaraman suggested that RSBY could be informed through HTA but an option for the patients should be kept open and let them decide that equivalent money to the intervention recommended would be reimbursed only and extra money would be borne by the patients if they wish to have another intervention. He also mentioned that costing should be undertaken both in public and private sectors to reflect the fact that RSBY empanelled hospitals do cover both the sectors.
- 10. Prof. Talwar disagreed for costing to be taken from private sector because it will add other costs like infrastructure, time, lenses used. He also suggested to add post-operative complications as well.
- 11. Dr. Vashisht told that RSBY offers to 30% of population and up to 70% under NPCB.
- 12. Prof. Peter said that costing data will be presented in Tamil Nadu ophthalmic conference next week that can be shared to MTAB.

Hemoglobinometer

- 1. The last proposal was presented by AIIMS team on Hemoglobinometer outlining the background, methodology, strategies and cost effectiveness
- 2. The objective of the study will be to establish the diagnostic accuracy of Digital Hemoglobinometer TrueHb (newer version), HemoCue and non invasive spectroscopic device against automated analyzers (gold standard) for screening of anemia in laboratory and community settings.
- 3. Prof. Sundaraman asked about the cost per test and shelf life. He also suggested looking at consumable flow as well as feasibility. AIIMS team responded that cost of each strip is 10 rupees. Manufacturers can bring down to 6 rupees depending on volume.

Finally Dr. Talwar thanked all the participants and assigned the date of next meeting to be held on first Tuesday of Sept -5^{th} Sept 2017.

After detailed deliberation the following action points emerged

- 1. The reference case, EQ-5D, Costing to be discussed in small groups of experts in a day or 2 long sessions discussing each and every point and to collate the results and finally present to the TAC for final approval.
- 2. The topics discussed on
 - Safety Engineered Syringes, PGIMER
 - Intra ocular Lenses for Cataract, MTAB Secretariat

- Screening for Breast Cancer, NHSRC and
- Hemoglobinometers, AIIMS

have been deliberated by TAC and the revised proposal to be submitted within 15 days.

- 3. A small economics core group to be consulted before finalizing the reference case
- 4. All proposal to be sent to the TAC at least before 15 days for proper scrutiny and understanding
- 5. The next meeting will be scheduled on the 5th of September 2017

Prof.K.K.Talwar
Ex-Director PGIMER
Chairman
Technical Appraisal Committee
MTAB

Annexure-1

- 1. Shri V.K Gauba, Joint Secretary, DHR, MoHFW
- 2. Prof. K. K. Talwar, Ex-Director, PGIMER-Chairman,
- 3. Prof. J. V. Peter, Director, CMC Vellore-Vice Chairman,
- 4. Prof. T. Sundaraman, Dean, TISS-Member
- 5. Prof. V.R. Muraleedaran, IIT, Chennai-Member
- 6. Prof. Indrani Gupta, Institute of Economic Growth, Delhi-Member
- 7. Prof. Rama Baru, JNU, Delhi-Member
- 8. Dr. Shankar Prinja, Associate Professor, PGIMER, Chandigarh
- 9. Shri. RajKumar-Deputy Secretary, DHR
- 10. Shri. Vinod Kumar, Under Secretary, DHR
- 11. Dr. Kavitha Rajsekar, Scientist-D,DHR
- 12. Dr. Miqdad Asaria, Consultant, Imperial College
- 13. Dr. Neeti Rao, Consultant, Imperial College
- 14. Dr. Oshima Sachin, Scientist-D, MTAB Secretariat
- 15. Dr. Shalu Jain, Scientist-C, MTAB Secretariat

- 16. Dr. Aamir Sohail, Health Policy Analyst, MTAB Secretariat
- 17. Dr. Deepshika, PGIMER
- 18. Dr. Gaurav Jyani, PGIMER
- 19 Dr. Mohammad Ameel, NHSRC
- 20. Dr. Vigneswaran, NHSRC
- 21. Dr. M. Zoieb, NHSRC
- 22. Prof.Renu Saxena,AIIMS
- 23. Dr.Sutapa Neogi,PHFI