

Record of discussion of the Technical Appraisal Committee meeting held on 14th October, 2019, 10.00 AM in the Department of Health Research (DHR), MoHFW, New Delhi under the Chairmanship of Prof. T. Sundararaman, Former ED, NHSRC to discuss HTA study proposals and outcome reports.

1. The 16th TAC meeting was held on 14th October, 2019, 10.00 AM in the Conference Room, DHR, MoHFW, 1st Floor, IRCS Building, New Delhi, under the Chairmanship of Prof. T. Sundararaman, Former ED, NHSRC in presence of Smt. Anu Nagar, Joint Secretary, DHR, MoHFW.

2. The purpose of the meeting was to discuss the following:

Outcome reports of:

- i. HTA on Neonatal Hearing Screening devices- Portable Automated ABR and OAE devices.
- ii. Rapid HTA for cost-effectiveness of incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India.
- iii. HTA for screening of Hepatitis B & C at PHC in Tamil Nadu

New Proposals on :

- i. Proposal on Telemedicine Otoscopy for Hearing Screening.ENTReview
 - ii. Point-of-Care Testing (POCT) devices for Blood Gas Analysis..
 - iii. Price Regulation & Value-Based Pricing for Anti-Cancer Drugs: Implications for Patients, Industry, Insurer & Regulator, PGIMER Chandigarh
3. HTA In Secretariat briefed the action point of the previous TAC and revision brought according and the agenda of current meeting was discussed.

4. Outcomes Reports

a. Neonatal Hearing Screening Devices (Sohum), RMRC Bhubaneswar

- i. The outcome report was presented with the previous TAC comments incorporated in the proposal.
- ii. TAC recommended a preliminary 6-months pilot that should include well defined objectives to look into the feasibility issues.
- iii. From both the pilot study and from ongoing screening, data has to be generated on proportion of neonatal population who are currently under-going screening, and amongst those so detected as having hearing loss how many actually go for the cochlear implant.
- iv. The TAC suggested that the results should be framed in a way so as to make clear that we are recommending a device for the existing screening strategies, rather than suggesting to roll out a completely new screening program.

- v. It was recommended not to scale up device unless choice can be given in terms of technology and also the services availability is limited.
- vi. TAC also suggested to look into the budgetary implication and include this in in the study report.
- vii. **The outcome report was approved with the above suggestions to be incorporated into the study and with recommendation for a six-month pilot study for feasibility and population-based outcome data.**

b. HTA for screening of Hepatitis B & C at PHC in Tamil Nadu, NIRT Chennai

- i. TAC suggested that high risk group and the population under study is not clearly defined it needs to be defined before conducting HTA.
- ii. Cohort size was not clearly defined and the cost data mentioned were not justified.
- iii. TAC suggested not to include cost of liver transplantation (for all patients) in the study as fraction of people going for liver transplantation is very low and liver transplantation is taken out from the Ayushman Bharat.
- iv. **The proposal needed to be revised and presented in the next TAC.**

c. TrueNat

- i. After presenting the proposal of "Rapid Health Technology Assessment for Cost-Effectiveness of incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India", the outcome report of the same was presented with changes as per TAC's comments.
- ii. Earlier comments on sensitivity and specificity were incorporated, also the shelf life of the product was suggested to be included in the proposal which was well incorporated this time along with budgetary implications and details of cost-effectiveness analysis
- iii. It was suggested to include capital cost of a refrigerator and UPS to maintain the reagents for TruNat.
- iv. Budgetary implications were to be included.
- v. **This Proposal was Approved.** *Revised with modifications to be included*

5. New Proposals:

a. Telemedicine Otoscopy (ENTRav device): In line with NPCD (National Programme for Prevention and Control of Deafness)

- i. TAC commented that the device under study is not a screening device for deafness. But the device can be useful once the deafness is identified.

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- ii. Comparator as Otoscope in the study is not justified, it was suggested to look for the appropriate comparator.
- iii. TAC suggested to carry out a 6 months' pilot study and based upon the data a further decision will be taken if it requires cost effectiveness study. At this stage it is a feasibility and validation study.
- iv. Medtronic through Shruti programme have already done some validation study. If data can be collected from shruti programme the same can also be analysed.
- v. **TAC referred this topic to PAC for consideration under Operational Research.**

b. POCT devices for Blood Gas Analysis (I-STAT):

- i. TAC commented that there are number of similar devices in market. If this device is effective, as evident from validation studies, a simple recommendation can be given instead of conducting a full HTA study. Since it is not using any new technology, and its advantages in terms of portability are clear, the usual procurement by tendering can be used to purchase the device which is most affordable and appropriate among the competing devices.
- ii. **Cannot be considered for HTA study. A report may be prepared and may be discussed with the TAC.**

c. Price Regulation & Value-Based Pricing for Anti-Cancer Drugs: Implications for Patients, Industry, Insurer & Regulator, PGIMER Chandigarh.

- i. Objective no. 4 of the proposed study aims to quantify the extent of change in out of pocket (OOP) expenditure and catastrophic health spending (CHE) in cancer patients post- price regulation. Concerns were raised over long recall period in pre-implementation period, and other potential confounders. It was suggested to keep Objective 4 as a secondary objective.
- ii. It was advised to confirm that the Pharmatrack data, which PGIMER Chandigarh will be analysing to assess the change in sale and market share of anti- cancer drugs, capture sales in the hospital pharmacy also, apart from general retail store sales.
- iii. To assess the change in the insurance claim amount pre- and post- price regulation, TAC members advised to redefine pre- and post- intervention period such that it coincides with time of insurance package revision.
- iv. **The proposal was approved with the above suggestions.**



List of Participants**A. Technical Appraisal Committee****1. TAC members:**

- a) Prof. T. Sundararaman, Ex-Dean, TISS, Mumbai & Former ED, NHSRC – Chairman
- b) Prof. V.R. Muraleedharan, IIT, Chennai
- c) Prof. Indrani Gupta, Institute of Economic Growth, New Delhi
- d) Prof. Rama Baru, JNU, New Delhi
- e) Dr. Sudha Chandrashekhar, World Bank

2. Government Officials

- a) Smt. Anu Nagar, Joint Secretary, DHR, New Delhi
- b) Shri Daulat Ram Meena, Deputy Secretary, DHR, New Delhi

3. Participants

- a) Prof. Barun Kanjilal, Independent (Former Professor, IIMR, Jaipur)
- b) Vivekanandan S., Managiva Trustee Chennai Liver Foundation.
- c) Chandra Singh J, Associate Director, CMC, Vellore
- d) Dr. John Verghese Thekkekkara, St. John's Medical College, Bnagalore.
- e) Mr. Indranil Mukhyopadhyay, OP Jindal University, Sonipat.
- f) Umakant Dash, IIT Madras
- g) Dr. Deepika Saraf, Scientist E, ICMR Hq., New Delhi

4. Resource Centre/ Technical Partner Representatives

- a) Dr. Sandra Albert, Director, IIPH, Shillong
- b) Dr. Krushna Sahoo, Public Health Specialist, RMRC, Bhubaneswar.
- c) Dr. Rinshu Dwivedi, Scientist C, RMRC, Bhubaneswar.
- d) Dr. Maninder Pal Singh, PGI, Chandigarh.
- e) Dr. Gaurav Jyani, PGI, Chandigarh.
- f) Dr. Rituparna Ghosh, IIPH, Shillong.

5. HTAI In. Sec., DHR

- a) Dr. Kavitha Rajshekar, Scientist-D, DHR, MoHFW, New Delhi
- b) Dr. Oshima Sachin, Scientist-D, HTAI In. Sec., DHR, MoHFW, New Delhi
- c) Dr. Aamir Sohail, Health Policy Analyst, HTAI In. Sec, DHR, MoHFW, New Delhi
- d) Mr Arvind Bhushan, Scientist-C, HTAI In. Sec, DHR, MoHFW, New Delhi
- e) Dr. Shalu Jain, Scientist-C, HTAI In. Sec, DHR, MoHFW, New Delhi
- f) Miss Jyotsna Naik, Scientist-C, HTAI In. Sec, DHR, MoHFW, New Delhi
- g) Dr. Malkeet Singh, Junior Health Economist, HTAI In. Sec, DHR, MoHFW, New Delhi
- h) Dr. Akshay Chauhan, Junior Health Economist, HTAI In. Sec, DHR, MoHFW, New Delhi
- i) Dr. K.V. Jagadeesh, Scientist B, HTAI In. Sec, DHR, MoHFW, New Delhi
- j) Dr. Shivangi Khanna, Scientist B, HTAI In. Sec., DHR, MoHFW, New Delhi
- k) Mrs. Safia Zaidi, Programme Manager, HTAI In. Sec, DHR, MoHFW, New Delhi
- l) Mrs. Kirti Tyagi, Scientist-C, HTAI In. Sec, DHR, MoHFW, New Delhi
- m) Ms. Jaspreet Kaur, Scientist C, HTAI In. Sec., DHR, MoHFW, New Delhi.
- n) Miss Himanshi Tomar, Scientific Consultant, HTAI In. Sec., DHR, New Delhi
- o) Mr. Vipin Kumar, Personal Assistant, HTAI In. Sec., DHR, New Delhi