A COMPRENDIUM OF HEALTH TECHNOLOGY ASSESSMENT IN INDIA

2017 | 2018

DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA, NEW DELHI
A COMPRENDIUM OF HEALTH TECHNOLOGY ASSESSMENT IN INDIA (2017-18)
PREFACE

Health Technology Assessment in India (HTAIn), which was previously known as Medical Technology Assessment Board was established in January 2017 under Department of Health Research, Ministry of Health and Family Welfare by the Government of India. It was envisioned that HTAIn will facilitate the process of transparent and evidence informed decision making in the field of health. HTAIn has the mandate to generate and compile evidences related to cost- effectiveness of healthcare technologies including drugs, devices, health programmes etc. by means of Health Technology Assessment (HTA) studies. It will evaluate appropriateness and cost effectiveness of the available and new health technologies in India, so that maximum people can have access to quality healthcare at minimum cost in the country.

HTAIn consists of three core bodies including HTAIn- Secretariat, HTAIn Technical Appraisal Committee (TAC), and HTAIn Board. The HTAIn secretariat works in collaboration with its identified Technical Partners (TPs) and regional resource hubs (RRHs) across India. Since its very beginning, requests for Health Technology Assessment (HTA) studies started to come from different policy makers both from central and from state level. HTAIn study proposals and outcome reports are evaluated by HTAIn Technical Appraisal Committee and after getting the approval from this committee, the completed studies are reviewed by HTAIn Board. Once approved by the board, a policy brief along with the HTA outcome report is sent to the user department from where the request has originally came.

During its two years’ existence, the DHR funded HTAIn has spread into eight regional resource hubs in different states of India, 12 technical partners working with us across the country, more than 20 ongoing studies commissioned by HTAIn, 4 completed HTA studies, with 10 workshops conducted for capacity building. This Compendium is a collation of all the progress been made by HTAIn during January 2017 till now. This compendium also presents a brief overview of all ongoing and completed studies commissioned by HTAIn, DHR.
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BACKGROUND:

Government of India (GOI) is committed to provide universal health coverage (UHC) to assure the availability of free and comprehensive primary health care services to its 1.2 billion population. The challenging task of extending the healthcare services to each and every patient can only be achieved with optimal utilization of the resources available. Therefore, it is required that decisions on resource allocation are policy relevant and evidence informed. The evidence-based decision-making involves clinical effectiveness studies, cost-effectiveness studies, budget impact studies, as well as ethical, social and political feasibility studies. Health Technology Assessment (HTA) is an internationally accepted tool to ensure that technology choice is participatory and is well guided by considerations of scientific evidence, safety, consideration on cost effectiveness and social values.

To facilitate the process of transparent and evidence informed decision making in the field of health, Government of India has set up 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 analyse 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.

In order to develop a broader vision, mission and objectives, a rigorous research was conducted by DHR before the formal start of HTAIn. This included a formal visit to The Health Intervention and Technology Assessment Program (HITAP), Thailand by a high-level expert committee from India. HITAP is a semi-autonomous research unit under Thailand’s Ministry of Public Health and it has set a great example of providing universal health coverage to Thai people. Another important task was to identify potential technical partners across the country to share the responsibilities with the HTAIn secretariat. HTAIn technical partners were identified from the potential collaborating institutions, which included Indian Counsel of Medical Research (ICMR) research Institutes, Medical Institutes of National Importance, Indian Institute of Technology (IITs), Indian Institute of Management (IIMs), Institutes working in the area of Public Health. Some of these centres were later upgraded into HTAIn’s
Regional Resource Hubs (RRHs) in eight states of India namely Maharashtra, Kerala, Punjab, Gujrat, Tamil Nadu, Meghalaya, Orrisa and Andhra Pradesh. These RRHs are functioning as HTAIn’s extended arms to cater the need of HTA requests of their states and the neighbouring states. Currently there are eleven technical partners and eight regional resource hubs working with HTAIn.

Health technology Assessment India (HTAIn) has started functioning congruously a year ago in January 2017 in Department of Health Research. Since its very beginning, requests for Health Technology Assessment (HTA) studies started to come from different policy makers in the country. The topics used to come from different divisions of union ministry of health and family welfare, state ministry of health and family welfare, Rastriya Swasthya Bima Yojna, National Pharmaceutical Pricing Authority, National Health mission, National innovation portal, etc.
HTAIn Structure:

HTAIn consists of three core bodies including HTAIn- Secretariat, HTAIn Technical Appraisal Committee (TAC), and HTAIn Board. The HTAIn secretariat works in collaboration with its identified Technical Partners (TPs) and regional resource hubs (RRHs) across India. (Figure 2)

Figure 2: Structure of HTAIn

How it functions: The requests for HTA study are first processed by HTAIn secretariat experts and then allocated to Technical partners. Technical partners develop the study proposal and present the study to Technical appraisal committee members. Once approved by TAC members, a stakeholder consultation meeting is convened to inform and apprise all concerned stakeholders regarding the HTA study. After completion of the HTA study, outcomes of the study are again presented to TAC members and after approval by TAC, a second stakeholder’s consultation meeting is convened to inform them about the study results and final recommendations. Finally, the study is put up to the HTAIn Board and once approved by the board; a policy brief along with the HTA outcome report is sent to the user department from where the request has originally come.
HTAIn Board

Prof. Vinod Paul, Member, NITI Aayog
The Government of India appointed Dr Paul as a Member of the National Institution for Transforming India, the NITI Aayog, in August 2017 where he leads the Health and Nutrition verticals. He has played a pivotal role in formulating the POSHAN Abhiyaan and the Ayushman Bharat initiative. Prof. Paul has recently been appointed as the Chairman of The Board of Governors of Medical Council of India. Prof. Paul is an internationally renowned paediatrician, academic, medical research and public health exponent.

Prof. Balram Bhargava, Secretary - DHR & DG – ICMR
Professor Balram Bhargava, Secretary, Department of Health Research, (Ministry of Health & Family Welfare), Government of India and Director General, Indian Council of Medical Research (ICMR) joined on 16th April, 2018. Prof. Bhargava is a Professor of Cardiology at All India Institute of Medical Sciences (AIIMS), New Delhi and also serves as the Executive Director for Stanford India Biodesign Centre, School of International Biodesign (SiB). Professor (Dr) Balram Bhargava is an outstanding cardiologist, one of the foremost leaders in biomedical innovation, public health, medical education and medical research.

Dr. Renu Swarup, Secretary, DBT
Dr Renu Swarup was appointed a Secretary in the Department of Biotechnology, Government of India on 10th April, 2018. She also holds the position of Chairperson, Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Company incorporated by the Government to nurture and promote innovation research in the Biotech Enterprise with special focus on Start-ups and SMEs. A Member of the National Academy of Sciences (NASI) India, she is also a Member of Governing Body of National Institutes, Universities and Centers.
Dr. S. Venkatesh, DGHS, MoHFW

Dr. Venkatesh is the current Director General of Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. He is also an ex-officio member of the Board of Governors, appointed to oversee all the duties and responsibilities being carried out previously, by the now dissolved, Medical Council of India (MCI).

Shri Vaidya Rajesh Kotecha, Secretary, AYUSH

Born on 18th June, 1963, Vaidya Rajesh Kotecha did his M.D. (Ayurveda) from Gujarat Ayurveda University, Jamnagar in 1991. Vaidya Rajesh Kotecha has many publications to his credit. Before joining as a Secretary to Government of India, Ministry of AYUSH, he has held the prestigious position of Vice-Chancellor, Gujarat Ayurveda University, Jamnagar and has been working as Chief Consultant of Chakrapani Ayurveda Clinic & Research Center, Jaipur.

Prof. K. K. Talwar, Ex-Director, PGIMER

Dr. Kewal Kishan Talwar (born 30 April 1946) is an Indian cardiologist, medical academic and writer, and a former Chairman of the Medical Council of India. He is a former director of the Post Graduate Institute of Medical Education and Research (PGIMER) and is reported to have performed the first implantation of Implantable cardioverter-defibrillator (ICD) therapy in South Asia. He has also been the Chairman of the technical appraisal committee (TAC) of HTAIn, DHR.

Dr. T. S. Ravikumar, Ex-Director, JIPMER

Dr. T S Ravikumar joined as Director cum Vice Chancellor, SVIMS on 2nd September, 2015. He was the first Director & CEO of Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, India after it was made an institution of national importance by an Act of Indian Parliament in 2008. He is a fellow of American College of Surgeons.
Dr. S.K. Acharya, Ex-Prof. & HOD (Gastro), AIIMS

Dr. Subrat Kumar Acharya is a gastroenterologist and liver transplant physician, a physician scientist, a prolific writer and a passionate teacher. After providing almost 40 years of service at AIIMS, New Delhi, he now serves as the Pro Chancellor, KIIT University, Bhubaneswar and HOD Gastroenterology and Hepatology, PBMH, KIMS (KIIT University, Bhubaneswar) and Executive Director of Gastroenterology and Hepatology at Fortis Flt. Lt., Rajan Dhall Hospital, Vasant Kunj, New Delhi.

Prof. Rajesh Kumar, Head of School of Public Health, PGIMER

Prof. Rajesh Kumar is the Head of the Department of Community Medicine and School of Public Health, PGIMER, Chandigarh and the Dean Academics at PGIMER as well. Additionally he is also an Honorary Professor at the London School of Hygiene and Tropical Medicine. Prof. Rajesh has a vast experience as an epidemiologist and public health specialist apart from being an academician.

Prof. M. Balakrishnan, IIT, Delhi

Dr. M. Balakrishnan is a Professor in the Department of Computer Science & Engineering at I.I.T. Delhi. For the last 22 years, he is involved in teaching and research in the areas of digital systems design, electronic design automation and embedded systems. More recently the focus of his work has been in development of affordable assistive devices for visually impaired. He is involved in a number of projects that can enhance safe mobility as well as assist in education.

Dr. G. Karthikeyan, Prof. of Cardiology, AIIMS

Dr. Karthikeyan is a Professor of Cardiology at All India Institute of Medical Sciences with an experience of almost 20 years in the field as an academician and a researcher. He is also the Editor-in-Chief of the BMJ Heart Asia, one of the three cardiology journals of BMJ.
Shri Vijay Chauthaiwale, Independent Healthcare Consultant
A swayamsevak who trained and worked as a molecular biologist until he joined the BJP, Shri Vijay Chauthaiwale heads its foreign policy department and the Overseas Friends of BJP cell. Prior to this he was a vice president at the Torrent Group after which he quit the corporate sector when he joined Prime Minister Narendra Modi’s Lok Sabha campaign.

Prof. S. Ramji, Ex-Dean, MAMC, New Delhi
Prof. SIDDARTH RAMJI is Director-Professor of Pediatrics and Neonatology and former Dean at Maulana Azad Medical College, New Delhi. He has over three decades of experience as a medical teacher. He has chaired, & been associated as a member, several technical and advisory committees of the Ministry of Health (Government of India), Indian Council of Medical Research and Department of Health Research, Department of Biotechnology and the University Grants Commission.

Shri V. K. Gauba, Joint Secretary, DHR, MoHFW
Shri Vijay Kumar Gauba is the Joint Secretary of the Department of Health Research, Ministry of Health and Family Welfare and the Co-Chair of the Technical Appraisal Committee of the Health Technology Assessment in India (HTAIn). It has been under his leadership and guidance that HTAIn has created its niche in the healthcare system of India and is working towards establishing itself as a statutory body for health technology assessments.
Technical Appraisal Committee

Prof. T. Sundararaman, TISS, Mumbai
Prof. Sundararaman was the Professor and Head of the School of Health System Studies, Tata Institute of Social Sciences, Mumbai and the Executive Director of National Health Systems Resource Centre in New Delhi. He is also a Member Secretary of the Sector Innovation Council for the Health Sector.

Dr. J V Peter, CMC Vellore
Dr. J.V. Peter started as the Director at CMC, Vellore on September 23, 2017 and is the Professor & Head of the Medical ICU Unit at CMC, Vellore. Dr. Peter has served as an Associate Director for Finance since 2015 as well.

Prof. Muraleedhran VR, IIT Madras
V R Muraleedharan currently works at the Department of Humanities and Social Sciences, Indian Institute of Technology Madras. Their research is focused on the equity and efficiency gains of investments in public primary healthcare system in India.

Prof. Indrani Gupta, IEG, Delhi
Dr. Indrani Gupta is the Professor and Head of the Health Policy Research Unit of the Institute of Economic Growth, Delhi. Apart from teaching and academics, she has also been associated with the World Bank and the Government of India, where she worked as a career economist.

Dr. Rama V Baru, JNU, Delhi
Dr. Rama Baru has been working as a Professor at the Centre of Social Medicine and Community Health, School of Social Sciences, Jawaharlal Nehru University, New Delhi since July 2007.
**Dr. Shankar Prinja, PGIMER, Chandigarh**

Dr. Shankar Prinja is an Additional Professor of Health Economics in the Department of Community Medicine and School of Public Health, PGIMER, Chandigarh. He is one of the pioneers in conducting economic evaluation studies and HTA in India.

**Dr. Sudha Chandrashekhar, SAST, Karnataka**

Dr. Sudha Chandrashekhar is a public health specialist and consultant based in Karnataka and associated with many organizations in conducting healthcare costing and economic evaluations. She was previously the Director MM, SAST.

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**Scientific/Technical Support from ICMR**

**Dr. Chander Shekhar** - Additional Director General, ICMR & Head (Innovation & Translational Research, Intellectual Property Rights)

**Dr. Anju Pradhan Sinha** – Scientist F, (Child Health)

**Dr. Ashoo Grover** - SCIENTIST E (Oral Health, Research Methodology, Gastroenterology)

**Dr. Harpreet Singh** - Scientist E and Head (Informatics, Systems & Research Management - ISRM)
HTAIn Secretariat Members

- Dr. Kavitha Rajsekar  HTAIn Coordinator
- Dr. Oshima Sachin  Scientist D
- Dr. Shalu Jain  Scientist C
- Dr. Aamir Sohail  Health Policy Analyst
- Ms. Jyotsna Naik  Scientist C
- Mr. Dambarudhar Pradhan  Financial Consultant
- Dr. Malkeet Singh  Health Economist
- Dr. Akshay Chauhan  Health Economist
- Ms. Safia Zaidi  Project Manager
- Ms. Kirti Tyagi  Scientist C
- Mr. Arvind Bhushan  Scientist C
- Dr. Nidhi Singh  Scientist C
COLLABORATIVE APPROACH

Academic and research collaboration is a very valuable strategy that not only accelerates the progress but also enhances the quality of the work and extends the repertoire of the partners. Academic collaboration is beneficial in learning new teaching tools and different approaches to solving a problem. In DHR we emphasise on intra- and inter-institutional collaboration that helps us, as well as our collaborators to impact and improve the quality, resources and capabilities of both researchers and institutions involved.

There are eight regional resource hubs in different states of India and 13 technical partners working with us across the country. It is very gratifying to see how the support from our regional resource hubs and technical partners helps us to improve and grow in every way possible.

Regional Resource Hubs (RRHs): The regional resource hubs (RRHs) are working as extended arms of HTAiN secretariat in different states of India. The RRHs are supporting us in catering the HTA requests coming from their own as well as from the nearby neighbouring states. These RRHs are established in collaboration with the State Governments in Institutes administered by the Centre/ States. The mentor of the hub liaises with the officials of the State Governments and sensitize them about a need for Health Technology Assessment (HTA) for any health intervention. The hubs would also ensure robust HTA on the topics relevant to the States and also ensure uniformity/ consistency of methodologies/ processes documented by DHR in its Process Manual. Details of our RRHs are given in next pages.
1. Postgraduate Institute of Medical Education and Research (PGIMER)

**Department:** Department of Community Medicine and School of Public Health

**Institute:** Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh

**State:** Chandigarh (UT)

**Adjoining States supported by RRH:** Haryana, Himachal Pradesh, Jammu & Kashmir

**RRH Chief:** Dr. Shankar Prinja, Additional Professor of Health Economics, Department of Community Medicine and School of Public Health, PGIMER, Chandigarh

**Staff recruited:**

1. Mr. Pankaj Bahuguna Economic Evaluation Specialist
2. Dr. Akashdeep Singh Chauhan, Senior Research Officer
3. Dr. Gunjeet Kaur, Senior Course Assistant
4. Dr. Gaurav Jyani, Research Officer
5. Dr. Maninder Pal Singh, Research Officer
6. Ms. Sehr Brar, Research Assistant
7. Ms. Mehak Sahni, Field Officer
8. Mr. Jaidev Bansal, Administrative Assistant
9. Mr. Sachin Sharma, Field Investigator cum Administrative Assistant
10. Ms. Himani, Field Investigator
11. Mr. Rajan Jaswal, Field Investigator
12. Mr. Anil Kumar, Field Investigator
13. Mr. Karam Singh, Field Worker
14. Mr. Vikash, Field Worker

**Studies from DHR:**

1. Health Technology Assessment (HTA) of Safety Engineered Syringes (SES) for therapeutic care in India
2. HTA for Cervical Cancer Screening Strategies in India
3. HTA for Screening of Type-2 Diabetes and Hypertension in India
4. Costing of Health services in different states of India
5. Development of Reference Case for undertaking Economic Evaluations for HTA in India
6. Development of health related quality of life (EQ-5D-5L) value set for India
7. Online courses in Basic Health Economics and Economic Evaluation for Health Technology Assessment
Completed studies:
1. Health Technology Assessment (HTA) of Safety Engineered Syringes (SES) for therapeutic care in India
2. HTA for Cervical Cancer Screening Strategies in India

Ongoing Studies:
1. HTA for Screening of Type-2 Diabetes and Hypertension in India
2. Costing of Health services in different states of India
3. Development of Reference Case for undertaking Economic Evaluations for HTA in India
4. Development of health related quality of life (EQ-5D-5L) value set for India
5. Online courses in Basic Health Economics and Economic Evaluation for Health Technology Assessment

It is a premier medical and research institution in Chandigarh, **Punjab.** Health Economics is one of the sub-specialties within the School of Public Health whose faculty is engaged in capacity building of health care professionals and conducting high-impact policy relevant economic analysis for health care programs and policies. PGIMER will liaise with the State Govt. of Jammu & Kashmir, Haryana and Himachal Pradesh. The resource hub is headed by Dr. Shankar Prinja (Additional Professor, Health Economics, School of Public Health). PGIMER is involved in following projects.
2. Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)

**Department:** Achutha Menon Centre for Health Science Studies (AMCHSS)

**Institute:** Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum

**State:** Kerala

**RRH Chief:** Dr. Raman Kutty V., Emeritus Professor, Achutha Menon Centre for Health Science Studies, SCTIMST, Trivandrum

**Staff recruited:** Three

- Dr. Antony Stanley – Research Associate
- Ms. Priya Abraham – Data Manager
- Dr. Hisham Moosan – Technical Expert – Epidemiology & Project Lead

**Ongoing Studies from DHR:** “Evaluation of pulse oximetry as a tool to prevent childhood pneumonia related morbidity and mortality”
3. National Institute for Research in Reproductive Health (NIRRH)

Department: Department of Operational Research

Institute: Indian Council for Medical Research - National Institute for Research in Reproductive Health (ICMR-NIRRH)

J M Street Parel Mumbai 400 012

State: Maharashtra

Adjoining States supported by Karnataka, Goa Diu and Daman

RRH: Dr. Beena Joshi

RRH Chief:

Staff recruited: 07

Studies from DHR: 2

Completed studies: Health Technology Assessment of long acting reversible contraceptives in India

Ongoing Studies: Health Technology Assessment of Uterine Balloon Tamponades to manage Post Partum Haemorrhage in India
Indian Institute of Public Health (IIPH), Gandhinagar, Gujarat

**Department:** Health technology Assessment- Regional Resource Hub

**Institute:** Indian Institute of Public Health Gandhinagar (IIPHG)

**State:** Gujarat

**Adjoining States supported by RRH:** Rajasthan and Madhya Pradesh

**RRH Chief:** Dr. Somen Saha, Associate Professor, IIPHG

**Chair:** Dr. Paresh Dave, Additional Director (Health), H&FW Department, Gujarat

**Lead from IIPHG:**
1. Dr. Somen Saha (Ph.D., MPH), Associate Professor
2. Dr. Deepak Saxena (Ph.D., MD (Community Medicine), Additional Professor
3. Dr. Tapasvi Puwar (Ph.D., MD (Community Medicine), Associate Professor

**Lead from Health and Family Welfare Department, Gujarat:** Dr. Bhavesh Modi, Associate Professor, Government Medical College, Gandhinagar

**Staff recruited:**
1. Dr. Komal Shah (Economic Evaluation Specialist)
2. Dr. Apurva Kumar Pandya (Scientist-D)
3. Dr. Priya Kotwani (Scientist-C)
4. Mr. Devang Raval (Program Associate)

**Ongoing Studies from DHR:** Health Technology Assessment of TeCHO+ Program in Gujarat State

IIPH, Gandhinagar
RRH team with Dr Balram Bhargav,
Secretary DHR &DG-ICMR
5. Kalam Institute of Health Technology (KIHT), Vishakhapatnam, Andhra Pradesh

**Department:** Cell for Health Technology Assessment  
**Institute:** Kalam Institute of Health Technology (KIHT), Visakhapatnam  
**State:** Andhra Pradesh  
**Adjoining States supported by RRH:** Telangana  
**RRH Chief:** Dr Jitendar Sharma  
**Staff recruited:** 5  
1. Dr Devarshi Bhattacharyya, Assistant Director  
2. Dr Pudi Nagaseshu, Technical Officer  
3. Ms Rashi Tomer, Senior Research Fellow  
4. Ms Megha Dabas, Senior Research Fellow  
5. Ms Madhavi Thakur, Technical Officer  

**Ongoing Studies from DHR:** 1  
Health Technology Assessment of New Automated Resuscitation Device versus self-inflating bags in Indian public health system.
6. **National Institute for Research in Tuberculosis (NIRT), Chennai, Tamil Nadu.** NIRT carries out research on TB and HIV-TB. Department of Bio-statistics in NIRT offers courses regarding public health and has been identified to be a regional resource hub for HTAIn. Dr. M. Muniswamy (Scientist C) who is assisted by Dr. Lunghar Jajo and Dr. Mathan Kumar heads the hub. The whole team has been actively involved in extending hands to DHR for completion of multiple tasks. Currently, this centre is working on HTA study on screening of diabetes and hypertension in collaboration with PGIMER, Chandigarh team. Besides this the RRH is working on screening of Hepatitis B and C in Tamil Nadu.

7. **Regional Medical Research Center (RMRC), Bhubaneswar, Odisha:** RMRC has been identified to be one of the resource hubs. It is an advanced research institute in the field of medical sciences. The main focus area of research of the institute is on locally prevailing communicable and non-communicable diseases, tribal health and malnutrition in Odisha and adjoining states. It will liaise with the State Govt. of Bihar, Chhattisgarh, West Bengal and Jharkhand. Dr. Sanghamitra heads the hub and her team includes Dr. Debdutta Bhattacharya (Scientist C) and Dr. Krushna Sahoo (Scientist C). Presently, they are involved in HTA study on neonatal screening on hearing loss using SOHUM device.

8. **Indian Institute of Public Health (IIPH), Shillong, Meghalaya:** This institute is established under the aegis of Public Health Foundation of India (PHFI). Its main objective is to build up a large human resource base of public health professionals by establishing a network of world-class colleges and schools of public health. IIPH resource hub will liaise with the North-Eastern States. The resource hub is constituted of its head, Dr. Sandra Albert and her team including Dr. Tiken Das, Ms Yoorisa and Ms Rituparna. They are conducting HTA study on hypothermia alert device BEMPU.

Besides all these, approval for the resource hub in SAST – Karnataka, and Medical College, Bhopal is underway. DHR is also getting in touch with other states' health officials regarding the establishment of hubs in Uttar Pradesh.
Technical Partners (TPs): HTAIn Technical Partners are our collaborators to whom we assign a HTA study based on their area of expertise and the capacities they have. These Technical Partners are research and academic institutions, usually under the Central or State Governments which have been identified with regards to their capacities, expertise and previous experiences in the HTA. TPs will undertake the HTA study allotted to them and ensure consistency and uniformity of their study with the guidelines in the Process Manual and through regular interactions with the secretariat and by periodic progress reports. Presently following are the technical partners of HTAIn:

1. All India Institute of Medical Sciences (AIIMS), Delhi:
   
   Studies undertaken: Non-invasive Hemoglobinometers, Dr Renu Saxena, Prof and HoD, Dept. of Haematology, AIIMS, New Delhi.

2. National Institute of Medical Statistics (NIMS), Delhi:
   
   Studies undertaken: Roles of Asha workers and ANMs in community healthcare, Dr Geeta Menon, Scientist-E, NIMS in collaboration with Dr Ashoo Grover, Scientist-E, ICMR

3. National Health Systems Resource Centre (NHSRC), Delhi
   
   Studies undertaken: Screening of Breast Cancer, Dr Rajni Ved, Executive Director, NHSRC, New Delhi

4. Public Health Foundation of India (PHFI), Delhi
   
   Studies undertaken: Non-invasive Hemoglobinometers, Dr Sutapa Neogi, Additional Professor, PHFI in collaboration with Dr Renu Saxena, Prof and HoD, Dept. of Haematology, AIIMS, New Delhi.

5. National Institute of Virology (NIV), Pune
   
   Studies undertaken: RT-PCR for H1N1, Dr Manohar Chaudhuri, Scientist C, NIV, Pune
6. National Institute of Research in Tribal Health, Jabalpur
   **Studies undertaken:** Sicklescan for screening for sickle cell anemia, Dr Raja Subramaniyam, Scientist E, NIRTH, Jabalpur.

7. National Centre for Disease Informatics and Research, Bengaluru
   **Studies undertaken:** National Stroke Care Registry Program, Development of Hospital based stroke registries in different regions of India, Dr Prashant Mathur, Director, NCDIR, Bengaluru.

8. Institute of Economic Growth (IEG), Delhi

9. Indian Institute of Technology (IIT), Mumbai

10. National AIDS Research Institute (NARI), Pune

11. Indian Institute of Health Management Research (IIHMR), Jaipur

12. Indian Institute of Public Health, Bhubaneswar

13. Indian Institute of Technology, Chennai

**Stakeholder Participation:** The stakeholders associated with DHR participate in the meetings for inputs on proposals and outcomes. These are agencies, organizations and institutions registered with DHR via the stakeholder registry and are from a variety of national institutions and organizations like FICCI, IMA, CII, NHSRC, industry partners, insurance companies, etc.
HTAIn - Progress
(2017 | 2018)

HTA studies
• Costing Study
• EQVT Study
• E-News Letter
• HTAIn Documents
HTA STUDIES

One of the major objectives of HTAIn is to conduct health technology assessment studies for the requests coming from central and state health ministry that includes systematic literature reviews, economic evaluations, primary costing as and when required, and measuring and valuing the health outcomes pertaining to that health technology. Along with clinical and cost effectiveness, the studies will also analyse evidences related to equity issues regarding the deployment of health technologies, that ensures efficient use of the limited health budget and provide people access to quality healthcare at minimum cost.

HTAIn consists of three core bodies including HTAIn Secretariat, HTAIn Technical Appraisal Committee (TAC) and HTAIn Board. The HTAIn Secretariat works in collaboration with its identified technical partners (TPs) and regional resource hubs (RRHs) across India. The requests for HTA study are first processed by HTAIn Secretariat experts and then allocated to TPs. TPs develop the study proposal and present the study to TAC members. Once approved by TAC members, a stakeholder consultation meeting is convened to inform and apprise all concerned stakeholders regarding the HTA study. After completion of the HTA study, outcomes of the study are again presented to TAC members and after approval by TAC, a second stakeholder’s consultation meeting is convened to inform them about the study results and final recommendations. Finally, the study is put up to the HTAIn Board, and once approved by the board, a policy brief along with the HTA outcome report is sent to the user department from where the request has originally come. A brief overview of all completed and ongoing HTA studies under HTAIn, DHR is presented in the subsequent pages.

Cost-effectiveness of Safety Engineered Syringes (SES) for Therapeutic Use in India

Principal Investigator: Dr Shankar Prinja, School of Public Health, PGIMER, Chandigarh

Background: Globally, 16 billion injections are administered each year of which 95% are for curative care. India contributes to 25-30% global injection load. Around 63% of these injections are reportedly unsafe or deemed unnecessary. It is estimated that each year approximately 33% of new Hepatitis B viral (HBV) infections and 42% of Hepatitis C viral (HCV) infections (2 million new infections) are attributable to the unsafe medical injections in developing nations. Similarly, the unsafe injection practices accounts for 9% of new HIV cases
in South Asia. Secondly, there is a risk of transmission of BBIs to healthcare professionals (HCPs) in case of adverse event of needle stick injuries (NSI). This study assessed the incremental cost per quality adjusted life year (QALY) gained with introduction of safety engineered syringes (SES) as compared to disposable syringes for therapeutic care in India.

Methods: Three SES – reuse prevention syringe (RUP), sharp injury prevention (SIP) syringe, and those with features of both RUP and SIP, were evaluated against a counterfactual current use of disposable syringes. A lifetime study horizon from a societal perspective was considered. A systematic review was undertaken to assess the SES effects in terms of reduction in needle stick injuries (NSIs) and reuse episodes, which was modelled in terms of QALYs gained.

Study Findings: The introduction of RUP, SIP and RUP+SIP syringes in India will incur an incremental cost of INR 43,064, INR 7,219,687 and INR 209,398 per QALY gained, respectively. A total of 96,296 HBV, 44,082 HCV and 5632 HIV cases will be averted due to RUP in 20 years. Similarly, use of SIP and RUP+SIP will avert 2869 HBV, 3111 HCV and 16 HIV; and 99,166 HBV, 47,193 HCV and 5648 HIV cases, respectively. There is a 93% probability for RUP to be cost effective at a willing to pay threshold of gross domestic product (GDP) of India. While SIP is not cost-effective, there is only 23% probability for RUP+SIP to be cost-effective at a willing to pay threshold of 1-time GDP per capita. RUP syringe will become cost saving at a unit price of INR 1.9. The SIP and RUP+SIP syringes are cost-effective only at a unit price less than INR 1.8 and INR 5.9, respectively.

Conclusion: Study findings suggest only RUP is cost-effective in Indian context. SIP and RUP+SIP are not cost-effectiveness at current unit prices. Efforts should be made to bring down the prices of SES to improve its cost-effectiveness.

Policy Use: As of result of economic evidence generated through this HTA study, several policy initiatives were taken pertaining to use of SES in therapeutic sector in India. In 2017, Punjab state piloted use of RUP syringes in therapeutic sector in 2 districts. On 28th July, 2018 (i.e. World Hepatitis day), State government of Andhra Pradesh passed an order to use auto-disable (AD) syringes in therapeutic sector . Lastly, on 28th July, 2018 (World Hepatitis day), country target of India was set i.e. to achieve 100% SES use for healthcare by 2020.

Status: Study Completed
Health Technology Assessment of intraocular lenses for treatment of age related cataract in India. Health Technology Assessment in India Secretariat, DHR, New Delhi.

Background: India’s commitment towards universal health coverage will require strategic planning to utilise the resources available and evidence-based decision-making will play a major role there. To facilitate the process of transparent and evidence informed decision making in the field of health, Government of India has set up an institutional framework called as Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW). The first HTA topic selected for study at HTAIn secretariat was “health technology assessment on intraocular lenses for treatment of age related cataracts in India”. The request for this topic came from Rashtriya Swasthya Bima Yojana (RSBY), a division of Department of Health and Family welfare, India. The HTA study on age related cataract presents a strong case as how to successfully connect research to policy change by providing the facts using the latest research strategies for decision-making.

Methods: The study included literature reviews, primary data collection along with multiple rounds of consultations with experts. A study working group of leading national experts including surgeons-ophthalmologists, community ophthalmologist, national blindness control program officers, scientists and health policy analysts was constituted to conduct the study. Five individual literature reviews were conducted to gather the evidences on clinical effectiveness, health related quality of life, economic evaluation studies, cost data and equity considerations. Primary data was collected on costing and quality of life. An economic evaluation was conducted with primary data collected from costing and quality of life studies.

Results and Discussion: Based on the results from the literature review and primary studies, Small Incision Cataract Surgery with rigid lens was found to be the most appropriate intervention to treat cataract patients in India in current scenario as it is clinically effective, less costly, more accessible, available and feasible. Phacoemulsification cataract surgery was suggested to be provided in those areas where infrastructure and experts are available for Phacoemulsification surgery. The cost of benefit packages for Phacoemulsification with foldable lens and small incision cataract surgery with rigid PMMA lenses was suggested as 9606 INR and 7405 INR respectively.

Status: Study Completed
Cost Effectiveness of Strategies for Cervical Cancer Screening in India

Principal Investigator: Dr Shankar Prinja, School of Public Health, PGIMER, Chandigarh

Background: The establishment of link between high-risk human papillomavirus (HPV) infection and occurrence of cervical cancer has resulted in recent development of HPV related control strategies for the prevention of the same. The present study was designed to assess the cost effectiveness of 3 screening strategies i.e., visual inspect with acetic acid (VIA), Papanicolaou test (Pap smear) and HPV DNA among the age group of 30-65 years old women at a frequency of every 3 years, 5 years and 10 years in the context of India.

Methods: The present study based on a markov model, societal perspective and discount rate of 3% estimated the lifetime costs and consequences in a hypothetical cohort of 30 year old women screened with either of the screening strategy at various time intervals. Sensitivity and specificity of the screening strategies was based on the recently published meta-analysis of Indian studies. Similarly, data on transition probabilities was derived from a published international meta-analysis. Further, primary data collection was undertaken using bottom up micro-costing method for estimating per person cost of screening and cost of treatment for cervical cancer in a public sector facility. In addition, 237 and 223 cervical cancer patients were interviewed from a tertiary care public sector hospital for assessing OOP expenditure and quality of life respectively.

Results: Introduction of screening led to reduction in occurrence of cervical cancer cases from 19% to 60% along with decrease in cancer deaths from 29% to 72% as compared to no screening in a lifetime cohort of 1-lakh women. This reduction in cancer cases and associated mortality translated into gain of 3147 to 6886 life years and 3647 to 8261 quality adjusted life years (QALYs) with implementing various screening strategies. The study concludes that VIA every 5 years is the most cost-effective option with an incremental cost of INR 9,613 (USD 145) per QALY gained in the context of India.

Status: Study Completed
Health Technology Assessment for breast Cancer Screening in India.
Healthcare Technologies Division, National Health Systems resource Centre, New Delhi

Background: Estimated 627,000 women died from breast cancer in the year 2018 accounting for 15% of all cancer deaths. The annual incidence of breast cancer is approximately 1, 44,000 new cases making it the most commonly occurring cancer in females in India for which early detection and prevention become key to preventing cancer-related deaths. Diagnostic accuracy of screening, cost-effectiveness, accessibility and equity are the three major factors essential for uptake and implementation of a screening technique in the Public Health System. Current policy recommends once in five year screening for all women over 30 years of age, using CBE at the Health and Wellness Centres/Sub-Health Centre level by Mid level Health Providers or /ANM followed by an Ultrasound scan for suspected (mass, nipple discharge, skin or nipple retraction, edema, erythema, peau d’orange, or ulcers) cases.

Methods: This Health Technology Assessment assessed the clinical and cost-effectiveness of various breast cancer screening modalities in women in the age groups of 35 – 40, 40-45, 45-50, 50-55, 55-60, 60-65 years, at screening intervals of 3 and 5 years. The modalities were CBE alone, CBE paralleled with USG, MMG alone, CBE followed by USG, Piezoelectric finger followed by USG, MMG followed by USG. Clinical effectiveness of each of the modalities was determined from the meta-analysis of the studies done. The cost-effective analysis included several parameters such as lifetime cost per woman (US $), Effect (QALY), Cost-Effectiveness ratio, incremental effect (QALY), ICER (US $), and Net monetary benefit to arrive at the dominance status of each screening strategy.

Results: The HTA findings show that CBE paralleled with USG was found to be the most clinically effective (Sensitivity: 91% & Specificity: 99 %) and cost effective technique compared to the rest of the methods across all age groups and screening intervals. This technique may optimise breast cancer detection in India. Whereas, CBE alone followed by USG has a sensitivity 61% and a specificity 100%. However, between these two methods there is not much difference in Incremental Net Monetary Benefit. Moreover, the pooled sensitivity of CBE alone is 73%, this means that there is a risk of missing out the true positive cases of breast cancer patient by 27 %. Therefore, the policy will need to evolve to strengthen USG as a followed method and ensure wide availability of USG machine and probe for CBE paralleled with USG.

Status: Study Completed
Health Technology Assessment for Long Acting Reversible Contraceptives in India

Principal Investigator: Dr Beena Joshi, NIRRH, Mumbai

India has been a signatory to the Family planning FP2020 program the target of which is to raise the modern methods Contraceptive prevalence rate (mCPR) to 63.7% by 2020 i.e. 20% increase from where it stands today. To achieve this target the basket of contraceptive choices needs to be expanded. In view of this, Ministry of Health, Government of India has a policy question of whether to introduce Implant contraceptives into the program. To aid this policy decision, a health technology assessment (HTA) study is being undertaken by ICMR-NIRRH HTA resource hub with support from the Department of Health Research.

The main objective of the study is to conduct an HTA for Nexplanon (Implanon NXT) to aid the policy decision of introduction into the program in India. The study population is reproductive age women (15-49 years) and Nexplanon is the intervention. The comparators include the available Long Acting Reversible Contraceptives in the government program: IUD and 3-monthly injectable (DMPA) and female sterilization. ICER/ICUR will be determined using costs and QALYs gained as well as unintended pregnancies averted. Decision Analytical Model considered for the study is Markow Model with five health states looking at life time horizon with one year cycle length. A disaggregated societal perspective is being considered for analysis.

A systematic review protocol to assess clinical effectiveness of Nexplanon is registered with PROSPERO (CRD Registration No: CRD42018116580). Targeted review of literature is being undertaken for clinical effectiveness and utility scores of comparators. Transition probabilities for different health states has been analyzed using raw data from National Family Health Survey (NFHS4). Unit cost for providing contraceptive services is being calculated by a primary costing study done at all levels of public health services in Maharashtra. Out of pocket expenses are being considered from NSSO. Final analysis will include sensitivity analysis and analysis for feasibility and equity Cost-effectiveness plane with the threshold, recommendations to the Ministry will be presented during the meeting. The study will help make informed decisions if Nexplanon is a cost-effective addition to the available contraceptive basket. The cost/QALY gained or unintended pregnancies averted could help the program managers decide where to allocate resources with the challenging priorities within the RMNCH+A program (Reproductive, maternal, neonatal, child + Adolescent health).

Status: Study Ongoing
Health Technology Assessment of Uterine Balloon Tamponades to manage Postpartum Hemorrhage in India

Principal Investigator: Dr Beena Joshi, NIRRH, Mumbai

Postpartum Haemorrhage (PPH) is the leading cause of maternal mortality. All women who carry a pregnancy beyond 20 weeks’ gestation are at risk for PPH and its sequelae. World Health Organization statistics suggest that 60% of maternal deaths in developing countries are due to PPH, accounting for more than 100,000 maternal deaths per year. Apart from uterotonic preventing bleeding by uterine massage, use of balloon tamponades is one of the known effective interventions. Condom catheters have been used however, they have some limitations as they can’t measure the blood loss. There are no clear-cut guidelines how and when to use these catheters and it is not the standard of care to manage PPH in many settings. Several dedicated devices have been in the market for long, which have proven advantages over the existing low-cost condom balloon tamponades. However, they are not being used in the current national program.

Hence, objective of the present study is, to evaluate the cost-effectiveness and cost utility of Intraterine balloon catheter tamponades for the management of severe PPH due to uterine atony among pregnant women diagnosed with PPH in India for its possible program introduction. Balloon Catheters Tamponade will be compared with Ultra-low-cost Uterine Condom Tamponade (ESM-UBT) and Standard care in India for the management of PPH. Decision Analytical Model considered for the study is being decided looking at life time horizon. A disaggregated societal perspective is being considered for analysis. Clinical impact of using balloon catheters tamponade in the form of deaths averted and QALYs gained will be the outcomes; economic impact (costs saved/extra cost incurred) due to use of balloon catheters tamponade and cost-effectiveness (ICER in terms of cost per death averted and cost per QALY gained) of using balloon catheters tamponade in comparison to current practice for management of post-partum haemorrhage in India. The study will help make informed decisions if a dedicated UBT is cost-effective to be introduced into the program for management of atonic PPH. The cost/QALY gained or maternal deaths/surgical procedures averted could help the program managers decide where to allocate resources with the challenging priorities within the RMNCH+A program (Reproductive, maternal, neonatal, child + Adolescent health).

Status: Study Ongoing
Health technology assessment for screening of type 2 diabetes & hypertension in India.

Principal Investigator: Dr Shankar Prinja, School of Public Health, PGIMER, Chandigarh

Background: Commonly referred to as epidemic of modernized world, Diabetes Mellitus (or T2DM) is a major lifestyle disease globally. Hypertension contributes to approximately 1.6 million deaths annually in India, due to ischemic heart disease and stroke (1). Recognizing the importance of burden of non-communicable diseases (NCD) the Government of India has started population-based screening for NCD including diabetes and hypertension. The present study is designed to assess the most cost-effective screening strategy for diabetes and hypertension in terms of its frequency (1 versus 3 versus 5 yearly frequency) under different age groups (30-65 years; 25 to 65 years; 40-65 years) in India.

Methodology: The present study will be based on a combination of decision tree and hypothetical cohort Markov model with societal perspective, considering a discount rate of 3% to estimate the lifetime costs and consequences with screening strategies for diabetes and hypertension in different age-groups and at various time intervals. Sensitivity and specificity of the screening tests will be based on meta-analysis of diagnostic accuracy studies. Similarly, review of literature will be done to derive information on transition probabilities. Further, primary data collection using principles of economic costing with bottom up approach will be done in three states of India- Tamil Nadu, Punjab and Haryana. Data related to direct costs would be collected for a reference period of financial year 2017-18. The cost of screening per person and per patient cost of treatment for diabetes and hypertension at various levels of public sector health facilities will be estimated. In addition, out of pocket expenditures and quality of life of people with diabetes and hypertension will be estimated through interview method from a tertiary care public sector hospital. Incremental cost effectiveness ratios will be calculated for all screening strategies. A sensitivity analysis will be undertaken to test the robustness of our analysis to various structural model and parameter uncertainties.

Status: Study Ongoing
Diagnostic Validation and Health Technology Assessment of ‘Sohum’ Neonatal Hearing Screening Device

Principal Investigator: Prof Sanghamitrpati, Dr. Debdutta

Congenital hearing impairment among children has been linked with lifelong deficits in speech and language acquisition, poor academic performance, individual and social maladjustments, and emotional difficulties. Studies indicate prevalence 5 – 6 per 1000 live births in India, of neonatal hearing loss, with highly considerable repercussion on lifelong disability and Quality of Life. However, this figure only indicates a tip of the iceberg as majority of hearing impairment remain undetected.

In India under Rashtriya Bal Swasthya Karyakarm (RBSK) since 2013, neonatal hearing loss is a part of the actions, which comprise of comprehensive hearing detection healthcare program. In RBSK program, (Oto-acoustic emissions) OAE is used at the facility level, while (behavioural audiometry approach) BOA is adopted at the community screening. For the further confirmation it is followed by BERA (brainstem evoked response audiometry) at referral facilities, which is costly and available at few facilities. In case of BOA, it is difficult to screen the infants as it is preliminary in nature, low specificity, which results increase in referral cost and Out-of-Pocket Expenditure, and causing delay in seeking timely care. Furthermore, the OAE needs soundproof infrastructure, not possible to screen 0 to 3 days newborn, and non-portable.

The “Sohum” a new hearing device been developed by Dept. of Biotechnology Govt. of India during July 2017. The ‘Sohum’ device can be used as a part of universal health coverage of hearing screening among infants in out-reach areas because of its portability and low infrastructural requirements. However, there is lack of information on clinical validation and cost effectiveness of ‘Sohum’. Hence this study will assess the clinical efficacy, cost effectiveness and operational challenges in implementation of ‘Sohum’ neonatal hearing screening devices in healthcare facilities in India. This HTAIn study is classified into three broad areas: diagnostic validation, economic evaluation, and Ethical, Legal and Social Implication of ‘Sohum’ implementation. This study was approved by Technical Appraisal Committee, Department of Health Research, Ministry of Health and Family Welfare, Government of India. The ethical clearance was obtained from the Institutional Ethical Committee of RMRC Bhubaneswar.

Status: Study Ongoing
Health Technology Assessment on Hypothermia Detection Devices (BEMPU, ThermoSpot and Fever Watch) for Premature Low Birth Weight Neonates in India.

Principal Investigator: Prof Sandra Albert, IIPH, Shillong, Meghalaya

This study aims to analyse the cost effectiveness of hypothermia devices in detecting and monitoring hypothermia in premature low birth weight (LBW) neonates, in India. The cost effectiveness analysis is being carried out for Bempu, ThermoSpot and Fever Watch. The two main indicators considered are cost per death averted and cost per illness averted by using the hypothermia detecting devices. Systematic literature reviews on clinical effectiveness and cost effectiveness of the hypothermia detecting devices, such as Bempu, ThermoSpot and Fever watch have been undertaken. The objectives of these two systematic reviews are as follows:

1. **Clinical Effectiveness:**
   - To determine the clinical effectiveness of Bempu, ThermoSpot and Fever Watch in detecting hypothermia in premature low birth weight (LBW) neonates.
   - To compare the clinical effectiveness of Bempu, ThermoSpot and Fever Watch to the Thermometer in detecting hypothermia in premature low birth weight (LBW) neonates.
   - To determine if there is an increase in Kangaroo care activity and birth weight in premature low birth weight (LBW) neonates as a result of the index test; Bempu, ThermoSpot and Fever watch.

2. **Cost Effectiveness:**
   - To assess the incremental cost associated with the use of Bempu, ThermoSpot and Fever Watch over Thermometer for hypothermia.
   - To ascertain the difference in quality adjusted life year (QALY) gained with the use of Bempu, ThermoSpot and Fever Watch.
   - To estimate the incremental cost per quality adjusted life years (QALY) gained with the use of Bempu, ThermoSpot and Fever Watch over Thermometer.

**Rationale:** The current standard of care for detecting neonatal hypothermia is the Thermometer. However, the Thermometer does not monitor for hypothermia continuously unlike the intervention devices viz. BEMPU, ThermoSpot and Fever Watch. It is important to understand the cost effectiveness of a health technology before introduction into the health system.

**Status:** Study Ongoing
Health technology assessment study on RT-PCR for H1N1 in India.

Principal Investigator: ML Choudhary, National Institute of Virology, Pune.

Lower respiratory tract viral infections, including those due to influenza, are among the most common infectious diseases in humans and they are associated with significant morbidity and mortality. Seasonal influenza viruses infect 5–15% of the human population each year, resulting in ~500,000 deaths worldwide. Influenza is vaccine-preventable. A significant number of severely ill patients infected with H1N1pdm09 requiring intensive care and mechanical ventilation for severe viral pneumonia.

Nucleic acid tests are sensitive and specific and provide a rapid diagnosis, making them invaluable for patient and outbreak management. Real-time polymerase chain reaction (PCR) can be considered the gold standard for detection of influenza viruses due to its high sensitivity and specificity. Real time RT-PCR developed by WHO is considered as gold standard method for influenza A H1N1pdm09 diagnosis from Nasal/throat swabs.

Currently in India, suspected patients are screened by clinician and prescribing Oseltamavir drug without waiting for test report. Indiscrimination use of anti influenza drug may develop resistance in virus. Limited labs are testing H1N1pdm09 virus in country and have not been able to effectively implement at large programs due to lack of adequate infrastructure, trained manpower and limited resources and high costing of kits. Different tests sensitivity, specificity and costs vary. The purpose of this assessment is to appraise the current evidence for the clinical effectiveness (in terms of sensitivity and specificity) and cost-effectiveness against CDC/WHO real time RT-PCR for diagnosis of influenza A/H1N1pdm09 in India.

Status: Study Ongoing
To assess cost and clinical effectiveness of the automated neonatal resuscitation in comparison to self-inflating bags in Indian context considering societal perspective.

**Principal Investigator:** Dr. Jitender Sharma, Devarshi Bhattacharyya

Birth asphyxia is defined as the failure to initiate and sustain breathing at birth. It is the medical condition resulting from deprivation of oxygen to a new-born that lasts long enough during the birth process to cause physical harm, usually to the brain. Hypoxic damage can occur to most of the infant's organs (heart, lungs, liver, gut, kidneys), but brain damage is of most concern and perhaps the least likely to quickly or completely heal. India has the highest number of new born deaths with 640 thousand deaths in 2016 that share 24% of all global new born deaths. India contributing to quarter of neonatal deaths globally. The major causes of new born deaths in India are pre-maturity/preterm (35 per cent); neonatal infections (33 per cent); intra-partum related complications/birth asphyxia (20 per cent); and congenital malformations (9 per cent).

**Target Population (Types of participants):** This study will include all newborn having symptom of birth asphyxia. Symptoms of not breathing or very weak breathing, skin color that is bluish, grey, or lighter than normal, low heart rate, poor muscle tone, weak reflexes, too much acid in the blood (acidosis), seizures and need resuscitation as per medical advice. All term babies will be included depending upon the symptoms and medical recommendation.

**Intervention:** Automated Resuscitation Device. The review would include automated resuscitation device which has inbuilt oxygen blending system and provide positive pressure ventilation at the fixed pressure and volume as set in the device, does not depend completely on the manual hand pressure. Its work on principle of T-piece resuscitator, it has Continuous Positive Airway Pressure (CPAP) and bubble CPAP modes which support breathing of neonates who could perform spontaneous breathing, therefore support in respiratory distress.

**Comparator:** The study will compare t-piece resuscitator with self-inflating bags (ambu-bag) most commonly used for ventilation in the resuscitation process and with mechanical ventilator to establish its usability in stabilizing the neonates with CPAP mode.

**Outcome:** The review would evaluate the clinical effectiveness of t-piece in comparison to self-inflating bag in terms of reduction in intubation, duration of ventilation days, length of stay in NICU, mortality rate, survival rate and minimal morbidity or long-term complication. The economic evaluation would be in terms of ICER, Net health benefit and QALYs.

**Status:** Study Ongoing
Health Technology Assessment of Pulse Oximeter for management of pneumonia in community settings

Principal Investigator: Dr. V. Raman Kutty, Achutha Menon Centre for Health Science Studies(AMCHSS), Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum

In order to answer the broad query, we realized the need to answer at least three issues. Firstly, field workers are not suspecting enough pneumonia cases via the current screening methods. The introduction of the pulse oximetry is likely to increase the detection of such cases in the field. Secondly, suspected pneumonia patients can either be treated at home using antibiotics or referred to a hospital for IP treatment. The pulse oximetry with appropriate cut-off values can play a role in appropriate referral. Finally, for facility based intervention, the pulse oximetry can be added to the existing standard treatment guideline, to aid in categorization of patients, which would serve as a basis for deciding further treatment.

The HTA proposal was prepared with the support of members of HTAIn, Secretariat in the Department of Health Research. The proposal was presented to the Technical Appraisal Committee, convened by DHR on November 10, 2018. The TAC engaged with the proposal, suggestions and comments were made by various members. The protocol was reworked based on the above inputs. The evidence synthesis phase is underway. Currently electronic searches are being performed and relevant studies are identified. In parallel the eligibility of the studies are also undertaken.

In the wake of the recently announced national health insurance scheme, the Government of Kerala has approached the resource hub for expert opinion and conduct of evidence summaries, HTA process etc. We hope to collaborate more with the state government in the future for generating evidence to support state specific needs.

Status: Study Ongoing
Health Technology Assessment of Sickle Scan™ as a point of care testing device for the Screening of sickle cell disease in India.

**Principle Investigator:** Dr Rajasubramaniam S, Division of Genetic Disorder, ICMR-NIRTH, Jabalpur.

Sickle cell gene is mainly prevalent in tribal populations generally living in remote areas. Therefore, screening has to be carried out in the field using minimum amount of blood sample. Despite of certain limitations, sickling and solubility test are currently being used as a screening test in community based screening program. Various point of care testing methods for the screenings of SCD are either under development and/or at the testing stages currently. The Sickle SCAN POC is based on lateral flow chromatographic qualitative immunoassay technique to rapidly detect the presence or absence of HbA, HbS and HbC. The Rational of the current study is to test the diagnostic accuracy, including the sensitivity, specificity, and limit of detection (LoD) of novel testing device ‘Sickle SCAN™’ under field and laboratory conditions to confirm the feasibility and validity of the test for large scale screening at the point of care (POC).

**Objectives:**

1. To identify the whether SickleScan™ is a cost effective strategy for screening and diagnosis of SCD as compared to other available tests in India.
2. To identify the feasibility and equitability of Sickle Scan test in Indian settings.

General Population of all age and gender will be screened using Sickle Scan Test and Solubility test. Results of both the test will be compared by the gold standard test (CE-HPLC, Variant). Sensitivity and specificity will be evaluated.

**Status:** Study Ongoing
Health Technology Assessment of TeCHO+ Program in Gujrat

Principle Investigator: Dr Somen Saha, HTA Regional Resource Hub, IIPH Gandhinagar, Gujarat

The Health & Family Welfare Department, Gujarat has implemented TeCHO+ programme in Gujarat. TeCHO+ is a mobile & web based application which works as a job-aid for health workers and administrators. TeCHO+ is expected to lead to further improvement of Gujarat’s performance on eleven priority areas including maternal health, infant health, low birth weight babies, complete immunization, malnutrition, anemia during pregnancy, epidemics, sex ratio at birth, mental health, birth spacing and non-communicable conditions.

A comprehensive health technology assessment (HTA) exercise is to be undertaken by the Regional Resource Centre (RRC) set up at Indian Institute of Public Health Gandhinagar, on request from the Health & Family Welfare Department, Gujarat. HTA of TeCHO+ will inform the programme and policy makers on the programme effectiveness including cost-effectiveness.

Study objectives of TeCHO+ HTA are:

1. Assess the incremental cost of delivering TeCHO+ solutions
2. Assess key outcome indicators for measuring programme impact
3. Estimate the incremental cost-effectiveness ratio of the program
4. Assess pathways to the observed programme outcome

To achieve the above mentioned study objectives, key programme outcome indicators will be compared before and after the launch of TeCHO+ program. The data for costing study will be collected keeping health system perspective in mind. An incremental costing approach will be adapted for the study. To establish baseline, the data obtained from e-Mamta software will be validated. For this purpose, in close supervision of the HTA RRC team, territory TeCHO+ coordinator will randomly select sampled households for data validation. Proximal outputs in terms of changes in service coverage will be modelled to estimate key outcome variables, deaths averted, and QALYs gained to estimate incremental cost-effectiveness ratio of the program. The study also focuses on understanding the pathway of change of this mHealth Intervention program. This is proposed to understand the influence of factors including supportive supervision, behaviour changes among female health workers and PHC medical officers and the contribution of the software application on the observed outcome.
This study is spread across a duration of three years for which the data will be collected on indicators related to maternal care, children care and immunization, feeding practices, mortality indicators, and NCD indicators, which will act as an endline data to establish the study outcomes.

**Status:** Study Ongoing
Costing of health services in different states of India (CHSI study)

**Principal Investigator:** Dr Shankar Prinja, School of Public Health, PGIMER, Chandigarh

Government of India (GOI) is committed to achieve Universal Health Coverage (UHC) assuring availability of free and comprehensive primary health care services. At present, more than 80% of the healthcare expenditures in India are met by out of pocket (OOP) which leads to the impoverishment of patients. To turn the vision of UHC into reality, the GOI rolled out Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) to cover over 10 crore poor and vulnerable families (approximately 50 crore beneficiaries) providing coverage up to 5 lakh rupees per family per year for secondary and tertiary care hospitalization. The government will pay for the package of healthcare services to the insurance company. So, the basic question is to determine package rates for different healthcare services based on robust scientific studies. Cost information plays a key role in strategic purchasing and in monitoring providers of centrally funded services. On the one hand, cost information is the vital element to any budgeting and fundraising in the form of projections of resource requirements or estimating budgetary needs such as understanding the cost of a healthcare insurance package.

‘Costing of health services in different states of India’ (CHSI) was initiated by Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW), New Delhi. The study is being conducted in 13 states with joint collaboration between DHR, School of Public Health, PGIMER Chandigarh and the respective Multi-disciplinary Research Unit (MRU) in each of the 13 states. The methodology to estimate package rates is mixed methodology (top down and bottom up approach) of economic costing. Plan included data collection from various cost centres like out-patient department (OPD), diagnostics, operation theatre (OT), intensive care unit (ICU), inpatient department (IPD), laundry, kitchen etc. under various heads (human resource, infrastructure, consumables, furniture, equipment, instrument etc.). Primary data collection for the estimation of cost of delivery for top-utilized 60 healthcare packages was planned in first phase. In every state, respective MRU of DHR were nodal points for the data collection. It was planned to collect data from 1 tertiary level public facility, 3 district hospitals and 3-4 private hospitals in each state. As this study intended to cover only 59 packages out of total 1350 health packages covered under AB-PMJAY, there remains a gap regarding cost pertaining remaining packages. To fill this gap, this study is now planned to be extended. In phase II of the CHSI study, all the 1350 packages and specialities as included in AB-PMJAY will be covered in the 13 states.
Development of health-related quality of life (EQ-5D-5L) value set for India

Principal Investigator: Dr Shankar Prinja, School of Public Health, PGIMER, Chandigarh

Health Technology Assessment (HTA) is a tool for prudent resource allocation and evidence informed decision making in health. However, unavailability of country specific health state valuation limits effective conduct of HTA in India. DHR HTA guidelines document recommends use of quality adjusted life years (QALYs) as preferred outcome measure and EQ5D as preferred tool for its health state valuation. Therefore, this study aims to develop EuroQol five-dimensional (EQ-5D-5L) health states value set for Indian population. In this study, a cross-sectional survey using the EuroQol Group’s Valuation Technology (EQ-VT) software will be undertaken in nationally representative sample. The study will be conducted in 6 different states of India (Haryana, Uttar Pradesh, Meghalaya, Odisha, Gujarat and Tamilnadu). The states are so selected that these are representative of geographical location and health status. The participants, which will be selected using multistage stratified random sampling technique, will be interviewed in a face to face setting using CAPI (computer assisted personal interviewing) technique. To estimate the value set, hybrid modeling approach using both composite time trade off (cTTO) and discrete choice experiment (DCE) will be applied. Sensitivity analysis will be conducted to explore the impact of severely inconsistent responders. The value set generated as a part of this study can then be useful for clinicians undertaking studies to measure clinical effectiveness of interventions, epidemiologists to measure the burden of disease, and health economists to undertake HTAs. In addition to enabling effective conduct of HTA in India, this value set will also be helpful in clinical practice/research for better monitoring of health-related quality of life. The scores can be used as an important input that better reflect Indian population’s preference for health technology assessment research. In addition, the results can be used for international comparison in order to understand similarities and differences of health preference across populations.
HTAIn’s e News Letter

As HTAIn is working with more than twenty collaborating partners across India, and there are many concerned stakeholders who needs to be regularly appraised about the progress HTAIn is making. To meet with this demand, we have started to issue quarterly e-News Letters. These e-News Letters are being prepared to inform our regional hubs, technical partners, central and state health governments, other collaborating agencies and institutes, international partners as well as for our technical appraisal committee, board and all other stakeholders. These e letters compile all the work done in that quarter; like, studies commissioned, status updates of the ongoing and completed studies, workshops and conferences conducted, meetings organised, new HTA requests received, and any other information like upcoming events and vacancies. So far, two issues of HTAIn e-newsletter have been released. Screenshots of the two e News letter released so far are given in next two pages.
First HTAIn e-News Letter

Health Technology Assessment in India - HTAIn

HTA in India

HTAIn Structure

HTAIn Procedure

HTAIn Objectives and Significance

Technical Approach and Translation (TAT)

Stakeholders

Capacity Building

Short Messages

First HTAIn e-News Letter
Second HTAIn e-News Letter
HTAIn Documents

To maintain the transparency, accessibility and consistency of the HTA methods used across different studies, some key documents have been prepared to help our collaborators as well as policy makers be aware of our mandates, vision, structure and functions. These open access documents will be available on DHR and HTAIn websites.

1. **Concept Note:** This document describes the establishment of HTAIn previously known as Medical Technology Assessment board (MTAB), within Dept of Health Research, how the background work was done and the mandates of HTAIn.

2. **Process manual:** This is a policy document which describes the overall structure of HTAIn within Ministry of health and Family Welfare, how it functions, and how the study goes through various rounds of review withing secretariat, TAC and HTAIn Board.

3. **HTAIn guidelines (Reference Case):** The guidelines are prepared to provide information to our collaborators as well as our stakeholder to appraise them about HTA methodology and different ways of conducting a Health Technology assessment study.

4. **HTA Manual:** The HTA manual is a very important document which is prepared to get all the information and updates about HTA in general as well as specific to HTAIn.

5. **Policy Briefs:** A policy brief is a concise summary of the study topic and its findings while highlighting the key recommendations for policy advocacy and decision makers. As such, the findings and recommendations of two completed studies – Intraocular Lenses for Cataract Surgery and Safety Engineered Syringes – have been drafted as policy briefs displayed in the following pages.
Intraocular Lens for Cataract Surgery*
"A hope to see again"

HTAIn Secretariat, Department of Health Research, Ministry of Health & Family Welfare
July 2018

Policy Brief

Summary
Cataract is the leading cause of blindness worldwide. In India cataract has been reported to be responsible for 50-80% of the blindness in the country most prevalent in older population. Women and people with low socioeconomic status are more at risk. In order to bridge the gap between the evidence-to-policy, a comprehensive Health Technology Assessment (HTA) study was undertaken by Health Technology Assessment in India Secretariat (HTAIn Sec.) to examine the comparative effectiveness and cost-effectiveness of various cataract surgeries and intraocular lenses (IOLs). Overall the study suggested that Manual Small Incision Cataract Surgery (MSICS) with Rigid PMMA lens was found to be the most appropriate strategy in a country like India where age related cataract is more reported in rural areas lacking in medical infrastructure and among the people with low socioeconomic status.

Background
Cataract is the leading cause of blindness (51%) and low vision (33%) worldwide (Fig. 1). The prevalence of blindness in India is around 1% where cataract contributes for almost 60-70% (2). As per the ongoing national blindness survey 2017-2018, the overall prevalence of blindness has reduced to almost 0.50% but cataract is still as prevalent as 70% (Fig. 2).

Under Rashtriya Swasthya Bima Yojna (RSBY) cataract is one of the most utilized (16-36%) packages in most of the states. RSBY offers four different packages for cataract ranging from 4000 to 7000 INR (Table-1) and among them "Cataract with foldable Intraocular lens (IOL) by Phacoemulsification tech. Unilateral" of 7000 INR was found to be the most utilized cataract package (3).

Experts reported that most common surgical options for the treatment of cataract in India are Phacoemulsification (Phaco) and Manual Small Incision cataract surgery (MSICS) that utilizes foldable Acrylic and rigid PMMA lenses, respectively. However, there is a lack of evidence in Indian context for comparing the clinical and cost-effectiveness of these surgical interventions and IOLs for the treatment of age-related cataracts.

Recommendations

• On the basis of clinical efficacy, cost, accessibility, availability and feasibility, MSICS with rigid lens is most appropriate intervention to treat cataract patients in India in current scenario.

• Phacoemulsification cataract surgery can be provided in those areas where infrastructure and experts are available for Phaco surgery.

• The benefit packages for Phaco with foldable lens and Small Incision Cataract Surgery with rigid PMMA lenses may cost as 9606 INR and 7405 INR respectively.

• The package is inclusive of initial OPD consultation, diagnostic tests (optometry, vision test etc.), counselling, pre-surgery/ anaesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.

* The policy brief is based upon the Health Technology Assessment of “Intraocular lenses for treatment of age-related cataract in India” - July 2018 and can be found on the link: https://dhr.gov.in/sites/default/files/htaincataract_0.pdf
Choice of cataract surgery and lenses in India are made depending upon the clinical, economic and social conditions of patients and surgeon's expertise. However, to bridge this gap between evidence and decision, the HTA study was undertaken by Health Technology Assessment in India Secretariat (HTAiN Sec.) to examine the clinical and cost-effectiveness of various cataract surgeries and intraocular lenses (IOLs) for the treatment of age-related cataracts. Since this HTA topic was given to the HTAiN Sec. by RSBY and Phaco. and MSICS was the most common intervention the two were compared for their effectiveness and equity implications.

**Clinical and Cost-Effectiveness**

The study included the secondary as well as primary data collection, wherever required. Phaco. and MSICS showed comparable clinical efficacy in terms of visual acuity and complications. There were comparable clinical benefits with rigid PMMA and foldable acrylic lenses when implanted after a Phaco. surgery. There is also not enough evidence suggesting the superiority of multifocal lens over monofocal or the role of IOL material in developing posterior capsule opacification (PCO). Overall, MSICS with rigid monofocal lenses sounds a wise strategy to cater to the huge backlog of cataract patients in India without compromising the quality of healthcare. There are very few studies reporting quantitative QALY for different types of cataract surgeries (Phaco. and MSICS) and lenses (rigid and foldable lenses). Our Study shows that MSICS leads to a better VQoL compared to Phaco (Fig. 4(a). However, the economic evaluation depicted phaco with foldable lens to be cost-effective over MSICS with rigid lenses (Fig. 4(b) with an incremental cost-effectiveness ratio of 3862.79 INR per QALY, Incremental Net Health Benefit of 0.55 QALYs and Incremental Net Monetary Benefit of 63255.2 INR.

There was no generalizable literature available on the cost of cataract surgery lenses in India. Therefore, a primary collection was done in secondary and tertiary hospital settings. Average Cost of Cataract Surgery package from three secondary centers was calculated to be 9606 INR for Phaco. and 7405 INR for MSICS while in tertiary setting it came out to be 13017.51 INR and 9215.89 INR, respectively. The package included OPD consultation, diagnostic tests (optometry, vision test etc.),

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**Quality Adjusted Life Years Gained - QALY (4)**

- QALY is a measure of gain in expected lifespan resulting from an intervention weighed by the quality of life; e.g., an intervention that leads to a five-year gain in life expectancy, but implies considerable pain during those years might be estimated to have a lower QALY than an intervention that results in four-year gain, but with less pain during that period.
- QALY is a generic measure of health and offers the potential to compare the health gain across different diseases and hence provide a rationale to decide while making investment across different health programmes in different areas of health care, such as treatments for heart disease and cancer, and to assess the opportunity cost (on the budget) of adopting programmes.
- EQSD is the most utilized tool worldwide to measure Qel.

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**Vision related quality of life - VQoL (5)**

- VQoL represents the degree to which vision impacts an individual's ability to complete activities of daily living and one's social, emotional and economic well-being.
- It is a specific measure of visual impairment and can be assessed by measuring the degree of impairment experienced in activities of daily living that rely on sight.
- A disease-specific tool (such as IND-VFQ39 for cataract) is used to measure the Qal.
counseling, pre-surgery/ anesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.

**Equity Considerations**

In terms of the suitability depending upon the health service determinants, resources available, accessibility, cost and clinical effectiveness etc. in the rural and low socioeconomic setting where cataract prevalence was most MSICS being less technology dependent seems to be advantageous for high-volume case-loads of age-related cataract whilst maintaining excellent visual outcomes. MSICS was mostly performed at secondary level hospitals without any requirement of the constant power supply while Phaco was performed mostly at the tertiary level, requires high capital investment and recurring expenditures of the Phaco machine and consumables and a specially trained personnel to handle the machine (6). Moreover, indigenous PMMA that is used in MSICS would be less expensive in contrast to the foldable lens used in Phaco which is mostly imported and expensive (6).

Studies reported that there was a provider-consumer mismatch for cataract in India i.e. cataract cases and backlogs were reported more from the rural area (7) and most of the ophthalmologists were concentrated in the urban areas. Moreover, cataract prevalence was more in the prevalence was more in the uneducated population with low socioeconomic status (8).

Therefore, for a public health programme in a populated and diverse country having enormous socio-economic differences, SICS seems to be more appropriate intervention to address the large backlog of cataract cases.

**Policy Brief**

![Figure 4. Pre and Post surgery scores for (a) EQSD and (b) IND-VFQ-33 subscales for different combinations of surgery and IOLs](image)

**Policy Implications**

RSBY was initially designed to target only the Below Poverty Line (BPL) households but has been expanded to cover other defined categories of unorganized workers (2).

As per the ongoing Blindness Survey of India (2017-18), cataract prevalence is estimated to be almost 4% in the 50+ age population of the country. Upon extrapolation of evidence, it was seen that treating all these patients with a combination of SICS with rigid lens may lead to a cost saving of 17.3 b INR.

According to the 2011 census, 70% of Indian population (mostly poor) reside in rural areas (9) where most of the cataract cases were reported (7) therefore, for a public health programme MSICS with rigid lens seems to be beneficial without compromising the quality of care and extra cost saving will help to cater more cataract patients/backlogs.

**Key Findings**

- Phaco vs. MSICS - Comparable Clinical Efficacy in terms of VA and complications.
- Foldable vs. Rigid PMMA lenses - Comparable Clinical Efficacy.
- MSICS + Rigid PMMA lens vs. Phaco + Foldable lens:
  - Better VAQoL
  - 0.57 QALY Gain
- MSICS + Rigid PMMA - Less Costly
- Phaco - More technology dependent mostly performed at secondary hospitals

**Conclusion**

Both Phaco and MSICS showed comparable clinical efficacy in terms of visual acuity and complications. Moreover, the clinical outcome of the rigid PMMA and acrylic foldable were also equally good. However, the cost of MSICS with rigid lens came to be lesser than phaco with foldable lens and also MSICS is less technology dependent hence MSICS with rigid lens seems advantageous in rural settings where the majority of cataract cases were reported and also help to cater more cataract patients.

**Sources**

2. National Programme for Control of Blindness Surveys. nhb.nic.in/
Summary

An unsafe injection can transmit serious diseases to patients instead of delivering treatment to them. An estimated 16 billion injections are given globally each year and out of which 40% are reported unsafe. So the cost of managing these infections poses a significant economic burden, much of this is borne by households. In order to prevent unsafe injections; World Health Organization (WHO) recommends a transition to safety engineered injection devices by 2020. These syringes are specially designed to prevent NSI and reuse episodes. Long back in 2008, Government of India (GoI) introduced auto-disable (AD) syringes for immunization but its use is not mandated in the therapeutic sector which constitute the bulk of injection use. This study was undertook to assess the cost-effectiveness of Safety Engineered Syringes for therapeutic use in India against a counterfactual scenario of use of exiting use of disposable syringes. The study suggested that the Reuse Prevention (RUP) syringes are cost-effective in Indian context. While Sharp Injury Prevention (SIP) and RUP+SIP are not cost-effective at the current unit prices. Efforts should be made to bring down the prices of SES to improve its cost-effectiveness.

Recommendations

It is expected that evidence provided in this document will contribute to preventing the re-use of syringes on patients and to a decrease in the rate of needle-stick injuries in HCWs related to injection procedures, thus contributing to the prevention of injection-transmitted infections.

The study estimated that if the current injection practices are continued for next 20 years, there will be 99,557, 47,618 and 5,650 new cases of HBV, HCV and HIV, respectively which are attributable to NSI and reuse. Implementing RUP, SIP and RUP+SIP will prevent the new BBIs due to unsafe injections by 96%, 3.9% and 99%, respectively.

It is found that RUP syringe to be cost-effective in Indian context. Unit cost of SES (RUP) was major determinant of overall costs, upon extrapolation of the evidence, it was seen that RUP intervention will become cost saving strategy, if procured at a unit cost INR 1.9 or lower.

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**TIMELINES**

- Protocol presented to Punjab TEG: Mar-2017
- Stakeholders meeting DHR: Aug-2017
- Presentation of findings to Punjab TEG: Oct-2017
- Report uploaded on DHR portal: Dec-2017
- Dissemination of findings in 28th national scientific meeting of INASL, New Delhi: Feb-2018
- Dissemination of findings in 2nd National Conference on HTA, PGIMER, Chandigarh: Aug-2018

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Policy question by NPPA: Sep-2017
Protocol presented to DHR TAC: Nov-2017
Preliminary findings presentation to Punjab TEG: Jan-2018
Presentation of findings to DHR TAC: Aug-2018
Scope of Problem

Injections are one of the most common health care procedures. Every year at least 16 billion injections are administered worldwide. The vast majority – around 90% – are given in curative care. India contributes to 25-30% global injection load. Over 63% of these injections are reportedly unsafe or deemed unnecessary. Addressing the unsafe injection practices is an important public health agenda due to several reasons. Firstly, these lead to the large-scale transmission of blood borne infections (BBIs) among patients. Approximately 33% of new Hepatitis B viral (HBV) infections and 42% of Hepatitis C viral (HCV) infections (2 million new infections) and 9% of new HIV cases are attributable to the unsafe medical injections in developing countries. Secondly, there is a risk of transmission of BBIs to healthcare professionals (HCPs) in case of needle stick injuries (NSI). Thirdly, poor sharp waste management practices puts the waste handlers (and community) at risk. The cost of managing HBV, HCV and HIV poses a significant economic burden for the health system. In India, much of this economic burden is borne by households, as they contribute to 71% of the total health care expenditures through out-of-pocket expenditures (OOPEx). Average health system cost and out of pocket expenditure for treating liver disorders in intensive care tertiary setting in India is USD 2,728 (INR 163,664) and USD 2,372 (INR 142,297) respectively. Moreover, since this burden is faced disproportionately more by the poor, it leads to inequities in utilization of care and financing. The World Health Organization (WHO) recommends a transition to safety engineered injection devices by 2020. These syringes are specially designed to prevent NSI and reuse episodes. While the Government of India (GoI) introduced auto-disable (AD) syringes for immunization in 2008, its use is not mandated in the therapeutic sector which constitute the bulk of injection use. Recently, Punjab state considered introduction of SES in therapeutic sector. The evidence on its cost-effectiveness is thus being sought as an essential criteria to decide on introduction of SES syringes. Moreover, the National Pharmaceutical Pricing Authority (NPPA), has requested India’s Health Technology Assessment Board to provide economic evidence on different forms of SES. In order to answer these policy questions, we undertook this study to assess the incremental cost per quality adjusted life year (QALY) gained with introduction of SES as compared to current practice of using disposable syringes for therapeutic care.

Key Findings

1. Implementing RUP, SIP and RUP+SIP will prevent the new BBIs due to unsafe injections by 96%, 3.9% and 99%, respectively.

2. The introduction of RUP, SIP and RUP+SIP syringes in India will incur an incremental cost of INR 43,064, INR 7,219,687 and INR 209,398 per QALY gained, respectively.

3. RUP has a 93% probability to be cost effective at a threshold of per capita gross domestic product (GDP).

4. RUP syringe will become cost saving at a unit price of INR 1.9. Similarly, SIP and RUP+SIP syringes will be cost-effective at a unit price less than INR 1.8 and INR 5.9 respectively.

5. At the national level, annual cost of disposable syringes for therapeutic care is INR 3.34 billion (USD 52.6 million). Introduction of RUP, SIP and RUP+SIP incurs an additional cost of INR 10.3 billion (USD 162 million), INR 32.3 billion (USD 509 million) and INR 32.4 billion (USD 511 million) per year. Implementing SES will save INR 4.2 billion (USD 66.2 million), INR 3.07 billion (USD 48.4 million) and INR 4.9 billion (USD 77.2 million) annually with use of RUP, SIP and RUP+SIP, respectively on account of treatment cost averted.

6. The study estimated that if the current injection practices are continued for next 20 years, there will be 99,557, 47,618 and 5,650 new cases of HBV, HCV and HIV, respectively which are attributable to NSI and reuse.
**Estimation of Cost-Effectiveness**

Three Safety Engineered Syringes – reuse prevention syringe (RUP), sharp injury prevention (SIP) syringe, and those with features of both RUP and SIP, were evaluated against a counterfactual current use of disposable syringes. We also included integrated trainings on safe injection practices which include training on use of SES, safe practices and waste management; along with behaviour change communication (BCC) for patients. We also considered the costs associated with these activities, however, we did not consider any incremental benefits associated with either training or BCC activities. In the counterfactual arm, the most appropriate choice was the prevailing current practice of using disposable syringes. In the unregulated private sector, there could be a possibility of using glass syringes, although to a lesser extent. However, for our analysis, we assume use of disposable syringes for therapeutic care, and avoid complexity of mixed practices. We used unit prices provided by WHO for respective SES. These prices, which were available in USD, were converted to local currency i.e. INR using conversion rates for the year 2017.

**Conclusion**

Our findings suggest RUP use for therapeutic care is cost-effective in Indian context. However, SIP and RUP+SIP are not cost-effective at current prices. So the study suggest that RUP should be considered for therapeutic care in India. The prices of these SES should be reduced either through price negotiation using bulk purchasing, or through price regulation by central agencies such as NPPA.

<table>
<thead>
<tr>
<th>Type of SES</th>
<th>HBV prevented</th>
<th>HCV prevented</th>
<th>HIV prevented</th>
<th>Incremental costs (In million)</th>
<th>Incremental health benefits (QALYs)</th>
<th>ICER per QALY gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUP</td>
<td>96,297</td>
<td>44,082</td>
<td>5632</td>
<td>113,577</td>
<td>1,673,535</td>
<td>40,358</td>
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<td>SIP</td>
<td>2869</td>
<td>3111</td>
<td>16</td>
<td>482,817</td>
<td>66,138</td>
<td>6,743,277</td>
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<tr>
<td>RUP+SIP</td>
<td>99,166</td>
<td>47,193</td>
<td>5648</td>
<td>462,078</td>
<td>1,739,678</td>
<td>196,021</td>
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</tbody>
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HTAIn-Work in Progress

- National HTA Database
- HTAIn Data Repository
  - HTAIn-Website
- DHR-PGIMER-Costing Database
- DHR-PGIMER-EQ-5D Database
DHR-HTA National Database

Since the very beginning of Health technology Assessment India (HTAIn) under DHR, requests for Health Technology Assessment (HTA) studies started to come from different policy makers in the country. The topics used to come from different divisions of union ministry of health and family welfare, state ministry of health and family welfare, Rastriya Swasthya Bima Yojna, National Pharmaceutical Pricing Authority, National Health mission, National innovation portal, etc. As HTAIn is now more than one and half year old and there are more than 25 HTA topics under process, it is crucial to record all the information properly and systematically. In order to manage the HTA study related information by storing it systematically and to make the information available in public domain transparently, a national HTA database is initiated under DHR. The national HTA database will be available on DHR and HTAIn website and will be periodically updated.

The DHR-HTA database will become a highly valuable resource for locating literature and information, which will be freely available from a single source. This database will enable funders and researchers to identify work already in progress and will help reduce unintended duplication of effort. The database will also serve as a one point source for policy makers where they can have a quick glance at the website to have an idea about studies under process, which can later become a basis for a new public health programs. The database will also be helpful to private manufacturers and clinicians as keeping them well informed about what all-new interventions are being considered under different HTA studies. Open access of such a database will bring the much-required transparency in the field of research and development(1).

The availability of data potentially transforms data into usable information. A better-managed database will not only ease accessibility to information but also make it possible to generate better-quality information on which better decisions are based. Quality of data is a comprehensive approach to promoting the accuracy and validity. Currently, HTAIn has accumulated data (approximately 50 mb) including raw data, completed study reports, published and grey data, and is undiscoverable and scattered at different places. HTAIn repository will ensure that all data stored on it is secure. Other government agencies/departments can benefit from our HTAIn studies. Preliminary data collected by HTAIn through their affiliated studies can be build up on to secondary data and advanced studies.
**HTAIn Data repository:** The proposed link for the repository would be

Link: [https://htadb.icmr.org.in/](https://htadb.icmr.org.in/)

Currently, data is being sorted in various libraries, namely: Proposals, Health Related Quality of life data, Costing Data, Epidemiological Data, Policy documents, Outcome Reports, Systematic reviews and Protocols, Raw Data; Primary & Secondary Data.

Other salient features of the repository will be limited access to users, visitors library - Open Access, Multi level access to data - Region wise, Disease wise, Topic wise, Centre wise etc. Interactive Dashboard, Mobile/Tablet app for data entry and uploading to the system and Hosted on DHIS platform.
DHR-PGIMER-Costing Database

Cost information plays a key role in setting reimbursement rates, strategic purchasing and in HTA. However, quality health facility cost data in India is scarce and limited in accessibility. As a result, there is an increasing and urgent need to generate and disseminate healthcare cost information. The School of Public Health at the Post Graduate Institute for Medical Education and Research, Chandigarh (PGIMER) has created an Indian national cost database and website to serve as a central resource for researchers and decision-makers for information on healthcare costs. The database provides a one-stop shop for cost information for healthcare decision-making in India.

The first iteration provides access to public sector facility cost data from 200 facilities across 6 states at the district hospital, community health care, primary health care and sub-health care centres. These cost data provide average costs for inpatient (IP) and outpatient (OP) services at different levels of the health system for the public sector, with both input and activity wise breakdowns. Estimates on cost for specific services such as antenatal care, postnatal care, institutional delivery, immunization, directly observed short-course treatment (DOTS) for tuberculosis are also provided. The data were collected using a standardised methodology, facilitating the collation of these data into a single dataset for use by researchers and health care decision-makers in India.

This cost database and web-based resource represents a first step in providing reference cost data for India and makes average health facility cost data collected from multiple states freely available for researchers and policy-makers for the first time. By improving the availability of these data, raising its profile and demonstrating its utility, it is hoped that the database will also lead to greater recognition of the importance of good quality data in this area and, in turn, enable better and more informed decision-making.
DHR-PGIMER-EQ-5D Database

HTAIn is mandated to generate and compile evidences related to cost-effectiveness, clinical-effectiveness and safety of medicines, devices, vaccines and health programmes by means of Health Technology Assessment (HTA) studies. However, an unavailability of India specific health state tariff value limits the calculation of quality-adjusted life years (QALYs) while conducting the economic evaluations of health care interventions.

Therefore, a study is planned to develop EuroQol five-dimensional (EQ-5D-5L) health states value set for Indian population. A cross-sectional survey using the EuroQol Group’s Valuation Technology (EQ VT) software will be undertaken in representative sample of 2700 respondents. The respondents will be selected from 12 districts in 6 different states of India using a multistage stratified random sampling technique. In order to select the states, the 29 Indian states were grouped into six categories based on the state gross domestic product (GDSP). State GDP was used as the basic criteria for grouping because income is a key factor associated with self-reported health. Further the states were so selected that these are representative of geographical location and health status. One state from each of the six groups thus selected are – Haryana, Uttar Pradesh, Gujarat, Odisha, Tamil Nadu and Meghalaya.

Value set for EQ-5D-5L health state will be estimated for the Indian general population. This will be helpful in clinical practice/research for better monitoring of health-related quality of life. The scores can be used as an important input that better reflect Indian population’s preference for health technology assessment research. In addition, the results can be used for international comparison in order to understand similarities and differences of health preference across populations. A database on Eq5D tariff will be hosted by DHR and PGIMER websites that will provide the required data on health related quality of life for future economic evaluations.
**HTAIn - Future Prospects**

To enhance the collaborative work and to be more efficient in serving the research in local context, HTAIn is planning to establish its regional resource hubs in some more states of India where Uttar Pradesh, Madhya Pradesh, Bihar and Chhattisgarh are being considered as priority.

HTAIn works closely with its concerned stakeholders in the field of policy making like Ministry of health and family welfare, State health Departments, Niti Aayog, National Pharmaceutical Pricing Authority (NPPA), NHM, NHSRC, etc., we wish to extend our interaction with such organizations to avoid any duplication in the field of health research and to be able to deliver the services in best way possible. We are in process of building networks with organizations like CDSCO, NIHFW, NTAGI, NACO, etc. Along with these organizations, we are in touch with institutions of national repute like AIIMS, IITs, IIMs, BHU, etc. to understand their potential contributions in the field of Health Technology Assessment.

Capacity building would be an important aspect of initial years of HTAIn. The Secretariat at the DHR is taking steps in this direction. A series of capacity building workshops have been initiated to train the participants from technical partners in various aspects of undertaking an HTA. These include developing the research question, synthesizing evidence through systematic reviews and meta-analysis, costing, developing decision models and interpreting evidence. The Secretariat has also created regional resource hubs to develop local capacity and expertise to support State-specific needs in these regions.

HTAIn has been privileged to be working with NITI Aayog to peer review the health benefit packages for Ayushman Bharat-PMJAY. HTAIn is also conducting a nationwide costing study, that would further support fixing the rates of benefit packages.

The outcome results of HTA studies completed by HTAIn are being implemented in central as well as by state heath ministries. The safety Engineered syringes HTA outcome is being considered by Punjab and Andhra Pradesh Governments. The outcome from Cataract -intraocular lenses study by HTAIn is being considered for PMJAY-packages.

Throughout the process of HTAIn development we enjoyed the support from all our stakeholders including policy makers, healthcare providers, clinicians, researchers and private companies. In future also we hope to be working in sync with all concerned stakeholders.