HEALTH TECHNOLOGY ASSESSMENT IN INDIA (HTAIn)

Policy Briefs

December 2021

सत्यमेव जयते

Department of Health Research
MINISTRY OF HEALTH & FAMILY WELFARE

THE LOGO

The logo of Health Technology Assessment in India (HTAIn) is in the form of ashield which represents the protecting role of HTAIn towards its citizens as the Board shields the citizens from financial hardship arising out of health care seeking. The top of the shield is marked with Ashok Chakra, depicting the allegiance of HTAIn towards the constitutional values and the nation. Rod of Asclepius and symbol of Indian Rupee are placed side by side below the National Emblem, as while making a decision about cost- effectiveness of an intervention, HTAIn gives due consideration to both public health potential and costs associated with an intervention. "सर्वे सन्तु निरामयाः। (*Sarve Santu Niramayah)*" is scripted in Devnagri script on a ribbon, which means "*Let All Be Healthy*', and expresses the devotion of HTAIn towards the values of Universal Health Cara

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PREFACE

To facilitate the process of evidence informed decision making in the field of health, Government of India has set up *Health Technology Assessment in India* (HTAIn) entrusted to conduct Health Technology Assessment and support Central and the State Governments in evidence based-decision making and policy formulations. HTAIn consists of a Secretariat based in the headquarter that coordinated with HTAIn Resource Centres and Technical Partners established throughout India in different states. Resource Centres conduct HTA studies allocated to them by the Secretariat. Secretariat can also conduct HTA studies in addition to Resource Centres and Technical Partners.

This document contains the Policy Briefs of the completed HTA Studies conducted by Health Technology Assessment in India (HTAIn), which includes HTAIn Secretariat, the Regional Resource Centers and Technical. There is an introductory overview of Health Technology Assessment in India (HTAIn) established under Department of Health Research (DHR), Ministry of Health & Family Welfare, New Delhi followed by the policy briefs of the completed studies.

डॉ. मनसुख मांडविया
DR. MANSUKH MANDAVIYA

सत्यमेव जयते

स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक मंत्री
भारत सरकार
Minister for Health & Family Welfare
and Chemicals & Fertilizers
Government of India

आज़ादी का अमृत महोत्सव

MESSAGE

It gives me immense pleasure to know that Department of Health Research is publishing the "Policy Briefs"- a compilation of Health Technology Assessment studies conducted by Health Technology Assessment of India (HTAIn). These studies will guide the Government and other healthcare givers for evidence based decision making for accessible and affordable healthcare.

Indian healthcare system is very complex and significantly different from other settings, so an assessment about how a technology can be adapted by adding value to current set of technologies is imperative. Generally new technologies are costlier than the older ones and have cumulative effect on overall healthcare expenditure when implemented. The comparison through HTA ensures that new technology added is proven to be clinically and cost-effective.

HTAIn with its objectives of maximizing health, minimizing out of pocket expenditure, and promoting equity will play a key role in India to provide quality accessible and affordable health care to our population.

(Dr. Mansukh Mandaviya)

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एफएएचए, एफएएमएस, एफएनएएससी, एफएएससी
Prof. (Dr.) Balram Bhargava, Padam Shri
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सत्यमेव जयते

सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक
भारतीय आयुर्विज्ञान अनुसंधान परिषद
Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General
Indian Council of Medical Research

Message

Government of India is committed for quality, affordable and accessible healthcare to its citizens. There are various challenges in this direction viz. limited health resources, introduction of new technologies, high out of pocket expenditure on healthcare etc.

Establishment of HTAIn in 2017 by Department of Health Research was a key milestone in strengthening Indian healthcare system. Health Technology Assessment is a valuable tool to examine healthcare technologies for their cost-effectiveness, clinical effectiveness, safety and accessibility. HTAIn has been providing guidance to central and state Governments for evidence informed decision making.

Recommendations from HTA studies have been implemented in the Operational Guidelines for National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) and the National Viral Hepatitis Control Programme. HTAIn has also supported Ayushman Bharat Yojana in revising the health benefit packages. This book is a compilation of the recommendation of HTA studies which will prove useful to understand the methodologies of HTA and facilitating the implementation of the policy recommendations.

Establishing HTAIn is a very promising step towards providing quality healthcare and taking India a step further towards Universal Health Coverage. I am sure that healthcare sector will witness transformation by the means of HTA.

Balram Bhargava

(Balram Bhargava)

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अनु नागर
संयुक्त सचिव

ANU NAGAR
Joint Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य अनुसंधान विभाग

Government of India
Ministry of Health & Family Welfare
Department of Health Research

Message

In the field of healthcare, it is very important to keep pace with the latest health technologies while maintaining affordable access to healthcare for patients. The Health Technology Assessment helps in maintaining this pace and provide the patients access to cost effective health technologies.

Health Technology Assessment in India (HTAIn) was established for a systematic and evidence based decision making which is proving to be a landmark for Indian healthcare and its commitment towards Universal Health Coverage.

During a short duration of four years HTAIn has completed 24 HTA studies including several multi-centric studies such as Costing of Health Services in India and generating EQ5D tariff value for India. All these studies have supported Centre and State Governments in several evidence based decision-making. It has also supported Ayushman Bharat in revising its packages.

All the completed studies as "knowledge synthesis" have been compiled in this book in the form of policy briefs which provide a quick overview of the key finding and policy recommendations. HTA is indeed the need of the hour for providing accessible and quality healthcare system in India.

(Anu Nagar)

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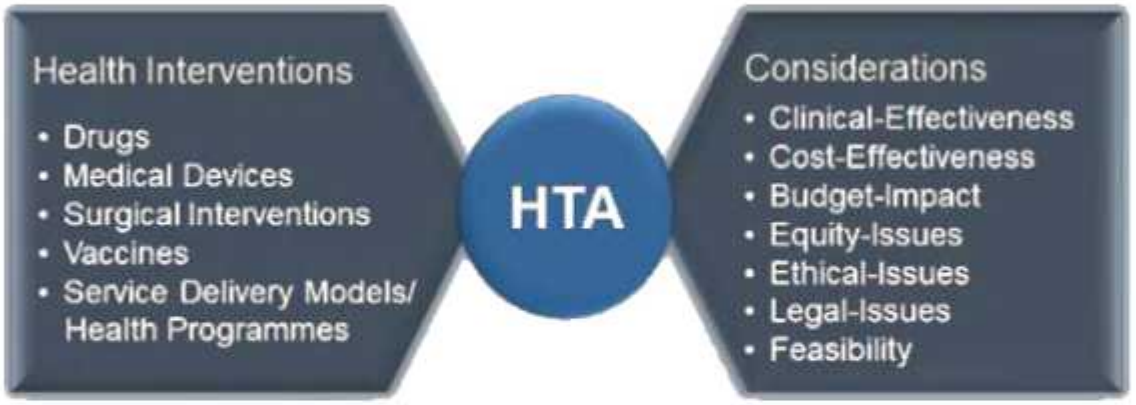
I. HEALTH TECHNOLOGY ASSESSMENT IN INDIA (HTAIn)

1. Health Technology Assessment (HTA)

Health technology assessment (HTA) is widely used methodology internationally for optimization of resource allocation in health. It is a multidisciplinary process that gathers policy relevant evidence about the medical (clinical effectiveness), economic (cost effectiveness), social and ethical issues related to the use of a health intervention in a systematic, inclusive, transparent and robust manner to assist policy makers in decision making in Health and Healthcare.



Health Technology Assessment

Health technology assessment is intended to provide a bridge between the **world of research** and the **world of decision -making** (1). HTA inform Government agencies while drafting policy recommendations in the field of health, health care professionals in drafting Standard Treatment Guidelines, hospitals and healthcare administration regarding the use of a health intervention, insurance companies while deciding their premium and reimbursement rate, manufactures during device or drug production, patient cares and advocacy groups regarding the ethical and legal issues of a health intervention. We can say, HTA is a multidisciplinary process and together it has the potential to help the country in its global commitment of Universal Health Coverage (UHC).

Who does the HTA inform?

2. Health Technology Assessment in India (HTAIn)

Recognizing the importance of Health Technology Assessment (HTA) in healthcare decision making and to facilitate the process of transparent and evidence-informed decision making in the field of health, Government of India has set up a body as "**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 analyze 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.

3. Purpose of establishing HTAIn

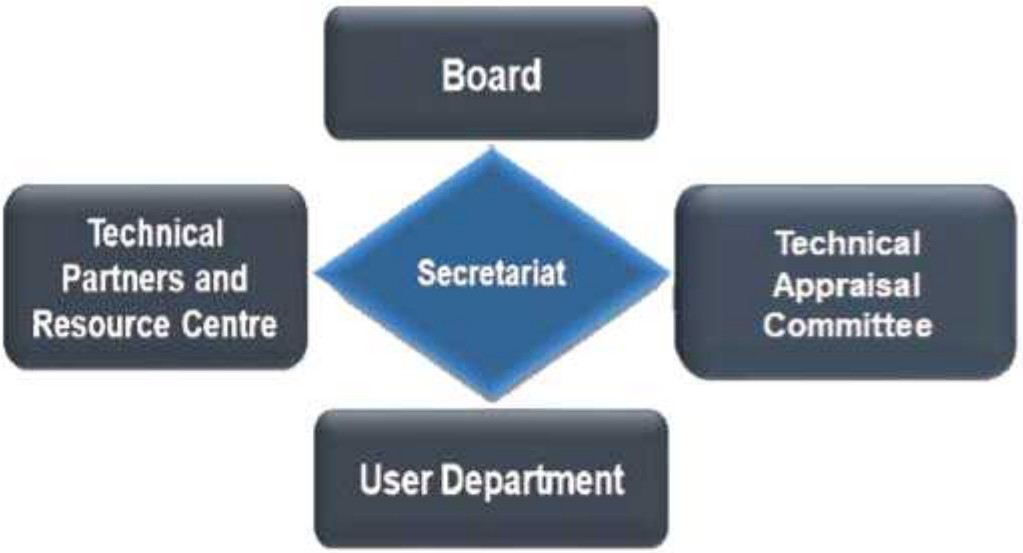
The Government of India is committed to extend healthcare services to its 1.34 billion population as part of India's Universal Health Coverage (UHC) agenda. One of the most important challenges in India that warrant immediate attention is increasing catastrophic out of pocket expenditures (OOP) in healthcare. According to National Health Accounts Report 2017-18 Household's Out of Pocket Expenditure on health (OOPE) was 61% of total health expenditure (2). 2017 World Bank report estimated the OOP spending on healthcare in India to be as high as 62% (3). Extending adequate healthcare services to the population requires optimal utilization of existing resources to ensure that the greatest amount of health is bought for every rupee spent. National Health Policy 2017 also proposes a responsive and strong regulatory framework so that challenges of quality of care, cost escalations and impediments to equity are addressed effectively. The main purpose of the HTAIn is to engage in explicit and evidence-based decision-making in health taking India towards universal health coverage. HTA will help to bridge the evidence-to-policy gap and ensure alignment of academic and policy interests through HTA towards the common goal of improving decision-making for health resource allocation to improve the health of the Indian population.

4. Objectives of HTAIn

- **Maximizing Health**
- **Reducing Out of Pocket Expenditure (OOP)**
- **Minimizing Inequality**

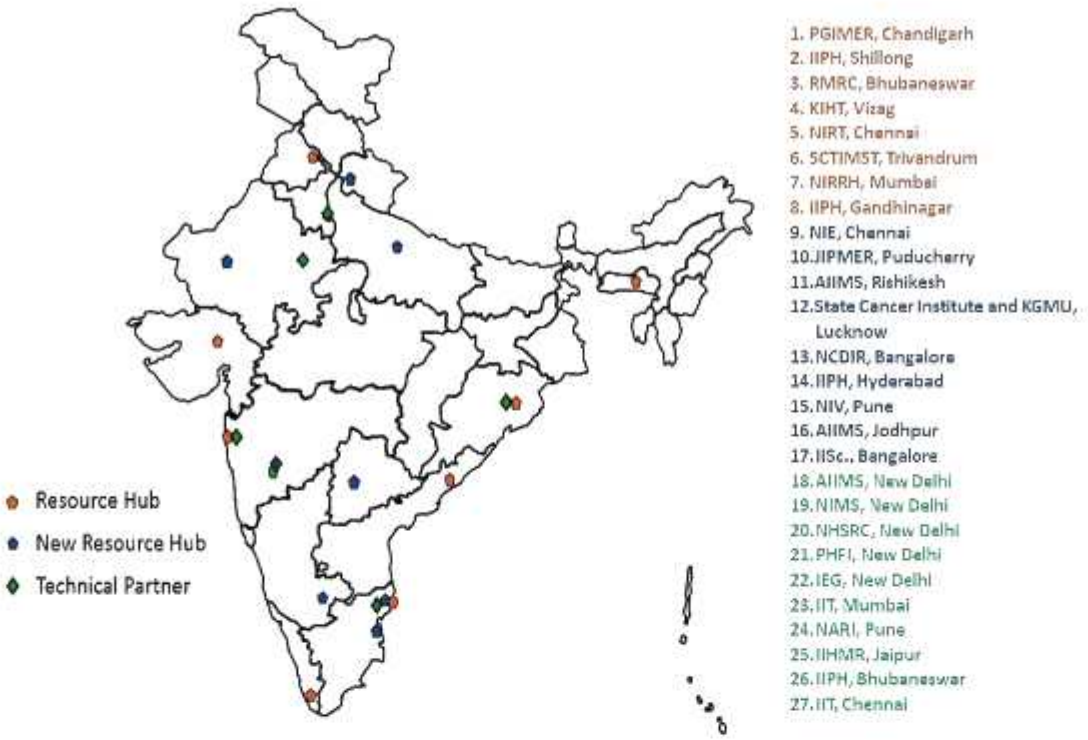
5. HTAIn Structure

HTAIn consists of – **(i) DHR In-house Secretariat, (ii) Technical Appraisal Committee (TAC), (iii) HTAIn Board and (iv) Regional Resource Centers/ Hubs and Technical Partners (TP).** The secretariat coordinates between the Resource Centres, Technical Partner(s) (TP), Technical Appraisal Committee (TAC) and the Board.



Organizational structure of HTAIn to conduct HTA

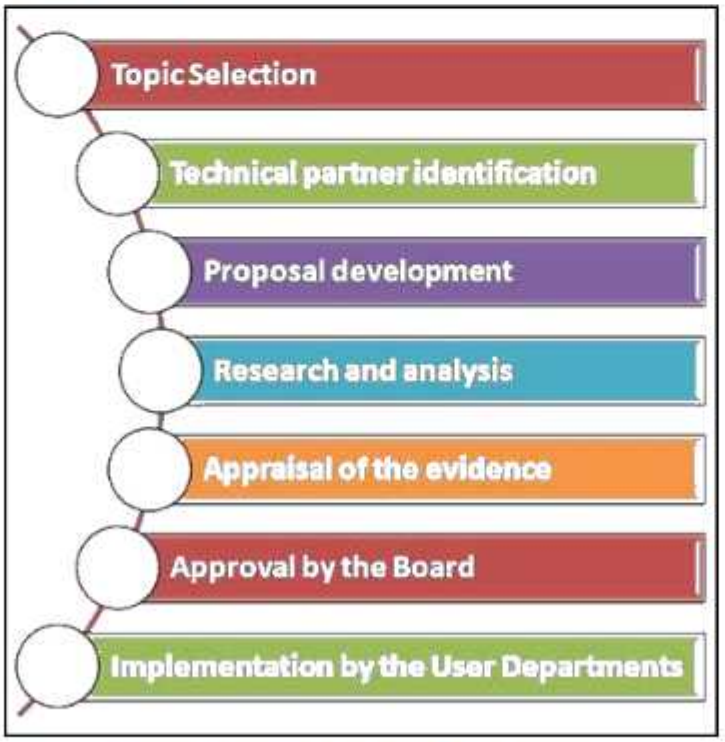
- *User Department/ User Agency:* Provides topics of study to HTAIn and implement the recommendations of the completed studies.
- *HTAIn Secretariat or Secretariat*: DHR-in-house body that coordinates between the User Department, TAC, Board, Regional Resource Centres and Technical Partners.
- *Technical Appraisal Committee (TAC):* It appraises the HTA study at different stages mainly after proposal development and the outcome of the study.
- *HTAIn Board:* Board appraises the recommendations of the studies from TAC and takes the final decision before sending the recommendations to the User Departmentfor implementation.
- *Technical Partners and Regional Resource Centres/ Hubs:* **Technical Partners are** Central/ State Government Institutes that conduct the HTA studies of HTAIn. **Regional Resource Centres** a have additional tasks of liaising and coordinating with the State Governments as an extended arm of HTAIn Secretariat.



HTAIn Regional Resource Centres and Technical Partners

6. HTAIn Functioning

7.1. Key Phases



Key Phases of the HTAIn Process

II. POLICY BRIFS

Intraocular Lens for Cataract Surgery

"A hope to See Again"

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 were more reported in rural areas lacking in medical infrastructure and among the people with low socioeconomic status.

* The policy brief is based upon the Health Technology Assessment of 'intraocular lenses for treatment of age-related cataracts in India' - July 2018 and can be found on the link:
https://dhr.gov.in/sites/default/files/htaincataract_0.pdf

Courtesy: International Agency for the Prevention of Blindness (IAPB)

Background

Cataract is the leading cause of blindness (51%) and low vision (33%) worldwide (Fig. 1) (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.*

Choice of cataract surgery and lenses in India are made depending upon the clinical, economic and social conditions of patients and surgeon's expertise, infrastructure available at clinic etc. To bridge this gap between evidence and decision for an evidence-informed policymaking, a comprehensive Health Technology Assessment (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.

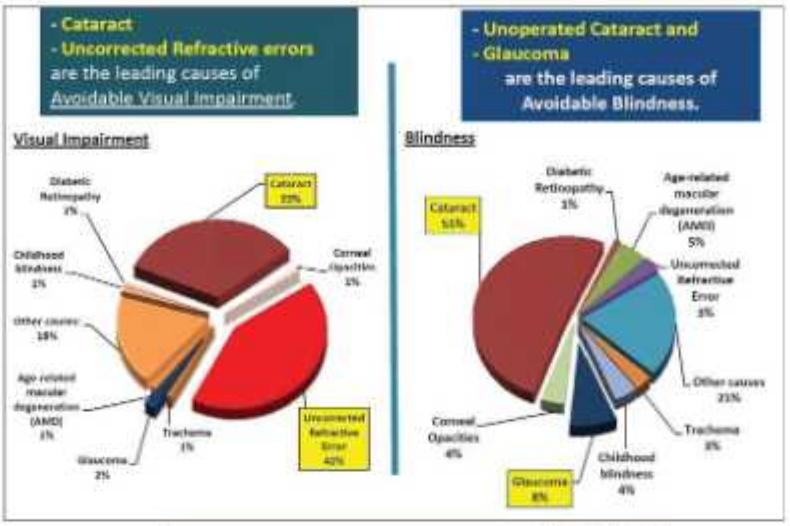


Figure 1. Visual Impairment and Blindness 2010 — World Health Organization

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 for different types of cataract surgeries (Phaco. and MSICS) and lenses (rigid and foldable lenses). Our Study showed that MSICS leads to a better VRQoL 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.

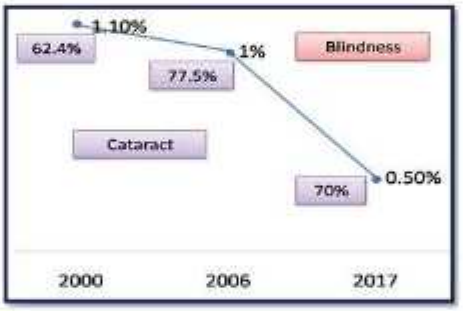


Figure 2. Prevalence of Blindness and cataract contribution.

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.),

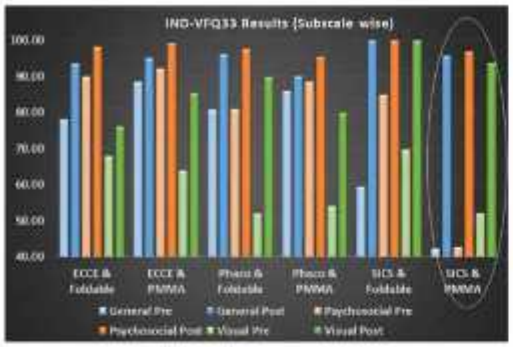
Quality Adjusted Life Years Gained -QALY (4)

- QALY is a measure of gain in expected lifespan resulting from an intervention weighed by the quality of that 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.
- EQ5D is the most utilized tool worldwide to measure QoL

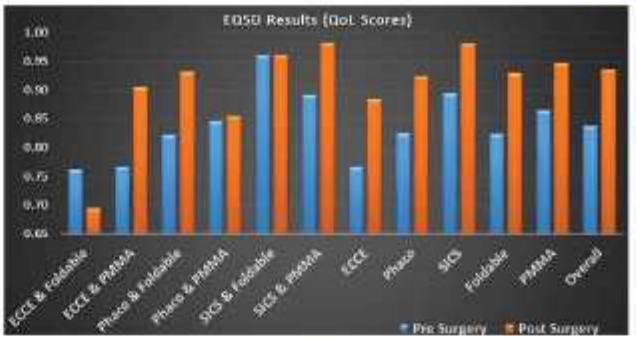
Figure 3. HTA overview

Vision related quality of life -VRQoL (5)

- VRQoL 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-VFQ33 for cataract) is used to measure the QoL



(a)



(b)

Figure 4. Pre and Post surgery scores for (a) EQ5D and (b) IND-VFQ-33 subscales for different combinations of surgery and IOLs

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 cataracts cases.

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.

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.

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] :*
  - *[MSICS + Rigid PMMA] → Better VRQoL*
  - *[Phaco.+ foldable lens] → 0.57 QALY Gain*
  - *[MSICS + Rigid PMMA] → Less Costly*
- *MSICS - Less technology dependent mostly performed at secondary hospitals*
- *Phaco. - More technology dependent, require good infrastructure and performed mainly at tertiary level.*

Sources

1. WHO. World Health Report, Visual Impairment and Blindness, 2010.
2. National Programme for Control of Blindness Surveys. npcb.nic.in/
3. RSBY::Rashtriya Swasthya Bima Yojna. http://www.rsby.gov.in/
4. Methods for the Economic Evaluation of Health Care Programmes. 4th Edition. Oxford Press.
5. Finger RP et al. Investig Ophthalmol Vis Sci. 2011, 52(9):6081-8.
6. Ruit et al. Am J Ophthalmol. 2007, 143(1):32-38.
7. Vajpeyi et al. Ophthalmic Res. 1999;31(2):86-92.
8. Rakhi Dandona LD. Br J Ophthalmol. 2001; (85:):1484-1488.
9. http://censusindia.gov.in/

Safety Engineered Syringes for Therapeutic Care in India

One Syringe, Only One Time

Safety Engineered Syringes for Therapeutic care in India

One syringe, Only one time

HTAIn Resource Hub, School of Public Health
Post Graduate Institute of Medical Education and Research
Chandigarh, India

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

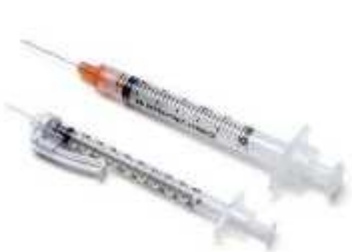
It is expected that evidence provided in this document will contribute to preventing the re-use of syringes on patients and to a decrease in the rate of needle-stick injuries in HCWs related to injection procedures, thus contributing to the prevention of injection-transmitted infections.

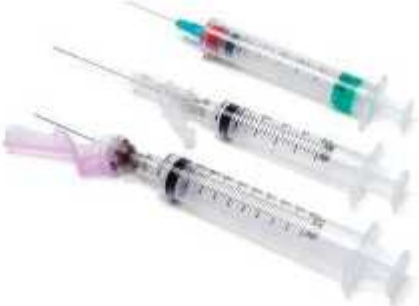
The study estimated that if the current injection practices are continued for next 20 years, there will be 99,557, 47,618 and 5,650 new cases of HBV, HCV and HIV, respectively which are attributable to NSI and reuse. Implementing RUP, SIP and RUP+SIP will prevent the new BBIs due to unsafe injections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

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 (OOPE). 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.

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

Health Technology Assessment of Strategies for Cervical Cancer Screening in India

Health Technology Assessment of Strategies for Cervical Cancer Screening in India

POLICY BRIEF

SUMMARY

Cancer of the uterine cervix is the second most common cancer among women world-wide. It is also the second most common cancer among Indian women, which constitute the largest burden of cervical cancer patients in the world. One out of every five women in the world suffering from this disease is an Indian. The establishment of a strong link between high-risk persistent human papillomavirus (HPV) infections and the occurrence of cervical cancer has resulted in the recent development of HPV related control strategies for the prevention of cervical cancer. Introduction of screening led to reduction in occurrence of cervical cancer cases from 19% to 58% along with decrease in cancer deaths from 28% to 70% as compared to no screening in a lifetime cohort of 1 lakh women. There was reduction in lifetime risk of cervical cancer among Indian women from 2.18% in the case of no screening to 0.879 - 1.729 % with implementation of various screening strategies. This reduction in cancer cases and associated mortality translated into gain of 3141 to 6848 life years and 3630 to 8198 QALYs among various screening strategies implemented in a cohort of 1 lakh women. The study concludes that VIA every 5 years is the most cost-effective option with an incremental cost of INR 21,196 (USD 320) per QALY gained in the context of India.

Introduction

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 prevention of the same.

The present study was designed to assess the cost effectiveness of 3 screening strategies i.e., visual inspection with acetic acid (VIA), Papanicolaou test (Pap smear) and HPV DNA test at a frequency of every 3 years, 5 years and 10 years in the context of India.

Methodology: 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. Diagnostic accuracy of the screening strategies and data on transition probabilities was based on the results of the existing meta-analysis studies. Primary data was collected for assessing per person cost of screening, cost of treating cervical cancer and quality of life.

Results: Introduction of screening leads to reduction in lifetime occurrence of cervical cancer cases from 19% to 58% and cervical cancer deaths from 29% to 70% as compared to no screening. Among various screening strategies, VIA every 5 years was found to be most cost-effective at an incremental cost of INR 16,905 (US$ 255) per QALY gained.

Table1: Reduction in cervical cancer cases and deaths with implementation of various screening scenarios for women (as compared to no screening) screened in the age group of 30-65 years

Screening strategy	Frequency	Cancer cases averted (%)	Deaths averted (%)
Visual inspection with acetic acid	3 Years	52	65
	5 Years	37	50
	10 Years	22	31
PAP smear	3 Years	49	63
	5 Years	33	48
	10 Years	19	29
HPV DNA test	3 Years	58	70
	5 Years	43	56
	10 Years	26	36

Rationale

As India is on the path towards universalizing national level screening program, the present study was designed to assess the cost-effectiveness of three screening strategies of VIA, Pap smear and HPV DNA as compared to no screening scenario at the frequency of every 3 years, 5 years and 10 years among women in the age groups 30-65 years in India. In addition, we also evaluated the costs and consequences of a scenario comprising of screening with HPV vaccination as compare to screening alone or do nothing.

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	5 Years	43	56
	10 Years	26	36

POLICY RECOMMENDATIONS

1. Screening with VIA every 5 years among the women of age 30-65 years is recommended for India.

2. A minimum 30% of screened positive patients are needed to be treated for VIA every 5 years to remain cost effective. Similarly, lifetime risk of cervical cancer of at least 0.7 is required for VIA 5 yearly to be cost effective.

3. In terms of equity considerations and specifically considering the screening strategy of VIA every 5 years, it was seen that there was around 30% more reduction in cervical cancer cases and subsequent mortality in the bottom 1/3rd of the income population group as compared to upper 2/3rd of the income group in India. Similarly, in terms of financial risk protection, bottom 1/3rd of the income group had greater reduction in OOP expenditure (INR 1073 vs INR 770 respectively) and more households averted catastrophic health expenditure (520 vs 245 respectively) as compared to upper 2/3rd in the cohort of 1 lakh women screened with VIA 5 yearly

. Crude incidence rates of HPV-related cancers

	Male	Female
Cervical cancer	-	14.9
Anal cancer	0.1-0.6	0.0-0.5
Vulva cancer	-	0.1-0.5
Vaginal cancer	-	0.0-1.0
Penile cancer	0.4-2.3	-
Oropharynx	2.2	0.4

Table 2. Burden of cervical cancer

	Incidence	Mortality
Annual number of new cases/deaths	96922	60078
Crude rate	14.9	9.2
Age-standardized rate	14.7	9.2
Cumulative risk 0-74 years (%)	1.6	1.0
Ranking of cervical cancer (all years)	2nd	2nd
Ranking of cervical cancer (15-44 years)	2nd	2nd

Table 3. Burden of cervical HPV infection India

	No. Tested	% (95% CI)
HPV prevalence in women with normal cytology	35349	7.0 (6.7-7.2)
HPV 16/18 prevalence:		
Normal cytology	8845	5.0 (4.6-5.5)
Low-grade cervical lesions	177	28.2 (22.1-35.3)
High-grade cervical lesions	253	62.8 (56.7-68.6)
Cervical cancer	2006	83.2 (81.5-84.8)

Table 2: Cost effectiveness of screening strategies

Strategy	Cost per women in INR (US$)	QALY per women	Incremental cost in INR (US$) per QALY gained	Status
VIA: 10 years	3,284 (49.6)	18.4838		ND
HPV: 10 Years	4,189 (63.2)	18.4871	273,904 (4,137)	ND
VIA: 5 Years	**4,457 (67.3)**	**18.5029**	**16,905 (255)**	**ND**
VIA: 3 Years	7,613 (115)	18.5186	200,666 (3,031)	ND
HPV: 3 Years	10,241 (155)	18.5265	333,583 (5,039)	ND
Pap: 3 years	8,100 (122.3)	18.5161		D
Pap: 10 Years	3,503 (53)	18.4796		D
Pap: 5 years	4,853 (73.3)	18.4995		D
HPV: 5 Years	6,036 (91.2)	18.5089		ED

*VIA: Visual inspection with acetic acid; Pap: Papanicolaou test; D: Dominated; ND: Non-Dominated; ED: Extended Dominance; ICER: incremental cost effectiveness ratio; QALY: Quality adjusted life years; INR: Indian National Rupees; US$: United States Dollar

Conclusion

Introduction of screening leads to reduction in occurrence of cervical cancer cases from 19% to 58% along with decrease in cancer deaths from 28% to 70% as compared to no screening in a lifetime cohort of 1 lakh women. This further implies reduction in lifetime risk of cervical cancer among Indian women from 2.18 in the case of no screening to 0.879 - 1.729 with implementation of various screening strategies. Furthermore, the decrease in incidence cancer cases with screening led to savings in terms of lifetime reduction in per women OOP expenditure of INR 636 (USD 9.6) to INR 810 (USD 12.2). Finally, the study concludes that among various screening strategies, VIA every 5 year is the most cost effective screening method in the context of India.

Cost and cost effectiveness

1. The overall lifetime cost incurred by the cohort of 1 lakh women in the scenario of no screening was INR 194 million (USD 2.93 million) and treatment expenditure (on invasive cancer) constituted 90% of this cost (INR 175 million; USD 2.65 million) (Table 6). Similarly, among various screening scenarios, the overall cost ranged from INR 327 (USD 4.94 million) to INR 951 million (USD 14.38 million) and the treatment expenditure constituted 12% (INR 114 million; USD 1.72 million) to 42% (INR 137 million; USD 2.07 million) of the overall cost. This proportional decrease in the cost of treatment during the scenario of screening led to savings in terms of lifetime reduction in per women OOP expenditure of INR 636 (USD 9.6) to INR 810 (USD 12.2) among various screening strategies.

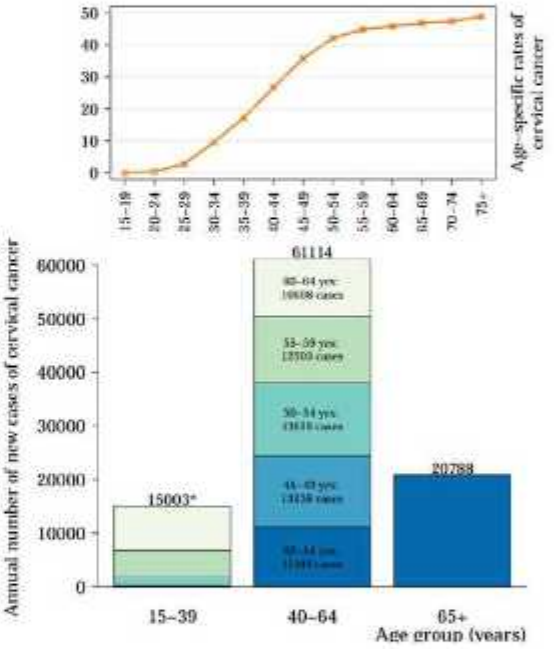


Figure 1: Annual number of cases and age-specific incidence rates of cervical cancer in India (estimates for 2018

2. The incremental cost per QALY gained with screening varied from of INR 33,354 (USD 504) to INR 92,209 (USD 1394) as compared to no screening as shown in table 8. Similarly, the incremental cost per cervical case prevented and death averted was found to be in the range of INR 598,675 (USD 9050) to INR 284,815 (USD 4306) and INR 682,287 (USD 10,314) to INR 264,715 (USD 4002) respectively with various screening strategies as compared to the scenario of no screening.

Acknowledgement:

The study was conducted by Postgraduate Institute of Medical Education and Research (PGIMER) Chandigarh, a resource hub of HTAIn, DHR, MohFW

References:

1) World health Organisation
2) https://hpvcentre.net/statistics/reports/IND.pdf
3) https://hpvcentre.net/statistics/reports/IND_FS.pdf

Expanding Informed Contraceptive Choice for Indian Women: Will Nexplanon Matter?

Expanding Informed Contraceptive Choice for Indian Women: Will Nexplanon Matter?

Policy Brief

Health Technology Assessment in India (HTAIn)
National Institute of Reproductive Health (NIRRH), Mumbai

Recommendations

- ***Addition of Nexplanon to current Family planning scenario in the public health sector of India is found to be cost-effective. It could be considered for program introduction to improve the contraceptive basket of choice in a phased manner. The model shows that larger the proportion of method users, the higher is the cost-effectiveness.***

- ***The pre-requisites recommended for Nexplanon introduction into the public health sector of India are recommended to be:***

  - ***Conducting feasibility and acceptability studies before introducing Nexplanon with due consideration to ethical issues of autonomy and coercion.***
  - ***Creating awareness regarding Nexplanon among all stakeholders and eligible couples.***
  - ***Program introduction could be phased top-down from Medical Colleges to 24X7 PHC level manned by Medical Officers (MBBS), as Nexplanon requires surgical removal.***
  - ***Effective pre-insertion counselling and preparedness for management of side-effects by trained health personnel.***
  - ***Efficient follow-up and tracking mechanism for users of Nexplanon***

Summary

Currently, India's National family planning program has two Long Acting Reversible Contraceptive (LARC) methods: Copper-Intra Uterine Device-380-A and Depot Medroxy Progesterone Acetate (DMPA) three-monthly injections. The policy question of whether another LARC (Nexplanon, a sub-dermal contraceptive implant) should be added to this basket is addressed in this brief. Health Technology Assessment (HTA) has been the chosen approach to explore this question. Literature review, primary data collection for costing and economic evaluation via decision analytic modelling was done as a part of HTA. The decision analytical model, which is a mathematical model, that simulates reality, showed that an additional cost of 17,716 INR will be incurred by the Indian government to gain one Quality adjusted life year (QALY) if Nexplanon is added to the current basket of contraceptive choices in the public health system. This shows that the intervention is very cost-effective, using the comparator as the threshold of GDP per capita.

Context and Gap Analysis

India's journey of providing family planning services to her people has seen multiple shifts in focus and strategy. The current approach tries to balance the demographic (population stabilization) and the health (improving, maternal, adolescent and child health) and economic benefits of family planning. The unmet need of spacing methods of contraception has increased over the past few decades(1). To counter this, one of the strategies has been to roll-out new contraceptives. The launch of two new contraceptives into the public health system of India in recent years: the injectable contraceptive Medroxyprogesterone acetate (MPA) named as 'Antara' and the contraceptive pill, named 'Chhaya'; reiterates this strategy of the National family planning program (2). Including these, we currently have seven modern contraceptive methods in our program.

Indian Council of Medical Research (ICMR) has conducted a phase-3 clinical trial on Implanon during 2004-2008 enrolling 3119 women across India. Implanon was offered along with other existing contraceptive methods available in the National family welfare program. The relative acceptability of Implanon was observed to be 2.1 % among all contraceptive methods and 3.4% among spacing methods.

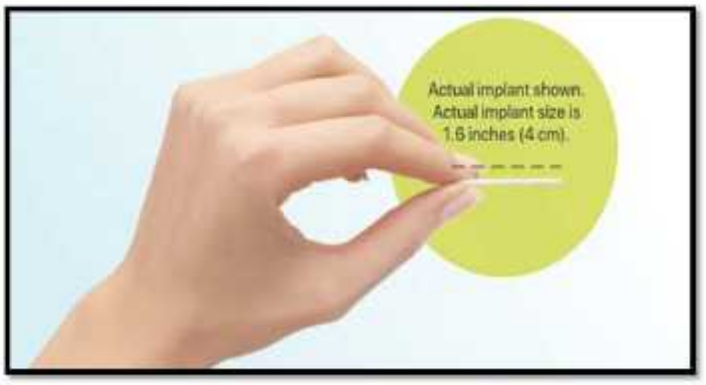


Figure 1: Shows the implant, Nexplanon

Aims and Objective

This policy brief addresses the policy question of whether adding a new contraceptive, Nexplanon into the National Family Planning program in India would be cost-effective. It summarizes the results of a Health Technology Assessment study on Nexplanon, conducted by the HTA Resource Hub, ICMR-National Institute for Research in Reproductive Health, Mumbai.

About Nexplanon

- ***What is it?*** *A subdermal contraceptive implant, the size of a match stick, inserted beneath the skin in the upper arm of the woman. Contains 68 mg of Etonorgestrel (Progestin-only-contraceptive).*
- ***How is it different from Implanon?*** *Nexplanon is bio-equivalent to Implanon but has an addition of barium sulphate that makes it radio-opaque.*
- ***Period of use:*** *Approved for a period of three years*
- ***Clinical effectiveness:*** *Highly effective. Best among long acting reversible contraceptives. 0.05% of Nexplanon users would have an unintended pregnancy during the first year of use(3)*
- ***Safety:*** *Commonest side effect is Menstrual irregularities; with Amenorrhea being highest (30%) and Menorrhagia being at 10%. Headache, acne and weight gain are other reported side-effects(4).*
- ***Return to fertility:*** *Within one month of removal(4)*
- ***Insertion and Removal:*** *Requires doctors who are trained in the procedure of insertion and removal. Removal involves a small incision in the upper arm*

Methods and Approach

To answer the policy question, a 'Health Technology Assessment' (HTA) approach was adopted. It is a systematic evaluation of properties, effects, and/or impacts of health technology. HTA is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology(5). As per the HTA India reference case, QALY is used as a measure of outcome (6). It is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health (7)The following steps were followed for the HTA:

1) A systematic review (A systematic review is an appraisal and synthesis of primary research papers using a rigorous and clearly documented methodology in both the search strategy and the selection of studies (8). for clinical effectiveness of Nexplanon
2) Extensive literature review for other contraceptive methods, costing, cost-effectiveness, quality of life during contraceptive use and related states and HTA on Nexplanon
3) Primary data collection for collecting cost data from four levels of public health system in Maharashtra
4) Estimation of age specific transition probabilities from Calendar data of National Family Health Survey-4
5) Review of literature on social and ethical issues
6) An economic evaluation to assess whether adding Nexplanon to the current system would be cost-effective. This involved conceptualization and running a decision analytic model, in our case a Markov model (shown in Figure 2).

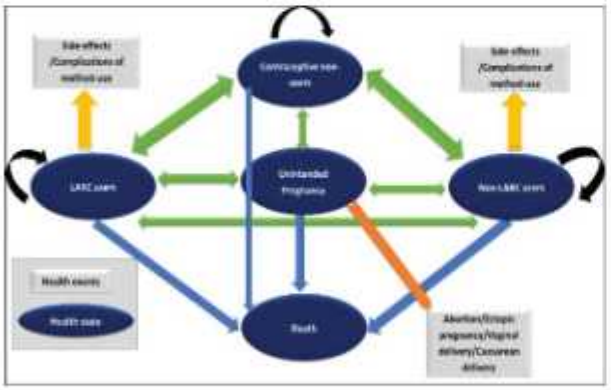


Figure 2: A Decision Analytic Model: Markov Model

1) When a simulated cohort of 15-year olds (from census 2011) went through the markov model, experiencing the mentioned health states, about 10.48 lakh pregnancies 1.17 lakh maternal deaths and 10. 22 lakh child births could be averted by adding Nexplanon to the public health system.
2) Increase in contraceptive users will improve cost-effectiveness (shown by sensitivity analysis)

Results

The economic evaluation using age specific data on contraceptive use demonstrates that an additional cost of INR 17,716 would have to be incurred by the government to gain one additional Quality adjusted life year (QALY). This is well within the threshold of GDP per capita (about 137945 INR). Represented in Figure 3.

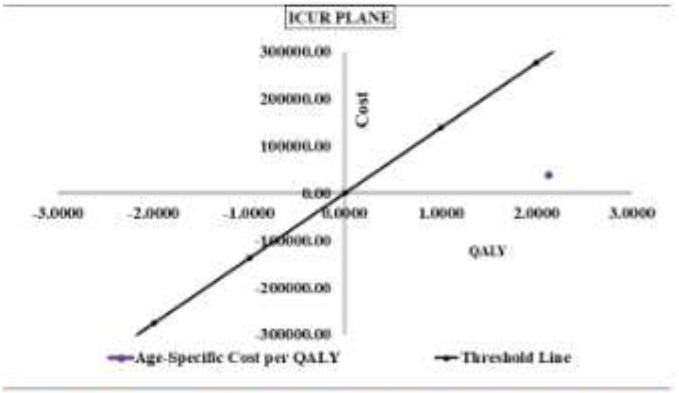


Figure 3. Incremental Cost-Utility Ratio. (Additional cost incurred by government to gain one QALY)

Budget Impact Analysis

A Budget Impact Analysis (BIA) was done to assess how introduction of Nexplanon into the Public health system of India would impact the budget of India. We considered the additional expenditure for Nexplanon over a period of three years at different levels of public health care facilities. This was expressed as a percentage of family planning budget and as a percentage of health budget. This is depicted in figure number 4.

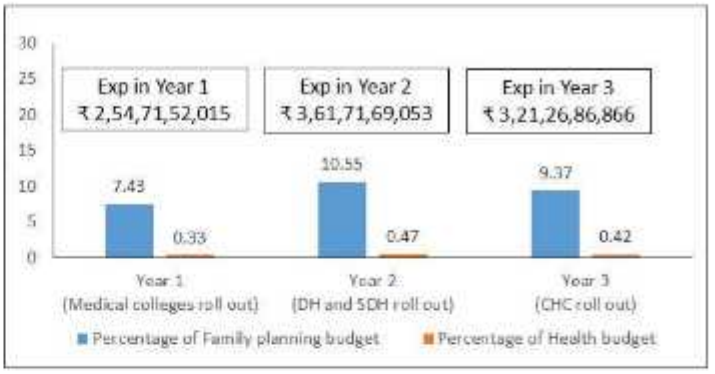


Figure 4. Expenditure for Nexplanon as a percentage of Family planning Budget and Total health budget

Figure 4 shows that expenditure towards Nexplanon will amount to less than 0.5% of the health budget of the country. The expenditure for Nexplanon (A) included product of price of Nexplanon device and estimated number of acceptors, information education and communication activities, training of health personnel, incentives on acceptance of Nexplanon and management of side-effects. The savings (B) due to unintended pregnancies that were prevented due to Nexplanon introduction were calculated. To calculate net savings over a period of three years, A was subtracted from B. Net savings were estimated to be at ₹ 76,04,85,91,940.

References

1. *Chaurasia AR, Singh R. 40 Years of Planned Family Planning Efforts In India. :23.*
2. *National Family Planning Programme [Internet]. Hum Do | Family Planning. 2017 [cited 2019 Feb 1]. Available from: https://humdo.nhp.gov.in/about/national-fp-programme/*
3. *Trussell J. Contraceptive failure in the United States. Contraception. 2011 May;83(5):397–404.*
4. *Hohmann H, Creinin MD. The contraceptive implant. Clin Obstet Gynecol. 2007 Dec;50(4):907–17.*
5. *WHO | Health technology assessment [Internet]. WHO. [cited 2019 Feb 4]. Available from: https://www.who.int/medical_devices/assessment/en/*
6. *HTA in India A Manual by DHR MOHFW . Oct 2018*
7. *Glossary [Internet]. NICE. [cited 2019 Feb 4]. Available from: https://www.nice.org.uk/glossary?letter=q*
8. *What is a Systematic Review - Systematic reviews - Library guides at QUT [Internet]. [cited 2019 Feb 4]. Available from: https://libguides.library.qut.edu.au/systematicreviews*
9. *Kuntz K, Sainfort F, Butler M, Taylor B, Kulasingam S, Gregory S, et al. Overview of Decision Models Used in Research [Internet]. Agency for Healthcare Research and Quality (US); 2013 [cited 2019 Feb 4]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK127474/*

Diagostic Efficacy of Digital Hemoglobinometer (TrueHB), Hemocue and Non-Invasive Devices for Screening Patients For Anaemia in the Field Settings

Diagnostic efficacy of digital hemoglobinometer (TrueHb), HemoCue and non- invasive devices for screening patients for anemia in the field settings

Health Technology Assessment in India (HTAIn)
Indian Institute of Public Health, Delhi (PHFI)

Policy Brief

Recommendations

- *Invasive devices shows overall better performance than Non-invasive devices in the field settings.*
- *For screening of Anemia, HemoCue (AUC 0.92, 95% CI 0.88-0.94) and True Hb (AUC 0.85, 95% CI 0.83-0.89) are comparable with no statistically significant difference between the two.*
- *For screening of Severe Anemia, TrueHb (AUC 0.91, 95% CI 0.85-0.97) fares better than all other devices including HemoCue (AUC 0.73, 95% CI 0.67-0.79)*
- *Both True Hb and HemoCue overestimates Hb in extreme cold weather conditions.*
- *Overall it appears that TrueHb is better than HemoCue in estimating Hb including severe anemia*
- *The cost of True Hb device is less but the running cost is high as compared to HemoCue.*

Summary

A Health Technology Assessment was conducted to establish the diagnostic accuracy of Digital Hemoglobinameter TrueHb (newer version), HemoCue and Non invasive Masimo and AJO spectroscopic device against automated analyzers (gold standard) for screening of anemia in laboratory and community settings. Invasive devices shows overall better performance than Non-invasive devices in the field settings. Among the invasive devices TrueHb fares better than all other devices including HemoCue in case of severe anemia.

Background

Anaemia, defined as a low blood haemoglobin concentration and it has been shown to be a public health problem that affects low-, middle- and high-income countries and has significant adverse health consequences, as well as adverse impacts on social and economic development. Most reliable methods for hemoglobin estimation requires equipped laboratory that may not be available everywhere, especially rural areas. Moreover these methods are not always cost effective and have operational challenges. Therefore, it is important to evaluate simple, cost-effective, user friendly and portable methods for diagnosis of anaemia where there are no or minimal laboratory facilities.

A comprehensive Health technology assessment (HTA) was conducted to assess and to obtain the evidence against the clinical and cost-effectiveness of various devices for hemoglobin estimation. The study was intended to get a scalable method of hemoglobin estimation, even to "Hard to Reach" can be obtained and this method could be incorporated with the public health programs for anemia prevention. The primary objective of the study was to establish the diagnostic accuracy of Digital Hemoglobinometer TrueHb (newer version), HemoCue and non invasive devices (AJO Spectroscopic device and Masimo Pulse Oximeter) against automated analyzers (gold standard) for screening of anemia in laboratory and community settings. The study also aimed to establish the level of agreement in the classification of anemia as reported by ANM (using the device that will be found better) and laboratory technician. The study concluded Invasive devices shows overall better performance than Non-invasive devices in the field settings.

Devices available for Hemoglobin Estimation

(a) (b)

Figure 1: Invasive (a) TrueHb (b) HemoCue

(c) (d)

Figure 2: Non-Invasive (c) Masimo's device (d) AJO spectroscopic device

Findings

- A total number of 1398 patients were included in the analysis, 752 in Puducherry and 646 in Kolkata. Their distribution as per ICMR Classification of Anemia is given below (Table 1).
- Table 2 shows the Diagnostic Accuracy Parameters for testing anemia and no anemia by ANM/ frontline workers (capillary sample) is given below. The overall performance of Hemocue is better as compared to all other devices with a sensitivity of 89.9% and Area under ROC of 0.92.

Table 1

Hb % (in gm%)	Total (n=1398)	Puducherry (n=752)	Kolkata (n=646)
Mean (SD)	11.64 (±2.7)	12.31 (±2.4)	10.8 (±2.8)
Range	2-20.2	2-20.2	4.2-18.6
No Anemia (Hb>11gm%)	938 (67.1%)	580 (77.1%)	358(55.4%)
Mild anaemia(Hb-10.10.9 gm%)	124 (8.8%)	58 (7.7%)	66 (10.2%)
Moderate anaemia (Hb 7-9.9 gm%)	240 (17.2%)	94 (12.5%)	146 (22.6%)
Severe anaemia (Hb<7 gm%)	96 (6.8%)	20 (2.6%)	76 (11.7%)

Table 2

Device	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive predictive value (PPV) (95% CI)	Negative Predictive value (NPV) (95% CI)	Positive likelihood ratio (LR+) (95% CI)	Negative likelihood ratio (LR-) (95% CI)	Area under ROC (95% CI)
HemoCue	89.9% (85.1-93.6)	93.1 % (90.5-95.0)	86.7 (81.6-90.9)	95 (92.3-96.8)	13.37 (9.49-18.94)	0.11 (0.07-0.16)	0.92 (0.89-0.94)
TrueHb	86.3% (81.0-90.6)	84.7 (81.3-87.6)	71.9 (66.0-77.3)	93.2 (90.4- 95.3)	5.63 (4.56-6.99)	0.16 (0.12-0.21)	0.85 (0.83-0.88)
Masimo's Pulse Oximetry Device	66.0% (59.2- 72.4)	97.0% (95.5- 98.2)	92.6 (87.2-96.3)	85.6 (82.2- 88.6)	21.99 (14.33- 46.96)	0.35 (0.29-0.42)	0.82 (0.78-0.85)
AJO Spectroscopic Device	56.4% (48.8- 63.7)	75.4% (71.3-79.2)	46.6 (39.8-53.4)	82 (78-85.5)	2.29 (1.87-2.81)	0.58 (0.49-0.69)	0.66 (0.62-0.70)

Table 3

Device	Sensitivity % (95% CI)	Specificity % (95% CI)	Positive predictive value (PPV) (95% CI)	Negative Predictive value (NPV) (95% CI)	Positive likelihood ratio (LR+) (95% CI)	Negative likelihood ratio (LR-) (95% CI)	Area under ROC (95% CI)
Hemocue	46.8 (34.0-59.9)	99.2 (98.1-99.7)	85.3 (68.9-95)	94.8 (92.7-96.4)	56.9 (22.6-140.2)	0.54 (0.42-0.68)	0.73 (0.67-0.79)
True Hb	87.1 (70.2-95.4)	95.7 (93.9-97.1)	68.2 (54.7-62.0)	99.4 (98.4-99.8)	20.15 (13.77-29.5)	0.13 (0.05-0.34)	0.91 (0.83-0.97)
Masimo Pulse Oximetry Device	17 (7.6-30.8)	95.6 (99.1-102)	88.9 (51.8-99.7)	93.8 (91.7-95.6)	101.2 (12.94-792.6)	0.83 (0.73-0.95)	0.58 (0.53-0.64)
AJO Spectroscopic Device	28 (12.1-49.4)	95.9 (94-97.1)	21.2 (9-38.9)	97.1 (95.5-98.3)	6.81 (4.27-14.16)	0.75 (0.59-0.96)	0.62 (0.53-0.71)

- Table 3 shows Diagnostic Accuracy Parameters for testing severe anemiaby ANM/ frontline workers (capillary sample) is given below. The overall performance of TrueHb fares better than any other device with a sensitivity of 87.1% and area under ROC of 0.91.
- Projected costs of resources for each test for measuring Hemoglobin (in INR) is given in table 4.
- Costs of the device and running cost for each test for measuring Hemoglobin (in INR)

Table 4

Component	HemoCue		TrueHb		AJO		Masimo's	
	Rural	Urban	Rural	Urban	Rural	Urban	Rural	Urban
Human resource (ANM)	16.7 (13.9%)	17.7 (10.7%)	17.1 (12.5%)	17.5 (9.9%)	18.1 (16.5%)	18.1 (12.9%)	16.6 (15.8%)	18.3 (12.6%)
Equipment (device, charger, adapter)	0.2 (0.1%)	0.2 (0.1%)	0.004 (0%)	0.004 (0%)	0.05 (0.04%)	0.05 (0.04%)	3.4 (3.2%)	3.4 (2.3%)
Accessories (Micro cuvettes/ strips)	11.9 (9.9%)	11.9 (7.2%)	26.4 (19.3%)	26.4 (14.9%)	0.0 (0%)	0.0 (0%)	0.0 (0%)	0.0 (0%)
Consumables (items used in the test)	12.3 (10.2%)	19.7 (12.0%)	12.3 (9.0%)	19.7 (11.1%)	6.1 (5.6%)	4.3 (3.1%)	6.1 (5.8%)	4.3 (3.0%)
Non-medical (items in facility rooms)	78.8 (65.5%)	113.4 (69.0%)	80.8 (59.0%)	112.3 (63.3%)	85.4 (77.6%)	116.4 (82.9%)	78.3 (74.7%)	117.2 (81.0%)
Capital space (rental)	0.4 (0.3%)	1.6 (0.9%)	0.4 (0.3%)	1.5 (0.9%)	0.5 (0.4%)	1.6 (1.1%)	0.4 (0.4%)	1.6 (1.1%)
Total cost / test	120.3	164.3	137.0	177.4	110.1	140.4	104.8	144.7

Table 5

Component	HemoCue		TrueHb	
	Rural	Urban	Rural	Urban
Equipment (device, charger, adapter)	0.2	0.2	0.004	0.004
Accessories (Microcuvettes/ strips)	11.9	11.9	26.4	26.4
Consumables (items used in the test)	12.3	19.7	12.3	19.7
Total cost per unit test	24.4	31.8	38.7	46.1

Conclusion

Invasive devices shows overall better performance than Non-invasive devices in the field settings and among the invasive devices TruHb appeared to perform better be . Overall it appeared that TrueHb is better than HemoCue in estimating Hb including severe anemia. However, both the devices over estimate Hb in cold and high altitude. TrueHb is also cheaper than HemoCue but the running cost is higher than HemoCue.

Health Technology Assessment of Uterine Ballon Tamponade for Management of Postpartum Haemorrhage in India

सत्यमेव जयते

Health Technology Assessment in India
Department of Health Research, MoHFW

Health Technology Assessment of Uterine Balloon Tamponade for Management of Postpartum Haemmorhage in India

SUMMARY

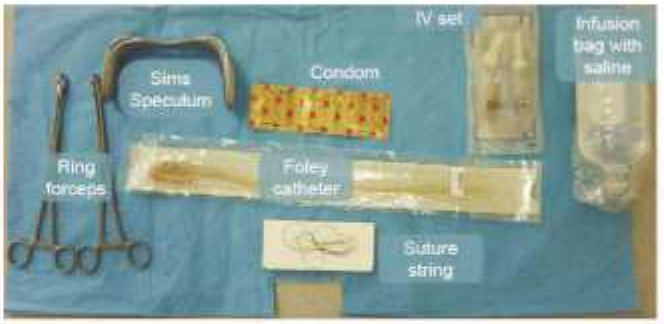
POLICY BRIEF

In the year 2015, there were an estimated 303,000 maternal deaths globally. Nearly 99 % of all maternal deaths occur in developing countries with more than half of them occurring in sub- Saharan Africa and one third occurring in South Asia. One of the top preventable and treatable causes of maternal death is post-partum hemorrhage. Operational Guidelines on Maternal and Newborn Health in India for management of PPH, guidance Note on PPH management and Dakshata Guidelines recommend use of intrauterine balloon tamponade for uterine atony cases or refractory bleeding cases when medical management fails. Various Uterine Balloon Tamponade devices available across the world includes condom uterine balloon tamponade device, ESM UBT, packed UBT devices like Bakri UBT. A decision tree model was used for a hypothetical cohort of women with atonic PPH in India. A primary costing study across five public health centers in Maharashtra centers was performed. The QALYs per woman in condom UBT, ESM UBT and Bakri UBT were 23.767, 23.769 and 23.763 respectively showing a very minute difference in QALYs.

Objective: To evaluate cost-effectiveness of Condom Uterine balloon device (that has been recommended in Govt. of India's guidelines for management of PPH) against ESM-UBT and Bakri uterine balloon tamponade techniques available for management of atonic type of postpartum hemorrhage.

Need of the Study:

Given the availability of different types of uterine balloon tamponade and effectiveness of UBTs in management of PPH, the Indian government is keen on introducing a cost effective uterine balloon tamponade in the public health system. No studies describe cost effectiveness of uterine balloon tamponade in India.

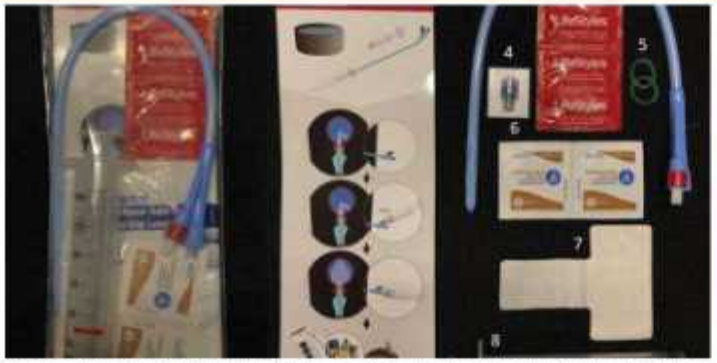


Condom Uterine balloon tamponade (source: Jhpiego)

Bakri Uterine balloon tamponade (source: Cook Medical Products)

Recommendations:

- Analysing the net health benefits based on QALY, there is less than 0.1 difference between the Condom, Bakri & ESM-UBT alternatives; indicating the similarity in health benefits of the three UBTs. ICUR value of ESM UBT against Condom UBT shows that ESM UBT is only 42.8% cost-effective. Good quality efficacy data on ESM-UBT should be generated by doing RCTs in Indian settings, before any decision regarding the same is undertaken. Considering the above statements, decision-making regarding ESM UBT's introduction into the public health system must be made with caution.
- If ESM-UBT is considered for introduction, it should be noted that to gain the benefits estimated by the model, a universal coverage needs to be attained (100%) which currently seems to be very challenging given the current poor use of condom UBT in spite of being recommended in the Govt. of India Guidelines.



Every second matters Uterine balloon tamponade a) Every Second Matters for Mothers and Babies – Uterine Balloon Tamponade (ESM-UBT) package. b) ESM-UBT package made of 8 components: 1/Instruction card, 2/2-way Foley catheters (retention catheters), 3/Condom, 4/Check valve for injection site, 5/O-Rings, 6/Povidone-iodine prep pads, 7/Catheter Holder, and 8/Syringe.

Findings: Of total 2,07,85,669 births in India in the year 2017-18, by applying incidence of PPH and the effectiveness of medical management, we estimated that 59,862 women will require UBT. In this cohort, our model estimates the total costs, deaths, QALYs, DALYs and surgeries of each of the three decision trees as presented in Table 1.

Table 1: Results of the three decision trees in terms of costs and outcomes per woman

	Condom UBT	ESM UBT	Bakri UBT
Total costs in INR (Health system perspective)	₹ 3,858.54	₹ 3,786.29	₹ 13,635.45
Total costs in INR (Societal perspective)	₹ 13,671.77	₹ 12,096.06	₹ 22,300.75
Total QALYs	23.77	23.77	23.76
Total DALYs	0.22082	0.20291	0.28829

Table 2 shows the incremental costs and outcomes, for the two comparisons i.e. ESM UBT vs. Condom UBT and Bakri UBT vs. Condom Balloon. Primary and secondary outcomes are presented in Table 3

Table 2: Incremental costs and outcomes of the two comparisons in UBT per woman

	ESM UBT Vs. Condom UBT	Bakri UBT Vs. Condom UBT
Incremental costs (Health system)	-₹ 72.25**	₹ 9,776.91
Incremental costs (Societal perspective)	-₹ 1,575.71**	₹ 8,628.98
Incremental QALYs	0.00131	-0.004926
Incremental DALYs	-0.0179	0.0675

** Negative sign implies that the value of first comparator is lesser than the second one

Table 3: ICURs of the two comparisons of UBT (Societal perspective)

	ESM UBT Vs. Condom UBT	Bakri UBT Vs. Condom UBT
ICUR (QALYs)	-12,05,590	-17,51,769.25##
ICUR (DALYs)	88,009.28##	1,27,880.92

** Negative values indicate that either the numerator or denominator is negative
These values are positive because both numerator (Incremental costs) as well as denominator (Incremental outcomes) are negative

Table 4: Maternal deaths averted as compared to current scenario (cause specific MMR)

	Total Deaths as per model	Deaths averted (compared to current scenario**)
Condom UBT	283.00	10038.16
ESM UBT	280.03	10041.13
Bakri UBT	294.19	10026.97

** Current scenario specifies deaths due to current cause specific mortality in India i.e. PPH. The current scenario can have situations with varying use of different UBTs as no such specific information is currently available

References:

1) Maternal mortality [Internet]. [cited 2019 Jul 19]. Available from: https://www.who.int/news-room/fact-sheets/detail/maternal-mortality

2) Sample Registration Survey. (2018). SPECIAL BULLETIN ON MATERNAL MORTALITY IN INDIA 2014-16. MMR India [Internet]. 2016; Available from: http://www.censusindia.gov.in/Vital_statistics/SRS_Bulletins/MMR%e2%80%93Bulletin-2014-16.pdf

3) Balloon Tamponade for Atonic Primary Postpartum Hemorrhage - Tabular View - ClinicalTrials.gov [Internet]. [cited 2019 Jul 25]. Available from: https://clinicaltrials.gov/ct2/show/record/NCT02430155

Table 5: ICURs (QALYs) and Net Benefit with UBT alternatives

	Societal Costs	QALYs	Net Health Benefit (QALYs)	Net Monetary Benefit (INR)
Condom UBT	₹ 13,671.77	23.767	23.67	₹ 32,77,376.36
ESM UBT	₹ 12,096.06	23.769	23.68	₹ 32,79,133.05
Bakri UBT	₹ 22,300.75	23.763	23.60	₹ 32,68,065.30

Table 6: Annual Deaths and surgeries averted, monetary savings in different coverage scenarios

	ESM UBT Deaths	Condom UBT Deaths	Deaths averted by ESM UBT	ESM UBT surgeries	Condom UBT surgeries	Surgeries averted by ESM UBT	Costs saved due to reduced surgeries
100% Coverage	280	283	3	2808	3919	1111	₹ 85,61,377
50% coverage	656	658	2	31335	31891	556	₹ 42,84,542
20% coverage	882	883	1	48452	48674	222	₹ 17,10,734

Table 4 shows maternal deaths averted due to intervention. ICURs are mentioned in the table 5. Annual deaths and surgeries averted, monetray savings are mentioned in Table 6.

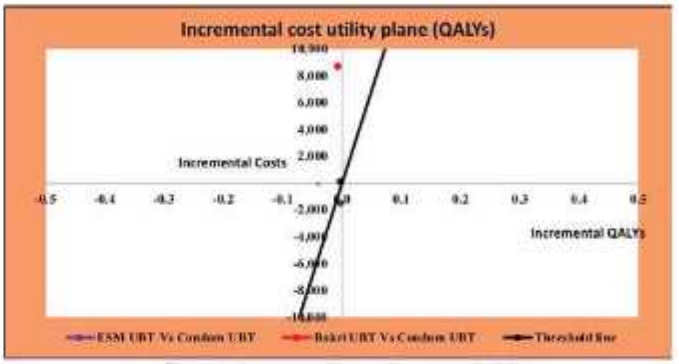


Figure 1: Incremental cost utility plane (QALYs)

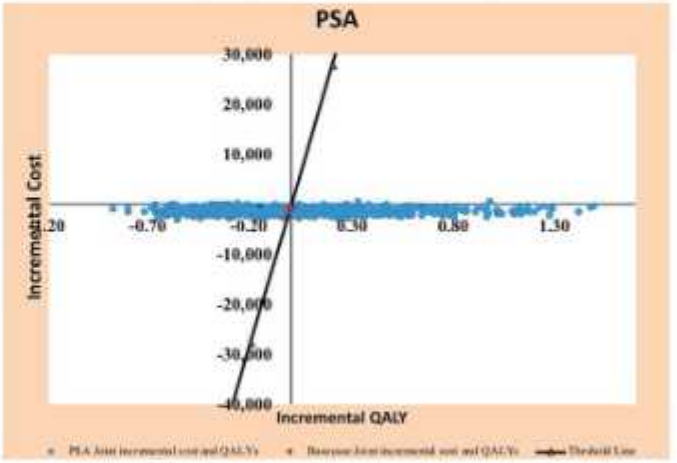


Figure 2: Cost-effectiveness plane showing Probabilistic sensitivity analysis

Budget impact analysis shows that annual additional budget required for introduction of ESM UBT into India's public health system is estimated to be 0.004 % of the total health budget and 0.005% of the total maternal and child health budget.

Conclusion:

Clinical effectiveness data available for ESM-UBT is currently limited to a few case studies. ICUR values suggest ESM-UBT to be cost-effective as compared to condom UBT, but probabilistic sensitivity analysis shows that only a 43% probability that ESM-UBT are cost-effective given the uncertainties. Decision making for introducing ESM-UBT should be made with caution.

Acknowledgement:

The study was conducted by the "HTAIn Resource Hub of the National Institute for Research in Reproductive Health."

Evaluation of Pulse Oximetry as a Tool to Prevent Childhood Pneumonia Related Morbidity and Mortality

Policy Brief

Health Technology Assessment in India (HTAIn)
Department of Health Research, MoHFW
Regional Technical Resource Centre for HTA, SCTIMST Trivandrum

Evaluation of pulse oximetry as a tool to prevent childhood pneumonia related morbidity and mortality

Summary

Pneumonia is the leading cause of death in children <5 years of age and it is estimated that pneumonia is responsible for 15% of childhood deaths worldwide.[1,2] This study primarily aimed to determine the cost-effectiveness of pulse oximetry devices in the screening of childhood pneumonia by health workers in resource-poor settings. Using a systematic review, a decision-tree modeling exercise and a budget impact analysis, the following findings were observed;

- ***The evidence from the systematic review was in favour of the use of pulse oximetry along with the existing guidelines***
- ***The deaths averted due to childhood pneumonia when IMCI+PO is used instead of IMCI alone is 21 and 36 per 1000 patients when the sensitivity of pulse oximetry is assumed at 70% and 85% respectively. The ICER for both sensitivities shows a negative value suggesting that PO, when added to the existing IMCI, would become a cost-saving intervention.***
- ***The costing and budget impact analysis showed that the introduction of pulse oximeter along with existing IMCI will increase the cost per patient per year by INR 0.36 only. The overall cost of roll-out of pulse oximeters in PHC's in India would amount to INR 9,04,59,000***

Recommendations

- Integrated Management of Childhood Illness (IMCI) guidelines along with Pulse Oximetry (PO) is a cost-saving prognostic tool as compared to IMCI alone provided there is supplementary oxygen availability.
- IMCI should be the basic prognostic tool for childhood pneumonia but PO is beneficial in the referral of cases. Pulse oximetry, in general, may be used to measure oxygen saturation in cases wherever required.
- Among outpatients with pneumonia, peripheral oxygen saturations (SpO2)<90% were associated with increased morbidity and mortality. A hospital admission threshold of <92% would be safer and clinically better justified. All severe cases irrespective of the availability of Pulse oximeter will be referred to a tertiary care facility for expert management.
- In tertiary care, when SpO2 ≥ 80%, pulse oximetry has high accuracy in estimating oxygen saturations and may be used instead of (Arterial Blood Gas) ABG; in patients with SpO2 < 80%, however, the evaluation of oxygenation by pulse oximeter is not a good substitute for ABG analyzer.
- In tertiary care hospitals, especially in ICU's, multipara monitors which measures advanced parameters like ECG, Respiration, Pulse Rate, Temperature should be preferred

Background

Globally, pneumonia is the leading cause of death in children <5 years of age. Despite interventions being available, it is estimated that pneumonia is responsible for 15% of childhood deaths worldwide.[1,2] The present recommended strategy for diagnosis and prognosis of pneumonia is IMCI tool for professional health workers at health facilities and Integrated Community Case Management (iCCM) tool for community health workers. In the absence of appropriate prognostic tools at the frontline, currently recommended World Health Organization (WHO) guidelines for integrated management of childhood illness (IMCI) often lead to an overuse of antibiotics and the under-referral of patients with severe pneumonia who require hospital care.[3,4] Currently, the identification of these IMCI symptoms remains inconsistent and unreliable among health-care personnel.

Objectives:

To determine the effectiveness (i.e. sensitivity, specificity, positive and negative predictive values) and cost-effectiveness of pulse oximetry devices in the screening of childhood pneumonia by health workers in resource-poor settings (LMICs) & to identify whether children have lower mortality rates, lower morbidity, and shorter length of stay where pulse oximeters are used to inform diagnosis and treatment compared with where pulse oximeters are not used.

Methods:

A systematic literature review (SLR) was conducted with PICO as a population consisting of patients aged 0-5 years with pneumonia in low and middle income countries (LMICs). Intervention was IMCI +Pulse Oximetry and the comparator was IMCI alone. The outcomes were diagnostic accuracy of pulse oximetry, cost per Quality Adjusted Life Years (QALY) gained, and incremental deaths averted with the introduction of pulse oximetry. The SLR was conducted using electronic databases such as Database of Cochrane, PubMed, Web of Science, ProQuest, Google Scholar and WHO Global Health Library, with no language restrictions.

We extracted the costs of the IMCI implementation in Indian primary healthcare settings from previous studies. The average number of hospital visits (outpatient and inpatient) were calculated including the associated out of pocket health expenditure for each category. We indexed the amount to the current INR rate using inflation tools. Pulse oximeters which fit the predefined specifications were shortlisted and their net average cost was taken for costing purposes. The training cost was derived from consultation with the program implementers.

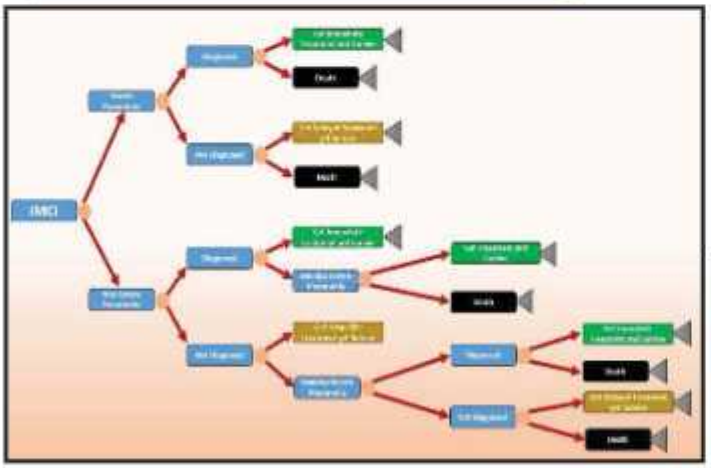
A decision tree model was developed for estimating the Incremental Cost Effectiveness Ratio (ICER). For populating the model, we required data pertaining to disease progression, care-seeking, healthcare, prognostic and cost parameters. In addition to data gathered from SLR, we did a scoping review wherever necessary to extract data for the decision model.

Systematic Review – Result Summary

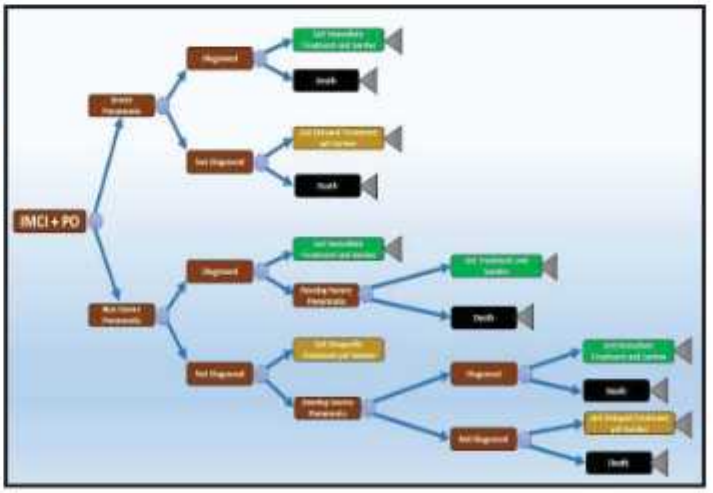
Out of the seven studies which were eventually shortlisted, 6 of them favoured the use of Pulse Oximetry. In general, the states having a high prevalence of pneumonia risk factors and poor access to health services had a higher burden of pneumonia cases and deaths.[5] Although hypoxemia is common, the absence of routine pulse oximetry results in most hospitalized hypoxemic children not receiving available oxygen treatment. It is important to recognize that referral/ admission rates are dependent on the thresholds for oxygen therapy.

Clinical signs alone are poor predictors of hypoxemia, and using pulse oximetry in resource-poor health facilities to target oxygen therapy is likely to save costs. The fingertip pulse oximeter was deemed the most usable and scalable in most of the studies. There is evidence to indicate that pulse oximetry may lead to improved health outcomes, with lower mortality rates (when combined with improved/adequate oxygen administration); pulse oximetry may change physicians' decisions regarding illness severity, and increase hospital admissions related to previously unrecognized hypoxemia. Oximetry can reduce resource waste by indicating when to end treatment, and by decreasing false positives.

Economic Evaluation – Result Summary



A decision tree was parameterized on a spreadsheet to estimate the incremental cost-effectiveness of implementing pulse oximetry + IMCI program over IMCI alone. A lifetime study horizon starting from the base year of 2019 was considered appropriate to cover all costs and effects comprehensively. Pneumonia has a predominant risk within the first 5 years of life, with gradually declining risk until about 15 years.



In absolute terms, the introduction of pulse-oximetry devices to IMCI is estimated to result in annual reductions in pneumonia deaths in India. The deaths averted per year for PO2 within a cohort of 10000 pneumonia cases would be 367 if the sensitivity is 85% and 213 if the sensitivity is 70%. Owing to the large under-five population (128 million) India could significantly reduce the mortality due to childhood pneumonia by the introduction of PO into the existing IMCI. We found that the ICER is -117.32 and -18.75 when the sensitivity of the IMCI+PO is 85% and 70% respectively. This suggests that it is a cost-saving intervention from a societal perspective.

Results of Cost-effectiveness of IMCI + PO as compared to IMCI Alone

Intervention	Cost (in INR)	LY	QALY	ICER
IMCI (0.55)	3,22,47,526	601736.1	601736.1	-117.32
IMCI+PO (0.85)	2,95,03,112	625127.9	625127.9	
Intervention	**Cost (in INR)**	**LY**	**QALY**	**ICER**
IMCI (0.55)	3,22,47,526	601736.1	601736.1	-18.7521
IMCI+PO (0.7)	3,19,93,096	615304.17	615304.17	

Number given in brackets in the first column is the sensitivity of each intervention

Budget Impact Analysis - Results Summary

The cost of the roll-out of pulse oximeters for 1.5 lakh health and wellness centres

- Number of health and wellness centres: 150000
- Cost of PO: INR 2500
- Overall cost of PO: 150000*2500 = INR 37,50,00,000

But, as on 31st March 2017, there were only 25650 Primary Health Centres (PHCs) functioning in India[6]. If we were to provide a pulse oximeter to all the PHC's in India, the cost of the roll-out of pulse oximeters would be INR 6,41,25,000 (25650*2500). The cost of training frontline health workers to use PO is INR 2,63,34,000. The overall cost of the roll-out of pulse oximeters in PHC's would amount to INR 9,04,59,000. The number of functioning Community Health Centres (CHCs) in India was 5510 as on 31st March, 2016.[7] Each community health centre would require at least 4 finger-tip pulse oximeters which should ideally be placed in the casualty, OP and inpatient ward. The cost of equipping all the CHC's with the specified number of pulse oximeters amount to INR 5,51,00,000 (5510*2500*4).

Key Findings

- ➔ Pulse oximetry, used in conjunction with clinical guidelines like the IMCI, is beneficial in screening and diagnosis of pneumonia in the community. It is important to note here that such diagnoses have to be coupled with the prompt provision of oxygen therapy at the community level institutions, in order to reap the benefits of a more early and accurate diagnosis.
- ➔ The deaths averted due to childhood pneumonia when IMCI+PO is used instead of IMCI alone is 21 and 36 per 1000 patients when the sensitivity is 70% and 85%. When we take a lifetime horizon this results in a QALY gain of 1356 and 2339 years respectively.
- ➔ The ICER for both sensitivities shows a negative value suggesting that PO, when added to the existing IMCI, would become a cost-saving intervention.
- ➔ The costing and budget impact analysis showed that the introduction of pulse oximetry along with existing IMCI will increase the cost per patient per year by INR 0.36 only.
- ➔ The overall cost of the roll-out of pulse oximeters in PHC's in India would amount to INR 9,04,59,000. The cost of equipping all the CHC's with the specified number of pulse oximeters amount to INR 5,51,00,000. The overall domestic general government health expenditure per capita for India is US$61.40[8]. For a three trillion dollar economy which spends 1.15% of its GDP on healthcare, the implementation of the IMCI+PO would cost only 0.003% of its annual budget.
- ➔ The decision tree was able to show that on top of the large reduction in deaths due to pneumonia, the addition of pulse oximetry to IMCI has the potential to increase the correct treatment of severe cases. Thus, pulse oximetry appears to be both an effective and cost-effective option for the government to contemplate implementation of the same in the primary healthcare institutions.
- ➔ In the case of IMCI+PO, the value of ICER was less than the GDP per capita in all simulations as part of the probabilistic sensitivity analysis. The sensitivity analysis also showed that the majority of the values fell into the right lower quadrant, signifying ICER to be negative with gain in QALYs and less cost incurred in the intervention scenario.

Conclusion

The evidence from the systematic review was overwhelmingly in favour of the use of pulse oximetry along with the existing guidelines. **The deaths averted due to childhood pneumonia when IMCI+PO is used instead of IMCI alone is 21 and 36 per 1000 patients when the sensitivity of pulse oximetry is assumed at 70% and 85% respectively.** When we take a lifetime horizon this results in a QALY gain of **1356 and 2339 years respectively**. The ICER for both sensitivities shows a negative value suggesting that **PO, when added to the existing IMCI, would become a cost-saving intervention.** The costing and budget impact analysis showed that the introduction of pulse oximeter along with existing IMCI **will increase the cost per patient per year by INR 0.36 only. The overall cost of roll-out of pulse oximeters in PHC's would amount to INR 9,04,59,000**. The cost of equipping all the CHC's with the specified number of pulse oximeters amount to INR 5,51,00,000. The overall domestic general government health expenditure per capita for India is US$61.40[7]. For a three trillion-dollar economy which spends 1.15% of its GDP on healthcare, the implementation of the IMCI+PO would cost only 0.003% of its annual budget.

References

1. Rudan I, Boschi-Pinto C, Biloglav Z, Mulholland K, Campbell H. Epidemiology and etiology of childhood pneumonia. Bull World Health Organ. 2008 May;86:408-416B.

2. Liu L, Oza S, Hogan D, Perin J, Rudan I, Lawn JE, et al. Global, regional, and national causes of child mortality in 2000–13, with projections to inform post-2015 priorities: an updated systematic analysis. The Lancet. 2015 Jan 31;385(9966):430–40.

3. Izadnegahdar R, Cohen AL, Klugman KP, Qazi SA. Childhood pneumonia in developing countries. Lancet Respir Med. 2013 Sep 1;1(7):574–84.

4. Rodrigues CMC. Challenges of Empirical Antibiotic Therapy for Community-Acquired Pneumonia in Children. Curr Ther Res. 2017 Jan 1;84:e7–11.

5. Farooqui H, Jit M, Heymann DL, Zodpey S. Burden of Severe Pneumonia, Pneumococcal Pneumonia and Pneumonia Deaths in Indian States: Modelling Based Estimates. PLoS ONE [Internet]. 2015 Jun 18 [cited 2019 Jul 24];10(6). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4472804/

6. State/UT-wise Functioning of Primary Health Centres as on 31st March 2017 [Internet]. Open Government Data(OGD) Community. [cited 2019 Aug 17]. Available from: https://community.data.gov.in/state-ut-wise-functioning-of-primary-health-centres-as-on-31st-march-2017/

7. Functioning Community Health Centres (CHCs) as on 31.03.2016 [Internet]. Open Government Data(OGD) Community. [cited 2019 Aug 20]. Available from: https://community.data.gov.in/functioning-community-health-centres-chcs-as-on-31-03-2016/

8. Domestic general government health expenditure per capita, PPP (current international $) | Data [Internet]. [cited 2019 Aug 19]. Available from: https://data.worldbank.org/indicator/SH.XPD.GHED.PP.CD?locations=IN

Cost Effectiveness Analysis of Hypothermia Detection Devices (BEMPU), ThermoSpot and Fever Watch for Premature and Low Birth Weight Neonates in India

Health Technology Assessment in India
Department of Health Research, MoHFW

Cost Effectiveness Analysis of Hypothermia Detection Devices (BEMPU, ThermoSpot and Fever Watch) for Premature and Low Birth Weight Neonates in India

POLICY BRIEF

SUMMARY

Hypothermia has been defined by World Health Organization (WHO) as body temperature below the normal range (36.5°C – 37.5°C) and has been sub-classified into three grades; mild (36.0°C – 36 .5°C), moderate (32.0°C – 35.9°C), and severe (<32.0 C) hypothermia. Premature and Low Birth Weight (LBW) neonates are at a greater risk for hypothermia because they lack body fat and have poor thermal regulation system. Often it goes undetected until it reaches a severe state where several complications arise and can even lead to death. The current standard of care (SoC) for detecting hypothermia includes measuring the body temperature of neonates every six hours with an axillary thermometer at neonatal intensive care unit (NICU). Early detection and continuous monitoring for hypothermia is desirable to prevent progression of hypothermia from the mild range to a more severe condition that can lead to further complications. This study aimed to assess the cost effectiveness of hypothermia detecting devices such as BEMPU, ThermoSpot and Fever Watch to monitor the body temperature continuously and give either a visual or audio- visual alert when the new-born's body temperature drops, in NICU setting for premature and low birth weight neonates in India. This study concluded that neither of the interventions are cost-saving from a societal perspective.

Recommendation

- Based on the ICER value, the CEA shows that Bempu and Thermospot are not cost-effective devices for detecting hypothermia in premature and low birth weight neonates in India.
- Considering that in practical terms these devices provide continuous monitoring as opposed to intermittently by the standard of care, we could have accepted the marginally higher cost if they resulted in an increase in life years, but this was not the case.
- When data becomes available of its use in a community setting; with the device being worn by discharged/at home pre-term babies, then the CEA could be re-visited with the fresh data.
- It is worth remembering that the device will not be a remedy for societal barriers like gender based discrimination, neglect of female new-borns that exist in some parts of the country nor of poor awareness of post detection care of new-borns.
- Additionally, it has been claimed that neonatal hypothermia is more due to the lack of knowledge about hypothermia and its prevention rather than lack of equipment.

BEMPU HYPOTHERMIA ALERT DEVICE

FEVER WATCH

Conducted by Indian Institute of Public Health Shillong (IIPHS)

Objective: To assess the cost effectiveness of BEMPU Hypothermia Alert device, ThermoSpot and Fever Watch against the standard of care i.e. thermometer in early detection of hypothermia among premature and low birth weight neonates in India.

Rationale: Hypothermia is common in infants born at hospital (prevalence range, 32% to 85%) and at home (prevalence range, 11% to 92%), even in tropical environments with the highest prevalence among LBW newborns, it would require frequent or continuous temperature monitoring to prevent this condition from progressing. However, SoC is available, it is largely designed for facility level care, which requires health-literate caregivers. Non-invasive newly introduced hypothermia detecting devices specifically designed for newborns, monitor the neonate's body temperature around the clock and gives either a visual or audio-visual alert

Findings: Cost-effectiveness analysis results were estimated from societal perspective. Table-1 shows cost parameters of intervention and standard of care. Results of one way sensitivity analysis are presented in a Tornado Diagram in Fig. 1. Both interventions lie in north-west quadrant of the cost-effectiveness plane which implies that the interventions are not cost-effective when compared to optimum use of standard of care with Thermometer (Fig 2). Fig 3 shows results from a simulation performed as part of the probabilistic sensitivity analysis (PSA). In the analysis, we reported findings by considering per capita gross domestic product of India as on April 2019 as threshold for determining the cost- effectiveness. India had a GDP per capita of INR. 1, 42,034 (2045.794 USD) in April, 2019 as per Census and Economic Information Centre (CEIC) data.

Table 1: Estimated incremental cost and effects of interventions vs. standard of care

Standard of care	
Cost for treating 100 neonates	1534431
Cost for treating per neonates	15344
Life years gained	55.540
BEMPU	
Cost for treating 100 neonates	1614096
Cost for treating per neonates	16141
Life years gained	55.537
Thermospot	
Cost for treating 100 neonates	2103779
Cost for treating per neonates	21038
Life years gained	55.490
Incremental cost in compared to SoC	
BEMPU	796
Thermospot	5693
Incremental life years gained	
BEMPU	-0.010
Thermospot	-0.060
Incremental cost effectiveness ratio	
BEMPU Vs. SoC	-128207
Thermospot Vs. SoC	-102660

*Measured the cost in INR

Figure -1: Tornado diagram for OWSA

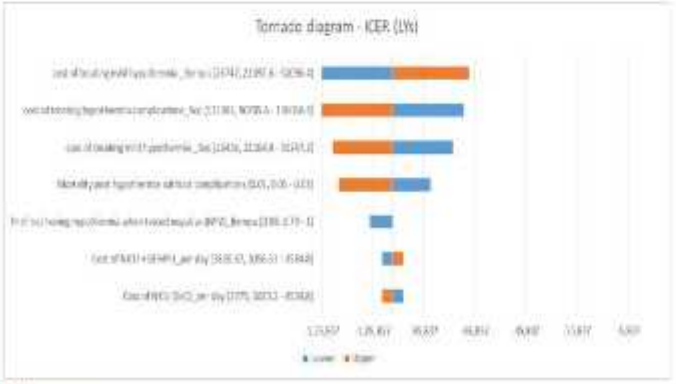


Figure -2: Cost effectiveness plane for BEMPU and ThermoSpot against Thermometer

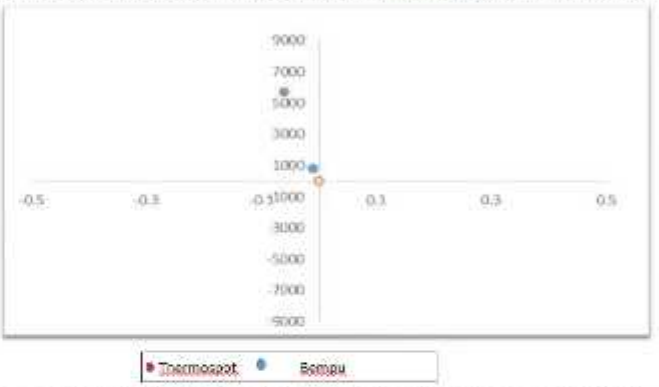
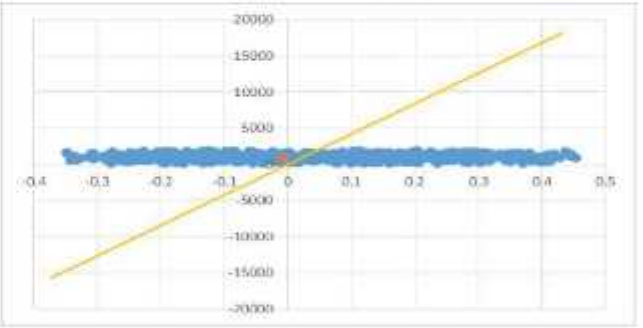


Figure 3: Cost effectiveness plane with incremental cost effectiveness ratio for BEMPU Probabilistic Sensitivity Analysis



Conclusion

The analysis carried out in this study shows that neither of the interventions are cost saving from a societal perspective. Based on the ICER value, this CEA shows that Bempu and Thermospot are not cost-effective devices for detecting hypothermia in premature LBW neonates. However, this study was carried out based on very limited evidence, a well-designed primary study that generates good quality evidence, would enable revisiting the CEA especially in community settings, which is potentially the setting where the use of such devices is needed.

References:

1) https://www.viaglobalhealth.com/product/bempu-hypothermia-device/

2) https://www.deccanchronicle.com/gadgets/110116/watch-ing-over-your-childs-health.html

3) Lunze, K., Bloom, D. E., Jamison, D. T., & Hamer, D. H. (2013): The global burden of neonatal hypothermia: Systematic review of a major challenge for newborn survival. BMC Medicine, pp. 11-24.

Decentralized Screening of Hepatitis B & C At Primary Health Centres in Tamil Nadu

DECENTRALIZED SCREENING OF HEPATITIS B & C AT PRIMARY HEALTH CENTRES IN TAMIL NADU

Health Technology Assessment in India
National Institute for Research in Tuberculosis, Chennai

Summary

A Health Technology Assessment (HTA) was conducted to establish the cost-effectiveness of decentralized diagnostic program for Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) implemented in Tamil Nadu, with specific focus on a selected key population at increased risk of HBV and HCV. It was found that decentralized HBV and HCV diagnosis followed by early treatment for HBV and HCV and vaccination for HBV negatives can save lives and reduce out-of-pocket expenditures.

RECOMMENDATIONS

- Decentralized HBV and HCV diagnosis at Primary Health Care level followed by early treatment in selected key population in Tamil Nadu is an appropriate intervention to reduce HBV and HCV burden.
- Active screening of selected key population helps in early identification of persons with chronic HBV or HCV infection and enables them to receive the necessary care and treatment to prevent or delay progression of liver disease.
- Considering vaccination for HBV negatives in selected key population in Tamil Nadu is cost-saving and could reduce transmission.
- Implementation of this intervention pose practical challenges to policy makers, where there is currently very limited access to HBV and HCV diagnostic and treatment services due to lack of awareness and other barriers. Vaccination coverage and increasing access to PHC is essential

Problem Statement

Viral hepatitis is a major public health problem which accounts for 2.85% of all deaths in India (1). Hepatitis B virus (HBV) is predominant in India affecting nearly 50 million people with an average prevalence of 4% (2). Chronic HBV infection leads to liver disorder and accounts for 10-20% of cirrhosis and 40-50% hepatocellular carcinoma (HCC) in India (3) HCV remains a major public health problem in India with an estimated prevalence of 0.5-1.5%. HCV prevalence among blood donors and pregnant women was found to be 0.44% and 0.88% (4) India has initiated the National Viral Hepatitis Control Program (NVHCP) in 2018 to eliminate viral hepatitis by 2030. HCV elimination efforts in India aims to reduce new chronic infections by 90% and mortality by 65% in comparison to 2015 status (5)

Background

The prevalence of HBV was 1.63% and HCV was 0.30% in Tamil Nadu. Three-fourths of HBV and HCV infected people were males. Prevalence of HBV and HCV was higher in rural areas. Systematic review of literature identified that key population including individuals with sexual risk behaviours, individuals with STDs, people living with HIV, blood donors and men who have sex with men (MSM) have higher prevalence of HBV and HCV. The pooled estimate of HBV and HCV prevalence among selected key population was 3% and 1% respectively. Overall burden of HBV and HCV was considerably higher in Tamil Nadu. Majority of people with hepatitis are unaware of their infection due to a lack of knowledge and availability at point-of-care testing services.

Delay in the diagnosis of HBV is common due to asymptomatic nature of the disease and lack of access to timely screening. At present in India hepatitis diagnosis is provided at the tertiary health care facility level and for individuals with abnormal liver functions.

At present, under NVHCP there is a gap in providing cost-effective diagnostic services at the primary health care level.

The implementation of decentralized HBV diagnosis strategy may effectively address the HBV and HCV disease burden in the state with favorable cost saving for the NVHCP in Tamil Nadu.6,7 Similarly, individuals test positive for HCV among selected key population at primary health care level is a cost saving.

KEY MESSAGES

- To achieve the HBV & HCV elimination goals, one of the key strategy adopted is to strengthen the decentralized diagnostics services for HBV & HCV to ensure early and accurate diagnosis.
- Key population with high prevalence of HBV & HCV would be highly benefited through early and accurate diagnosis at point-of-care facility.
- The point-of-care screening strategy was economically dominant for HBV & HCV for selected key population is cost saving to health system.
- Decentralised diagnostic strategy could avert deaths, gain life years and reduce out-of-pocket expenditure to patients.

Decentralized HBC & HCV Diagnositcs

The new action plan of Government of Tamil Nadu had initiated HBV and HCV screening at PHC level will provide a major opportunity to improve identification and treatment of persons with chronic hepatitis, and help to achieve the targets outlined. Active screening and diagnosis of HBV and HCV infection among key population at PHC level is the gateway for access to both prevention as well as care and treatment services.

3/4th of HBV & HCV infected people were males

Summary of Evidence

Provision of diagnostic services for selected key population who will be identified by health care providers at primary health care level. The screened key population with or without symptoms will be diagnosed using a rapid test kit. Those who test positive with rapid test will be further referred to tertiary health care for gold standard ELISA test. Individuals test positive for ELISA will progress to HBV treatment. Individuals who test negative for rapid test and ELISA will progress to HBV vaccination. This decentralised diagnosis followed by early treatment for HBV and HCV patients and vaccination for negatives of HBV at primary health care level for selected key population in Tamil Nadu is cost saving.

Early screening and hepatitis B vaccination will provide an opportunity to link to interventions to reduce transmission and cost to the patients and their family members. HBV infection rates can be reduced by active screening of key population and increasing HBV vaccination rate and linking patients with the care cascade.

CONCLUSION

The implementation and expansion of decentralized HBV diagnosis strategy may effectively address the HBV and HCV disease burden in the state with favorable cost saving for the NVHCP in Tamil Nadu. It will likely identify HBV and HCV infection among asymptomatic cases, prevent chronic cases and would improve quality of life of HBV and HCV infected individuals and reduce out-of-pocket expenditure

References

1. World Health Organization. Global Disease Estimates 2016. World Health Organization, Geneva. 2016.
2. Ray G. Current Scenario of Hepatitis B and Its Treatment in India. J Clin Transl Hepatol 2017; 5: 277-296.
3. Kumar A. Current practices in management of hepatocellular carcinoma in India: results of an online survey. J Clin Exp Hepatol 2014; 4: S140- 146.
4. Trickey A, Sood A, Midha V, et al. Clustering of hepatitis C virus antibody positivity within households and communities in Punjab, India. Epidemiol Infect. 2019; 147: e283.
5. World Health Organization. Guidance for hepatitis programme managers: Analysis and use of health facility data. World Health Organization, Geneva, Working Document 2019
6. Muniyandi M , Kirti T, Malkeet S, Prakash V, Karikalan N, Senthilkumar S, Sananthya K, Rajendran K, Kavitha R, Vivekanandan S, Selvavinayagam TS. Economic evaluation of implementing a decentralised Hepatitis B virus diagnostic intervention under National Viral Hepatitis Control Programme in Tamil Nadu, South India. Tropical Medicine and International Health 2020;https://onlinelibrary.wiley.com/doi:10.1111/tmi.13528
7. Muniyandi M, Karikalan N, Kirti T, Malkeet S, Prakash V, Senthilkumar S, Sananthya K, Rajendran K, Kavitha R, Vivekanandan S, Selvavinayagam TS. Economic evaluation of implementing a rapid point-of-care screening test for the identification of hepatitis C virus under National Viral Hepatitis Control Programme in Tamil Nadu, South India. Under review.

Health Technology Assessment of Various RT-PCR kits/Methods for the Diagnosis of Influenza A/H1N1pdm09 Virus in All Age Group Patients in India

Health Technology Assessment in India
Department of Health Research, MoHFW

Health Technology Assessment of various RT-PCR kits/methods for the diagnosis of Influenza A/H1N1pdm09 virus in all age group patients in India.

INTRODUCTION

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. 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 as 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. Government of India recommended testing of sample from suspected patients of category C only. Indiscriminatory use of anti influenza anti-viral drug may develop resistance. 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.

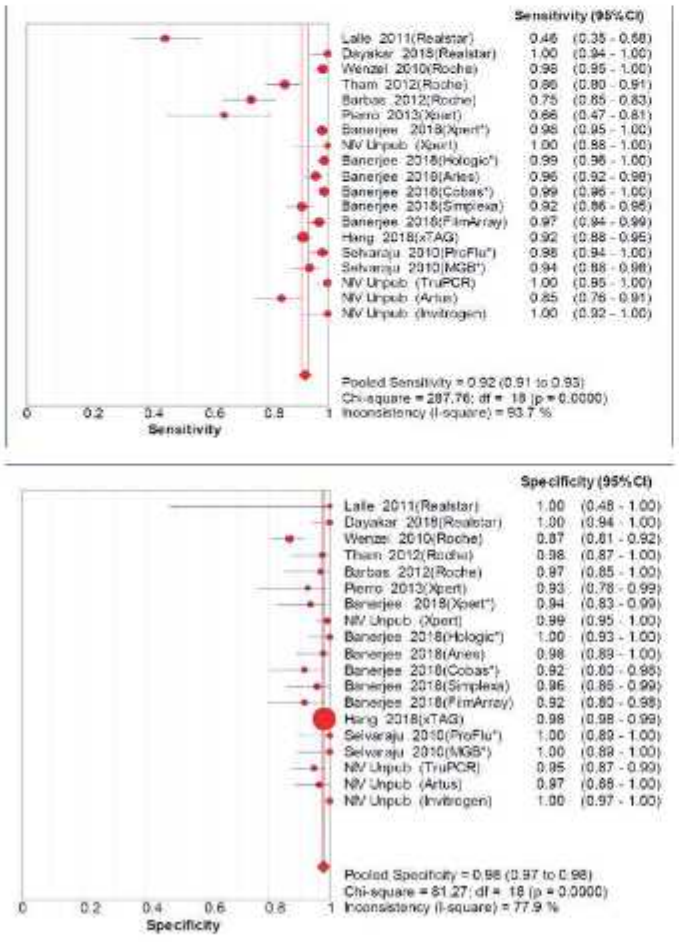


Figure 1: Forest plot for sensitivity (A) and specificity (B) of each individual study for overall kit, the pooled estimate are represented by diamond and the horizontal lines represent 95% confidence intervals (CI).

RECOMENDATIONS

1. In view of highest diagnostic accuracy (100% sensitivity and 100% specificity) among all the kits evaluated in this study, invitrogen kit is recommended for diagnosis of Category C patients for Influenza A/H1N1pdm09 virus from clinical samples with an incremental cost of 355 Rs/test.

2. Diagnostics of H1N1in India, is currently being provided by ICMR-VRDL and NCDC network and all these centres are using real time PCR based technique with Invitrogen kits. The present study reconfirms the fact Invitrogen kit is most cost effective kit for H1N1 diagnostics with no additional burden to the healthcare system.

RATIONALE OF THE STUDY

Indiscriminatory use of anti influenza anti-viral drugs may develop resistance. 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. Sensitivity, specificity and cost of different molecular tests exhibits huge variation. The purpose of this assessment was to appraise the current evidence for the clinical effectiveness (in terms of sensitivity and specificity) and cost-effectiveness of different RTPCR kits against CDC/WHO real time RT-PCR for diagnosis of Influenza A/H1N1pdm09 in India.

Target*		Invitrogen Kit	Qiagen kit	TruPCR kit	Cepheid kit
Cost (Rs) Per Sample		2015	1902	1660	4342
Ease of doing		Easy	Easy	Easy	Easiest
Turnaround time		4 hours	4 hours	4 hours	2 hours
Samples in one go		29 Samples	34 or 46 samples, depending upon the rotor used	29 Samples	1 to 4 samples, depending upon the machine module
Operational Feasibility		Open system Existing labs equipped with RT-PCR machine	Open system Can be used in existing facilities.	Open system Can be used in existing facilities.	Closed system Health system will need to buy new RT-PCR machines, if this kit is introduced.
Influenza A	Sensitivity (95%CI)	100 (91-100)	84 (76-90)	100 (95-100)	100 (88-100)
	Specificity (95%CI)	100 (96-100)	96 (88-99)	94 (87-97)	99 (95-99)
H1N1	Sensitivity (95%CI)	100 (91-100)	94 (85-98)	94 (84-98)	93 (78-93)
	Specificity (95%CI)	100 (96-100)	98 (94-99)	100 (96-100)	100 (96-100)
H3N2	Sensitivity (95%CI)	100 (85-100)			63 (38-81)
	Specificity (95%CI)	100 (97-100)			100 (97-100)
B	Sensitivity (95%CI)				96 (83-99)
	Specificity (95%CI)				100 (96-100)

Table 1: Summary table for key findings of the study

METHODOLOGY

Clinical Effectiveness (Sensitivity & Specificity) Literature Review

The research methodology was designed using PRISMA-P (Preferred Reporting Items for Systematic reviews and Meta-analyses Protocols) statement guidelines including the preparation of a pre-specified protocol and analysis plan.

Primary Data Collection

Primary data were collected from in-house reports (NIV data), four (n=4) kits evaluated during the financial year 2018-2019.

Validation and costing Study

From four different companies' influenza diagnosis molecular kits [Thermo Fisher Scientific (Invitrogen); TRUPCR H1N1 kit (3BBlackBio Bhopal); Qiagen artus Infl./H1 LC/RG RT-PCR Kit; and Cepheid Xpert® Flu kit] were evalaueted and compared with CDC/WHO gold standard kit.

KEY FINDINGS

- **Literature Review: Diagnostic accuracy of the kits for detection of H1N1 showed huge variation. The sensitivity of different kits varied from 76% to 100% whereas the specificity of different kits varied from 67% to 100% among the studies included in the review. Even for the same kit, there was huge variation between different studies both for sensitivity and specificity.**
- **Validation Study: Invitrogen kit exhibited the highest sensitivity and specificity for detection of H1N1 among 4 kits evaluated in validation study.**
- **Costing Study: Cephied kit was most expnsive with cost/test of Rs.4342, whereas TRUPCR was least expensive with cost/test of Rs. 1660.**
- **Operational Feasibility: Integrated Disease Surveillance Programme (IDSP) assisted lab network of 12 Laboratories are providing laboratory support in terms of testing, providing viral transport medium and diagnostic reagents. The laboratory network of ICMR-VRDL (30 labs) has also been activated to test for H1N1 cases. All these labs are currently using real time RT-PCR test for diagnosis of influenza H1N1 using Invitrogen kit. The present study reconfirms that Invitrogen kit is most cost effective kit for diagnosis of influenza H1N1 with an incremental cost of 355 Rs/test. As the kit uses an open system, it could be used in any real time PCR platform. Already being used in the system, the staff is trained in using the kit also. Therefore, there will be no addional burden in terms of procuring new platforms, or training of staff and cost of kits.**
- **Cost Effectiveness: If only H1N1 detection (not considering H3N2 and Influenza B) is considered for deciding the cost effectiveness, TRUPCR kit dominated over Qiagen and Cephied kit with least cost (1660 Rs/test) and highest accuracy (sensitivity 94%, specificity 100%) among these three kits, and thus Qiagen and Cephied were excluded from cost-effectiveness analysis. While comparing the TRUPCR kit and Invitrogen kit, later shows higher accuaray with an incremental cost of 355 Rs/test. If accuracy of overall kit is considered including Influenza A and Influenza B, Cephied kit can detect both subtypes in single reaction including the subtypes also. In addition to detecting both subtypes, the Cephied kit can provide results in least of the time. The kit is highly automated and thus easiest to be performed among the four kits. But at the same time, this kit works in a closed system model, that means the kit works only in a given platform and only 1-4 samples can be tested in one go, depending upon the machine module being used.**

Acknowledgement:

The study was conducted by NIV, Pune as a Regional Resource hub for HTAIn Secretariat, DHR, MoHFW

References

1. **Lim FJ, de Klerk N, Blyth CC, Fathima P, Moore HC. Systematic review and meta-analysis of respiratory viral coinfections in children. Respirology 2016;21:648-55.**
2. **Stöhr, K. Influenza—WHOcares. Lancet Infect. Dis. 2, 517 (2002).**
3. **Koul PA, Broor S, Saha S, Barnes J, Smith C, Shaw M, Chadha M, Lal RB. Differences in influenza seasonality b latitude, northern India.Emerg Infect Dis. 2014 Oct;20(10):1725-6.**
4. **Chadha MS, Potdar VA, Saha S, Koul PA, Broor S, Gar L, Chawla-Sarkar M, Biswas D, Gunasekaran P, Abraham AM, Shrikhande S, Jain A, Anukumar B, Lal RB, Mishra AC. Dynamics of influenza seasonality at sub-regional levels in India and implications for vaccination timing. PLoS One. 2015 May 4;10(5):e0124122.**

Rapid Health Technology Assessment for Incorporating TrueNat as a Diagnostic Tool for Tuberculosis under RNTCP in India

Rapid Health Technology Assessment for incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India

SUMMARY

India has world's highest tuberculosis (TB) and multi-drug resistant tuberculosis (MDR-TB) burden with the incidence rate of approximately 2.8 million annually[i]. Due to the poor diagnostics tool at the health care facilities with low sensitivity and low linkage-to-care rates, over 25% of patients who prefer public sector are neither diagnosed nor started on treatment[ii]. Hence there is an urgent need for an affordable and high-sensitivity screening or diagnostic test which could be installed in peripheral health facilities with minimal infrastructure and training.

Based on preliminary search of literature and available evidences, this study aims to compare clinical effectiveness of smear microscopy, GeneXpert and TrueNat with reference to culture as gold standard. We also analysed the cost-effectiveness study conducted by Lee et. al., 2019. The study also looked in to operational feasibility and challenges of implementing TrueNat under RNTCP.

If used as a point-of-care (POC) test within primary healthcare facilities, Truenat could increase treatment initiation by reducing turnaround time for test results and decreasing the need for laboratory referrals.

In India, CB NAAT has been used for diagnosis of TB under RNTCP program. Recently, the Andhra Pradesh State Government adopted TrueNat for TB diagnosis at various health levels like CHCs, PHCs and DMCs. A total of 225 TrueNat Duo modules have been installed so far in the state. Out of these, 200 have been installed at CHC level and 25 at PHC level.

POLICY BRIEF

POLICY RECOMMENDATIONS

- TrueNat is more cost-effective and feasible option for peripheral healthcare facilities (due to portability and requirement of less sophisticated infrastructure).
- GeneXpert is almost equally good (in terms of sensitivity as well as cost) and cost-effective as compared to other diagnostic tools like Smear Microscopy and can be used at District level and above due to its ease of use and less chances of error (due to automation) results.

TrueNat - MolBio Diagnostics

Apart from published literature on these devices interviews with program experts were also conducted. These experts had been working with TrueNat and had experience of working with CB NAAT as well. This exercise was done in order to understand operational feasibility of the TrueNat system.

Table 1: Summary table of studies conducted on TrueNat

Study Title	Author/year	Place of study	Sample size	Type of study	Data reported (Sensitivity/ specificity)
ICMR Study: Operational feasibility and performance of TrueNat MTB RiF assays in field settings under the Revised National Tuberculosis Control Program	Tripathi et al, 2019	India	10878	Sensitivity/ Specificity analysis	TrueNat: 84.1% (Sensitivity) GeneXpert: 81.0% (Sensitivity)
Rapid, point-of-care diagnosis of tuberculosis with novel TrueNat assay: Cost-effectiveness analysis for India's public sector	Lee et al, 2019	Indian setting	-	Cost-effectiveness analysis	-
Evaluation of the Indian TrueNat micro RT-PCR device with GeneXpert for case detection of pulmonary tuberculosis	Nikam et al,2014	Mumbai	247	Observational	TrueNat: 99% (Sensitivity) GeneXpert: 100% (Sensitivity)
Rapid Diagnosis of Mycobacterium tuberculosis with TrueNat MTB: A Near-Care Approach	Nikam et al,2013	Mumbai	266	Validation	TrueNat: 91.1% & 100% GeneXpert: 90.58% & 91.43%

CONCLUSION

- Truenat as compared to GeneXpert is very cost-effective in Indian settings with ICER: INR 8400 per Life Year saved (against threshold of per capita GDP 1,20,000). Sensitivity and Specificity of both equipment are comparable but TrueNat is more sensitive (Difference=3.1%).
- As per Lee et al., 2019 deploying Truenat POC instead of GeneXpert increased 5-year expenditures by $270 million, due mostly to treatment costs. Cost per test for both is also comparable but GeneXpert is cheaper. (Difference = Rs. 86 per test).
- Budgetary Impact of TrueNat for RNTCP

1. Capex Model (To Install machine in 1 TU): ANNUAL
   COST FOR 1 TU = 10,45,738
   ANNUAL COST FOR 2698 TUs = 282 Crores
2. Opex Model
   (To Install machine in 1 TU): ANNUAL COST FOR 1 TU = 17,72,833
   ANNUAL COST FOR 2698 TUs = 478 Crores

Acknowledgement:

The study was conducted by HTAIn Secretariat, DHR, MoHFW

References:

1) World Health Organization. Global tuberculosis report 2017 [Internet]: World Health Organization, Geneva, Switzerland; 2017.

2) Subbaraman R, Nathavitharana RR, et al. The tuberculosis cascade of care in India's public sector: a systematic review and meta-analysis. PLoS Med. 2016; 13: e1002149.

Health Technology Assessment of Automated Resuscitation Device (ARD) for Neonatal Resuscitation at Point of Delivery in Indian Healthcare System

Policy Brief

FEBRUARY, 2020 | Health Technology Assessment in India (HTAIn)
Department of Health Research, Ministry of Health & Family Welfare – New Delhi
Kalam Institute of Health Technology – Vishakhapatnam

Health Technology Assessment of Automated Resuscitation Device (ARD) for Neonatal Resuscitation at point of delivery in Indian Healthcare System

Executive Summary

Health Technology Assessment of ARD was carried out at Kalam Institute of Health Sciences, Andhra Pradesh. Negative Incremental Cost Effectiveness Ratio (ICER) value implies that the ARD is both clinically and cost effective compared to the standard of care. Based on the analysis, the device can be used at a tertiary level healthcare setting in Andhra Pradesh. However, a pilot study in any part of India is recommended for a more comprehensive overview of this intervention. Budget impact modelling for five states in India with the worst Neonatal mortality rates was also carried out to find out the impact on the exchequer of these states with gradual switching to ARD device.

Introduction

Perinatal asphyxia, neonatal asphyxia or birth asphyxia is the medical condition resulting from deprivation of oxygen to a newborn infant that if lasted long enough during the birth process it may lead to brain damage and multiple organ dysfunction. Birth asphyxia is a serious clinical problem worldwide and contributes greatly to neonatal mortality and morbidity [1]. Birth asphyxia is one of the most common causes of admission to NICU. Approximately 10% of new born babies fail to initiate effectual breathing at birth; most of these starts breathing after initial stimulation by the health personnel, about 3-5% need basic resuscitation, but <1% require advanced resuscitative effort to achieve efficient circulation to the vital organs [2].

Among four million neonatal deaths annually about ninety-nine percent occur in low middle income countries, mostly due to home based delivery without a skilled attendant where the neonate is more prone to asphyxia. Another one million children who survive birth asphyxia live with chronic neuro-developmental morbidity, including cerebral palsy, mental retardation, and learning disabilities, although there is significant uncertainty regarding this estimate [3]. In India alone, around one million babies die each year before they complete their first month of life, contributing to one-fourth of the global burden [4]. Common risk factors of birth asphyxia are high/ low maternal age, prolonged membrane rupture, meconium stained fluid, multiple births, non-attendance for antenatal care, low birth weight infants, malpresentation, augmentation of labor with oxytocin, ante partum hemorrhage, severe eclampsia and pre-eclampsia, ante partum and intrapartum anemia) [5].

Birth asphyxia continues to be the leading cause of morbidities in newborn babies, in spite of many advances in neonatal care. Systematic review concludes that mortality and morbidity of Birth asphyxia can be prevented with appropriate interventions including skilled resuscitation technique.

State-wise Neo-natal Mortality Rate during 2016 [6]

Sl.No	State	2016 - Total	2016 - Rural	2016 - Urban
India	India	24	27	14
1	Andhra Pradesh	23	27	11
2	Assam	23	24	13
3	Bihar	27	28	17
4	Chhattisgarh	26	27	20
5	Delhi	12	16	12
6	Gujarat	21	27	13
7	Haryana	22	24	16
8	Himachal Pradesh	16	16	15
9	Jammu and Kashmir	18	19	15
10	Jharkhand	21	23	13
11	Karnataka	18	22	10
12	Kerala	6	7	4

13	Madhya Pradesh	32	35	20
14	Maharashtra	13	17	9
15	Odisha	32	33	24
16	Punjab	13	13	12
17	Rajasthan	28	31	17
18	Tamil Nadu	12	16	9
19	Telangana	21	25	15
20	Uttar Pradesh	30	32	19
21	Uttarakhand	30	32	24
22	West Bengal	17	17	14

A Health Technology Assessment (HTA) of the Automated Resuscitator Device (Fig.2) vis a vis Self Inflating Bag (Fig. 1) was carried out to find out the Clinical and Cost Effectiveness of the new device as compared to Standard care.

Figure 1: Self-inflating bag

Figure 2: T-piece resuscitation device (with manometer)

Methods

To assess the cost-effectiveness of the device at the Tertiary level healthcare setting in Andhra Pradesh, a decision analytic model was constructed to compare the device to standard of care- Self Inflating bag. The cost of both the interventions were considered from a societal perspective, and Disability Adjusted Life Years (DALYs) to measure the economic burden. Robustness of the results were checked through Sensitivity Analysis and Monte-Carlo Simulation. Budget impact modelling was done for the five states in India having the worst Neonatal mortality rates.

Why DALY?

- DALY can be thought of as one lost year of "healthy" life (WHO).
- DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or its consequences. In neonatal resuscitation patients, premature mortality is the main problem and disability due to a number of reasons is also important as highlighted before. [7]
- EQ-5D has been derived from adult scores. For neonates there is no accepted EQ-5D methodology.

Results

The Incremental Cost Effectiveness ratio (ICER) for the new device when compared to self-inflating bag was found to be –1443.16 Rupees per DALY averted. The negative ICER value implies that the ARD is both clinically and cost effective compared to the standard of care (Fig. 3). Monte-Carlo simulations implied that ARD would be cost-effective with 95% probability at Rs 1250/- (Fig.4). Based on the Incremental Cost Effectiveness ratio value we obtained, the ARD device reduces both the cost and averts Disability adjusted life years by the virtue of reducing the number of severe cases caused due to birth asphyxia. Based on this analysis, the device was found to be Cost-Effective and can be used at a tertiary level healthcare setting in Andhra Pradesh. budget impact modelling for the five states in India with the worst Neonatal mortality rates to find out what impact would it have on the exchequer of these states with gradual switching to ARD device. The Budget impact study was carried out for Madhya Pradesh, Odisha, Uttar Pradesh

and Rajasthan. It was found that the gradual switch to ARD from SIB would lead to net cost saving for all the top five adversely affected states in India by neonatal birth asphyxia.

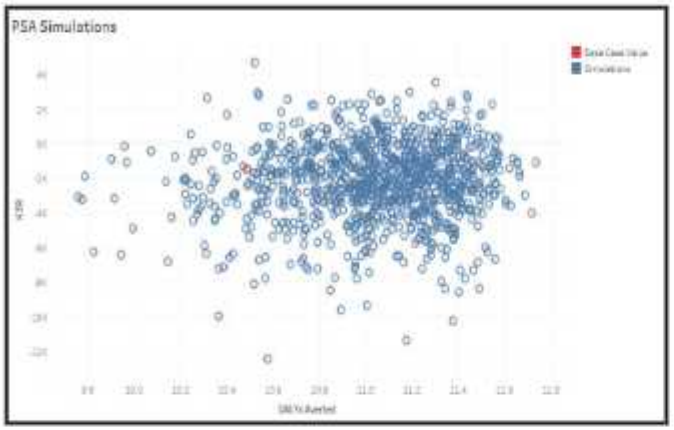


Figure 3: Probabilistic Sensitivity Analysis

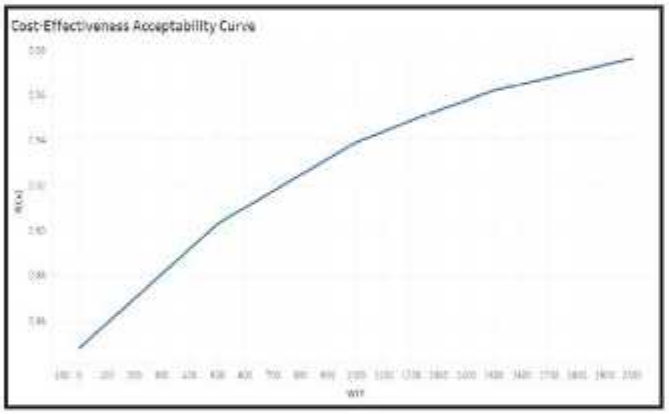


Figure 4: Cost-Effectiveness Acceptability Curve

ARD was also recommended by the practitioners using it, in a survey conducted, to find out the operational challenges, due to the features such as automation and ability to vary PEEP.

Key Findings

- ICER for ARD compared to self-inflating bag – 1443.16 Rupees per DALY averted.
- Negative ICER value implied ARD is both clinically and cost effective compared to the standard of care.
- ARD would be cost-effective with 95% probability at Rs 1250/-.
- ARD was found to be Cost-Effective and can be used at a tertiary level healthcare setting in Andhra Pradesh.
- Gradual switch to ARD from SIB would leads to net cost saving strategy for the states having high Neonatal mortality rate.

Conclusion

Birth asphyxia is one of the most common causes of admission to NICU and neonatal morbidity and mortality. It can be prevented with appropriate interventions including skilled resuscitation technique. Based upon the analysis ARD could be recommended to be used at a tertiary level healthcare setting in Andhra Pradesh.

Policy Recommendations

- ARD is both clinically and cost effective compared to the standard of care at a tertiary level healthcare setting.
- The new device would be cost-effective with 95% probability at Rs. 1250.
- The device can be used at tertiary level healthcare setting with centralized oxygen supply.
- A pilot study is recommended in other part of India in order to collect real world data before scaling it up for the state and later for India.

References

1. *Pitsawong C, Panichkul P. Risk factors associated with birth asphyxia in Phramongkutklao Hospital. Thai J Obstet Gynaecol. 2012;19(4):165–171.*
2. *Aslam HM, Saleem S, Afzal R, Iqbal U, Saleem SM, Shaikh MW, et al. Risk factors of birth asphyxia. Ital J Pediatr. 2014;40(1):94.*
3. *World Health Organization. World Health Report 2005.*
4. *National Health Profile Report, Central Bureau of Health Intelligence, Ministry of Health and Family Welfare. pp. 9–16, 2010.*
5. *Kaye D. Antenatal and intrapartum risk factors for birth asphyxia among emergency obstetric referrals in Mulago Hospital, Kampala, Uganda. East Afr Med J. 2003;80(3):140–143.*
6. *State-wise Neo-natal Mortality Rate during 2016, Ministry of Health and Family Welfare. Source: RAJYA SABHA SESSION - 245 UNSTARRED QUESTION NO. 4113*
7. *Metrics: Disability-Adjusted Life Year (DALY) – WHO.*

Health Technology Assessment of "Portable Automated ABR" Neonatal Hearing Screening Device

Policy Brief
February 2020
Health Technology Assessment in India (HTAIn), Department of Health Research, MoHFW
Regional Medical Research Centre (RMRC), Bhubaneswar

Health Technology Assessment of "Portable Automated ABR" Neonatal Hearing Screening Device

Summary of findings

- Clinical efficacy, cost-effectiveness and operational challenges were assessed in the implementation of 'Portable Automated ABR' neonatal hearing screening devices in health-care facilities of Odisha.
- "Portable Automated ABR", designed based on the principle of BERA, developed by the School of International Bio design (SIB), Dept. of Biotechnology (DBT) Govt. of India.
- It was found to be cost-effective as compared to OAE and can be used as a part of Universal Health Coverage (UHC) of hearing screening among infants in out-reach areas.

Background

Hearing impairment is one of the leading contributors to years lived with a disability, with over 5 percent of the world's population (360 million people) currently living with a disabling Hearing Loss (HL). Congenital hearing impairment in infants and children has been linked with lifelong deficits in speech and language acquisition, poor academic performance, individual and social maladjustments, and emotional difficulties. Excessive emphasis is placed on the importance of early detection, reliable diagnosis, and timely intervention, as it can help in developing better skills among the hearing impaired infants equivalent to their peers.

Figure 1: Effects of hearing impairment on child development

Studies indicated a prevalence of 5-6 per 1000 live births in India [1], of neonatal hearing loss (HL), with highly considerable repercussion on lifelong disability and Quality of Life (QoL). However, this figure only indicates a tip of the iceberg as the majority of hearing impairment cases remain undetected [2, 3].

Policy Recommendations

- **For Universalizing the hearing screening services, provisions of screening services should be available at nearest facilities such as sub-divisional hospital, CHCs, and if possible at PHCs to reduce both indirect as well as intangible cost.**
- **Portable Automated ABR can be recommended in out-reach areas replacing BOA in RSBK at SDHs, CHCs and PHCs for greater coverage of UNHS.**
- **It is suggested to conduct a small scale implementation using existing infrastructure to identify, if any, operational challenges of the implementation as well as facilities available for cochlear implant for assessing budgetary implications before a large scale implementation.**

As per RBSK program, an Otoacoustic Emission (OAE) is used at the facility level, while Behavioural Observation Audiometry (BOA) is adopted at the community level for hearing screening. For further confirmation, it is followed by Brainstem Evoked Audiometry Response (BERA) at referral facilities (4). Community-based screening is being carried out using a brief questionnaire and behavioural testing by a trained health worker during visit of mobile health team (MHT) under RBSK. Any infant who did not pass the screening is to be followed up at the district hospital for OAE and automated Auditory Brainstem Response audiometry (AABR) testing.

Major concern associated with the present hearing screening program under Rashtriya Bal Swasthya Karyakram (RBSK) was that it is provided through the District Early Intervention Centres (DEICs) which are available at the DHH level or higher level of medical care. In India, where non-institutional deliveries are still among the prevalent practices, the vast majority of the infants are left out from the early detection and intervention for the hearing impairment. Deliveries at CHC, PHCs and community level are also among the few missed cases of hearing screening and goes without any intervention or treatment. Other issues in the implementation of the program were identified as a lack of human resources, inadequate infrastructure, equipment-related shortcomings, and low priority for deafness prevention. These indicated the need for a portable technology which can detect the hearing impairment through first level of screening with better or similar diagnostic accuracy at various levels of care and at the same time it should be user-friendly too.

The "Portable Automated ABR" is a non-invasive, safe and simple technology been designed based on the principle of BERA. The device has been developed by the School of International Bio design (SIB) start-up Portable Automated ABR Innovation Labs India Pvt. Ltd by Dept. of Biotechnology (DBT) Govt. of India. The present Health Technology Assessment (HTA) was aimed to determine the cost-effectiveness of this technology by comparing Portable ABR against OAE as well as BERA, and examine the potential ethical implication prior to its introduction into the universal screening program.

Figure 2: Portable Automated ABR Neonatal Hearing Screening Device

Methods

OAE hearing screening test, which is commonly used under RBSK program, was compared with 'Portable Automated ABR'. HTA was classified into three broad areas: diagnostic validation of 'Portable Automated ABR', economic evaluation and assessment of Quality of Life (QoL) of 'Portable Automated ABR', and ethical and social implication of 'Portable Automated ABR' implementation.

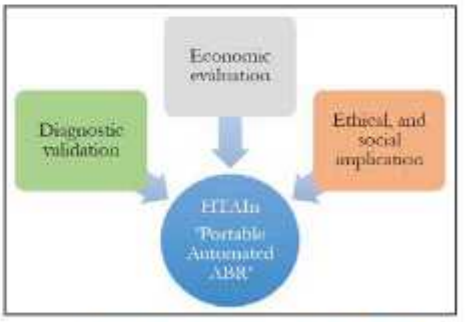


Figure 3: Overview of Health

Results

'Portable Automated ABR' was found to be cost-effective. The sensitivity results revealed that the 'Portable Automated ABR' device had higher sensitivity in comparison to OAE. The number of false positive cases were far less in 'Portable Automated ABR as compared to the OAE method, resulting into lower costs (direct, indirect and intangible), and less stress and anxiety on the families of new-borns. Study revealed that per unit cost for screening a new-born using 'Portable Automated ABR' was lower than that of OAE device.

The Portable Automated ABR device was found to be less costly and more effective. Cost-Effective Analyses (CEA) indicates that implementing Portable Automated ABR in the UNHS program will help in reducing the cost for the health system in long run but also to significantly reduce the societal cost.

	PHCs		CHCs		SDHs	
	Portable Automated ABR	OAE	Portable Automated ABR	OAE	Portable Automated ABR	OAE
Cost per facility	7,31,025	6,60,500	7,42,750	6,71,000	7,42,750	6,71,000
Total facilities in India	25650	25650	5624	5624	1108	1108
Amount in Crore (INR)	1876	1695	418	377	82	74

Table I: Expected overall budget implication for implementation of Portable Automated ABR at Primary Health Centres/ Community Health Centres (CHCs)/Sub-Divisional

Key Findings

- The Portable Automated ABR device has portability and doesn't requires any soundproof room.
- The test duration per baby was recorded between 10-15 minutes and it does not require considerable reliance on high manpower such as audiologist and is user-friendly in the nature. Hearing screening can be performed by any healthcare staffs, (preferably a staff nurse) with basic skill based training (3–5 days).
- Per-unit cost for screening a new-born using 'Portable Automated ABR' was lower than that of OAE device.
- Portable Automated ABR can detect **6240 cases** and OAE, **9360 cases** per annum
  - per unit cost of ABR and OAE are **INR 97** and **INR 67** respectively.
- The UNHS by Portable Automated ABR will cost lesser if we focus on the budgetary provisions as compared to OAE as it results into
  - **ICERs -7,17,889** for system implementation.
- Considering the annual birth rate, the prevalence rate of hearing loss, and the high diagnostic accuracy of device,
  - Portable Automated ABR imposes lower costs than the OAE device in long run.
  - In absence of skilled manpower can be easily taught to other staffs.

References

1. Khurmi M, Gupta M, Patle A, Kaur P, Mathur N, Chaudhari G, Prabhakar PK, Mohammed SK, Khera A. Improving child survival under National Health Mission in India: Where do we stand? Indian Journa of Child Health. 2015:49-54.
2. World Health Organization. New-born and infant hearing screening: current issues and guiding principles for action. 2009.
3. World Health Organization. Global costs of unaddressed HL and cost-effectiveness of interventions: a WHO report, 2017. World Health Organization; 2017.
4. Khurmi MS, Gupta M, Chaudhari G. Addressing the public health challenge of birth defects in India. Indian Journal of Child Health. 2014:95-8.

A comprehensive HTA of Project Lifeline - A Portable ECG Facility at PHCs of Ahmedabad District of Gujarat

INDIAN INSTITUTE OF PUBLIC HEALTH GANDHINAGAR

Policy Brief

Health Technology Assessment in India (HTAIn)
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A comprehensive HTA of Project Lifeline – A portable ECG facility at PHCs of Ahmedabad district of Gujarat

Summary

Background: Ahmedabad Zilla Panchayat, Gujarat introduced Project Lifeline, 12-lead portable ECG devices across all Primary Health Centres (PHC) in the district for the screening of cardiac abnormalities among high-risk and symptomatic adults for providing primary management and proper timely referral. Objective of the study was to assess the cost-effectiveness of portable ECG for the screening of Cardiovascular Disease (CVD) among high-risk and symptomatic adults at Primary Health Centre in Ahmedabad, Gujarat.

Methods: Cost-effective analysis was conducted using a societal perspective. An incremental costing approach was adapted and cost-effectiveness analysis was done using decision-analytic model. We surveyed seventy-three patients who were screened positive for cardiac abnormality, to document the type of ECG abnormalities and if they were diagnosed for CVD. The program cost was obtained from the implementers. Transition probabilities were derived from primary data supported by expert opinion for the intervention arm while systematic search of literature was undertaken to derive transition probabilities for the control arm.

Results: Introduction of ECG screening at PHCs saved 2.90 life years at an incremental cost of 89.97 USD (6,657.47 INR), yielding a cost-effectiveness ratio of 31.07 USD (2,299.06 INR) per life-year saved which is below the willingness to pay threshold. Results are sensitive to the relative risk reduction associated with non-participation and the cost of initial screening.

Conclusion: Cost-effectiveness analysis clearly shows that the facility to screen cardiac abnormality at the PHC level is highly recommended for high-risk adult and symptomatic cases.

Policy recommendations

At an additional cost of Rs. 2,299 for saving an additional life year, the ECG screening facility at primary health centres for high risk group is cost-effective and acceptable for replication in other districts and states. Further, the initiative can be linked with existing e-Sanjeevani (telemedicine) program which allow the utilization of physician available on e-Sanjeevani platform.

INTRODUCTION

Cardiovascular diseases (CVD) progress silently. There are requirement of specific expertise for early diagnosis and referral of the disease at primary health care level. In Gujarat, primary health centres (PHCs) are not yet equipped with these facilities. With an aim to screen all the high-risk and symptomatic adults, the District Health Team at Zilla Panchayat Ahmedabad, Gujarat introduced a 12-lead portable ECG machine across 40 PHCs in the district for the first time in the State. Linkage was established with a medicine specialist for reading ECG through a web-based interface for identification and confirmation of Cardiovascular Diseases and provides primary management (with thrombolytic and anti-platelet like Aspirin) coupled with timely referral.

Figure 1: ECG Device used in Project Lifeline

The objective of the present study was to assess cost-effectiveness introducing portable ECG facility at PHCs for the screening of cardiovascular disease among high risk and symptomatic adults and estimate budgetary implications for the scale-up of the ECG facility.

METHODS

Cost-effectiveness analysis was done using decision-analytic modelling with a societal perspective on health care costs and benefits. The target population for the study were high-risk and symptomatic adults which included adults having diabetes, hypertension, cardio-metabolic syndrome, family history of cardiac disease or signs and symptoms suggestive of cardiovascular disease. Intervention scenario viz. screening of population with portable ECG machine for early detection of cardiac abnormalities at PHC, was compared with no intervention scenario/ routine care scenario. Early diagnosis, prompt treatment of CVD, and life years saved were the outcome measures.

The type of ECG abnormalities identified during screening were categorised into five major disorders based on the primary data and expert opinion of the practitioners. The five cardiovascular disorder reported in the high-risk adults mentioned in the table 1 were considered for building the decision tree model. Data of 12,105 individuals screened for CVD using portable ECG device during 2018-19 were assessed. Of this, 208 individuals were screened with abnormality were selected from the database maintained at Zilla Panchayat, Ahmedabad.

Of the 208 patients screened positive, 73 were high risk symptomatic adults. Further follow-up of 73 high risk symptomatic adults led to 54 individuals who were diagnosed positive for CVD.

Table 1: Categorization of ECG abnormalities based on expert opinion

Cardiovascular Disorders	ECG Abnormalities
Arrhythmia	• Supraventricular Arrhythmia • Ventricular Arrhythmia
Action Sequence Conduction Defect	• Atrioventricular Conduction Defect (Block) • Bundle Branch Block
Increase in wall thickness or size of Atria or Ventricles	• Atrial Hypertrophy • Ventricular Hypertrophy
Myocardial Ischemia	• Myocardial Ischemia or Infarction
Others	• Valvular Issues

Cost data

Both the program cost i.e. the cost borne by the health system for implementing ECG program as well as the direct and indirect medical cost incurred by the patients were taken into consideration. All costs were reported in Indian Rupees and USD at 74 INR per dollar.

For deriving the cost of treatment, physicians were consulted for their opinion on the line of treatment. The cost of interventions (as suggested by the experts) were taken from Pradhan Mantri Jan Arogya Yojana (PMJAY) Package.[1] Since the cost for undergoing diagnostic test was already included in the PMJAY, we have not added additional diagnostic cost to avoid over-calculation of the treatment cost.

Clinical outcome

Transition probabilities were derived from primary data supported by expert opinion for the intervention arm while systematic search of literature was undertaken to derive transition probabilities for the control arm. Three experts included two prominent Cardiologists from Gujarat and one community medicine expert from Maharashtra with substantive experience in the subject. We used following indicators for calculating transition probabilities:

1. Total number of high-risk and symptomatic adults underwent ECG screening at PHC
2. Number of patients referred and underwent diagnostic test
3. Type of ECG abnormality
4. Type of treatment

The data on survival rates for each abnormality were derived on applying hazard ratio [2] to the survival rates reported in the published literature for each cardiovascular disorder.

The transition probabilities in the control arm were derived through systematic search of published literature. Indian data was used for all the transition probabilities except for survival rate of Action Sequence Conduction Defect which was

obtained in global context. In addition to this, due to unavailability of disorder specific data on QALY, the cost-effectiveness analysis was done using Life Years (LYs) saved as an outcome indicator.

For the purpose of estimating Life Years saved, the average age of high-risk adults who underwent the ECG screening was 54.6 years i.e., average age of cohort in intervention arm. From literature we found in usual condition mean average age is 57.5 years as mentioned in the CREATE registry.[3] The ECG screening programme resulted in people getting diagnosed on an average 2.9 years in advance.

Budget Impact Analysis was performed to estimate the cost for scaling up of the ECG program at the District, State and National levels at 2020 prices. The Budget Impact Analysis depicted the allocation of budget for 1st year, 2nd year, 5th year and 10th year.

RESULTS

We surveyed seventy-three patients who screened positive for abnormality, to document the type of ECG abnormalities as well as if their further diagnosis was CVD.

Program cost

The annualized cost incurred by the program implementers was estimated to be 16.92 lakhs. With this investment, around 12,105 patients were screened. The calculated cost per cases screened amounted to (INR) 139.85. The time-motion study was used to estimate shared human resource costs. It was found that an approximate time of 12 minutes of staff nurses was used towards the ECG program and its estimated annual cost was 209.38 USD (15494.43 INR).

Cost-effectiveness Analysis

The cost of intervention arm was 97.07 USD (7,183.64 INR) with 14 life years saved, while the cost incurred in the comparator arm (routine care scenario) was 7.11 USD (526.16 INR) for 11 life-years saved. The ECG screening intervention in primary care has proved itself to be extremely cost-effective for high risk adult and symptomatic population resulting in saving of around 2.896 life-years at an incremental cost of approximately 89.97 USD (6657.47 INR) with ICER of 31.07 USD (2299.06 INR) per life-year saved.

Figure 2: Cost-Effectiveness Plane for High Risk Adults

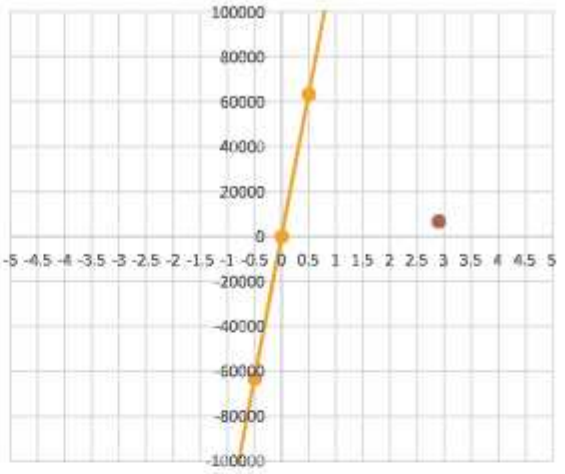

Figure 2 depicts the Cost-effectiveness plane with ICER (orange dot) lying in the first quadrant as incremental cost of 89.97 USD is incurred for saving 2.9 incremental life years. The intervention is found to be cost-effective as the ICER lies well below the CE Plane or willingness to pay threshold which is fixed at GDP per capita. The intervention is considered cost-effective. The One-Way Sensitivity Analysis indicate that parameters have the largest effect on ICER when they are varied individually.

Budget Impact Analysis (BIA)

While performing BIA, the budget of 1st year incorporated major capital investment required in the first year of program scale-up. The budget for 2nd, 5th, and 10th year depicted the incurred annual implementation cost. In addition, the budget of 5th year was estimated by taking into account the need for short refresher training to the health workers.

The state-wide scale up cost across 1,474 PHCs in 33 districts of Gujarat for the ECG programme is estimated to be around INR 155.2 million for the first year while nation-wide scale up cost was calculated for 24,029 PHCs across 720 districts was INR 2,706 million in the first year. This budget was calculated by projecting the annualized cost of implementing in Ahmedabad district.

CONCLUSION

The ECG screening facility at primary health care level for high risk group is cost effective and can be replicable in other districts and states. It can be linked with program which allow the utilization of physician available on e-Sanjeevani platform.

A standardized risk-stratification tool (such as Framingham risk score or CBAC) may assist in identifying high-risk population and only those identified for high risk should be subjected to ECG. screening. Further, cost data should be validated on larger cohort on prospective manner.

References

1. Ayushman Bharat. Pradhan Mantri Jan Arogya Yojana Health Benefit Package. Available at https://pmjay.gov.in/sites/default/files/2020-01/HBP_2.0-For_Website_V2.pdf
2. Lindekleiv H, Løchen ML, Mathiesen EB, Njølstad I, Wilsgaard T, Schirmer H. Echocardiographic screening of the general population and long-term survival: a randomized clinical study. JAMA internal medicine. 2013 Sep 23;173(17):1592-8.
3. Xavier D, Pais P, Devereaux PJ, Xie C, Prabhakaran D, Reddy KS, Gupta R, Joshi P, Kerkar P, Thanikachalam S, Haridas KK. Treatment and outcomes of acute coronary syndromes in India (CREATE): a prospective analysis of registry data. The Lancet. 2008 Apr 26;371(9622):1435-42.

Health Technology Assessment of Population based Screening for Type 2 Diabetes & Hypertension in India

Health Technology Assessment of Population based Screening for Type 2 Diabetes & Hypertension in India

Health Technology Assessment in India (HTAIn)
Department of Health Research

POLICY BRIEF

Background

The present study involved Health Technology Assessment of population-based screening for diabetes and hypertension in India. A systematic review and meta-analysis was undertaken to assess the diagnostic accuracy of screening tests in previously undiagnosed population. Primary data was collected using standard bottom-up costing methods, from Haryana and Tamil Nadu states, to assess the cost of screening. The National Health System Cost Database was used to determine the cost of diagnostic tests as well as the health system cost of treatment for diabetes and hypertension. The cost of treating complications in tertiary care setting was obtained from the Cost of Health Services in India (CHSI) study. Out-of-pocket expenditure for treatment in public and private sector was assessed by analysing the 71st round of National Sample Survey data on Health and Morbidity. Primary data was collected from 954 patients to assess the OOP expenditure in tertiary hospital and quality of life among those affected with diabetes, hypertension, co-morbidity, as well as different complications.

A hybrid decision model comprising of 3 parts was used to assess the incremental cost per quality adjusted life year (QALY) gained as a result of screening. The first part comprised of the decision tree which predicted the number of individuals who would be detected with either prediabetes, diabetes, hypertension, and a co-morbid state. These cases were further classified into true positives, false negative, true negative and false negative based on sensitivity and specificity of screening methods. The second part used a Markov model to track the transition of diseased individuals over annual cycles to identify occurrence of disease-related complication. The third part comprised of five separate Markov models for the complications (retinopathy, nephropathy, foot ulcer, coronary heart disease, stroke) which predicted the life course in terms of life years, QALYs and costs. Several alternative screening scenarios were considered depending on the methods used (random blood glucose, fasting blood glucose), frequency of screening (annual, every three or five or ten or fifteen or twenty years and one-time) and population age group to be screened (30-65 years or 45-65 years).

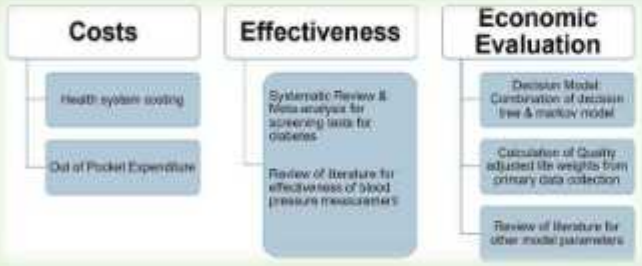

Figure 1: Process of HTA conducted

Conclusions

In summary, we report on the current scenario of PBS implementation and explored on the health system challenges and opportunities in regard to the existing program. Given the escalating dual burden of DM and HTN, and the current challenges noted in the provision of PBS program, there is a need to focus on addressing the same for providing quality services to patients with effective strengthening of primary health care. However, there is little empirical information about the benefits of such population based screening within current health care systems in developing countries.

Key findings

1. In the absence of screening, there are 9267, 28,206, 2982, 3030 and 1239 cases of stroke, myocardial infarction, end stage renal disease (ESRD), amputation and blindness due to diabetes and hypertension per 1 lakh population respectively. With the implementation of annual population based screening with random blood glucose test followed by fasting glucose test (as compared to no screening), there is reduction in 23% (n=2123), 13% (n=3753), 27% (n=807), 40% (1224) and 35% (n=429) cases of stroke, myocardial infarction, end stage renal disease (ESRD), amputation and blindness per 1 lakh population respectively.

2. In the scenario of no screening, for a cohort of 1 lakh population, the lifetime treatment cost of complicated cases comprised of around 96.5% (INR 7794 million) of the total cost, followed by cost of treating uncomplicated cases (3.37%; INR 271 million). In the case of annual screening, treatment cost of uncomplicated cases constitutes the major component (64.5%; INR 10929 million), followed by the cost of treating complicated cases (35%; INR 5980 million). The cost of implementing screening comprised of 0.5% (INR 65 million) of the total cost.

3. Implementation of annual population-based screening with random blood glucose test followed by fasting glucose test (as compared to no screening), lead to gain in 6387 life years, 19.656 quality adjusted life years and reduction in 1259 deaths (due to diabetes and hypertension) per one lakh population respectively.

Policy Recommendations

This study explored potential health system challenges and opportunities that need to be considered for PBS from the health system perspective. There are potential challenges existing in various aspects of PBS; however, some focus areas as opportunities were also recognized:

- Improving coverage rates for screening, subsequent referral for confirmatory testing and put on treatment.

- Focussing on follow up of those who started on treatment and how to achieve control for the disease conditions.

- Assessing cost-effectiveness of annual screening.

- Assessing on screening for complications.

- Promoting the prevention programs and increasing awareness for diabetes and hypertension.

- Improving the reporting formats to avoid the multiplicity in reporting.

- Functioning of NCD clinics to ensure early treatment.

- Incorporating formats that facilitate in capturing data regarding incidence and can be of subsequent policy use.

- Understanding the PBS with equity lens to assess any improvement in access to vulnerable populations.

Acknowledgements

The study was conducted by PGIMER, Chandigarh as a Regional Resource centre for HTAIn, DHR in collaboration with NIRT, Chennai.

References

1. Forouzanfar MH, Alexander L, Anderson HR, Bachman VF, Biryukov S, Brauer M, et al. Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet (London, England). 2015;386(10010):2287-323.
2. Travasso C. High blood pressure is the leading health risk factor in India, finds study. BMJ (Clinical research ed). 2015;351:h5034.
3. Beran D. The impact of health systems on diabetes care in low and lower middle income countries. Current diabetes reports. 2015;15(4):20.
4. WHO. World Health Statistics 2015. Geneva: World Health Organization; 2015. 5. WHO. Principles of Screening (Draft). Geneva: World Health Organization; 2001. 6. Echouffo-Tcheugui JB, Ali MK, Griffin SJ, Narayan KM. Screening for type 2 diabetes and dysglycemia. Epidemiologic reviews. 2011;33:63-87.

Economic-Evaluation of Percutaneous Coronary Intervention as Compared to Coronary Artery Bypass Grafting in Left Main Coronary Artery Disease

Policy Brief

Health Technology Assessment in India
Department of Health Research, Ministry of Health & Family Welfare

ECONOMIC-EVALUATION OF PERCUTANEOUS CORONARY INTERVENTION AS COMPARED TO CORONARY ARTERY BYPASS GRAFTING IN LEFT MAIN CORONARY ARTERY DISEASE

Introduction

Cardiovascular diseases (CVDs) are one of the leading causes of mortality in India. Among CVDs, coronary artery disease (CAD) is the major cause of cardiovascular mortality and morbidity globally. Coronary Artery Disease (CAD) refers to the pathological narrowing of arteries that supply blood to heart muscles. Individuals with coronary artery disease have different phenotypic variations. At present, Coronary Artery Bypass Graft surgery (CABG) and Percutaneous Coronary Intervention (PCI) are commonly available treatment options for Left Main coronary artery Disease. Although CABG is considered as a gold standard treatment for left main coronary artery disease (CAD). PCI has also gained attention in recent years as an alternative approach for the treatment of these coronary artery diseases. However, the best approach for the treatment of stable patients of these complex coronary artery diseases is still a subject of debate. This study evaluated the economic and health outcomes of CABG vs PCI for left main coronary artery disease over the lifetime of a patient in Indian healthcare settings. This study is a model based estimation of incremental costs and QALYs gained in CABG group and percutaneous coronary intervention group in LMCAD patients (figure1,2,3). We used two separate Markov models to estimate the overall costs and health outcome for the comparison. Data pertaining to the costs, clinical effectiveness and Quality of Life was taken from the secondary literature.

SUMMARY

Coronary artery disease (CAD) is the major cause of mortality and morbidity globally, causing approximately 7 million deaths annually. Coronary Artery Bypass Graft surgery (CABG) and Percutaneous Coronary Intervention (PCI) are commonly available treatment options for Left Main coronary artery Disease. Aim of this Study was to conduct a full economic evaluation of Percutaneous Coronary Intervention in patients with stable Left Major Coronary Artery Disease as compared to Coronary Artery Bypass Graft in Indian healthcare setting. CABG is found more clinically effective and also ost-effective as compared to PCI.

RECOMMENDATIONS

- **In cases of Left Main Coronary Artery Disease, the mainstay treatment should be centered on Coronary Artery Bypass Graft.**
- **PCI may be considered as the second line of treatment in cases requiring revascularization as per clinical experts' opinion.**

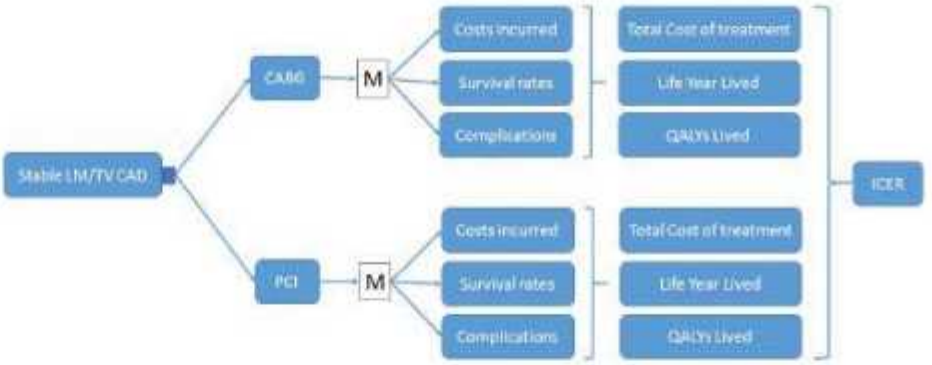

Figure 1. Conceptual framework for the economic evaluation for PCI versus CABG

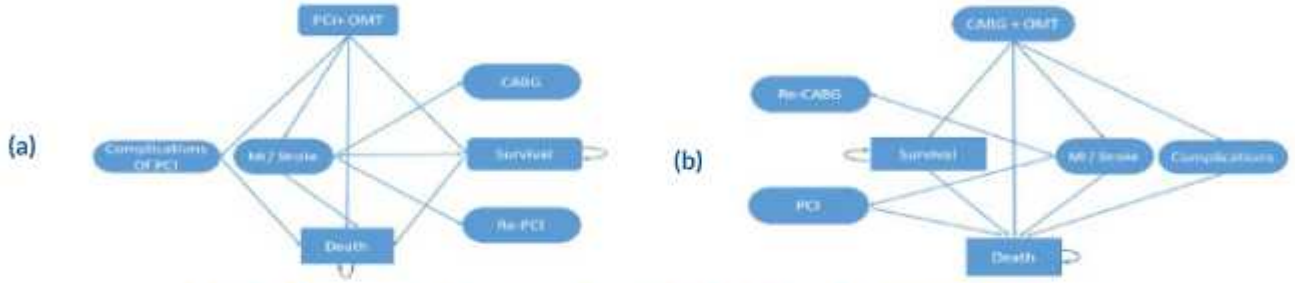

Figure 2. Markov's Model used for the (a) PCI Scenario and (b) CABG Scenaria

Results

The analysis was done for both scenarios with four different time horizons(1yr,5yr,10yr, lifetime). In the first case, when estimations were done using a one-year time horizon, these results are favoring PCI as there are almost the same mortality and significantly lesser cost than CABG and for a longer period, especially for the twenty years period, results actually change. One year and lifetime horizon results per patient are summarized in the table1.

Table 2: ICER of PCI versus CABG over four different time horizon

ICER at 1 year

Cost with PCI	129973	Incremental Cost	Incremental QALYs	ICER
Cost with CABG	131339			
QALYs with PCI	0.839	-1366	0.002617	-5,22,023
QALYs with CABG	0.837			

ICER at 5 years

Cost with PCI	160083	Incremental Cost	Incremental QALYs	ICER
Cost with CABG	150619			
QALYs with PCI	3.857	9464	-0.033419	-2,83,196
QALYs with CABG	3.891			

ICER at 10 years

Cost with PCI	202948	Incremental Cost	Incremental QALYs	ICER
Cost with CABG	176206			
QALYs with PCI	6.827	26742	-0.107237	-2,49,373
QALYs with CABG	6.934			

ICER at 20 years

Cost with PCI	255295	Incremental Cost	Incremental QALYs	ICER
Cost with CABG	211869			
QALYs with PCI	10.927	43426	-0.248610	-1,74,674
QALYs with CABG	11.176			

Table 1:Total cost of PCI versus CABG for one year and lifetime horizon

TIME HORIZON	PCI (1 year)	CABG (1 year)	PCI (life time)	CABG (life time)
Cost OMT	4506	3572	74837	60557
Cost CABG	0	123307	52452	149844
Cost PCI	122319	0	125593	7626
Cost MI	2532	2537	35432	11200
Cost Stroke	571	1407	6707	8875
Cost Re-opening for bleeding	18	398	171	104
Cost Surgery for Sternum Infection	0	106	45	27
Cost Surgery for access complication	6	13	6	4
Total Cost	129973	131339	295243	238236
Discounted Cost			255295	211869

When comparing the costs and QALYs gained, over the first year; the ICER of PCI versus CABG is -5,22,023, which is primarily due to more upfront cost of CABG as compared to PCI and comparatively lesser peri-procedural complications in PCI than CABG. In the five years,10 years, and 20 years' time horizon, PCI yields less health outcomes in terms of QALYs lived and has the incremental costs as shown in the table. Hence, at five years,10 years, and 20 years' CABG dominates as PCI is not a cost-effective strategy as compared to CABG.

Sensitivity analysis (OWSA) was conducted for life time horizon by varying key parameters by twenty percent of their base value; except for mortality of PCI and CABG follow-up, which was varied to the upper and lower bound of studies included in the meta-analysis (figure4).

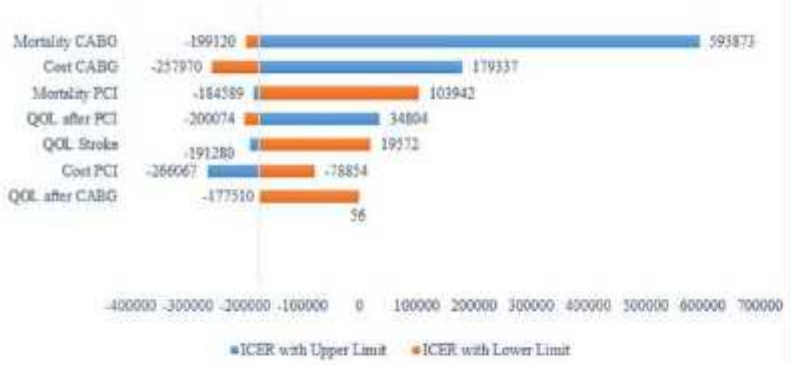

figure4:One Way Sensitivity Analysis results for lifetime horizon

CONCLUSION

As evident from results of our study, upfront cost of CABG is more in the first year as compared to PCI with and there is not much difference in the clinical outcomes of the these interventions. However, in the subsequent years, i.e. 5 years horizon, 10 years horizon and lifetime (twenty years' time) horizon; CABG is more clinically effective and also cost-effective as compared to PCI. Although, there is only a marginal difference in the health outcome of CABG over PCI in management of stable LM CAD patients in terms of QALYs gained, the overall cost of CABG is significantly less as compared to PCI due to difference in the need of repeat revascularization subsequently.

Economic Evaluation of Different Treatment Modalities for Management of Patients with Multivessel Coronary Artery Disease (MV-CAD)

Health Technology Assessment in India (HTAIn)
Department of Health Research
Ministry of Health & Family Welfare
Government of India
Policy Brief

Economic Evaluation of Different Treatment Modalities for Management of Patients with Multivessel Coronary Artery Disease (MV-CAD)

Summary

A Health Technology Assessment was conducted to establish the cost-effectiveness of the therapies looking at MV-CAD be used in the treatment of double and triple vessel diseases (DVD and TVD respectively). Conservative therapy of OMT should thus be the initial therapy to start treating patients. If the patient does require invasive therapy for one or the other reason, CABG should be the preferred therapy over PCI due to it being cost-effective as well as cost-saving over PCI.

Policy Recommendations

- To keep the conservative therapy regimen of OMT alone as the mainstay treatment with CABG being the preferred invasive therapy for cases showing unfavorable or worsening prognosis with OMT alone.
- PCI might be considered but owing to its higher costs attributable to the number of stents to be implanted, it is not recommended by this study (as the health gains are not that prominent as compared to CABG so as to justify investing in that higher cost).

The policy brief is based upon the Economic Evaluation of Different Treatment Modalities for Management of Patients with Multivessel Coronary Artery Disease (MV-CAD)

Background

MVD is often associated with a higher burden of comorbidities, left ventricular dysfunction, and cardiovascular risk The goal in the management of MVD is to reduce angina and heart failure symptoms and a patient's subsequent risk of adverse cardiovascular events Patients either undergo: Percutaneous Coronary Intervention (PCI) with Optimal Medical Therapy (OMT), Coronary Artery Bypass Graft (CABG) surgery with Optimal Medical Therapy (OMT) OR Optimal Medical Therapy (OMT) alone. Studies conducted in western countries and have focused on eliciting the difference in clinical outcomes for patients with left main coronary artery disease with or without triple vessel disease. The existing data specifically looking at MV-CAD is quite low and what studies do exist are dated with no conclusive response to which strategy be used in the treatment of double and triple vessel diseases (DVD and TVD respectively).

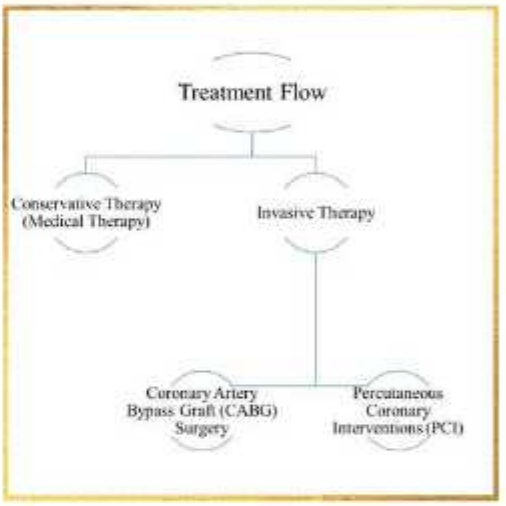

Figure 1: Treatment flow followed for patients with MV-CAD

In addition to that, very little literature exists pertaining to the cost-effectiveness of the therapies. This is compounded by the scarcity of studies from the South-East Asian and specifically Indian subcontinent region for clinical outcomes of OMT alone versus PCI with OMT and CABG with OMT in MV-CAD treatment. Hence, the present study was undertaken to bridge a few of these existing gaps and lay the foundation for future economic evaluations and health technology assessments.

The Research Question in the present study was to find out that what is the most cost-effective treatment modality available for the management of patients with multivessel coronary artery disease (MV-CAD). The aim was to do the full economic evaluation to see which treatment modality among Invasive Procedures (i.e. percutaneous coronary interventions or PCI and coronary artery bypass graft or CABG surgery) and Conservative Therapy (i.e. Optimal

Medical Therapy or OMT) is the better alternative for managing patients with MV-CAD and within invasive procedures which is the better alternative among PCI and CABG for the same.

Findings

As per the findings, when treating either MV-CAD, the between invasive and conservative (OMT) therapies, the invasive therapy is highly cost-ineffective with negative net health and monetary benefits. Regarding the patients that do undergo invasive therapy, CABG proves to dominate PCI with a positive net health benefit along with being cost-effective (Table I). The results of the subgroup analysis are illustrated below. Overall, invasive therapy does have a QALY gain over conservative OMT but when comparing amongst themselves, CABG had a better gain n QALYs for diabetics than non-diabetics (Table II).

Table I: Summary of results for MV-CAD patients

Category (MV-CAD patients)		BPPI Price of drugs			
		ICER (in INR)	ICER:GDP	NHB (in QALYs)	NMB (in INR)
Stage 1	*Invasive vs Conservative*	12,97,907.37	8.55	-0.698	-1,05,970.17
Stage 2	*CABG vs PCI*	-70,250.59	-0.46	0.906	1,37,464.71

ICER = Incremental Cost-Effectiveness Ratio, GDP = Gross Domestic Product (per capita per person), NHB = Net Health Benefit, NMB = Net Monetary Benefit, QALY = Quality Adjusted Life Year, INR = Indian National Rupee, BPPI = Bureau of Pharma Public Sector Undertakings of India, *CEA Threshold = GDP per capita per person of India (INR 1,51,793.69 as of May 31st, 2020 as per World Bank)

Table II: Summary of results for Diabetic MV-CAD patients

Category (Diabetic MV-CAD patients)		BPPI Price of drugs			
		ICER (in INR)	ICER:GDP	NHB (in QALYs)	NMB (in INR)
Stage 1	*Invasive vs Conservative*	7,77,458.76	5.12	-0.611	-92,730.82
Stage 2	*CABG vs PCI*	-34,856.08	-0.23	1.01	1,53,329.18

Major Findings

- Among invasive and conservative therapies for treating MV-CAD, invasive therapy was found to be cost-ineffective with negative net health and monetary benefits.
- MV-CAD patients that undergo invasive therapy, CABG proves to dominate PCI with a positive net health benefit along with being cost-effective.
- CABG had a better gain n QALYs for diabetics than non-diabetics.
- In the case of invasive vs conservative therapy, even at a really high willing-to-pay threshold of almost INR 60,00,000 invasive therapy can only have a 50% probability of being cost-effective.
- In case the patient does need to go for invasive therapy, CABG is the dominant therapy to choose from among the two (i.e. PCI and CABG). In diabetics, the trends seen were almost similar to those seen in the general population.

Conclusion

Invasive therapy is not a cost-effective strategy to start treatment of MV-CAD patients. Conservative therapy of OMT should thus be the initial therapy to start treating patients. If the patient does require invasive therapy for one or the other reason, CABG should be the preferred therapy over PCI due to it being cost-effective as well as cost saving over PCI. Based on this study, our recommendation would be to keep the conservative therapy regimen of OMT alone as the mainstay treatment with CABG being the preferred invasive therapy for cases showing unfavourable or worsening prognosis with OMT alone. PCI might be considered but owing to its higher costs attributable to the number of stents to be implanted, it is not recommended by this study (as the health gains are not that prominent as compared to CABG so as to justify investing in that higher cost). In the case of diabetics, our recommendation remains the same that the mainstay treatment be focussed around OMT alone and the patients be moved to CABG on the discretion of physician and the patient's response to OMT therapy.

Economic-Evaluation of Percutaneous Coronary Interventions (PCI) Against Optimal Medical Therapy (OMT) for Management of Patients with Single Vessel Coronary Artery Disease (SV-CAD) Without Left main Coronary Artery (LMCA) Involvement

POLICY BRIEF

ECONOMIC-EVALUATION OF PERCUTANEOUS CORONARY INTERVENTIONS (PCI) AGAINST OPTIMAL MEDICAL THERAPY (OMT) FOR MANAGEMENT OF PATIENTS WITH SINGLE VESSEL CORONARY ARTERY DISEASE (SV-CAD) WITHOUT LEFT MAIN CORONARY ARTERY (LMCA) INVOLVEMENT

Health Technology Assessment in India Secretariat
Department of Health Research, MoHFW, New Delhi

SUMMARY

Single vessel coronary Artery disease (SV-CAD) is often usually referred to as the presence of at least a ≥70% stenosis of a major coronary artery (left anterior descending, left circumflex, or right coronary arteries) or one of their respective major branches and associated with a higher burden of comorbidities, left ventricular dysfunction, and cardiovascular risk. Optimal medical therapy and revascularization are the required treatment to alleviate symptoms, avert disease progression, prevent Cardiovascular events, and decrease mortality. A Health technology Assessment (HTA) was undertaken to see which treatment modality between percutaneous coronary interventions (PCI) with optimal medical therapy (OMT) and OMT alone is the better alternative for managing patients with SV-CAD. Overall study suggested PCI is not a cost-effective strategy for management of SV-CAD as compared to OMT.

POLICY RECOMMENDATIONS

- ***OMT would have been the better option of treatment both clinically and cost-effectiveness wise***
- ***Study recommends that in cases of SV-CAD, the mainstay treatment be centered around the use of OMT therapy alone.***
- ***PCI may be considered as the second line of treatment in cases requiring revascularization as per clinical experts' opinion.***

INTRODUCTION

Coronary artery disease (CAD) disease of the blood vessels supplying to the heart muscle) are mostly involves single vessel and multi-vessel coronary artery disease. Single vessel disease (SV-CAD) is usually referred to as the presence of at least a ≥70% stenosis of a major coronary artery (left anterior descending, left circumflex, or right coronary arteries) or one of their respective major branches. Single vessel disease is often associated with a higher burden of comorbidities, left ventricular dysfunction, and cardiovascular risk. All patients with CAD first require optimal medical therapy (OMT) to alleviate symptoms, avert disease progression, prevent Cardio vascular events, and decrease mortality. Revascularization is indicated in patients who remain symptomatic despite OMT, for this the patient may either undergo percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) surgery along with optimal medical therapy (OMT) or in some cases only OMT. PCI is generally preferred in patients with single or low risk two vessel. A Health Technology Assessment was conducted to assess which treatment modality between percutaneous coronary interventions (PCI) with optimal medical therapy (OMT) and OMT alone is the better alternative for managing patients with SV-CAD. Conceptual framework and transitions used in the study shown in figure 1 and 2.

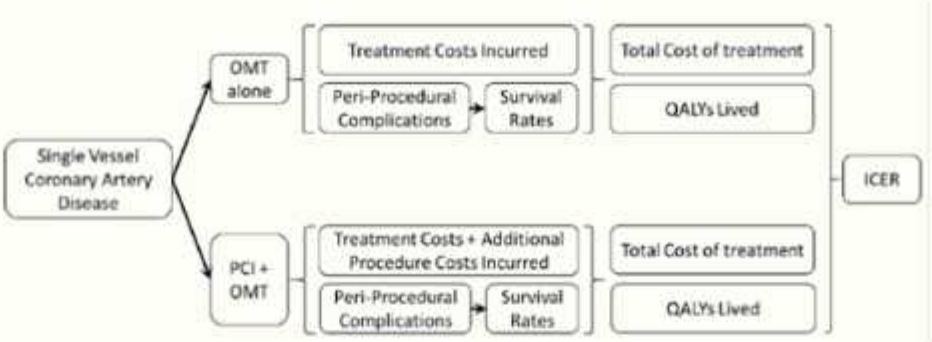

Figure 1: Conceptual Framework for the processes to be modelled and generated in treatment of patients with SV-CAD with either PCI + OMT or OMT alone

RESULTS

The results are as summarized in the table 1. Separate ICERs and Net Benefit values were calculated as per the prices of drugs in the Jan Aushadhi list. In terms of Net Health Benefit (NHB) there is an overall loss of health benefits if we spend in providing treatment with PCI + OMT as opposed to simply treating patients with OMT alone. There is also a net monetary loss if an investment is made in PCI rather than OMT as per our findings. As per the sensitivity analysis the parameter most likely to influence results was the rate or revascularization in the PCI arm followed by hospitalization for ACS in OMT and PCI + OMT arms respectively. The next 7 parameters are listed in the diagram in descending order of their tendency to have an effect on the ICER values(figure3).

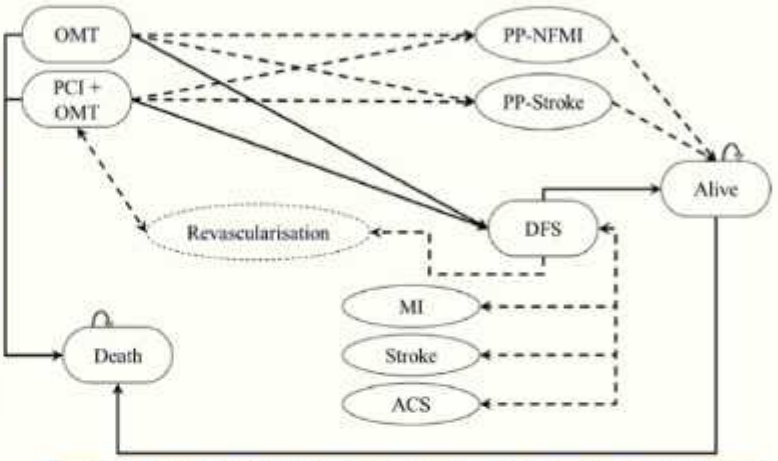

Figure 2: Illustration of the Markov model with the various transitions used in this study

Overall, only 48% of the total generated ICER iterations from the PSA fall in the cost-effective range as per our cost-effectiveness threshold (kept at one time the current GDP per capita per person of India). Findings of the study found that the use of PCI + OMT is not something that can be recommended easily over OMT alone therapy, specifically for SV CAD.

Also, seen that even at a high willing-to-pay (WTP) threshold of INR 8,00,000, the use of PCI will have a maximum of 60% chances of being cost-effective. To sum up, as per our findings, the ICER is higher than the CEA threshold which means that using PCI + OMT to treat SV-CAD, as against those treated with OMT alone, is not a cost-effective strategy in India.

Table 1: Results for the base case scenarios

Result (per patient)	With BPPI Price rates of OMT Drugs	With Average Market Price rates of OMT Drugs
Incremental QALYs (in years)	0.311	0.311
Incremental Cost (in INR)	66,286.6	75,565.5
ICER per QALY (in INR)	2,12,979.69	2,42,793.09
ICER : CEA Threshold*	1.4	1.6
NHB (in QALYs)	-0.125	-0.187
NMB (in INR)	-19,043.17	-28,322.12

ICER = Incremental Cost-Effectiveness Ratio, GDP = Gross Domestic Product (per capita per person), NHB = Net Health Benefit, NMB = Net Monetary Benefit, QALY = Quality Adjusted Life Year, INR = Indian National Rupee, BPPI = Bureau of Pharma Public Sector Undertakings of India, *CEA Threshold = GDP per capita per person of India (INR 1,51,793.69 as of May 31st, 2020 as per World Bank)

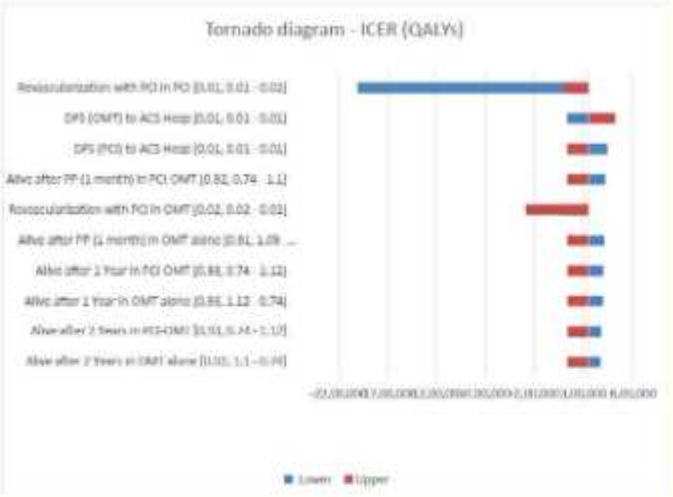

Figure 3: Tornado diagram illustrating the top 10 parameters likely to influence the ICER values based on changes in independent values of the parameters

SUMMARY

As evident from results of our study, PCI is not a cost-effective strategy for management of SV-CAD as compared to OMT. Even in terms of net benefits, investing in PCI results in a negative net health benefit for the patient meaning that OMT would have been the better option of treatment both clinically and cost-effectiveness wise. Considering that just for a gain of 0.3 QALYs the incremental cost per patient is INR 66292, PCI does not seem to be an effective strategy for treatment. Thus, this study concluded that in cases of SV-CAD, the mainstay treatment be centered around the use of OMT therapy alone. PCI may be considered as the second line of treatment in cases requiring revascularization as per clinical experts' opinion.

Health Technology Assessment of Low Cost Portable Ventilator

Health Technology Assessment of Low cost portable ventilator

HEALTH TECHNOLOGY ASSESSMENT IN INDIA
KALAM INSTITUTE OF HEALTH TECHNOLOGY-VIZAG

CONTEXT OF THE STUDY

- The Covid-19 crisis highlighted the lack of adequate ventilators in healthcare systems all over the world, leading to panic due to lack of evidence on the clinical effectiveness of ventilation systems needed for acute respiratory failure and other diseases.
- This HTA was an initiative to inform the policymakers on the same issue and help the exchequer in allocating resources optimally and make informed investment decisions on scaling up the most appropriate respiratory support devices.
- As poor choices lead to inappropriate use or non-use of medical devices and a waste of resources.

SUMMARY OF FINDINGS

- This new LCPV can be a promising lifesaving intervention in epidemics like the current COVID-19 and other disaster scenarios.
- Taking the willingness to pay threshold as GDP per capita per month and assuming non-inferiority in terms of clinical effectiveness, the new ventilator turns out to be cost-effective.

INTRODUCTION

Acute respiratory failure, and the need for ventilation, remains one of the most common reasons for admission to the intensive care unit (ICU). The burden of acute respiratory failure is high in terms of mortality and morbidity as well as the cost of its principal treatment of ventilation. A medical ventilator can be a lifesaving as it is used when a person can't breathe properly on its own. Ventilators can be of two types non-invasive ventilator (NIV) and invasive ventilator (IV). Mechanical ventilation is used to treat 30–40% of patients admitted to critical care. The growing prevalence of respiratory diseases and COVID-19 pandemic, low-cost portable ventilators were introduced in the healthcare system. As we know India has limited number of ICU beds, and using a low-cost ventilator for patients would reduce the burden on healthcare system. Utility of ventilators in homecare, ambulatory and emergency medical services, are driving the growth of the portable ventilator segment in the market.

SUMMARY OF RESEARCH

As part of this technical consultation, the current study was undertaken to assess the clinical and cost effectiveness on the use of non-invasive ventilation (NIV) in acute respiratory failure (ARF) and other diseases. Based upon the available clinical evidence, we constructed a decision analytic tree, Incremental Cost Effectiveness Ratio per QALY gained was calculated. A rigorous sensitivity analysis was undertaken to check the robustness of our analysis.

RESEARCH FINDINGS

Systematic review and meta-analysis on non- invasive ventilator verses mechanical invasive ventilator was performed to evaluate the clinical effectiveness of the ventilator. The forest plot showed Low-cost portable. ventilator (LCPV) was reducing mortality by 40% when compared to mechanical invasive ventilation.

We also performed economic modelling and calculated cost-saving per Quality Adjusted Life Years (QALYs), assuming non-inferiority, the cost- savings if this ventilator is used for domiciliary purpose.

This intervention is cost-effective at Rs 4845/- per QALY gained, while the standard of care is cost- effective at Rs 4859/- per QALY gained. The difference in Incremental Cost Effectiveness Ratio between the other non-invasive ventilator and the new ventilator turns out to be approximately Rs. 14 per QALY gained per patient. The forest plot showed Low-cost portable. ventilator (LCPV) was reducing mortality by 40% when compared to mechanical invasive ventilation.

POLICY RECOMMENDATIONS

- This LCPV may be particularly useful in the current situation of COVID-19 pandemic to overcome ventilator shortage and resource constraints in India.
- LCPV can be used for the patients requiring long term ventilation.
- Ease of accessibility of the device makes it useful in emergency conditions and it can be used in ambulance also.
- Introduction of LCPV in the Indian healthcare system appears to be fiscally sustainable.
- Future research should be considered as data was very limited on which this analysis was performed.

We also performed economic modelling and calculated cost-saving per Quality Adjusted Life Years (QALYs), assuming non-inferiority, the cost- savings if this ventilator is used for domiciliary purpose. This intervention is cost-effective at Rs 4845/- per QALY gained, while the standard of care is cost-effective at Rs 4859/- per QALY gained. The difference in Incremental Cost Effectiveness Ratio between the other non- invasive ventilator and the new ventilator turns out to be approximately Rs. 14 per QALY gained per patient.

ACKNOWLEDGEMENT

HTAIn Secretariat, Department of Health Research, Ministry of Health & Family Welfare, Government cf India.

REFERENCES

HTA on Low-cost portable ventilator (LCPV) by Kalam Institute of Health Technology, Vizag, Andhra Pradesh.

Health Technology Assessment in India
DEPARTMENT OF HEALTH RESEARCH
Ministry of Health & Family Welfare
Government of India
New Delhi (India)