

FEBRUARY, 2020 | Health Technology Assessment in India (HTAI)  
 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].

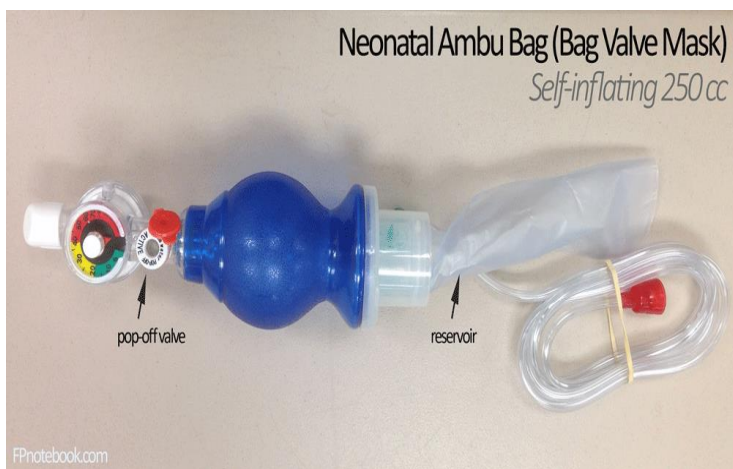
Birth asphyxia continues to be the leading cause of morbidities in newborn babies, in spite of many advances in neonatal care. Systematic review concludes that mortality and morbidity of Birth asphyxia can be prevented with appropriate interventions including skilled resuscitation technique.

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

Sl.No	State	2016 - Total	2016 - Rural	2016 - Urban
<b>India</b>	<b>India</b>	<b>24</b>	<b>27</b>	<b>14</b>
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?

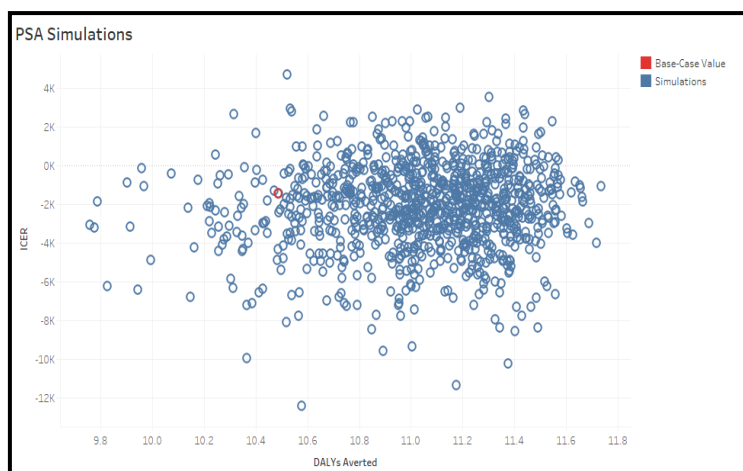
- DALY can be thought of as one lost year of "healthy" life (WHO).
- DALYs for a disease or health condition are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or 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

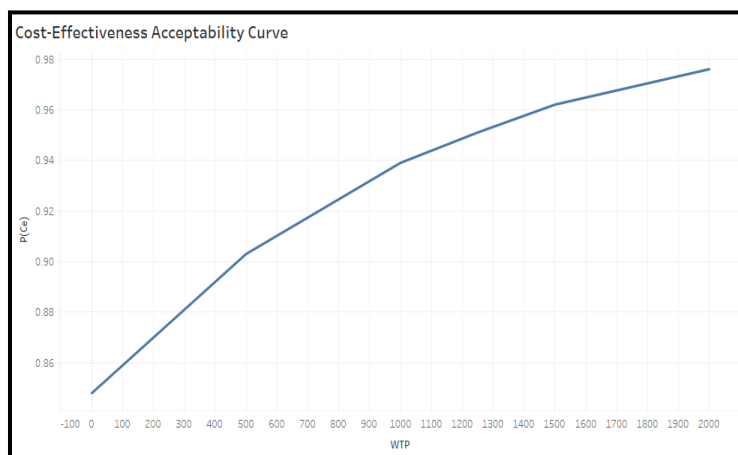
The Incremental Cost Effectiveness ratio (ICER) for the new device when compared to self-inflating bag was found to be – 1443.16 Rupees per DALY averted. The negative ICER value implies that the ARD is both clinically and cost effective compared to the standard of care (Fig. 3). Monte-Carlo simulations 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.

- Gradual switch to ARD from SIB would lead to net cost saving strategy for the states having high Neonatal mortality rate.



**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.

## 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 Phramongkutkiao 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. 4115*
7. *Metrics: Disability-Adjusted Life Year (DALY) – WHO.*