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Complete List of Authors:	Shetty, Siddesh; National Institute for Research in Reproductive Health, Regional Resource Hub for Health Technology Assessment in India Moray, Kusum; National Institute for Research in Reproductive Health, Regional Resource Hub for Health Technology Assessment in India Chaurasia, Himanshu; National Institute for Research in Reproductive Health, Regional Resource Hub for Health Technology Assessment in India Joshi, Beena; National Institute for Research in Reproductive Health, Department of Operational Research
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Cost of managing atonic postpartum hemorrhage using Uterine Balloon Tamponade at public health facilities in Maharashtra, India

Authors and Affiliations:

Dr. Siddesh Sitaram Shetty

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Kusum Venkobrao Moray

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Mr. Himanshu Chaurasia

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Beena Nitin Joshi (**Corresponding Author)**

Department of Operational Research,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai

Jehangir Merwanji Street, Parel, Mumbai, Maharashtra, India

Phone number: +91-9820252672 / Office number: +(91-22)24192043

Email ID – bjoshithane@gmail.com

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ABSTRACT

Objective

Post-partum hemorrhage (PPH) is the leading preventable cause of maternal mortality. India offers free treatment for pregnancy and related complications in its public health facilities. Uterine Balloon Tamponade (UBT) is recommended for refractory atonic PPH management. This study estimated health system costs of managing atonic PPH with condom-UBT, Every Second Matters (ESM) UBT and Bakri balloon UBT, three commonly used UBT devices in Maharashtra, India

Design

Health system cost estimation using primary bottom-up economic costing, data from Health Management Information System (HMIS) and published literature for event probabilities.

Settings

Four public health facilities from the state of Maharashtra, India representing primary, secondary and tertiary level care were chosen for primary costing.

Outcome measures

Unit, package and annual costs for managing atonic PPH using three UBT devices. This included medical management, UBT insertion and surgical intervention costs in the public health system of Maharashtra for the year 2017-18.

Results

Cost of medical management for atonic PPH in Maharashtra is USD 37 (95% CI 29-45) per case, increasing to USD 44 (95% CI 36-53) if condom-UBT and surgical interventions are needed. Similar cost was reported for ESM-UBT device. Use of Bakri-UBT reported a higher cost of USD 59 (95% CI 46-73) per atonic PPH case. Implied package and annual costs incurred by the public health system of Maharashtra in managing atonic PPH was estimated.

Conclusions

Atonic PPH management in public health facilities of Maharashtra using condom-UBT, ESM-UBT or Bakri UBT accounts to 3.8%, 3.8% or 5.2% of the annual health spending on reproductive and child health services. The study results can guide policy makers in planning budgetary allocations for atonic PPH management. This data can be used in economic evaluation studies to determine cost-effectiveness of UBT intervention in public health settings of India.

Strengths and limitations of this study

- To our knowledge, this is the first study from India comprehensively assessing public health system costs in overall management of atonic PPH with uterine balloon tamponade, medical and surgical interventions across public healthcare levels
- The study uses clinical effectiveness data of individual uterine balloon tamponade devices to determine health system costs
- As disaggregated HMIS data in the study setting was not available for PPH, literature-based probability estimates were used to derive costs
- An assumption was made that all atonic PPH patients eligible for UBT insertion would receive it and a uniform UBT device would be available across all facilities

INTRODUCTION

The global shift towards Universal Health Coverage (UHC) as indicated by Sustainable Development Goals (SDG) needs robust financing mechanisms. To achieve desired targets, evidence informed by costing studies can be vital to support financing decisions. Information on cost enables improved resource allocation, thus strengthening policy measures to attain highest value for a given investment. A key priority under the SDG health goal is reduction of maternal mortality level to less than 70 per 100,000 live births by the year 2030. Evidence confirms women's health to be associated with development and economic performance of a country.[1] A marginal health investment is found to have higher effects on health outcomes at lower GDP levels, seen commonly in low or low-middle income countries.[2] Improved maternal health not only reduces household healthcare expenditure but is associated with long term economic benefits to the society.

In spite of a low spending of 1% of GDP on public health expenditure, India has successfully reduced maternal mortality ratio down to 122 per 100,000 live births by the year 2015-17, attributable largely to reforms such as the institutionalization of deliveries, providing free cashless services to pregnant women and addressing social determinants of health.[3–5] Despite ongoing efforts, India still accounts for nearly one-fifth of all maternal deaths globally with hemorrhage as the leading cause.[6] Post-Partum Hemorrhage (PPH) accounts for more than two-third of all global maternal deaths due to bleeding.[7,8] PPH is defined as maternal blood loss of 500 ml or more within 24 hours after delivery and affects 3-6% of all women giving birth.[9] Atony of uterus is the most common PPH type responsible for 80% of all cases in India.[10]

Indian guidelines base PPH management on principles of shock treatment, cause-specific PPH management, and patient stabilization before referral to higher facilities.[11] India has initiated standardization of labour rooms (LR) under the 'Dakshata' initiative, equipping delivery rooms to provide comprehensive care at all times. In accordance with the WHO guideline for atonic PPH management, uterotonics remain the mainstay treatment in India.[12] Hemodynamic stabilization and supportive resuscitation measures are to be kept ongoing. Use of UBT device is recommended if uterotonic agents fail

in controlling atonic PPH bleeding. All atonic PPH cases at primary level care in India are expected to be provided with medical management and UBT intervention measures to stabilize and control bleeding before referral to a higher facility for observation or further interventions. Cases uncontrolled after UBT insertion at secondary or tertiary level may require B-Lynch compression suturing, stepwise devascularization surgery (uterine, or internal iliac artery ligation) or other procedures based on the availability of expertise and infrastructure. Hysterectomy, a lifesaving procedure is indicated after failed conservative measures or directly after UBT insertion depending on patient response. Obstetric intensive care unit (ICU) admission may be needed for observation or managing complications due to PPH.

UBT intervention for atonic PPH is a relatively simple life-saving technique that can be used even in low resource settings with limited provisions for surgery, blood transfusion or referral mechanisms. UBT technique is clinically effective in controlling PPH bleeding and acts as a step avoiding further surgical interventions.[13] Timely use of the UBT device can potentially lead to cost-saving by improving maternal morbidity and mortality outcomes. Multiple UBT devices specifically designed, assembled or modified for use in PPH management are available. Being economical, assembled condom-UBT device is the recommended standard of care (SOC) for atonic PPH management in India.[14] In the state of Maharashtra where this study was undertaken, apart from recommended condom-UBT device, Bakri balloon and ESM-UBT, two ready to use sterile pack devices for atonic PPH management and used across different public health settings.[15–17] The three UBT devices have certain distinct features giving each an advantage over the other. Literature reports varying clinical effectiveness rates for the UBT devices in controlling atonic PPH and they differ widely in costs. Table 1 shows the distinct characteristics of these UBT devices used for atonic PPH management derived from an extensive literature review undertaken separately.

Table 1: Characteristics of UBT devices used commonly for atonic PPH management in India

UBT device	Cost of device*	Clinical effectiveness	Advantages
Condom-UBT	USD 2 (INR 128) Available in facilities	92.3%	Inexpensive, Assembled using available resources, Modified versions are used to assess blood loss post insertion
ESM-UBT	USD 6 (INR 397) Currently not available over the counter	95.3%**	Relatively inexpensive, Specifically designed for PPH use, All components needed for assembly available in a sterile pack, US-FDA approved device
Bakri Balloon UBT	USD 148 (INR 9,554) Available over the counter	84.3%	Ready to use, Specifically designed for PPH use, Comes in a sterile pack, Has drainage outlet to measure ongoing blood loss, US-FDA approved device

* - Derived from facility purchase lists and online available resources

** - Strength of evidence is low, based on limited evidence available from three case series studies

Under India's flagship public health insurance scheme Pradhan Mantri Jan Arogya Yojana (PMJAY), a patient is entitled to a treatment package cost of USD 178 (INR 11,500) for high risk vaginal and all cesarean section deliveries to ensure institutional deliveries. Though package cost for institutional delivery in India is determined, costs for handling a post-partum complication like PPH is not available at present.

Moreover, choosing a specific UBT device has cost and outcome implications for the health system and if not examined, can result in catastrophic expenditure for the beneficiaries. This study aimed to calculate public health system costs of atonic PPH management using the recommended condom-UBT device with similar projections for different UBTs such as the ESM-UBT and Bakri balloon UBT used in the Indian public health settings.

METHODS

This costing study was part of a Health Technology Assessment (HTA) project evaluating UBT devices for atonic PPH management in India. An economic costing from the health system perspective using primary bottom-up costing, data from HMIS and literature review for event probabilities was used to determine and compare unit, package and annual costs of managing atonic PPH at different levels of public healthcare facilities in Maharashtra, India. Health system costs of three commonly used UBT alternatives such as condom-UBT, ESM-UBT or Bakri balloon UBT was assessed. The study was approved by the NIRRH Ethics Committee for Clinical Studies (Approval number: D/ICEC/Sci-29/31/2018). State health department administrative approvals and consent from the respective health facility authority was obtained before undertaking the study. There was no patient or public involvement in this study and hence no consent was needed.

Study settings:

Maternal healthcare in the Indian public system is delivered through a three-tier system. The facilities in this study were classified depending on availability of services for atonic PPH management. The primary level of care for PPH management comprises of Primary Health Centres (PHC) and is equipped with skilled birth attendants and a medical officer. Secondary level is made by the Community Health Centres (CHC) and Sub-District Hospitals (SDH) which additionally are equipped with obstetrics-gynecology (OBGYN) specialist, operation theater (OT), and facilities for blood transfusion. Tertiary level comprises of District Hospitals (DH) and medical colleges with additional advanced intervention and ICU facilities.[18,19] The

study enrolled four public health facilities from the state of Maharashtra to ensure representation of all three levels of care. A convenience sample of one PHC, SDH, DH, and a tertiary medical college from Mumbai metropolitan region in Maharashtra was chosen for data collection.

Data collection:

Cost data for one-year duration from April 2017 to March 2018 was collected by adapting a validated standard tool developed for costing of health services in India.[20] Cost resources were broadly classified into human resources, infrastructure, medical equipment, non-medical equipment, drugs, consumables, and utilities such as electricity, water, and laundry. Consumption data for these resources were obtained from Hospital Management Information System (HMIS) for patient-level information, electronic hospital records, written registers, building plan of health facilities, salary slips, bills, etc. from statements of the accounts department. Additionally, staff interviews were undertaken to assess time spent on different activities for time allocation. A total of 16 doctors, 26 nursing staff, 5 pharmacists and 11 administrative staff across chosen study facilities were interviewed. For example, doctors were asked for time spent on each patient in out-patient department (OPD), in-patient department (IPD), surgery, and other routine tasks but the time spent by the senior-most doctor in performing an obstetric hysterectomy out of all routine tasks was used to derive time allocation statistic for costing of obstetric hysterectomy procedure. Floor area measurement and facility observations for details on infrastructure of the IPD, LR, ICU, laboratory, pharmacy and administration were undertaken as needed. As facility HMIS did not report specific PPH data, literature based estimates for incidence of atonic PPH in Indian settings, clinical effectiveness of the three UBT devices in controlling atonic PPH, probability of undergoing a specific surgical intervention, surgery success rates, morbidity, mortality related to PPH were used to determine unit, package and annual costs for atonic PPH management in Maharashtra, India.[9,10,21–23] Table 2 enlists the parameters used to determine service utilization for PPH across chosen facilities.

Table 2: Parameters used to determine service utilization for atonic PPH management in Maharashtra based on event probability from literature

Parameter	Value in cost analysis*	Source
Annual number of deliveries at primary level facility (1 PHC)	Vaginal – 494	Facility HMIS 2017-18
Annual number of deliveries at secondary level facility (1 SDH)	Vaginal – 1526 Caesarean section – 330	Facility HMIS 2017-18
Annual number of deliveries at tertiary level facilities (1 DH & 1 Medical college)	Vaginal – 5188 Caesarean section – 2186	Facility HMIS 2017-18
Incidence of PPH in vaginal deliveries in India	3%	9, 21
Incidence of PPH in cesarean section deliveries in India	6%	9, 21
Probability of PPH due to uterine atony in India	0.80	10
Probability of atonic PPH controlled with medical management	0.90	23
Probability of stepwise devascularization surgical procedures for uncontrolled cases after UBT	0.85	23
Probability of obstetric hysterectomy surgery for uncontrolled cases after UBT	0.15	23

* - Values relevant to the Indian context

Data analysis:

For analysis, cost resources were classified into capital and recurrent cost items. Capital resource items were annualized using a 3% discount rate and factoring in life expectancy and annual maintenance rate of the items.[24] For shared or jointly used resources, apportioning factors were used depending on the type of resource utilized. Monetary value was obtained from the individual facility purchase lists. Data was analyzed using Microsoft Excel 2016. Worksheets were developed for cost calculation of each component at each facility followed by aggregating costs to the level of care separately for each UBT. For example, unit condom UBT insertion cost at DH and medical college was aggregated to get a unit condom UBT insertion cost at tertiary level. All the costs are presented in United States Dollars (USD) and Indian National Rupee (INR) currency. A conversion rate of 1 USD = 64.5 INR for the year 2017-18 was used.[25]

Unit costs

We derived unit costs for individual component of atonic PPH management algorithm at each facility as mentioned in the Indian guidelines. This include unit costs of medical management for atonic PPH, UBT insertion cost for refractory cases, devascularization surgery, hysterectomy, IPD admission per patient, ICU admission per patient, and unit cost of patient referral. Unit cost of UBT insertion included cost of the UBT device. Unit cost of medical management, referral and IPD admission were expected to remain unaffected irrespective of the type of the UBT device used. For such services, costs were calculated only for SOC treatment i.e. management using condom-UBT device.

Package costs

To account for treatment combinations used in management of atonic PPH, package costs were determined. For a certain treatment, package cost was calculated by adding unit costs associated with all treatment components at that particular healthcare level. For all patients accessing primary level and for those at secondary level requiring ICU services, referral costs were added to get package costs.

Annual costs

Unit and package cost calculation was followed by annual health system cost estimation for all women of Maharashtra availing public healthcare facilities for atonic PPH. This consists of the combined annual cost of medical management, further course of interventions using UBT device in uncontrolled cases and training cost for UBT use. Unit cost for every treatment component at each facility was first aggregated to primary, secondary and tertiary level and then applied to the annual population cohort using epidemiological and clinical parameters relevant for each specific UBT device to calculate annual costs.

Certain methodological assumptions were made for data analysis. It was assumed that all women eligible for UBT insertion would receive the device and would uniformly get a single UBT type across all facilities. It was assumed that at primary level, all women after medical management or UBT insertion would immediately be referred to secondary level. Unit cost for IPD and ICU admission per patient was based on per day calculation for an admitted OBGYN patient followed by apportioning to the average length of stay for atonic PPH.[26–28] Cost of blood transfusion and other resuscitation measures were incorporated in unit costs throughout management and have not been calculated separately. Training costs were estimated for one day training of healthcare providers.[29] Certain assumptions were made due to the unavailability of relevant data. Health system referral cost for all primary care patients and those from secondary level requiring ICU in this study was obtained from a published Indian study after making inflation adjustment.[30] B-Lynch suturing and stepwise devascularization surgery in this study were considered a single unit for cost calculation.

Probabilistic sensitivity analysis was used to address joint uncertainty effect of input parameters on costs. A beta distribution for probabilities and proportions and a gamma distribution for cost and resource use was assigned before varying the parameters on both sides. As drugs and consumables show wide variation in prices, these were varied by 99% whereas UBT device price was assumed to vary by 50%. Remaining parameters such as salaries, rental prices, medical and non-medical equipment, utilities and utilization of services were varied by 25%.[31] This was followed by running Monte Carlo simulations to obtain 1000 cost estimates. These estimates were then used to determine 95% confidence interval (CI) limit for all costs.

RESULTS

The chosen sample of four public health facilities from Maharashtra reported 7,208 vaginal and 2,516 cesarean section deliveries in the year 2017-18. Of the 9,724 total deliveries, 293 women were expected to experience atonic PPH. Twenty-nine out 293 cases would remain uncontrolled in spite of medical management, thus becoming eligible for UBT device insertion. Further, depending on clinical effectiveness of the individual UBT device in controlling bleeding, remaining cases would undergo surgical intervention depending on infrastructure and resource availability at respective clinical setting.

Unit costs:

Medical management of atonic PPH costs the health system USD 0.7 (INR 42), USD 5 (INR 322) and USD 9.4 (INR 609) per patient at primary, secondary and tertiary level respectively. For uncontrolled cases requiring further intervention, condom-UBT (SOC) insertion costs USD 2.5 (INR 160), USD 5.3 (INR 339) and USD 6.5 (INR 422) at the three respective levels. Devascularization surgery for uncontrolled cases after condom-UBT insertion costs the health system USD 75.4 (INR 4864) per case at secondary and USD 52.9 (INR 3,418) per case at tertiary level. Similarly, hysterectomy procedure costs USD 120.6 (INR 7,782) per case at secondary and USD 84.8 (INR 5,471) at tertiary level. Table 3 provides information on health system unit costs for condom-UBT, ESM-UBT and Bakri balloon. IPD admission for an atonic PPH case costs the health system USD 27.5 (INR 1,776) per patient at secondary and USD 28.0 (INR 1,806) per patient at tertiary level. ICU admission at tertiary facility costs the health system USD 75.9 (INR 4,900) per patient getting admitted for atonic PPH management. Cost of transport or referral of a patient in the Indian public health system after inflation adjustment was USD 15.5 (INR 1,001) per case. One-time training of medical officers and OBGYN specialists across public health facilities of Maharashtra costs USD 12.1 (INR 778) per eligible case for UBT device insertion.

Table 3: Unit costs for atonic PPH management across public health facility levels in Maharashtra, India [1 USD = 64.5 INR]

Facility level	Medical management	UBT insertion	Devascularization	Hysterectomy	Inpatient Admission	ICU admission
Per patient unit cost with Condom-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	2.5 (1.5-3.5)	NA	NA	NA	NA
Secondary	5.0 (3.6-6.5)	5.3 (4.1-6.5)	75.4 (49.7-105)	120.6 (80.1-165.3)	27.5 (16.2-40.1)	NA
Tertiary	9.4 (6.6-12.7)	6.5 (5.4-8)	52.9 (42-64.9)	84.8 (67.1-104)	28.0 (20.3-36.2)	75.9 (50.2-104.7)
Per patient unit cost with ESM-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	6.7 (3.7-9.7)	NA	NA	NA	NA
Secondary	5.0 (3.6-6.5)	8.8 (6.1-11.5)	56.9 (37.5-77.6)	119.9 (76.6-163.7)	27.5 (16.2-40.1)	NA
Tertiary	9.4 (6.6-12.7)	10.4 (8.5-12.4)	51.7 (40.7-63.0)	86.5 68.6-106.6)	28.0 (20.3-36.2)	75.9 (50.2-104.7)
Per patient unit cost with Bakri-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	148.6 (74.8-223.4)	NA	NA	NA	NA
Secondary	5.0 (3.6-6.5)	151.1 (88.8-215.8)	76.8 (50.9-106.1)	119.7 (76.8-166.8)	27.5 (16.2-40.1)	NA
Tertiary	9.4 6.6-12.7)	153.1 (111.5-194.4)	53.0 (41.5-64.9)	84.8 (66.7-104.8)	28.0 (20.3-36.2)	75.9 (50.2-104.7)

Package cost:

Of the eligible cases, condom-UBT successfully controls 92.3% of the cases after device insertion and ongoing medical and resuscitation measures. This combined treatment costs the health system a total of USD 46.2 (INR 2,979), USD 37.8 (INR 2,437) and USD 43.9 (INR 2,837) at three respective levels. This package consists costs of medical management, UBT insertion, IPD admission and additional referral cost for primary level care. Package cost of control with devascularization surgery group after condom-UBT insertion and medical treatment costs the health system a total of USD 113.2 (INR 7,301) and USD 96.9 (INR 6,255) per patient at secondary and tertiary levels respectively. Similarly, a direct hysterectomy for uncontrolled atonic PPH after UBT insertion costs USD 158.4 (INR 10,218) and USD 128.8 (INR 8,308) at secondary and tertiary level care. Less than 4% of the uncontrolled atonic PPH cases are expected to require ICU facility for atonic PPH management. Health system package costs for such treatment combinations can be derived from the given unit cost table. Alternatively, if ESM or Bakri-UBT device is used in controlling atonic PPH, package costs are expected to vary depending on the effectiveness of respective UBT. Table 4 lists package cost estimates for atonic PPH management with three UBT devices.

	Condom UBT	ESM UBT	Bakri UBT
Package cost for atonic PPH controlled after UBT insertion in USD (95% Confidence interval)			
Primary	46.2 (35-58)	50.4 (38-63)	192.3 (153-233)
Secondary	37.8	41.3	184.1

	(28-49)	(31.8-52.1)	(146-223)
Tertiary	43.9 (35-54)	47.8 (39-58)	190.4 (152-230)
Package cost for atonic PPH controlled with devascularization surgery after UBT failure in USD (95% Confidence interval)			
Secondary	113.2 (92-134)	98.2 (81-116)	260.9 (217-305)
Tertiary	96.9 (81-114)	99.6 (84-116)	243.5 (203-285)
Package cost for atonic PPH controlled with direct hysterectomy after UBT failure in USD (95% Confidence interval)			
Secondary	158.4 (128-192)	161.1 (152-172)	303.8 (252-354)
Tertiary	128.8 (106-152)	134.4 (112-159)	275.3 (229-323)

Table 4: Package cost for atonic PPH management across public healthcare levels in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

Annual costs:

Annual cost to the public health system was estimated for managing 27,915 women experiencing atonic PPH annually out of the 969,264 deliveries reported by the state of Maharashtra in the year 2017-18.[32] The estimated annual cost of medical management for atonic PPH was USD 1,032,647 (INR 6,66,05,750) or USD 36.9 (INR 2,386) per atonic PPH patient. Additionally, 2,791 women were estimated to require

UBT intervention followed by devascularization surgery, hysterectomy or ICU facility for uncontrolled cases. The annual cost of managing these uncontrolled cases in public health facilities of Maharashtra, India is USD 193,963 (INR 1,25,10,610) for condom-UBT, USD 188,090 (INR 1,21,31,800) for ESM-UBT and USD 620,297 (INR 4,00,09,169) for Bakri-UBT if used in atonic PPH management. This corresponds to a UBT insertion per eligible beneficiary cost of USD 69.5 (INR 4,482) for condom-UBT, USD 67.4 (INR 4,346) for ESM-UBT and USD 222.2 (INR 14,333) for Bakri-UBT. Overall, the health system incurs a per atonic PPH patient treatment cost of USD 43.9 (INR 2,834) if condom-UBT, USD 43.7 (INR 2,820) if ESM-UBT and USD 59.2 (INR 3,819) per case if Bakri-UBT is made available and used in atonic PPH management. Table 5 describes the annual health system cost of atonic PPH management in Maharashtra, India.

Table 5: Annual public health system cost of managing atonic PPH using three UBT devices in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

Cost centre	Condom-UBT USD (95% CI)	ESM-UBT USD (95% CI)	Bakri-UBT USD (95% CI)

Atonic PPH medical management cost (a)	1,032,647 (688893 – 1375716)		
Atonic PPH medical management cost per case	36.9 (29-45)		
UBT training cost (b)	34,109 (25817 – 42579)		
UBT device cost	5,540 (2362 – 8664)	17,182 (7324 – 26770)	413,485 (180,326 – 652,695)
Uncontrolled atonic PPH management cost with UBT and surgical interventions (c)	193,963 (152,772 – 232,481)	188,090 (150393 – 226901)	620,297 (386981 – 857415)
Uncontrolled atonic PPH management cost per case	69.5 (47 – 94)	67.4 (47 – 88)	222.2 (145 – 299)
Annual total cost for atonic PPH management (a + b + c)	1,226,610 (870250 – 1581596)	1,220,737 (876187 – 1566385)	1,652,944 (1224827 – 2061670)
Cost of atonic PPH management per case	43.9 (36 – 53)	43.7 (35 – 52)	59.2 (46 – 73)

DISCUSSION

To our knowledge, this is the first study comprehensively assessing public health system costs associated with atonic PPH management in India. A study conducted in Myanmar at a 25 bedded hospital reported cost of PPH management along with other obstetric complications.[33] Similarly, an Egypt study reported

estimates of direct health system costs for different procedures used in PPH management from two district hospitals.[34] Our study specifically estimates health system costs of managing atonic PPH across all healthcare levels in the Indian public health system as per its guidelines. This paper focuses on estimating cost implications of using different uterine balloon tamponade techniques to control atonic PPH bleeding with their reported clinical effectiveness. Additionally, we have undertaken costing of medical management, surgical interventions subsequent to failed UBT treatment and patient referral across all public healthcare levels of India.

Our analysis reports a total cost of USD 43.9 (95% CI 36-53) per atonic PPH patient for condom-UBT, USD 43.7 (95% CI 35–52) for ESM-UBT and USD 59.2 (95% CI 46-73) for Bakri-UBT use in Maharashtra's public health system for the year 2017-18. The study from Myanmar reports an inflation adjusted unit cost of USD 28 (±1.61) per case for managing PPH in their hospital study setting.[35] The Egypt study reports an adjusted treatment cost of USD 110 per case for PPH but reports use of UBT intervention in 3.9% cases as compared to 9.9% in our study. As primary data was not available, the assumption that all those needing UBT intervention would receive it could be one of the reasons for lower unit costs in our study as there would be reduction in subsequent surgical interventions. Neither of the two studies reported costs for UBT intervention separately.

The unit cost of medical management for atonic PPH case in our study was USD 36.9 (INR 2,386). Unit cost of UBT device insertion increased gradually with higher facility level and was dominated by the cost of the UBT device. Package costs for UBT insertion at primary level included referral cost and hence reported higher costs as compared to secondary or tertiary level. Unit and package costs for surgical intervention subsequent to UBT failure was found to be higher at secondary level as compared to tertiary level in our study. Tertiary level hysterectomy cost at USD 84.8 (INR 5,471) per case in our study is in a similar range as reported by another Indian study at an adjusted cost of USD 95.7 (INR 6174) at district hospital.[36] Likewise, stepwise devascularization surgery in the Egypt study reported an adjusted cost of USD 62 per case, along the same range as reported in our findings. Unit and package surgical costs in our

study varied depending on clinical effectiveness of the UBT device affecting consumption of resources. Cost of condom-UBT device in Indian public health facilities was USD 1.9 (INR 128), one-third the price of ESM-UBT device. Bakri balloon at a market price of USD 148 (INR 9554) in India, costs significantly higher in comparison to the other two devices. Bakri-UBT at a higher price and lower reported clinical effectiveness in controlling atonic PPH, accounted for higher unfavorable unit and package costs in our analysis. ESM-UBT reported a marginally higher clinical effectiveness but had a three-time higher device cost as compared to condom-UBT. The unit cost however for both condom and ESM-UBT was similar at USD 43.9 (INR 2,834) and USD 43.9 (INR 2820).

Cost of medical management of atonic PPH across healthcare levels in this study constitutes a major component of annual costs (84.2% for Condom-UBT, 84.6% for ESM-UBT and 62.5% for Bakri-UBT). This is expected as majority patients are controlled with uterotonics and supportive measures. Remaining portion of annual costs are accounted by UBT and subsequent interventions for uncontrolled cases (15.8% for condom-UBT, 15.4% for ESM-UBT and 37.5% for Bakri-UBT). Both condom and ESM-UBT have lower unit, package and annual costs as compared to Bakri-UBT. However, the strength of clinical effectiveness evidence available for ESM-UBT at the time this study was conducted was limited to a few case series studies.[37–39]. Cost implication for using ESM-UBT device would vary if higher quality of clinical effectiveness evidence and procurement cost for equipping all Indian public health facilities uniformly with the device is made available. The cost of UBT device itself as a proportion of the annual cost accounted to 0.5% for condom-UBT, 1.4% for ESM-UBT and 25% for Bakri-UBT. In the absence of UBT intervention, uncontrolled atonic PPH cases would need surgical intervention, thus inflating overall costs for the health system and having an impact on maternal morbidity and mortality outcomes.

The state of Maharashtra in the year 2017-18 would have spent USD 1,226,610 (INR 7,91,16,359) if it catered to all atonic PPH cases in public facilities with condom-UBT as per treatment guidelines. Alternatively, if ESM-UBT or Bakri Balloon was used, the state would spend USD 1,220,737 (INR 7,87,37,549) or USD 1,652,944 (INR 10,66,14,919) respectively. Atonic PPH management using condom-

UBT in Maharashtra thus accounted for 3.8% of the annual spending on Reproductive and Child Health (RCH) activities in the year 2017-18.[40,41] With ESM or Bakri-UBT in place, atonic PPH management would account for 3.8% or 5.2% of the annual RCH spending.

This study has empirically derived costs for atonic PPH management across public healthcare levels for a state in India. The WHO guideline development group has identified use of uterine balloon tamponade in PPH as a research priority.[42] Our study provides evidence for equipping health systems with a choice for a clinically effective UBT intervention that is affordable and suitable for low resource settings like India. Findings of this study can be used to optimize efficiency by improving financial allocation within the health system. Under the revised Janani Shishu Suraksha Karyakaram (JSSK) scheme in India, pregnant women accessing public facilities are entitled to free treatment for childbirth and pregnancy complications.[43] However, studies have reported relatively higher out of pocket expenditures among women with post-delivery complications availing these entitlements.[44] The PMJAY scheme has revised high risk and caesarean section delivery package costs to USD 178 (INR 11,500). This package is inclusive of drugs, diagnostics, consultations, procedures, stay and food for the patient availing care.[45] The results from our study can be used to address package costs for the post-partum PPH complication across different publicly financed health schemes to reduce the financial burden on beneficiaries.

Limitations:

The study bases its cost findings from one region of Maharashtra by collecting data form sample facilities across healthcare levels. Given the differences within districts and across states in India, provisioning and utilization of healthcare services vary on account of epidemiological, social and contextual factors. Although we have undertaken an uncertainty analysis to address these factors to an extent, generalizability of the study across India may be difficult. For analysis, it was assumed that all atonic PPH cases requiring UBT intervention will receive it and a uniform UBT device would be available across all facilities. However, in practice this might differ resulting in deviation of cost estimates from those reported. Facility

level disaggregated HMIS data on PPH and corresponding service utilization was not available, so we had to rely on literature-based probabilities to derive service utilization for costing.

CONCLUSION

The study provides health system costs for managing atonic PPH complication in public facilities of India. Policy makers can use cost estimates to inform budgetary allocation decisions to equip the Indian health system with a suitable UBT device choice. However, programs must optimize performance of the health providers, equip facilities and supply lines with the right commodities and ensure efficient referral systems necessary to save a woman's life. This cost evidence can be used to undertake economic evaluation for UBT device options at public health facilities in India to determine the most cost-effective choice.

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Author Contributions

BJ, SS and KM were responsible for conceptualization and design of the study. KM and HC undertook data collection. SS and KM analyzed the data. BJ checked the analysis and edited the manuscript. SS was responsible for the first draft and all authors contributed to further revisions. All authors read and approved the final manuscript.

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Competing interests

None declared

Patient consent

Not required

Data sharing statement

All unpublished data are available upon reasonable request to the corresponding author BJ through E-mail

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Cost of managing atonic postpartum hemorrhage with uterine balloon tamponade devices in public health settings of Maharashtra, India: An economic micro-costing study

Authors and Affiliations:

Dr. Siddesh Sitaram Shetty

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Kusum Venkobrao Moray

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Mr. Himanshu Chaurasia

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Beena Nitin Joshi (**Corresponding Author)**

Department of Operational Research,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai

Jehangir Merwanji Street, Parel, Mumbai, Maharashtra, India

Phone number: +91-9820252672 / Office number: +(91-22)24192043

Email ID – bjoshithane@gmail.com

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Research Checklist

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Economic costing, postpartum hemorrhage, Uterine balloon tamponade, public health system cost

Cost of managing atonic postpartum hemorrhage with uterine balloon tamponade devices in public health settings of Maharashtra, India: An economic micro-costing study

ABSTRACT

Objective

Post-partum hemorrhage (PPH) is the worldwide leading cause of preventable maternal mortality. India offers free treatment for pregnancy and related complications in its public health facilities. Management with Uterine Balloon Tamponade (UBT) is recommended for refractory atonic PPH cases. As part of health technology assessment to determine the most cost-effective UBT device, this study estimated costs of atonic PPH management with condom-UBT, Every Second Matters (ESM) UBT and Bakri balloon UBT in the public health system of Maharashtra, India.

Design

Health system cost estimation using primary economic micro-costing, data from Health Management Information System (HMIS) and published literature for event probabilities.

Settings

Four public health facilities from the state of Maharashtra, India representing primary, secondary and tertiary level care were chosen for primary costing.

Outcome measures

The outcomes measured were unit, package and annual costs of atonic PPH management with three UBT devices. This included cost of medical management, UBT intervention and PPH related surgeries undertaken in public health system of Maharashtra in the year 2017-18.

Results

Medical management of atonic PPH cost the health system USD 37 (95% CI 29-45) per case, increasing to USD 44 (95% CI 36-53) with condom-UBT and surgical interventions for uncontrolled cases. Similar cost was estimated for ESM-UBT. Bakri-UBT reported a higher cost of USD 59 (95% CI 46-73) per case. Overall annual cost of managing all atonic PPH cases in Maharashtra was USD 1,226,610 (95% CI 870,250 – 1,581,596).

Conclusions

Atonic PPH management in public health facilities of Maharashtra with condom-UBT, ESM-UBT or Bakri UBT use accounts to 3.8%, 3.8% or 5.2% of the state's annual spending on reproductive and child health services. These findings can guide policy makers to include the PPH complication in publicly financed health schemes. Economic evaluation studies can use this evidence to determine UBT cost-effectiveness in Indian settings.

Strengths and limitations of this study

- To our knowledge, this is the first study from India comprehensively assessing public health system costs in overall management of atonic PPH with medical interventions, uterine balloon tamponade and surgical management across all public healthcare levels in the state
- The study uses clinical effectiveness of individual uterine balloon tamponade devices to determine health system costs
- As disaggregated HMIS data in the study setting was not available for PPH, literature-based event probability estimates from the Indian context were used to estimate costs
- An assumption was made that for a particular UBT device, all eligible cases would receive only that particular UBT across all facilities.

INTRODUCTION

The global shift towards Universal Health Coverage (UHC) indicated by Sustainable Development Goals (SDG) needs robust financing mechanisms. To achieve desired targets, evidence informed by costing studies can be vital to support financing decisions. Information on cost enables improved resource allocation, thus strengthening policy measures to attain high value for a given investment. A key priority under the SDG health goal is reduction of maternal mortality level to less than 70 per 100,000 live births by the year 2030. Evidence confirms women's health to be associated with development and economic performance of a country.[1] A marginal health investment at lower GDP levels seen commonly in low or low-middle income countries is found to have higher effects on health outcomes.[2] Improved maternal health not only reduces household healthcare expenditure, but is also associated with long term economic benefits to the society.

In spite of a low spending of 1% of GDP on public health expenditure, India has managed to reduce maternal mortality ratio down to 122 per 100,000 live births by the year 2015-17, largely attributed to reforms such as institutionalization of deliveries, provisioning of free cashless services to pregnant women and addressing social determinants of health.[3–5] Despite ongoing efforts, India still accounts for nearly one-fifth of all maternal deaths globally with hemorrhage as its leading cause.[6] Post-Partum Hemorrhage (PPH) accounts for more than two-third of all global maternal deaths due to bleeding.[7,8] PPH is defined as maternal blood loss of 500 ml or more within 24 hours after delivery and affects nearly 3-6% of all women giving birth in India.[9] Atony of uterus is the most common PPH type responsible for 80% of all cases.[10]

Indian guidelines base PPH management on principles of treatment for shock, cause-specific PPH management and patient stabilization before referral to higher facilities.[11] India has initiated standardization of Labour Rooms (LR) under the 'Dakshata' initiative, equipping delivery rooms to provide comprehensive care at all times. In accordance with the WHO guideline for atonic PPH management, uterotonics remain the mainstay of treatment in India.[12] Hemodynamic stabilization and supportive

resuscitation measures are expected to be ongoing. Use of UBT device is recommended if uterotonic agents fail in controlling atonic PPH bleeding. At primary level in India, all atonic PPH cases are expected to be provided with medical management and UBT intervention to stabilize and control bleeding before referral to a higher facility for observation or further interventions. Cases uncontrolled after UBT insertion at secondary or tertiary level may require B-Lynch compression suturing, stepwise devascularization surgery (uterine, or internal iliac artery ligation) or other procedures depending on availability of expertise and facility infrastructure. Hysterectomy, a lifesaving procedure is indicated after failed conservative measures or directly after UBT insertion based on patient response. Obstetric intensive care (ICU) admission may be needed for observation or managing complications due to PPH.

UBT intervention for atonic PPH is a relatively simple life-saving technique that can be used even in low resource settings with limited provisions for surgery, blood transfusion or referral mechanisms. UBT technique is clinically effective in controlling PPH bleeding and reduces need for further surgical interventions.[13] Timely use of UBT device can potentially be cost-saving by improving maternal morbidity and mortality outcomes. Multiple UBT devices specifically designed, assembled or modified for use in PPH management are available. Being economical, an assembled condom-UBT device is the recommended standard of care (SOC) for atonic PPH management in India.[14] In the state of Maharashtra where this study was undertaken, apart from the recommended condom-UBT device, Bakri balloon and ESM-UBT, two ready to use sterile packed devices made available by non-governmental organizations are being used across different public health settings.[15–17] The three UBT devices have certain distinct features giving each an advantage over the other. Literature reports varying clinical effectiveness and price for these UBT devices. Table 1 shows distinct characteristics of these three UBT devices used in atonic PPH management, collated from a literature review undertaken separately. (Supplementary material 1)

Table 1: Characteristics of UBT devices used commonly for atonic PPH management in India

UBT device	Cost of device	Clinical effectiveness#	Advantages
Condom-UBT	USD 2 (INR 128) * Assembly components commercially available	92.3%	Inexpensive, Assembled using available resources, Modified versions are used to assess blood loss post insertion
ESM-UBT	USD 6 (INR 397).[18,19] Commercially not available at present	95.3%**	Relatively inexpensive, Specifically designed for PPH use, All components needed for assembly available in a sterile pack, US-FDA approved device
Bakri Balloon UBT	USD 148 (INR 9,554).[20] Commercially available at present	84.3%	Ready to use, Specifically designed for PPH use, Comes in a sterile pack, Has drainage outlet to measure ongoing blood loss, US-FDA approved device

- Estimated from literature review of 33 studies

* - Calculated using health facility purchase lists

** - Strength of evidence is limited, based on evidence available from three case series studies

Under India's flagship *Pradhan Mantri Jan Arogya Yojana (PMJAY)* public health insurance scheme, a woman is entitled to cashless treatment package cost of USD 178 (INR 11,500) for high risk vaginal deliveries and all cesarean sections. Evidence suggests that despite improved maternal outcomes with publicly sponsored schemes, extent of out-of-pocket expenditure for institutional delivery remains high

especially with pregnancy complications.[21] At present, the existing packages do not cover the post-partum PPH complication and there is no documented health system cost available for management of this condition. The Ministry of Health and Family Welfare (MOHFW), Government of India is assessing the most cost-effective UBT device for atonic PPH management in the public health system given the emerging evidence for the relatively low cost ESM-UBT alternative.[22–24] The policy decision to make a UBT device available for PPH management across health facilities will have associated cost and health outcome implications. This study aimed to calculate public health system cost of atonic PPH management with SOC i.e. condom-UBT, recommended by the 2015 Indian guidelines for PPH management with similar projections for ESM-UBT and another globally used Bakri-UBT device.[14]

METHODS

This costing study was part of a Health Technology Assessment (HTA) project to evaluate the most cost-effective UBT device for atonic PPH management in India. An economic costing from the health system perspective using primary bottom-up micro-costing, data from HMIS and literature review for event probabilities were used to determine and compare unit, package and annual cost of atonic PPH management with three UBT devices namely condom-UBT, ESM-UBT and Bakri balloon UBT in public health facilities of Maharashtra, India. The study was approved by the NIRRH Ethics Committee for Clinical Studies (Approval number: D/ICEC/Sci-29/31/2018). State health department administrative approvals and consent from respective health facility authorities were obtained before undertaking the study.

Patient and public involvement:

There was no patient or public involvement in this study design, conduct or reporting of this study and hence no consent was obtained.

Study settings:

Maternal healthcare in the Indian public system is delivered through a three-tier system. The facilities in this study were classified depending on availability of services for atonic PPH management. Primary level care for PPH management comprises of Primary Health Centers (PHC) that are equipped with skilled birth attendants and a medical officer. Secondary level is made by Community Health Centers (CHC) and Sub-District Hospitals (SDH) that additionally are equipped with obstetrics-gynecology (OBGYN) specialist, operation theater (OT) and facilities for blood transfusion. Tertiary level comprises of District Hospitals (DH) and medical colleges having additional advanced intervention and ICU facilities.[25,26] The study enrolled four public health facilities from the state of Maharashtra in India to ensure representation of all three levels of care. A convenience sample of one PHC, SDH, DH, and a tertiary medical college from Mumbai metropolitan region in Maharashtra was chosen for data collection.

Data collection:

Cost data for one-year duration from April 2017 to March 2018 was collected by adapting a validated standard tool developed for costing of health services in India.[27] Cost resources were broadly classified into human resources, infrastructure, medical equipment, non-medical equipment, drugs, consumables, and utilities like electricity, water and laundry. Consumption data for these resources were obtained from available facility level and Hospital Management Information System (HMIS) sources. As PPH specific patient indicators were unavailable in the HMIS, obstetric patient aggregate information such as number of vaginal or cesarean section deliveries, number and type of obstetric surgeries, hysterectomies, number of blood transfusions, in-patient admissions, emergency or obstetric ICU admissions as reported for chosen facilities were obtained. Available electronic hospital records, written registers, building plan of health facilities, salary slips, bills, statements of the accounts department were accessed to obtain facility level resource utilization details. Floor area measurement and facility observations were undertaken to get details on infrastructure of the IPD, LR, ICU, laboratory, pharmacy and administrative departments. For unavailable patient level information specific to PPH, we relied on literature based event probability estimates of atonic PPH incidence in Indian settings, clinical effectiveness of three UBT devices in

controlling atonic PPH bleeding from a targeted literature review, probability of PPH related surgeries, its success rate, morbidity and PPH mortality rates applied to the available facility level data to allocate utilization of resources for costing.[9,10,28–30] Staff interviews were undertaken to assess proportion of time spent on PPH specific activities. A total of 16 doctors, 26 nursing staff, 5 pharmacists and 11 administrative staff across chosen study facilities were interviewed. As an example, all doctors were asked questions pertaining to the time spent on each patient in out-patient department (OPD), in-patient department (IPD), surgery, teaching, documentation, administrative and other routine tasks but the time spent by the senior-most doctor in performing an obstetric hysterectomy out of all routine tasks was used in costing obstetric hysterectomy procedure for eligible PPH cases. Collected data from individual facilities including staff interviews along with India specific PPH literature was used to determine unit, package and annual costs for atonic PPH management components across all healthcare levels in Maharashtra, India. Table 2 enlists the input parameters used to determine service utilization for PPH across chosen facilities.

Table 2: Parameters used to determine service utilization for atonic PPH management in Maharashtra based on event probability from Indian context literature

Parameter	Value in cost analysis*	Source
Annual number of deliveries at primary level facility (1 PHC)	Vaginal – 494	Facility HMIS 2017-18
Annual number of deliveries at secondary level facility (1 SDH)	Vaginal – 1526 Caesarean section – 330	Facility HMIS 2017-18
Annual number of deliveries at tertiary level facilities (1 DH & 1 Medical college)	Vaginal – 5188 Caesarean section – 2186	Facility HMIS 2017-18
Annual number of institutional deliveries in public health facilities of Maharashtra, India (Includes home deliveries)	9,69,264	HMIS 2017-18
Incidence of PPH in vaginal deliveries in India	3%	[9,31]
Incidence of PPH in cesarean section deliveries, India	6%	[9,31]
Probability of PPH due to uterine atony in India	0.80	[10]
Probability of atonic PPH controlled with medical management	0.90	[30]
Annual number of atonic PPH cases eligible for UBT device insertion in Maharashtra, India	2,791	Calculation using India specific PPH event probabilities
Probability of stepwise devascularization surgical procedures for uncontrolled cases after UBT	0.85	[30]
Probability of obstetric hysterectomy surgery for uncontrolled cases after UBT	0.15	[30]

Data analysis:

To determine PPH events occurring at facility level, PPH incidence rates in vaginal and cesarean section deliveries were applied to facility reported deliveries to determine number of cases occurring annually. Proportion of atonic PPH cases uncontrolled after medical management determined the number of beneficiaries eligible for UBT device insertion after failed medical management. Clinical effectiveness of each individual UBT device derived from literature review determined the requirement of subsequent utilization of surgical resources with each individual UBT expected to take place at each healthcare level. (Supplementary material 1)

For cost analysis, resources were classified into capital and recurrent items. Capital resource items were annualized using the India recommended 3% discount rate and factoring in life expectancy and annual maintenance rate of the items.[32] Cost resources were apportioned using standard methods based on shared or exclusive nature of utilization and classification into capital or recurrent items.[33] Human resource salaries were apportioned based on the time spent for an activity out of all the respective services provided. Space was apportioned based on proportion of time and quantity spent on different activities in a given area. Drugs and consumables were apportioned as a proportion of utilization for PPH out of utilization for all healthcare services. Medical and non-medical equipment were first annualized and then apportioned as the proportion of time used specifically for the given PPH event out of all activities. Utilities such as water/electricity were apportioned as the proportion of floor area occupied for a particular service. The apportioning factors were determined from staff interviews, available facility or HMIS data and literature. Monetary value of cost resources was obtained from the individual facility purchase lists. Data was analyzed using Microsoft Excel 2016. Worksheets were developed for cost calculation of each component at each facility followed by weighted aggregation of costs to the level of care individually for each UBT. For example, unit condom UBT insertion cost at DH and medical college was aggregated to get a unit condom UBT insertion cost for tertiary level. All costs are presented in United States Dollars (USD) and

Indian National Rupee (INR) currency. A conversion rate of 1 USD = 64.5 INR for the year 2017-18 was used.[34]

Unit costs

Unit costs were calculated for each component of atonic PPH management expected at respective healthcare level. The components included cost of medical management for atonic PPH, UBT insertion for refractory cases, devascularization surgery, hysterectomy, IPD admission, ICU admission and cost of patient referral at respective levels. Number of deliveries and obstetric surgeries from facility and HMIS data, staff interviews and literature evidence determined denominators like number of atonic PPH cases at the healthcare level, number of UBT eligible beneficiaries, number of referrals, number of consequential conservative or obstetric hysterectomy surgeries at the facility level. This with collected cost data was used to compute per beneficiary unit cost for the identified components of atonic PPH management at respective healthcare level. Unit cost of UBT insertion included the cost of UBT device. Unit cost of medical management, referral and IPD admission were expected to remain unaffected irrespective of the type of the UBT device used. For these services, costs were calculated only for SOC i.e. management with condom-UBT device.

Package costs

To account for treatment combinations used in management of atonic PPH, treatment package costs were determined. For a certain treatment, package cost was calculated by adding unit cost associated with all treatment components for management at respective healthcare level. For all patients at primary and secondary care requiring transport, referral costs were added to get package costs.

Annual costs

Unit and package cost calculation was followed by annual health system cost estimation for an annual cohort of women in Maharashtra experiencing atonic PPH after delivering in public healthcare facilities. Number of deliveries occurring across the three respective public healthcare levels in Maharashtra were

combined with respective PPH service utilization units to get pooled annual cost for a given service. Annual health system cost was then estimated by combining annual health system cost of medical management, further course of interventions using UBT device in uncontrolled cases and training cost for UBT. Unit cost for every treatment component at each facility was first aggregated to primary, secondary and tertiary level and then applied to the annual eligible population cohort in Maharashtra to estimate annual costs with each UBT device.

Certain methodological assumptions were made during cost analysis. It was assumed that for a particular UBT device, all eligible atonic PPH cases would receive only that particular UBT across all facilities. It was assumed that at primary level, all women after medical management or UBT insertion would immediately be referred to secondary care. Unit calculated cost of per day IPD or ICU admission for patients at chosen facilities were apportioned to literature based atonic PPH length of stay to estimate IPD and ICU costs for atonic PPH management.[35–37] Cost of blood transfusion and other resuscitation measures were incorporated in unit costs throughout management and are not calculated separately. Training costs were estimated for one day training of healthcare providers.[38] Due to time and resource limitation for primary estimation of PPH referral costs, an inflation adjusted cost of USD 15.5 (INR 1,001) per case was used from a published Indian primary economic costing study that calculated public health system cost of transportation for institutional delivery services in three districts of an Indian state.[39] B-Lynch suturing and stepwise devascularization surgery in this study were considered as a single unit for cost calculation.

Probabilistic sensitivity analysis was used to address joint uncertainty effect of input parameters on costs. A beta distribution for probabilities and proportions, a gamma distribution for cost and resource use was assigned for parameter variation on both sides. As drugs and consumables are procured by the government at a negotiated price whereas market prices show variation on the higher side, these were varied by 50% and 100% on lower and upper limit respectively. UBT device price was assumed to vary by 50% on both sides. Remaining parameters such as salaries, rental prices, medical and non-medical equipment, utilities and utilization of services were varied by 25%.[40] Monte Carlo simulations were run to obtain 1000 unit

cost estimates. These estimates were used to determine 95% confidence interval (CI) limits for all reported costs.

RESULTS

The chosen sample of four public health facilities from Maharashtra reported 7,208 vaginal and 2,516 cesarean section deliveries in the year 2017-18. Of the 9,724 total deliveries, 293 women were expected to experience atonic PPH. Twenty-nine out 293 cases would remain uncontrolled after medical management, thus becoming eligible for UBT device insertion. Further depending on clinical effectiveness of individual UBT device in controlling bleeding, remaining cases undergo surgical intervention depending on infrastructure and resource availability at respective clinical setting.

Unit costs:

Medical management of atonic PPH cases costs the health system USD 0.7 (INR 42), USD 5 (INR 322) and USD 9.4 (INR 609) per patient at primary, secondary and tertiary levels respectively. For uncontrolled cases requiring further intervention, condom-UBT (SOC) insertion costs USD 2.5 (INR 160), USD 5.3 (INR 339) and USD 6.5 (INR 422) at the three respective levels. Devascularization group of surgery for uncontrolled cases after condom-UBT insertion costs the health system USD 75.4 (INR 4864) per case at secondary and USD 53.0 (INR 3,419) per case at tertiary level. Similarly, hysterectomy procedure costs USD 120.6 (INR 7,782) per case at secondary and USD 84.8 (INR 5,471) at tertiary level. Table 3 provides the health system unit costs with condom-UBT, ESM-UBT and Bakri-UBT. IPD admission for an atonic PPH case costs the health system USD 27.5 (INR 1,776) per patient at secondary and USD 28.0 (INR 1,806) per patient at tertiary level. ICU admission at tertiary facility costs the health system USD 76.0 (INR 4,902) per patient getting admitted for atonic PPH management. One-time training of medical officers and OBGYN specialists across public health facilities of Maharashtra costs USD 12.1 (INR 778) per eligible case of UBT device insertion.

Table 3: Unit costs for atonic PPH management components across public health facility levels in Maharashtra, India [1 USD = 64.5 INR]

	Medical management	UBT insertion	Devascularization	Hysterectomy	Inpatient Admission	ICU admission
Per patient unit cost with Condom-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	2.5 (1.5-3.5)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	5.3 (4.1-6.5)	75.4 (49.4-104.4)	120.6 (77.9-168.2)	27.5 (16.8-39.5)	NA
Tertiary	9.4 (6.7-12.6)	6.5 (5.3-7.9)	53.0 (41.9-64.4)	84.8 (66.3-104.4)	28.0 (20.7-35.9)	75.9 (50.3-104.6)
Per patient unit cost with ESM-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	6.7 (3.6-9.9)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	8.8 (5.9-11.6)	56.9 (37.1-79.0)	119.9 (79.3-162.7)	27.5 (16.8-39.5)	NA
Tertiary	9.4 (6.7-12.6)	10.4 (8.5-12.5)	51.7 (40.6-63.7)	86.5 68.0-107.1)	28.0 (20.7-35.9)	75.9 (50.3-104.6)
Per patient unit cost with Bakri-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	148.6 (74.3-219.0)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	151.1 (88.0-214.8)	76.8 (51.2-103.9)	119.7 (80.1-165.4)	27.5 (16.8-39.5)	NA
Tertiary	9.4 6.7-12.6)	153.1 (113.0-191.8)	53.0 (41.6-64.7)	84.8 (67.2-103.7)	28.0 (20.7-35.9)	75.9 (50.3-104.6)

Package cost:

Of the eligible cases, condom-UBT successfully controls 92.3% of the cases after device insertion and ongoing medical and resuscitation measures. This combination treatment costs the health system a total of USD 46.2 (INR 2,979), USD 37.8 (INR 2,437) and USD 44.0 (INR 2,838) at three respective levels. This treatment package comprises costs of medical management, UBT insertion, IPD admission and additional referral cost for primary care patients. Treatment package cost of control with devascularization surgery after condom-UBT insertion and medical treatment costs the health system a total of USD 113.2 (INR 7,301) and USD 97.0 (INR 6,256) per patient at secondary and tertiary levels respectively. Similarly, a direct hysterectomy for uncontrolled atonic PPH after UBT insertion costs USD 158.4 (INR 10,218) and USD 128.8 (INR 8,308) at secondary and tertiary levels respectively. Less than 4% of the uncontrolled atonic PPH cases with condom-UBT insertion are expected to require ICU facility for atonic PPH management. Health system package costs for such treatment combinations can be derived from the given unit cost table. Alternatively, if ESM or Bakri-UBT device is used in controlling atonic PPH, package cost varies on account of device effectiveness and associated resource use. Table 4 lists treatment package cost estimates for atonic PPH management with three UBT devices.

Table 4: Treatment package cost for atonic PPH management across public healthcare levels in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

	Condom UBT	ESM UBT	Bakri UBT
Package cost for atonic PPH controlled after UBT insertion in USD (95% Confidence interval)			
Primary	46.2 (34.9-59.1)	50.4 (38.5-63.8)	192.3 (153.8-230.8)
Secondary	37.8 (28.5-48.3)	41.3 (31.9-52.0)	184.1 (147.0-222.4)
Tertiary	43.9 (35.4-53.3)	47.9 (39.6-57.0)	190.5 (149.9-233.2)
Package cost for atonic PPH controlled with devascularization surgery after UBT failure in USD (95% Confidence interval)			
Secondary	113.2 (103.2-123.8)	98.2 (88.5-108.7)	260.9 (218.6-304.2)
Tertiary	96.9 (88.7-106.3)	99.6 (91.4-109.3)	243.5 (202.2-286.9)
Package cost for atonic PPH controlled with direct hysterectomy after UBT failure in USD (95% Confidence interval)			
Secondary	158.4 (149.6-168.9)	161.1 (152.1-171.7)	303.8 (256.0-355.6)
Tertiary	128.8 (120.5-138.6)	134.4 (126.2-144.0)	275.3 (231.2-319.1)

Annual costs:

Annual cost to the public health system was estimated for managing 27,915 women experiencing atonic PPH annually out of the 969,264 deliveries reported by the state of Maharashtra in the year 2017-18.[41] The estimated annual cost of medical management for atonic PPH was USD 1,032,647 (INR 6,66,05,750) or USD 36.9 (INR 2,386) per atonic PPH patient. Additionally, 2,791 women were estimated to require UBT intervention followed by devascularization surgery, hysterectomy or ICU facility for uncontrolled cases. The annual cost of managing these uncontrolled cases in public health facilities of Maharashtra, India is USD 193,963 (INR 1,25,10,610) with condom-UBT, USD 188,090 (INR 1,21,31,800) with ESM-UBT and USD 620,297 (INR 4,00,09,169) with Bakri-UBT when used for uncontrolled atonic PPH cases. This corresponds to a per eligible beneficiary cost of USD 69.5 (INR 4,482) for control with condom-UBT and subsequent interventions, USD 67.4 (INR 4,346) for ESM-UBT and USD 222.2 (INR 14,333) for Bakri-UBT respectively. Overall, the health system incurs a per atonic PPH patient treatment cost of USD 43.9 (INR 2,834) with condom-UBT, USD 43.7 (INR 2,820) with ESM-UBT and USD 59.2 (INR 3,819) per case with Bakri-UBT if made available for atonic PPH management in Maharashtra, India. Table 5 describes the annual health system cost of atonic PPH management in Maharashtra, India.

Table 5: Annual public health system cost of managing atonic PPH using three UBT devices in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

Cost center	Condom-UBT USD (95% CI)	ESM-UBT USD (95% CI)	Bakri-UBT USD (95% CI)
Annual atonic PPH medical management cost (a)	1,032,647 (688893 – 1375716)		
Annual UBT training cost (b)	34,109 (25817 – 42579)		
Annual cost for uncontrolled atonic PPH cases managed with UBT device and surgical interventions (c)	193,963 (152,772 – 232,481)	188,090 (150393 – 226901)	620,297 (386981 – 857415)
Total annual cost of atonic PPH management (a + b + c)	1,226,610 (870250 – 1581596)	1,220,737 (876187 – 1566385)	1,652,944 (1224827 – 2061670)
Annual UBT device cost	5,540 (2362 – 8664)	17,182 (7324 – 26770)	413,485 (180,326 – 652,695)
Per patient cost of medical management for atonic PPH	36.9 (29-45)		
Per patient cost of managing uncontrolled atonic PPH cases with UBT and surgical interventions	69.5 (47 – 94)	67.4 (47 – 88)	222.2 (145 – 299)
Per patient health system cost of atonic PPH management	43.9 (36 – 53)	43.7 (35 – 52)	59.2 (46 – 73)

DISCUSSION

To our knowledge, this is the first study comprehensively assessing public health system costs associated with atonic PPH management in India. A study conducted in Myanmar at a 25 bedded hospital reported cost of PPH management along with other obstetric complications.[42] Similarly, an Egypt study reported estimates of direct health system costs for different procedures used in PPH management in two district hospitals.[43] Our study specifically estimates health system cost of managing atonic PPH across healthcare levels in the Indian public health system using primary cost data. This paper focuses on estimating the cost of using different uterine balloon tamponade devices given their varying reported clinical effectiveness in controlling atonic PPH bleeding. Additionally, we have undertaken costing of medical management and surgical interventions subsequent to failed UBT treatment across public healthcare levels of India.

Our analysis reported a total cost of USD 43.9 (95% CI 36-53) per atonic PPH patient with condom-UBT, USD 43.7 (95% CI 35–52) with ESM-UBT and USD 59.2 (95% CI 46-73) with Bakri-UBT use in Maharashtra's public health system for the year 2017-18. The study from Myanmar reported an inflation adjusted unit cost of USD 28 (±1.61) per case for managing PPH in their hospital study setting.[44] The Egypt study reported an adjusted treatment cost of USD 110 per case for PPH but reported use of UBT intervention in 3.9% cases as compared to 9.9% in our study. As primary data was not available, the assumption that all those needing UBT intervention would receive it may be one of the reasons for lower unit costs in our study as UBT intervention would reduce subsequent surgical interventions. Neither of the two studies reported UBT intervention costs specifically.

The unit cost of medical management for an atonic PPH case in our study was USD 36.9 (INR 2,386). Unit cost of UBT device insertion increased gradually with higher facility level and was dominated by the cost of UBT device itself. Treatment package costs for UBT insertion at primary level included referral cost and hence reported higher costs as compared to secondary or tertiary level. Unit and package costs for surgical

intervention subsequent to UBT failure was found to be higher at secondary level as compared to tertiary level in our study. Tertiary level hysterectomy cost at USD 84.8 (INR 5,471) per case in our study is in the similar range as reported by another Indian study at an adjusted cost of USD 95.7 (INR 6174) for a district hospital.[45] Likewise, stepwise devascularization surgery in the Egypt study reported an adjusted cost of USD 62 per case is in the similar range to those reported in our findings. Unit and package surgical costs in our study also varied depending on clinical effectiveness of the UBT device affecting consumption of resources. Cost of condom-UBT device in Indian public health facilities was USD 1.9 (INR 128), one-third the price of ESM-UBT device. Bakri balloon at a market price of USD 148 (INR 9554) in India, costs significantly higher in comparison to the other two devices. Bakri-UBT at a higher price and lower reported clinical effectiveness in controlling atonic PPH, accounted for higher unfavorable unit and package costs in our analysis. ESM-UBT reported a marginally higher clinical effectiveness but had a three-time higher device cost as compared to condom-UBT. The unit cost however for both condom and ESM-UBT was similar at USD 43.9 (INR 2,834) and USD 43.7 (INR 2820).

Cost of medical management for atonic PPH across healthcare levels in this study constitutes a major component of the annual costs (84.2% for Condom-UBT, 84.6% for ESM-UBT and 62.5% for Bakri-UBT). This is expected as majority patients are controlled with uterotonics and supportive measures. Remaining portion of annual costs are accounted by UBT and subsequent interventions for uncontrolled cases (15.8% for condom-UBT, 15.4% for ESM-UBT and 37.5% for Bakri-UBT). Both condom and ESM-UBT have lower unit, package and annual costs as compared to Bakri-UBT. However, the strength of clinical effectiveness evidence available for ESM-UBT at the time of this study was limited to a few case series studies reporting survival rates.[19,22,23]. Cost implication of using ESM-UBT device would vary if higher quality of clinical effectiveness evidence and procurement cost of equipping all Indian public health facilities with the device is available. Cost of UBT device accounted to 0.5% of the annual health system costs with condom-UBT, 1.4% for ESM-UBT and 25% for Bakri-UBT respectively.

The state of Maharashtra in the year 2017-18 spent an estimated USD 1,226,610 (INR 7,91,16,359) by catering to all atonic PPH cases of public health facilities with condom-UBT intervention as per the treatment guidelines. Alternatively, if ESM-UBT or Bakri Balloon was available, the state would spend USD 1,220,737 (INR 7,87,37,549) or USD 1,652,944 (INR 10,66,14,919) respectively. Atonic PPH management with condom-UBT in Maharashtra thus accounted to 3.8% of the annual state spending on reproductive and child health (RCH) activities in the year 2017-18.[46,47] With ESM or Bakri-UBT in place, atonic PPH management would account to 3.8% or 5.2% of the annual RCH spending.

This study empirically derived costs of atonic PPH management across public healthcare levels for a state in India. The WHO guideline development group has identified use of uterine balloon tamponade in PPH as a research priority.[48] Our study provides economic evidence for equipping health systems with the choice of a clinically effective UBT intervention that is affordable and suitable for low resource settings like India. Findings of this study can be used to optimize efficiency by improving financial allocation within the health system. Under the revised *Janani Shishu Suraksha Karyakar*am (JSSK) scheme in India, pregnant women accessing public facilities are entitled to free treatment for childbirth and pregnancy complications.[49] Implementation under the PMJAY scheme has revised high risk and caesarean section delivery package costs to USD 178 (INR 11,500). This package is inclusive of drugs, diagnostics, consultations, procedures, stay and food for the patient availing care.[50] The results from our study can be used to address package costs for the post-partum PPH complication across different publicly financed health schemes to avoid any financial burden to the beneficiaries as reported with institutional deliveries in India.[21]

Limitations:

The study bases its cost findings from one region of Maharashtra by collecting data form sample facilities across healthcare levels. Given the differences within districts across the state, provisioning and utilization of healthcare services vary on account of socio-economical, epidemiological and other contextual factors. Although we have undertaken an uncertainty analysis to address these factors to an extent, generalizability

of the study results across states of India may be difficult. For analysis, it was assumed that all atonic PPH cases requiring UBT intervention will receive it and a uniform UBT device would be available across all facilities. However, in practice this might differ resulting in deviation of cost estimates from those reported. Facility level disaggregated HMIS data on PPH and corresponding service utilization was not available, so we had to rely on literature-based probabilities to derive PPH service utilization for costing.

CONCLUSION

The study provides health system cost of managing atonic PPH complication in Indian public health settings. Policy makers can use these findings to include the PPH clinical condition to treatment benefit packages under publicly financed health schemes and to inform budgetary allocations in order to equip the Indian health system with a suitable UBT choice. Economic evaluation studies can use this evidence to determine the most cost-effective UBT choice in Indian settings. In addition to equipping facilities and supply lines with the right commodities, programs must optimize performance of the health providers and ensure efficient referral systems in place to save a woman's life.

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Author Contributions

BJ, SS and KM were responsible for conceptualization and design of the study. KM and HC undertook data collection. SS and KM analyzed the data. BJ checked the analysis and edited the manuscript. SS was responsible for the first draft and all authors contributed to further revisions. All authors read and approved the final manuscript.

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Competing interests

None declared

Patient consent

Not required

Data sharing statement

All unpublished data are available upon reasonable request to the corresponding author BJ through E-mail

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Supplementary material

Table 1.1: Literature based event probabilities used for PPH utilization calculation of healthcare facilities

Input	Value	Reference
PPH incidence in vaginal delivery	3 percent	[1,2]
PPH incidence in caesarean delivery	6 percent	[1,2]
Atonic PPH incidence	80 percent	[3]
Atonic PPH controlled with medical management	90 percent	[4]
Clinical effectiveness of condom-UBT device in controlling atonic PPH	92.3 percent	Calculated from literature review of 33 studies reported in Table 1.3
Clinical effectiveness of ESM-UBT device in controlling atonic PPH	95.3 percent*	Calculated from literature review of 33 studies reported in Table 1.3
Clinical effectiveness of condom-UBT device in controlling atonic PPH	84.3 percent	Calculated from literature review of 33 studies reported in Table 1.3
Probability of stepwise devascularization procedure for uncontrolled atonic PPH cases after UBT insertion	0.85	[4]
Probability of obstetric hysterectomy for uncontrolled atonic PPH cases after UBT insertion	0.15	[4]
Probability of delivery at primary care level	0.19	[5]
Probability of delivery at secondary care level	0.33	[5]
Probability of delivery at tertiary care level	0.48	[5]

***** - *Estimated from limited evidence from 3 case-series studies reported in Table 1.3*

PPH incidence rate in vaginal/caesarean section delivery was applied to reported number of deliveries at each health facility to estimate number of PPH and thus proportional atonic PPH cases at the facility. Proportion of these atonic PPH cases uncontrolled after medical and supportive management were eligible for UBT device insertion. Literature review based clinical effectiveness of individual UBT device determined number of patients consequently needing conservative (devascularization) or obstetric hysterectomy surgical intervention.

Table 1.2: Utilization of services for atonic PPH at chosen health facilities of Maharashtra based on primary collected data and event probabilities from literature

Type of Health facility	Mode of Delivery	Annual number of deliveries	Atonic PPH cases	Atonic PPH controlled with medical management	Cases requiring UBT insertion	Controlled with UBT insertion Condom Bakri ESM	Cases requiring further intervention Condom Bakri ESM
PHC	Vaginal	494	11.86	10.67	1.18	1.09 1.00 1.13	0.09 0.19 0.06
SDH	Vaginal	1526	36.62	32.96	3.66	3.41 3.09 3.49	0.26 0.57 0.17
	Cesarean	330	15.84	14.26	1.58	1.47 1.34 1.51	0.11 0.25 0.07
DH	Vaginal	2986	71.66	64.49	7.17	6.66 6.04 6.83	0.50 1.13 0.34
	Cesarean	1045	50.16	45.14	5.02	4.66 4.23 4.78	0.35 0.79 0.24
Medical college	Vaginal	2202	52.84	47.56	5.28	4.87 4.44 5.03	0.37 0.83 0.25
	Caesarean	1141	54.76	49.29	5.47	5.05 4.61 5.21	0.42 0.85 0.25

Table 1.3: Details of the studies included in targeted literature review for the three UBT devices

Authors	Study design	PPH success rate	Atonic PPH success rate	Reference
Condom-UBT				
Darwish et al.	RCT	28/33 (84.8)	28/33 (84.8)	[6]
Tindell et al.	Systematic Review	186/193 (96.4)	NR	[7]
Santhanam et al.	Prospective	59/61 (96.7)	59/61 (96.7)	[8]
Rathore et al.	Prospective	17/18 (94.4)	NR	[9]
Aderoba et al.	Prospective	203/229 (88.6)	193/214 (90.2)	[10]
Mishra et al.	Prospective	59/60 (98.3)	NR	[11]
Kandeel et al.	Prospective	48/50 (96.0)	28/28 (100)	[12]
Anger et al.	RCT	56/64 (87.5)	NR	[13]
Dumont et al.	RCT	48/57 (84.2)	NR	[14]
Lohano et al.	Prospective	126/139 (90.6)	126/139 (90.6)	[15]
Hasabe et al.	Prospective	34/36 (94.4)	NR	[16]
Yadav et al.	Prospective	117/122 (95.9)	117/122 (95.9)	[17]
Bakri-UBT				
Darwish et al.	RCT	30/33 (90.9)	30/33 (90.9)	[6]
Revert et al.	Prospective	188/226 (83.2)	155/183 (84.7)	[18]
Brown et al.	Prospective	55/58 (94.8)	52/55 (94.5)	[19]
Vintejoux et al.	Retrospective	25/36 (69.4)	25/36 (69.4)	[20]
Guo et al.	Retrospective	288/305 (94.4)	131/142 (92.3)	[21]
Mathur et al.	Retrospective	40/49 (81.6)	14/17 (82.4)	[22]
Wang et al.	Prospective	373/407 (91.6)	373/407 (91.6)	[23]
Alkis et al.	Retrospective	43/47 (91.5)	NR	[24]
Kaya et al.	Prospective	34/45 (75.6)	27/34 (79.4)	[25]
Laas et al.	Before and after	37/43 (86)	37/43 (86)	[26]
Olsen et al.	Retrospective	25/37 (67.6)	17/24 (70.8)	[27]
Kong et al.	Retrospective	59/81 (72.8)	37/59 (62.7)	[28]
Cetin et al.	Retrospective	29/39 (74.4)	29/39 (74.4)	[29]
Gauchotte et al.	Before and after	35/38 (92.1)	NR	[30]
Grange et al.	Retrospective	80/108 (74.1)	26/39 (66.7)	[31]
Kadioglu et al.	Retrospective	42/50 (84)	NR	[32]

Martin et al.	Retrospective	32/49 (65.3)	28/42 (66.7)	[33]
Ogoyama et al.	Retrospective	66/71 (93)	31/32 (96.9)	[34]
Son et al.	Retrospective	239/306 (78.1)	190/241 (78.8)	[35]
ESM-UBT				
Ramanathan et al	Prospective/ Retrospective case series	189/201 (94) *	NR	[36]
Burke et al.	Prospective case series	190/201 (94.5) *	NR	[37]
Burke et al.	Prospective case series	298/306 (97.4) *	298/306 (97.4)	[38]

* - Reported survival rates
NR – Not reported

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Research Checklist

CHEERS CHECKLIST

Items to include when reporting economic evaluations of health interventions

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	Page number 03, lines 01 to 02
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	Page number 03, lines 05 to 22 Page number 04, lines 01 to 11
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	Page number 08, lines 01 to 05
		Present the study question and its relevance for health policy or practice decisions.	Page number 08, lines 03 to 07
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	Page number 08, lines 13 to 17
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Page number 08, lines 03 to 09 Page number 08, lines 13 to 17
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Page number 08, lines 13 to 17

Section/item	Item No	Recommendation	Reported on page No/ line No
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Page number 08, lines 07 to 09
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Page number 09, lines 12 to 13
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Page number 12, lines 10 to 12
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Not applicable
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	Not applicable
	11b	*Synthesis-based estimates*: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	Page number 07, Table 1 Supplementary material file 1, Table 1.3
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	Not applicable
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource	Page number 08 to page number 15

Section/item	Item No	Recommendation	Reported on page No/ line No
		item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Not applicable
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Page number 12, line 24 Page number 13, lines 01 to 02
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	Not applicable
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	Page number 14, lines 07 to 18
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle	Page number 14, lines 19 to 25 Page number 15, lines 01 to 02

Section/item	Item No	Recommendation	Reported on page No/ line No
		corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Page number 14, lines 19 to 25 Page number 15, lines 01 to 02 and lines 05 to 10
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Page number 15, lines 12 to 24 Page number 16, Table 3 Page number 18, Table 4 Page number 20, Table 5
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	Page number 16, Table 3 Page number 18, Table 4 Page number 20, Table 5
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	Not applicable
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations	Not applicable

Section/item	Item No	Recommendation	Reported on page No/ line No
		between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	Page number 21, lines 03 to 24 Page number 22, lines 01 to 24 Page number 23, lines 22 to 25 Page number 24, lines 01 to 13
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	Page number 25, lines 19 to 21
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	Page number 25, lines 22 to 23

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Cost of managing atonic postpartum hemorrhage with uterine balloon tamponade devices in public health settings of Maharashtra, India: An economic micro-costing study

Authors and Affiliations:

Dr. Siddesh Sitaram Shetty

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Kusum Venkobrao Moray

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Mr. Himanshu Chaurasia

Regional Resource Hub for Health Technology Assessment in India,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai, India

Dr. Beena Nitin Joshi (**Corresponding Author)**

Department of Operational Research,

Indian Council of Medical Research - National Institute for Research in Reproductive Health, Mumbai

Jehangir Merwanji Street, Parel, Mumbai, Maharashtra, India

Phone number: +91-9820252672 / Office number: +(91-22)24192043

Email ID – bjoshithane@gmail.com

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ABSTRACT

Objective

Post-partum hemorrhage (PPH) is the worldwide leading cause of preventable maternal mortality. India offers free treatment for pregnancy and related complications in its public health facilities. Management with Uterine Balloon Tamponade (UBT) is recommended for refractory atonic PPH cases. As part of health technology assessment to determine the most cost-effective UBT device, this study estimated costs of atonic PPH management with condom-UBT, Every Second Matters (ESM) UBT and Bakri balloon UBT in public health system of Maharashtra, India.

Design

Health system cost was estimated using primary economic micro-costing, data from Health Management Information System (HMIS) and published literature for event probabilities.

Settings

Four public health facilities from the state of Maharashtra, India representing primary, secondary and tertiary level care were chosen for primary costing.

Outcome measures

Unit, package and annual cost of atonic PPH management with three UBT devices were measured. This included cost of medical management, UBT intervention and PPH related surgeries undertaken in public health system of Maharashtra for year 2017-18.

Results

Medical management of atonic PPH cost the health system USD 37 (95% CI 29-45) per case, increasing to USD 44 (95% CI 36-53) with condom-UBT and surgical interventions for uncontrolled cases. Similar cost was estimated for ESM-UBT. Bakri-UBT reported a higher cost of USD 59 (95% CI 46-73) per case. Overall annual cost of managing 27,915 atonic PPH cases with condom-UBT intervention in Maharashtra was USD 1,226,610 (95% CI 870,250 – 1,581,596).

Conclusions

Atonic PPH management in public health facilities of Maharashtra with condom-UBT, ESM-UBT or Bakri UBT accounts to 3.8%, 3.8% or 5.2% of the state's annual spending on reproductive and child health services. These findings can guide policymakers to include PPH complication management in publicly financed health schemes. Economic evaluation studies can use this evidence to determine cost-effectiveness of UBT in Indian settings.

Strengths and limitations of this study

- To our knowledge, this is the first study from India comprehensively assessing public health system costs for overall management of atonic PPH with medical interventions, uterine balloon tamponade and surgical management across all public healthcare levels in the state
- The study uses clinical effectiveness evidence of individual uterine balloon tamponade devices to determine health system costs
- As disaggregated HMIS data in the study setting was not available for PPH, literature-based event probability estimates from the Indian context were relied upon to estimate costs
- An assumption was made that for a particular UBT device, all eligible cases would receive only that particular UBT across all facilities.

INTRODUCTION

The global shift towards Universal Health Coverage (UHC) indicated by Sustainable Development Goals (SDG) needs robust financing mechanisms. To achieve desired targets, evidence informed by costing studies can be vital to support financing decisions. Information on cost enables improved resource allocation, thus strengthening policy measures to attain highest value for a given investment. A key priority under the SDG health goal is reduction of maternal mortality levels to less than 70 per 100,000 live births by year 2030. Evidence confirms women's health to be associated with development and economic performance of a country.[1] A marginal health investment at lower GDP levels seen commonly in low or low-middle income countries is found to have higher effects on health outcomes.[2] Improved maternal health not only reduces household healthcare expenditure, but is also associated with long term economic benefits to the society.

In spite of a low spending of 1% of GDP on public health expenditure, India has managed to reduce maternal mortality ratio down to 122 per 100,000 live births by the year 2015-17, largely attributed to reforms such as institutionalization of deliveries, provisioning of free cashless services to pregnant women and by addressing social determinants of health.[3–5] Despite ongoing efforts, India still accounts for nearly one-fifth of all maternal deaths globally with hemorrhage as the leading cause.[6] Post-Partum Hemorrhage (PPH) accounts for more than two-third of all global maternal deaths due to bleeding.[7,8] PPH is defined as maternal blood loss of 500 ml or more within 24 hours after delivery and affects nearly 3-6% of all women giving birth in India.[9] Atony of uterus is the most common PPH type responsible for 80% of all cases.[10]

Indian guidelines base PPH management on principles of treatment for shock, cause-specific PPH management and patient stabilization before referral to higher facilities.[11] India has initiated standardization of Labour Rooms (LR) under the '*Dakshata*' initiative, equipping delivery rooms to provide comprehensive care at all times. In accordance with the WHO guidelines for atonic PPH management, uterotonics remain the mainstay of treatment in India.[12] Hemodynamic stabilization and supportive

resuscitation measures are expected to be ongoing. Use of UBT device is recommended if uterotonic agents fail in controlling atonic PPH bleeding. At primary level in India, all atonic PPH cases are expected to be provided medical management and UBT intervention to stabilize and control bleeding before referral to higher facility for observation or further interventions. Cases uncontrolled after UBT insertion at secondary or tertiary level may require B-Lynch compression suturing, stepwise devascularization surgery (uterine, or internal iliac artery ligation) or other procedures depending on availability of expertise and facility infrastructure. Hysterectomy, a lifesaving procedure may be indicated after failed conservative measures or directly after UBT insertion based on patient response. Obstetric intensive care (ICU) admission may be needed for observation or managing complications due to PPH.

UBT intervention for atonic PPH is a relatively simple life-saving technique that can be used even in low resource settings with limited provisions for surgery, blood transfusion or referral mechanisms. UBT technique is clinically effective in controlling PPH bleeding and reduces need for further surgical interventions.[13] Timely use of UBT device can potentially be cost-saving by improving maternal morbidity and mortality outcomes. Multiple UBT devices specifically designed, assembled or modified for use in PPH management are available. Being economical, an assembled condom-UBT device is the recommended standard of care (SOC) for atonic PPH management in India.[14] In the state of Maharashtra where this study was undertaken, apart from the recommended condom-UBT device, Bakri balloon and ESM-UBT, two ready to use sterile packed devices made available by non-governmental organizations are used across different public health settings.[15–17] The three UBT devices have certain distinct features giving each an advantage over the other. Literature reports varying clinical effectiveness and price for these UBT devices. Table 1 shows distinct characteristics of these three UBT devices used in atonic PPH management, collated from a literature review undertaken separately. (Supplemental material, Table 1.1)

Table 1: Characteristics of UBT devices used commonly for atonic PPH management in India

UBT device	Cost of device	Clinical effectiveness#	Advantages
Condom-UBT	USD 2 (INR 128) * Assembly components commercially available	92.3%	Inexpensive, Assembled using available resources, Modified versions are used to assess blood loss post insertion
ESM-UBT	USD 6 (INR 397).[18,19] Commercially not available at present	95.3%**	Relatively inexpensive, Specifically designed for PPH use, All components needed for assembly available in a sterile pack, US-FDA approved device
Bakri Balloon UBT	USD 148 (INR 9,554).[20] Commercially available at present	84.3%	Ready to use, Specifically designed for PPH use, Comes in a sterile pack, Has drainage outlet to measure ongoing blood loss, US-FDA approved device

- Estimated from literature review of 33 studies

* - Calculated using health facility purchase lists

** - Strength of evidence is limited, based on evidence available from three case-series studies

Under India's flagship *Pradhan Mantri Jan Arogya Yojana (PMJAY)* public health insurance scheme, a woman is entitled to cashless treatment package cost of USD 178 (INR 11,500) for high-risk vaginal deliveries and all cesarean sections. Evidence suggests that despite improved maternal outcomes with publicly sponsored schemes, extent of out-of-pocket expenditure for institutional delivery remains high

especially with pregnancy complications.[21] At present, the existing packages do not cover the post-partum PPH complication and there is no documented health system cost available for management of this condition. The Ministry of Health and Family Welfare (MOHFW), Government of India is assessing the most cost-effective UBT device for atonic PPH management in the public health system given the emerging evidence for relatively low cost ESM-UBT alternative.[22–24] The policy decision to make a UBT device available for PPH management across health facilities will have associated cost and health outcome implications. This study aimed to calculate public health system cost of atonic PPH management with SOC i.e. condom-UBT recommended by the 2015 Indian guidelines for PPH management with similar projections for ESM-UBT and another globally used Bakri-UBT device.[14]

METHODS

This costing study was part of a Health Technology Assessment (HTA) project to evaluate the most cost-effective UBT device for atonic PPH management in India. An economic costing from the health system perspective using primary bottom-up micro-costing, data from HMIS and literature review for event probabilities were used to determine and compare unit, package and annual cost of atonic PPH management with condom-UBT, ESM-UBT and Bakri balloon UBT devices in public health facilities of Maharashtra, India. The study was approved by the NIRRH Ethics Committee for Clinical Studies (Approval number: D/ICEC/Sci-29/31/2018). State health department administrative approvals and consent from respective health facility authorities were obtained before undertaking the study.

Patient and public involvement:

There was no patient or public involvement in this study design, conduct or reporting of this study and hence no consent was obtained.

Study settings:

Maternal healthcare in the Indian public system is delivered through a three-tier system. The facilities in this study were classified depending on availability of services for atonic PPH management. Primary level care for PPH management starts at Primary Health Centers (PHC) that are equipped with skilled birth attendants and a medical officer. Secondary level is made by Community Health Centers (CHC) and Sub-District Hospitals (SDH) that additionally are equipped with obstetrics-gynecology (OBGYN) specialist, operation theater (OT) and facilities for blood transfusion. Tertiary level comprises of District Hospitals (DH) and medical colleges having additional advanced intervention and ICU facilities.[25,26] The study enrolled four public health facilities from the state of Maharashtra in India to ensure representation of all three levels of care. A convenience sample of one PHC, SDH, DH, and a tertiary medical college from Mumbai metropolitan region in Maharashtra were chosen for data collection.

Data collection:

Cost data for one-year duration from April 2017 to March 2018 was collected by adapting a validated standard tool developed for costing of health services in India.[27] Cost resources were broadly classified into cost centres like human resources, infrastructure, medical equipment, non-medical equipment, drugs, consumables and utilities like electricity, water and laundry. Data on annual quantity or facility consumption for resources were obtained from sources like salary slips, departmental records, facility stock reports, patient record registers, pharmacy records, indent books, bills, statements of the accounts department, building plan of health facilities and civil department records. Source of data for each respective costing centre is reported in Table 2. This data was complemented by facility surveys to further collect information on infrastructure and availability of medical and non-medical equipment. Floor area measurements were undertaken to account for area utilization across different departments of the facility. Staff were interviewed for time allocation to assess time spent on different PPH activities as a proportion of their total working hours. A total of 16 doctors, 26 nursing staff, 5 pharmacists and 11 technical or administrative staff across chosen facilities were interviewed. As an example, all doctors were asked questions pertaining to time spent on each patient for PPH specific activities and other routine tasks like

time spent in out-patient department (OPD), in-patient department (IPD), surgery, teaching, documentation and administrative services. Time spent by the senior-most doctor in performing an obstetric hysterectomy out of all routine tasks was used in costing obstetric hysterectomy procedure for eligible PPH cases. Time allocation interview findings are presented in supplemental material. (Supplemental material, Table 1.2)

Data on number of obstetric services like vaginal or cesarean section deliveries, number of obstetric surgeries, hysterectomies, number of blood transfusions, in-patient admissions, emergency or obstetric ICU admissions provided at respective facilities were obtained from available facility records like written registers, patient record registers, electronic health records and Hospital Management Information System (HMIS) sources. This data was collected as facility records and HMIS indicators specifically for PPH were unavailable. To compute number of PPH services provided annually at each facility, event probability estimates for atonic PPH incidence in Indian settings, clinical effectiveness of three UBT devices in controlling atonic PPH bleeding (targeted literature review), probability of PPH related surgeries, its success rate, morbidity and PPH mortality rates were obtained from published literature sources.[9,10,28–30] Facility collected data along with India specific PPH clinical literature was used to analyze and compute unit, package and annual cost for atonic PPH management components across healthcare levels in Maharashtra, India.

Data analysis:

To determine PPH events occurring at facility level, PPH incidence rates in vaginal and cesarean section deliveries were applied to facility reported deliveries to determine number of atonic PPH cases expected annually at the given facility. Proportion of atonic PPH cases uncontrolled after medical management determined number of beneficiaries eligible for UBT insertion at the facility. Clinical effectiveness parameters for each individual UBT device derived from literature review determined requirement of subsequent type and number of surgeries with each individual UBT expected at the healthcare level. Supplemental material provides PPH parameters obtained from literature along with computed number of services specific to facilities used in cost calculation. (Supplemental material, Table 1.3, Table 1.4)

Monetary value obtained from sources like salary slips, department records for human resources, civil department records for area, facility records for drugs and equipment, and departmental records, facility registers and bills for utilities were respectively attached to collected quantity of each resource utilized across cost centers. For cost analysis, resources were classified into capital and recurrent items. Capital resources were annualized using the India recommended 3% discount rate and factoring in life expectancy and annual maintenance rate of items.[31] Overall cost for services provided at the facility across cost centers was apportioned specific to atonic PPH management component by considering time or proportion calculated for atonic PPH activity being costed, number of total activities under the same category performed at facility and applying standard apportioning methods based on shared or exclusive nature of service utilization.[32] Human resource salaries were apportioned based on time allocation interviews for a given atonic PPH activity out of total working hours for all services provided. Area was apportioned based on proportional time spent for an atonic PPH activity in the given area out of all activities taking place in the same area. Drugs and consumables were apportioned as a proportion of utilization for number of PPH cases out of utilization for all treated patients. Medical and non-medical equipment were first annualized and then apportioned as the proportion of time used specifically for the given PPH activity out of all activities. Utilities like water and electricity were apportioned proportionally to floor area occupied for a particular service. Table 2 provides apportioning methods and corresponding data sources used in cost calculation. Supplemental material provides an example of apportioning methods and assumptions used in cost calculation. Worksheets were developed for cost calculation of each component at each facility followed by weighted aggregation of costs to the level of care individually for each UBT type. For example, unit condom-UBT insertion cost at DH and medical college was aggregated to get a unit condom-UBT insertion cost for tertiary level. All costs are presented in United States Dollars (USD) and Indian National Rupee (INR) currency. A conversion rate of 1 USD = 64.5 INR for the year 2017-18 was used.[33] Data was analyzed using Microsoft Excel 2016.

1 Table 2: Costing assumptions and apportioning

Cost center	Source of data	Numerator	Denominator
Human resource cost	Salary slips, departmental records, time allocation interview	Proportional cost for time spent on specific component of atonic PPH management	Total working hours
Area cost	Facility survey, civil department records	Proportional cost for time spent on spent on specific component of atonic PPH management	Total time spent in the given facility area
Drug and consumable cost	Facility stock reports, indent books, patient record registers, pharmacy records	Proportional cost for number of patients requiring drugs and consumable for a specific component of atonic PPH management	Total number of cases accessing drugs and consumables
Medical and non-medical equipment cost	Facility observations, facility stock reports,	Proportional cost for time spent on specific component of atonic PPH management	Total working hours
Electricity	Facility survey, departmental records, electricity bills	Proportional cost for time spent on specific component of atonic PPH management	Total working hours
Water	Departmental records, water bills	Proportional cost of area required for specific component of atonic PPH management	Total facility area
Laundry	Departmental records, facility registers	Proportional cost for atonic PPH patients requiring laundry	Total number of indoor patients at the facility

Unit costs

Unit costs were calculated for each component of atonic PPH management expected at the respective healthcare level. This included cost of medical management for atonic PPH, UBT insertion for refractory cases, devascularization surgery, hysterectomy, IPD admission, ICU admission and cost of patient referral at respective levels. Denominators like number of atonic PPH cases, number of UBT eligible beneficiaries, number of referrals, number of consequential conservative or obstetric hysterectomy surgeries determined from collected data sources along with apportioned facility cost across cost centers was used to compute per beneficiary unit cost for the identified component of atonic PPH management. Unit cost of UBT insertion included the cost of UBT device. Unit cost for medical management, referral and IPD admission were expected to remain unaffected irrespective of the type of the UBT device used. For these services, costs were calculated only for SOC i.e., management with condom-UBT device.

Package costs

To account for treatment combinations used in management of atonic PPH, treatment package costs were determined. For a certain treatment, package cost was calculated by adding unit cost associated with all treatment components for management at respective healthcare level. For all patients at primary and secondary care requiring transport, referral costs were added to get package costs.

Annual costs

Unit and package cost calculation was followed by annual health system cost estimation for an annual cohort of women in Maharashtra experiencing atonic PPH after delivering in public healthcare facilities. Number of deliveries occurring across the three respective public healthcare levels in Maharashtra were combined with respective PPH service utilization units to get pooled annual cost for a given service. Overall annual health system cost was then estimated by combining annual health system cost of medical management, further course of interventions using UBT device in uncontrolled cases and training cost for

UBT. Unit cost for every treatment component at each facility was first aggregated to primary, secondary and tertiary level and then applied to the annual eligible population cohort in Maharashtra to estimate annual costs with each UBT device.

Certain methodological assumptions were made during cost analysis. It was assumed that for a particular UBT device, all eligible atonic PPH cases would receive only that particular UBT across facilities. It was assumed that at primary level, all women after medical management or UBT insertion would immediately be referred for secondary care. Unit calculated cost for per day IPD or ICU admission of patients at chosen facilities were apportioned to literature based atonic PPH length of stay to estimate IPD and ICU costs for atonic PPH management.[34–36] Cost of blood transfusion and other resuscitation measures were incorporated in unit costs throughout management and are not calculated separately. Training costs were estimated for one day training of healthcare providers.[37] Due to time and resource limitation for primary estimation of PPH referral costs, an inflation adjusted cost of USD 15.5 (INR 1,001) per case was used from a published Indian primary economic costing study that calculated public health system cost of transportation for institutional delivery services in three districts of an Indian state.[38] B-Lynch suturing and stepwise devascularization surgery in this study were considered as a single unit for cost calculation.

Probabilistic sensitivity analysis was used to address joint uncertainty effect of input parameters on costs. A beta distribution for probabilities and proportions, gamma distribution for cost and resource use was assigned to vary parameters on both sides. As drugs and consumables are procured by the government at a negotiated price whereas market prices show variation on the higher side, these were varied by 50% and 100% on lower and upper limits respectively. UBT device price was assumed to vary by 50% on both sides. Remaining parameters such as salaries, rental prices, medical and non-medical equipment, utilities and utilization of services were varied by 25%.[39] Monte Carlo simulations were run to obtain 1000 unit cost estimates. These estimates were used to determine 95% confidence interval (CI) limits for all reported costs.

RESULTS

The chosen sample of four public health facilities from Maharashtra reported 7,208 vaginal and 2,516 cesarean section deliveries in the year 2017-18. Of the 9,724 total deliveries, 293 women were expected to experience atonic PPH. Twenty-nine out 293 cases would remain uncontrolled after medical management, thus becoming eligible for UBT device insertion. Further depending on clinical effectiveness of individual UBT device in controlling bleeding, remaining cases undergo surgical intervention depending on infrastructure and resource availability at respective clinical setting.

Unit costs:

Medical treatment of atonic PPH cases costs the health system USD 0.7 (INR 42), USD 5 (INR 322) and USD 9.4 (INR 609) per patient at primary, secondary and tertiary levels respectively. For uncontrolled cases requiring further intervention, condom-UBT (SOC) insertion costs USD 2.5 (INR 160), USD 5.3 (INR 339) and USD 6.5 (INR 422) at the three respective levels. Devascularization group of surgery for uncontrolled cases after condom-UBT insertion costs USD 75.4 (INR 4864) per case at secondary and USD 53.0 (INR 3,419) per case at tertiary level. Similarly, hysterectomy procedure costs USD 120.6 (INR 7,782) per case at secondary and USD 84.8 (INR 5,471) at tertiary level. Table 3 provides the health system unit costs with condom-UBT, ESM-UBT and Bakri-UBT. IPD admission for an atonic PPH case costs the health system USD 27.5 (INR 1,776) per patient at secondary and USD 28.0 (INR 1,806) per patient at tertiary level. ICU admission at tertiary facility costs the health system USD 76.0 (INR 4,902) per patient getting admitted for atonic PPH management. One-time training of medical officers and OBGYN specialists across public health facilities of Maharashtra costs USD 12.1 (INR 778) per eligible case of UBT device insertion.

Table 3: Unit costs for atonic PPH management components across public health facility levels in Maharashtra, India [1 USD = 64.5 INR]

	Medical management	UBT insertion	Devascularization	Hysterectomy	Inpatient Admission	ICU admission
Per patient unit cost with Condom-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	2.5 (1.5-3.5)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	5.3 (4.1-6.5)	75.4 (49.4-104.4)	120.6 (77.9-168.2)	27.5 (16.8-39.5)	NA
Tertiary	9.4 (6.7-12.6)	6.5 (5.3-7.9)	53.0 (41.9-64.4)	84.8 (66.3-104.4)	28.0 (20.7-35.9)	75.9 (50.3-104.6)
Per patient unit cost with ESM-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	6.7 (3.6-9.9)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	8.8 (5.9-11.6)	56.9 (37.1-79.0)	119.9 (79.3-162.7)	27.5 (16.8-39.5)	NA
Tertiary	9.4 (6.7-12.6)	10.4 (8.5-12.5)	51.7 (40.6-63.7)	86.5 68.0-107.1)	28.0 (20.7-35.9)	75.9 (50.3-104.6)
Per patient unit cost with Bakri-UBT in USD (95% Confidence interval)						
Primary	0.7 (0.4-0.9)	148.6 (74.3-219.0)	NA	NA	NA	NA
Secondary	5.0 (3.5-6.6)	151.1 (88.0-214.8)	76.8 (51.2-103.9)	119.7 (80.1-165.4)	27.5 (16.8-39.5)	NA
Tertiary	9.4 6.7-12.6)	153.1 (113.0-191.8)	53.0 (41.6-64.7)	84.8 (67.2-103.7)	28.0 (20.7-35.9)	75.9 (50.3-104.6)

Package cost:

Of the eligible cases, condom-UBT successfully controls 92.3% cases after device insertion and ongoing medical and resuscitation measures. This combination treatment costs the health system a total of USD 46.2 (INR 2,979), USD 37.8 (INR 2,437) and USD 44.0 (INR 2,838) at three respective levels. This treatment package comprises costs of medical management, UBT insertion, IPD admission and additional referral cost for primary care patients. Treatment package cost of control with devascularization surgery after condom-UBT insertion and medical treatment has a total health system cost of USD 113.2 (INR 7,301) and USD 97.0 (INR 6,256) per patient at secondary and tertiary levels respectively. Similarly, a direct hysterectomy for uncontrolled atonic PPH after UBT insertion costs USD 158.4 (INR 10,218) and USD 128.8 (INR 8,308) at secondary and tertiary levels respectively. Less than 4% of the uncontrolled atonic PPH cases with condom-UBT insertion are expected to require ICU facility for atonic PPH management. Health system package costs for such treatment combinations can be derived from the given unit cost table. Alternatively, if ESM or Bakri-UBT device is used in controlling atonic PPH, package cost varies on account of device effectiveness and associated resource use. Table 4 lists treatment package cost estimates for atonic PPH management with three UBT devices.

Table 4: Treatment package cost for atonic PPH management across public healthcare levels in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

	Condom UBT	ESM UBT	Bakri UBT
Package cost for atonic PPH controlled after UBT insertion in USD (95% Confidence interval)			
Primary	46.2 (34.9-59.1)	50.4 (38.5-63.8)	192.3 (153.8-230.8)
Secondary	37.8 (28.5-48.3)	41.3 (31.9-52.0)	184.1 (147.0-222.4)
Tertiary	43.9 (35.4-53.3)	47.9 (39.6-57.0)	190.5 (149.9-233.2)
Package cost for atonic PPH controlled with devascularization surgery after UBT failure in USD (95% Confidence interval)			
Secondary	113.2 (103.2-123.8)	98.2 (88.5-108.7)	260.9 (218.6-304.2)
Tertiary	96.9 (88.7-106.3)	99.6 (91.4-109.3)	243.5 (202.2-286.9)
Package cost for atonic PPH controlled with direct hysterectomy after UBT failure in USD (95% Confidence interval)			
Secondary	158.4 (149.6-168.9)	161.1 (152.1-171.7)	303.8 (256.0-355.6)
Tertiary	128.8 (120.5-138.6)	134.4 (126.2-144.0)	275.3 (231.2-319.1)

Annual costs:

Annual cost to the public health system was estimated for managing 27,915 women experiencing atonic PPH annually out of the 969,264 deliveries reported by the state of Maharashtra for the year 2017-18.[40] The estimated annual cost of medical management for atonic PPH was USD 1,032,647 (INR 6,66,05,750) or USD 36.9 (INR 2,386) per atonic PPH patient. Additionally, 2,791 women were estimated to require UBT intervention followed by devascularization surgery, hysterectomy or ICU facility for uncontrolled cases. The annual cost of managing these uncontrolled cases in public health facilities of Maharashtra, India is USD 193,963 (INR 1,25,10,610) with condom-UBT, USD 188,090 (INR 1,21,31,800) with ESM-UBT and USD 620,297 (INR 4,00,09,169) with Bakri-UBT when used for medically uncontrolled atonic PPH cases. This corresponds to a per eligible beneficiary cost of USD 69.5 (INR 4,482) for control with condom-UBT and subsequent interventions, USD 67.4 (INR 4,346) for ESM-UBT and USD 222.2 (INR 14,333) for Bakri-UBT respectively. Overall, the health system incurs a per atonic PPH patient treatment cost of USD 43.9 (INR 2,834) with condom-UBT, USD 43.7 (INR 2,820) with ESM-UBT and USD 59.2 (INR 3,819) per case with Bakri-UBT if made available for atonic PPH management in Maharashtra, India. Table 5 describes the annual health system cost of atonic PPH management in Maharashtra, India.

Table 5: Annual public health system cost of managing atonic PPH using three UBT devices in Maharashtra, India [1 USD = 64.5 INR] (95% Confidence interval)

Cost center	Condom-UBT USD (95% CI)	ESM-UBT USD (95% CI)	Bakri-UBT USD (95% CI)
Annual atonic PPH medical management cost (a)	1,032,647 (688893 – 1375716)		
Annual UBT training cost (b)	34,109 (25817 – 42579)		
Annual cost for uncontrolled atonic PPH cases managed with UBT device and surgical interventions (c)	193,963 (152,772 – 232,481)	188,090 (150393 – 226901)	620,297 (386981 – 857415)
Total annual cost of atonic PPH management (a + b + c)	1,226,610 (870250 – 1581596)	1,220,737 (876187 – 1566385)	1,652,944 (1224827 – 2061670)
Annual UBT device cost	5,540 (2362 – 8664)	17,182 (7324 – 26770)	413,485 (180,326 – 652,695)
Per patient cost of medical management for atonic PPH	36.9 (29-45)		
Per patient cost of managing uncontrolled atonic PPH cases with UBT and surgical interventions	69.5 (47 – 94)	67.4 (47 – 88)	222.2 (145 – 299)
Per patient health system cost of atonic PPH management	43.9 (36 – 53)	43.7 (35 – 52)	59.2 (46 – 73)

DISCUSSION

To our knowledge, this is the first study comprehensively assessing public health system costs associated with atonic PPH management in India. A study conducted in Myanmar at a 25 bedded hospital reported cost of PPH management along with other obstetric complications.[41] Similarly, an Egypt study reported estimates of direct health system costs for different procedures used in PPH management in two district hospitals.[42] Our study specifically estimates health system cost of managing atonic PPH across healthcare levels in the Indian public health system using primary cost data. This paper focuses on estimating the cost of using different uterine balloon tamponade devices given their varying reported clinical effectiveness in controlling atonic PPH bleeding. Additionally, we have undertaken costing of medical management, and surgical intervention subsequent to failed UBT treatment across public healthcare levels of India.

Our analysis reported a total cost of USD 43.9 (95% CI 36-53) per atonic PPH patient with condom-UBT, USD 43.7 (95% CI 35–52) with ESM-UBT and USD 59.2 (95% CI 46-73) with Bakri-UBT use in Maharashtra's public health system for the year 2017-18. The study from Myanmar reported an inflation adjusted unit cost of USD 28 (±1.61) per case for managing PPH in their hospital study setting.[43] The Egypt study reported an adjusted treatment cost of USD 110 per case for PPH but reported use of UBT intervention in 3.9% cases as compared to 9.9% in our study. As primary data was not available, the assumption that all those needing UBT intervention would receive it may be one of the reasons for lower unit costs in our study as UBT intervention would reduce subsequent surgical interventions. Neither of the two studies reported UBT intervention costs specifically.

The unit cost of medical management for an atonic PPH case in our study was USD 36.9 (INR 2,386). Unit cost of UBT device insertion increased gradually with higher facility level and was dominated by the cost of UBT device itself. Treatment package costs for UBT insertion at primary level included referral cost and hence reported higher costs as compared to secondary or tertiary level. Unit and package costs for surgical

intervention subsequent to UBT failure was found to be higher at secondary level as compared to tertiary level in our study. Tertiary level hysterectomy cost at USD 84.8 (INR 5,471) per case in our study is in similar range as reported by another Indian study at an adjusted cost of USD 95.7 (INR 6174) for a district hospital.[44] Likewise, stepwise devascularization surgery in the Egypt study reported an adjusted cost of USD 62 per case is in the similar range to those reported in our findings. Unit and package surgical costs in our study also varied depending on clinical effectiveness of the UBT device affecting consumption of facility resources. Cost of condom-UBT device in Indian public health facilities was USD 1.9 (INR 128), one-third the price of ESM-UBT device. Bakri balloon at a market price of USD 148 (INR 9554) in India, costs significantly higher in comparison to the other two devices. Bakri-UBT at a higher price and lower reported clinical effectiveness in controlling atonic PPH, accounted for higher unfavorable unit and package costs in our analysis. ESM-UBT reported a marginally higher clinical effectiveness but had a three-time higher device cost as compared to condom-UBT. The unit cost however for both condom and ESM-UBT was similar at USD 43.9 (INR 2,834) and USD 43.7 (INR 2820).

Cost of medical management for atonic PPH across healthcare levels in this study constitutes a major component of the annual costs (84.2% for Condom-UBT, 84.6% for ESM-UBT and 62.5% for Bakri-UBT). This is expected as majority patients are controlled with uterotonics and supportive measures. Remaining portion of annual costs are accounted by UBT and subsequent interventions for uncontrolled cases (15.8% for condom-UBT, 15.4% for ESM-UBT and 37.5% for Bakri-UBT). Both condom and ESM-UBT have lower unit, package and annual costs as compared to Bakri-UBT. However, the strength of clinical effectiveness evidence available for ESM-UBT at the time of this study was limited to a few case series studies reporting survival rates.[19,22,23]. Cost implication of using ESM-UBT device would vary if higher quality of clinical effectiveness evidence across UBT devices along with procurement cost of equipping all Indian public health facilities with a particular device is made available. Cost of UBT device accounted to 0.5% of the annual health system costs for condom-UBT, 1.4% for ESM-UBT and 25% for Bakri-UBT respectively.

The state of Maharashtra in the year 2017-18 spent an estimated USD 1,226,610 (INR 7,91,16,359) by catering to all atonic PPH cases in public health facilities with condom-UBT intervention as per the recommended treatment guidelines. Alternatively, if ESM-UBT or Bakri Balloon was available, the state would spend USD 1,220,737 (INR 7,87,37,549) or USD 1,652,944 (INR 10,66,14,919) respectively. Atonic PPH management with condom-UBT in Maharashtra thus accounted to 3.8% of the annual state spending on reproductive and child health (RCH) activities in the year 2017-18.[45,46] ESM-UBT would account to a similar 3.8% whereas Bakri-UBT for atonic PPH management would account to a higher 5.2% proportion of the state's annual RCH spending.

This study empirically derived costs of atonic PPH management across public healthcare levels for a state in India. The WHO guideline development group has identified use of uterine balloon tamponade in PPH as a research priority.[47] Our study provides economic evidence for equipping health systems with the choice of a clinically effective UBT intervention that is affordable and suitable for low resource settings like India. Findings of this study can be used to optimize efficiency by improving financial allocation within the health system. Under the revised *Janani Shishu Suraksha Karyakar*am (JSSK) scheme in India, pregnant women accessing public health facilities are entitled to free treatment for childbirth and pregnancy complications.[48] Implementation under the *PMJAY* scheme has revised high risk and caesarean section delivery package costs to USD 178 (INR 11,500). This package is inclusive of drugs, diagnostics, consultations, procedures, stay and food for the patient availing care.[49] The results from our study can be used to address package costs for the post-partum PPH complication across different publicly financed health schemes to avoid any financial burden on the beneficiaries as reported with institutional deliveries in India.[21]

Limitations:

The study bases its cost findings from one region of Maharashtra by collecting data form sample facilities across healthcare levels. Given the differences within districts across the state, provisioning and utilization of healthcare services vary on account of socio-economic, epidemiologic and other contextual factors.

Although we have undertaken uncertainty analysis to address these factors to an extent, generalizability of the study results across states of India may be difficult. For analysis, it was assumed that all atonic PPH cases requiring UBT intervention will receive it and a uniform UBT device would be available across all facilities. However, in practice this might differ resulting in deviation of cost estimates from those reported. Facility level disaggregated HMIS data on PPH and corresponding service utilization was not available, so we had to rely on literature-based probabilities to derive PPH service utilization for costing.

CONCLUSION

The study provides health system cost of managing atonic PPH complication in Indian public health settings. Policy makers can use these findings to include the clinical condition of PPH to treatment benefit packages under publicly financed health schemes and to inform budgetary allocations to equip the Indian health system with a suitable UBT choice. Economic evaluation studies can use this evidence to determine the most cost-effective UBT choice for Indian settings. In addition to equipping facilities and supply lines with the right commodities, programs must optimize performance of the healthcare providers and ensure efficient referral systems are in place to save a woman's life.

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Author Contributions

BJ, SS and KM were responsible for conceptualization and design of the study. KM and HC undertook data collection. SS and KM analyzed the data. BJ checked the analysis and edited the manuscript. SS was responsible for the first draft and all authors contributed to further revisions. All authors read and approved the final manuscript.

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Competing interests

None declared

Patient consent

Not required

Data sharing statement

All unpublished data are available upon reasonable request to the corresponding author BJ through E-mail

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Supplemental material

Table 1.1: Details of the studies included in targeted literature review for the three UBT devices

Authors	Study design	PPH success rate	Atonic PPH success rate	Reference
Condom-UBT				
Darwish et al.	RCT	28/33 (84.8)	28/33 (84.8)	[1]
Tindell et al.	Systematic Review	186/193 (96.4)	NR	[2]
Santhanam et al.	Prospective	59/61 (96.7)	59/61 (96.7)	[3]
Rathore et al.	Prospective	17/18 (94.4)	NR	[4]
Aderoba et al.	Prospective	203/229 (88.6)	193/214 (90.2)	[5]
Mishra et al.	Prospective	59/60 (98.3)	NR	[6]
Kandeel et al.	Prospective	48/50 (96.0)	28/28 (100)	[7]
Anger et al.	RCT	56/64 (87.5)	NR	[8]
Dumont et al.	RCT	48/57 (84.2)	NR	[9]
Lohano et al.	Prospective	126/139 (90.6)	126/139 (90.6)	[10]
Hasabe et al.	Prospective	34/36 (94.4)	NR	[11]
Yadav et al.	Prospective	117/122 (95.9)	117/122 (95.9)	[12]
Bakri-UBT				
Darwish et al.	RCT	30/33 (90.9)	30/33 (90.9)	[1]
Revert et al.	Prospective	188/226 (83.2)	155/183 (84.7)	[13]
Brown et al.	Prospective	55/58 (94.8)	52/55 (94.5)	[14]
Vintejoux et al.	Retrospective	25/36 (69.4)	25/36 (69.4)	[15]
Guo et al.	Retrospective	288/305 (94.4)	131/142 (92.3)	[16]
Mathur et al.	Retrospective	40/49 (81.6)	14/17 (82.4)	[17]
Wang et al.	Prospective	373/407 (91.6)	373/407 (91.6)	[18]
Alkis et al.	Retrospective	43/47 (91.5)	NR	[19]
Kaya et al.	Prospective	34/45 (75.6)	27/34 (79.4)	[20]
Laas et al.	Before and after	37/43 (86)	37/43 (86)	[21]
Olsen et al.	Retrospective	25/37 (67.6)	17/24 (70.8)	[22]
Kong et al.	Retrospective	59/81 (72.8)	37/59 (62.7)	[23]

Cetin et al.	Retrospective	29/39 (74.4)	29/39 (74.4)	[24]
Gauchotte et al.	Before and after	35/38 (92.1)	NR	[25]
Grange et al.	Retrospective	80/108 (74.1)	26/39 (66.7)	[26]
Kadioglu et al.	Retrospective	42/50 (84)	NR	[27]
Martin et al.	Retrospective	32/49 (65.3)	28/42 (66.7)	[28]
Ogoyama et al.	Retrospective	66/71 (93)	31/32 (96.9)	[29]
Son et al.	Retrospective	239/306 (78.1)	190/241 (78.8)	[30]
ESM-UBT				
Ramanathan et al	Prospective/ Retrospective case series	189/201 (94) *	NR	[31]
Burke et al.	Prospective case series	190/201 (94.5) *	NR	[32]
Burke et al.	Prospective case series	298/306 (97.4) *	298/306 (97.4)	[33]

* - Reported survival rates

NR – Not reported

Table 1.2: Staff time allocation parameters used in costing analysis

Parameter	Value in cost analysis*	Source
Average time taken for UBT device insertion	10 minutes	Reported by senior most doctor
Average time taken for normal vaginal delivery in labour room	7.25 hours	
Average time taken for vaginal delivery with PPH complication, controlled after medical management in LR	10.25 hours	
Average time taken for UBT device retention among those controlled with UBT	24 hours	
Average time in operation theatre for a caesarean section without complications	45 minutes	
Average time in operation theatre for a caesarean section with PPH complication controlled with medical management	60 minutes	
Average time in operation theatre for a caesarean section with PPH complication requiring UBT insertion	75 minutes	
Average time for devascularization surgery after PPH	75 minutes	
Average time for hysterectomy after PPH	120 minutes	
Average time spent in out-patient department	12 hours/week	
Average time spent in indoor patient management	12 hours/week	
Average time spent in operation theatre	12 hours/week	
Average time spent in labour room	2 hours/week	
Average time spent in administration and documentation	10 hours/week	
Average time spent in teaching and training	5.15 hours/week	
Average time spent in out-patient department	12 hours/week	Reported by sister-in-charge
Average time spent in indoor patient management	12 hours/week	
Average time spent in operation theatre	6 hours/week	
Average time spent in administrative work	15 hours/week	
Average time spent in labour room by Grade 4 worker	12 hours/week	Reported by grade 4 worker
Average time spent in operation theatre by Grade 4 worker	12 hours/week	
Mean length of stay for OBGYN patients in ICU	3.47 days	[34]
Mean length of ICU stay for PPH patients	1.5 days	[5]

Table 1.3: Literature based event probabilities used for PPH utilization calculation of healthcare facilities

Input	Value	Reference
PPH incidence in vaginal delivery	3 percent	[35,36]
PPH incidence in caesarean delivery	6 percent	[35,36]
Atonic PPH incidence	80 percent	[37]
Atonic PPH controlled with medical management	90 percent	[38]
Clinical effectiveness of condom-UBT device in controlling atonic PPH	92.3 percent	Calculated from literature review of 33 studies reported in Table 1.1
Clinical effectiveness of ESM-UBT device in controlling atonic PPH	95.3 percent*	Calculated from literature review of 33 studies reported in Table 1.1
Clinical effectiveness of condom-UBT device in controlling atonic PPH	84.3 percent	Calculated from literature review of 33 studies reported in Table 1.1
Probability of stepwise devascularization procedure for uncontrolled atonic PPH cases after UBT insertion	0.85	[38]
Probability of obstetric hysterectomy for uncontrolled atonic PPH cases after UBT insertion	0.15	[38]
Probability of delivery at primary care level	0.19	[39]
Probability of delivery at secondary care level	0.33	[39]
Probability of delivery at tertiary care level	0.48	[39]

***** - *Estimated from limited evidence from 3 case-series studies reported in Table 1.1*

PPH incidence rate in vaginal/caesarean section delivery was applied to reported number of deliveries at each health facility (Table 1.4) to estimate number of PPH and thus proportional atonic PPH cases at the facility. Proportion of these atonic PPH cases uncontrolled after medical and supportive management were eligible for UBT device insertion. Literature review based clinical effectiveness of individual UBT device determined number of patients consequently needing conservative (devascularization) or obstetric hysterectomy surgical intervention at each facility. Table 1.4 shows results of these calculations for each chosen facility.

Table 1.4: Utilization of services for atonic PPH at chosen health facilities of Maharashtra based on primary collected data and event probabilities from literature

Type of Health facility	Mode of Delivery	Annual number of deliveries	Atonic PPH cases	Atonic PPH controlled with medical management	Cases requiring UBT insertion	Controlled with UBT insertion Condom Bakri ESM	Cases requiring further intervention Condom Bakri ESM
PHC	Vaginal	494	11.86	10.67	1.18	1.09 1.00 1.13	0.09 0.19 0.06
SDH	Vaginal	1526	36.62	32.96	3.66	3.41 3.09 3.49	0.26 0.57 0.17
	Cesarean	330	15.84	14.26	1.58	1.47 1.34 1.51	0.11 0.25 0.07
DH	Vaginal	2986	71.66	64.49	7.17	6.66 6.04 6.83	0.50 1.13 0.34
	Cesarean	1045	50.16	45.14	5.02	4.66 4.23 4.78	0.35 0.79 0.24
Medical college	Vaginal	2202	52.84	47.56	5.28	4.87 4.44 5.03	0.37 0.83 0.25
	Caesarean	1141	54.76	49.29	5.47	5.05 4.61 5.21	0.42 0.85 0.25

Methodology for apportioning of unit cost estimation

Example: Unit cost for condom-UBT insertion in labour room of the district hospital

Unit cost for condom-UBT device insertion in labour room (vaginal delivery) of the district hospital was USD 2.84 (INR 182.9). This cost along with unit cost of condom-UBT insertion in operation theatre after cesarean section delivery in district hospital was weighted to get unit cost of condom-UBT insertion at district hospital. The average of weighted insertion cost at district hospital along with similar estimated unit cost for medical college was combined to report the average condom-UBT insertion cost at tertiary level (USD 6.5 (INR 422).

Annual consumption and price data for cost resource heads were obtained from respective sources as stated in Table 2 of the manuscript. Atonic PPH specific clinical data on number of services utilized at respective facilities as stated in Table 1.4 for specific PPH management components were apportioned to that of the total quantity of that particular service category provided at the facility by using time allocation parameters and following reported apportioning methods for each resource head to arrive at unit cost of a particular atonic PPH service delivery at the facility.

The following example describes methodology, apportioning factors and quantity of resources used in calculating unit cost for condom-UBT insertion in labour room (vaginal delivery) of the district hospital (DH). A similar methodology was used for calculation of each respective unit cost reported in the study.

1. Human resources (HR) - For total annual vaginal deliveries (2986) reported at DH, proportional time for annual condom-UBT insertions was obtained as a proportion of total time spent for all condom-UBT insertion (1.19 hours: 10 minutes for single UBT insertion, 7 UBT insertions) to that of total time for vaginal deliveries (21996 hours for 2986 vaginal deliveries) occurring at the facility **(Factor 1: 0.00054)**. This time allocation factor was used to calculate proportional time spent by workforce in all condom-UBT insertions to that of their respective total annual working hours (for 19 working staff of labour room including overhead workers) **(Factor 2: 0.0000023)**. For the working staff, the total annual working hours included time spent across OPD, IPD, Labour room administration, training, teaching, etc. obtained from time allocation interviews (2463 to 2934 total working hours annually). Proportion of labour room time for condom-UBT insertion to total annual working hours (in this case labour room) gave Factor 2.
2. Area - The area cost for labour room was calculated by first factoring the proportion of area used for condom-UBT insertion (labour room area-220 square feet, pharmacy-1800, blood bank-2660) to that of the total hospital area (1246881 square feet) **(Factor 1: 0.0038)**. Factor 2 was time allocation proportion of annual condom-UBT insertion time to that of the total time for all patients in the labour room **(Factor 2: 0.00054).** Unit space cost for condom-UBT insertion in labour room of DH was obtained by dividing annual area cost by number of condom-UBT insertions at DH.
3. Drug cost – Available drugs and their corresponding annually utilized quantities were used to calculate total annual cost of drugs in labour room of the DH. This was then multiplied with proportion of UBT insertion eligible cases in the labour room (**Factor 1: 0.00222)** to get annualized and thus unit cost of drugs used along with condom-UBT insertion in labour room of the DH.
4. Medical and non-medical equipment – Using the expected life time of the equipment (10/15 years), a discount rate of 3 percent and an annual maintenance rate of 0.01, annualized costs were calculated. Proportional equipment time spent on condom-UBT insertion to the total time for use of equipment in labour room **(Factor 1: 0.00054)** gave annual cost of medical and non-medical equipment. This was then divided by eligible UBT beneficiaries to calculate unit cost of equipment for condom-UBT insertion in labour room of the DH.

5. Electricity – As electricity was shared and accounted across the facility, it was first apportioned by proportional area for the labour room out of total facility area multiplied by 2 for electricity to get the first factor (**Factor 1: 0.00751)**. The second factor for apportioning was based on proportional time spent for condom-UBT insertion in labour room **(Factor 2: 0.00054).**
6. Water – Water as a shared resource was first apportioned by proportional area for labour room out of the total facility area to get the first factor (**Factor 1: 0.00751)**. The second apportioning factor was proportional time spent for condom-UBT insertion in labour room **(Factor 2: 0.00054).**
7. Laundry – Laundry was apportioned as proportion of eligible cases for condom-UBT insertion to the total indoor patients at the DH (22036). (**Factor 1: 0.000256).**

Similarly, for surgeries, the district hospital data reported a total of 1169 obstetric surgeries annually. This included 1045 cesarean sections, 39 major surgeries (non-specified) and 85 cases of female sterilization. We derived the number of expected atonic PPH specific surgeries from the given 1045 cesarean sections by applying literature probability estimates as reported in Table 1.1 and 1.2. Time allocation parameters for each type of surgery was then applied to get proportional time factors that was applied to relevant cost centres along with apportioning methods as stated to arrive at unit surgical costs.

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CHEERS CHECKLIST

Items to include when reporting economic evaluations of health interventions

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	Page number 03, line 01 to 02
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	Page number 03, line 05 to 22 Page number 04, line 01 to 11
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study.	Page number 08, line 01 to 07
		Present the study question and its relevance for health policy or practice decisions.	Page number 08, line 03 to 09
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	Page number 08, lines 13 to 17
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	Page number 08, line 03 to 09 Page number 08, line 13 to 17
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	Page number 08, line 13 to 17
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	Page number 06, line 14 to 22 Page number 07, Table 1

Section/item	Item No	Recommendation	Reported on page No/ line No
			Page number 08, line 03 to 05
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	Page number 09, line 12 to 13
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	Page number 11, line 04 to 06
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	Not applicable
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	Not applicable
	11b	*Synthesis-based estimates*: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	Page number 07, Table 1 Supplemental material, Table 1.1
Measurement and valuation of preference-based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	Not applicable
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource	Page number 09, line 11 to Page number 14, line 23 Page number 12, Table 2 Supplemental material

Section/item	Item No	Recommendation	Reported on page No/ line No
		item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	Not applicable
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	Page number 11, line 22 to 24
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	Not applicable
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	Page number 14, line 04 to 15
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle	Page number 14, line 16 to 23

Section/item	Item No	Recommendation	Reported on page No/ line No
		corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	Page number 14, line 16 to 23
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	Page number 15, line 01 to Page number 20, line 03 Page number 16, Table 3 Page number 18, Table 4 Page number 20, Table 5
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	Page number 16, Table 3 Page number 18, Table 4 Page number 20, Table 5
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	Not applicable
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline	Not applicable

Section/item	Item No	Recommendation	Reported on page No/ line No
		characteristics or other observed variability in effects that are not reducible by more information.	
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	Page number 21, line 02 to Page number 24, line 15
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	Page number 25, line 19 to 21
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	Page number 25, line 22 to 23