## PEER REVIEW HISTORY



## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Cost of managing atonic postpartum hemorrhage with uterine balloon tamponade devices in public health settings of Maharashtra, India: An economic micro-costing study |
| **AUTHORS** | Shetty, Siddesh; Moray, Kusum; Chaurasia, Himanshu; Joshi, Beena |

## VERSION 1 – REVIEW

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| **REVIEWER** | Mercy Mvundura<br>USA |
| **REVIEW RETURNED** | 01-Sep-2020 |

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| **GENERAL COMMENTS** | In Table 1, it is odd to see the terms “available over the counter” and “currently not available over the counter” for medical devices that need a trained health worker in order for them to be used. I would suggest the authors use alternative wording. Also, what is the different between available over the counter and available at facilities?<br>Can the authors provide the links to the price data mentioned in Table 1 for each of the devices, especially the ones listed as not available at the health facilities / over the counter?<br>On page 9 line 3-4, does the patient have choice on which device is used on them is they have PPH that needs to be treated with a UBT? If costs for the health care interventions are covered by insurance, how do the catastrophic expenditures result for the beneficiaries, as mentioned in these sentences?<br>Page 9 line 7-8, who is recommending one UBT device over the other as implied in this sentence?<br>Page 10 line 21 - 22, it is not clear what consumption data with patient level information was accessed? Where these data for patients with PPH?<br>How were the data described on page 10 used to allocate costs to PPH related treatments?<br>On page 12 line 10 to 12, what were the apportioning factors used and how were these factors determined?<br>Page 12 section on unit costs – it is not clear what was done here to estimate the unit costs and what the data sources were. Are you using ICD-10 codes or some medical codes to extract the data or come up with cost estimates? Mentioning the use of Indian guidelines is not enough information to help the reader understand the methods.<br>On page 13 line 34 to 35, what were the assumed health system referral costs – how much was assumed.<br>Page 13 line 49, the varying drugs and consumable costs by 99% is an odd number, why not just 100%?<br>In general, the methods section lack the necessary details for the reader to understand how the data used to generate the costs were |

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| | derived. There are broad descriptions of data but no specifics of the unit cost or quantities to enable an understanding of how the costs were generated.<br>The table at the beginning of page 16 is oddly placed. Is that a continuation of Table 3 – note some text warps around this table.<br>The Table on page 17 dose not have a title – please fix that.<br>On Table 3, I do not understand why the authors artificially break down the costs by device to have cost components like medical management, devascularization, hysterectomy, inpatient admissions and ICU admissions when these costs don't differ (at all or even differ much) across the three devices. The only costs that are differing across the three devices are the UBT insertion costs and these are driven by the different device prices. The whole premise of the manuscript is not clear to me, as it seems to be built on the artificial differences between the devices and yet the only real difference is on the price and maybe the effectiveness. |

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| **REVIEWER** | Dr.Vidyadhar Bangal<br>Pravara Institute of Medical Sciences,India |
| **REVIEW RETURNED** | 10-Sep-2020 |

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| **GENERAL COMMENTS** | There are lot many lacunae in the manuscript.very many assumptions are made while costing.Very few health facilities are involved in the study.Results of less than 10,000 deliveries are applied to more than 10,00,000 deliveries.There is no clear and reliable data available in the state for comparison.Results are unrealistic and not useful for the policy makers,as the assumptions made in the whole study are unrealistic and imaginary. |

**VERSION 1 – AUTHOR RESPONSE**

| **Reviewer comments to Author**<br><br>**Reviewer 1** | | |
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| 1. | In Table 1, it is odd to see the terms "available over the counter" and "currently not available over the counter" for medical devices that need a trained health worker in order for them to be used. I would suggest the authors use alternative wording. Also, what is the different between available over the counter and available at facilities? | Apologies for the confusion. We were trying to differentiate the availability of the assembled condom-UBT device in the Indian public health settings. This device is assembled in the health facility using components such as condom, Foleys catheter, suture material, etc. available at the health facility to make the uterine balloon tamponade device. Alternatively, Bakri-UBT and ESM-UBT are currently provided by non-government organizations and used in certain facilities of the Indian public health system. These devices are dedicated devices specifically designed for managing the postpartum haemorrhage complication. Bakri-UBT is a ready to use device commercially available in India at present. ESM-UBT is not commercially available at the moment.<br><br>We have revised the wordings in Table 1 on page number 07 to indicate this. |
| 2. | Can the authors provide the links to the price data mentioned in Table 1 for each of the devices, especially the ones listed as not available at the health facilities / over the counter? | Price data links for the devices are now added to Table 1, page number 07 as references. |
| 3. | On page 9 line 3-4, does the patient have choice on which device is used on them is they have PPH that needs to be treated with a UBT? If costs for the health care interventions are covered by insurance, how do the catastrophic expenditures result for the beneficiaries, as mentioned in these sentences? | No, the patient does not have an option of choosing UBT device used for PPH management in the publicly financed health system.<br><br>However, it is a policy decision as to which specific UBT device is to be made available in all facilities of the Indian public health system. Page number 08, lines 03 to 07 in the revised manuscript conveys this more clearly. |

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| | | Despite coverage by publicly sponsored schemes, evidence shows out-of-pocket and catastrophic spending to remain high with institutional deliveries (pregnancy complications, caesarean sections, private healthcare) in the Indian context. Management of a complication like PPH is thus likely to translate into high out-of-pocket expenses (OOPE) for the beneficiaries. A 2019 nationally representative Indian literature reference for OOPE evidence has been added in the revised manuscript on page number 07 line 08 to page number 08, line 01 to clarify this point. |
| 4. | Page 9 line 7-8, who is recommending one UBT device over the other as implied in this sentence? | The 2015 Indian guidance on prevention and management of postpartum haemorrhage issued by the Ministry of Health and Family Welfare (MOHFW), Government of India suggested using condom-UBT as Bakri-UBT was more expensive. With recent emerging literature evidence for relatively low-cost ESM-UBT device, the Maternal Health Division, MOHFW, India is assessing the most cost-effective UBT intervention for atonic PPH management in the Indian context.<br><br>To highlight this better, we have revised the statements on page number 08, lines 07 to 09. |
| 5. | Page 10 line 21 - 22, it is not clear what consumption data with patient level information was accessed? Where these data for patients with PPH? | The revised manuscript on page number 09, lines 15 to 20 specifies details of the accessed consumption data for patient level information on all cost resource categories. As Health Management Information System (HMIS) data did not specifically report PPH related indicators, we used aggregate obstetric patient data available at the facilities where this costing exercise was undertaken. The methods used to determine PPH consumption levels are now mentioned in a more detailed manner in data collection section of the revised manuscript on page number 09, lines 15 to 25, page number 10, lines 01 to 12 and supplementary material file 1 Tables 1.1 and 1.2. |

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| 6. | How were the data described on page 10 used to allocate costs to PPH related treatments? | The revised manuscript in data analysis, unit costs and annual cost sub-section of methods section on page number 12, lines 03 to 09, page number 13 lines 04 to 15, lines 22 to 24 and page number 14, lines 01 to 06 elaborates the methods used to estimate costs for PPH related treatments.<br><br>Supplementary material file 1 Table 1.1 and 1.2 give further details for cost analysis methodology. |
| 7. | On page 12 line 10 to 12, what were the apportioning factors used and how were these factors determined? | The revised manuscript on page number 12, lines 12 to 20 gives methodology details of apportioning factors used for all cost resource categories. |
| 8. | Page 12 section on unit costs – it is not clear what was done here to estimate the unit costs and what the data sources were. Are you using ICD-10 codes or some medical codes to extract the data or come up with cost estimates? Mentioning the use of Indian guidelines is not enough information to help the reader understand the methods. | We have not used ICD-10 codes for cost estimation. Reimbursement under public health insurance schemes (*PMJAY/MJPJAY)* as stated in the manuscript is based on pre-defined Health Benefit Packages (HBP) determined by clinical diagnosis made by the treating doctor. As HBPs or HMIS indicators specific to PPH were not available, we relied on available HMIS and facility level obstetric patient data at respective facilities. This along with relevant atonic PPH literature determined service utilization denominators for PPH at respective healthcare facility that were then used in unit cost calculation.<br><br>The unit costs section in the revised manuscript on page number 13, lines 04 to 15 and the supplementary material file 1 gives a detailed description of these methods used to estimate unit costs |
| 9. | On page 13 line 34 to 35, what were the assumed health system referral costs – how much was assumed. | Referral cost in this study was obtained from a primary economic costing study that calculated unit public health system cost of transport related to institutional deliveries in three districts of an Indian state (Reference number 39). Details of the inflation adjusted cost used in this analysis |

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| | | are now mentioned in the revised manuscript on page number 14, lines 14 to 17. |
| 10. | Page 13 line 49, the varying drugs and consumable costs by 99% is an odd number, why not just 100%? | Thank you for pointing this out. As we were initially uncertain about bringing the cost of drugs and consumable down to zero, we had chosen to vary them by 99% on both sides. We realize that this is not an ideal variation measure for this health system costing parameter.<br><br>We have now revised to vary drugs and consumable cost parameters (obtained from government facility purchase lists) by 50% on the lower limit and by 100% on the upper limit for PSA analysis. The reason being that prices are already negotiated by government during procurement and hence expected to have limited variation on the lower side. To account for high market prices, upper limit variation has been revised to 100%. Methods section in the revised manuscript on page number 14, lines 21 to 23 states this.<br><br>Results of the PSA analysis along with 95% confidence interval limits has now been revised with changes in the result section on page number 15, 17, Table 3, page number 16 and Table 4, page number 18 respectively. |
| 11. | In general, the methods section lacks the necessary details for the reader to understand how the data used to generate the costs were derived. There are broad descriptions of data but no specifics of the unit cost or quantities to enable an understanding of how the costs were generated. | Methods section in the manuscript has been revised in data collection, analysis subsections from page number 08 to 15 along with supplementary material file 1 to give more detailed description of methods and input parameters used to generate costs. Tables 1.1 and 1.2 in the supplementary material file 1 give details on quantity estimation methods for PPH resources utilization at respective healthcare facilities used in this costing analysis. |
| 12. | The table at the beginning of page 16 is oddly placed. Is that a continuation of | The table was indeed continuation of Table 3. The alignment unfortunately was altered in the |

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| | Table 3 – note some text warps around this table. | PDF builder of the submission system.<br><br>We have ensured that the table remains within the page in the revised version. |
| 13. | The Table on page 17 does not have a title – please fix that. | We have fixed the table title for Table 4, page number 18 now. The alignment was altered in the submission system. |
| 14. | On Table 3, I do not understand why the authors artificially break down the costs by device to have cost components like medical management, devascularization, hysterectomy, inpatient admissions and ICU admissions when these costs don't differ (at all or even differ much) across the three devices. The only costs that are differing across the three devices are the UBT insertion costs and these are driven by the different device prices. The whole premise of the manuscript is not clear to me, as it seems to be built on the artificial differences between the devices and yet the only real difference is on the price and maybe the effectiveness. | Given the emerging evidence for low cost ESM-UBT alternative, MOHFW-India is assessing cost-effectiveness of UBT devices to determine the most cost-effective UBT intervention for atonic PPH management in the Indian public health context by undertaking Health Technology Assessment (HTA). This costing study was done as part of this HTA exercise.<br><br>Our literature review highlighted a variation in reported clinical effectiveness for different UBT devices in addition to the price differences (Supplementary material file 1 Table 1.3). Given this variation of reported clinical effectiveness across devices, management of uncontrolled cases after failure of a particular UBT device to control bleeding will impact subsequent utilization of resources for further interventions, thus having an implication on the health system in terms of resources and opportunity costs. This study uses literature reported effectiveness of individual devices along with associated resource utilization using staff interviews, expert opinions and available primary data to estimate UBT specific resource utilization and thus differentiate these cost implications for the health system. The data analysis sub-section on page number 12, lines 03 to 09 in the revised manuscript explains this.<br><br>For India with its limited available cost data, high PPH burden and resource constraints, this health system costing presents cost evidence for management of atonic PPH that individually |

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| | | ranges from medical management to UBT intervention or conservative surgery or hysterectomy depending on patient's clinical condition. This available data for three alternate UBT devices may thus be beneficial in the decision of choosing the most cost-effective UBT device for India.<br><br>The specific unit costs for PPH management components may be useful evidence in inclusion of this clinical condition to health benefit packages of the state and centrally financed public health schemes (*MJPJAY or PMJAY)*. Treatment package cost of medical, specific UBT intervention and corresponding surgical management can be obtained to be added to the HBPs and help with resource allocation decisions for respective UBT devices. |
| **Reviewer 2** | | |
| 1 | There are lot many lacunae in the manuscript. Very many assumptions are made while costing. Very few health facilities are involved in the study. Results of less than 10,000 deliveries are applied to more than 10,00,000 deliveries. There is no clear and reliable data available in the state for comparison. Results are unrealistic and not useful for the policy makers, as the assumptions made in the whole study are unrealistic and imaginary. | We apologize for not providing a clear background to the work presented in this manuscript.<br><br>This study was part of a Health Technology Assessment (HTA) project to determine the most cost-effective uterine balloon tamponade device for atonic PPH management in the Indian public health system. This policy question was received by HTAIn, Department of Health Research, India from the Maternal Health Division, Ministry of Health and Family Welfare, India. Government of India has created the HTAIn institutional mechanism to facilitate evidence informed policy decision making. HTA process is used globally and involves systematic use of decision analysis to estimate possible costs and consequences of an intervention to aid decision making amid uncertainties. HTA evaluation also helps decide |

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| | | reimbursement rates for healthcare interventions.<br><br>We have undertaken economic micro-costing with available primary data for the state of Maharashtra at the selected public healthcare facilities. With limited available guidance for sampling of healthcare service costing as recognised by the Global Health Cost Consortium ( https://ghcosting.org/), we believe improving representativeness to cover a larger population by including more facilities to compare UBT devices from the economic evaluation perspective would have been a resource intensive and time-consuming exercise to answer the given policy question. We have revised the annual cost methodology section on page number 13, lines 22 to 24 and page number 14, lines 01 to 06 to give a more detailed description on methods used to estimate annual costs for the state. In calculating these costs, we have calculated the state service utilization by considering number of deliveries taking place across healthcare levels of Maharashtra in the year 2017-18 applied to Indian PPH event probabilities mentioned in Table 2, page number 11 and supplementary material file 1 to determine PPH resource utilization for the state and thus the costs. As you have rightly indicated that PPH specific clinical data is not available for the state and given the resource and time intensive nature of such a prospective collection, we believe that this is a feasible method of cost estimation for the given intervention.<br><br>We have used relevant published literature evidence from the Indian context for deficient PPH clinical data to feasibly estimate health system costs. To plausibly address and account for these expected uncertainties with resource utilization and cost parameters, we have undertaken a detailed probabilistic sensitivity |

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| | | analysis with 1000 Monte Carlo simulations to give the 95% confidence interval limits for all reported costs in the study.<br><br>This study uses standard costing practises to answer the policy question. A country like India has limited health system cost data. The revised HBPs under the flagship *PMJAY* health scheme accounts packages for high risk institutional deliveries (premature delivery, previous caesarean section, eclampsia, maternal or foetal conditions like diabetes, anaemia, growth retardation, etc.). The PPH condition is currently not included in any of these packages. This study findings can be used to include management of PPH condition to the forthcoming packages of state and centrally financed public health schemes (*MJPJAY or PMJAY).* |

**VERSION 2 – REVIEW**

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| **REVIEWER** | Mercy Mvundura<br>PATH USA |
| **REVIEW RETURNED** | 10-Dec-2020 |

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| **GENERAL COMMENTS** | The new results on total costs for managing atonic PPH that have been added to the abstract need to also include the associated number of women / PPH cases that is assumed with that estimated cost of $1.2 million.<br>The authors have not adequately addressed some of my comments related to the study methods. Note that when I state page numbers in the comments below, I am referring to the tracked / marked up version of the revised manuscript.<br>For example, one comment that has not been adequately addressed was the request for the authors to clarify how the data used to generate the costs were derived. What has been added on page 12 does not explain how costs were estimated. The authors state that PPH specific indicators are unavailable and so they obtained numbers of vaginal and caesarean section deliveries and so on. How are these data used to estimate costs? What facility records, salary slips etc. specifically were obtained and how were the allocation of costs done to PPH treatment versus other conditions treated at the facilities?<br>Can the India specific PPH literature that is mentioned as the source of costs also on page 12 be cited.<br>Please provide the findings from the interviews that you state were conducted with providers and assumptions about time spent for each PPH-related treatment intervention. Provide the information on the time costs, and other resources that are used per PPH case and the associated quantities. |

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| | Can you also provide details (quantitative values) of the proportions / apportions alluded to on page 16 for PPH relative to all other treatments provided by the staff or facilities. |

**VERSION 2 – AUTHOR RESPONSE**

| **Reviewer comments** | **Author responses** |
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| The new results on total costs for managing atonic PPH that have been added to the abstract need to also include the associated number of women / PPH cases that is assumed with that estimated cost of $1.2 million. | Number of atonic PPH cases (27,915) contributing to the cost of $1.2 million is now specified in abstract of the revised manuscript on Page 04, lines 04 to 05. |
| For example, one comment that has not been adequately addressed was the request for the authors to clarify how the data used to generate the costs were derived. What has been added on page 12 does not explain how costs were estimated. The authors state that PPH specific indicators are unavailable and so they obtained numbers of vaginal and caesarean section deliveries and so on. How are these data used to estimate costs? What facility records, salary slips etc. specifically were obtained and how were the allocation of costs done to PPH treatment versus other conditions treated at the facilities? | The Methods section of the revised manuscript from Page 09, line 11 to Page 14, line 23 is revised to sequentially give details on cost data collection, data sources, and data analysis section to explain how the available data was used to allocate costs by apportioning for PPH treatment. Table 2 in the manuscript is now revised to give apportioning assumptions and sources of data used in cost calculation. The manuscript data analysis section along with supplemental material Tables 1.2, 1.3, 1.4 and apportioning methodology explanation section in supplemental material describes details on how facility costs specific to atonic PPH activity were derived. |
| Can the India specific PPH literature that is mentioned as the source of costs also on page 12 be cited. | Except for referral costs obtained from an Indian study as mentioned and cited on Page 14, lines 11 to 14 of this revised manuscript, we have not used Indian costing literature for estimation of costs in this study. The previous statement suggested India specific clinical literature evidence that was used in clinical event probability calculation for denominators of cost estimation and is cited on Page 10, lines 13 to 14. To clarify the confusion, we have revised the statement on Page 10, lines 14 to 16. |

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| Please provide the findings from the interviews that you state were conducted with providers and assumptions about time spent for each PPH-related treatment intervention. Provide the information on the time costs, and other resources that are used per PPH case and the associated quantities. | Table 1.2 in the revised supplemental material<br><br>presents time allocation parameter findings obtained from staff interviews and published literature. Table 2 of the manuscript and apportioning methodology example in supplemental material explains use of time allocation and quantity/number of resources used in cost estimation across different cost centres. We have used annual number of services expected to be provided for specific PPH management components (Supplemental material, Table 1.3 and Table 1.4), total number of annual services provided at the facility under the same category (total surgeries for corresponding PPH surgeries) along with time allocation parameters apportioned to atonic PPH component from total allocated time/working hours (Supplemental material, Table 1.2) to calculate unit, package and annual costs. |
| Can you also provide details (quantitative values) of the proportions / apportions alluded to on page 16 for PPH relative to all other treatments provided by the staff or facilities? | The revised manuscript on Page 11, lines 06 to 19 and supplemental material give apportioning methodology details along with quantitative values used in cost calculation. An example of unit cost calculation for condom-UBT insertion at district hospital is explained in the supplemental material provided. As similar methodology was used across all unit cost calculations, we have provided apportioning factor values only for the example explained in supplementary material. |

**VERSION 3 – REVIEW**

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| **REVIEWER** | Mercy Mvundura<br>PATH USA |
| **REVIEW RETURNED** | 26-Jan-2021 |

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| **GENERAL COMMENTS** | The authors have adequately addressed all the comments I provided. |