Estimating the Cost of Early Infant Male Circumcision in Zimbabwe: Results From a Randomized Noninferiority Trial of AccuCirc Device Versus Mogen Clamp

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Background: Safe and cost-effective programs for implementing early infant male circumcision (EIMC) in Africa need to be piloted. We present results on a relative cost analysis within a randomized noninferiority trial of EIMC comparing the AccuCirc device with Mogen clamp in Zimbabwe.

Methods: Between January and June 2013, male infants who met inclusion criteria were randomized to EIMC through either AccuCirc or Mogen clamp conducted by a doctor, using a 2:1 allocation ratio. We evaluated the overall unit cost plus the key cost drivers of EIMC using both AccuCirc and Mogen clamp. Direct costs included consumable and nonconsumable supplies, device, personnel, associated staff training, and environmental costs. Indirect costs comprised capital and support personnel costs. In 1-way sensitivity analyses, we assessed potential changes in unit costs due to variations in main parameters, one at a time, holding all other values constant.

Results: The unit costs of EIMC using AccuCirc and Mogen clamp were \$49.53 and \$55.93, respectively. Key cost drivers were consumable supplies, capacity utilization, personnel costs, and device price. Unit prices are likely to be lowest at full capacity utilization and increase as capacity utilization decreases. Unit

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prices also fall with lower personnel salaries and increase with higher device prices.

Conclusions: EIMC has a lower unit cost when using AccuCirc compared with Mogen clamp. To minimize unit costs, countries planning to scale-up EIMC using AccuCirc need to control costs of consumables and personnel. There is also need to negotiate a reasonable device price and maximize capacity utilization.

Key Words: AccuCirc, cost, early infant male circumcision, Mogen clamp, Zimbabwe

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INTRODUCTION

Results from 3 randomized controlled trials indicate that voluntary medical male circumcision (VMMC) can reduce the risk of HIV infection among men by up to 60%.^{1–3} These findings and those from other studies suggesting that VMMC is cost-effective^{4–6} have led 14 African countries to scale-up VMMC in an effort to reduce the number of new HIV infections plus the overall costs of combating HIV/AIDS.^{5–9} Some of these countries, Zimbabwe included, have begun to pilot early infant male circumcision (EIMC).^{10–15}

The World Health Organization (WHO) and UNICEF recommend EIMC (performed ≤ 60 days of life) for prevention of HIV in countries with high HIV prevalence.^{16,17} EIMC is a quick and simple procedure, characterized by complete wound healing within 7 days and accompanied by a low rate of adverse events (AEs).¹⁸ Integrating EIMC within existing child health services in resource-limited settings is likely to be easier and less costly than establishing parallel programs because EIMC can be combined with existing routine postnatal or expanded immunization programs. With adequate training, EIMC can be performed by nonphysician providers, thereby minimizing the strain on human resources for health.¹⁷

The Gomco clamp, Plastibell, and Mogen clamp are the 3 EIMC devices currently prequalified by WHO.¹⁸ These 3 devices are characterized by rare, but potentially serious, complications, including laceration of the glans penis if a mismatch in sizes of the separate pieces of the Gomco

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clamp occurs,^{13,18} the possibility of partial or total amputation of the glans penis with Mogen clamp,^{15,18–20} and necrosis of the glans and other injuries if migration of the Plastibell occurs during circumcision.^{12,18,21,22} Use of incorrect "bell" size can actually increase this risk.^{12,18,21,22} A relatively new device, AccuCirc, can potentially reduce these device-related AEs, as it has a shielding ring that protects the glans penis from possible laceration or amputation. In addition, it comes prepackaged and is disposable, factors which make it appealing for use in sub-Saharan Africa, particularly in resourcelimited rural settings where health centers may lack electricity and sterilization equipment.¹³ AccuCirc is also suitable for use by midlevel personnel such as nurse midwives who are in greater supply than medical doctors in many HIV-affected countries.^{13,23} Thus, in sub-Saharan Africa, AccuCirc may provide a safer, more acceptable, feasible, and less costly alternative to the already prequalified EIMC devices.

As part of the WHO male circumcision device prequalification process,²⁴ AccuCirc is undergoing pilot study in countries where EIMC rollout is intended, including Zimbabwe. Between January and June 2013, a randomized noninferiority EIMC pilot trial was conducted in Zimbabwe to assess the safety, acceptability, feasibility, and cost of AccuCirc compared with the Mogen clamp.²⁵ This comparison was chosen because the WHO prequalification process requires that any new EIMC device be compared with an already prequalified device.²⁴ Of the 3 already prequalified devices, the Mogen clamp is perceived to be the safest.^{10,12} Here, we present results of a cost analysis conducted alongside the EIMC comparative trial to determine the relative cost profile of AccuCirc compared with Mogen clamp.

METHODS

Trial methods are described in detail elsewhere.²⁵ In brief, 150 male infants aged 6–60 days were randomized to AccuCirc or Mogen clamp in a 2:1 ratio (100 AccuCirc; 50 Mogen clamp) and followed for 2 weeks after circumcision. The EIMC trial was conducted at Edith Opperman, a polyclinic in Zimbabwe's capital, Harare. The polyclinic has the highest number of deliveries in Zimbabwe (approximately 400 deliveries per month).²⁶ Primary outcomes for the trial were EIMC safety, acceptability, and cost.

Direct and indirect cost data were analyzed using the Decision Makers Program Planning Tool (DMPPT) for Costing Male Circumcision Programmes.²⁷ DMPPT is a Microsoft Excel–based model developed by the US Agency for International Development Health Policy Initiative in collaboration with the Joint United Nations Programme on HIV/AIDS (UNAIDS) to assist decision makers understand the potential cost and impact of various options for male circumcision scale-up.

Direct costs included consumable and nonconsumable supplies, device, personnel, associated staff training, and environmental costs. Indirect costs comprised capital and support personnel costs. This analysis adopted the perspective of the Zimbabwe Ministry of Health as a health care payer. Client costs such as transport to and from the EIMC facility, opportunity costs of time spent seeking EIMC services and caregiver costs were therefore excluded. Costs of demand creation were also excluded. As our cost analysis is based on a pilot EIMC study, we estimated our costs based on the assumption of a vertical EIMC program. We present costs in 2013 constant US dollar prices and assume an exchange rate of US1 = US1 because Zimbabwe officially adopted the US dollar as its principal currency in 2009.

Collection, Management, and Analysis of Cost Data

Detailed cost data collection was performed between January and June 2013 guided by the UNAIDS Costing Guidelines for HIV Prevention Strategies from which economic data collection instruments were adapted.²³

Facility Inventory

A list of all resources required to perform an EIMC procedure using AccuCirc and Mogen clamp was identified during a facility inventory conducted at the beginning of the study. Resources included supplies, devices, capital equipment, and staff. Resource-use data were collected routinely during the trial, including quantity of supplies and devices used, procedure duration, and quantity of waste. Actual usage of supplies was recorded in a supplies charge sheet maintained in each infant's binder. Total usage of each consumable item was derived by aggregating these records.

Time Spent Performing EIMC Tasks

Procedure duration was measured through a time and motion study conducted alongside procedures. A stopwatch was used to measure procedure duration that was recorded on a study form. To verify the recorded time, a video camera recorded the entire procedure. Total procedure time was therefore based on direct and continuous observation of the procedure.

Direct Costs

Consumable and Nonconsumable Supplies

Actual costs of supplies used were based on actual invoices and receipts from research partners. Total number of units of each supply item used was multiplied by its price per unit to produce the total cost for that item. Total costs of all supply items were then summed up, and the grand total was divided by the number of procedures to derive the cost contribution of supplies to each procedure.

Device Costs

For device costs, we relied on purchase prices as quoted by the international suppliers. The price of an AccuCirc device, based on an invoice by Clinical Innovations, was \$10 per unit, which also represented the per procedure cost given that AccurCirc is a single-use device. Mogen clamps were supplied by Sklar Instruments at a unit price of \$213.15. Unlike AccuCirc, the Mogen clamp is reusable up to 1000

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times.⁷ Therefore, we divided its price per unit across 1000 EIMC procedures to derive its cost per EIMC.

Personnel Training Costs

The EIMC team (4 doctors and 3 nurse midwives) received four 8-hour days of training. For each device, we assumed that training would still require the same amount of time and therefore allocated the full four 8-hour days to each device in our cost analyses. Our estimates are however likely to be a conservative estimate of the training costs. Training kits were supplied at no cost by the supplier as they come complimentary for large orders. However, for purposes of calculating training costs and upon request, the supplier provided a quotation for training materials. While doctors received an hourly rate for attending training equivalent to what they would have earned for providing an EIMC procedure, study nurse midwives did not as they were already on a monthly salary. However, in view of the fact that government nurse midwives normally receive a daily allowance for attending training workshops, it was necessary to calculate the opportunity cost of time they spent at training for which we used their hourly salary rate.

Total training costs therefore comprised fees for 2 consultant trainers, costs of time spent by doctors and nurse midwives at training, and costs of training materials plus catering. To estimate annual training costs, the study team adopted an approach used in a Zimbabwe PrePex device cost study where annual turnover among public sector nurse midwives in Zimbabwe was estimated at 50%, necessitating training of a new team every 3.6 years.²⁸ Total training costs were therefore spread over a 3.6-year period to derive an annual training cost. The per EIMC training cost was calculated by dividing the annual training cost by the annual number of EIMC procedures (1512). EIMC training took place in the study clinic boardroom, and as scale-up is anticipated to use government personnel and facilities, we excluded travel and training venue costs.

Personnel Costs

As EIMC was still at the pilot stage, we relied on salaries of EIMC staff to calculate personnel costs. Doctors' salaries comprised basic pay and benefits (\$31,800 per year), whereas nurse midwives' salaries comprised basic pay plus allowances [housing allowance (\$45 per month) and transport allowance (\$65 per month)], amounting to \$13,596 per year. Hourly salary rates were computed by dividing annual salary by annual number of hours worked. Hourly salary rates were then multiplied by time contributed to the procedure, and results for all staff members were summed up. In practice, in an integrated EIMC scale-up, we anticipate that personnel will have other clinic responsibilities in addition to EIMC procedures, including among others, maternity services, antenatal and postnatal care, voluntary counseling and testing, and providing antiretroviral therapy. Furthermore, and based on discussions with clinic facility managers and officials at the Ministry of Health, we anticipate that EIMC will likely consume a small proportion of staff effort and that allocating 10% of staff salaries to EIMC is a conservative estimate. In

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sensitivity analyses, we therefore explored the impact of assuming only 10% of total salary costs on EIMC unit cost.

Environmental costs

Environmental costs were calculated based on the estimated number of burn bin (ie, sharps tin container) disposals. For the AccuCirc procedures, a total of 18 burn bins were used compared with 6 for the Mogen clamp. Environmental costs for each device were derived by multiplying the number of burn bins disposed by the cost of incineration (\$10 per burn bin), based on quotations provided by private service providers.

Indirect Costs

Capital Costs (Buildings)

EIMC procedures were performed in a renovated space in the clinic where the study took place. Because of this and the likelihood of an integrated EIMC scale-up, our analysis assumes zero physical infrastructure development costs for a scaled-up EIMC program.

Capital Costs (Durable Equipment)

Clinic equipment used for EIMC procedures included a refrigerator, a medium-size autoclave for sterilizing Mogen clamps, and heaters to keep infants warm. Purchase prices of each capital item were divided by an appropriate amortization period to derive annualized depreciation values. Annualized depreciation values for all capital goods were summed up, and the grand total was divided by the annual number of EIMC procedures. As an integrated EIMC scale-up is anticipated and as this equipment is already found in government facilities, we explored the effect of excluding durable capital equipment on EIMC unit cost in sensitivity analyses.

Support Personnel Costs

Monthly gross salaries of support staff (clinic clerk and caretaker), including benefits [housing allowance (\$45 per month) and transport allowance (\$65 per month)], were multiplied by 12 months to produce an annual salary of \$9492 and \$7152, respectively. As support personnel are involved in a range of clinic services, we assumed 10% of each personnel type's salary to support personnel costs and summed up the contributions. Our model divides the result by the annual number of EIMC procedures to derive the support personnel contribution to EIMC unit cost.

One-Way Sensitivity Analyses

A number of factors could potentially introduce uncertainty into our results. First, Clinical Innovations, the manufacturer of AccuCirc, has indicated that future supplies of the device will be priced higher than \$10. The unit cost of an EIMC would therefore be much higher than that reflected here. Also, in a future scale-up, poor demand for EIMC could potentially raise EIMC unit cost. For instance, our cost analyses were based on a daily maximum rate of 6 EIMC procedures, whereas on the ground, the study team experienced challenges in recruiting infants.²⁵ Reduced EIMC uptake in a scaled-up

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program would lead to a failure to fully use facility capacity, a situation which would raise unit cost of EIMC procedure.

Personnel salary costs for EIMC used here are based on research study salaries, and therefore the cost results here may not reflect those of a model that uses government personnel salaries. In addition, we included durable capital equipment costs in this analysis, although most clinics in Zimbabwe already use the durable equipment required to conduct an EIMC procedure for other clinical services. In an integrated EIMC delivery model, durable capital equipment may therefore not represent an additional cost because that infrastructure already exists. These factors individually or combined could potentially raise or lower the cost of an EIMC procedure in a scaled-up EIMC program.

We therefore considered the sensitivity of results to variations in the AccuCirc device unit price, personnel salaries, and capacity utilization, one at a time, holding all other values constant. Additionally, as the AccuCirc retail price has not yet been determined by the manufacturer, we investigated the exact price at which the AccuCirc unit cost would break even with the Mogen clamp. As durable capital equipment is already available in Zimbabwean clinics for other forms of health care, we also tested the sensitivity of results if capital equipment was excluded. In sensitivity analyses, we also estimated the unit cost of an EIMC procedure if EIMC were integrated into existing clinic programs such that medical personnel would also provide other services in addition to EIMC.

Ethical Considerations

The study received approvals from the Medical Research Council of Zimbabwe and the Ethics Committees of the University College London and the London School of Hygiene and Tropical Medicine.

RESULTS

In the EIMC comparative trial, 150 infants aged 6-54 days were circumcised between January and June 2013 according to their allocated intervention (n = 100 AccuCirc;n = 50 Mogen clamp). The mean time taken to perform the actual EIMC procedure was 15.5 minutes and was similar for both devices {mean difference = 0.1 minutes [95% confidence interval (CI): -1.2 to 1.4]}. Two moderate AEs (2%, 95% CI: 0.2 to 7.0) were observed in the AccuCirc arm. These were one case of excess skin removal (hydrocortisone cream applied and wound was completely healed 4 months after EIMC) and one case of inadequate skin removal, which warranted corrective surgery and was completely healed 20 days after corrective surgery. No AEs (95% CI: 0.0 to 7.1) occurred in the Mogen clamp arm. Nearly all mothers (99.5%) reported great satisfaction with the outcome. All mothers, regardless of arm, said they would recommend EIMC to other parents and would circumcise their next son. Trial outcomes are described in detail elsewhere.²⁵

Table 1 summarizes the results of cost analyses for both AccuCirc and Mogen clamp. The unit costs of EIMC using AccuCirc and Mogen clamp were \$49.53 and \$55.93, respectively. Costs of consumable supplies were higher for Mogen clamp (\$30.18 compared with \$13.48). This large difference is explained by the fact that the prepackaged AccuCirc kit comes with a number of consumable supplies required for an EIMC procedure, and because AccuCirc is disposable, it does not require the sterilization supplies required for the Mogen clamp (Table 1). The contribution of device cost was higher for AccuCirc, at \$10, compared with \$0.21 for the reusable Mogen clamp.

Key cost contributors to the unit cost of AccuCirc were consumable supplies, device price, and personnel costs. For AccuCirc, consumable supplies (\$13.48), device price (\$10),

Cost Category	AccuCirc		Mogen Clamp	
	Cost (in \$) Per EIMC	% Contribution to Unit Cost	Cost (in \$) Per EIMC	% Contribution to Unit Cos
Direct costs				
Device	10.00	20.2	0.21	0.4
Consumable supplies	13.48*	27	30.18†	54
Nonconsumable supplies	0.27	0.5	0.31	0.6
Environmental	1.80	4	1.20	2
Personnel	19.11	39	19.11	34
Training	3.69	7	3.69	7
Subtotal (direct)	48.35	98	54.70	98
Indirect costs				
Capital equipment	0.08	0	0.13	0
Support personnel	1.10	2	1.10	2
Subtotal (indirect)	1.18	2	1.23	2
Total	49.53	_	55.93	_

All costs are presented in 2013 US dollars.

*Sterile gloves, nonsterile gloves, antiseptic solution, 3 linen savers, EMLA topical cream, Vitamin K, wet wipes, liquid cleaner, cotton wool, methylated spirit, bin liners, baby diapers, sharps tin containers, syringe 2 mL with needle, paper towels, hard surface cleaner, hand wash, hand cream.

[†]Sterile gloves, nonsterile gloves, antiseptic solution, ⁴ linen savers, surgical blade, sterile gauze pad, EMLA topical cream, autoclave sterilizing sensitive tape, sterile marker pen, Vitamin K, autoclave sterilizing towels, paraffin gauze pad, petrolatum foil packs, wet wipes, syringe 2 mL with needle, liquid cleaner, cotton wool, methylated spirit, bin liners, baby diapers, sharps tin containers, paper towels, hard surface cleaner, hand wash, hand cream.

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and personnel costs (\$19.11) accounted for a combined 86.2% of EIMC unit cost. For Mogen clamp, key cost contributors were consumable supplies (\$30.18) and personnel costs (\$19.11), which together contributed 88% to the unit cost. The wide difference in consumable supplies costs between the 2 devices reflects the cost-savings due to the lower number of supplies costed for the AccuCirc procedure, as a number of EIMC supplies come prepacked in the AccuCirc kit already priced at \$10. Overall, other direct costs (training and environmental costs) and indirect costs (capital equipment and support personnel costs) had a smaller contribution to the total costs of EIMC for both devices.

Table 2 presents 1-way sensitivity analysis results and demonstrates unit cost impacts for AccuCirc when the main parameters (AccuCirc device price, capacity utilization, and personnel salaries) are varied and also when capital equipment is excluded. We explored EIMC unit cost impacts in an integrated EIMC program where personnel time is shared with other medical services in addition to EIMC. Results

TABLE 2. One-Way Sensitivity Analysis Results for AccuCirc Device Price, Personnel Salaries, Capacity Utilization, and Capital Equipment

Cost Category	AccuCirc EIMC Unit Cost (in \$)	Mogen Clamp EIMC Unit Cost (in \$)
Device costs (in \$)		
10 (base case)	49.53	55.93
15	54.53	N/C
16.40 (break-even price)	55.93	N/C
20	59.53	N/C
25	64.53	N/C
Salaries		
Base case	49.53	55.93
Public sector*	43.71	50.11
Salaries		
Base case	49.53	55.93
Integrated EIMC program†	30.26	36.61
Capacity (No. EIMC/d)		
2	59.25	65.75
4	51.95	58.38
6 (base case)	49.53	55.93
Capital equipment		
Base case	49.53	55.93
Excluding capital equipment	49.45	55.80
Staff time		
-10%	47.62	54.02
Base case	49.53	55.93
+10%	51.44	57.84
Consumable supplies		
-10%	48.18	52.91
Base case	49.53	55.93
+10%	50.88	58.95

*Public sector salaries inclusive of benefits are doctor (\$26,400), nurse midwife (\$8400), receptionist (\$3000), and caretaker (\$1800). †10% of total salaries of doctors and nurse midwives.

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show EIMC unit cost for AccuCirc rising from \$49.53 to \$64.53 as device price increases from \$10 to \$25. The exact price at which the AccuCirc unit cost would break even with the Mogen clamp is \$16.40. We also varied capacity utilization between 2 and 6 procedures per day to study the impact of low EIMC uptake (low capacity utilization). While at maximum capacity utilization EIMC unit cost is \$49.53, when only 2 EIMC procedures are performed per day, EIMC unit cost rises to \$59.25.

As EIMC scale-up is likely to use government facilities, in sensitivity analyses we tested the impact on unit cost if lower civil service salaries were used rather than research staff salaries. Results show that EIMC unit cost decreases from \$49.53 in the base case to \$43.71 in the public sector. Furthermore, as durable equipment required for EIMC already exists in Zimbabwe's public health facilities, we also tested EIMC unit cost impacts when durable equipment is excluded. However, as durable equipment has a relatively low contribution to EIMC unit cost, excluding equipment costs does not have a large impact on EIMC unit costs.

DISCUSSION

In this cost analysis, we sought to estimate the unit costs of EIMC using the AccuCirc device and Mogen clamp, establish key cost contributors, and potential changes in EIMC unit costs, using AccuCirc, due to variations in the key cost drivers. It would cost \$49.53 to perform an EIMC procedure in Zimbabwe using AccuCirc compared with \$55.93 using Mogen clamp in a vertical EIMC program. In an integrated program (using 10% of staff salaries), AccuCirc unit cost would be \$30.26 compared with \$36.61 for the Mogen clamp. The key cost drivers are consumable supplies, capacity utilization, personnel costs, and device price.

Considerable potential for reductions in EIMC unit cost exists in the future. Given the high likelihood of an EIMC scale-up integrated in government facilities, differences in study and civil service personnel salaries would result in cost differences. Moreover, in an integrated EIMC scale-up, medical personnel costs are likely to come down because they would be shared with other clinic services. Additionally, in this trial, doctors conducted EIMC, whereas in practice, EIMC with AccuCirc could be conducted using nurse midwives; the safety and feasibility of using the latter providers have been investigated in a field implementation study in Harare.²⁹ Furthermore, this model assumes that between 2 and 6 EIMCs are performed daily. In smaller or rural settings where the number of deliveries per month is low, fewer EIMCs would be undertaken. In these settings, the model for delivering EIMC would need to be different from that costed here and this would likely affect the cost per procedure.

Experiences from the trial that accompanied this study indicated low EIMC uptake for a number of reasons, one of which is that parental awareness of the fact that the 2 EIMC devices were under study may have led (incorrectly) to doubts about the safety of the procedure and consequently lowered uptake.²⁹ As our results also show, capacity utilization is indeed an important cost driver. In sensitivity analyses, lower levels of capacity utilization resulted in significantly higher

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EIMC unit costs using AccuCirc (due to consequent increase in costs of training, durable equipment, and support personnel costs). However, acceptance of EIMC will likely rise as greater numbers of procedures are performed and adult VMMC continues to be scaled-up.²⁹ With increased uptake, the unit costs of EIMC are likely to decrease further. Demand creation efforts will therefore be important to ensure efficient use of EIMC services and achievement of lower unit costs due to economies of scale.

The significance of the price of the AccuCirc device on the unit cost of an EIMC procedure underscores the vulnerability of the cost per procedure to the device price that is ultimately negotiated. Clearly, it will be important to negotiate a reasonable pricing structure with the manufacturer before scale-up begins. As future scale-up assumes use of the AccuCirc device, a significant increase in price such as the one proposed is likely to adversely affect the possibility and speed of EIMC scale-up. To the best of our knowledge, this is the first study to explore actual costs of EIMC offered through the AccuCirc device in sub-Saharan Africa. It is possible that cost of EIMC in other contexts might differ from that presented here. For example, a study that modeled direct costs of EIMC in Rwanda using a hypothetical cohort of 150,000 infants found that infant male circumcision only costs \$15 using the Mogen clamp and was found to be a costsaving intervention overall.⁷ Our results show that an EIMC procedure using the Mogen clamp costs \$55.93.

It is important to note, however, that the Rwanda study analyzed direct costs only (excluding environmental costs but including demand creation and costs of AEs) of an integrated model, where staff costs are shared with other clinic services, whereas our study analyzed both direct and indirect costs using a vertical model. Also, we included essential consumables that were omitted in the Rwanda study (eg, surgical blades, linen savers, wet wipes, and sterilization materials) (Table 1). Moreover, our list of consumables included Vitamin K (at \$3.30), which is usually given routinely at birth but is currently unavailable in Zimbabwe and is expensive to import. Finally, our analyses included costs of consumables at 3 follow-up visits (gloves, linen savers, wet wipes, and paper towels), whereas the Rwanda study only included consumables used during the circumcision itself. Of note, in the sensitivity analysis conducted in the Rwandan study, they only found the procedure to be cost-saving up to a cost of \$25 but that it was still highly cost-effective up to \$38.50, which is higher than \$36.61 we found for scale-up in an integrated program.

Limitations

This cost study has some limitations. First, EIMC procedures were performed in a pilot study within an urban setting, and therefore cost results may not reflect those of a scaled-up program. In this context, we also assumed staff dedicated to performing EIMC in a vertical program. Particularly important to note is that the pilot study itself lasted 6 months with a sample of 150 EIMC procedures. To make this cost analysis possible, a number of assumptions had to be made including use of an estimated annual number

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of EIMC procedures and apportioning training costs over a 3.6-year period to arrive at annual training costs. These assumptions may not accurately reflect a scaled-up program environment and, as a result, may either lead to higher or lower procedure unit costs.

This cost study also excluded costs of a demand creation campaign, which is especially important in a setting like Zimbabwe where EIMC is a relatively new procedure requiring extensive promotional activities. Further research may be warranted in a scaled-up program to establish the contribution of demand creation costs. Additionally, the site for the pilot study had on-site incineration facilities for EIMC waste disposal. Our environmental costs therefore excluded transport costs and only included the costs of actual incineration. In a scale-up situation, some clinics may not have access to on-site incinerators, implying that transportation of waste to other sites will need to be costed. Utility costs (electricity and water supply) were also excluded from the analyses, as they were deemed identical and unlikely to affect the choice between the 2 devices. Finally, AEs were also excluded from the analyses because the study experienced only 2 moderate AEs, which resolved quickly. Nonetheless, costs of AEs might be negligible, as EIMCrelated AEs are rare.18

CONCLUSIONS

Despite the stated limitations, this cost analysis of EIMC using devices in Zimbabwe provides valuable data that can inform which devices to use when scaling up EIMC and determine overall resources needed to implement a scaled-up EIMC program. It is important to adopt strategies, which enable that costs of supplies and devices are contained to ensure low EIMC costs. An extensive demand creation campaign would need to be integral to scale-up in order to provide economies of scale. Further research in other contexts or alongside future scale-up should investigate impact of different costs of supplies, different personnel structures, and higher uptake rates that should result in substantial economies of scale being gained.

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