Annex 2. Evidence Profile for WHO *Guideline on the Use of Devices for Adult Male Circumcision*, October 2013

A. GRADE Evidence Profile

The evidence used was guided by the PICO Question: *Among adolescent and adult men seeking circumcision for HIV prevention in a high HIV prevalence resource-limited setting, are male circumcision devices a safe, efficacious and acceptable method for circumcision compared to conventional surgical male circumcision?*

The WHO secretariat, with inputs from methodologists, used the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) methodology to rate the quality of evidence (high, moderate, low or very low) for the critical outcomes. In keeping with the GRADE approach, evidence profiles were prepared. Evidence that was based on randomized controlled trials (RCTs) was generally classified as high quality, but the rating was downgraded if the WHO secretariat judged that there was a risk of bias, inconsistency of results, indirectness of evidence, imprecision or publication bias. The evidence from observational studies was not formally categorized but was used to support and supplement the evidence obtained from the randomized studies. The GRADE evidence profiles in this Annex are the final result and the grading.

Evidence was included on two devices from different categories of *in-situ* MC devices, classified by their mechanism of action, as the required data were available. The two device categories were: collar clamp and elastic collar compression

- ***Clamp devices:*** The mechanism of action is a rapid, tight compression of the foreskin between hard surfaces to achieve haemostasis. Compression is sufficient to prevent slippage of tissue so that the foreskin can be removed at the time of, or soon after, placement of the device. Part of or the entire device is left *in situ* for a period of time to prevent bleeding. Because the device crushes the foreskin upon placement, and live tissue is excised immediately after device placement, injection of local anaesthesia is required for pain control. This category includes two subcategories: collar clamp devices and vice clamp devices.
- ***Elastic collar compression devices:*** The mechanism of action is a slow compression of the foreskin between an elastic ring and a hard surface that is sufficient to occlude circulation and produce tissue ischaemia, devitalisation and necrosis. Part of or the entire device and the foreskin are left in position after device placement until the foreskin necrosis and can be excised. This type of device can be applied without injected local anaesthetic.

For the collar clamp device, the quality of the evidence for eligibility, successful circumcision, and serious or moderate AEs was rated 'moderate' due to limited numbers (some imprecision). For healing time, the evidence was also rated 'moderate' but in this case the reason was for some risk of bias (subjective outcome measures and impossibility to "blind" assessors or clients). For the elastic collar compression device, the quality of the evidence for eligibility, successful circumcision, and severe or moderate AEs was rated 'high'. For healing time, the evidence was rated 'low' due to some risk of bias (subjective outcome measures and impossibility to "blind" assessors or clients) and to some imprecision (limited numbers).

Combining the evidence for critical outcomes for both types of devices, the overall quality of evidence was rated as 'moderate'. The overall judgement of the methodologist and the WHO secretariat was that further research would be unlikely to change the estimates of effect for eligibility, successful circumcision, and serious or moderate AEs, especially if evidence from the RCTs is supplemented by evidence from the observational studies. For healing times, the judgement was that, while further data might change the magnitude of the difference between devices and surgery, the main conclusion, that healing times were longer following device circumcision, would be unlikely to change. Therefore, the quality of evidence for healing time was upgraded to 'moderate' and the overall quality of evidence was judged to be 'moderate', the lowest rating among critical outcomes.

Table1: Evidence profile for the collar clamp device

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Shang Ring (collar clamp)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Eligibility – Proportion of men eligible for circumcision in whom device could be placed												
2 [4-6]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	197/200 (97.5%)	200.0/200 (100%)	RR 0.98 (0.97, 1.00)	15 fewer per 1000 (from 32 fewer to 0 fewer)	⊕⊕⊕O Moderate	Critical
4 [1-3, 7-9]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	1786/1805.5 (98.9%)					Critical
Successful circumcision – Proportion of men in whom device successfully placed circumcised by device alone												
2 [4-6]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	197/197 (100%)	200/200 (100%)	RR 1.00	0 fewer per 1000	⊕⊕⊕O Moderate	Critical
4 [1-3, 7-9]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	1783/1786 (99.8%)					Critical
Procedure time – Total procedure time (minutes; better indicated by lower values)												
2 [4-6]	Randomized trials	No serious risk of bias	Some inconsistency [2]	No serious indirectness	Some imprecision [1]	None	Mean 10.3, SD 2.7 (n 197)	Mean 20.3, SD 4.7 (n 198)		Mean 10.0 lower (10.8 to 9.2 lower)	⊕⊕⊕O Moderate	Important
4 [1-3, 7-9]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 9.3, SD 4.4 (n 1786)					Important
Adverse events (Safety) – Proportion of clients with Serious or Moderate Adverse Events												
2 [4-6]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	0/197 (0.0%)	2/198 (1.0%)	RR 0.00	10 fewer per 1000	⊕⊕⊕O Moderate	Critical
4 [1-3, 7-9]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	20/1786 (1.1%)					Critical

[1] Limited number of clients

[2] Mean device removal time longer in Zambia than Kenya, likely attributable to less experience with device procedures among Zambian operators.

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Shang Ring (collar clamp)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Adverse events (Safety) – Proportion of clients with Mild Adverse Events												
2 [4-6]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	15/197 (7.6%)	8/198 (4.0%)	RR 0.53 (0.23, 1.22)	36 more per 1000 (from 10 fewer to 82 more)	⊕⊕⊕O Moderate	Important
4 [1-3, 7-9]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	28/1786 (15.7%)					Important
Pain - during placement (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [4-6]	Randomized trials	Some risk of bias [3]	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	Mean 2.3, SD 1.4 (n 197)	Mean 2.4, SD 1.5 (n 200)		Mean 0.1 lower (0.4 lower to 0.2 higher)	⊕⊕⊕O Moderate	Important
1 [2, 3]	Observational study	Some risk of bias [3]	Not applicable	No serious indirectness	Serious imprecision [4]	None	Mean 4.5, SD 2.0 (n 50)					Important
Pain during erection (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [4-6]	Randomized trials	Some risk of bias [3]	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	Mean 3.5, SD 1.9 (n 197)	Mean 2.3, SD 1.7 (n 200)		Mean 1.2 higher (0.8 to 1.6 higher)	⊕⊕⊕O Moderate	Important
1 [2, 3]	Observational study	Some risk of bias [3]	Not applicable	No serious indirectness	Serious imprecision [4]	None	Mean 3.8, SD 2.0 (n 50)					Important
Pain during removal (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [1-3]	Observational studies	Some risk of bias [3]	No serious inconsistency	No serious indirectness	Serious imprecision [4]	None	Mean 4.3, SD 2.4 (n 90)					Important
Cosmetic result (proportion 'very satisfied', assessed 6 weeks post procedure)												
2 [4-6]	Randomized trials	Some risk of bias [3]	No serious inconsistency	No serious indirectness	Some imprecision [1]	None	182/187 (96.3%)	152/193 (78.8%)	RR 1.22 (1.13, 1.32)	175 more per 1000 (from 112 more to 239 more)	⊕⊕⊕O Moderate	Important
2 [2, 3, 9]	Observational studies	Some risk of bias [3]	No serious inconsistency	No serious indirectness	No serious imprecision	None	541/551 (98.2%)					Important

[3] Subjective assessment, prone to biased assessment and reporting
[4] Small number of clients

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Shang Ring (collar clamp)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Healing time (measured with: days to complete healing; better indicated by lower values)												
2 [4-6]	Randomized trials	Some risk of bias [5]	Some inconsistency [6]	No serious indirectness	Some imprecision [1]	None	Mean 44.1, SD 12.6 (n 197)	Mean 38.9, SD 12.6 (n 200)		Mean 5.2 longer (2.7 to 7.7 longer)	⊕⊕⊕O Moderate	Critical
Healing time (measured with: proportion of men healed by 4 – 6 week follow-up visit)												
2 [8, 9]	Observational studies	Some risk of bias [5]	Serious inconsistency [7]	No serious indirectness	No serious imprecision	None	1444/1621 (89.1%)					Critical

Table 2: Evidence profile for the elastic collar compression device

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PrePex (elastic collar compression)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Eligibility – Proportion of men eligible for circumcision in whom device could be placed)												
2 [11, 16]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	304/347 (87.6%)	153/156 (98.1%)	RR 0.89 (0.85, 0.93)	105 fewer per 1000 (from 65 fewer to 146 fewer)	⊕⊕⊕⊕ High	Critical
5 [10, 12-15, 17, 18]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	1926/2068 (93.1%)					Critical
Successful circumcision – Proportion of men in whom device successfully placed circumcised by device alone												
2 [11, 16]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	302/304 (99.3%)	153/153 (100%)	RR 0.99	7 fewer per 1000	⊕⊕⊕⊕ High	Critical
6 [10, 12-15, 17-19]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	2103/2113 (99.5%)					Critical

[5] Assessors not masked as healing process clearly different following device or conventional surgical circumcision.
[6] Longer healing times in Zambia than Kenya, though healing times following Shang Ring placement longer than surgery in both studies.
[7] Proportion healed assessed at different times

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PrePex (elastic collar compression)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Procedure time – Total procedure time (minutes; better indicated by lower values)												
2 [11, 16]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 5.7, SD 1.4 (n 304)	Mean 19.2, SD 3.9 (n 153)		13.5 less (14.0 to 13.0 less)	⊕⊕⊕⊕ High	Important
3 [12-15, 17]	Observational studies	No serious risk of bias	Some inconsistency [8]	No serious indirectness	No serious imprecision	None	Mean 6.7, SD 1.9 (n 908)					Important
Adverse events (Safety) – Proportion of clients with Moderate or Severe Adverse Events												
2 [11, 16]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	2/304 (0.7%)	2/153 (1.3%)	RR 0.50 (0.07, 3.53)	6 fewer per 1000 (from 27 fewer to 14 more)	⊕⊕⊕⊕ High	Critical
6 [10, 12-15, 17-19]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	25/2113 (1.2%)					Critical
Adverse events (Safety) – Proportion of clients with Mild Adverse Events												
2 [11, 16]	Randomized trials	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	4/304 (1.3%)	6/153 (3.9%)	RR 0.34 (0.10, 1.17)	26 fewer per 1000 (from 59 fewer to 10 more)	⊕⊕⊕⊕ High	Important
6 [10, 12-15, 17-19]	Observational studies	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	25/2113 (0.5%)					Important
Pain during placement (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [11, 16]	Randomized trials	Some risk of bias [9]	Some inconsistency [10]	No serious indirectness	No serious imprecision	None	Mean 0.4, SD 0.8 (n 304)	Mean 3.5, SD 1.1 (n 153)		Mean 3.1 lower (3.3 to 2.9 lower)	⊕⊕⊕O Moderate	Important

[8] Procedure times generally shorter as providers gained more experience with placing and removing the devices.
[9] Subjective assessment, prone to biased assessment and reporting
[10] Pain control protocols during placement evolved from initial to most recent studies

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PrePex (elastic collar compression)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
4 [10, 12-15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	Some inconsistency Error! Bookmark not defined.	No serious indirectness	No serious imprecision	None	Mean 0.5, SD 0.9 (n 1301)					Important
Pain 3h after placement (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [11, 16]	Randomized trials	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 1.3, SD 1.2 (n 304)	Mean 0.9, SD 1.4 (n 153)		Mean 0.5 higher (0.2 to 0.7 higher)	⊕⊕⊕O Moderate	Important
3 [10, 15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 0.0, SD 0.1 (n 686)					Important
Pain during erection (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [11, 16]	Randomized trials	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 1.8, SD 1.5 (n 304)	Mean 3.5, SD 1.9 (n 153)		Mean 1.7 lower (2.0 to 1.3 lower)	⊕⊕⊕O Moderate	Important
3 [12-15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 1.9, SD 1.6 (n 1239)					Important
Pain during removal (measured with: pain VAS; range of scores: 0-10; better indicated by lower values)												
2 [11, 16]	Randomized trials	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 2.4, SD 1.6 (n 301)	Not applicable			⊕⊕⊕O Moderate	Important
4 [10, 12-15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	Mean 3.0, SD 1.6 (n 1297)					Important

No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PrePex (elastic collar compression)	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Cosmetic result (satisfaction assessed 6 weeks post procedure)												
1 [11]	Randomized trial	Some risk of bias Error! Bookmark not defined.	Not applicable	No serious indirectness	Some imprecision [11]	None	91/92 (99%)	55/55 (100%)		11 fewer per 1000	⊕⊕⊕O Moderate	Important
2 [15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	No serious inconsistency	No serious indirectness	No serious imprecision	None	302/325 (93%)					Important
Healing time (measured with: days to complete healing; better indicated by lower values)												
1 [11]	Randomized trial	Some risk of bias Error! Bookmark not defined.	Not applicable	No serious indirectness	No serious imprecision	None	Mean 38, SD 12.1 (n 144)	Mean 23, SD 7.5 (n 73)		Mean 15 longer (11 to 18 longer)	⊕⊕⊕O Moderate	Critical
4 [10, 12-15, 17]	Observational studies	Some risk of bias Error! Bookmark not defined.	Some inconsistency	No serious indirectness	No serious imprecision		Mean 42.7, SD 7.1 (n 1410)					Critical
Healing (measured with: proportion of men healed by day 42 follow-up visit)												
1 [16]	Randomized trial	Serious risk of bias [12]	Not applicable	No serious indirectness	Serious imprecision Error! Bookmark not defined.	None	137/144 (95%)	54/55 (98%)	RR 0.97 (0.92, 1.02)	30 fewer per 1000 (from 80 fewer to 19 more)	⊕⊕OO Low	Critical

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[11] Limited number of clients

[12] Inconsistent follow-up schedule in PrePex and surgical arms, subjective measure prone to biased assessment and reporting

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B. Costing evidence: summary of studies reviewed

A systematic search of the literature identified three published studies on resource use and costs, and authors shared one study in press. The studies were undertaken in Zambia (Bratt & Zyambo, 2013), Uganda (Duffy et al., 2013), Kenya (Obiero, Young & Bailey, 2013) and Zimbabwe (unpublished, Njeuhmeli et al., 2013). One study compared the collar clamp device to surgical circumcision (Bratt & Zyambo, 2013); the other studies evaluated costing aspects of the elastic collar compression device. A summary of the review of each article is provided.

The collar clamp costing study took place in the context of a randomized controlled trial conducted in Zambia with 96 device clients and 95 surgery clients. Direct costs included staff time, the device and other consumables. The study assumed that all indirect costs (e.g. clinic administration, equipment, infrastructure, demand creation, supply chain and waste disposal) would be similar for the two methods. The study found that the unit cost of the two approaches was roughly the same. The higher costs of clinician time for the surgical method were offset by the higher costs of disposable supplies required for the device method, including the cost of the device itself. The authors reasoned that, with increased demand, the unit cost for the device method would fall substantially due to the potential for more efficient use of staff and other fixed-cost resources.

The second study involved a cross-sectional descriptive cost-analysis of 48 265 MC procedures (Obiero, Young & Bailey, 2013). The study compared actual expenditure data from a non-governmental organization providing surgical MC services in Kenya and from the Kenya Ministry of Health. The majority of costs associated with the device were estimated on a prospective basis and the improved efficiencies attributed to the device method were hypothetical rather than observed. Direct costs included staff time and consumables but excluded the cost of the device. Indirect costs included all programme costs, including staff supervision. The unit costs for the device method were calculated for different scenarios and found to be between $5.5 and $10.75 less expensive than surgical circumcision excluding the cost of the device. At current device prices, the study concluded that introduction of the device method was unlikely to result in significant cost-savings over conventional surgery. The study made a number of assumptions for the device method that may not hold up as more data become available including that sterilisation costs would be entirely eliminated

and the costs for supply chain logistics and training would be minimal. The referral costs for men not eligible for the device method (approximately half of MCs included in the study, primarily because those under age 18 were excluded), nor were the costs of conversion to conventional surgery required by adverse events with a device.

The third study was a cross-sectional descriptive cost analysis using data from a high-volume urban site in Uganda on 10000 surgical circumcisions compared with 625 circumcisions completed with an elastic collar compression device(Duffy et al., 2013) . Direct costs included all consumables and reusable kits for both methods, including the cost of the device. Estimates of indirect costs were based on existing operations and included all overhead and shared costs including procurement costs but not the cost of demand creation. The unit cost for the device method was 35% higher than the surgical unit cost at current device prices. However, the device method improved operator efficiency by 60%, meaning that a team could perform more procedures in the same time using the device method than with the surgical method. At current device cost, the cost-effectiveness of the two methods, measured in terms of future costs avoided by averting HIV infections, was nearly identical.

The fourth study (unpublished) used data from field studies in Zimbabwe to identify the costs of introducing devices into an existing surgical circumcision programme (Njeuhmeli et al., 2013). The unit cost for a circumcision at a dedicated site offering only surgical circumcision was compared with the unit cost at an actual dedicated "mixed" site where staff and equipment were added to offer circumcision using a device method, and at a hypothetical dedicated "mixed site" with a staffing and equipment configuration comparable to that of the routine surgery site. During the period of data collection, 84% of circumcisions at the actual mixed site involved conventional surgery, and 16% used a device method. Calculation of unit costs did not include indirect costs or costs for demand creation. Also, the study assumed that the costs of supply chain management, waste management and durable equipment would remain the same across all three sites but that training would increase by 2.5 days at the latter two sites with introduction of the device method. At current device cost the introduction of a device method did not greatly affect overall unit cost. As in other studies the cost of consumables (particularly of the device itself) and staff time were the two largest contributors to unit cost. The authors concluded that a responsibly low public-sector price for the device and shifting to a lower cadre of health workers could result in cost-savings and make services available to more people in need if the acceptability of the device method turns out to be great. A low level of service utilization would result in the highest unit price for both methods.

The conclusion regarding the use of devices was that the studies suggest the potential to:

- reduce human resource costs by shifting the performance of MC procedures to lower cadres of health-care providers
- reduce consumable costs other than the cost of the device
- improve efficiency, particularly by increasing the output rate at a given level of staffing, and
- improve the cost effectiveness of MC as an HIV prevention strategy by accelerating the pace at which MC targets are reached and HIV infections are averted.

However, there remain many uncertainties including whether there will be sufficient demand to realize potential efficiency gains, many costs are unknown including the cost of the device, and costs are highly contextual and will vary from country to country. These uncertainties warrant a conditional recommendation.

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