

Voluntary Male Medical Circumcision is Safe and Effective: But beware of unsafe devices

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Joint statement by the Treatment Action Campaign (TAC), SECTION27 and the Southern African HIV Clinicians Society

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Summary

The Southern African HIV Clinicians Society and the Treatment Action Campaign support the implementation of a country-wide voluntary male medical circumcision (VMMC) programme. Male medical circumcision reduces the risk of heterosexual men contracting HIV and the Human Papilloma Virus (HPV). Despite the effectiveness of VMMC, it is essential that circumcised men are encouraged to continue using condoms during sexual intercourse.

We welcome the steps the South African government is taking to implement VMMC. Kwazulu-Natal has run several events encouraging youth to have medical circumcisions and the Department of Health together with the South African National AIDS Council is developing circumcision guidelines. The continuous disturbing reports of traditional circumcisions that have resulted in deaths and penile mutilations show how important it is to implement a medical circumcision programme that is safe and in which adverse events are kept to an absolute minimum. The success of VMMC is dependent on public confidence in the programme's safety.

We are therefore deeply concerned that a Malaysian company, Taramedic Corporation, and its South African partner, Carpe Diem Enterprises, are aggressively marketing a circumcision device called the Tara KLamp (TK) to several sub-Saharan African countries, including South Africa, Lesotho, Kenya, Botswana and Zimbabwe. A randomised controlled trial in adolescents and adults found a very high rate of adverse events and much greater pain associated with this device compared to the standard forceps-guided circumcision technique.

The TK must be withdrawn from sale and distribution for adolescent and adult circumcision throughout sub-Saharan Africa until the device's safety concerns are addressed.

A review of the Tara KLamp (TK)

The TK is a circumcision device that is clamped onto the foreskin with the purpose of necrotising it. After approximately seven days the device, along with the foreskin, usually falls off. In some cases the device does not fall off forcing the patient to have the TK removed surgically.

The Orange Farm clinical trial showed that VMMC can reduce a heterosexual male's risk of contracting HIV by 60%. In 2005 the Orange Farm researchers performed a randomised controlled trial to see if the TK could be used as an

alternative method of circumcision. 35 men were circumcised with the TK and 34 with the standard forceps-guided technique that was used during the original trial.

Adverse events from use of the TK were far higher: 37% compared to 3.4% for the forceps-guided method. This was a statistically significant result ($p=0.004$). Men circumcised using the TK also reported worse pain than men circumcised using the forceps-guided method. Furthermore, the device clearly causes consternation: 97 men refused to participate in the trial, 94 of them giving the reason that they did not wish to use the TK.

The TK trial was stopped early due to the unacceptably high rate of adverse events. The researchers concluded, "Given the high rates of adverse events in this study and the low number of available studies, we strongly caution against the use of the TK for young adults, and we recommend careful evaluation of the procedure when performed on children."

Safety must be proven before any new medical intervention is implemented. Currently, the balance of evidence shows that the TK is unsafe for use on adolescents and adults. We cannot find any published studies of the TK being shown to be safe for adolescents and adults. Two studies, neither of them randomised and consequently of questionable quality, indicate that the device might be safe for young children.

The marketing practices of Carpe Diem Enterprises

Carpe Diem Enterprises is the distributor of the TK in South Africa. The company has disregarded the safety concerns raised in the Orange Farm study. The device's website states, "This invention enables circumcisions to be performed not only **safely and easily** but also ----- for the first time in surgical history ----- enables circumcisions to be performed just as aseptically, at home, on the roadsides or out there in the bush, as in an operating theater. ?

The device is marketed as a faster method of performing circumcisions, as it can be carried out in less than 10 minutes. This is not much faster than the medical forceps-guided method of circumcision and certainly does not outweigh safety concerns. It also does not take into account the additional time needed to surgically remove the device from some patients.

The TK is also more expensive than the forceps-guided method of circumcision. According to our discussions with the manufacturer, the TK is being sold to general practitioners for R160 excluding VAT. However the device only slightly reduces the number of surgical instruments needed in a circumcision. Consequently we estimate that using the TK adds significant cost, even without considering the extremely large additional cost that would be incurred from hospitalisations due to increased adverse events.

The attitude of the company towards critical research of its device is exemplified by Dr. G. Singh, the inventor of the TK, who made the following threat in an email exchange with one of the authors of the Orange Farm study, "All it needs is a simple withdrawal of your manuscript and gracefully accept the reality. I am even not asking for an apology, for I am a very forgiving man..... but there is a limit!?"[1](#)

The TK has also been used throughout the region as a part of the evangelical mission of the marketers of the device, Tony Lawrence and Magda Van Der Walt. A book promoting the device and the work of Tony Lawrence states the following:

"Twice per year... young male initiates in South Africa alone take an important step toward manhood by undergoing circumcision during a time of initiation ? But what should be a glorious occasion for these teenagers often turns out to be a nightmare. One out of five boys end up with their genitals partially or fully amputated.... The Seize the Day foundation is rescuing these children in a holistic way. Among other things, Tony Lawrence and the seize the day volunteer distribute a pack to each initiate. (The pack contains a TK and a bible) ... The solution is to circumcise and evangelize."[2](#)

The TK is being aggressively marketed and, at times, with an inappropriate religious agenda. The marketers of the

device make unsubstantiated claims and disregard safety concerns. They have threatened researchers who published data critical of the TK. The TK must be withdrawn from use throughout sub-Saharan Africa for adults and adolescents until its safety concerns are addressed.

1 This correspondence was forwarded to TAC by Carpe Diem Enterprises

2 W Cambell et al., "Be a hero: The battle for mercy and social justice." 2004. Pg. 204

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