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TAC lodges a complaint with the Public Protector against KZN MEC for health and KZN DoH

KZN Government continues to rollout expensive and dangerous circumcision device

The Treatment Action Campaign (TAC) has lodged a complaint with the Public Protector against the KwaZulu-Natal (KZN) Member of the Executive Council (MEC) for health and the KZN Department of Health (DoH). The complaint asks the Public Protector to investigate the procurement and ongoing use of the Tara KLamp (TK) to perform medical circumcisions on adolescent and adult men in KZN. The TK is a plastic device that is clamped over the foreskin of a man?s penis for 7 to 10 days until the foreskin dies and falls off (sometimes it has to be surgically removed).

The TK is a dangerous device. It has specifically not been approved by the World Health Organisation because it failed in the only clinical trial conducted to test its safety.

The TK is also more expensive to use than the standard surgical circumcision methods.

TAC has been asking the KZN government to halt the use of the TK since we first learned of its use in early 2010. We have also asked the National Department of Health to intervene. Our efforts have been in vain and we have therefore been left with no choice except to lodge a complaint with the Public Protector.

Our complaint is supported by the South African Medical Association and the Southern African HIV Clinicians Society.

That the KZN government continues to roll out the TK against the advice of the country's foremost medical practitioners and scientists is arrogant and irresponsible. It raises our suspicion that all is not above board with the procurement of this device.

In medicine, it is a fundamental ethical principle not to implement an intervention unless it has been tested and shown to be safe. The only clinical trial of the TK in adults, which was carried out in Orange Farm, Gauteng, showed that it is very unsafe. Attached is a table comparing the side effects of the Tara KLamp to the control arm in the clinical trial. Because of the high rates of adverse events, the trial was suspended early and the researchers cautioned against the use of the TK in young adult men.

Following numerous complaints by TAC, we were informed by the KZN government that it would carry out its own research on the TK. TAC sent a letter to the KZN government requesting the details of this research, but we never received a response. In January 2012, we received a draft document outlining the research that was carried out. However, the methodology of this research was so poor that it provided no evidential value regarding the safety of the TK. Several of the researchers involved in this study were so appalled by its quality that they distanced themselves from the study. Critically, the study did not have ethical clearance.
Since 2010, TAC has received picture and video evidence of TK injuries and spoken to men who have experienced adverse events as a result of the device.

As well as our safety concerns, our complaint to the Public Protector asks questions about the procurement of the TK. The KZN government is paying more to perform circumcisions using the TK than it would cost to use a standard

surgical method. Using the TK costs approximately R120 more per circumcision and this does not include the additional costs due to the high rates of adverse events caused by the TK. A cost comparison of the two methods is attached.

No tender was published for the procurement of the TK and the TK was purchased from a supplier with links to the government, rather than a competitor company offering a lower price. We have therefore requested that the Public Protector investigate the procurement of the device.

On 18 September 2011 the Zulu edition of the Sunday Times newspaper reported that the local supplier of the TK, Ibrahim Yusuf, gave King Goodwill Zwelithini a car worth R1 million.

There are numerous unanswered questions about the TK. We are deeply suspicious of the officials in the KZN government who have driven its use.

We are also concerned about the haphazard and chaotic way in which the KZN government is implementing circumcision. Circumcision camps are being organised in which community service doctors are carrying out circumcisions without supervision. We have supported the rollout of circumcision since the publication of clinical trials showing its massive effect on reducing HIV incidence. We supported voluntary medical male circumcision when former president, Thabo Mbeki, and the late health minister, Manto Tshabalala-Msimang, failed to support it. But we cannot support chaos and a disorganised approach that endangers patients.

One of the reasons the KZN government has managed to persist with the TK and its chaotic circumcision programme is that the National Department of Health, despite our requests, has failed to publish circumcision guidelines. It is negligent and unacceptable that two years into the circumcision rollout we still do not have guidelines. We have met with the Minister of Health to alert him to our concerns.

TAC?s complaint was sent to the Public Protector on 2 August and we have received an acknowledgement of receipt. The deponent in the complaint is Patrick Mdletshe, the elected provincial Chairperson of TAC KZN.

For media comments, please contact:
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Table 1. Comparison of adverse events: Tara KLamp vs forceps guided method

Event	Tara KLamp (%)	Forceps Guided (%)
Complication rate	37	3
Delayed wound healing	21	3
Problems with penis appearance	31	3
Participants more likely to report bleeding	21	0
Injury to the penis	21	0
Infection	32	0
Swelling	83	0
Problems urinating	16	0

Table 2. Comparison of cost: Tara KLamp vs forceps guided method

Item	Cost TK	Cost FGM
Surgical circumcision kit	R40	R140
TK device	R222	N/A
Pain relief (paracetamol, paracodeine)	R1	R1
Local anaesthesia (7.5mm lignocaine, 2.5mm bupivacaine)	R 35	R10
Antibiotics (doxycyline)	R1	N/A
Doctor's time (at R300/hour)	R 25	R50
Total	**R 324**	**R201**

Background documents and timeline for TK complaint:

2009 - The South African Medical Journal published a study demonstrating the high rates of adverse events associated with the use of the TK on young male adults http://www.ncbi.nlm.nih.gov/pubmed/19563093

2 July 2010 ? TAC sent a letter to Premier Mkize regarding TAC?s concerns with the roll out of the TK

19 July 2010 ? TAC received a response from KZN Health MEC, Dr Dhlomo, regarding the concerns raised by TAC on the rollout of the TK

3 August 2010 ?TAC sent a letter to the KZN DoH requesting copies of financial documentation related to procurement of the TK

All three letters are available at http://www.tac.org.za/community/node/2928

November 2010 ? TAC representatives and men who had experienced adverse events from the TK met with Premier Mkhize and representatives of the KZN government. Premier Mkhize informed TAC that KZN would carry out its own research on the use of the TK

2 November 2010 ? TAC published an article raising our concerns with the procurement of the TK http://www.tac.org.za/community/node/2960

13 December 2010 ? TAC sent a letter to Premier Mkhize requesting the details of the study http://www.tac.org.za/userfiles/Annexure%201%20-%20PP.pdf

2010 ? TAC circulated a flier encouraging circumcision but warning against the use of the TK http://www.tac.org.za/userfiles/TK%20flier%202.pdf

September 2010 to October 2011 - the Mail&Guardian (M&G) published a series of articles calling into question the procurement of the TK. The articles can be found at the links below: http://mg.co.za/article/2010-09-03-tender-details-get-the-klamp

http://mg.co.za/article/2010-10-25-tara-klamp-director-faces-extradition
http://www.mg.co.za/article/2010-12-17-confusion-over-the-future-of-tara-klamp
http://mg.co.za/article/2011-10-21-the-wellconnected-mr-klamp/

October 2011 ? TAC published an article on Quackdown, questioning the tender of the TK
http://www.quackdown.info/article/king-car-and-clamp/

January 2012 ? TAC received a draft report on research carried out by the KZN government on the TK
http://www.tac.org.za/userfiles/2nd%20Annexure%281%29.pdf

March 2012 ? TAC published the draft report and photos of injuries that occurred as a result of the TK
http://www.quackdown.info/article/tara-klamp-scandal-deepens/

March 2012 ? The Mercury and Health-e News published an article in which researchers distance themselves from the draft report http://www.health-e.org.za/news/article.php?uid=20033478

August 2012 ? TAC began running a series of advertisements in the Mercury and Isolezwe newspapers encouraging men to get circumcised but warning against the use of the TK

August 2012 ? TAC lodged a complaint with the Public Protector regarding the use of the Tara KLamp
http://www.tac.org.za/community/node/3305

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