

TAC responds to MEC Dhlomo's defence of a dangerous circumcision device

The Kwazulu-Natal (KZN) MEC for Health, Dr Sibongiseni Dhlomo, today released a press statement responding to the Treatment Action Campaign's (TAC) complaint to the Public Protector about the use and procurement of an unsafe circumcision device called the Tara KLamp. His full statement can be read [here](#)

Dhlomo's defence fails to provide any compelling responses to the concerns raised in our complaint to the Public Protector. Below, we respond to a number of the arguments he makes in defence of using the Tara KLamp and list a number of crucial issues he failed to respond to.

1. Dhlomo notes the strong evidence that medical male circumcision reduces the risk of HIV infection in heterosexual men. He also quotes a number of people who support medical circumcision in general.

This is not what is at issue in our complaint to the Public Protector. TAC supports and has for many years campaigned for the responsible provision of voluntary medical male circumcision services in the public sector as an important means of HIV prevention. We recommend the rollout of voluntary medical male circumcision using standard surgical methods, which are supported by strong medical evidence and recommended by the World Health Organisation (WHO). Our concern is that the Tara KLamp is an unsafe and irresponsible method of performing medical male circumcision. The Tara KLamp is not recommended by the WHO and has failed in the only clinical trial conducted on its use in adults.

2. Dr Dhlomo quotes U.S. Secretary of State, Madam Hillary Rodham Clinton as saying: 'I am pleased to announce that PEPFAR will provide an additional 40 million US Dollars to support South AFRICA's plan provide voluntary medical circumcisions for almost half a million boys and men in the coming year.'

Dr Dhlomo fails to mention that PEPFAR has specifically rejected funding circumcisions done using the Tara KLamp.

3. Dr Dhlomo writes: 'Thus far the Department has had no adverse events such as penile mutilation or erectile dysfunction.'

TAC has received reports about serious adverse events from both patients and doctors working in the KwaZulu-Natal circumcision programme. We have published pictures of severe side effects. You can see some of those pictures at the links below. Either the department is in denial about adverse events or the Department's monitoring of adverse events is less reliable than TAC's ad-hoc efforts.

Warning: These pictures are both graphic and upsetting. If you are sensitive please do not view the photos.

[Link 1](#)

[Link 2](#)

4. Dr Dhlomo states: 'The department has also observed that it is cheaper to both the client and the department to circumcise with the Tara Klamp than with the forceps ?? He then goes on to give reasons why he believes it to be cheaper.'

Dr Dhlomo does not provide a price breakdown to back up his claims. In our press statement released last week we included a breakdown of the comparative costs of forceps guided versus Tara KLamp circumcisions precisely so that we can engage with the actual costs and not hear-say. According to our price breakdown Tara Klamp circumcisions were R120 more expensive per circumcision than the standard forceps guided method. (TAC's statement, containing the price breakdown is available [here](#)).

5. Dr Dhlomo quotes from a provisional research report from a Dr Friedman and based on this report concludes that adverse events related to the Tara KLamp are not of concern.

This draft research report has not been published and has not undergone any peer-review. A copy of this draft report was leaked to TAC and we identified serious methodological problems that make a mockery of its conclusions. It has also emerged that this study did not receive the necessary ethical approval to be undertaken and was likely unlawful. One of the principle researchers, the Health Systems Trust, withdrew from the research following these revelations. (Health-e News reported on the draft research report, the story is available [here](#)).

The only reliable scientific evidence relating to the Tara KLamp remains the Orange Farm study. This randomized-controlled trial was peer-reviewed and published in the South African Medical Journal in 2009. It found much higher adverse event rates associated with the Tara KLamp, than standard surgical methods. The study was conducted by highly respected circumcision researchers ? incidentally, one of the same research teams that initially showed that medical circumcision reduces the risk of HIV infection in heterosexual men. (The Orange Farm study can be accessed [here](#)).

It is deeply worrying that Dr Dhlomo considers the findings of an unpublished research report to carry more weight than a randomized controlled trial, which has been peer reviewed and published in a prestigious medical journal.

Dr Dhlomo continues to make a number of unfounded allegations against TAC that are not worth responding to here. However, we note again that our complaint is supported by the Southern African HIV Clinicians Society and the South African Medical Association. In addition, the substance of our concerns is based on the best available scientific evidence and reports from on the ground in Kwazulu-Natal.

Some of the questions Dr Dhlomo's statement did not respond to are:

- Why is the Kwazulu-Natal Department of Health using a circumcision device that is not recommended by the WHO?
- Given that a device not recommended by the WHO is being used, why did the Department specifically choose one of the devices that has already been shown to be unsafe? Whereas devices like the Shang Ring and Prepix are also not WHO recommended, and we would also oppose their use, these other devices have at least have shown some promise in preliminary trials.
- How is it possible that TAC can have undeniable evidence of severe adverse events and the Department not?
- Why have the tender details relating to the procurement of the Tara KLamp not been shared with TAC or the Mail & Guardian (who have also requested access to the tender)?

We reaffirm that the use of the Tara KLamp is a violation of basic medical ethics and its use is both irrational and irresponsible. Dr Dhlomo's statement has failed to address our concerns and underlines the urgent need for a serious investigation into the use of the Tara KLamp.

Read our full complaint to the Public Protector [here](#)

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