

Correspondence between TAC and the KZN government about unsafe circumcision device

By *moderator*

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Here we publish correspondence between the TAC and the Kwazulu-Natal (KZN) Government about an unsafe circumcision device called the Tara KLamp.

On 12 July 2010, the TAC sent a letter to the KZN MEC for Health, Dr Sibongiseni Dhlomo, alerting him to our concerns about the rollout of the Tara KLamp in Kwazulu-Natal. At that point approximately 600 Tara KLamp circumcisions had been carried out in the province.

TAC received a letter dated 19 July 2010 from Dr Dhlomo in which he responded, "What we have explained to the Minister and now indirectly to you is that we are committed to massive Medical Male Circumcision in KZN as directed by His Majesty our King. We will do it medically as the Majesty instructed us. The king has instructed us that no one should die as a result of our MMC intervention but he did not instruct us that no one should have pain. We think it is unfair and unnecessary to prescribe for us how to conduct MMC. Some of us who are medical doctors can differ with your notion of expense as we don't know how you arrive at that. We have in the past and we continue to invite TAC to come and observe MMC in KZN provided it is your members who are registered with HPCSA or SANC."

In the meanwhile, the KZN government carried out several hundred more Tara KLamp circumcisions.

On 4 August 2010, the TAC sent another letter to the KZN government, requesting documentation about the province's purchase of the device. We requested the documentation to be provided by 9 August 2010, but have received no response yet.

The letters follow in reverse chronological order.

- [Letter dated 3 August \(sent 4 August\): TAC request for financial documentation.](#)
- [Letter dated 19 July 2010: Response by Dr Dhlomo to TAC's letter of 12 July 2010.](#)
- [Letter dated 12 July 2010 \(sent 12 July\): TAC letter to KZN Government expressing concern about Tara KLamp.](#)

Letter to the KZN MEC for Health requesting information regarding expenditure on the Tara KLamp

Dr Maxwell Sibongiseni Dhlomo [sic]
MEC for Health
Kwazulu-Natal Provincial Executive Council
Private Bag X9051
Pietermaritzburg, 3201

By fax and email: 033-394 0597 and Sibongiseni.Dlomo@kznhealth.gov.za

Dr Sibongile Zungu
Head of the Department
KwaZulu-Natal Department of Health
Fax: 033 345 0792
Email: sibongile.zungu@kznhealth.gov.za

3 August 2010

Dear Dr Dlomo [sic] and Dr Zungu

RE: Request for information regarding expenditure on Tara KLamp

This is a request for documentation for the contractual agreement entered into between the KwaZulu-Natal (KZN) Department of Health (DoH) and Carpe Diem Enterprises as well as any other relevant financial information concerning the purchase of Tara KLamps by the Kwazulu-Natal government. Carpe Diem Enterprises is supplying the Tara KLamp, a medical device used to perform medical circumcisions, to the KZN DoH.

Mr. Biyele, KZN DoH Chief Financial Officer, informed TAC that the KZN DoH did not enter into a competitive quotation or bid process around the supply of the Tara KLamps because Carpe Diem Enterprises is the only supplier of the device.

In the case that the KZN DoH did not put out a tender for the device, it would still need to adhere to Treasury Regulation 16A6.4. Under this regulation, the motivations for entering into a contractual agreement must be recorded and approved by the accounting officer. The department must motivate for why it did not enter into a competitive bid process. In this case we still require the following documentation: a quote; a pricing schedule; a declaration of interest and a contract with the supplier.

Please provide us with all the above mentioned documentation by 9 August 2010.

Thank you for your assistance.

Regards

Vuyiseka Dubula

GENERAL SECRETARY OF THE TREATMENT ACTION CAMPAIGN

CC: Dr Zweli Mkhize, Premier, Kwazulu-Natal, Fax: (033) 341 3383

Mr N Biyele, Chief Financial Officer, KwaZulu-Natal Department of Health, Fax: 033 394 0597

Mr Leslie Simiso Magagula, Head of the Department, KwaZulu Natal Provincial Treasury, Fax: 033 897 4562

Response from KZN MEC for Health to TAC?s letter of 12 July 2010

19 July 2010

Treatment Action Campaign
Ms Vuyisile [sic] Dubula
3rd Floor Westminster House
Longmarket Street
Cape Town
8003

Dear Vuyisile [sic]

RE: URGENT CONCERNS REGARDING THE ROLLOUT OF THE TARA KLAMP CIRCUMCISION DEVICE IN KWAZULU-NATAL

We are in receipt of your letter. The content of your letter is noted. I got the copy of the letter you wrote to the Minister of Health and prior to your meeting with the Minister, I met the Minister.

What we have explained to the Minister and now indirectly to you is that we are committed to massive Medical Male Circumcision in KZN as directed by His Majesty our King. We will do it medically as the Majesty instructed us. The king has instructed us that no one should die as a result of our MMC intervention but he did not instruct us that no one should have pain. We think it is unfair and unnecessary to prescribe for us how to conduct MMC.

Some of us who are medical doctors can differ with your notion of expense as we don't know how you arrive at that. We have in the past and we continue to invite TAC to come and observe MMC in KZN provided it is your members who are registered with HPCSA or SANC.

Lastly, there is no leadership in the country, Political and Traditional that is more concerned about safe and efficacious MMC in KZN than KZN leadership.

Regards;

Dr S M Dhlomo
MEC FOR HEALTH KZN, MPL

Letter to the KZN MEC for Health requesting information regarding urgent concerns about the rollout of the Tara KLamp

Dr Sibongiseni Dhlomo
MEC for Health
Kwazulu-Natal Provincial Executive Council
Private Bag X9051
Pietermaritzburg, 3201
By Fax and Email: 033-3940597 and Sibongiseni.Dlomo@kznhealth.gov.za

12 July 2010

Dear Dr Dhlomo

RE: Urgent concerns regarding the rollout of the Tara KLamp circumcision device in Kwazulu-Natal

As you are aware, the Treatment Action Campaign (TAC) has been at the forefront of the campaign to implement voluntary male medical circumcision (VMMC). This is because scientific studies show that if carried out properly, circumcision can help reduce HIV incidence substantially. It is of course essential that VMMC be carried out safely.

In a statement issued jointly with the Southern African HIV Clinicians Society on 8 July 2010, we mentioned the Kwazulu-Natal government for the lead it is taking on the rollout of circumcision. [1]

However, it has come to our attention that a circumcision device known as the Tara KLamp (TK) is being used in KwaZulu-Natal's circumcision programme. We understand that approximately 600 circumcisions using this device have already been carried out under the auspices of the Kwazulu-Natal Department of Health. We have serious concerns about this device and, with the Southern African HIV Clinicians Society, have called for it to be withdrawn from use in adolescent and adult males until its safety has been established.

On Friday 2 July 2010 we met with the National Minister of Health to discuss our concerns about this device with him. The Minister emphasised that there is no policy to use the Tara KLamp for circumcision. But in an interview on SAFM last week, a spokesperson for the Kwazulu-Natal Department of Health indicated that the device will continue to be used. He further explained that it will be used in a forthcoming circumcision drive weekend. We have learned that this circumcision drive is scheduled to take place during the third weekend of July.

The device is manufactured in Kuala Lumpur by TARAMedic Corporation and distributed in South Africa by Carpe Diem Enterprises. The device is clamped onto the penis in order to necrotise the foreskin. The device is intended to remain on the penis for 7 - 10 days until it is removed or falls off with the necrotised foreskin. We are deeply concerned about the aggressive and unethical marketing practices of this company.

Before a medical intervention is made available it must be shown to be safe and effective. No clinical trial has shown the Tara KLamp to be safe for use on adolescent and adult males. On the contrary, a trial published last year in the South African Medical Journal raised serious concerns about the device. This trial was carried out by experts in circumcision, the same experts who ran one of the three randomised controlled trials that showed the effectiveness of circumcision at reducing HIV infections. It provides the best available evidence on the Tara KLamp yet.

The researchers explained that compared to the standard forceps-guided method, less favourable outcomes were associated with the TK method, including any sign of an adverse event (37% v. 3%; $p=0.004$), delayed wound healing (21% v. 3%; $p=0.004$) and problems with penis appearance (31% v. 3%; $p=0.001$). [2]

A randomised controlled trial is the highest standard in medical evidence. It would be unethical and in contradiction of medical evidence to roll out the Tara KLamp in Kwazulu-Natal, even if this is accompanied by safety monitoring and a comparison of results with the standard forceps-guided method. In accordance with medical ethics, the Tara KLamp could only be used again as part of a repeated controlled clinical trial in which patients are informed of the outcome of the previous trial. Such a repeated trial would have to receive ethical approval from a reputable and authorised ethics review committee.

Furthermore using the Tara KLamp is substantially more expensive than using the forceps-guided method. It is not clear to us what advantage is sought by using this device. The additional adverse events it will generate will not only cost the KwaZulu-Natal government more money and consume additional much needed human resources, it will also neutralise any time-saving as claimed by the distributors. There is also the very real possibility that high rates of adverse events could derail the medical circumcision programme in the province.

Please confirm whether or not the Kwazulu-Natal government intends to use or promote the use of the Tara KLamp. Given that it is our understanding, possibly mistaken, that the device will be used again this or the next coming weekend, we request that this letter be responded to this week. We would be willing to meet you as a matter of urgency to discuss the contents of this letter.

Yours sincerely

Vuyiseka Dubula
TAC GENERAL SECRETARY

1. TAC et al. Voluntary Male Medical Circumcision is Safe and Effective: But beware of unsafe devices.
<http://www.tac.org.za/community/node/2905>

2. Lagarde, E. Taljaard, D. Puren, A. Auvert, B. High rate of adverse events following circumcision of young male adults with the Tara KLamp technique: A randomised trial in South Africa. SAMJ. March 2005, Vol. 95, No. 3

[END OF NEWSLETTER]

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