



Cape Town , 2 November 2017

The Vaccine Advocacy Resource Group, an independent, advocate led, global team of AIDS prevention research advocates that play a critical liaison role in the highly complex field of HIV Vaccine research, in partnership with the South African Medical Research Council, have just emerged from a 2 day pre summit Imbizo with its partners and CAB members from around South Africa and the region which sought to :

- Centre the contributions that black African, mainly women, have made to clinical research globally by prefacing the Imbizo with a spiritual devotion that was led by an African faith traditional practitioner and practicing Muslim and Christian advocates.
- Explore ways in which advocates and CAB members can build the collective capacity and agency of scientists and researchers in advocacy
- Re-affirm that the consensus view in HIV research – based on ten randomised control trials – is that oral PrEP works, including in African women, if adhered to.
- Recognizing the reality that we live in a country where 2000 new infections occur every week amongst mostly young African women, much like myself, we must continue to advocate that oral PrEP should be used by all people at risk of HIV who want it. While we still need to monitor, investigate and continue to explore oral prep and how best to deliver it – we must not put on hold what we know works ! PrEP now!!!!

Advocates need to use the same passion, knowledge, insight and conviction of spirit that we used to get access to antiretrovirals in the fight for PrEP, while continuing to advocate for research into new prevention options – especially HIV vaccines!

Having established this, advocates from South Africa, Nigeria, Malawi, Zimbabwe, Kenya and Uganda are demanding that the Standard of Care in clinical research centres basic human rights, is ethical, scientifically valid and developed with meaningful and sincere collaboration with communities and advocates.

As part of the Imbizo, advocates discussed the current status of care in research and what should be included in a minimum standard of care:

As advocates we demand a standard of care that is:

- Rights based, informed by choice and agency
- Policy aware, but not environmentally-limited
- Accountable
- Client centred, transparent and provides clear mechanisms for advocates and community members to monitor its implementation and inform its evolution.

- Grounded in rights based and community owned publically available PrEP plans.

There are organized groups of advocates, such as the VARG, and civil society organizations in Southern Africa with which researchers can sustainably partner with so we shift the language from buy in to ownership.

As community members and PrEP users, our experience is critical in shaping PrEP roll out and PrEP plans. We can enhance researchers' understanding of the complex PrEP landscape to inform the plan to include PrEP as part of the standard of care.

The standard of care, in addition to the existing package, should include access to oral PrEP in a way that fits into the realities of the participants' lives, (onsite or refferal) and interacts with and moves forward national delivery mechanisms. Researchers and advocates in this room have been at the forefront of national conversations around Voluntary Medical Male Circumcision and ARV treatment, and they must continue to engage with these discussions when new prevention interventions are introduced.

The recommendations for a minimum package of standard of care are universal - but the precise nature, shape and messaging of these minimum standards should be discussed and agreed upon during the design - not after - by a range of stakeholders (including advocates, CABs, government agencies, researchers and regulators). As we roll out this standard of care, we need to keep the multitude of lessons that we have learnt so far from trials such as femPrEP and VOICE studies that demonstrated and confirmed the importance of understanding and acknowledging the lived realities of participants.

To be clear, we have two demands :

1. PrEP works. We know this. PrEP should be provided by trial sites to participants who want it. This does not exclude our government from its obligations to give us the choice and range of tools that we know work to prevent HIV – female and male condoms and yes, PrEP.
2. Networks need to meangingfully support a broader national conversation to advance PrEP for all. It is an ethical and a political imperative. PrEP works to prevent HIV – it works for women who take it.

The road towards this standard, will not be easy, nothing worth achieving ever is easy. Our lives, the lives of those we love and the lives of those around us *literally depend on it*. We all want to advance the science, we all want to live to see answers to these longstanding questions and we all have the passion, conviction and commitment to continue to sustain the journey.

The concern raised this morning that if standards of care are comprehensive then we might put off donors is problematic. Let us be clear, while there is room for refinement of delivery of the standard of care, the human rights of participants is not an area of negotiation or a grey area.

We know that our proposed standard of care works

We know that it is on the back of black african women that live in some of the worlds most unequal societies that we claim the scientfci successes that we claim here today

We know that there cannot be a trade off of human rights or dignity in return for our goal to become a global clinical research capital.

As we hold science to account as we have done in the past, we commit today to move forward with you, to have the difficult conversations, to put in the long hours, to centre the realities of the communities that we come from.

Comrades, this is not the last time you will hear from us or engage with us but we will leave here knowing that you have heard us and that we have claimed our seat and voice at this table.

The Vaccine Advocacy Resource Group and its partners will release a details proposal for Standard of Care in Clinical Research on World AIDS Day, 1st December 2017.

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