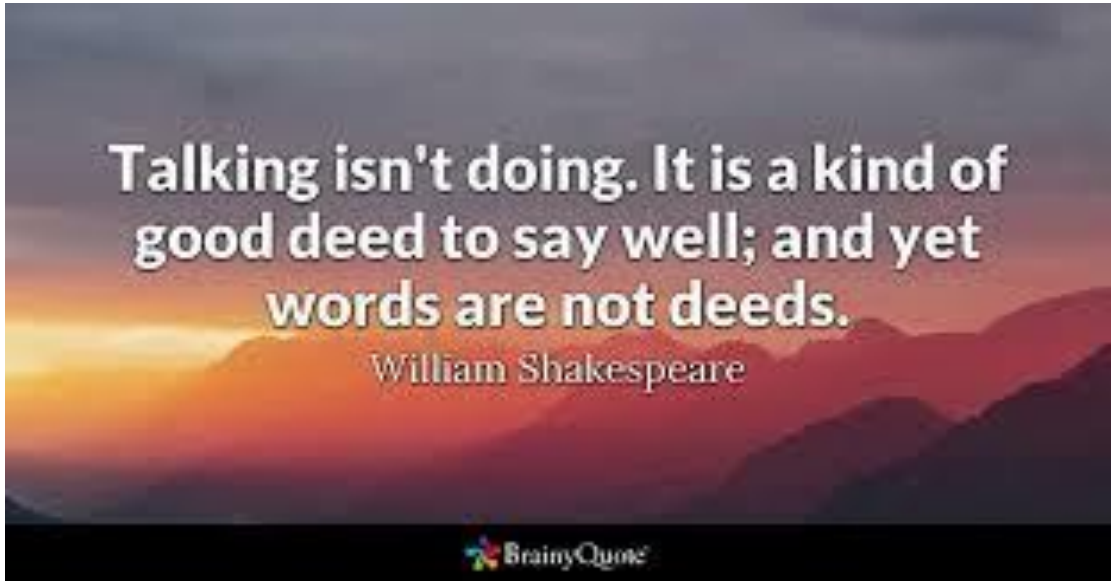
“It is the responsibility of research funding organizations and researchers to ensure access, uptake and adherence to free, onsite oral HIV pre-exposure prophylaxis as the standard of care for all participants at risk for HIV infection in all HIV prevention clinical trials.”



The overarching aim of HIV prevention studies is to prevent new infections through the development of new technologies and interventions so….

- **If we care about prevention, and being exemplars of doing prevention well, we should do prevention**
- PrEP works for women and men, and is licensed for use in many of the countries where studies are being done
- We don’t know if a study product is protective and some participants may be on placebo i.e. not protected
- It is an ethical and professional obligation to provide study participants with the best standard of prevention available
- We have always introduced new technologies as the standard of prevention into trials, sometime when not yet widely available in the public sector e.g. Female condom, VMMC

But if we offer PrEP, won't prevention studies for new and potentially more effective prevention technologies become impossible to implement – just too big and without endpoints?

- Study sites will be ensuring access but cannot compel PrEP use
- PrEP use and adherence will never be 100%, so new infections will continue to occur even if we offer PrEP
- Studies and cohort size can be designed to take into account PrEP use e.g. ECHO
- Arguably, anything new in prevention will roll out in a context in which PrEP exists - best to figure out the synergies/interactions sooner than later

Isn’t this going to put the costs up and make studies unaffordable?

Example from the ECHO Study: 7800 women in 12 sites in 4 African countries, 9 in South Africa, Kenya, Swaziland, Zambia

- Overall cost of ECHO ~ $50 million
- Tenemine (Truvada generic) used in SA study sites: Tenemine is ~ $7 per bottle vs Truvada between $34 and $50 per bottle
- Study staff can provide PrEP
- Do the maths……

Isn’t it unethical to offer something in a study that wont necessarily be available after the study closes?

- No: participants in HIV prevention trials are at high risk of HIV so protection over duration of a trial may change a participants lifetime risk AND
- Many countries are rolling out PrEP in demonstration sites or national programmes so good chance that referral will be possible once study finishes
- By being in the vanguard of providing PrEP, participants and providers can become advocates for its use and develop strategies to optimize uptake and adherence outside the study context

“How will history judge scientists who don’t find a way of offering PrEP?”

Nelly Mugo