Research into Mobile Health Technologies for TB treatment adherence: What’s ethics got to do with it?

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BACKGROUND
South Africa remains a major contributor to the global TB epidemic and is one of eight countries that contributed to two-thirds of all new cases of TB in 2017.

There is a need for innovative tools, like mobile health (mHealth) technologies, to end the TB epidemic.

“Everyone with TB should have access to the innovative tools and services they need for rapid diagnosis, treatment and care”
Dr Margaret Chan, former Director General of the World Health Organization, 2015

The World Health Organization’s Guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update lists four recommendations as part of cross-cutting interventions towards effectiveness of patient care and support. Includes suggested TB treatment adherence interventions through mHealth applications, such as Video observed treatment (VOT) where:

- Suitable communication technology is available and can be appropriately organized
- Can be operated by health-care providers and patients
- This recommendation is conditional recommendation, with very low certainty in the evidence

Thus, more research as to the implementation of VOT as a mobile health technologies for TB treatment adherence will likely be conducted.

Research focus is on VOT on high-burden areas in lower and middle income countries and suitability has been proven in more developed country settings. The very nature of VOT raises several ethical questions since the identification of research participants is necessary.

VIDEO OBSERVED TREATMENT (VOT)
VOT is a mobile health technology that can address adherence challenges stemming from patient-related factors. These include stigmatization and loss of control when a DOT supporter is responsible for monitoring treatment adherence. VOT requires a person to use a smartphone or other video technologies to daily record a video of themselves swallowing their TB treatment. This video is then shared with health workers over a mobile network. A health worker or designated person then observes and records the daily dose as taken. The taking of the treatment is at the sole discretion of the patient in terms of convenient time and place. Thus, VOT enhances the autonomy of the person taking TB treatment. The digital sharing of such sensitive information does raise ethical concerns.

Privacy and confidentiality
Any person’s TB status should be kept confidential to ensure that the trust between patients and their health care providers is maintained. Such trust is needed to prevent and mitigate TB-related stigma (WHO, 2017)

By using VOT, a person’s TB status is recorded and this protected information is shared through a digital network. Videos transmitted via an encrypted network can be hacked, intercepted and shared through social and other media, thus privacy and confidentiality can be compromised through involuntary disclosure (Story et al, 2016; Mirsaeidi et al, 2015)

Respect and dignity
All persons taking TB treatment should be treated with equal care and attention, as ends in themselves and not instrumentally or for the good of others. Resources should be distributed based on varied and ethically relevant criteria (such as need, utility etc.). Persons taking TB treatment should not be subject to prejudice, discrimination and stigma on the basis of their beliefs or life choices or circumstances (WHO, 2017)

The novelty of mHealth applications such as VOT in resource-poor settings can degenerate into concern for reliability, efficiency and affordability of VOT technology for its own sake. When selecting participants in research studies, those who own and can afford the technology costs will likely be recruited for research studies where the technology is tested, thus excluding poorer persons living with TB.

Amnesty
The guarantee to individuals of the right to make decisions about their own lives, including with regards to their health. Respecting for autonomy means that patients should have the right to choose where and when to receive TB services. (WHO, 2017)

Participants in VOT research studies may feel compelled to participate given the novelty of the technology. Even if their participation is voluntary, their enthusiasm to record and send a daily video of themselves may become depleted, especially when they do take their treatment as prescribed

RESULTS
Research protocols that include VOT for TB must be aware of possible risks to ethical principles, especially that of Privacy and confidentiality, Respect and dignity, and Autonomy.

The general principles of research participation in South Africa (and elsewhere) is that it must be voluntary and based on informed consent. Informed consent should not only be administered prior to the start of a study, but must be ongoing and affirmed during the study as well (Department of Health, 2015).

Information sheets to potential participants, on which informed consent will be based, should include statements to make potential participants aware of the risks and to satisfy requirements of accredited research ethics committees.

For example:

To maintain ‘Privacy and confidentiality’

“When transferring your video to the server, there is a very small possibility that it may be intercepted or hacked once stored on the server. We will be using secure encryption and data management techniques in an attempt to ensure this does not happen.”

“When you use a mobile phone which is shared with others in your home, please make sure that the video is erased once you see a confirmation that the video has been received by the server.”

To maintain ‘Respect and dignity’

“You need not have your own mobile phone to participate in this study, you only need to have regular access to a mobile phone. We know that using one mobile phone is a reality in many homes.”

“A project staff member will assist with downloading the mobile application (app) needed for the study.”

To maintain Autonomy

“You may feel that having to video record yourself taking your treatment after a while is no longer necessary and that you can monitor yourself. When this happens, you are welcome to inform the researchers, but we will appreciate it if you could still share your reasons for doing so with us at the end of your TB treatment period.”

“Your decision to participate in this study is voluntary. You may also decide to withdraw from the study at any time and this will have no impact on your access to TB treatment at this clinic.”

LESSONS LEARNT
Research on the feasibility of VOT for TB treatment adherence, poses the greatest threat to the ethical principles of Privacy and confidentiality, Respect and dignity, and Autonomy.

These risks can be also be present when in-person DOT is administered either in a home or clinic setting. Both can aggravate TB-related stigma from community and household members (Story et al, 2016).

Even when VOT is used for a research project, monitoring of adherence can be deemed more confidential and less of a burden to the person taking TB treatment (Zuniga et al, 2016)

The ethical principles of the Common good and Solidarity, compels public health researchers to undertake VOT research. Informed consent from participants is paramount for collection and resuting storage of video recordings on which VOT will be based.

The approval of VOT research protocols by an accredited research ethics committee is mandatory.

KEY MESSAGES FOR OTHERS
Mobile Health (mHealth) technologies are becoming essential for TB treatment adherence and research on their feasibility will increase, especially in high-burden TB settings. However daunting, ethical principles must be adhered to, as set out above, so as to not infringe on the rights of individuals infected and affected by TB.

The full reference list is available from the author at: adlaidavids@hsrc.ac.za

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