Do we really do DOT and should we?: Human rights and person-centered approaches to TB treatment

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DOTS Strategy Vs. Direct Observation (DOT)

WHO DOTS Strategy (2014) and Ethical Guidance (2017)

- Patient-centered. Multiple options for treatment including, but not limited to observed treatment.
- Should include economic, social, and psychological support
- If DOT is used it should :
  - Be available at a location of one's choice.
  - Be provided by a supporter of one’s choice.
- Costs associated with treatment (transport, etc.) should *not* be borne by the patient.

Directly Observed Therapy

- A person is observed by someone (or some device) while they take their treatment.

History

- Madras, India and Hong Kong studies conducted in 1959-1960s provided initial evidence
- Aim was to have cost-effective treatment and to increase adherence.
- Prior to this, TB was mainly treated in specialized hospitals and sanatoria on an inpatient basis.
- Initially the debate was hospitalization vs. DOT. Now the need for DOT is being debated.
- **DOT is NOT used widely under programmatic conditions for any other disease, including HIV.**

Do we really do direct observation?

- Many studies, as well as WHO program reviews and Green Light Committee reports show that direct observation is NOT happening as described, especially in rural areas. (eg. Benbaba et al 2015 and de Colombani et al 2015).
  - Romania reported 100% “DOTS coverage” since at least 2006, however, in 2013 announced that in rural areas (where 45% of the people live) even dispensary or family doctor-based DOT was not possible due to health system limitations.

DOT as a burden or as harm?

- Generally, direct and indirect economic costs are bore by the patient and their family. Such as:
  - **Transportation**
  - **Time off of work**—especially for people involved in agriculture and other work that has seasonal requirements.
  - **Time needed to care for small children or older adults—This places greater burdens on women especially.**
- DOT is expensive to health systems and is often weak or non-existent in rural areas.
- DOT may be stigmatizing –being seen going to a TB treatment center or having DOT staff (especially identifiable vehicles) visit one's home

Tools or “magic bullets”?

- “Smart” pillboxes
- Video observed treatment (VOT)
- Mems blister packs/sleeves
- Wirelessly observed treatment (WOT) (edible sensor)
- Slowly dissolving coils of pills (in trials now not pictured)

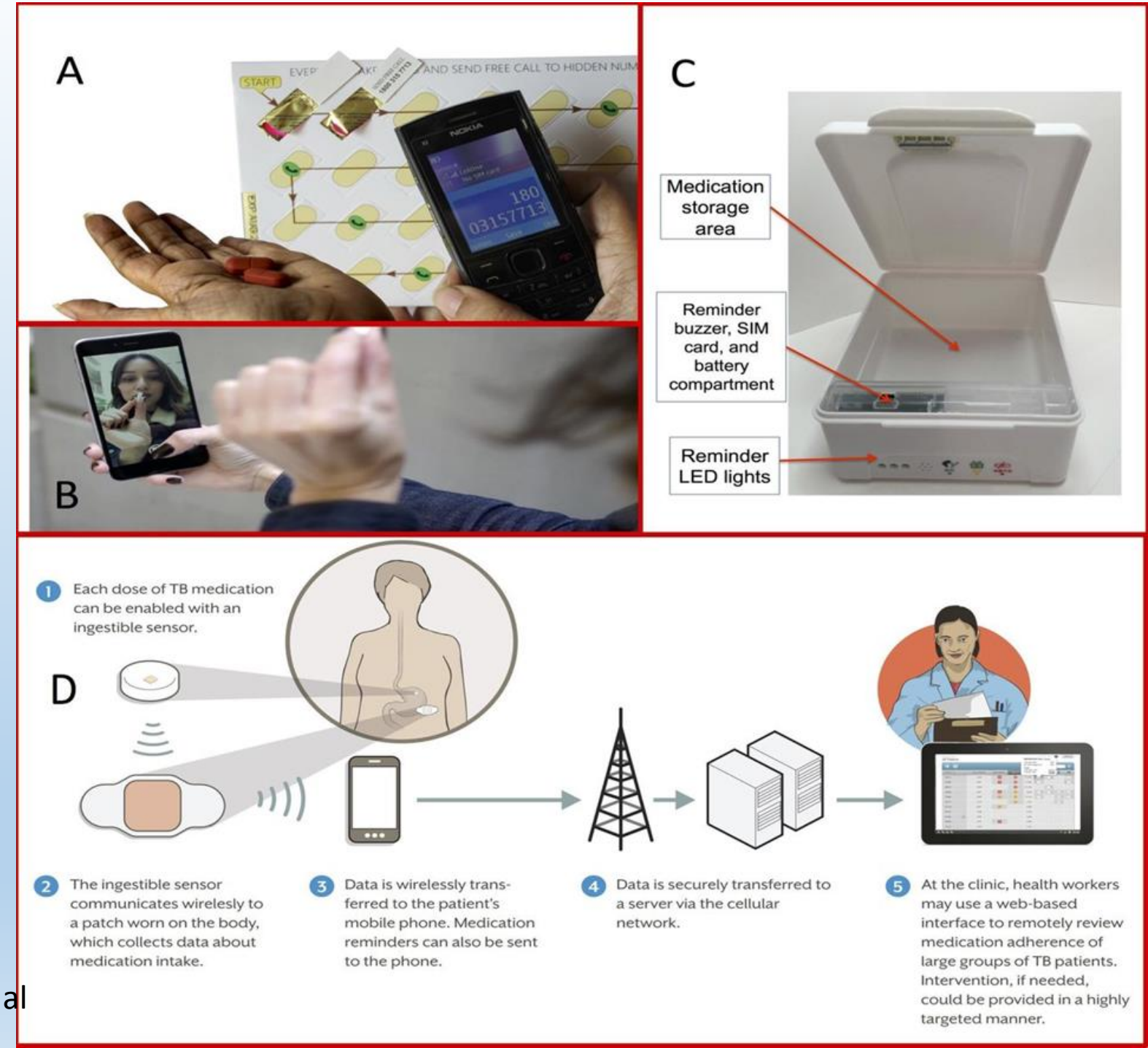

Photo credit: Subbaramen et al 2018

What does the data say?

- **Evidence is generally weak and sometimes contradictory**
- **Multiple systematic reviews and meta-analyses show that there is no clear benefit from DOT vs. self-administered treatment (SAT) for active and latent TB treatment. (Most recently Karumbi and Garner 2015)**
- **A systematic review of *community-based* DOT did show benefit vs. SAT. (Zhang et al 2016)**
- There is strong data showing that economic, social, and psychological support increase adherence (sometimes these are delivered as part of DOT, but sometimes they are separate)
- WHO recommendations prefer community-based DOT over health facility DOT and observation by trained workers is preferred over family observation or SAT. However the quality of evidence this is based on is low.

Human rights and ethical concerns connected to DOT (an incomplete list)

- Privacy
- Dignity
- Health accessibility (especially economic)
- The principle of reciprocity-People with TB endure long and difficult treatment which provides a public health benefit to society. In return, society has an obligation to provide social and economic support.
- The right to work
- The right to education
- The right to participate in cultural life

Is DOT patient/person centered?

- No, not for everyone, but maybe (with the right combination of supports) for some. Patient-centered care (PCC) requires that the care be tailored to the specific needs of the patient and their loved ones.

- DOT, especially as it is most commonly practiced, is “one-size fits all”

- PCC requires that multiple possibilities for treatment and support be available and a patient, in collaboration with medical staff, choose what is the most supportive and least difficult for them.

In conclusion:

- The evidence base for directly observed therapy is weak and recent research suggests it provides no adherence or outcome benefit.
- DOT is based in a historical mistrust of people with TB.
- DOT is already NOT happening for many people with TB.
- The clinic or hospital-based DOT that most people receive is **NOT patient-centered** and may be an economic burden to them.
- Adherence technologies like VOT and WOT are tools. They may be appropriate for some, but they are **not "magic bullets".** They also introduce additional human rights concerns.
- **Now is the time to talk about what does work and to promote strategies that are patient-centered, evidence-based, and that respect human rights.**

Thank you for your time!

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