VOT in the UK
Results of a Randomised Control Trial

AI Story
University College London Hospitals, UK
Hypothesis

• **Primary outcome**
  – VOT increases the proportion of patients who have >80% of doses observed during a 2 month period compared to DOT

• **Secondary outcomes**
  – Adherence over planned treatment course
  – Loss to follow up - Treatment completion
  – Culture conversion - Acquired resistance
  – Impact on transmission - Quality of life
  – Cost effectiveness
Inclusion criteria

• Any patient 16 years of age or older eligible for DOT at participating clinics (16 London, 3 outside capital)

• Exclude
  – Can’t charge phone
  – <2 months treatment remaining

• Non-Randomised arm
  – MDR / Children / ‘last chance saloon’
Selective DOT

- Non-adherence
- Previous TB treatment
- Homelessness, drug or alcohol misuse
- In prison, or have been in the past 5 years
- Major psychiatric, memory or cognitive disorder
- Denial of TB diagnosis
- MDRTB
- Request DOT
- Too ill to self administer
Interventions

VOT

- Initial training and follow-up as required
- Daily VOT clip, SMS reminder, Telephone contact if missed
- Standardized smartphone device and App with unlimited data
- No further incentives

DOT

- 3 or 5 in-person clinic or community observations per week
- Incentives and enablers as per local protocols
Baseline characteristics

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<thead>
<tr>
<th>Category</th>
<th>DOT</th>
<th>VOT</th>
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<td>16-24</td>
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<td>Ever LFU</td>
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Complex cases

Any current social risk factor = Homeless, problem drug use, alcohol
Analysis - primary outcome

• **Primary analysis** – All randomized regardless of whether they ever took up either arm of the intervention.
  – 84 DOT vs 81 VOT

• **Secondary analysis** - All who started the randomized intervention and have primary outcome data
  – 45 DOT (54% started) vs 68 VOT (84% started)
Observation classification

1. All meds observed
2. Some meds observed – out of shot
3. No meds observed – no clip
4. Unknown, unable to tell – too dark
5. Other – hospital admission
6. Probably took meds – not 100% clear
7. Technical issues with clip (VOT) – Self Administered (DOT)
Main analysis – High confidence

1. All meds observed
2. Some meds observed
3. No meds observed
4. Unknown, unable to tell
5. Other
6. Probably took meds
7. Technical issues with clip (VOT) – Self Administered (DOT)
Strict

1. All meds observed
2. Some meds observed
3. No meds observed
4. Unknown, unable to tell
5. Other
6. Probably took meds
7. Technical issues with clip (VOT) – Self Administered (DOT)
AOR \(7.27\) (3.36-15.8) \(p<0.001\)

AOR \(4.59\) (2.05-10.3) \(p<0.001\)

AOR \(3.54\) (1.68-7.5) \(p<0.001\)

AOR \(2.03\) (1-4.1) \(p=0.05\)

OR adjusted for age, sex, clinic and time on treatment
VOT adherence over time

- Month 1: 84%
- Month 2: 88%
- Month 3: 90%
- Month 4: 89%
- Month 5: 91%
- Month 6: 90%
Current status

- Closed: Total recruited = 251 (NR= 26 R=225)
  - DOT = 114 (5 switched to VOT)
  - VOT = 111 (6 switched to DOT)
- Secondary outcomes end March 2017
IMPACT - Real world

• >200 VOT patients treated since 2009
• 41 MDR and 7 XDR
• Youngest 8
• Socially complex patients
• 90% completed or on target to complete
How did you feel when VOT was suggested?

• *I was getting a bit tired of DOT – I thought I would be a lot freer to continue with my daily life, without having to wait around for someone – all that time and effort you’ve saved me – I didn’t need much convincing...*
How does VOT compare with DOT?

• “With the DOT, it felt like you had a disease and you felt like there was some kind of stigma and for that reason they are monitoring you – It felt almost like being a criminal...I felt like probably they don’t trust me to take my own medication...but with VOT, it’s different...it’s definitely a welcome alternative.”
How do you feel about sharing your image?

• “It’s important to know the person – if you forget to send the video, they can call you back and they will remind you. It’s much better to know who you are dealing with.”
Liberating – Flexible - Empowering
'I have tuberculosis in my brain'
Factors influencing treatment adherence

• Economic and structural
  – Poverty. Unstable accommodation. Poor social networks

• Patient-related

• Regimen complexity
  – Pill burden. Toxicity and side-effects. Treatment duration

• Supportive providers / Good patient relationships
  – Patient satisfaction. Empathic professionals

• Pattern of health care delivery
  – Service organisation, access and flexibility. Professional expertise. Patient support systems
Health Belief Model

- Modifying Variables
- Perceived Seriousness
- Perceived Susceptibility

Perceived Benefits vs. Perceived Barriers

Perceived Threat

Self-Efficacy

Cues to Action

Likelihood of Engaging in Health-Promoting Behavior
Take
Video Observed Treatment
Video Supported Care
VS Care - Conclusion

• At least twice as effective as DOT
• More acceptable to patients than DOT
• More acceptable to providers than DOT
• Cheaper
  • Less than half the cost of clinic DOT and one third cheaper than community DOT
Next steps

• Role out - Scale up
  – Centralised model with clinical networks

• Technical development
  – Real-time consultation

• Wider applicability
  – LTBI – HCV – OST - ???

• International collaboration
  – high burden – MDR/XDR – RCT (SAT/SMS/VS-Care/DOT)
Smartphone
Basic phone
Mobile PC

Mobile subscriptions in Sub-Sa Africa
Mobile penetration 105% by 2022

Global Smartphones
• 55% of all mobile subscriptions in 2016
• 80% of all mobile phones sold in 2016
• 90% percent of all subscriptions by 2022
• 75% of mobile data traffic video by 2022

Source: Ericsson Mobility Report Nov 2016
https://www.ericsson.com/mobility-report
Overcoming the connectivity challenge

On device processing
Facial recognition
Pill recognition
Swallowing confirmation

Video’s stored on device for QA when meds collected / clinical review
VS-Care
A new option
Better patient choice
= improved treatment delivery
Fox W. *The problem of self-administration of drugs, with particular reference to pulmonary tuberculosis.*

*Tubercle.* 39: 269-274. 1958
Acknowledgements

• Prof Andrew Hayward (PI)
• Prof Richard Garfein
• Dr Rob Aldridge
• Prof John Watson
• Prof Andrew Nunn
• Prof Ibrahim Abubakar
• Dr Marc Lipman
• Liz Garber
• Sara Hemming
• Lucia Posas
• Gloria Fernandez
• Josie Mavromatis
• Malcolm Cocksedge
• Joe Hall
• Find&Treat team
• Collaborating Clinics