Video Observed Treatment (VOT)

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2017 WHO TB guidance recommends:

- Community or home-based DOT over health facility-based DOT or unsupervised treatment
- DOT administered by trained lay providers or health care workers over DOT administered by family members or unsupervised treatment
- The use of thrice-weekly dosing is not recommended...and daily dosing remains the recommended dosing frequency
In England DOT is recommended as part of Enhanced Case Management for those with History of homelessness, imprisonment, mental health problems, drug use, previous TB, previous poor adherence, MDRTB

*NICE TB Guideline NG33;
Case Management & Cohort Review Toolkit;
Collaborative TB Strategy for England;
NICE Quality Standards for TB (QS141)

– Only two-thirds of patients who need DOT get DOT

– Main reasons:
  • Lack of resources
  • No out of hours service
  • Complex drug regimens (bd, tds & qds)
And...

- It’s expensive and time consuming
- It usually amounts to max 71% of doses observed – 5-x-week
- Limited to once daily dosing
- Patients don’t like it
  - High rate of refusal
  - High rate of self administered doses
  - High rate of drop out
“...I’d rather not go every morning to my pharmacy...if I can do it from home...that’s better for me.”

“...but to the clinic I have to go everyday far away...so to me it’s better to be the phone”

“At the pharmacy I had to take them [the tablets] in front of everyone...Now I do it in my own personal time...I can do that without no issue”

From interviews conducted at UCL as part of VOT RCT. Awaiting publication
VOT in 3 easy steps

1. Enter unique pin code
2. Film tablets and ingestion, report side effects
3. Films uploaded automatically
Governance and data protection issues covered by F&T

- Fully GDPR compliant ✓
- Easy, safe & secure filming ✓
- End-to-end encryption ✓
- Password protection on app & CMS ✓
- No patient identifiable information ✓
  - unique username and pin code
- Films do not get stored on patient’s phone ✓
  - films automatically uploaded using WiFi or mobile data
- Films date & time stamped ✓
  - patients decide where/what time to film
- Phones/data can be provided ✓
Smartphone-enabled video-observed versus directly observed treatment for tuberculosis: a multicentre, analyst-blinded, randomised, controlled superiority trial

Alistair Story, Robert W Aldridge, Catherine M Smith, Elizabeth Garber, Joe Hall, Gloria Ferenando, Lucia Possas, Sara Hemming, Fatima Wurie, Serena Luchenski, Ibrahim Abubakar, Timothy D McHugh, Peter J White, John M Watson, Marc Lipman, Richard Garfein, Andrew C Hayward

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Inclusion / Exclusion Criteria

• Inclusion
  – Eligible for DOT under national or local guidance
  – Age > 16 years

• Exclusion
  – No place to charge a smart phone*
  – <2 months treatment left
  – MDRTB (non randomised arm)

  – 22 clinics in England (UK; London [17 sites], Birmingham [three], Coventry [one], and Leicester [one])

  – * if street homeless the VOT started once accommodation found
548 assessed for eligibility

322 excluded
  98 did not meet inclusion criteria
  127 declined to participate
  45 other reasons*
  27 not approached
  25 MDR tuberculosis

226 randomised

114 allocated to DOT
  56 ≥1 week of DOT
  58 <1 week of DOT

114 intention-to-treat analysis
  56 restricted analysis

112 allocated to VOT
  101 ≥1 week of VOT
  11 <1 week of VOT

112 intention-to-treat analysis
  101 restricted analysis
Baseline characteristics
Balanced randomisation

Age group | Sex | Born in UK | Previous TB
--- | --- | --- | ---
16-24 | Male | No | No
25-34 | Female | Yes | Yes
35-44 | Male | No | Yes
45-54 | Female | Yes | Yes
55-64 | Male | No | No
>=65 | Female | No | Yes

DOT
VOT
Socially complex cases

* Any current social risk factor = Homeless, problem drug use, alcohol, prison
Interventions

VOT
  • 7 days a week - Initial training by main VOT observer
  • All videos acknowledged via personalised e-mail or text
  • Telephone contact if no video sent
  • Weekend videos read on Mondays
  • Standard smartphone and App + unlimited UK calls and texts
  • No further incentives

DOT
  • 3 or 5 in-person clinic or community observations per week
  • Incentives and enablers as per local protocols - usually £5 per dose observed + Travel card payments
• 58% had history of homelessness, drug use, imprisonment, alcohol problems, mental health problems.

• The primary outcome was completion of 80% or more scheduled treatment observations over the first 2 months following enrolment.

• Intention-to-treat (ITT) and restricted (including only patients completing at least 1 week of observation on allocated arm) analyses were done.
Initial engagement with VOT and DOT

• Overall levels of initial engagement with VOT were 90% and exceeded 70% in all subgroups,

• Overall levels of initial engagement with DOT were 50% and were particularly low (<50%) in younger adults, foreign-born patients and those without social risk factors or mental health problems
ITT analysis

- % Achieving ≥ 80% of scheduled observations during 1st 2 months
  - VOT 70% (78/112)
  - DOT 31% (35/114)
  - adjusted OR 5.48, 95% CI 3.10–9.68; p<0.0001.

- % of scheduled observations completed over first 2 months
  - VOT 79% (5091/6474)
  - DOT 45% (1774/3922)

- % of scheduled observations completed up to 6 months
  - VOT 77% (12422/16230)
  - DOT 39% (3884/9882)
  - p<0.0001.
Restricted analysis

- % Achieving ≥ 80% of scheduled observations during 1st 2 months
- VOT 77% (78/101)
- DOT 63% (35/56)
- adjusted OR 2.52; 95% CI 1.17–5.54; p=0.017.

- % of scheduled observations completed over first 2 months
- VOT 86% (5091/5893)
- DOT 73% (1774/2418)

- % of scheduled observations completed up to 6 months
- VOT 83% (12422/14907)
- DOT 61% (3884/6351)
- p<0.0001.
Costs

- Average staff time per dose observed
- 56 min for community based DOT (including travel time);
- 15 min for clinic-based DOT,
- 3.2 min for VOT.

- Cost over 6 months
  - 5 times weekly DOT £5700 per patient
  - 3 times weekly DOT £3420 per patient
  - Daily VOT £1645 per patient
I’ve been down with some of my medication...stopping my medication for no reason...this gave me an opportunity to take my medication whenever I had to take it...I felt good’
(From VOT RCT)

“I also had a very bad addiction to substances and stuff...I think it’s probably not a very good idea to just give it [medication]... I think VOT did a really good job. It’s a really good programme’
(from VOT RCT)

“...the process was very quick. All I had to do was wake up in the morning...and record the patient video...that’s all’
(from VOT RCT)

“I enjoy doing my films and managing my medication myself...It’s good and really easy to use. I’m happy with it”

“I don’t think I would’ve taken the medications regularly...I wasn’t going to be compliant” (from VOT RCT)
Video observed treatment (VOT) can replace DOT when the video communication technology is available and it can be appropriately organised and operated by health care providers and patients.

VOT vs DOT

• More effective
• Cheaper
• Preferred by patients

• Video observed treatment (VOT) should replace DOT
VOT is rapidly expanding nationally

- **> 120 + referrals in last 18 months** (350 + patients since 2009)
  - Nearly **40%** of these in last 6 months
    - 17% are out of London referrals
- **54** of these have completed Rx on VOT
- **8 (6%)** have crossed-over to DOT (VOT unsuccessful)
- **60 +** patients currently on VOT (or waiting to start)
- **One-third** of patients on VOT have MDR/XDR TB
  - VOT is standard Rx option for MDR patients
VOT in London

= new services referring patients for VOT (since 01/04/17)
= Services previously using VOT (prior to 01/04/17)
= referrals for VOT (since 01/04/17)
Find&Treat National VOT Service

• Available nationwide
• Easy to use VOT app (developed by SureAdhere)
  – Available for iOS & Android phones
• Patient uses own phone or F&T provided VOT phone
• Easy referral process
  – Contact F&T to discuss referral
  – Complete out of London VOT agreement form
• Quick set-up
  – Same day set up if patient using own phone
• Cheap daily costs (tariff basis)
## VOT Tariff costs

<table>
<thead>
<tr>
<th></th>
<th>£6.99 per film</th>
<th>£48.93 p/w</th>
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<tbody>
<tr>
<td>Fully sensitive TB (with VOT phone)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fully sensitive TB (with patient's own device)</td>
<td>£6.23 per film</td>
<td>£43.61 p/w</td>
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<tr>
<td>MDR TB (with VOT phone)</td>
<td>£5.99 per film</td>
<td>From £41.93 p/w</td>
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<tr>
<td>MDR TB (with patient's own device)</td>
<td>£5.23 per film</td>
<td>From £36.61 p/w</td>
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Tariff cost covers app rental, phone/data charges (if applicable), server rental/maintenance costs & VOT observer/admin time
13 year old male multi-organ MDRTB

Breakfast
Linezolid - Cycloserine - Delaminid - Prothionamide - Pyrazinamide
Thank you

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Find&Treat National VOT Service

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