

Use of Live Video Directly Observed Therapy (LVDOT) in New York City: A Six Month Review, September 2013-March 2014

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BACKGROUND

- New York City's (NYC) tuberculosis (TB) cases have fallen sharply since the peak of the epidemic in the early 1990's
 - There were 656 new cases counted in 2013, an 83% reduction since the peak of the epidemic in 1992
- Directly Observed Therapy (DOT) is one of many interventions that has contributed to this decline
- DOT is the standard of care in NYC
- DOT has been shown to:
 - Increase adherence
 - Reduce the risk of disease recurrence
 - Prevent the development of acquired drug resistance
- The NYC Bureau of Tuberculosis Control (BTBC) provides DOT to approximately 200-250 patients at any given time
 - DOT is offered to all individuals with suspected or confirmed TB disease
- It is very costly to provide face to face DOT to all eligible patients
 - Costs include staff salaries, transportation, and maintenance of car-fleet
- Factors such as scheduling, school, work, and privacy concerns limit face-to-face DOT enrollment
- Video DOT (VDOT) can maximize public health resources and has been shown to be more convenient and less intrusive for patients
- Many jurisdictions are now implementing VDOT
- BTBC began piloting Live VDOT (LVDOT) in 2013 in the borough of Queens
- LVDOT has expanded to other boroughs based on demand

OBJECTIVES

- The LVDOT project aims to:
 - Assess the acceptability and efficacy of VDOT for monitoring patients' adherence to TB treatment
 - Assess the feasibility of implementing VDOT as a permanent supplement to face-to-face DOT
- Enrollment goal of at least twenty-five patients on VDOT within 12 months
- Results will be used to:
 - Estimate the likelihood of increasing the number of patients that receive TB treatment via DOT
 - Enumerate the potential costs and benefits of expanding VDOT citywide
- Identify operational barriers

METHODS

PLANNING PHASE

- A workgroup was convened to craft the implementation plan and process
- BTBC collaborated with internal and external partners:
 - Department of Health and Mental Hygiene (DOHMH) Department of Information and Informatics Technology (DIIT)
 - DOHMH General Counsel
 - DOHMH Institutional Review Board
 - University of California, San Diego (UCSD)
 - New York State Department of Health
 - Verizon Foundation
- BTBC obtain in-kind contribution of 25 smartphone with service and data plans

WORKGROUP ACTIVITIES

- Crafted a protocol to address enrollment, responsibilities of staff and patients, and program evaluation
- Secure, HIPAA compliant video conferencing software that met DOHMH DIIT approval was identified
- Staff were selected to conduct LVDOT observations
- Staff were trained to enroll patients in LVDOT and observe medication ingestion
- Create a database to capture DOT data and implementation issues

LVDOT ENROLLMENT PROCESS

- LVDOT was offered to patients receiving treatment for suspected or confirmed TB disease who met enrollment criteria (Fig 1)
- Participants signed two forms:
 - DOT enrollment form
 - Statement of responsibility form for use and care of DOHMH issued smartphone
- After enrollment in LVDOT patients were:
 - Loaned a smart phone programmed with a video conferencing application
 - Assigned a unique conference number
- DOT observation time and frequency were scheduled
- Patients were trained by BTBC staff to:
 - Use phone and conference calling features
 - Initiate the call to the observer
 - Pour medication in front of the camera so medication name and bottle are visible to DOT observer
- LVDOT participants may choose to return to face-to-face DOT at any time
- Uninterrupted participation in LVDOT is dependent on patient's adherence rate
- During the pilot project, VDOT was offered 7:00 AM and 7:00 PM
- Patients should ideally begin on face to face DOT and maintain 80% -100% adherence for 2-4 weeks prior to enrollment in LVDOT

Figure 1: NYC LVDOT Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria ¹
<ul style="list-style-type: none"> Demonstrate proficiency in using a smartphone after 1 or 2 training sessions Accurately identify each medication and self-administer by mouth Communicate in English or in a language spoken by available observers Have access to a private area that support patient confidentiality in the observation environment 	<ul style="list-style-type: none"> Patients with disabilities that prevent full participation e.g. vision or hearing impaired Patients on court ordered DOT Patients who experience adverse reaction(s) to prescribed medication Patients with low adherence rate on face-to-face DOT Patients at risk for hepatic complications Pediatric patients Homeless patients

1. If any of these characteristics occurred after enrollment, VDOT was discontinued

RESULTS

Figure 2: Patients enrolled on LVDOT by site of disease

Site of Disease	Number of patients
Pulmonary	27
Lymphatic	2
Other	2
Pleural	2
Bone/joint	1
Genitourinary	1
Pulmonary/Lymphatic	1
Pulmonary/Pleural	1
Grand Total	37

- 78% of enrolled patients were diagnosed with pulmonary TB disease
- 22% were diagnosed with extrapulmonary disease
- 5% had a strain of TB resistant to at least isoniazid and rifampin
- 15 females and 22 males were enrolled
- 35% of females and 51% of males had confirmed TB disease

Figure 3: Age and Employment by Gender

Gender	Number of patients	Median Age (Range)	Employed (%)
Females	15	29 (21-70)	8 (53)
Males	22	41 (19-59)	13 (59)
Grand Total	37	33 (19-70)	21 (57)

- The median age of females was 12 years less than the median age of males
- The age range for females was wider than for males
- 92% (34) of patients had adherence rates \geq 80%

Figure 4: LVDOT Adherence Rates¹

Adherence Rates	Number of patients (%)
100%	13 (35)
95-99%	8 (22)
90-94%	5 (14)
85-89%	5 (14)
80-84%	3 (8)
74-49%	3 (8)

1. Adherence is calculated as the percentage of ingestions observed

Figure 5: Reasons patients chose to enroll in LVDOT

Reason for selecting LVDOT	Number of patients
Convenient method	13
Accommodate work schedule	8
Time convenience	8
Preserve privacy	3
Accommodate school hours	2
Saves travel time	2
Location convenience	1
Grand Total	37

- Patients selected LVDOT primarily due to increased convenience

Figure 6: Reasons that patients discontinued LVDOT

Reason for discontinuing LVDOT	Number of patients
Completed treatment	10
Not a TB case	3
Lost telephone	2
Changed mind	1
Died	1
Moved	1
Commissioner's order issued	1
Work-related difficulties	1
Low adherence rate	1
Treatment ongoing	16
Grand Total	37

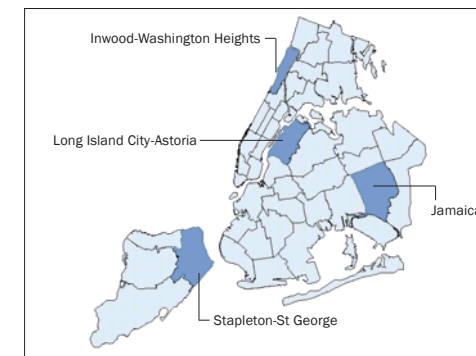
- 27% of the patients who started LVDOT completed treatment for TB on LVDOT
- 8% were found to not be a case of TB
- 5% lost the phone issued to them by BTBC and were returned to face-to-face DOT
- 3% each were returned to face-to-face DOT because of non-adherence or refusal to continue on LVDOT
- 3% died after starting LVDOT
- 43% are still on treatment

Figure 7: Technical issues encountered during LVDOT and frequency of occurrence

Technical issue encountered by patient and/or observed	Frequency
Audio problem	38
Video problem (image freezing)	33
Connectivity problem at patient's location	16
Conferencing program not functioning	10
Phone was not charged	7
Connectivity problems at observer's location	3
Patient had difficulty maneuvering phone position	2
Other	5
Grand Total	114

- 114 technical issues were experienced either during the attempt to connect or during the LVDOT session
- All issues were resolved within 1-2 days of identification
- Image freezing issues were resolved shortly after start-up

Figure 8: Locations of patients observed using LVDOT



- On a single day, LVDOT observations were conducted for 8 patients whose locations covered 98 miles in 4 different neighborhoods of NYC
 - 126 minutes spent observing all 8 patients; on average, 9 minutes of observation and 5 minutes of paperwork per patient
- By comparison face to face DOT for the same 8 patients would have taken an estimated 395 minutes
 - 170 minutes allotted for driving, 45 minutes to find parking, 180 minutes for observation
- An estimated 269 minutes were saved by LVDOT observation

STRENGTHS/LIMITATIONS

LIMITATIONS

- LVDOT still requires specified time frame when observer and patient can meet
- Similar to face-to-face DOT, LVDOT is not available seven days per week
- LVDOT is dependent on quality of technology used
- LVDOT is dependent on patients having personal smart phones or the ability of the DOT program to provide equipment

STRENGTHS

- LVDOT does not depend on weather conditions
- Multiple conferencing capability-including on the spot medical consultation for patient's with adverse reactions
- Multidisciplinary team working to provide DOT
- Allows observation of patients who travel out-of-state
- Reduces manpower and other resources needed to provide DOT; meaningful cost savings realized.

CONCLUSIONS

- Preliminary findings suggest VDOT is a promising supplement to face-to-face DOT
- Patients were receptive to LVDOT
- Most LVDOT patients selected LVDOT for privacy or convenience purposes
 - Historically, patients have cited time restrictions, work, and school as reasons for not enrolling in traditional DOT
- The number of patients who identified accommodating work/school schedules was lower than expected
- No significant differences in acceptance were observed among employed and unemployed patients
- LVDOT adherence rates appear equal to or better than face-to-face DOT
- One observer could observe up to 25 patients daily vs. 2 to 3 observers in the field
- The flexibility of LVDOT allows patients to be observed at times and places where traditional DOT is limited

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