Video Directly Observed Therapy (VDOT) for Monitoring Tuberculosis Treatment Adherence

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Richard S. Garfein, PhD, MPH
UC San Diego, School of Medicine
rgarfein@ucsd.edu

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Durham, NC
August 12, 2015
Monitoring TB Medication Adherence

• Purpose:
  – Document that all doses were taken
  – Promote treatment completion
  – Detect side effects

• Goals:
  – Reduce TB morbidity and mortality
  – Prevent TB transmission
  – Prevent acquired drug resistance
Directly Observed Therapy (DOT)

- Patient observed swallowing each dose

Rationale:
- Improves adherence
- Reduces risk of acquired drug resistance, treatment failure, and relapse
- Permits intermittent dosing
- May reduce total number of doses
- Saved 6.8 million lives between 1995 and 2010
- Recommended by CDC & WHO
First Line TB Treatment

**Initial phase (8 weeks):**
- 4 drugs daily (~500 pills)

**Continuation phase (18 weeks):**
- 2 drugs daily (~500 pills)

~1000 pills over 6 months
Global TB Treatment Burden

2 Billion Doses
11 Billion Pills
Barriers to DOT

- Cost
- Manpower
- Transportation
- Impractical in some rural settings
- Coordination b/w patient and provider
- Restricts mobility
- Privacy and stigma
- Patient autonomy
Other Technologies (non-observed)
Mobile Technology for DOT

- **Synchronous Video DOT (VDOT)**
  - Streaming video
  - Live conferencing

- **Asynchronous Video DOT (VDOT)**
  - Recorded videos
  - Store-and-forward

- **Non-video Technologies**
  - Ingestible sensors
  - Facial recognition apps
Videophone DOT Experiments

• 6 patients for up to 6 months
  – 95% adherence
  – High patient satisfaction; ease of use
  – Saved $1810/patient in staff and miles

San Diego (2004)
• 33 patients over 9 month period
  – High patient acceptance
  – Saved 27,840 travel miles ($10,161)
  – Saved 795 staff hours ($15,000)

DeMaio, CID 2001;33:2082-2084
Bethel and Moser, ATS Conference, San Diego, CA, May 2006
Videophone utilization as an alternative to directly observed therapy for tuberculosis

K. Krueger,* D. Ruby,† P. Cooley,‡ B. Montoya,§ A. Exarchos,* B. M. Djojonegoro,¶ K. Field*

*Washington State Department of Health, Olympia, Washington, †University of Washington, Tacoma, Washington, ‡Tacoma-Pierce County Health Department, Tacoma, Washington, §Snohomish Health District, Everett, Washington, ¶Francis J Curry National Tuberculosis Center, University of California San Francisco, San Francisco, California, USA

SUMMARY

To demonstrate whether the use of videophone technology is an effective alternative method to direct observation of tuberculosis (TB) medication administration, a retrospective chart review and data analysis were performed on records for 57 patients with active TB in two Washington state counties who utilized videophone technology for the administration of medications from 2002 through 2006. A total of US$139,546 was saved in staff salaries, benefits and travel costs. The average cost savings per patient was US$2,448. The use of videophone technology is a cost-effective alternative to in-home directly observed administration of TB medication.

KEY WORDS: videophone; tuberculosis; medication
“2002 marked an historic turning point in history when mobile telephone subscribers overtook fixed-line subscribers worldwide”

Fixed-line vs mobile penetration based on connections, 2012

Source: GSMA Intelligence, ITU

“Mobile Phone-Based Video Directly Observed Therapy (VDOT) for Tuberculosis”  
(NIH Grant #R21-AI088326)
UCSD VDOT Pilot Study

- **Objective:**
  - To assess the feasibility, acceptability and potential efficacy of VDOT for monitoring TB treatment.

- **Setting:**
  - TB control programs in San Diego and Tijuana
  - Conducted by program staff

- **Design:**
  - Phase I = Focus groups
  - Phase II = Single-arm pilot trial
    - Eligibility: Age>18, pansensitive pulmonary TB
    - Patients interviewed pre & post VDOT
Asynchronous Video DOT Flow Diagram

(PI: R. Garfein)

Videos & Data Stored in Cloud

DOT Worker

Patient Records Video

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SMS reminders sent to patients and providers
## UCSD VDOT Pilot Phase II: Results

<table>
<thead>
<tr>
<th></th>
<th>San Diego</th>
<th>Tijuana</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong># videos observed / # videos expected</strong></td>
<td>Mean IQR Range</td>
<td></td>
</tr>
<tr>
<td></td>
<td>93% 91-99% 51-100%</td>
<td>96% 91-99% 88-100%</td>
</tr>
<tr>
<td><strong>How often did you have problems recording a video?</strong></td>
<td>Never/Rarely ≥1/2 the time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>38 (97) 3 ( 7)</td>
<td>8 (89) 1 (11)</td>
</tr>
<tr>
<td><strong>Did you find VDOT more or less confidential than in-person DOT?</strong></td>
<td>More No Difference Less</td>
<td></td>
</tr>
<tr>
<td></td>
<td>33 (80) 6 (15) 2 ( 5)</td>
<td>7 (78) 0 ( 0) 2 (22)</td>
</tr>
<tr>
<td><strong>If you had to redo your TB treatment, would you choose VDOT or in-person DOT?</strong></td>
<td>VDOT No Preference In-Person</td>
<td></td>
</tr>
<tr>
<td></td>
<td>38 (93) 2 ( 5) 1 ( 2)</td>
<td>8 (89) 1 (11) 0 ( 0)</td>
</tr>
<tr>
<td><strong>Would you recommend VDOT to other TB patients?</strong></td>
<td>Yes No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>41 (100) 0 ( 0)</td>
<td>9 (100) 0 ( 0)</td>
</tr>
<tr>
<td><strong>As a result of participating in the study, are you more comfortable using a smart phone?</strong></td>
<td>More No Difference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>28 (68) 13 (32)</td>
<td>8 (89) 1 (11)</td>
</tr>
</tbody>
</table>

Funded by NIH (R21-AI088326; PI: Garfein)  
Accepted for publication in *Int J Tuber Lung Dis.*
## UCSD VDOT Expansion Trial: Phase III

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n=156)</th>
<th>San Diego (n=60)</th>
<th>San Francisco (n=48)</th>
<th>New York City (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>40.5(15.9)</td>
<td>39.0(16.0)</td>
<td>47.1(15.7)</td>
<td>35.8(14.0)</td>
</tr>
<tr>
<td>Education ≤High School (n=150)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male Gender</td>
<td>56.7</td>
<td>50.9</td>
<td>55.3</td>
<td>65.2</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>42.3</td>
<td>40.0</td>
<td>64.6</td>
<td>22.9</td>
</tr>
<tr>
<td>Black/African-American</td>
<td>12.8</td>
<td>1.7</td>
<td>0</td>
<td>39.6</td>
</tr>
<tr>
<td>Caucasian/White</td>
<td>7.1</td>
<td>10.0</td>
<td>8.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>31.4</td>
<td>41.7</td>
<td>20.8</td>
<td>29.2</td>
</tr>
<tr>
<td>Other/Mixed Race</td>
<td>6.4</td>
<td>6.7</td>
<td>6.3</td>
<td>6.3</td>
</tr>
<tr>
<td>Country of Birth</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S.</td>
<td>25.0</td>
<td>26.7</td>
<td>12.5</td>
<td>35.4</td>
</tr>
<tr>
<td>Mexico</td>
<td>12.2</td>
<td>21.7</td>
<td>8.3</td>
<td>4.2</td>
</tr>
<tr>
<td>Other</td>
<td>62.8</td>
<td>51.7</td>
<td>79.2</td>
<td>60.4</td>
</tr>
<tr>
<td>Annual Income &lt;$10,000 (n=144)</td>
<td>49.3</td>
<td>45.5</td>
<td>44.4</td>
<td>59.1</td>
</tr>
<tr>
<td>Currently Insured (n=155)</td>
<td>78.7</td>
<td>75.0</td>
<td>85.4</td>
<td>76.6</td>
</tr>
<tr>
<td>Own Cell Phone at Baseline (n=154)</td>
<td>90.9</td>
<td>86.7</td>
<td>95.8</td>
<td>87.5</td>
</tr>
<tr>
<td>Own Smart Phone at Baseline (n=154)</td>
<td>69.5</td>
<td>75.8</td>
<td>60.4</td>
<td>70.8</td>
</tr>
</tbody>
</table>
UCSD VDOT Expansion: Phase III Preliminary Results

Adherence (n=153)

Preference (n=129)

VDOT is better than in-person DOT
No Difference
In Person DOT

Adherence

Preference

Medication Adherence (Observed Doses/Expected Doses)
“Patients have busy lives and often cannot come into the clinic. VDOT facilitates treatment without the inconvenience of coming to clinic. For staff there are less patients waiting in a congested busy clinic.” – TB Clinic Nurse
UCSD VDOT Pilot: Cost Analysis

- **VDOT costs** based on UCSD pilot study
  - Includes staff salaries, transportation, and telephone service.
  - Excludes the cost of the VDOT application

- **Home-based DOT** based on information obtained from TB control programs
  - Included staff salaries and transportation

<table>
<thead>
<tr>
<th>Site</th>
<th>In-person DOT</th>
<th>VDOT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost*</td>
<td>(95% CI)</td>
</tr>
<tr>
<td>San Diego</td>
<td>$4,167</td>
<td>($3,634-$5,780)</td>
</tr>
<tr>
<td>Tijuana</td>
<td>$458</td>
<td>($336-$652)</td>
</tr>
</tbody>
</table>

*estimates based on 6 month treatment
## San Francisco VDOT Program Cost Analysis

<table>
<thead>
<tr>
<th>Mode</th>
<th>Expense</th>
<th>Monthly Cost (USD)</th>
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</thead>
<tbody>
<tr>
<td>VDOT</td>
<td>Phone plan</td>
<td>42.99</td>
</tr>
<tr>
<td></td>
<td>Staff Time</td>
<td>52.81</td>
</tr>
<tr>
<td></td>
<td>Patient transport (bus tokens)</td>
<td>16.00</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td><strong>$111.80</strong>*</td>
</tr>
<tr>
<td>Clinic DOT</td>
<td>Staff Time</td>
<td>70.05</td>
</tr>
<tr>
<td></td>
<td>Patient Transport (subway, bus tokens)</td>
<td>73.00</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td><strong>$143.05</strong></td>
</tr>
<tr>
<td>Home DOT</td>
<td>Staff Time</td>
<td>336.42</td>
</tr>
<tr>
<td></td>
<td>Staff Transport (car)</td>
<td>22.51</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td><strong>$358.93</strong></td>
</tr>
</tbody>
</table>

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San Francisco VDOT Program Cost Analysis

- Asynchronous VDOT provides DOT at a lower per-patient cost than in-person DOT
- VDOT is a cost-effective alternative to in-person DOT
- VDOT increased the program’s ability to provide DOT for all its TB patients

Other mHealth Technologies

- Ingestible sensors
- Facial recognition app
Legal Environment

- **California MediCal**
  - TB-related services reimbursable as fee-for-service
  - DOT reimbursable at $19.23/encounter
  - eDOT not reimbursed currently
  - Evidence of comparability to in-person DOT is needed

- **CA Telehealth Advancement Act of 2011 (AB 415)**
  - Expands types of eligible telehealth providers
  - Eliminates restrictions on acceptable telehealth modalities
  - Eliminates restrictions on where telehealth occurs
  - Changes can be made administratively without legislative order

- **Center for Connected Health Policy** ([www.cchpca.org](http://www.cchpca.org))
  - Database of state laws and eDOT reimbursement policies
State Laws and Reimbursement Policies

The Center for Connected Health Policy helps you stay informed about telehealth-related laws, regulations, and Medicaid programs. We cover current and pending rules and regulations for the U.S. and all fifty states.
Laws and Reimbursement Policies: Advanced Search

Filter legislation and regulations by jurisdiction(s), rule type(s), or topic(s).

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Rule type</th>
<th>Topic</th>
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<tr>
<td>Federal</td>
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<td>Regulation</td>
<td>Demonstrations &amp; Pilot Projects</td>
<td>2015 Approved Leg/Reg</td>
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<tr>
<td>Utah (partial)</td>
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<td>Current</td>
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<td>Provider-Patient Relationship/In-Person Exam</td>
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<td>Telemedicine/Telehealth Definition</td>
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<td>Arizona</td>
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<td>Live Video Reimbursement</td>
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<tr>
<td>Arkansas</td>
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<td>Store and Forward Reimbursement</td>
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<tr>
<td>California</td>
<td></td>
<td>Remote Patient Monitoring Reimbursement</td>
<td></td>
</tr>
<tr>
<td>Colorado</td>
<td></td>
<td>Email / Phone / Fax</td>
<td></td>
</tr>
</tbody>
</table>

Alaska

**AK Medicaid Program Remote Patient Monitoring Reimbursement**

Alaska Medicaid will reimburse for services delivered through self-monitoring.
3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC shall cover Telemedicine and Telepsychiatry services when medically necessary under all of the following conditions:

a. The beneficiary shall be present at the time of consultation.

b. The medical examination of the beneficiary must be under the control of the consulting provider.

c. The distant site of the service(s) must be of a sufficient distance from the originating site to provide service(s) to a beneficiary who does not have readily available access to such specialty services.

d. The consultation must take place by two-way real-time interactive audio and video telecommunications system.

Note: The licensed provider using Telemedicine or Telepsychiatry Services shall ensure the availability for appropriate follow-up care and maintain a complete health record that is available to the beneficiary and other treating providers.
Existing Guidelines

- **National: CDC & NTCA**
  - Treatment of Tuberculosis. *MMWR*, (2003), 52(RR11);1-77
    - Only refers to in-person DOT

- **State: CDPH/CTCA**
  - Joint Guidelines for Directly Observed Therapy Program Protocols in California (2011)
    - Definition of VDOT
    - Considerations for use of VDOT
    - Sample protocol from one health department
VDOT Practice to Policy Project (P³): Overview

- **Purpose:**
  - To inform health policy and develop best practices for expanding mHealth in California

- **Funded by the California HealthCare Foundation (2014-2016):**
  - University of California San Diego (Epidemiology)
  - Center for Connected Health Policy (Policy/Legislation)

- **Other Collaborators:**
  - University of California San Diego
  - Center for Connected Health Policy
  - California Department of Public Health
  - Five county health departments
P³: UCSD Study Aims

- To determine whether VDOT is as reliable as in-person DOT for observing medication ingestion
- To determine whether VDOT can be applied in both low-volume rural and high-volume urban counties in California
- To estimate patient and provider costs associated with VDOT
- To develop Best Practice guidelines for the use of VDOT throughout California
P³: UCSD Study Description

**Design**
- Patients with pulmonary TB prospectively treated using VDOT compared to record review of patients treated using in-person DOT

**Sites**
- **High-volume**: San Diego, San Francisco, Santa Clara (n=50 ea.)
- **Low-volume**: San Joaquin, Imperial (n=10 ea.)

**Primary Analysis**
- Compare mean adherence rates between VDOT and in-person DOT
- Assess VDOT feasibility and acceptability in low-volume sites
- Calculate cost-effectiveness of VDOT by site
P³: CCHP Study Aims

- To describe current legislation policies, procedures and practices related to TB control and compliance at the federal, state and county levels.

- To assess acceptance and concerns among federal, state & county officials regarding the use of VDOT compared to in-person DOT, and produce recommendations for future use.

- To develop and/or refine policy recommendations for state & federal agencies governing the use of VDOT including the potential for expanding Medicaid/Medi-Cal reimbursement for VDOT.

- To assess the application of VDOT for other infectious diseases.
**P³: CCHP Study Description**

**Participants**
- New & experienced VDOT providers
- Non-providers of VDOT
- Medicaid/Medi-Cal policy experts

**Data Collection Methods**
- Literature review
- Interviews
- Stakeholder surveys

**Deliverables**
- White paper
- Presentations
- Journal articles
- Issue brief
- Meetings
Collaborators

UC San Diego School of Medicine
Richard Garfein (PI), Kevin Patrick, Jazmine Cuevas-Mota, Kelly Collins, Fatima Munoz, Maria Luisa Zuniga, Jose Luis Burgos, Timothy Rodwell, Lin Liu, Michelle Bulterys, Paola Claros, Maricris Arandia, Marthew Wong

UC San Diego Qualcomm Institute
Fredric Raab, Phillip Rios, Allison Flick, Mark Sullivan, Ganz Chockalingam, David McCarter

San Diego County Health and Human Services Agency
Kathleen Moser, Krystal Liang, Deborah McIntosh, Pamela Kennedy, Janette Dubski

San Francisco
Julie Higashi, Laura Romo, Theresa Ampie, Chris Keh

New York City
Christine Chuck, Nikolas Mitropoulos, John Soma, Virginia Vasquez-Stewart

ISESALUD, Tijuana, BC, Mexico
Remedios Lozada, Paris Cerecer, Cristhian Ambriz, Rafael Laniado-Laborin

Mexico-US Border Health Commission and COLEF, BC, Mexico
Maria Gudelia Rangel, Gabriela Escalante

Center for Connected Health Policy
Mario Gutierrez (Executive Director), Mei Kwong (Sr. Policy Associate), Lois Ritter (Consultant)

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For more information contact:

Richard S. Garfein, PhD, MPH
Division of Global Public Health
School of Medicine
University of California San Diego
San Diego, California, USA
rgarfein@ucsd.edu
+1-858-822-3018