

# Video DOT Implementation in Maryland: Outcomes & Opportunities

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# Directly observed therapy remains the standard of care to promote successful adherence to therapy

## KEY PRINCIPLES OUTLINED IN NEW IDSA/CDC GUIDELINES:

"To be consistent with principles of patient-centered care, decisions regarding use of DOT must be made in concert with the patient"

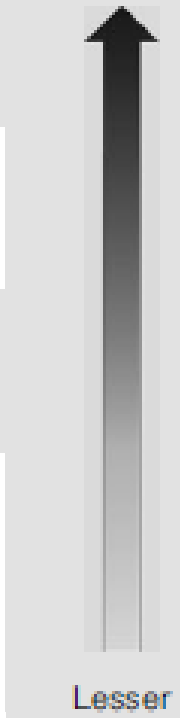
The "least restrictive public health interventions that are effective are used to achieve adherence"

"Implementation of DOT may not be readily feasible when resources are limited"

"DOT has expanded to other modalities such as web-based video and mobile phones which have been well received by both patients and health dept staff"

# New guidelines prioritize daily therapy

Regimen	Intensive Phase		Continuation Phase		Range of Total Doses	Comments <sup>a,d</sup>	Regimen Effectiveness
	Drug <sup>a</sup>	Interval and Dose <sup>b</sup> (Minimum Duration)	Drugs	Interval and Dose <sup>b,c</sup> (Minimum Duration)			
1	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	7 d/wk for 126 doses (18 wk), or 5 d/wk for 90 doses (18 wk)	182–130	This is the preferred regimen for patients with newly diagnosed pulmonary tuberculosis.	Greater
2	INH RIF PZA EMB	7 d/wk for 56 doses (8 wk), or 5 d/wk for 40 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	110–94	Preferred alternative regimen in situations in which more frequent DOT during continuation phase is difficult to achieve.	
3	INH RIF PZA EMB	3 times weekly for 24 doses (8 wk)	INH RIF	3 times weekly for 54 doses (18 wk)	78	Use regimen with caution in patients with HIV and/or cavitary disease. Missed doses can lead to treatment failure, relapse, and acquired drug resistance.	
4	INH RIF PZA EMB	7 d/wk for 14 doses then twice weekly for 12 doses <sup>a</sup>	INH RIF	Twice weekly for 36 doses (18 wk)	62	Do not use twice-weekly regimens in HIV-infected patients or patients with smear-positive and/or cavitary disease. If doses are missed, then therapy is equivalent to once weekly, which is inferior.	Lesser





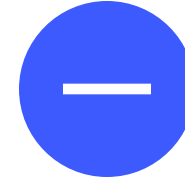
## Positives of DOT

- + Increases patient support
- + Allows early detection of side effects
- + Allows for earlier identification of poor clinical response

The Effect of Directly Observed Therapy on the Rates of Drug Resistance and Relapse in Tuberculosis

Tuberculosis Treatment Outcomes: Directly Observed Therapy Compared with Self-Administered Therapy

First Do No Harm—Adverse Events, Drug Intolerance, and Hepatotoxicity: How Can We Not Justify Directly Observed Therapy for Treating Tuberculosis?



## Negatives of DOT

- Increased cost to programs
- Time consuming for program and patient
- Difficult to schedule

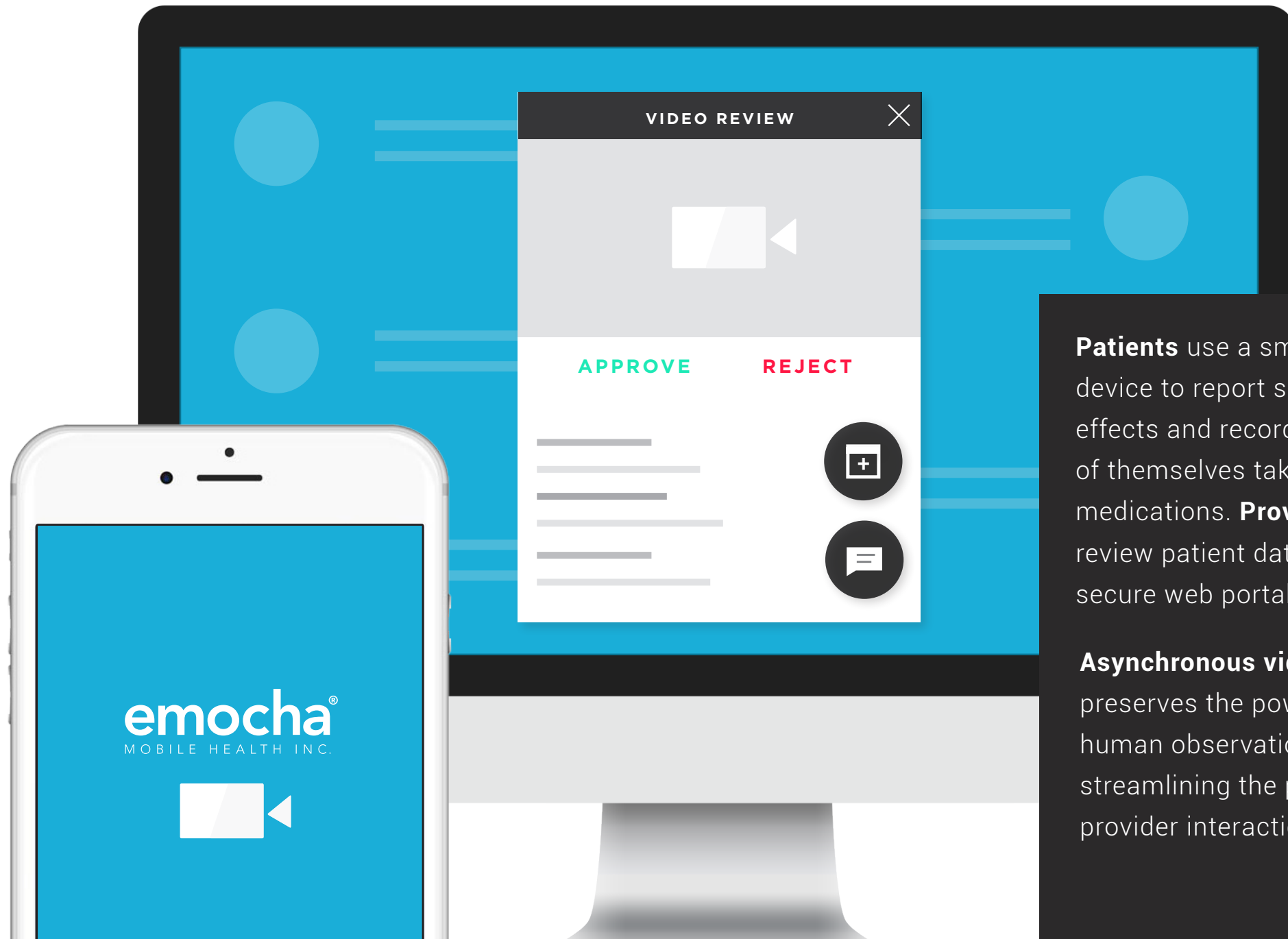
Directly Observed Therapy for Treating Tuberculosis (Review)

A meta-analysis of self-administered vs directly observed therapy effect on microbiologic failure, relapse, and acquired drug resistance in tuberculosis patients

<http://www.cdc.gov/tb/education/ssmodules/module9/ss9reading2.htm>

**Successful TB therapy decreases morbidity, mortality, and transmission and DOT plays a critical role**

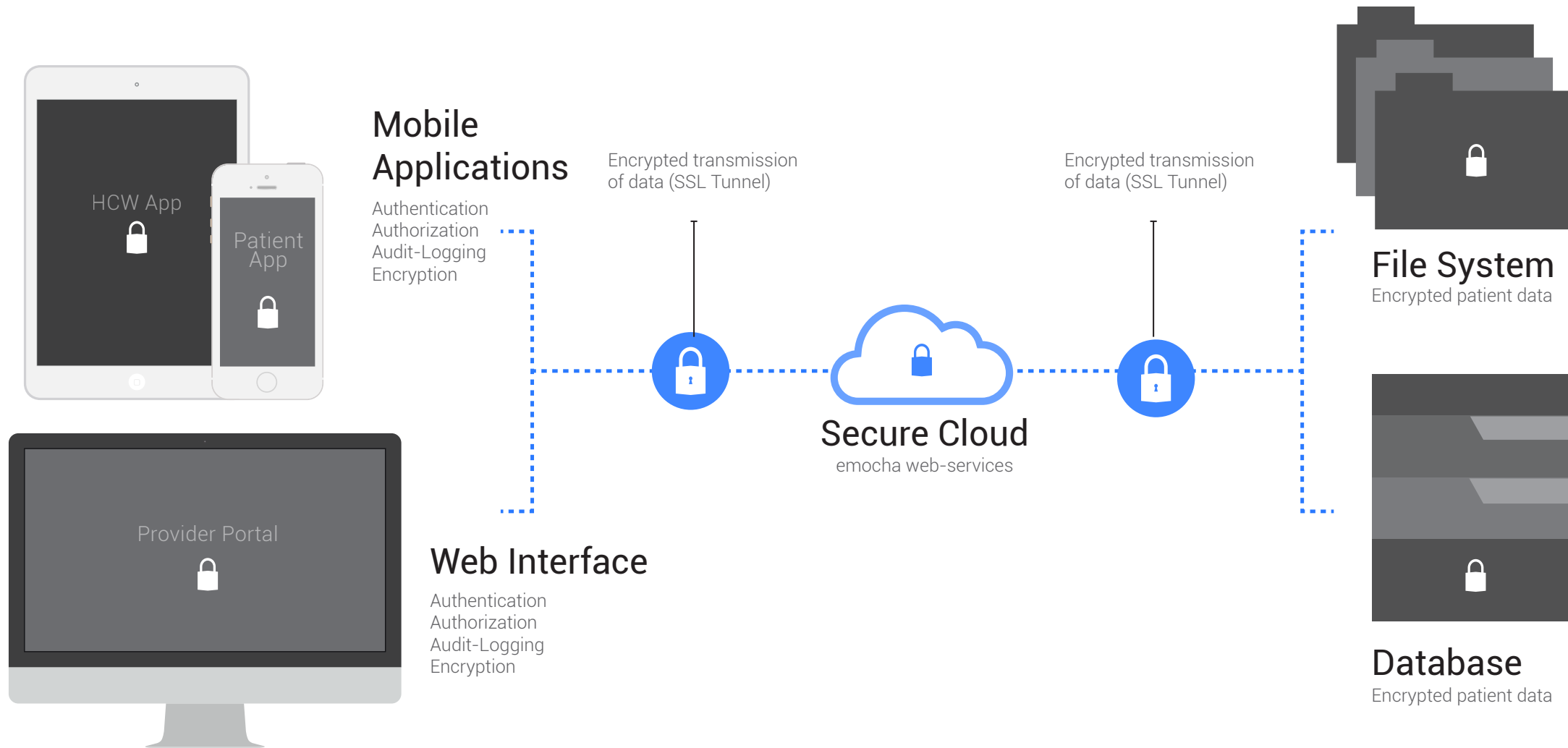
# Asynchronous Video DOT



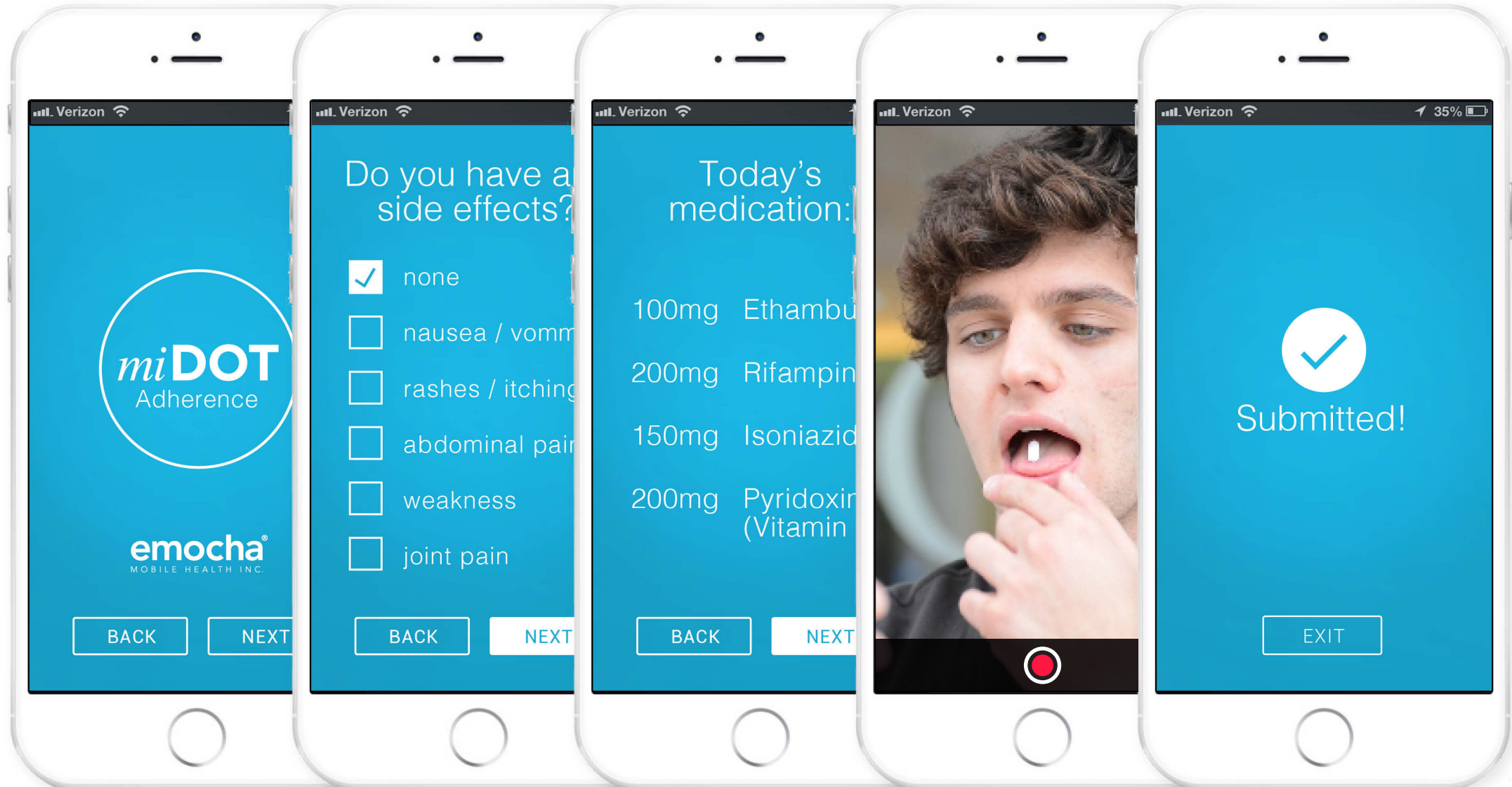
**Patients** use a smart device to report side effects and record a video of themselves taking medications. **Providers** review patient data on a secure web portal.

**Asynchronous video DOT** preserves the power of human observation, while streamlining the patient-provider interaction.

# Security & HIPAA Compliance

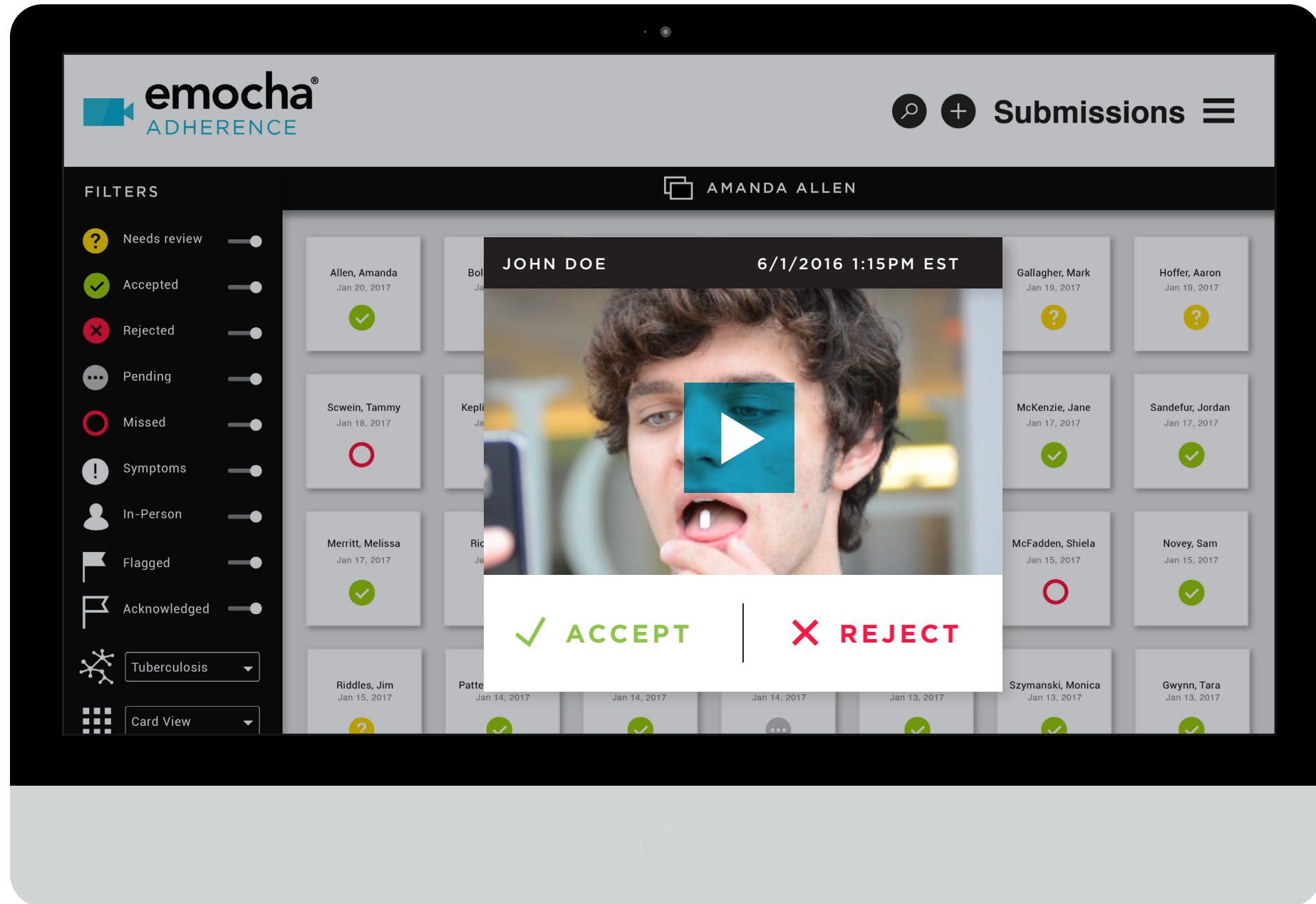


# Patient-facing Mobile Application





# Provider-facing Web Interface



# NIH funded study: Feasibility, acceptability, & costs of video DOT in Maryland

## STUDY DESIGN:

Pragmatic, pilot prospective implementation study from July 2016-current

## INCLUSION CRITERIA:

Adult TB patients in Montgomery Co, Baltimore City, or Anne Arundel County at the discretion of local providers

- + Intensive or continuation phase
- + No prior adherence requirement
- + Selected at the discretion of local providers based on individual considerations

## PRIMARY OUTCOMES:

### **Qualitative data:**

Staff and patients attitudes and impressions, before and after implementation of video DOT

### **Quantitative data:**

**Adherence:** defined as the percentage of 'expected' doses that are verified by video observation per person during Video DOT implementation (compared to before Video DOT implementation)

### **Percentage of 'observable doses' observed:**

defined as total doses prescribed during phase (DOT doses + self-admin) that are observed before and after Video DOT implementation

## COST & IMPLEMENTATION OUTCOMES

# NIH funded study: Feasibility, acceptability, & costs of video DOT in Maryland

## METHODS

- + Used an 'ingredients' approach in which we multiply quantity of consumables /labor utilized by their unit costs
- + Conducted time motion studies at each site, and obtained local costing information from clinics/clinic managers
- + Divide costs into Labor, Consumables (e.g. supplies), Equipment (e.g. vehicles, computers, etc)
- + Conducted 'sensitivity analysis' to examine different methods of implementation and different program structures

# Preliminary Data

## TOTAL PATIENTS ENROLLED

28

## QUALITATIVE DATA *(not fully analyzed)*

23

Provider interviews and surveys  
Pre-Video DOT

20

Patient interviews and surveys  
Pre-Video DOT

+

Ongoing provider and patient interviews  
6 months post-video DOT implementation

Baseline characteristics	
Patients having completed therapy, n (%) <sup>1</sup>	18 (64)
Age, median (IQR)	35 (22-48)
Male, n (%)	6 (38)
Treatment type, n (%)	
Active tuberculosis (TB)	15 (83)
Latent tuberculosis (LTBI)	3 (17)
Phase at miDOT initiation, n (%) <sup>2</sup>	
Intensive	1 (7)
Continuation	14 (93)
Duration of phase (days), median (IQR)	
Pre-Video DOT	68 (47-117)
Video DOT	84 (38-150)
Average video length (sec), median (IQR)	49 (30-63)

<sup>1</sup> Data only presented for those having completed therapy (n=18)

<sup>2</sup> Includes only patients being treated for active TB (n=15)

<sup>3</sup> DOT dosing schedule for active TB cases only

# Preliminary Data

	<b>In-person DOT</b>	<b>Video DOT</b>
DOT adherence (%), median (IQR) <sup>1</sup>	91 (87-100)	95 (82-99)
Percent with adherence <80%, n (%)	2 (11)	4 (22)
Observed fraction (%), median (IQR) <sup>1</sup>	66 (62-71)	73 (63-95)

<sup>1</sup> Differences between treatment groups not significant ( $\alpha=0.05$ , two-sided paired t-test)

## NOTE ON CALCULATIONS

DOT adherence = Fraction of planned DOT days which were completed successfully

Observed Fraction = Fraction of total treatment days with observed dosing

# Cost Data

DOT strategy	Equipment	Consumables	Labor	Total	Incremental
In person DOT (range)	\$175 (\$69-\$562) <sup>1</sup>	\$52 (17.16-141) <sup>2</sup>	\$1838 (\$521-\$6169) <sup>3</sup>	\$2065 (\$608-\$6872)	REFERENCE
miDOT (range)	\$46(\$2.20-\$136) <sup>4</sup>	\$468 (\$0-1200) <sup>5</sup>	\$131(\$37-\$578)	\$645 (\$39-1914)	<b>-\$1420</b>

**1** Based on a base-case scenario of a health department provided vehicle (economy class), and based on a range of patients per DOT worker, annualized over expected lifespan of vehicle. In sensitivity analysis, we calculated alternative pricing structures assuming health care workers utilize personal vehicles, but receive mileage reimbursement (factored into the range of costs for total costs).

**2** Mileage estimated based on discussions with clinic managers, DOT workers, and evaluation of monthly gas and mileage reimbursements at sites. Range incorporates variable gas prices, and ranges of mileage between patients per day, as well as dosing frequency (daily M-F versus thrice weekly dosing).

**3** Base case assumes LPN conducting DOT, at daily M-F dosing throughout treatment, using average time per patient. Low range calculating using Community Health Worker (lower salary), with intermittent dosing schedule, and lowest possible estimates of time used per patient. High range calculated based on RN (highest salary) conducting DOT, at highest possible range value of time spent per patient, at M-F dosing schedule.

**4** In the base-case scenario, we included a program provided mobile phone for the duration of the treatment, and included costs related to a devoted computer to watching videos. In the range, we considered scenarios in which patient phones were used (i.e. no clinic costs incurred).

**5** Commercial pricing may vary; in the base-case we utilized commercial costs in which 3 health care workers use the software for 5 patients each; low range assumes free software, and high range represents 3 health care workers for 1 patient each.

# Video DOT Implementation

## Successes

- + Clinical team commitment and participation
- + Workflow fit
- + User-friendly software
- + IT support and training
- + Staffing model support
- + Alternative to self-administered medication
- + Support client travel and employment needs
- + Support of client independence
- + Client participation, interaction and connection

## Challenges

- Change in workflow
- Management of perceived impact on roles and responsibilities
- Individualized client enrollment
- Ongoing assessment and evaluation of client response and participation
- Additional data base and documentation

# Conclusions and Considerations

- + Using video DOT for selected patients resulted in high rates of adherence

*Analysis is ongoing to compare adherence during video DOT, to their pre-video DOT in-person adherence*

- + Video DOT appears to be acceptable, and preferred by included patients compared to in-person DOT

*Caveat: this study did not randomize patients to video DOT vs in-person DOT. This data represents a selected subset of TB clinic population. Determining which patients will benefit most from video DOT vs in-person DOT requires clinician/clinic judgment*

- + Per patient, video DOT costs are comparable or lower than standard approaches to DOT

- + Incorporation of video DOT may allow clinics to dedicate time and resources towards patients requiring greater attention/needs

- + Determining the optimal frequency for video DOT may improve care

*80% adherence to 7 days/week therapy results in greater number of observed doses than 100% adherence to 5 days/week therapy over the same period of time*



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"The concept of confirming pill taking by observation seems at first so simple that the mind is repelled. Yes, how obvious, you say. **But successful observed therapy (i.e., directly observed therapy – DOT) is really more than the mechanical act of watching patients ingest their medications,** more than ocular confirmation of treatment. To be successful, it must be based on a patient-centered approach. This involves consistent health care providers, be they nurses, care coordinators, community health workers or other trained and trusted individuals (e.g., family members) capable of establishing a supportive relationship with the patient that promotes treatment adherence."

**- Patrick Chaulk, MD, MPH**

Assistant Commissioner, Baltimore City Health Dept