

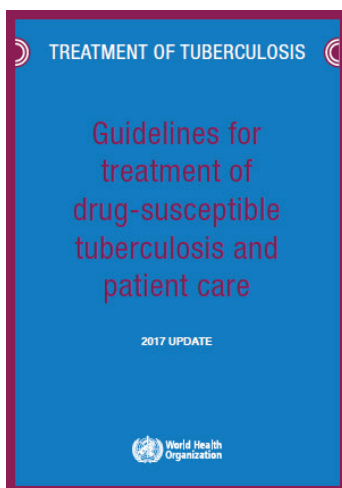
BACKGROUND

- Tuberculosis (TB) is now the leading infectious disease cause of death globally.¹
- Multiple studies show that irregular adherence to TB therapy — even for patients who achieve treatment completion or cure — is significantly associated with increased rates of disease relapse or development of drug resistance.^{2,3}
- The strategy of “directly observed therapy” (DOT) was designed to reduce non-adherence and has contributed to substantial improvements in TB treatment outcomes.^{4,5} Despite its success, DOT as implemented currently in resource-limited settings also has limitations:
 - Facility-based DOT, still the most common model in many countries, is expensive, resource-intensive and highly burdensome on patients, providers and health systems.⁶
 - DOT is often inadequately implemented, with patient self-administration increasingly becoming the norm in both the private and public sectors.^{7,8}

POLICY RECOMMENDATIONS

Link to download WHO guidelines⁹: <http://bit.ly/2pRx8yu>

- WHO recommends the use of additional adherence interventions to ensure good treatment outcomes.
- Video observed treatment (VOT) has been approved for use as a treatment adherence intervention and may be offered to patients on TB treatment or to healthcare providers.



Recommendations

2.1.4 *The following treatment administration options may be offered to patients on TB treatment:*

- Community- or home-based DOT is recommended over health facility-based DOT or unsupervised treatment (Conditional recommendation, moderate certainty in the evidence).*
- DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members or unsupervised treatment (Conditional recommendation, very low certainty in the evidence).*
- Video observed treatment (VOT) may replace DOT when the video communication technology is available and it can be appropriately organized and operated by health-care providers and patients (Conditional recommendation, very low certainty in the evidence).*

BENEFITS OF VIDEO OBSERVED TREATMENT

- VOT is highly accurate and provides reliable evidence that medications were swallowed
- Doses are recorded wherever and whenever they are taken
- VOT provides patients greater autonomy and privacy compared to DOT, thereby reducing TB stigma
- VOT is patient-centered and increases communication with providers
- Providers spend less time observing adherent patients, giving them more time to support patients who require more attention
- Adherence data is used to identify poorly adherent patients, individualize patient education and promote treatment completion
- VDOT is evidence-based and scalable

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As treatment supervision alone is not likely to be sufficient to ensure good TB treatment outcomes, additional treatment adherence interventions need to be provided.”

WHO DS-TB Guidelines, 2017

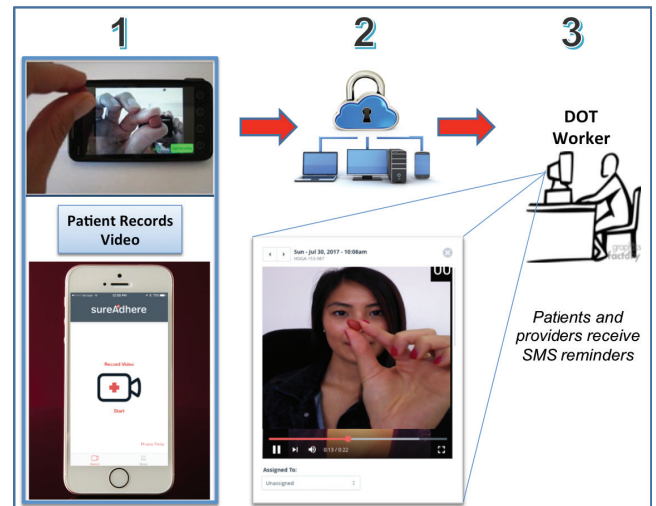
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COMPREHENSIVE APPROACH TO ADHERENCE MONITORING / MANAGEMENT

VOT FOR ADHERENCE ENHANCEMENT & DIFFERENTIATED CARE

- 1 TB medications are provided and taken as usual.
- 2 Providers train patients to use the simple VOT app.
- 3 Patients use a smartphone or tablet to video themselves swallowing each medication dose. The app automatically date/time stamps and encrypts the videos, and uploads them to a secure server using cellular or WiFi networks. If service is unavailable, videos are securely stored on the device until a connection is made, then automatically uploaded and deleted to save memory and ensure privacy.
- 4 Providers efficiently view videos through a password-protected, web-based patient dashboard and track their patients' adherence. Providers immediately know who missed doses and who needs support.



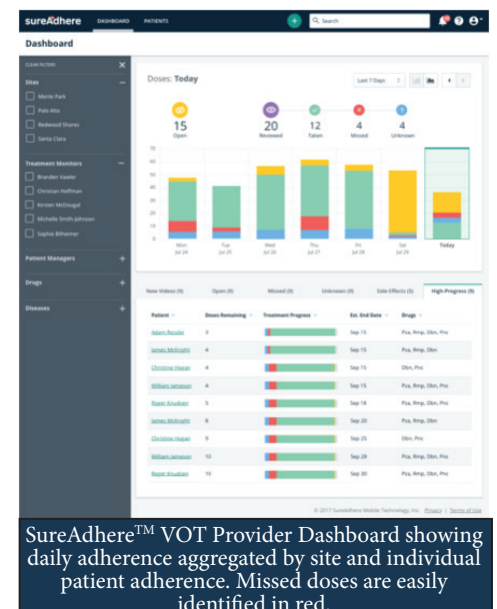
SureAdhere™ VOT: AN EVIDENCE-BASED, PATIENT-CENTERED SOLUTION

Developed and evaluated with funding from federal, state and private grants by researchers at the University of California San Diego¹¹ and healthcare providers in the U.S., U.K., Mexico, and Vietnam, VOT is evidence-based and user-informed. SureAdhere™ VOT (www.sureadhere.com) is a system that gives providers the same high level of assurance that patients swallowed their medications as in-person DOT, while eliminating the burden of travel, time and limiting when doses can be taken. This highly secure, customizable system is designed for public- and private-sector providers to monitor TB caseloads ranging from a single patient to a national program. Using SureAdhere's web-based graphical interface, providers can efficiently monitor treatment status for all of their TB patients' throughout treatment; **when adherence slips, providers know when to increase support for those patients.** Analytics using data captured in the system provide powerful tools for program managers and policy makers.

By 2016, 378 U.S. and 30 Mexican TB patients used VOT in health department pilot studies for a mean of 5.5 months (range: 1-13) with ages ranging from 18 to 87 years and half having less than a high school education. The average number of expected doses observed was 81%-96% across study sites which was comparable or higher than patients using DOT alone. Most patients reported that VOT was "very easy to use", more confidential than DOT, preferred over DOT, and recommended over DOT to other TB patients. TB program staff reported that VOT was feasible, took less time per patient and cost less than DOT. No differences were observed between urban versus rural or U.S. versus Mexican sites.

SureAdhere™ VOT technological features include:

- Meets or exceeds tough U.S. (HIPAA) and European (GDPR) medical data privacy standards
- Fast, simple set-up: After downloading the free VOT app to an Android and iOS smartphone or tablet, and registering the device from any computer internet browser, patients can begin sending videos
- Uses cellular and WiFi networks to maximize coverage and minimize data charges
- Videos stored on device until upload to server is verified, so doses can be taken with or without a signal
- Video upload process is fully automated to prevent user error or tampering
- Medications can be dispensed from pill bottles, blister packs or digital monitoring systems such as evriMED®
- Supports SMS and email dose reminder messages
- Supports split and intermittent dosing schedules
- Tracks reported and/or observed side-effects
- Accumulated adherence data exportable at the patient and program level for medical records, surveillance reports, and research
- User friendly graphical dashboards make individual and program level monitoring quick and easy
- Works in consort with in-person DOT, video conferencing, SAT, digital monitors, and other systems to document the status of every dose



PROGRAMMATIC GUIDANCE

- Hardware needs: Apple iOS (ver 8.4 or higher) or Android (ver 2.3.5 or higher) smartphone or tablet to record videos, and a laptop, desktop or tablet computer to view videos and track adherence.
- The SureAdhere VOT app is free to download from the Apple App Store or Google Play Store. Providers pay an affordable monthly per-patient fee to use the website and a nominal training and set-up charge, which are set to accommodate both high- and low-burden TB program budgets. Special pricing available for TB REACH pilot studies (~\$15-\$30/patient/month) and greater discounts for high-burden NTPs (~\$3-\$4/patient/month US) based on volume.
- Patient and staff training materials are provided and free troubleshooting help is available.
- Contact Kelly Collins (CEO) Kelly.Collins@sureadhere.com, phone +1 775-343-5302 or Lisa Skow (Customer Relations Director) Lisa.Skow@sureadhere.com to schedule a demo. Visit our website www.sureadhere.com.