

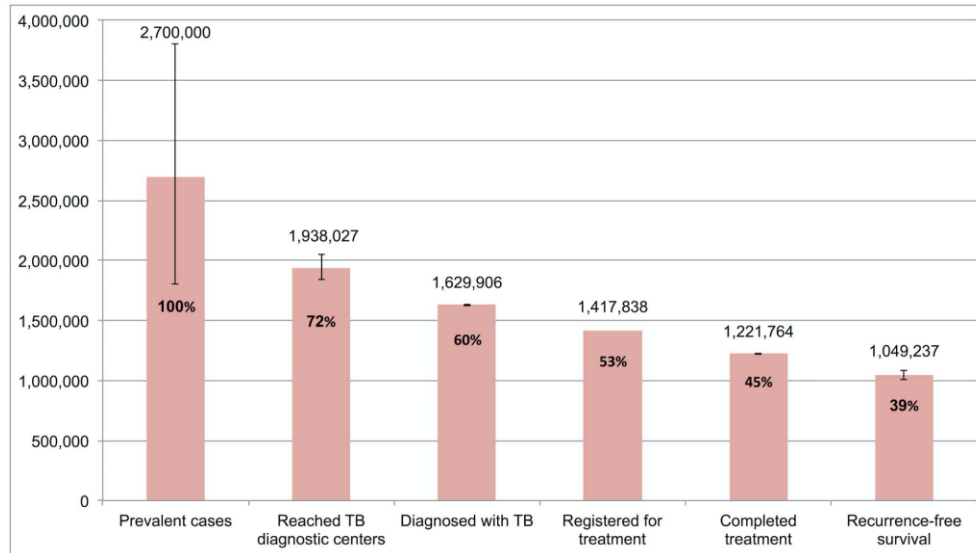
Tackling TB In The Time of COVID-19

Digital Adherence Technologies and Other “Ready-Now” Tools To Facilitate More Differentiated and More Virtual Care For Persons Affected By TB

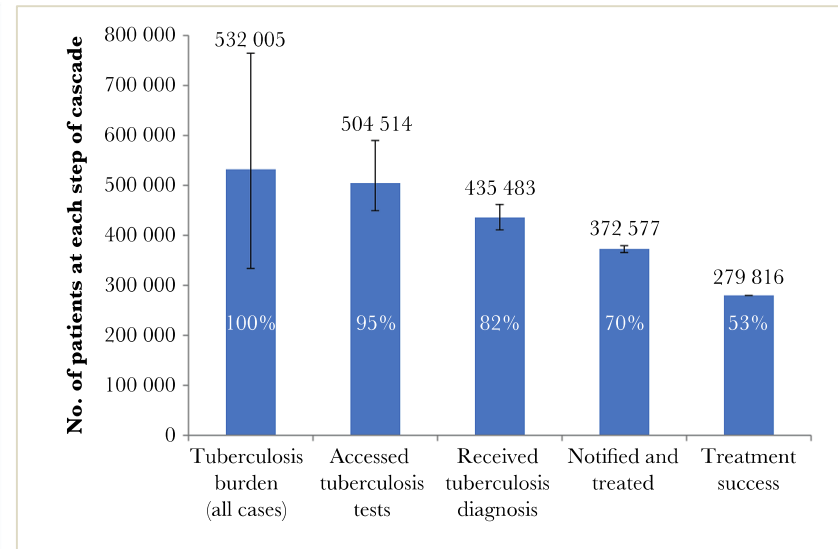
TB IS A TREATABLE AND CURABLE DISEASE, AND YET . . .

In Many High Burden Regions Health Outcomes Remain Suboptimal

All Forms of TB – RNTCP in India

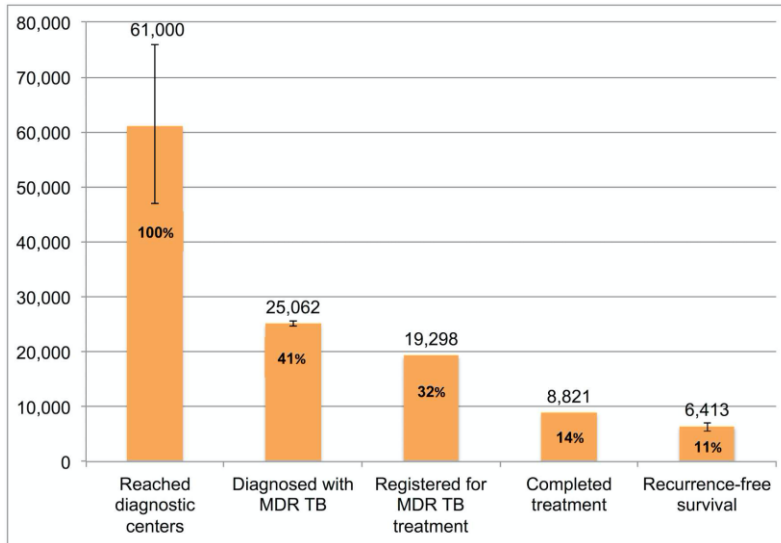


All Forms of TB – South Africa

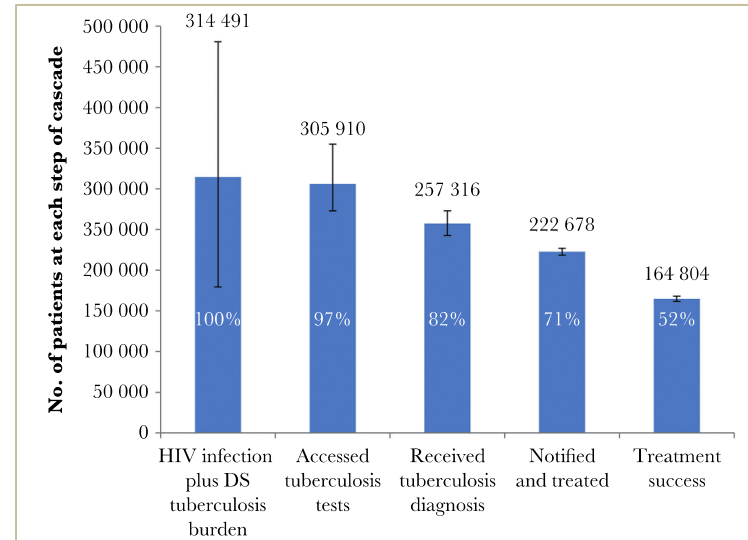


FOR MDR-TB AND TB/HIV-AFFECTED PEOPLE, THE SITUATION IS EVEN WORSE

MDR-TB Patients – RNTCP in India



TB/HIV Patients – South Africa



■ AND COVID-19 HAS MADE THINGS WORSE*

- Fewer people tested and treated for TB
 - An 18% reduction in 2020 compared to 2019
- Fewer people treated for MDR-TB and for XDR-TB
 - Persons on MDR-TB treatment declined by 19%
 - Persons on XDR-TB treatment declined by 37%
- Fewer HIV-positive TB patients treated for HIV and TB
 - Persons on ARV and TB treatment declined by 16%

Overall, Around 1,000,000 Fewer Persons Affected By TB Were Treated In 2020 Compared To 2019

PARADOXICALLY, COVID-19 HAS ACCELERATED THE SCALED ADOPTION OF SOME OF THESE NEW TOOLS

- Care for persons affected by TB was already moving away from pure facility-based care (e.g., DOT to SAT). Health facility access challenges during COVID-19 have accelerated that “medication custody” shift.
- Health facility access challenges also have forced TB programs to rely on alternative options, such as digital adherence and tele-health technologies, to bring required TB services to the people and communities affected by TB.

“COVID-19 has catalyzed a multitude of innovations across all three diseases, such as multi-month dispensing of TB and HIV drugs; using digital tools to monitor TB treatment or enhance prevention interventions; and introducing patient-centered diagnostic approaches, such as co-testing for HIV, TB and COVID-19. Many of these innovations will outlast the crisis and strengthen our fight against HIV, TB and malaria.”

*Results Report 2021, The Global Fund,
Letter From The Executive Director*



ADHERENCE TO TB TREATMENT IS ESSENTIAL

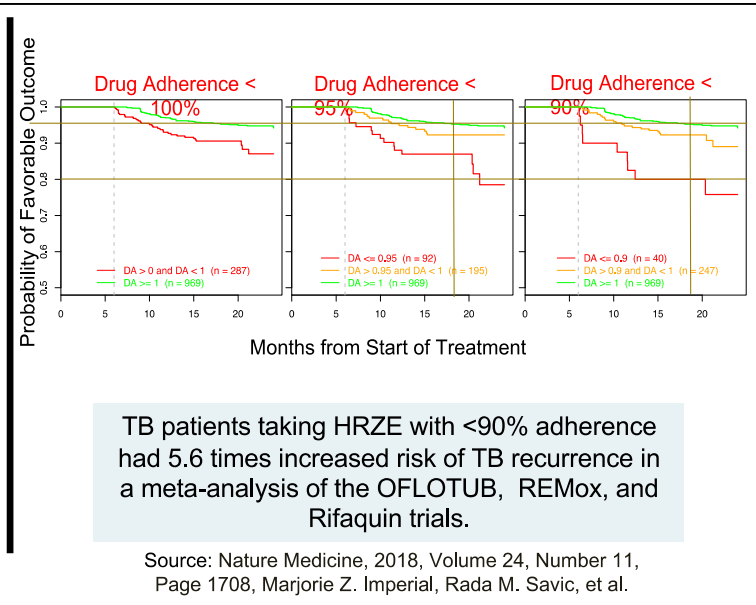
We Also Know That Baseline Adherence Is Poor

- Adherence Is A Multi-Factor Behavioral Issue That Changes Over Time
- Some of The Reasons for Poor Adherence:
 - Long, complicated regimens,
 - Dosing confusion,
 - Side effects,
 - DOT, which is:
 - burdensome on patients
 - inconsistent with patient lifestyle
 - stigmatizing

Severity of non-adherence (in patients who "completed treatment")	TB recurrence rate, 18 months after completing treatment
"Regular" adherence (Complete treatment within 8 months)	9%
"Irregular" adherence (Complete within 10 months)	15%
"Very irregular" adherence (Complete treatment within 12 months)	25%

Study of 534 smear + patients in India found a strong relationship between adherence and post-treatment TB recurrence.

Source: Thomas et al. Int J TB Lung Dis 2005; 9(5): 556-61⁶



There Is Now Real Hope For Better, Shorter Regimens

In The Interim, We've Developed Tools To Improve Treatment Outcomes By Mitigating **THESE** Challenges To Treatment Adherence

INTEGRATED DIGITAL ADHERENCE TECHNOLOGIES



Hub

Unified platform with many options for
treatment support

Support for Tuberculosis, HIV, COVID, and mental health in various settings



Everwell

sureAdhere

wisepill



Three Independent Entities Have Collaborated to Create One Integrated System Providing Technology **CHOICES** To Patients and Providers



99DOTs: Uses augmented packaging to reveal codes as a person takes their medication. Users report their dose adherence through a toll-free call or SMS.



VOT/ VDOT: Video-observed therapy allows for people to share videos of them taking their medication. Nurses or healthcare workers can review the videos to understand adherence.



evriMED/ MERM/ Smart Pillboxes: All these terms refer to an electronic pillbox which holds medications in a box with reminders and alerts. When the box is opened, the device sends a signal reporting adherence.

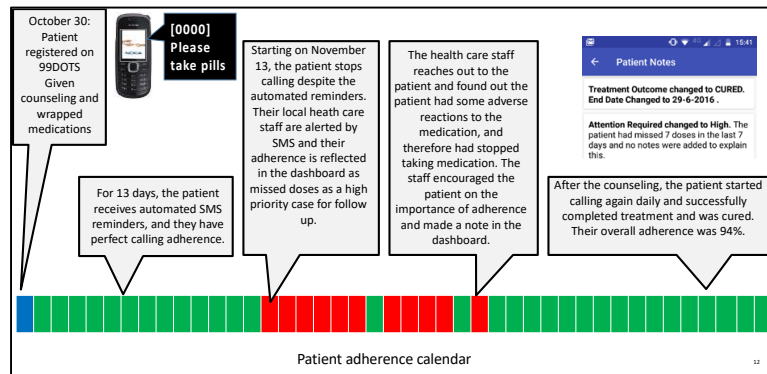
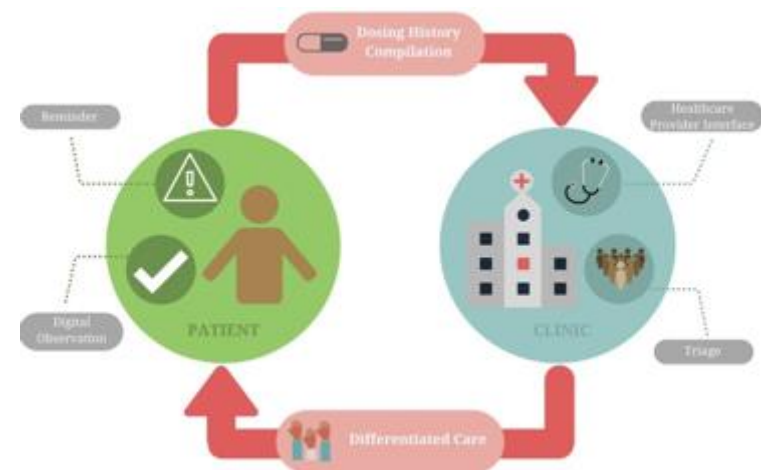


The Everwell Hub: An open-source digital platform that allows providers to register patients and allocate them to any of the three DATs using a web-based dashboard, or Android mobile application. Behind secure logins, providers can also review historical adherence, task lists, and other data.



THE ARCADY GROUP

DAT – TOWARD DIFFERENTIATED AND VIRTUAL CARE

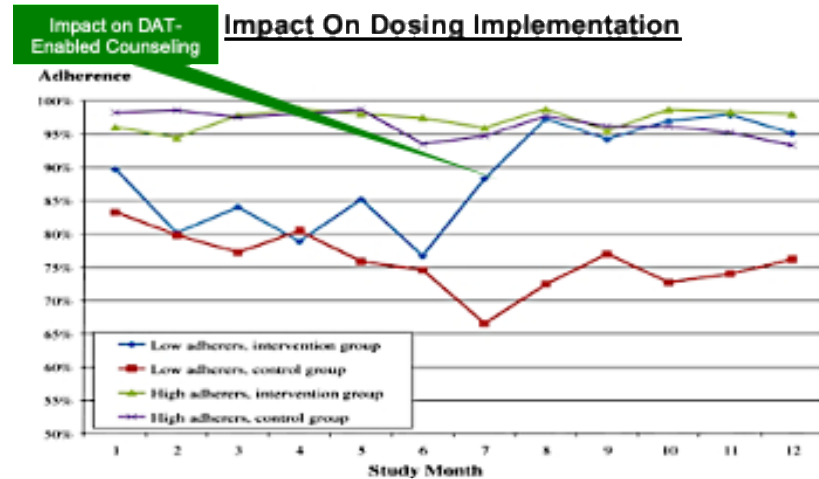


DAT-Enabled Differentiated Care – How It Works:

1. DATs provide self-administering patients with reminders or other **dosing assistance** – medication organizers, pictograms, labels
2. DATs **electronically observe/verify daily dosing** and deliver detailed dosing histories to health systems
3. Applying evidence-based escalation protocols, dosing histories are used to **triage patients** and identify patients who are problematically non-adherent
4. Those non-adherers are **prioritized for engagement** by providers to understand and to address reasons (side effects, refill required, asymptomatic) for poor adherence

WHY THIS APPROACH?

- **Low patient burden** -- Patients are left alone unless they are demonstrably having adherence issues
- **Transparent** -- Both patients and providers can see the patient's dosing history – promoting trust and transparency
- **Just Another “Vital Sign”** – like BP, weight
- **Behavioral Insights** -- Dosing histories highlight specific non-adherence patterns unique to each patient
- **Enables/Informs Patient-Provider Discussions:**
 - of the specific adherence challenges each patient is experiencing,
 - of specific steps the patient can take to address their specific adherence challenges
- **It's WHO Approved -- Based On Favorable Results from A Range Of Trials Conducted In US, EU, and High Burden Regions**



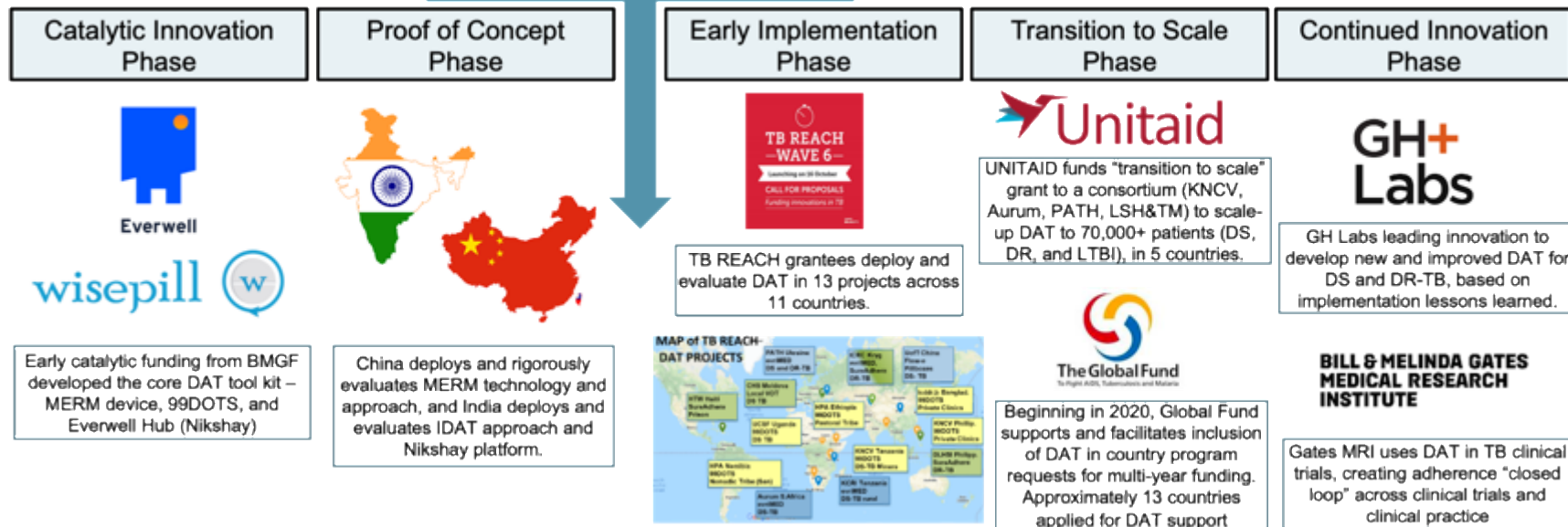
"... a simple intervention involving monthly adherence counseling based on DAT feedback significantly improved mean adherence among Chinese ART patients. **We found an impact on adherence that was both very high — above the 95% threshold — and sustained, with mean adherence above 95% throughout the 6-month intervention period.**"
Sabin et al. AIDS Behavior, 2010.



PROGRESS MADE THROUGH SPRING, 2020



Supportive Guidance for DAT from WHO Issued



Over 400,000 People Using DATs In Clinical Trials And Clinical Practice Across More Than 25 Countries

KEY INSIGHTS, AND HOW COVID-19 HAS “HELPED”

- DATs are relatively affordable, readily scalable, and well accepted by patients and providers
- If health care professionals don't engage, patients **disengage**
- Escalation-based task lists generated for each provider facilitate patient engagement and follow-up
- Patients see their DAT as a connection with their provider and want the DAT tools to facilitate and leverage that connection:
 - E-prescribing and refill
 - Questions about facility locations, hours of operation, etc.
 - Questions about dosing
 - Questions about side effects
 - Questions about direct benefit transfer
 - Desire for more “virtual care”

Because facility access has been challenging during COVID-19, there has been tremendous focus on enhancements that facilitate “at home” and more “virtual care”

The DAT toolkit has evolved to support that model



RECENT PROGRESS IN PATIENT ENGAGEMENT/VIRTUAL CARE

Everwell Hub partner application to support better citizen and patient engagement, review and manually indicate adherence, and **reach out to providers for virtual care.**



Hub Health Companion

Everwell Health Solutions Pvt. Ltd. Medical



Add to Wishlist

Install

India's Nikshay partner application to deliver health information, **identify symptoms, locate facilities**, review and indicate adherence and **view direct benefit payments.**



TB Aarogya Sathi

National TB Elimination Program (NTEP) Medical



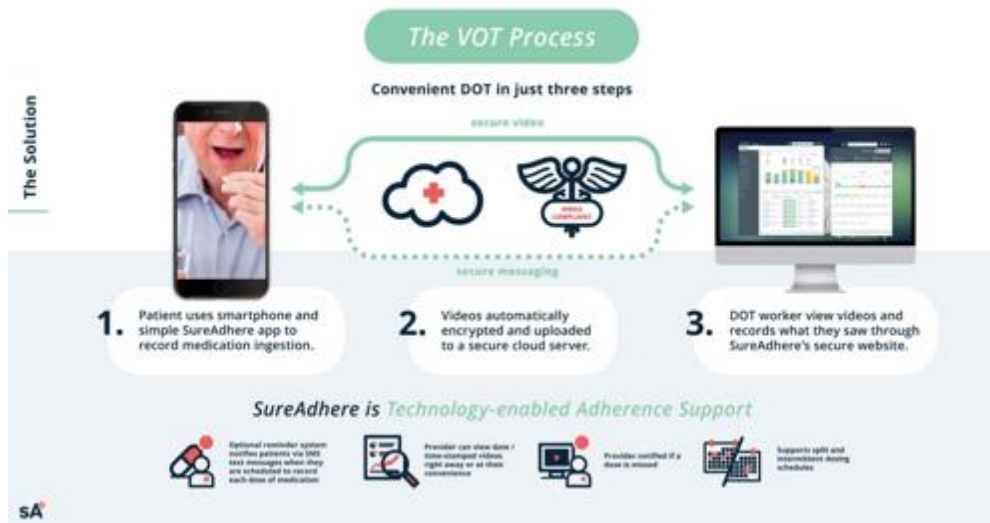
Add to Wishlist

★★★★★ 13

Installs
50,000+



VIDEO OBSERVATION TECHNOLOGY: NO LONGER JUST DOSE MONITORING



HOW ASYNCHRONOUS VOT WORKS

Some Of The Real-World Advantages of An Asynchronous Approach:

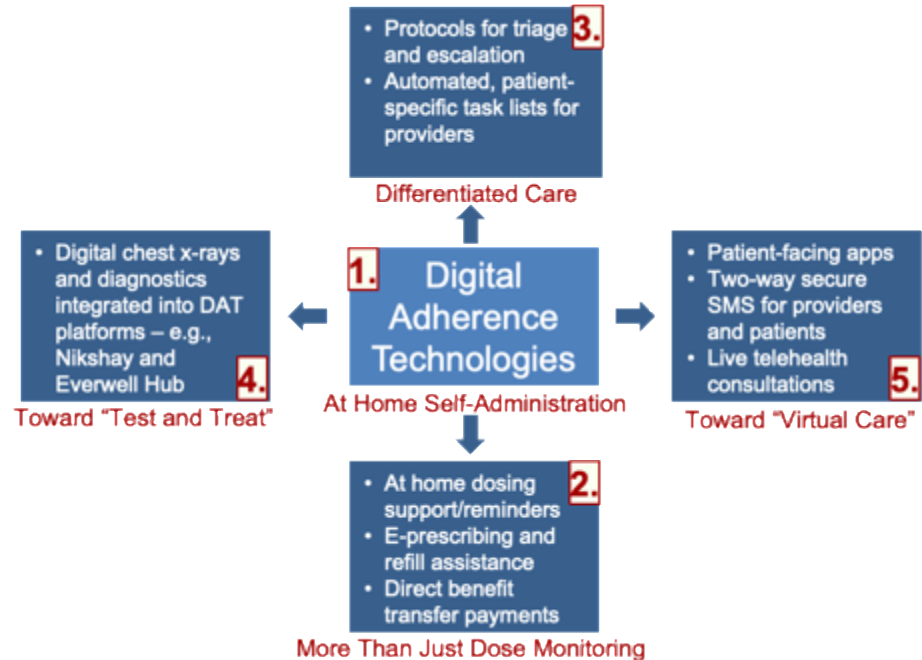
- 'Check-in' videos may be recorded according to personal schedules;
- Videos can be recorded with or without a network signal;
- Video upload process is fully automated to prevent mistakes or tampering;
- Provider may view videos when convenient and follow up as required.

- SureAdhere's VOT can operate as a stand-alone system or can be part of an "integrated" DAT approach via the Everwell Hub
- SureAdhere (and other VOT solutions) can be used in clinical trial as well as clinical practice-programmatic settings:
 - For clinical trials, these technologies provide complex regimen support and pill-by-pill dosing histories
- In clinical practice-programmatic setting and driven by the facility access challenges of COVID-19, several "virtual care" features have been added:
 - **Two-way secure SMS between provider and patients** facilitates engagement around issues such as dosing confusion and side effects,
 - Soon, SureAdhere's VOT will enable **Zoom interaction to enable "live" teleconsultation** if and as required



CONCLUSION – COVID HAS ACCELERATED A SHIFT TOWARD LARGELY “AT HOME CARE” FOR PERSONS AFFECTED BY TB

- COVID-19 has created unprecedented willingness to consider changes in traditional facility-based care and tools
- During this time, existing digital adherence technologies have been leveraged to move toward a more “at home care” model:
 - **Step 1** – self-administering patients remotely monitored
 - **Step 2** – self-administering patients receive dosing and other support
 - **Step 3** -- dose history-informed differentiated care
 - **Step 4** – integrated diagnostics move us toward a “test and treat” model
 - **Step 5** – patient-provider engagement moves toward more virtual care



COVID-19 Has Moved TB Care To More Of An “At Home” Model. The Toolkit Has Evolved To Support That Model. Let’s Not Go Back To Largely Facility-Based Care!

* This More “Virtual Care” Toolkit Is Being (i) Widely Used In TB Drug Development Trials, (ii) Scaled Up In Programmatic Settings In India, (iii) Rigorously Evaluated by ASCENT, and (iv) Demonstrated in 10-12 Other Global Fund Countries.

