Stop TB Partnership

TECHNOLOGIES FOR IMPROVING TB MEDICATION ADHERENCE & TREATMENT OUTCOMES

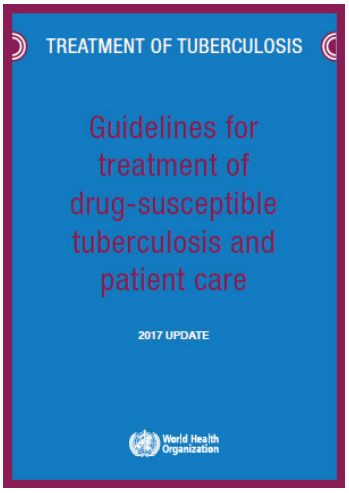
BACKGROUND

- 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 guidelines[9]: http://bit.ly/2pRx8yu

- WHO recommends the use of additional adherence interventions to ensure good treatment outcomes.
- Digital medication monitors have been approved for use as a treatment adherence intervention and may be offered to patients on TB treatment or to healthcare providers.



Recommendations

2.1.1 Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment (Strong recommendation, moderate certainty in the evidence)

2.1.2 A package of treatment adherence interventions[25] may be offered to patients on TB treatment in conjunction with the selection of a suitable treatment administration option[26] (Conditional recommendation, low certainty in the evidence)

2.1.3 One or more of the following treatment adherence interventions (complementary and not mutually exclusive) may be offered to patients on TB treatment or to health-care providers:

a) tracers[27] and/or digital medication monitor[28] (Conditional recommendation, very low certainty in the evidence)

b) material support[29] to patient (Conditional recommendation, moderate certainty in the evidence)

c) psychological support[30] to patient (Conditional recommendation, low certainty in the evidence)

d) staff education[31] (Conditional recommendation, low certainty in the evidence).

> "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**

BENEFITS OF DIGITAL MEDICATION MONITORS

- WHO has concluded that adherence interventions significantly improve treatment outcomes for both DOT and SAT patients.
- Digital medication monitors are a proven-effective adherence intervention, delivering reminders and enabling enhanced counseling and differentiated care.[10]
- Digital medication monitors are highly patient-centric and low patient burden. They permit remote, electronic observation of medication taking by self-administering patients.
- Digital medication monitors should save health system time and money by focusing provider time on demonstrably poor adherers.
- In large, cluster-randomized trials in China, digital medication monitors were shown to significantly improve medication adherence and be well accepted by both patients and providers.[10]

> "The evidence also showed that when patients receiving treatment adherence interventions (e.g. different combinations of patient education, staff education, material support, psychological support, tracer and use of medication monitor) in conjunction with DOT or SAT, the treatment outcomes were significantly improved compared to DOT or SAT alone."
>
> **WHO DS-TB Guidelines, 2017**

REFERENCES

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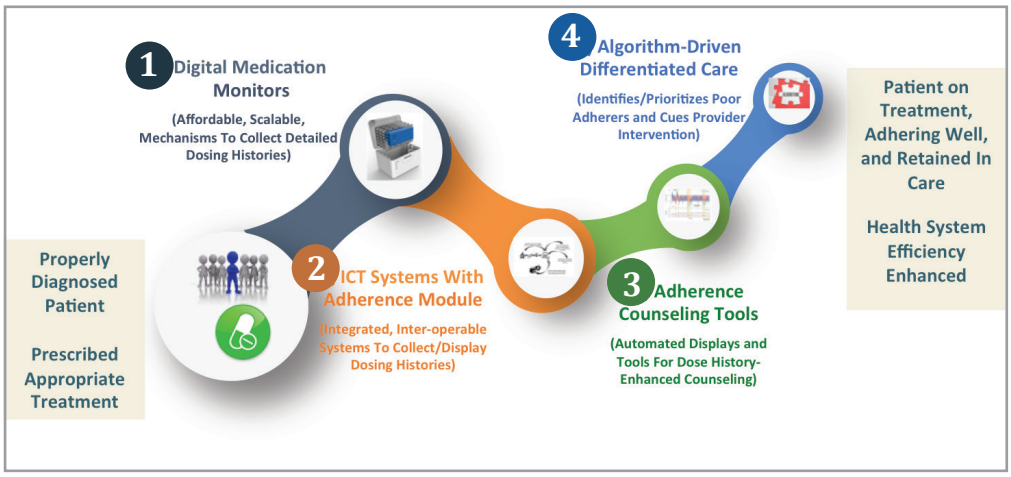
10.Liu X, Lewis JJ, Zhang H, Lu W, Zhang S, Zheng G, et al. Effectiveness of electronic reminders to improve medication adherence in tuberculosis patients: a cluster-randomised trial PLoS Med. 2015;12(9):e1001876.

COMPREHENSIVE APPROACH TO ADHERENCE MONITORING / MANAGEMENT
DIGITAL MEDICATION MONITORS FOR ADHERENCE ENHANCEMENT & DIFFERENTIATED CARE

1. TB medications are provided in a digital monitor box, which provides visual and audible dosing and refill reminders.
2. The monitors are integrated with ICT systems to deliver dosing histories to providers and health systems.
3. Dosing histories are used to tailor counseling based on a patient's specific medication-taking behavior.
4. Dosing histories are used to triage patients -- automatically identifying poor adherers for more intensive patient management.



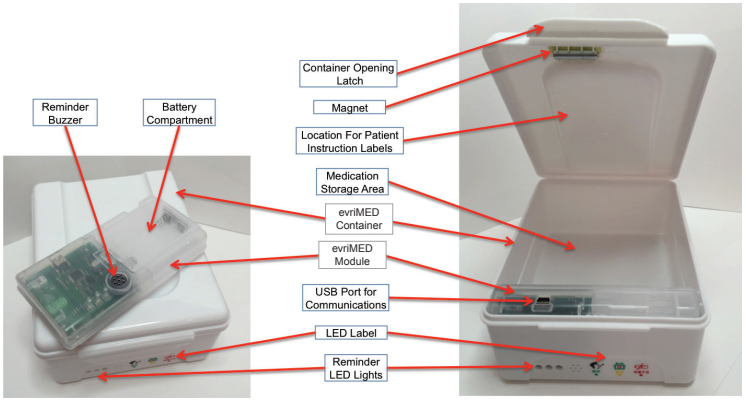
THE RESULT: More patients properly adhering and retained in care. Enhanced health system efficiency.

evriMED®: AN AVAILABLE, SCALABLE SOLUTION

Developed with funding from the Bill & Melinda Gates Foundation, and currently in use in clinical trials and in clinical practice in public and private sectors in high-burden regions, evriMED is an affordable, scalable, TB-appropriate digital medication monitor. Using a unique, modular approach that permits customization of the container for DS-TB, MDR-TB and TB-HIV patients, the evriMED device is a highly-accurate, low patient burden, adherence monitoring technology. www.evrimed.com

The salient technological features include:

- Suitable for use with blister packaged TB medications.
- Modular construction to reduce cost and permit container customization.
- Significant billboard space to communicate to patients and allow for region-specific customisation.
- Simple data acquisition using a magnetic sensor to detect container opening.
- Programmable Alert Mechanisms consisting of:
  - Three (3) LED Lights: Green - Dose Alert; Yellow – Refill; Red - Low Battery
  - An Audible tone to indicate that a dose is due
- Two versions available: basic (monthly data transfer via USB) and real-time (using highly available and affordable 2G capability).
- Affordable and reusable -- less than 10 USD per patient based on conservative re-use assumptions.
- Very low patient burden -- no recharging required.
- Easily integrated into existing open source and national health data systems.
- The evriMED device has been seamlessly integrated with the 99DOTS back-end system, so the devices can be used interchangeably depending on patient needs and phone access. For both devices, patient initiation is simple and representation of adherence data is identical (see dashboard at right).



The evriMED technology provides highly patient-centric adherence monitoring, reminders of dosing and refill, supports enhanced adherence counseling, and enables differentiated care to drive health-system efficiency and improve treatment outcomes.

A screen shot of the adherence dashboard clinicians see. Each line represents a patient, and each red square indicates a missed dose.

PROGRAMMATIC GUIDANCE

- Digital medication monitors such as Wisepill Technologies' evriMED devices, provide affordable, scalable, low patient burden electronic assistance to, and observation of, self-administering patients. They are approved for use by WHO and are available for purchase as, in essence, a "pillbox" for TB medications (DS or MDR-TB).
- evriMED devices have been extensively tested and are in use at scale in India and China – for both DS and MDR-TB patients. They are supported by a range of web monitoring/adherence ICT solutions also provided by Wisepill. Moreover, evriMED devices are fully integrated with and can be supported by the 99DOTS adherence platform – which is open source and highly affordable.
- To procure evriMED devices, contact James Deck with Wisepill Technologies at james@wisepill.com. Please be aware that lead times are generally 14-16 weeks and minimum order quantities are 2,000 units. Approximate pricing (excluding batteries and shipping costs) for evriMED500® (non-"real-time") is US$ 14-16, depending on the type of container desired. Approximate pricing for evriMED1000® ("real-time) (again excluding batteries and shipping costs) is US$ 21-23, depending on container. NOTE: these devices are highly reusable, therefore per patient costs are much lower. Supporting web monitoring/adherence system support from Wisepill or from the 99DOTS platform is approximately US$ $0.50 per month, per device.