Treating Patient, Not Disease: People-Centered Approach

7th TB Symposium – Ministry of Health of the Kyrgyz Republic and Médecins Sans Frontières

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Patient-centred care: the heart of the management of TB

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**Preliminary results of the STREAM 1 trial presented at UNION meeting in Mexico, October 2017**

<table>
<thead>
<tr>
<th></th>
<th>Study Arm</th>
<th>Control arm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Total assessed</td>
<td>210</td>
<td>100.0</td>
</tr>
<tr>
<td>Favourable</td>
<td>164</td>
<td><strong>78.1</strong></td>
</tr>
<tr>
<td>Unfavourable</td>
<td>46</td>
<td>21.9</td>
</tr>
<tr>
<td><strong>Difference in response (crude)</strong></td>
<td><strong>2.5%</strong></td>
<td></td>
</tr>
<tr>
<td><strong>95% confidence interval</strong></td>
<td>-6.9%, 11.8%</td>
<td></td>
</tr>
<tr>
<td><strong>Difference in response (standardised)</strong></td>
<td><strong>2.1%</strong></td>
<td></td>
</tr>
<tr>
<td><strong>95% confidence interval</strong></td>
<td>-6.9%, 11.2%</td>
<td></td>
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</table>
Treatment outcomes at 24 months, Trial 213 – Delamanid trial results presented at UNION meeting in Mexico

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Delamanid + OBR</th>
<th>Placebo + OBR</th>
<th>Total</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>Cured</td>
<td>264</td>
<td>78%</td>
<td>130</td>
</tr>
<tr>
<td>Completed</td>
<td>12</td>
<td>4%</td>
<td>8</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>13</td>
<td>4%</td>
<td>6</td>
</tr>
<tr>
<td>Lost to follow up</td>
<td>36</td>
<td>11%</td>
<td>20</td>
</tr>
<tr>
<td>Died</td>
<td>14</td>
<td>4%</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>339</td>
<td></td>
<td>170</td>
</tr>
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- there was an equal likelihood of serious TEAE in the delamanid and placebo arms (26.1% vs 27.6% respectively), of discontinuations due to adverse events (2.3% vs 1.8%) and hepatotoxicity (6.5% vs 7.1%). The principal cardiotoxicity signal from the initial Phase IIb trials was reproduced in the Phase III with QT-interval prolongation being more common in delamanid than the placebo group, albeit overall infrequent (3.5% vs 1.2% respectively).
Practical question

What was the common element in the four trial arms which report 80% MDRT-TB treatment success?
Most often neglected finding of MDR-TB trials on delamanid and shorter MDR-TB regimen

80% treatment success is reachable when a properly designed MDR-TB regimen is delivered with a patient-centred care approach
TB treatment AND patient-centred care are to work hand-in-hand!
Patient-centred care IS not the cherry on top of the cake.
Patient-centred care is the heart of the cake.
# CHAPTER 12

**Patient-centred care, social support and adherence to treatment**

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Treatment adherence package

Recommendation 1

A package of treatment adherence interventions* may be offered for patients on TB treatment in conjunction with the selection of a suitable treatment administration option.

Remarks:

- **Treatment adherence interventions** include social support, communication with patient, medication monitor, and staff education.

- **Treatment administration options** include DOT, VOT, non-daily DOT (e.g. not every dose supervised treatment, weekly or a few times per week supervision), or unsupervised treatment.

- The interventions should be selected on the basis of the assessment of individual patient's needs, provider's resources and conditions for implementation.
Informational and educational support

Recommendation 2

Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment

(Strong recommendation, moderate certainty of evidence)
Treatment adherence interventions

Recommendation 3

One or more of the following treatment adherence interventions may be offered to patients on TB treatment or to health-care providers:

- **material support to patient** (e.g. meals, food baskets, food supplements, food vouchers, transport subsidies, living allowance, housing incentives, or financial bonus)

- **psychological support to patient** (e.g. counselling sessions or peer-group support)

- **tracers** (e.g. SMS, telephone calls, or home visit) or digital medication monitor

- **staff education** (adherence education, chart or visual reminder, educational tools and desktop aids for decision-making and reminder)
The following **treatment administration options** may be offered to patients on TB treatment:

- **Community- or home-based directly observed treatment (DOT)** is recommended over health facility-based DOT or unsupervised treatment.

- **DOT administered by trained lay providers or health-care workers** is recommended over DOT administered by family members or unsupervised treatment.

- **Video observed treatment (VOT) can replace DOT** when the video communication technology is available and can be appropriately organized and operated by health-care providers and patients.
Recommendation

A decentralized model of care is recommended over a centralized model for patients on MDR-TB treatment.
VOT for TB

Electronic medication monitors

The SIMpill® Medication Adherence System is a medication adherence solution that assists patients and/or caregivers in making sure that medication is taken as prescribed.

The SIMpill® Medication Adherence System will monitor the patient's medication schedule and intake of medication and remind patients and caregivers as necessary by sending a text message to the patient and/or caregivers mobile phone if the patient does not take their medication as prescribed. All monitoring and reminders happen in real-time.

The SIMpill® SMART
Digital health for TB

PILLARS AND COMPONENTS

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION
   A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
   B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
   C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
   D. Preventive treatment of persons at high risk, and vaccination against tuberculosis

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS
   A. Political commitment with adequate resources for tuberculosis care and prevention
   B. Engagement of communities, civil society organizations, and public and private care providers
   C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
   D. Social protection, poverty alleviation and actions on other determinants of tuberculosis

3. INTENSIFIED RESEARCH AND INNOVATION
   A. Discovery, development and rapid uptake of new tools, interventions and strategies
   B. Research to optimize implementation and impact, and promote innovations

- Electronic tools to help stock management and procurement
- SMS communication
- Electronic notification of TB cases
- Mobile phone credit as enabler
- Automated laboratory results
- VOT
- eLearning for staff
- eLearning for patients
- Digital unique identifier
- Add-on hardware to smartphones to permit clinical measurement
- Mobile devices as resources for data collection
Direct relevance of digital health to management of MDR-TB

- **Patient care** (eg VOT in Belarus to support adherence)

- **Surveillance** (eg, electronic TB monitoring, aDSM)

- **Programme management** (eg, 2\(^{nd}\) line drug management, «connected diagnostics»)

- **eLearning** (eg, PMDT training tools in electronic format, clinical decision support tools; WHO/ERS TB consilium)
Some ideas about how to choose and implement digital tools in common use to help patients complete their treatment

Focused on SMS, medication event monitoring systems (MEMS) and video-supported treatment (VOT)

Evidence emerging

Technologies in constant flux
Patient-centred care: the heart of the management of TB
Checklist to verify if your MDR-TB is patient-centred care:

- Ethics and human rights protected?
- Access to all recommended TB diagnostics and medicines?
- Patient counselling?
- Psychological support?
- Material support?
- Social protection?
- aDSM?
- Infection control?
- Protection from stigma
- Palliative and end-of-life care?
- Care to caregivers?