Decentralized Management of MDR TB

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South Africa

- Population 2013 - 53 million
- EThekwini Population - 3 442 361

HIGH TB BURDEN, HIGH HIV BURDEN, HIGH MDR-TB BURDEN
Why is TB managed differently from other chronic diseases?

- Tuberculosis (TB) remains one of the world’s deadliest communicable diseases.
- MDR-TB is a global health security risk and carries grave consequences for those affected.
- WHO therefore called for MDR-TB to be addressed as a public health crisis in 2013.
Burden of Disease (WHO Report 2014)

• In 2013, ± 9.0 million people developed TB
• ± 1.5 million – deaths
• 360 000 - HIV-positive.
• Among patients with pulmonary TB who were notified in 2013, ± 300 000 (range: 230 000–380 000) had MDR-TB.
Burden of Disease (WHO Report 2014)

- Of the MDR/RR-TB cases reported globally in 2013, almost 80% were from the European Region (45 136), India (35 385) and South Africa (26 023).
Extensively drug-resistant TB (XDR-TB)

- Reported by 100 countries.
- On average, an estimated 9.0% (95% CI: 6.5–11.5%) of people with MDR-TB have XDR-TB.
Reported cases of RR-/MDR-TB in SA - 2013

<table>
<thead>
<tr>
<th></th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Cases tested for RR-/MDR-TB</td>
<td>258 401</td>
</tr>
<tr>
<td>Laboratory-confirmed RR-/MDR-TB cases</td>
<td>26 023</td>
</tr>
<tr>
<td>Patients started on MDR-TB treatment</td>
<td>10 663 (&lt;50%)</td>
</tr>
<tr>
<td>Category</td>
<td>Success Rate</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>New and relapse cases registered in 2012</td>
<td>77</td>
</tr>
<tr>
<td>Previously treated cases, excluding relapse, registered in 2012</td>
<td>64</td>
</tr>
<tr>
<td>HIV-positive TB cases, all types, registered in 2012</td>
<td>74</td>
</tr>
<tr>
<td>RR-/MDR-TB cases started on second-line treatment in 2011</td>
<td>45</td>
</tr>
<tr>
<td>XDR-TB cases started on second-line treatment in 2011</td>
<td>15</td>
</tr>
</tbody>
</table>
Models of care for MDR-TB Recommended by WHO:

- Ambulatory or community based care

- Hospital-based models of care.

From centralized hospital-based services
to decentralized ambulatory care
FIVE PRIORITY ACTIONS TO ADDRESS CRISIS

1. Prevent the development of drug resistance through high quality treatment of drug-Susceptible TB

2. Expand rapid testing and detection of drug-resistant TB cases

3. Provide immediate access to effective treatment and proper care

4. Prevent transmission through infection control

5. Increase political commitment with financing
The Picture at KDHC

- $\pm 2500$ patients managed as outpatients
- $\pm 250$ new inpatients per month
- Waiting times for treatment initiation = 10 – 42 days
- Staff constraints – doctors, nurses, pharmacists
- Infrastructure constraints
Strategy – Policy Implementation

Multi-Drug Resistant Tuberculosis: A Policy Framework on Decentralized and Deinstitutionalized Management for South Africa, August 2011

TRANSLATING POLICY INTO PRACTICE
Satellite MDR-TB Unit exist to complement bed capacity of decentralised sites. They are essentially transitional and should be capacitated to become decentralised sites. Mobile teams are to be attached to PHC services but operate within the community.

PROVINCE OF KWAZULU-NATAL
Phased in Approach......

- Phase 1: The activation of satellite sites (hospitals and CHCs) to manage stable patients who have completed the injectable phase
  
  (SOP: EThekwini DR TB 1)

- Phase 2: The activation of satellite sites (PHC Clinics).
Phased in Approach......

• **Phase 3:** The **activation of decentralized sites** that will **initiate and manage patients on MDR TB treatment** (not a new approach).

• Upgrading of satellite sites to decentralized sites.
<table>
<thead>
<tr>
<th>District</th>
<th>Decentralized Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>UMkhanyakude</td>
<td>Manguzi</td>
</tr>
<tr>
<td>UMkhanyakude</td>
<td>Hlabisa</td>
</tr>
<tr>
<td>UThungulu</td>
<td>Catherine Booth</td>
</tr>
<tr>
<td>UMzinyathi</td>
<td>Greytown</td>
</tr>
<tr>
<td>UMgungundlovu</td>
<td>Doris Goodwin</td>
</tr>
<tr>
<td>UGu</td>
<td>Murchison</td>
</tr>
<tr>
<td>Sisonke (Harry Gwala)</td>
<td>St. Margaret</td>
</tr>
<tr>
<td>Zululand</td>
<td>Thulasizwe</td>
</tr>
<tr>
<td>Amajuba</td>
<td>Madadeni</td>
</tr>
<tr>
<td>ILembe</td>
<td>Montebello</td>
</tr>
<tr>
<td>UThukela</td>
<td>Estcourt</td>
</tr>
<tr>
<td>EThekwini</td>
<td>**Charles James, **Don McKenzie</td>
</tr>
</tbody>
</table>

**no DR TB Register currently**
Phased in Approach……

Phase 4: NIMDR Treatment
Nurse-initiated MDR-TB treatment will be part of decentralized MDR-TB services and will be phased in.
Continuum of Care of a patient with DR TB

STEP 1: Screening and linkage to care

STEP 2: Diagnosis and treatment initiation

STEP 3: Clinical Management

STEP 4: Pharmacovigilance

STEP 5: Retention in care

STEP 6: Reporting and Recording
Step 1: Screening and Linking To Care

- **Where?** – at every facility (PHC, CHC, Hospital, GP, Private sector, Public sector.
- **How?** Screening questionnaire. Routine care. Gene Xpert - Rifampicin Resistant cases
- **Contact tracing**
- **Linking to care** – aim to initiate DR TB treatment within 5 days of diagnosis.
Linking to care - DR TB treatment initiation

- centralized site (KDHC)
  - Pre – XDR TB, XDR TB, Difficult to treat MDR TB, Paediatrics

- decentralized site (CJM / DM) – EThekwini
  - MDR TB patients
Tools

• **Pre-printed booking form** - To be completed and sent to KDHC by all hospitals, PHC and CHCs. PHC Clinics close to DM and CJM can book directly with them.

• Requires the diagnosing facility to work patient up for treatment initiation and obtain expert opinion.

• Enables us to track the time lag to treatment initiation.
Discussion……

• Are aware of the booking forms?

• Benefits to using the booking form……

• Challenges if any to using the booking forms….

• Challenges if any to working up the patient at the diagnosing facility if any……
Current Situation

• Not all facilities are using the booking form.
• Missing information.
• Delayed time to treatment initiation
• Difficult to track patients.
Step 2: Diagnosis and Treatment Initiation

- Every patient must have their diagnosis confirmed prior to starting treatment.
- 2 Sputum samples must be sent for LPA / DST to confirm resistance patterns before Tx. start.
- This information is needed to ensure appropriate treatment and for programmatic management and is entered into the DR TB register.
- Every patient must be entered into a DR TB register and have a DR TB number allocated to them from an approved site.
- WHO advocates starting standardized DR TB treatment as soon as possible followed by individualized treatment based on DST results, etc.
Clinical work-up prior to treatment initiation (to be done at the diagnosing facility if possible)

- Urine Dipstick, Pregnancy test, Weight
- Chest X Ray
- Audiology
- Assessment of Eyesight
- Examination/Clinical Condition
- HCT/ ART

Is this possible at every facility? If not, make a plan
Laboratory tests (prior to treatment initiation)

- FBC (Hb, platelets, white cell count)
- U & E (Urea and Creatinine, Egfr)
- Liver function tests (Bilirubin, ALT)
- Thyroid function test (TSH)
- Electrolytes (Potassium and sodium)
- HBsAg if HIV+
- 2 sputum samples must be sent for smear, culture and sensitivity before starting drug therapy.

Is this possible at every site? If NOT, what is the plan?
Discussion……..

• Is your site diagnosing patients with DR TB?
• Are you initiating patients on DR TB treatment? If yes, are you sending sputum for testing prior to treatment start. Do you get a DR TB number before treatment start?
• Do you work patients up prior to the appointment date? If not why?
Step 3: Clinical Management

• Help Desk set up at KDHC

• Interdisciplinary team clinical meeting held on Wednesdays at KDHC.

• Mortality and Morbidity meeting held on Fridays.

• Ongoing training
Access to Standardized MDR TB Medicine

Available at all Decentralized sites. Pre-dispensed at KDHC for satellite sites.

- Kanamycin
- Moxifloxacin
- Ethionamide
- Terizidone
- Ethambutol
- Pyrazinamide

CJM / DM order from KDHC. Others have their own budget and order from PPSD.
Access to non-standardized MDR TB Medicine

- Pregnant patients with MDR TB cannot take ethionamide (teratogenic) and Kanamycin (hearing loss to baby)
- Need access to **Capreomycin** (part of XDR TB treatment) and **PAS** (part of pre-XDR and XDR TB treatment).
- **Ethionamide** - To use PAS
- The **section 88 request form** (request to order medicine on a named patient basis) must be used to access medicine.
Access to adjuvant medicine and ARVs

• All facilities should have access to medicine to treat side effects and comorbidities.

• Antiretroviral medicine may be provided by the decentralized site or PHC clinic.

• If patient is being sent to satellite site and collecting ARVs at KDHC, this will be predispensed.

• Ideally ARVs and DR TB medicine should be issued at the same facility.
Access to DR TB medicine as an interim measure until a booking is obtained

- High risk of transmission
- Delays in booking - capacity issues
- Sites that are not approved to initiate treatment can access the meds if they are confident that they can manage the patient.
- Do a booking – if delay of >10 days complete form for interim access to treatment.
Discussion.....

• Does your facility order DR TB medicine even if not an approved decentralized site?

• What are the challenges if any to this strategy of DR TB medicine access?

• What are the benefits of this strategy?
Step 4: Pharmacovigilance

• Overlapping toxicities of DR TB medicine is a huge problem. Compounded by ARV side effects.

• All patients initiated on DR TB medicine must be monitored closely for side effects and adverse drug reactions.

• Adverse effects must be treated aggressively as this will enhance treatment adherence.
Reporting of Adverse Drug Reactions

• It is important for grade 3, 4 or 5 adverse drug reactions to be reported timeously. A special pre-printed adverse drug reaction reporting form has been developed for reporting of adverse drug reactions related to TB medicine.
Grading of ADRs

1 = **MILD**; asymptomatic; intervention not indicated,

2 = **Moderate**; minimal, local or non-invasive intervention indicated;

3 = **Severe** or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL (bathing, dressing/ undressing, feeding self, using the toilet, taking medication AND NOT BEDRIDDEN)
Grading of ADRs

4 = Life-threatening consequences; urgent intervention indicated

5 = DEATH
Action Taken

The suspected drug must be indicated as well as the action taken.

A = DISCONTINUE SUSPECTED DRUG,

B = DECREASED DOSE,

C = ADJUVANT TREATMENT
Patient Outcome

The patient outcome must be reported:

1 = RECOVERING

2 = MONITORING PATIENT

3 = DIED
Assessment of Causality

• The ADR reports must be sent to KDHC Pharmacy and this must be presented at the KDHC clinical meeting.

• Reports must be sent to the MCC and NDOH and reported on DHIS.
Discussion....

• Have you seen patients with grade 3, 4 and 5 ADRs?

• What are the benefits of reporting ADRs?

• How can we ensure that ADRs related to DR TB medicine are reported?
Step 5: Retention in Care

- Non adherence to DRTB treatment and loss to follow up has huge implications for the whole country.
- Retention in care cuts across all steps – from screening and diagnosis to treatment outcomes.
- All facilities must actively engage in this step.
Counselling

• Counsel and educate the patient and family member. This should include information on what MDR- or XDR-TB is, how one is infected, out-patient / in-patient initiation and what to expect.

• Address any patient concerns.

• Verify patient’s physical and work address.

• Enquire about close contacts at home or work and arrange for screening of and testing of all contacts.
Counselling

• Ensure that all details regarding the treatment are communicated to the patient; this will enable the patient to take an informed decision on consent to treatment.

• Provide a checklist of things the patient will need to take with to hospital.

• Make the necessary transport arrangements for the patient and a family member where necessary to the MDR-TB hospital.
DOTS Strategy

• Patient must be linked to a community treatment supporter and a primary healthcare clinic to administer the injectable and monitor treatment adherence daily.
• District TB co-ordinators to assist with linking.
• Patients down referred to satellite sites must also be linked to a treatment supporter.
DOTS Strategy

- Patients who are unable to access a health facility daily should, for the duration of the injectable phase of treatment, be visited daily at home (five times a week) by a mobile team, which should consist of a driver and nurse.

- DOTS supporters may be community caregivers, community DOTS volunteers or family members
Defaulters

• As per the National TB Programme a DR TB defaulter is someone who misses two consecutive months’ (8 weeks) appointments without informing.

• A patient who does not collect treatment on the appointment date will be classified as a Pharmacy defaulter.
Defaulters

• Tracer team to be informed to find patients.

• Feedback must be given to the Pharmacy at the decentralized and satellite site by the tracer team on an approved defaulter tracer form.
Defaulters

• If TB Defaulter – outcome in register entered as default. **New DR TB number should be allocated and treatment restarted – duration of treatment ??**

• If Pharmacy Defaulter – patient to be counselled and medicine re-issued. Appointment dates adjusted on prescription and patient carrier card.

• Medicine o be handled as per finding of the tracer team.
Discussion....

• Is the DOTS strategy being implemented?
• Are defaulters being managed appropriately.
• What are the challenges if any with defaulter tracing?
• What are the best practices if any?
Step 6: Recording and Reporting

- DR TB is a notifiable condition.
- R&R is critical for Programmatic Management.
- Recommended by WHO
- Needs to be strengthened.
Manual DR TB registers and DR TB Numbers

• All approved Decentralized sites and the Centralized sites should have their own DR TB registers.

• A DR TB number from KDHC DR TB register prior to starting treatment.

If you are starting DR TB treatment, make sure patient is allocated a DR TB number and entered in DR TB register at an approved site.
Shadow Manual DR TB registers

- It is recommended that the Decentralized sites maintain a shadow register that is updated whilst the patient is at the decentralized site.
- Baseline information and monthly results must be entered into this register at the decentralized site.
- The register will be brought monthly to KDHC OPD Clinic and information entered from here into KDHC DR TB register.
- This information will be captured on the EDR at KDHC.

Shadow registers can be used to track patients at your facility.
Routine updating of registers

• Every month the patients results must be updated into the register – sputum date, smear results and culture results.

• These results are used to monitor patient response to treatment and outcomes.

Ensure sputum test date, smear and culture results are sent to approved site with DR TB registers for updating of the registers.
R&R at satellite sites

• Patients are sent to satellite sites for 5 months at a time.

• A manual monitoring sheet has been developed to be updated monthly at the satellite site.

• On the 6 month visit the monitoring sheet and hard copies of the results must be sent to KDHC for updating the registers.

• Satellite sites should also maintain a shadow register.

NDOH will be conducting clinical chart audits and hard copies of the results must appear in the patients files.
Routine Reports sent to NDOH

• All reports to be generated from the EDR.
• Quarterly reports generated
  - Case Reports
  - 6 month interim outcomes
  - 24 month outcomes
  - 36 months outcomes

In complete data will not show the “BIG PICTURE”
Discussion…..

• Do you see the importance of recording and reporting?

• Do you have any recommendations to improve the proposed strategy to ensure accurate and timely recording and reporting?
Implementation and Monitoring

• It is the responsibility of all the different role players and heads of Department to implement this policy at their site and to monitor their component of the project.

• Indicators to monitor implementation have been developed and monthly monitoring must be done.
## KDHC Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Phoenix</th>
<th>KMPC</th>
<th>Tongaat</th>
<th>Inanda C</th>
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</thead>
<tbody>
<tr>
<td>1. Total number of patients down referred on the 1st day of the reporting period.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Number of new patients down referred during the reporting period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Number of prescriptions predispensed during the reporting period</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Number of patients sent back to KDHC before the review date during the reporting period.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5. Number of patients’ medication returned to KDHC due to default during the reporting period.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Number of patients whose medication was returned to Pharmacy due to death.</td>
<td></td>
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<td></td>
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<tr>
<td>7. Total number of patients down referred on the last day of the reporting period.</td>
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</tbody>
</table>
# Satellite Site Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Number in reporting period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Total number of patients down referred.</td>
<td></td>
</tr>
<tr>
<td>2 Total number of patients who collected their medicine on the appointment date.</td>
<td></td>
</tr>
<tr>
<td>3 Total number of patients who did not keep their appointments.</td>
<td></td>
</tr>
<tr>
<td>4 Total number of patients referred to the tracing team.</td>
<td></td>
</tr>
<tr>
<td>5 Total number of patients traced and returned to the facility.</td>
<td></td>
</tr>
<tr>
<td>6 Total number of patients who died.</td>
<td></td>
</tr>
<tr>
<td>7 Total number of patients who are smear negative</td>
<td></td>
</tr>
<tr>
<td>8 Total number of patients who are smear positive.</td>
<td></td>
</tr>
<tr>
<td>9 Total number of patients who are culture negative</td>
<td></td>
</tr>
<tr>
<td>10 Total number of patients who are culture positive.</td>
<td></td>
</tr>
<tr>
<td>11 Total number of patients who have been referred back to KDHC to management of adverse drug reactions.</td>
<td></td>
</tr>
<tr>
<td>12 Total number of patients who have been referred back to KDHC because of suspected breakdown (sputum reversion to positive, weight loss, etc.).</td>
<td></td>
</tr>
<tr>
<td>13 Total number of patients admitted at the district hospital with non-TB related conditions.</td>
<td></td>
</tr>
<tr>
<td>14 Total number of patients admitted to the district hospital with TB related complications.</td>
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</tr>
</tbody>
</table>
Discussion…..

• Will the identified indicators assist us to manage the programme.

• Are there any amendments or new indicators that can be included?
Tools to assist with Decentralized Site Activation

• Booking form, booking response form

• Request for approval to use non-Standard MDR TB medication on a named patient basis

• Pre-printed ADR Reporting form
Tools to assist with Satellite Site Activation

Annexure 1: Referral letter
Annexure 2: Pre-printed Prescription Chart
Annexure 3: Batch Tracking Sheet
Annexure 4: Patient Monitoring Sheet
Annexure 5: Referral note for unscheduled visit to KDHC
Annexure 6: Defaulter Tracing Sheet
Annexure 7: Adverse Drug Reaction Reporting Form
Annexure 8A: KDHC Monthly Reporting Template
Annexure 8B: Satellite Site Monthly Reporting Template
Together we can enhance drug resistant TB patient care
TOGETHER WE CAN......
Thank you / Siyabonga

• Acknowledgment: Dr. Sunpath, Dr. I. Master, Dr. K. Naidu, Dr. S. Maharaj, CAPRISA, Red Cross, S. Fynn

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