SELF-ADMINISTERED TREATMENT FOR DRUG-RESISTANT TUBERCULOSIS

MSF KHAYELITSHA FEEDBACK REPORT
We would like to acknowledge the City of Cape Town Health Department, Western Cape Government Health, TB/HIV Care Association, LifeLine and the Department of Health staff dedicated to working with DR-TB patients in Khayelitsha facilities. Most importantly we would like to recognize the many patients suffering from DR-TB in Khayelitsha whose courage and strength on their long, tiresome treatment journeys is inspiring.
ABBREVIATIONS AND ACRONYMS USED IN THE REPORT

BDQ - Bedaquiline
CCW - Community care worker
DOT - Directly observed therapy
DR-TB - Drug-resistant tuberculosis
DS-TB - Drug-sensitive tuberculosis
HIV - Human immunodeficiency virus
LFU - Loss to follow-up
LZD - Linezolid
MSF - Médecins Sans Frontières
MDT - Multi-disciplinary team
MO - Medical officer
PGWC - Provincial Government of the Western Cape
PHC - Primary health care
PN - Professional nurse
RIC - Retention in care
SAT - Self-Administered rifampicin-resistant tuberculosis treatment
SOC - Standard of care
TI - Treatment interrupter
This report provides information on lessons learnt from the progressive implementation (2012 onward) of a community-supported self-administered treatment (SAT) pilot programme for drug-resistant tuberculosis (DR-TB) treatment in primary health care (PHC) facilities in Khayelitsha, South Africa. Given there is a high burden of DR-TB in this setting, the standard model of care (SOC, directly observed therapy (DOT)), is being modified, allowing patients to self-administer treatment at home as to relieve the pressures faced by the health care system and adapt to patient needs. Thus the aim of the SAT pilot programme was to remove the barriers to DR-TB treatment adherence posed by the SOC and to relieve burden on health care facilities and patients with DR-TB. The SAT pilot programme was modeled after the drug-sensitive tuberculosis (DS-TB) treatment programme which is recognized by the TB/HIV Integrated Adherence Framework. The aim of this report was to provide city and provincial partners with feedback on SAT implementation in PHC facilities to date. It details numbers of participants enrolled in the SAT pilot programme to date as well as outcomes among those on DR-TB treatment for 24 months. Additionally, success and challenges with implementation in each facility in Khayelitsha are detailed in situational analyses throughout.

SAT was offered to adherent (as judged by health care staff) DR-TB patients who were clinically well upon the completion of the intensive phase of DR-TB treatment (6-8 months of treatment with an injectable). Patients were presented to a multi-disciplinary team (MDT) and discussed for ‘placement out’ into the pilot programme. Patients ‘placed out’ were allocated a pill box and given a weekly or monthly supply of DR-TB medications to self-administer at home and were given the choice of the added support of a community care worker (CCW) (the majority of patients ‘placed out’ were ‘placed out’ with a community care worker). Patients enrolled in SAT were required to go to their health care facility monthly for clinical assessment.

To date 192 out of 231 (83%) patients presented to the MDT were placed out to receive SAT; 93% (179/192) were ‘placed out’ with the support of a CCW. The number enrolled has varied based on time of SAT implementation in each facility and size of facility size. A situational analysis highlighted factors contributing to such small numbers of patients being identified for presentation to the MDT in 2016. Only 7% (14) of those patients ‘placed out’ had to be returned to the SOC. One hundred and thirty nine patients started treatment before August 2014 and had 24 month treatment outcomes available, of whom 86% (119) had an outcome of treatment success (cure or completion).

The major successes associated with implementation of the SAT pilot programme to date have been the improved patient support for those enrolled, decreased burden placed on the health care facilities and patients, and the high rate of treatment success among patients on DR-TB treatment for 24 months, suggesting that SAT is a feasible model of care and does not lead to a reduction in retention in care when patients are given autonomy over their treatment journey. The challenges associated with SAT have mainly surrounded the wider rollout and sustained implementation of SAT; there was some confusion regarding enrollment processes in some of the clinics.

SAT should be considered as an alternative method to alleviate the pressures on both the health care system and patients in settings with high burdens of DR-TB and difficulties associated with the SOC (daily DOT); the SAT model should be adjusted to best fit the programmatic setting within which DR-TB patients are being treated.

“We were all suffering. I was the only one who could work for my family. I was taking kanamycin injections which meant that I had to attend the clinic every day and this was preventing me from finding a job.”
BACKGROUND

In 2012, Médecins Sans Frontières (MSF) started a pilot initiative in collaboration with City Health, Provincial Government of the Western Cape (PGWC) and TB/HIV Care to provide community-supported, self-administered treatment (SAT) for patients on the continuation phase of drug-resistant tuberculosis (DR-TB) treatment in Khayelitsha. The intervention was introduced to enable adherent RR-TB patients in the continuation phase of treatment to take their oral medications on a daily basis in the community (i.e. outside of the clinic setting) with close support from a chosen treatment partner (non-paid) as well as an allocated Community Care Worker (CCW) from their respective clinic, through the model of the already established Cape Metro TB/HIV Integrated Adherence Framework. The drug-sensitive tuberculosis (DS-TB) treatment programme functions within this framework, where all patients on DS-TB treatment receive a treatment supply to self-administer at home.

The primary objective of the SAT pilot was to assess the feasibility of this approach in supporting patients to complete their DR-TB treatment, a structured alternative to the Standard Model of Care (SOC) for DR-TB in primary health care (PHC) clinics, which as per National Treatment Guidelines was Directly Observed Therapy (DOT). Despite the fact that DOT was the recommended SOC, both patients and the health care system were struggling to comply with the guidelines. As the risk of experiencing an outcome of loss to follow-up (LFU) increases with time on treatment (Figure 1) additional objectives of the SAT pilot were to improve overall retention in DR-TB care (RIC) as well as to decongest the health care facilities by reducing the burden of patients entering each facility to receive DOT every day for at least two years. We disseminate lessons learnt from the implementation of the SAT programme in Khayelitsha, South Africa to local collaborators and other relevant partners throughout South Africa.

Figure 1. Time to cumulative 24-month loss to follow-up among DR-TB patients who initiated treatment 2012 & 2013
The SAT pilot was rolled out progressively to 9 of the 10 PHC facilities across Khayelitsha from 2012 through July 2016 providing decentralised DR-TB treatment and care – see timeline below. Clinic staff at Site B and Site B Youth implemented a modified version of SAT (described later) independently of MSF, and so patients enrolled in SAT at Site B and Site B Youth are not reported upon in this report nor for patients enrolled in Zakhele as SAT had not yet been implemented at the time of this report. The pilot has yet to be rolled out in one remaining facility; the date of proposed implementation for that facility is outlined in the timeline below (Figure 2).
Once DR-TB patients are no longer receiving an injectable agent and potentially eligible for SAT, they are identified by facility staff (DR-TB professional nurse [PN] and/or medical officer [MO]) and a DR-TB counselor does a counseling session to congratulate the patient on reaching the milestone, motivate them to continue treatment and to discuss the potential option of SAT. The patient is then allocated to a CCW who carries out a home visit to confirm the patient’s address, confirm disclosure of DR-TB diagnosis to the family, meet the treatment partner, and identify any potential concerns.

Patients are routinely offered the support of a CCW if available, however this arrangement is not always feasible (e.g. no CCW available or patient working long hours), thus some patients are enrolled in SAT without a CCW but usually with an alternative arrangement for community support (e.g. nurse in workplace). The patient’s case is presented at the clinic’s weekly Multi-Disciplinary Team (MDT) meeting and a decision is made whether or not to ‘place out’ the patient for SAT.

If approved for SAT, the patient receives an adherence counseling session to confirm the treatment regimen, learn how to pack their pill boxes which are issued upon SAT enrolment, and to identify and address any potential barriers to adherence. These process are detailed in the MSF toolkit entitled “Patient Support Interventions to Improve Adherence to Drug Resistant Tuberculosis Treatment: Counseling Toolkit” 2. The patient then receives either a weekly or monthly (depending on the clinic and the patient’s preference) supply of medications to take at home and the CCW arranges to visit the patient at home on a weekly basis throughout the remainder of treatment. The patient is required to attend clinic at least monthly for review by the MO, give sputum, have relevant investigations and collect the next supply of medication. Any problems identified by CCWs are reported to their supervisor, and the DR-TB counselor may again intervene to address specific adherence barriers. This process is detailed in the Figure 3 below.

SAT ELIGIBILITY CRITERIA IMPLEMENTED INCLUDE

- Patient no longer receiving injectable agent
- Patient has a good adherence record on current TB treatment episode, and on ART if applicable
- Patients who self-report inability to adhere to SOC due to personal barriers
- Good response to treatment, e.g. culture conversion, persistently negative cultures, clinical improvement, resolution of TB symptoms and initial adverse events
- Patient doesn’t have serious adverse events which would require more frequent monitoring

**Figure 3.** Outline of the activities involved in the SAT programme

* Details of all DR-TB counseling sessions have been described in detail in other publications3
Implementation of the SAT programme in Khayelitsha required the following resources:

<table>
<thead>
<tr>
<th>PERSONNEL</th>
<th>FUNCTION WITHIN THE SAT PILOT PROGRAMME</th>
<th>NUMBER OF PERSONNEL PER SITE*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSF supervisor (doctor or nurse)</td>
<td>To facilitate initial implementation of pilot until independently functional within each facility, to provide training, and to provide ongoing feedback and monitoring of pilot</td>
<td>1 for the sub-district</td>
</tr>
<tr>
<td>MSF Lay Counselor</td>
<td>To provide post intensive phase and initial SAT adherence counseling sessions, to follow up on any adherence concerns; also to contribute to CCW training</td>
<td>1-2 for the sub-district</td>
</tr>
<tr>
<td>Community Care Worker (TB/HIV Care)</td>
<td>To carry out initial home visit for potentially eligible patients, to attend MDT meetings, to conduct weekly/monthly home visits for patients enrolled in SAT, to report back on any adherence concerns. An important factor to note is that CCWs are outsourced by Department of Health, as there is not enough capacity internally to support their hire.</td>
<td>7 – 30 per clinic depending on size of clinic</td>
</tr>
<tr>
<td>CCW supervisor (TB/HIV Care)</td>
<td>To ensure CCWs received training on DR-TB, to receive reports on patients linked to CCWs, to troubleshoot problems with MSF</td>
<td>1 per clinic</td>
</tr>
<tr>
<td>Medical Officer (Dept of Health, based in facility)</td>
<td>To identify patients potentially eligible for SAT, to attend MDT meetings and monitor clinical progress (monthly)</td>
<td>1-2 per clinic</td>
</tr>
<tr>
<td>DR-TB Nurse</td>
<td>To identify patients potentially eligible for SAT, to assist with medication supply and pill box packing, to assess adverse events and adherence at regular clinic visits, to ensure sputum and bloods done</td>
<td>1-2 per clinic</td>
</tr>
<tr>
<td>Pharmacy personnel</td>
<td>To dispense supply of medications</td>
<td>1 per clinic</td>
</tr>
</tbody>
</table>

*The number of personnel per site is likely to vary by site, contingent upon the size of the facility and the patient load

Table 1. Human Resource Requirements for the SAT pilot programme in Khayelitsha

Lay TB/HIV counselors provide the standardized DR-TB counseling sessions, post completion of the intensive phase [Table 1] and the adherence counseling sessions. In the Khayelitsha the high DR-TB burden requires a mobile MSF DR-TB counselor to support the facility counselors in providing ongoing adherence sessions.

Community based adherence support relies strongly on the CCW’s who conduct home visits for SAT patients weekly or monthly depending on the patients adherence support needs. A SAT champion, either the medical officer or the TB nurse is an essential element, as they take responsibility for the identification of SAT patients to ensure that eligible patients are presented at MDT meetings.

It is integral that all TB clinic staff work together in the implementation of the SAT programme as to ensure the greatest benefit from the programme is ascertained. SAT should not be viewed as a new programme in and of itself but rather an extension of the SOC for Integrated TB/HIV Adherence Framework for DR-TB patients.

“TB is a giant but not a killer. TB can be cured.”
“I’m happy I got this treatment, because I couldn’t even walk back then, but if I see myself now, I’m doing everything I couldn’t do before.”
A total of 231 DR-TB patients have been presented to MDT meetings in all 7 pilot clinics to date; 39 (17%) were not considered eligible or appropriate for SAT, whereas 192 were ‘placed out’ to receive SAT, 179 (77%) with and 13 (6%) without a supporting CCW.

The 39 patients not ‘placed out’ were unsuitable for SAT for the following reasons:
- History of LFU and treatment interruption
- HIV/ARV related issues
- Patient/family choice
- Patient stays out of the area (i.e. no CCW available)
- Patient due to be transferred out soon
- CCW unable to conduct home visit
- Patient is due to complete treatment successfully or treatment has likely failed
- Unknown

Median time from DR-TB treatment initiation to SAT enrollment among those enrolled was 9.3 months (Interquartile range (IQR) 7.0-12.3) – this is due to the initial gradual implementation of the pilot where patients were identified some time into their treatment. The bar graph below demonstrates the total number (n=192) of DR-TB patients ‘placed out’ to receive SAT in all 7 pilot clinics to date, by year of placement out (Figure 4).

As can be depicted from the rise in the number of patients enrolled in SAT from 2012 to 2014, the gradual implementation of the pilot in each clinic led to initial enrolments of a large number of patients who were considered eligible immediately upon implementation of the pilot in each clinic. Once the backlog of eligible patients was addressed, the number of new enrolments in each clinic dropped, thereby reflecting the ongoing small number of patients routinely identified as they became eligible for SAT – this graph would be expected to level out now that the majority of clinics have implemented the pilot. The greatest numbers of patients were ‘placed out’ to receive SAT in 2014; SAT was rolled-out to two new facilities so patients who completed the intensive phase of treatment some time ago were likely enrolled immediately upon implementation. Active case finding and enrollment into SAT is best represented by the numbers of patients enrolled in 2013 and 2015. In 2016, enrollment has slowed down due to programmatic challenges following slow withdrawal of MSF support. The main reasons for slowed enrollment were difficulties regarding patient identification, lack of compliance to the SAT model and premature withdrawal of guidance from MSF. These challenges are further detailed in the situational analyses conducted for each individual facility.

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**CLINIC SPECIFIC ENROLLMENT**

Differences in terms of enrollment at the clinic level were observed in part due to SAT implementation date and were additionally impacted by clinic size. Some of the clinics described in this section are managed by the PGWC while others are managed by Cape Town City Health.

The following bar chart [Figure 5] demonstrates the total number of patients (n=231), per clinic, who were (n=192) and were not (n=39) ‘placed out’ to receive SAT to date:

![Bar chart](image)

**Figure 5. Cumulative numbers of patients considered for and enrolled in the SAT pilot per clinic to date**

The numbers of patients presented and enrolled in SAT per clinic are cumulative and therefore mostly explained by date of SAT implementation in each facility. There are more patients ‘placed out’ on SAT in clinics in which SAT was implemented earlier; this is true with the exception of Site C which is a larger provincial clinic with a higher burden of DR-TB patients. The majority of the patients presented were ‘placed out’ and with the support of a CCW.

**RETURN TO THE SOC**

Note that 14 (7.3%) of the 192 patients who were ‘placed out’ for SAT had to return to SOC (clinic DOT) at a later stage for the following reasons: poor adherence, CCW unavailable, reconverted to culture positive, missed appointments with the MO, started on treatment with a strengthened regimen including bedaquiline (BDQ) and linezolid (LZD) (and therefore ineligible to receive SAT in earlier years).
Of the 192 patients ‘placed out’ for SAT, 139 (72%) started treatment before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were ‘placed out’ on SAT are depicted in Figure 6.

As can be seen in Figure 6, 86% of the 139 patients who were ‘placed out’ on SAT and who initiated treatment before August 2014 had a successful treatment outcome (cure or treatment completion), with only 9 (6%) LFU. These data are suggestive that SAT has a positive impact on RIC. It is important to keep in mind however that these SAT patients were carefully selected, adherent patients who were therefore likely to have a better outcome than less adherent patients not ‘placed out’ on SAT, however it appears that introduction of SAT did not have a negative impact on treatment outcomes overall.

Treatment outcomes for patients enrolled in the SAT pilot programme will be described in more detail and compared to patients from other treatment cohorts in a manuscript anticipated to be published by the end of the year.

Figure 6. Final 24-month treatment outcomes of patients ‘placed out’ on SAT who initiated treatment before August 2014
ADDITIONAL PATIENT SUPPORT MEASURES

For those patients not offered SAT due to concerns over adherence to treatment, as well as for those patients identified as interrupting treatment while on SAT, MSF DR-TB counsellors try to provide additional support in the form of home visits, family meetings, and referral to the MSF DR-TB Treatment Interrupter (TI) programme in Khayelitsha. Patients enrolled in the TI programme receive an enhanced, holistic adherence support intervention to in order to ensure the patient is retained in care. For more details on this intervention see the 2015 MSF DR-TB decentralised programme report4.

MODIFICATION OF THE SAT MODEL

SITE B, UBUNTU CLINIC

SAT roll out to Site B, Ubuntu clinic was delayed for various unforeseen reasons; MSF unfortunately lacked the time and resources to roll out to Site B. The TB team in the clinic, however were quite innovative in adapting and implementing a model of SAT of their own to relieve the pressure in the busy clinic. This model entailed the provision of SAT without the use of CCW’s which might be a more sustainable model for consideration in other programmes lacking resources to employ CCW’s. More research on the model of care implemented at Site B is needed in order to assess outcomes post SAT implementation to ascertain impact of this programme in this specific facility.

SAT IMPLEMENTATION SITUATIONAL ANALYSIS

A situational analysis was conducted for each of the 7 PHC facilities in which the SAT pilot was implemented by MSF in order to determine if staff understood SAT, if MDT meetings were well attended, if patients were being identified correctly and if facility staff were implementing SAT as per procedure. Success and challenges in each facility were highlighted (Individual clinic reports in the appendices).

Results of the situation analysis shed light on the fact that there are breakdowns in the implementation of SAT in the various facilities. Refresher trainings in each facility would be beneficial in order to redefine SAT procedures and processes.

CONCLUSION/LESSONS LEARNT

To date the SAT pilot has been rolled out in seven facilities providing integrated DR-TB and HIV treatment in Khayelitsha, South Africa. Since implementation some clinics have experienced challenges with the identification and enrollment of patients as per the SAT pilot processes; a plan moving forward has been employed to resolve confusion regarding SAT processes and instill clarity regarding the programme. Final outcomes among patients enrolled on the SAT pilot following the completion of the intensive phase of treatment are promising, with an overall 86% of patients with a successful outcome among those who initiated treatment before August 2014.
CHALLENGES

- Some patients are receiving a supply of medication to take at home without following the SAT process or receiving the intervention of counseling and CCW support
  - Easier to give patients a supply of medications than to present them to the MDT
  - Patients not receiving an injectable due to medication substitutions do not fit the SAT eligibility criteria but often request treatment supplies
- Lack of clarity regarding the pilot programme eligibility criteria and enrollment processes
- Poor participation of facility members in the programme at some PHC facilities
- Limited familiarity with the programme due to frequent staff turnover in PHC facilities
- Programmatic costs associated with human resource needs (hire of CCW’s) for the implementation of the SAT model

RECOMMENDATIONS

- Monitoring and evaluation (M&E) systems should be adapted as to indicate which patients have received SAT (whether it is formalized or not)
- SAT should be offered to any patients who have culture converted, defined as two consecutive negative cultures taken at least 30 days apart, (particularly for those on an injectable free regimen) if they meet the other eligibility criteria
- Patients enrolled in SAT who receive a weekly supply of medication do not need a CCW if they access the nurse during weekly refill visits
  - CCWs are only needed for patients receiving monthly supplies of DR-TB medications
- SAT can be offered to patients with poor adherence that verbally report to health staff their difficulties collecting their drugs at PHC facilities as per SOC
- SAT can be offered to patients who are still culture positive dependent on overall clinical wellbeing based on MDT and MO expert opinions
- MO’s can also decide if patients are eligible for ‘placement out’ if MDT meetings do not occur on a regular basis
- SAT processes should be clearly outlined and training and mentorship provided regarding implementation and ongoing M&E
- SAT models should be modified and adapted to best fit the setting within which you are working

THE WAY FORWARD

Patients can be empowered to self-administer treatment using this patient-centered approach to treatment, encouraging patients to take responsibility for completion of their long, challenging treatment journey. This intervention should be considered for wider implementation in high burden settings as it decreases the burden of daily DOT on the facilities as well as on patients.

SAT is already being implemented in some PHC’s, however without formalized structure and additional adherence support, thus the outlined programme is a formalized version of SAT. As SAT was only offered to patients deemed to have good adherence in the current model, the utility of SAT among less adherent patients should be explored in more detail; offering SAT to this group of patients might further improve RIC, as barriers associated with DOT often hinder treatment adherence. Additionally, MSF plans to conduct qualitative assessment of perspectives of patients, CCWs and HCWs who received or provided support for SAT.

Nonetheless, with support and mentorship regarding implementation is it evident that SAT is a feasible model of care which could potentially lead to improved RIC among those receiving SAT.
REFERENCES


APPENDIX 1. TOWN II CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=54) of DR-TB patients presented to MDT meetings in Town II clinic to date, and the total number (n=45) ‘placed out’ to receive SAT, with or without a supporting CCW (Figure 1). Median time to placement out into SAT among the 45 DR-TB patients ‘placed out’ was 7.8 months (IQR 6.5-10.8).

Note that 8 (18%) of the 45 patients who were ‘placed out’ for SAT had to return to clinic DOT at a later stage for the following reasons: poor adherence, CCW unavailable, reconverted to culture positive, identified as eligible for a strengthened regimen.

Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Town II clinic

54 Presented to the MDT
- Placed out without a CCW, n=2
- Not placed out, n=9
- Placed out with a CCW, n=43

FINAL TREATMENT OUTCOMES

Of the 45 patients ‘placed out’ to receive SAT, 33 (73%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were ‘placed out’ on SAT are depicted in Figure 2.

Figure 2. Final 24-month treatment outcomes of patients ‘placed out’ on SAT who initiated treatment before August 2014 in Town II clinic
SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>Mostly, but some patients already receiving a supply of medications from the clinic without first being counselled, visited by a CCW and presented to MDT meetings to be placed out.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>All of the TB clinic staff are aware of the SAT programme.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>Takes place every Tuesday afternoon at 2pm. Well attended by PN, CCW supervisor, CCWs and clinic counselor, but MOs not present.</td>
</tr>
<tr>
<td>CCWS</td>
<td>CCWs are usually successfully assigned to patients in their specific area. CCWs always carry out home assessments if allocated to a patient. Some patients reside out of area and placed out without CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The medical officer in the clinic actively identifies eligible patients to be placed out, on completion of the injectable phase – this is documented in the file.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>The medical officer is proactively involved in the SAT process by identifying patients. The CCWs are very conscientious with the DR-TB patients, and there has been little turnover of CCWs and so all of them are comfortable with managing these patients, also limited stigma among them.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>Once MO has identified eligible patients for placing out and provided the pharmacy scripts for supply, the CCW supervisor is not always informed and so a CCW is not allocated and the patient does not receive the relevant counseling.</td>
</tr>
<tr>
<td>OTHER</td>
<td>CCWs have been mentored by MSF DR-TB counselor to teach patient how to use the pillbox.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Town II clinic

“I couldn’t eat, my body was painful, my throat was sore – I thought I had a virus. My wife tried to cook – sour milk and maize meal. I couldn’t swallow. I had to drink many cups of water. I was sweating – I couldn’t walk even couple of metres.” “My wife was very supportive of me. She would leave me taxi money and go and stand in the hospital queue for me from 5am.”
APPENDIX 2. MICHAEL MAPONGWANA CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=43) of DR-TB patients presented to MDT meetings in Michael Mapongwana clinic to date, and the total number (n=40) ‘placed out’ to receive SAT, with or without a supporting CCW (Figure 1). Median time to placement out into SAT among the 40 DR-TB patients ‘placed out’ was 7.9 months (IQR 6.4-11.4).

Note that none of the patients who were ‘placed out’ for SAT had to return to clinic DOT at a later stage.

FINAL TREATMENT OUTCOMES

Of the 40 patients ‘placed out’ to receive SAT, 32 (80%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were ‘placed out’ on SAT are depicted in Figure 2.

The majority (84%) of patients who started treatment before August 2014 in Michael Mapongwana clinic who were also ‘placed out’ to receive SAT had a final 24-month treatment outcome of success.

Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Michael Mapongwana clinic

Figure 2. Final 24-month treatment outcomes of patients ‘placed out’ on SAT who initiated treatment before August 2014 in Michael Mapongwana clinic
SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>SAT processes are not being followed in this facility. New DR-TB patients are receiving a supply of medications from the clinic before the completion of the injectable phase and are going to the clinic for injections.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>Upon the time of the assessment, the PN was not familiar with the programme however the CCWs and MOs were well educated on the programme.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>MDT meetings take place every Monday afternoon. They are well attended by the MOs, CCWs, counsellors and on occasion the social workers.</td>
</tr>
<tr>
<td>CCWS</td>
<td>The CCWs are assigned to a specific area and do home assessment for patients ‘placed out’ unless the patient resides out of the area, in which case the patient is placed out without a CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The MOs admit that they have neglected the DR-TB patients and have requested assistance from an MSF counselor to flag patients eligible for SAT. The MSF counselor and the DR-TB PN are now assisting with flagging eligible patients.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>MDT meetings are taking place regularly and are well attended.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>Patients are receiving a supply of medication to take at home before the completion of the injectable phase of treatment and are thus being placed out, however without a CCW. When such patients are offered the support of a CCW they often refuse.</td>
</tr>
<tr>
<td>OTHER</td>
<td>This facility would benefit from refresher trainings on SAT.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Michael Mapongwana clinic
APPENDIX 3. MAYENZKE CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=31) of DR-TB patients presented to MDT meetings in Mayenzeke clinic to date, and the total number (n=23) ‘placed out’ to receive SAT, with or without a supporting CCW (Figure 1). Median time to placement out into SAT among the 23 DR-TB patients ‘placed out’ was 10.5 months (IQR 8.3-13.1).

Note that 3 (13%) of the 23 patients who were ‘placed out’ for SAT had to return to clinic DOT at a later stage for the following reasons: poor adherence, CCW unavailable, reconverted to culture positive, and missed appointments with the MO.

![Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Mayenzeke clinic](image)

FINAL TREATMENT OUTCOMES

Of the 23 patients ‘placed out’ to receive SAT, 20 (87%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were ‘placed out’ on SAT are depicted in Figure 2.

The majority (80%) of patients who started treatment before August 2014 in Mayenzeke clinic who were also ‘placed out’ to receive SAT had a final 24-month treatment outcome of success.

![Figure 2. Final 24-month treatment outcomes of patients ‘placed out’ on SAT who initiated treatment before August 2014 in Mayenzeke clinic](image)
SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>SAT processes are not being followed in this facility; patients are being ‘placed out’ without first being counselled, visited by a CCW, and/or presented to the MDT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>The CCWs were familiar with their roles and responsibilities regarding the SAT programme. The PN seemed familiar with SAT, however clarification is needed regarding his/her role in assisting with the identification of eligible patients.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>The MDT meetings are supposed to take place every Thursday at 14:00, however they do not take place regularly. They are attended by the PN, CCWs, and TB counselor, the MO does not attend.</td>
</tr>
<tr>
<td>CCWS</td>
<td>The CCWs are assigned to a specific area and do home assessment for patients ‘placed out’ unless the patient resides out of the area, in which case the patient is placed out without a CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The facility staff are relying on the MSF counselor for identification of eligible patients.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>The CCWs are well functioning within the SAT programme.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>The DR-TB PN relies on the MSF counselor to identify patients eligible for SAT. MDT meetings are not occurring regularly. Additionally, the CCWs delay the reporting of adherence concerns among SAT patients.</td>
</tr>
<tr>
<td>OTHER</td>
<td>This facility would benefit from a refresher training on SAT; it is highly recommended that the MOs also attend this training.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Mayenzeke clinic
APPENDIX 4. NOLUNGILE CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=60) of DR-TB patients presented to MDT meetings in Nolungile clinic to date, and the total number (n=46) 'placed out' to receive SAT, with or without a supporting CCW (Figure 1). Median time to placement out into SAT among the 46 DR-TB patients 'placed out' was 11.1 months (IQR 7.6-15.9).

![Pie chart showing patient enrollment]

Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Nolungile clinic

Note that 3 (7%) of the 46 patients who were 'placed out' for SAT had to return to clinic DOT at a later stage due to poor adherence.

FIGURE 1.
60 Presented to the MDT
- Placed out without a CCW, n=1
- Not placed out, n=14
- Placed out with a CCW, n=45

FINAL TREATMENT OUTCOMES

Of the 46 patients 'placed out' to receive SAT, 37 (80%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were 'placed out' on SAT are depicted in Figure 2. The majority (92%) of patients who started treatment before August 2014 in Nolungile clinic who were also 'placed out' to receive SAT had a final 24-month treatment outcome of success.

![Bar chart showing final treatment outcomes]

Figure 2. Final 24-month treatment outcomes of patients 'placed out' on SAT who initiated treatment before August 2014 in Nolungile clinic
SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>SAT processes are not being followed in this facility; patients are being ‘placed out’ without first being counselled, visited by a CCW, and/or presented to the MDT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>All of the TB clinic staff are aware of the SAT programme.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>The MDT meetings take place consistently every Tuesday afternoon and are well attended by the MOs, CCWs, and counsellors.</td>
</tr>
<tr>
<td>CCWS</td>
<td>The CCWs are assigned to a specific area and do home assessment for patients ‘placed out’ unless the patient resides out of the area, in which case the patient is placed out without a CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The DR-TB MOs and PN identify patients eligible for SAT.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>The MDT meetings are taking place regularly and are well attended.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>The CCWs do not visit the SAT patients weekly and they are delayed with the reporting of adherence concerns to the MOs and the MSF counsellors.</td>
</tr>
<tr>
<td>OTHER</td>
<td>This facility would benefit from a refresher training on SAT.</td>
</tr>
</tbody>
</table>

*Table 1. Situational Analysis of SAT programme in Nolungile clinic*

“By end December she started MDR treatment which included painful daily kanamycin injections. The injections were painful and some days she asked not to go to the clinic.”
APPENDIX 5. MATTHEW GONIWE CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=17) of DR-TB patients presented to MDT meetings in Matthew Goniwe clinic to date, and the total number (n=16) placed out to receive SAT, with or without a supporting CCW (Figure 1). Median time to placement out into SAT among the 16 DR-TB patients placed out was 11.2 months (IQR 9.4-15.5).

Note that none of the patients who were placed out for SAT had to return to clinic DOT at a later stage.

![Pie chart showing patient enrollment]

Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Matthew Goniwe clinic

FINAL TREATMENT OUTCOMES

Of the 16 patients placed out to receive SAT, 8 (50%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were placed out on SAT are depicted in Figure 2.

The majority (75%) of patients who started treatment before August 2014 in Matthew Goniwe clinic who were also placed out to receive SAT had a final 24-month treatment outcome of success.

![Bar chart showing final outcomes]

Figure 2. Final 24-month treatment outcomes of patients placed out on SAT who initiated treatment before August 2014 in Matthew Goniwe clinic
SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>Mostly, but some patients are already receiving a supply of medications from the clinic without first being counselled, visited by a CCW and presented to MDT meetings to be placed out.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>CCWs familiar with SAT pilot and understand their role in it. PN at that time was familiar with the pilot but was unclear about their role in identifying eligible patients (i.e. after completing injectable).</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>Should take place every Friday afternoon, but do not always happen every week. Well attended by PN, counselor, CCW supervisor and CCWs.</td>
</tr>
<tr>
<td>CCWS</td>
<td>CCWs are usually successfully assigned to patients in their specific area. CCWs always carry out home assessments if allocated to a patient. Some patients reside out of area and placed out without CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>Clinic staff were relying heavily on MSF counselor to identify patients who could be place out – should ideally be the PN to identify eligible patients.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>Patients are already familiar with the SAT pilot and processes by the time they are placed out. The patients usually know their treatment well and are able to use the pillbox properly. The Matthew Goniwe clinic order their own pillboxes so MSF no longer supplying for these patients.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>PN not actively identifying patients who have completed the injectable and there for does not refer patients to the counselor and CCW supervisor to prepare for presenting the case to the MDT meetings. CCWs often report late on patients interrupting treatment. MO is not involved in MDT meetings and therefore not actively involved in placing patients out on SAT.</td>
</tr>
<tr>
<td>OTHER</td>
<td>New PN had just started in Matthew Goniwe clinic at that point. The SAT enrolment process may run more smoothly and independently of MSF as staff gain more experience, however the TB staff (aside from CCWs) would likely benefit from SAT refresher training.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Matthew Goniwe clinic

“By end December she started MDR treatment which included painful daily kanamycin injections. The injections were painful and some days she asked not to go to the clinic.”
APPENDIX 6. KUYASA CLINIC

PATIENT ENROLLMENT

There have been 20 DR-TB patients presented to MDT meetings in Kuyasa clinic to date, all of whom (100%) have been ‘placed out’ to receive SAT, with the support of a CCW. Median time to placement out into SAT among the 20 DR-TB patients ‘placed out’ was 9.8 months (IQR 5.7–11.2).

Note that none of the patients who were ‘placed out’ for SAT had to return to clinic DOT at a later stage.

FINAL TREATMENT OUTCOMES

Of the 20 patients ‘placed out’ to receive SAT, 9 (45%) started before August 2014 and have final treatment outcomes available. Final treatment outcomes for these patients who were ‘placed out’ on SAT are depicted in Figure 2.

Figure 2. Final 24-month treatment outcomes of patients ‘placed out’ on SAT who initiated treatment before August 2014 in Kuyasa clinic

SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>SAT processes are not being followed in this facility; patients are being ‘placed out’ without first being counselled, visited by a CCW, and/or presented to the MDT.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>At the time of the assessment the MO was new and thus not familiar with the SAT programme.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>The MDT meetings take place every Friday at 14:00 and are attended by the PN, CCW supervisors as well as the CCWs.</td>
</tr>
<tr>
<td>CCWS</td>
<td>The CCWs are assigned to a specific area and do home assessment for patients ‘placed out’ unless the patient resides out of the area, in which case the patient is placed out without a CCW.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The DR-TB PN identifies patients eligible for SAT.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>The DR-TB PN is good at notifying the MSF counselor when patients are eligible to be ‘placed out’ and the MDT meetings are taking place regularly.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>The MO does not attend the MDT meetings.</td>
</tr>
<tr>
<td>OTHER</td>
<td>This facility would benefit from a refresher training on SAT; it is highly recommended that the MOs also attend this training.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Kuyasa clinic
APPENDIX 7. LUVUYO CLINIC

PATIENT ENROLLMENT

The pie chart below demonstrates the total number (n=6) of DR-TB patients presented to MDT meetings in Luvuyo clinic to date, and the total number (n=2) ‘placed out’ to receive SAT, with or without a supporting CCW (Figure 1). Time to placement out into SAT among the 2 DR-TB patients ‘placed out’ was 1.8 and 12.2 months.

Note that none of the patients who were ‘placed out’ for SAT had to return to clinic DOT at a later stage.

Figure 1. Number/frequency of patients presented to MDT meetings and MDT outcomes at Luvuyo clinic

6 Presented to the MDT
- Placed out without a CCW, n=4
- Not placed out, n=2
- Placed out with a CCW, n=0

FINAL TREATMENT OUTCOMES

The two patients who have been ‘placed out’ on SAT in Luvuyo clinic to date are still on treatment.

SITUATIONAL ANALYSIS

An informal review of various aspects of the SAT pilot in this clinic was carried out by MSF staff around September 2015. Therefore some of the issues described below may have improved or deteriorated or changed by now (Table 1).

<table>
<thead>
<tr>
<th>SAT PROCESS FOLLOWED?</th>
<th>Some patients were already receiving a supply of medications from the clinic without first being counselled, visited by a CCW and presented to MDT meetings to be placed out when this assessment was conducted.</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAFF AWARENESS</td>
<td>The PN and CCWs are familiar with SAT; the CCWs received training not long before this assessment however seemed uncomfortable with the idea of visiting DR-TB patients.</td>
</tr>
<tr>
<td>MDT MEETINGS</td>
<td>The MDT meetings are taking place every Wednesday afternoon.</td>
</tr>
<tr>
<td>CCWS</td>
<td>When this assessment was conducted, no DR-TB patients had been placed out yet.</td>
</tr>
<tr>
<td>PATIENT IDENTIFICATION</td>
<td>The DR-TN PN assumed responsibility for flagging eligible patients for SAT.</td>
</tr>
<tr>
<td>SUCCESSES</td>
<td>The CCWs seemed keen to enrol DR-TB patients in this programme.</td>
</tr>
<tr>
<td>CHALLENGES</td>
<td>This is the most recent clinic starting the SAT pilot, and there are still not many patients being identified as eligible for placing out. The PN seems reluctant to present and ‘place out’ patients even though they are receiving a supply of medication without the intervention. Additionally, there are new MOs at this facility that are not familiar with SAT.</td>
</tr>
<tr>
<td>OTHER</td>
<td>The nursing sister was resistant to SAT. At the time of this assessment no DR-TB patients had been presented to the MDT.</td>
</tr>
</tbody>
</table>

Table 1. Situational Analysis of SAT programme in Luvuyo clinic
Doctors Without Borders/Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters, and exclusion from health care.

MSF offers assistance to people based on need, irrespective of race, religion, gender, or political affiliation. MSF actions are guided by medical ethics and the principles of neutrality and impartiality. MSF has been working in response to the DR-TB epidemic in Khayelitsha, South Africa since 2007.

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