

Using the 99DOTS (directly observed treatment, short course) application for improved adherence to tuberculosis treatment in Namibia: A mixed-methods study

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Background. In Namibia, community-based directly observed tuberculosis (TB) treatment (C-DOT) has been effective for individuals living in settled villages, but it is problematic for mobile indigenous people who survive through hunting and gathering and have among the highest TB and multidrug-resistant TB rates and lowest adherence to TB treatment globally.

Objectives. The 99DOTS (directly observed treatment, short course) programme was piloted in the Tsumkwe Healthcare Centre and the 25 villages in the catchment area from quarter 2, 2019 to quarter 1, 2020. Programme staff facilitated and monitored TB treatment adherence.

Methods. Twenty patients and two healthcare workers who managed the patients were interviewed on treatment completion using a semi-structured interview process.

Results. Respondents were of low socioeconomic status; many were not schooled and not employed, and few had a monthly household income >NAD100 (USD5.50). According to the programme server reports, only six of the respondents did not miss any doses of their TB treatment, although few doses were missed proportionally. Most respondents reported a supportive family structure and health system, with treatment support given by families and regular follow-up by health workers. Positive feedback was received about use of the 99DOTS application; respondents found the application easy to use and did not mind using it in front of other people, in and out of their homes.

Conclusion. 99DOTS was a feasible, innovative and accessible treatment adherence component integrated directly into the existing C-DOT approach. National TB programmes in similar high-burden settings could consider this approach to improve adherence.

Keywords: operational research, infectious diseases, indigenous populations, San, Namibia

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Namibia has a high national tuberculosis (TB) incidence rate of 450/100 000 (95% confidence interval (CI) 247 - 598/100 000) and a high prevalence of 465/100 000 (95% CI 340 - 590/100 000), ranking 11th among the 30 high-burden countries in the world.^[1-5] Community-based directly observed therapy (C-DOT) has contributed to improved treatment success among individuals living in settled villages or communities,^[6] but the approach is problematic for mobile indigenous people who survive on hunting and gathering, nomadic pastoralism, forest products or migrant labour, and who have among the highest TB rates in the world, ~40% higher than nationally.^[7] Many travel alone or in small groups, accessing TB drugs and treatment in various government and private clinics along the way, with the risk of treatment interruption, expired or fake drugs, lack of specialist care, adherence failure and incomplete treatment.^[8] Owing to their mobility and scattered settlement patterns, and the fact that they reside in remote villages with little infrastructure far from health facilities, they are particularly hard to reach with mainstream TB approaches. These 'missing millions' are key to reaching the 90-90-90 TB targets described in the Global Fund and the new End TB Strategy.^[9] The majority of semi-mobile hunter-gatherer San in Namibia live in the Tsumkwe Conservancy, where the prevalence of TB, and particularly drug-resistant (DR)-TB, is the highest in the country.^[10] This small conservancy with a population of 14 740 accounts for 89% of multidrug-resistant (MDR)-TB cases in the region, hypothetically because of people's small shelters, mobility and

mistrust of or ethnic tensions with health workers. Of TB patients, 38% are HIV positive.^[11] The Tsumkwe Health Centre (THC) offers TB treatment facilitated by the Ministry of Health and Social Services (MHSS). It is a 12-hour walk to the THC for many people, and few can afford transportation. The THC has a tented village where many DR-TB patients live because the THC is so far away from their homes. The nearest laboratory is 300 km away, and sputum specimens often spoil owing to lack of efficient transportation.^[11] Previous research projects and experience have highlighted reasons for low adherence to TB treatment (personal communication, Health Poverty Action (HPA), Namibia, July 2021). There are few outreach services to TB patients in the area, and community healthcare workers administering C-DOT were previously sponsored by international organisations but are now volunteering with little remuneration. During the intensive phase of treatment, patients are encouraged to move closer to the treatment facility. During the continuation phase, they are sent home with a month's supply of medication.

The 99DOTS (directly observed treatment, short course) pilot programme piloted a digital solution, the 99DOTS application (app), for treatment monitoring, aiming to improve treatment outcomes among marginalised mobile populations with drug-sensitive (DS) bacteriologically confirmed TB. Use of the 99DOTS app was co-implemented with the National Tuberculosis and Leprosy Programme (NTLP) for a local, sustainable model to ensure scalability. No such system had previously been used in Namibia.

Research questions. The research questions were:

- In these contexts, with mobile and migrant populations, did 99DOTS improve TB medication adherence and treatment outcomes?
- What revisions in the 99DOTS model were required to successfully implement it in mobile and migrant populations in Namibia?
- In remote areas with predominantly mobile ethnic minority populations, was this technology feasible, culturally appropriate, gender sensitive and acceptable to patients and providers?

Methods

Population

The THC catchment area, with a population of 4 593, was the target population, inclusive of 25 villages in the area that have mobile phone coverage. There is one small town and sparsely populated rural areas, with mobile San communities living in tents and makeshift homes moving around frequently. The programme integrated 99DOTS into the traditional C-DOT approach. The control area was the neighbouring Mangetti Health Centre catchment area, with a population of 3 256. Standard of care was maintained in the control area.

Study design

Patient respondents were recruited from the area and an in-depth qualitative analysis was conducted through semi-structured questionnaires, investigating the feasibility and acceptability of the 99DOTS approach, patients' and health workers' knowledge of, attitudes towards and perceptions of the programme, and the impact of the programme on treatment adherence and outcomes. Two healthcare workers from the THC were also interviewed. Case notification data were received from the MHSS.

Sample size and power

The target was to enrol all DS-TB patients from the evaluation area. The expected number of cases was 25, which was the number of notified bacteriologically confirmed cases for 2017. When including 60 participants, the power calculation showed a power of 80% to detect a minimum effect of interest of 30% for the cure rate when comparing the evaluation area with the control area (expected rate 25%), with a type 1 error rate of 0.05.

Enrolment

Patients treated at the THC who had new or relapsed bacteriologically confirmed DS-TB and lived in areas with mobile phone coverage were eligible. The programme enrolled all newly diagnosed DS-TB patients, but not presumptive, extrapulmonary or complicated TB cases such as severely ill, hospitalised, HIV/TB-coinfected or MDR-TB patients who required admission to or close follow-up at health facilities. Patients with negative sputum cultures or who were initially seeking medical care at a hospital were also excluded.

Adherence support

Newly diagnosed DS-TB patients received C-DOT from the MHSS and 99DOTS from HPA. Each participant received a mobile phone, airtime, a SIM card and a solar charger from the 99DOTS programme. Participants kept the phones once the project was concluded. Once enrolled, participants were counselled about the programme and given 1 month's supply of free TB treatment through the NTL, packaged in 99DOTS packaging with a series of unpredictable, hidden symbols that were revealed on removal of the pills from the packaging. Each day participants were asked to make a missed call, by dialling the number revealed when they removed their medication from the blister pack,

on the 99DOTS phone app. Information was sent to an open-source information technology platform for 99DOTS.

Five smart phones were used as server phones to which patient calls could be made. The call-in status of patients who failed to call one of the server phones was updated daily and triggered a follow-up call to the patient on that same day and a possible face-to-face visit the next day. Real-time adherence reports were received on the app and available on the internet, allowing health workers to focus their attention on those patients who needed extra counselling.

HPA organised staff training, packaged the NTL-provided pills into the 99DOTS envelopes and sleeves, and procured and distributed the phones. HPA field officers supported MHSS staff to brief new patients and their C-DOT watchers about 99DOTS, particularly during the first 4 months. When the 99DOTS mobile phone call-in system reported cases of treatment interruption or loss to follow-up, HPA supported the MHSS to follow up cases using field officers who spoke the San language.

Data management

An interview guide was used to collect information from participants by nurses and programme staff, once they completed treatment. The interview guide was prepared in English, and the field officers translated it into the San language during the interview. Field officers were selected from the programme site and were centrally trained.

Ethics approval and consent to participate

The University of Namibia (UNAM) had obtained ethics clearance from the MHSS and the health research ethics committee at UNAM (ref. no. UREC/443/2018). Written consent was sought from each participant after an informed consent process. Unique identifiers were used to ensure anonymity. Recruitment was only for the purpose of the pilot, and participants were only recruited if they met the requirements for inclusion. Information was kept confidential.

Results

Baseline comparison evaluation

The programme enrolled 24 patients (16 female and 8 male), of whom 3 had to be removed because of a regimen change to DR-TB. These 24 patients constituted all the DS-TB patients diagnosed at THC for the enrolment period, quarter 2, 2019 - quarter 1, 2020, giving an incidence rate of 523/100 000 population (95% CI 516 - 529/100 000). Of the 24, 15 (63%) were cured, 8 (33%) completed treatment and 1 (4%) failed treatment. At the same time, 33 DS-TB patients were initiated on treatment at the neighbouring Mangetti Health Centre, translating into an incidence rate of 1 014/100 000 population (95% CI 1 003 - 1 025/100 000). Of the 33, 9 (27%) were cured, 22 (67%) completed treatment and 2 (6%) died.

Sociodemographic characteristics of respondents

HPA interviewed 20 of the 21 participants (14 female and 7 male) who were initiated on treatment at THC during the study period and completed their DS-TB treatment. One participant was not available for an interview at the time. Of the 20 patient interviewees, 13 were female (65%) and 7 were male (35%). Two healthcare workers were interviewed, one male and one female.

For the females, the average age was 26 years, with a range of 14 - 40 years; one respondent did not give her age. Three females' highest level of education was primary school, 5 did not complete primary school, 1 did not attend school at all, and 4 attended secondary school. Six were not employed, 2 were employed by a private organisation, 1 was self-employed, 1 was a student, and 3 were homemakers. Six had a household income of <NAD100 (USD5.50) per month, 3 had a

household income of NAD100 - 500 per month and 4 had a household income of >NAD1 000 per month. All used the programme phone, but 2 also had their own phones that no one else used. None of the phones were smart phones.

For the males, the average age was 23 years, with a range of 14 - 43 years. One male did not attend school at all, 4 did not complete primary school, and 2 went to secondary school. Five were not employed and 2 were students. Six had a household income of <NAD100 per month and 1 had a household income of NAD100 - 500 per month. Six used the programme phone, and 1 had his own phone that no one else used. One of the phones supplied by the programme to a respondent was reported to be a smart phone, but none of the respondents' phones were smart phones as confirmed by the project staff.

Treatment adherence and outcomes

Of the 20 respondents, 15 were cured, 4 completed treatment and 1 failed treatment. For each month, 600 doses were expected over 30 days for the 20 respondents. Overall adherence was 99%. In month 1, three doses were missed; in month 2, 10 doses were missed; in month 3, eight doses were missed; in months 4 and 5, six doses were missed; and in month 6, eight doses were missed. The respondent who failed treatment was 100% adherent, i.e. all the expected doses were taken.

Phone use

Of the females, two reported having changed their phone numbers or SIM cards twice within the past few months. All reportedly always had airtime credit on their phones, but never internet data credit. Of the males, one reported having changed his phone number or SIM card three times within the past few months. All reportedly always had airtime credit on their phones, but never internet data credit.

Responses to questions about 99DOTS knowledge

All the respondents reportedly knew how to use 99DOTS, had instructions on how to use 99DOTS, knew the reason behind 99DOTS, and took less than a minute to call or text 99DOTS.

Responses to questions about TB treatment adherence

Of the females, all reported having taken their treatment once a day, apart from one who said that she had missed a dose within the few months since starting the programme. All but two had family members who reminded them to take their treatment, but none set their own alarms as reminders. Seven reported having contacted a health worker within the past month, and the same women said that they were contacted by a health worker within the past month.

Of the males, all reported having taken their treatment once a day, apart from one who said that he had missed three doses within the few months since starting the programme. All but two had family members who reminded them to take their treatment, and two set their own alarms as reminders. One reported having contacted a health worker within the past month, and the same man said that he was contacted by a health worker within the past month.

No patient ever missed a dose because of side-effects, forgetfulness, being too busy, or a flat phone battery; only one reported a poor network connection. All were supported by the health worker.

Responses to questions about 99DOTS usage

Of the females, all reported that the people they lived with knew they were using 99DOTS and that they received reminders from 99DOTS to take their TB treatment. Only one ever took her treatment without calling 99DOTS. None ever missed a dose because they did not want to call or text, and none ever missed a dose because they did not want anyone to see them calling or texting.

Of the males, all reported that the people they lived with knew they were using 99DOTS and that they received reminders from 99DOTS to take their TB treatment. None ever took their treatment without calling 99DOTS. Only one ever missed a dose because he did not want to call or text, and none ever missed a dose because they did not want anyone to see them calling or texting.

All the respondents used 99DOTS when at home or out of their homes, and none of them reportedly did not use 99DOTS because they did not like it. None experienced problems with 99DOTS they told their health worker about, and all received feedback from their health worker after calling or texting. All were comfortable using 99DOTS in front of other people. All would recommend 99DOTS to their families, and all found 99DOTS very easy to use and very useful, liked the visual appearance very much, and would not change anything about the programme.

Additional costs associated with the programme

Of the females, none reported any costs to get to the clinic or extra associated costs because of the programme. Five women reported clinic visits within the past 30 days, one of whom visited the clinic twice. They all reported that they visited the clinic less because of the programme. Seven lived within 0 - 30 minutes of the clinic, 5 within 30 - 59 minutes of the clinic, and 1 - >2 hours away.

Of the males, none reported any costs to get to the clinic or extra associated costs because of the programme. Two men reported clinic visits within the past 30 days. They all reported that they visited the clinic less because of the programme. Four lived within 0 - 30 minutes of the clinic, 2 within 1 - 2 hours of the clinic and 1 - >2 hours away.

Other aspects of the programme

Of the women, none disliked anything about the programme, none experienced any problems with the programme, and none wanted to change anything about the programme. Of the men, none disliked anything about the programme, none experienced any problems with the programme, and none wanted to change anything about the programme.

In open-ended questions, most of the participants responded that 99DOTS was for calling the health worker or clinic after taking treatment to ensure they were aware that the respondent had taken his/her treatment. They liked 99DOTS because it reminded them to take their treatment while decreasing the number of their clinic visits and ensured that they got feedback when taking their treatment. Some respondents also mentioned that they specifically liked the phone that was given to them by the programme.

Most of the respondents told the people they lived with that 99DOTS allowed them to call the health worker after they took their treatment and that it was particularly useful when they lived far away from the clinic. They also commented that the programme was very helpful in supporting their treatment and they would not make any changes to it.

Health worker responses

Two health workers from THC were interviewed, one male and one female.

The female was in the age category 35 - 44 years with a post-secondary school certificate in nursing. The male was in the age category 18 - 24 years and had done university-level training courses in nursing. They reportedly saw 20 - 40 TB patients daily on average, received 99DOTS data from all these patients daily, and thought that 99DOTS was a programme for treatment adherence and monitoring. They received training on using 99DOTS which they thought was helpful and informative and enabled them to use the app, with a

friendly instructor; nothing was missed. They found it fairly easy to show a patient how 99DOTS worked.

Usually, to assess adherence, they would tell patients to come to the clinic so that they could observe them taking the treatment, especially during the initial phase of treatment; during the continuation phase, patients would be sent home with 1 month's supply of medication. They would also talk to the family members to facilitate family support structures. During the programme, health workers would use the software platform in addition to seeing whether patients were taking their medication. They found that 99DOTS made it easier and faster to monitor and follow up patients, and that it was easy to interpret. They easily located the data for each of their patients and used this information to give them ongoing counselling, especially for those who were not adherent.

Interestingly, the female reported that she was not sure that she believed the information she received from a patient's 99DOTS result, but the male readily believed it.

Both found the programme very useful, especially in lightening their workload. They reported sometimes running out of airtime (for the patients and the server) or having no network connection, but always having electricity. They never found it difficult to find their patients' dosing history and knew how to use the dosing history. The 99DOTS app never stopped working, but if they had issues with the programme, they would phone the programme co-ordinator.

They believed that 99DOTS improved the way they took care of their patients and that it enabled them to spend less face-to-face time with their patients. They recommended that MDR-TB and HIV/AIDS patients would benefit most from the programme, and would recommend the app to their future patients, but they felt neutral about the visual appearance of the platform. Another suggestion was to provide Wi-Fi for server phones.

Discussion

The 99DOTS pilot programme in Namibia focused on an area mainly populated by the marginalised semi-nomadic San. This remote area, with its poor laboratory capacity and many other healthcare implementation challenges, was in dire need of an easy-to-use effective tool to improve TB treatment adherence. Funding was received from TB REACH in 2018 to implement the 99DOTS pilot. During the study, the DS-TB incidence rate in the evaluation area of Tsumkwe was lower than in the neighbouring control area of Mangetti, and the cure rate was higher. This may give an indication of the impact of the 99DOTS programme, but further evaluation, which could include a pragmatic randomised controlled trial or an implementation science research study, would be needed to confirm the findings.

The NTLP, which is responsible for issuing TB medication, made use of two brands/manufacturers, McCleods and Pfizer. These tablets differ in size and shape. Pill envelopes for Namibia had to be modified to be able to accommodate all sizes. In projects elsewhere in the world, envelopes displayed a full digit telephone number for patients to call when dispensing their daily medication. In the case of Namibia and with the San population mostly illiterate, the project procured five smart phones of which the telephone numbers were all the same except for the last two digits, out of ten digits. For easier use, the patients would then have to dial the number displayed on the outside (with eight digits) of the envelope and only add the two digits that were displayed to the patient when dispensing the pills from the sleeves. Follow-ups to patients who did not make a call to one of the five smart phones, which were kept by the MHSS and HPA project staff, were done daily instead of after three non-calls, allowing for prompt action to ensure that no patient would default.

Twenty DS-TB patients from the Tsumkwe Conservancy were interviewed after using the 99DOTS app during their TB treatment. Two health workers who cared for these patients were also interviewed. The results of the semi-structured interviews have been discussed in depth; main findings include the generally poor socioeconomic status of the study population (many were not schooled and were not employed; few had a monthly household income >NAD100). Interestingly, all the respondents always had airtime for calls or messages but never had data/internet on their phones; only three reported a change in their cellphone numbers during the study period, which contrasts with the expectation that patients are often not traceable because of changes in phone numbers.

Only two of the respondents reported having missed any of their scheduled doses; however, according to the server reports only six of the respondents did not miss any doses. Most of the respondents reported a supportive family structure and health system, with treatment support given by families and regular follow-ups by health workers. In general, positive feedback was received in terms of usage of the 99DOTS app; respondents found the app easy to use and did not mind using it in front of other people, both at home and out of their homes. None reported additional costs, direct or indirect, associated with the programme; they rather felt that the programme facilitated fewer visits to the clinic, which was particularly useful if they lived far away. None wanted to change anything regarding the 99DOTS system as it was implemented.

Similarly, the two healthcare workers who were interviewed perceived that the 99DOTS system was a good tool for treatment adherence monitoring and that it would be particularly useful for MDR-TB and HIV-infected patients.

99DOTS has been implemented in other countries since 2015. In India, it was introduced by the Revised National Tuberculosis Programme at high-burden antiretroviral therapy centres and launched for the first time in Rajkot district in Gujarat.^[12] Among 347 registered TB patients, the overall 99DOTS adherence rate was 96%. The authors commented that the 99DOTS app would be helpful for access to treatment from remote areas, and this was shown to be true in the Namibian context.

A qualitative study investigating the acceptability of the 99DOTS strategy among HIV-coinfected and HIV-uninfected TB patients showed varied acceptance of 99DOTS.^[13] Lower patient acceptance had to do with perceptions of reduced face-to-face contact with health workers, or problems with cellphone access, literacy, cellular signal or technology fatigue. Higher patient acceptance was linked to perceptions of improved patient-health worker relationships, pill-taking habit formation due to SMS reminders, and a reduced need to visit facilities. Health workers in general felt that 99DOTS improved the quality and efficiency of care, the patient-health worker relationship, and co-ordination among health workers.^[13] These positive findings were mirrored in our study.

In another study, 99DOTS was compared with urine isoniazid testing; it showed suboptimal accuracy for measuring adherence, partly owing to poor patient engagement.^[14] Implementation challenges of 99DOTS at a tertiary centre in Delhi, India, were reported in January 2020.^[15] There were substantial discrepancies in missed doses and treatment outcomes between the 99DOTS dashboard and the TB treatment card. Further challenges were software malfunction, missing custom envelopes, and patients' inability to call or text. However, patient benefits included the convenience of the programme, less work absenteeism and less travel cost.^[15] These challenges should be investigated further in Namibia.

A TB REACH project in Tanzania used 99DOTS in the goldmining Geita region in the northwest.^[16] One of the patients using 99DOTS

commented that his improved adherence was because of the programme, especially the automated reminder messages that reminded him to take his medication.^[16] Similarly, in the Philippines, a patient reported that 99DOTS digital technology helped him get cured from TB.^[17] In general, the experience of the Namibian respondents and health workers in the present study was positive. Future projects should build on this work, which we have shown is feasible, and explore different ways of comparing the 99DOTS tool with other ways of measuring adherence.

Conclusion

Namibia's 2017 - 2022 draft Medium-Term Strategic Plan for Tuberculosis and Leprosy lays out ambitious plans to ensure universal access to TB care and prevention. It states: '... the strategic plan also takes into account the special needs of these high-risk key populations for TB as it seeks to intensify case finding and case holding among these groups including migrants and nomadic groups (such as the Ovahimba, San and Ovazemba)'. The plan states an intention to increase the quality of C-DOT. Our programme strongly supported the plan to serve hard-to-reach mobile groups by introducing 99DOTS, an innovative component integrated directly into the existing C-DOT approach. It thereby enhanced and tailored the MHSS's national C-DOT programme. This approach specifically targeted individuals who were left out of treatment initiatives.^[18] Participants perceived the intervention to be acceptable, and treatment adherence among participants was excellent.

We did not include a cost-effectiveness analysis for this pilot, which mainly focused on the feasibility and acceptability of the 99DOTS app in this rural population. To scale, one would need cost-effectiveness data from a larger cohort and a comparison with other adherence improvement strategies, in collaboration and discussion with the NTLP.

We would like to raise additional funding for scale-up and advocate this approach to the national authorities, to move it forward and potentially extend it to other areas and regions. The HPA programme manager has already been asked to assist by the NTLP on a qualitative study on the use of digital solutions. In addition, we advocate for the 99DOTS model to be supported and implemented by other actors in TB and in other thematic areas such as HIV and TB/HIV.

Data availability. The data that support the findings of this study are available from the MHSS, but restrictions apply to the availability of these data, which were used under licence for the current study and are therefore not publicly available. The data are, however, available from the authors upon reasonable request and with permission of the MHSS.

Declaration. None.

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