

Experiences, challenges and looking to the future in a clinical tuberculosis cohort in the time of COVID-19 in the Philippines

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A cohort study of Filipino tuberculosis patients is currently undergoing data collection amidst the coronavirus disease 2019 pandemic. In this article we present the current experiences, challenges and obstacles of our team during this period as we attempt to fulfil our roles and responsibilities in Metro Manila, Cebu and Negros Occidental in the Philippines. Each site had different lockdown restrictions and experienced problems to different degrees. The underlying themes were similar, covering the supply chain, mobility, communication, physical and mental health and disruption of health services due to reallocation of staff. While we maximized the use of mobile devices, logistical challenges remained. Institutional support for the field teams, creative problem solving and resilience are required to adapt in a rapidly changing environment.

Keywords: clinical study, COVID-19, diabetes, malnutrition, health services accessibility, tuberculosis

Introduction

By February 2020, our tuberculosis (TB) treatment cohort study had completed enrolment of >900 people newly starting TB treatment from the government National TB Programme (NTP) TB directly observed treatment (DOT) clinics at hospitals, primary care clinics and multidrug resistant (MDR)-TB treatment sites in three administrative regions/provinces (Metropolitan Manila, Negros Occidental and Cebu).¹ As the study aims to estimate the effect of malnutrition and diabetes on the risk of adverse TB treatment outcomes, participants are followed up monthly at a designated NTP DOT centre or barangay (village) health post. Data collection using the Open Data Kit (<https://opendatakit.org/>) on tablets includes finger-prick blood sampling, clinical measurements, interviews and data extraction from clinic records, requiring coordination with government health centres and barangay health workers (BHWs). When the first confirmed coronavirus disease 2019 (COVID-19) case was reported on 30 January 2020, more than half of our enrolled participants were due to be enrolled in post-treatment follow-up to include spirometry assessments requiring consent.

A public health emergency was declared on 8 March and Manila was placed under community lockdown on 15 March. This

expanded to Luzon and then the Visayas and Mindanao island groups. As of 24 August, there are 189 601 confirmed COVID-19 cases, with 107 110 in the National Capital Region (includes Manila), 19 115 in Central Visayas (includes Cebu) and 3182 in Western Visayas (includes Negros Occidental). Reported deaths were 2998.²

Here we share our experience as a research team implementing clinical, observational research within the NTP in a low- and middle-income country in the midst of an evolving pandemic with varying levels of community transmission. The lessons gained through our experiences may provide insights and further discussion for healthcare and research personnel facing similar situations or applicable in times of emergency.

Government response

Government guidelines changed rapidly, posing challenges regarding study management and the health and safety of staff and participants. Initial government measures included restricting mobility to essential services and work, closing non-essential businesses, imposing travel restrictions across local government units, school closures and public transportation suspension. Contiguous towns at times had different transport restrictions. Under

Table 1. Participant follow-up, mode of interview and reported non-adherence pre- and post-implementation of community lockdown restrictions

Measures of non-adherence	Pre-lockdown	Lockdown ^a		
	15 January–15 March 2020	16 March–15 May 2020	16 May–15 July 2020	16 July–13 September 2020
All participant follow-ups, n	512	387	276	167
Face to face, n (%)	501 (98)	103 (27)	176 (64)	139 (83)
Mobile phone, n (%)	11 (2)	284 (73)	100 (36%)	28 (17)
Participant follow-ups (ongoing treatment), n	358	296	177	66
Reported issues of stockout or inability to travel to health centre to collect treatment in the previous month, n (%)	13 (4)	9 (3)	8 (4)	2 (3)
Patients reporting having taken ≤ 5 of last 7 d of expected treatment, n (%)	10 (3)	32 (11)	25 (14)	31 (47)
Patients reporting having taken 0 of the last 7 d of expected treatment, n (%)	5 (1)	21 (7)	14 (8)	21 (32)

^aNote that not all areas had equal levels or periods of community and extended community lockdown restrictions.

a decentralized government-based healthcare system, health centre adjustments included skeletal workforces working continuous 24- to 48-h schedules and each implemented individual practices. Many healthcare workers (HCWs) were reassigned to COVID-19 duties. Our team had to adjust to changes in transportation, clinic schedules and lockdown guidelines varying by town.

Operational challenges

Early in the pandemic, procurement of supplies was the first obstacle. As personal protective equipment (PPE) was reprioritized for COVID-19, we were unable to purchase N-95 masks (locally or abroad) and had to extend the recommended use of masks. This was followed by difficulty in coordinating with government health workers, who had been reassigned to COVID-19, and disruption of TB services. Once community transmission was documented and lockdown introduced, we also had to readdress our own health and safety protocols to minimize risk and reduce anxiety. The key operational challenges in reaching participants were, and remain, logistics/mobility, communication and safe spaces for access to patients.

An initial blanket ban on public transportation and continued public transport restrictions have limited mobility, particularly crossing town borders, making it difficult for the research team to reach study participants and in many cases for participants to reach health services. Data collection using phone interviews prevented complete suspension of data collection but required a protocol amendment, particularly for reconsenting, resulting in more delays. In the first 2 months of lockdown, three of four interviews were by phone, slowly decreasing to one in five follow-ups 6 months into the pandemic (Table 1). More than half

of study participants were unreachable because of the lack of a phone, cell reception or disabled numbers. Some participants were not comfortable communicating in this way and data collection was sometimes incomplete due to difficulties in hearing, understanding and the longer time required. It is also evident that the participants with whom we were able to maintain contact are a non-representative subset of those enrolled, which is going to introduce significant bias into our study for which we had invested significant resources (staff time and travel) to limit. With phone interviews, however, we were unable to measure our two main exposures of weight and haemoglobin A1c.

With limited testing capacity early in the pandemic, we were concerned about exposure to undiagnosed COVID-19 cases in communities and health centres. The research team feared inadvertently transmitting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) while asymptomatic. Discrimination against health workers was a problem. Several of us experienced harassment by the public, for example, while returning from work wearing a scrub suit. Some felt isolated from family because they could not stay or dine with them. Our government partners were likewise affected. On several occasions we had to isolate team members exposed to COVID-19 cases from participants or government health centre staff. There had been reports of front-line HCWs who had died due to COVID-19. The infection rate among Filipino HCWs in a tertiary hospital was 2.5%.³ Although no formal assessment of anxiety or depression was made, other reports among Filipino HCWs reported anxiety in 28–38% using different tools during the pandemic.^{4,5}

Measures to control the spread of COVID-19, such as transport restrictions and reassignment of HCWs to COVID-19, affected regular TB services. Designated TB personnel from two centres

(three nurses, two medical technologists) were indefinitely deployed to take on management of and case finding in COVID-19 facilities. Three other centres reassigned six HCWs to home visits to dispense TB medications for patients unfit or unable to travel and/or collect sputum samples; BHWs, who at some sites had been actively managing TB patients, were redirected to COVID-19 activities, sometimes with limited PPE. NTP staff from one centre had a total of five positive COVID cases among HCWs within a span of 2 months in a skeletal workforce. These new responsibilities and an occasional COVID-positive HCW led to multiple instances of limited available manpower for regular services. Sputum testing was temporarily ceased in certain study areas for up to 2 months. Patients were sometimes redirected to alternative health facilities. TB medications were often dispensed in up to a 2-month supply and in Cebu and Negros Occidental could be collected at nearby health centres. As a result of these changes, we anticipate incomplete TB treatment records, which will affect the determination of TB treatment outcomes. At health centres, TB drug collection is now mostly at 'gate clinics', severely limiting privacy and the ability to conduct any clinical assessments.

The pandemic also affected our participant's mental health; there was no policy for regular SARS-CoV-2 screening among the TB afflicted or suspected. Some reported that they were fearful of leaving their homes because they felt more at risk from COVID-19 than from their TB, while others shared their frustration with transport restrictions affecting their access to clinic services. Others reported increased stigma from being visited by HCWs in PPE when delivering drugs. Despite efforts, some patients reported ceasing treatment because of a lack of medication. Although stockouts of TB medication also occurred before COVID, restrictions on travel and shipping affected supply chains from national/regional to local health units.⁶ However, impacts appear to affect new patients more than those already on treatment. This is evidenced by the increase in non-adherence among our participants both pre- and post-lockdown and its steady increase (Table 1), at least in the subset in whom we have been able to conduct interviews. As TB and COVID-19 symptoms are overlapping, there is fear and confusion among staff and the community concerning processes for diagnosing new TB cases.

Transitioning into a new 'normal'

As it stands today, the new normal should assume local transmission and exposure to asymptomatic, infective individuals while trying to limit disruption to essential lifesaving primary care services, including TB treatment, the breakdown of which may have further-reaching impacts on population health than COVID-19 itself.⁷ Households affected by TB represent populations at greater risk of negative impact.⁸ This inference and initial difficulties encountered (possible exposure to SARS-CoV-2 in our field staff, limited transportation options, government coordination and guideline amendments and regular patient contact) required appropriate responses by the team. We had to be mindful of our study's objective while minimizing risks.

We meet (virtually) regularly to evaluate risks and anticipate future disruptions and work towards flexible 'fail-safe' plans and long-term solutions. For instance, we have now committed to

utilizing private car rental services in Cebu and Metro Manila, where transport options were most restricted, as needed, for data collection needing in-person interaction and are working to find new safe spaces for patient interviews and assessments, including planning when and how to implement spirometry assessments, for which it is very difficult to obtain clear safety information. Particularly in Metro Manila and Cebu, the team has had to deviate from usual procedures while being mindful of impacts on expenditures. These logistical modifications, plus the gradual ease of public transportation in Negros Occidental, have allowed for a slow resumption of physical interviews.

Constant communication by listening to participants and team members has proved to be a key factor in identify new procedures in data collection, anticipate potential problems, address our physical and mental health concerns and optimize resource use. Contact with health centres is now more frequent to coordinate our activities with theirs; this primary measure is to avoid unnecessary exposure for everyone. We reduced risk by implementing staff rotas for accessing the study office/lab to minimize staff contact. This would avoid the whole team having to quarantine in cases where one staff member is infected. We expanded our use of web/mobile-based project management tools to better track staff resources. We have adjusted our purchasing practices to allow for delays in procurement due to COVID-19.

Conclusions

While the pandemic may provide impetus to scale-up mobile health tools to facilitate TB case finding and management, our experiences demonstrate significant logistical and social challenges, even in a middle-income setting with high mobile penetration. Arguably, the need for contextual observational and implementation research has never been greater, the successful conduct of which requires flexible support from funders, research infrastructure such as rationalized processes for ethical review and buy-in from all levels of health service delivery. Finally, a nimble, creative approach to problem solving, institutional support for field teams and team resilience is required to adapt to rapidly changing circumstances and the pressures of working during a pandemic.

Authors' contributions: JAS and SEC conceptualized the study. SS carried out the study design and implementation. CA, CB, MC, BC, PIF, RJJ, AL, TO, MS and AV carried out the data collection. JAS, BNF, JPF and SEC carried out the analysis and interpretation of collected data. JAS and JPF drafted the manuscript. JAS and SEC critically revised the manuscript. All authors reviewed the manuscript and approve all the contents.

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