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Mixed Methods Evaluation of Data Systems for Tuberculosis in Uganda

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Abstract

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Surveillance is a cornerstone of public health, providing the data required to monitor disease trends, evaluate the impact of interventions, inform policy, and guide programmatic decision making. In order for this data to be informative and useful, however, it must be timely, accurate, and complete. In the context of tuberculosis (TB), which continues to cause millions of cases of disease and deaths each year, surveillance data is known to have gaps including undercounting cases and incomplete reporting by health facilities. To accelerate TB control and elimination, reliable data is needed to improve quality of TB care. Furthermore, challenges with unique patient identification may limit quality of care, monitoring and evaluation, and data integrity for TB in low and middle-income (LMIC) settings.

This dissertation addresses these questions in the context of Uganda, a LMIC setting with a high burden of TB and HIV. Chapters 1 and 2 describe research conducted in collaboration with Uganda's National Tuberculosis and Leprosy Programme (NTLP) to understand the quality of TB surveillance data, while Chapter 3 presents an evaluation of the delivery of a biometric technology to facilitate individual patient identification. This dissertation used both quantitative and qualitative methods to measure data quality and characterize underlying factors that influence data collection, quality, and use.

In Chapter 1, I quantitatively assessed agreement between surveillance data from the Uganda NTLP and high-fidelity data from a research study in 2017 and 2019. Agreement was measured using agreement ratios, their 95% limits of agreement, and

concordance correlation coefficients, all calculated from linear mixed models. I found good overall agreement with some variation in expected facility-level agreement for smear positive diagnoses, bacteriologically confirmed treatment initiations, and TB patients who were people living with HIV. Surveillance data undercounted positive GeneXpert results, but overcounted clinically diagnosed treatment initiations and number of people taking antiretroviral therapy, relative to research data. Average agreement was similar across study years for all six measurements, but facility-level agreement varied from year to year and was not explained by facility characteristics. This chapter concluded that future research should elucidate and address reasons for variability in the quality of routine TB data in order to advance its use as a quality improvement tool.

In Chapter 2, I conducted a qualitative study to answer the questions raised by Chapter 1. Specifically, I sought to understand sources of variation in the quality of routine TB data in Uganda by characterizing the experiences, processes, and perspectives of TB data collectors and users through semi-structured interviews. Together with two Ugandan researchers, I interviewed programmatic and health facility stakeholders, including TB clinical staff and data officers. Using the Performance of Routine Information Systems Management framework, we identified four themes that explained how technical, organizational, and behavioral factors influence data system processes and outcomes. Importantly, the mutually reinforcing relationship between data quality and data use relies on availability of technical components, data knowledge and skill, ongoing training, and teamwork. As Uganda transitions to an electronic, case-based surveillance system for TB, addressing ongoing technical, organizational, and behavioral challenges will be key to ensuring that the new system produces data that is feasible for routine use.

Finally, in Chapter 3, I conducted a mixed-methods study to understand the feasibility, acceptability, and adoption of digital fingerprinting for patient identification in a study of household TB contact investigation in Kampala, Uganda. First, I tested associations between demographic, clinical, and temporal characteristics and failure to capture a digital fingerprint, and evaluated clustering of outcomes by household and community health worker (CHW). Digital fingerprints were captured for 74% of eligible participants, with extensive clustering of failures by household arising from software and hardware failures and increasing over time. In addition, to understand determinants of intended and actual use of fingerprinting technology, I conducted in-depth interviews with CHWs and applied the Technology Acceptance Model 2. The interviews revealed that digital fingerprinting was feasible and acceptable for individual identification, but failures lowered CHWs' perceptions of the quality of the technology, threatened their social image as competent health workers, and made the technology difficult to use. This chapter emphasizes the need for routine process evaluation of digital technologies in resource-constrained settings to assess implementation effectiveness and guide improvement of delivery.

This dissertation advances the understanding of both traditional surveillance and novel approaches to collecting TB data in one high-burden setting. However, it also provides an analytic approach that can be replicated in other settings to guide quality assessments and targeted improvement of TB data systems. Finally, it highlights the importance of ongoing assessment and end-user engagement at all stages of implementation to ensure that data systems produce high-quality data that can be used to improve public health outcomes.

Mixed Methods Evaluation of Data Systems for Tuberculosis in Uganda

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Dedication

I would like to dedicate this dissertation to the community health workers, clinicians, data officers, and programmatic stakeholders in Uganda who participated in the interviews in Chapters 2 and 3. Besides being so generous with their time and expertise, they are also the ones doing the difficult and important work of caring for people with TB, looking after their communities, and setting ambitious goals for their country. TB is a historically stubborn and devastating disease. But as one TB focal person reminded me, "it takes a heart to work in TB," and I am greatly encouraged that there are such dedicated, caring individuals who remain committed to the fight.

Introduction

Surveillance is a cornerstone of public health, providing the data required to monitor disease trends, evaluate the impact of interventions, inform policy, and guide programmatic decision making. The COVID-19 pandemic has only highlighted the importance of and challenges in collecting timely, accurate, and complete data that can be used to respond to disease threats and prevent further cases and deaths. In the United States, traditional surveillance has been used to monitor national and local COVID-19 trends, and yet gaps in this data have prevented public health leaders from using it consistently and clearly to guide decision-making.[1] In the United States and low and middle income country (LMIC) settings alike, digital approaches to collecting COVID-19 case and contact data—such as Bluetooth,[2] GPS,[3] and SMS[4]—have been introduced widely, with highly variable acceptability and success.[5] While COVID-19 has brought these challenges to the forefront of the scientific community's and general public's awareness over the past two years, they are not new for a disease like tuberculosis (TB).

TB remains a major cause of morbidity and mortality worldwide, with an estimated 9.9 million cases and 1.5 million deaths in 2020;[6] prior to the COVID-19 pandemic, it was the leading cause of death due to a single infectious agent worldwide. In the context of TB, surveillance data is known to have gaps including undercounting cases and incomplete reporting by health facilities. To accelerate TB control and elimination, reliable and actionable data is needed to achieve high-quality care,[7] defined by WHO as being effective, safe, people-centered, timely, equitable, integrated, and efficient.[8] However, low-quality TB care persists in many high-burden settings, including LMICs also experiencing high rates of poverty, under-resourced healthcare systems, co-

epidemics with HIV, and rapidly increasing urbanization. Low-quality TB care results in poor case detection, a high proportion of missed incident cases each year (4 million, or 40% worldwide), poor adherence to treatment, and suboptimal treatment outcomes; together these gaps contribute to slow annual declines in TB incidence (2%) and mortality (3%).[7,9] Aiming to close these gaps, the WHO has set ambitious targets as part of the End TB Strategy, including an 80% reduction in TB incidence and 90% reduction in TB deaths by the year 2030, compared to 2017 levels.[10]

In order to monitor quality of TB care and track progress toward these goals, health systems must have the capacity to collect and utilize accurate data on their TB epidemics.[11] One way in which data can be used for these purposes is by constructing care cascades, which measure process and outcome indicators including the proportions of TB patients who are evaluated for TB symptoms, undergo microbiological testing, receive a diagnosis, initiate treatment, and complete treatment. This method has been widely applied in the HIV literature[12–14] to characterize losses and delays at each stage of treatment,[15] inform policy,[16,17] and guide the development and implementation of quality improvement interventions.[18–20] More recently, TB care cascades from South Africa,[21] India,[22] and Zambia[23] have produced some of the first national estimates of total TB burden, diagnostic practices, treatment initiation, and treatment success. Strengths of these analyses include their rigorous methods[24] and stratification by disease type, drug susceptibility, and HIV status. However, the methods used to produce these cascades are not replicable in real time and do not capture factors that directly impact TB care, such as facility structures or processes. Another study used cross-sectional data from the World Health Organization to produce national TB cascades for 30 high-burden countries;[25]

while more pragmatic, this approach is limited by the absence of validation against individual-level data and the inability to produce similar estimates on sub-national scales. Other studies have produced TB care cascades for sub-populations, such as children,[26] PLHIV,[27] TB contacts,[28] and people with drug resistant TB.[29] However, these studies relied on methods such as retrospective chart review, prospective follow-up, and retrospective cohorts, all of which are infeasible in routine practice. In order to advance the role of TB care cascades as tools for quality improvement, validated methods are needed to produce accurate, timely measurements from the routine, aggregated data that is readily available in high-burden settings.[24,30]

One setting that has prioritized TB data collection and use is the high TB-HIV burden setting of Uganda, where the 2015 prevalence survey[31] and 2020 WHO TB report[6] continue to show high TB prevalence and low treatment coverage. Studies have further identified specific gaps in the TB care cascade in Uganda, but less is known about the reasons for these gaps or how to measure them quickly and reliably.[28,32–34] In Uganda, routine TB data is collected from all health facilities that treat TB patients by the National Tuberculosis and Leprosy Programme (NTLP), which in 2016 adopted an open-source, web-based platform, District Health Information System 2 (DHIS2). Since 2018, the DHIS2 has been the sole source of TB data for reporting and use by the NTLP, district health officials, and implementing partner organizations. The process of collecting and reporting this data involves a series of steps. First, patient data are recorded by clinical staff into paper registers including the outpatient register, the presumptive TB register, the laboratory register, and the TB treatment register. Second, data are manually counted and aggregated by clinical and data staff into standardized reporting forms that specify

different datasets on weekly, monthly, and quarterly bases. Finally, the reporting forms are entered by a data officer into the DHIS2 database and submitted to the NTLP, where the Monitoring and Evaluation department oversees data cleaning and review.

Currently, the NTLP is in the process of rolling out an electronic, case-based TB surveillance system that will ultimately replace the paper system and provide patient-level data. Patient-level data would create the possibility of high-quality cascade analyses with denominator-denominator linkage, meaning that the same group of patients is followed through all steps; denominator-numerator linkage, where within each step, the patients in the numerator are a subset of those in the denominator; sufficient breadth, or the range of steps encompassed by the cascade; and sufficient depth, or the granularity within each step.[13] However, the current DHIS2 dataset resulting from the processes described above consists of aggregated counts of data elements encompassing diagnoses, HIV testing and treatment, drug susceptibility testing, treatment initiation, sputum conversion, and treatment outcomes; many of these data elements are further stratified by age group, sex, or prior treatment outcome. Without individual-patient data to provide an accurate denominator, it is impossible to precisely measure many process indicators, such as the proportion of those diagnosed who initiate treatment and ultimately achieve cure. Nevertheless, the breadth of data available still provides great opportunities to track progress toward goals and identify quality improvement targets in near-real time, provided the data is accurate, complete, and timely. Therefore, understanding the quality of this data and sources of variation in its quality are important to guide its use for these objectives, presently and in the context of the transition to a patient-level database.

The first two chapters of this dissertation examine the quality, gaps, and opportunities in Uganda's routine TB data. These studies were conducted in collaboration with Uganda's NTLP, with the goal of providing actionable information to enhance the quality of TB data and patient care. In Chapter 1, I aim to characterize the potential for routine TB data to be used as a QI tool by measuring how closely it agrees with a reference dataset. In the absence of a gold standard, I use a research dataset collected from the same source documents, health facilities, and time period. I hypothesize that routine TB data would be undercounted relative to research data. Using linear mixed models, I characterize agreement for six key measurements, including how agreement varied across health facilities and over time. I also seek to identify facility-level factors associated with agreement, such as size, location, or remoteness.

Chapter 2 aims to develop a deeper understanding of sources of variation in the quality of routine TB data collection seen in Chapter 1. Whereas Chapter 1 takes a quantitative approach, in Chapter 2 I employ qualitative methods to elicit the experiences, views, and challenges of stakeholders who engage with the data. In collaboration with two Ugandan social scientists, I conduct semi-structured interviews with 31 health facility-based staff, including TB focal persons and data officers, as well as 10 programmatic stakeholders from the NTLP, Ministry of Health, and implementing partners. I use the Performance of Routine Information Systems Management (PRISM) framework to identify technical, organizational, and behavioral factors that act as barriers and facilitators of data system processes and outcomes, including data quality and data use.

In Chapter 3, I perform a process evaluation of a novel technological approach to uniquely identify patients: digital fingerprinting. This analysis takes place in the context of a study of a mobile health intervention to improve rates of TB evaluation among household contacts of index TB patients, where digital fingerprinting was used to enroll study participants and match records at follow-up visits. I use a parallel-convergent mixed methods study design to identify sources of fingerprinting success or failure through both the quantitative study data and qualitative interviews with the community health workers who carried out fingerprinting. In my qualitative analysis, I identify themes that contextualize the feasibility, acceptability, and adoption of digital fingerprinting by community health workers. This study provides important considerations to guide the implementation of novel technologies, which often show great promise in ideal settings but present challenges in routine practice.

This dissertation contributes to a growing literature on the quality and use of routine TB data for assessing quality of care, as well as the implementation of newer data collection systems such as biometrics. It produces actionable targets for closing gaps in the quality of TB data in the context of Uganda's current aggregate data system, and considers future directions as it moves toward a patient-based system. These studies were conducted in the context of TB in Uganda, but many of the methods and themes have implications for other settings aiming to use routine health data or novel digital technologies to inform national, local, and health facility-level decision making.

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Chapter 1

Assessing the agreement of routine tuberculosis data with high-fidelity research data in Uganda

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Abstract

To accelerate tuberculosis (TB) control and elimination, reliable data is needed to improve the quality of TB care. We assessed agreement between surveillance data routinely collected for Uganda's national TB program and high-fidelity data collected from the same source documents for a research study from 32 health facilities in 2017 and 2019 for six measurements: 1) Smear-positive and 2) GeneXpert-positive diagnoses, 3) bacteriologically confirmed and 4) clinically diagnosed treatment initiations, and the number of people initiating TB treatment who were also 5) living with HIV or 6) taking antiretroviral therapy. We measured agreement as the average difference between the two methods, expressed as the average ratio of the surveillance counts to the research data counts, its 95% limits of agreement (LOA), and the concordance correlation coefficient. We used linear mixed models to investigate whether agreement changed over time or was associated with facility characteristics. We found good overall agreement with some variation in the expected facility-level agreement for the number of smear positive diagnoses (average ratio [95% LOA]: 1.04 [0.38-2.82]; CCC: 0.78), bacteriologically confirmed treatment initiations (1.07 [0.67-1.70]; 0.82), and people living with HIV (1.11 [0.51-2.41]; 0.82). Agreement was poor for Xpert positives, with surveillance data undercounting relative to research data (0.45 [0.099-2.07]; 0.36). Although surveillance data overcounted relative to research data for clinically diagnosed treatment initiations (1.52 [0.71-3.26]) and number of people taking antiretroviral therapy (1.71 [0.71-4.12]), their agreement as assessed by CCC was not poor (0.82 and 0.62, respectively). Average agreement was similar across study years for all six measurements, but facility-level agreement varied from year to year and was not explained by facility characteristics. In

conclusion, the agreement of TB surveillance data with high-fidelity research data was highly variable across measurements and facilities. To advance the use of routine TB data as a quality improvement tool, future research should elucidate and address reasons for variability in its quality.

Introduction

Recent efforts to control and eliminate tuberculosis (TB), a leading infectious cause of death worldwide, have highlighted the importance not only of increasing access to diagnosis and treatment, but also of ensuring that TB care is of high quality.[1] Improving the quality of currently available TB services could avert up to one-third of all annual TB deaths, saving some 470,000 lives annually.[2] However, in many high-burden settings such as Uganda, these efforts are hindered by a lack of information about how and where to prioritize quality improvement (QI) efforts on local, regional, and national scales.[3]

One approach to measuring the quality of TB services is developing quality metrics that quantify success of the key processes of accessing care, screening, diagnosis, and treatment that are required to achieve TB cure. These quality metrics have been constructed through TB care cascades at the national level[4,5] and among sub-populations[6–9] to identify where treatment gaps lie in different contexts. To date, these analyses have utilized study designs including modeling,[5] systematic reviews with meta-analysis,[4,9] large population-based cross-sectional studies,[6] and prospective cohorts.[7,8] However, these approaches to constructing quality metrics are not able to be replicated in real time to inform QI efforts in many high-burden settings such as Uganda. An approach that utilizes the routinely collected, readily available, and representative data routinely collected by national TB programs would enable the use of quality metrics to inform program decisions.

In order to guide the use of routine TB data as a QI tool, it is important to understand how well it agrees with high-fidelity research data. A commonly cited

disadvantage of routine data systems is that they are decentralized and without robust quality assurance systems, leading to variable data quality requiring adjustment (e.g. inventory and modeling studies to measure and correct undercounting of TB cases).[10–12] Previous studies have taken various approaches to assess the quality of routinely collected health data with the ultimate goal of using it to inform program management, including examining the data's consistency, timeliness, and completeness.[13–15] A more difficult dimension of data quality to measure is accuracy because of the lack of a gold standard. Validated methods are therefore needed to enable the use of surveillance data to produce timely, accurate measures of the quality of TB services.[16,17] One promising approach, described by the WHO[18] and previously applied for maternal and newborn health, HIV care, acute respiratory infection, and immunizations in sub-Saharan Africa,[19–21] is to evaluate the agreement of routine data with external data sources.

In the current study, we used a similar approach to WHO by leveraging previously-collected source document data from a research study and comparing it to TB surveillance data from Uganda. Our objectives were to assess how well TB surveillance data agreed with high-fidelity research data collected from the same source documents, and to determine whether agreement changed over time, varied by health center, or was associated with facility characteristics. In doing so, we aimed to provide an example for researchers and public health leaders who wish to identify needs for future improvement in data capture toward the goal of producing real-time, routine data that can be used in QI efforts.

Methods

Study design and rationale

We conducted a cross-sectional study to assess agreement between two sources of routine TB data: 1) aggregated, facility-level surveillance data from the MOH's national electronic disease reporting database (DHIS2, District Health Information Systems 2), and 2) individual patient data collected by the XPEL-TB research study. The XPEL-TB Study was a cluster-randomized trial examining the effect of a multicomponent diagnostic strategy on the number of TB patients initiating treatment within 14 days of diagnosis. The intervention included on-site GeneXpert testing for TB and monthly feedback of quality metrics to staff. [22–24]

In the current study, both the surveillance and research datasets drew from the same source documents – handwritten TB treatment and laboratory registers – at the same health centers over the same time periods. We hypothesized that agreement between surveillance and research data might vary across measurements, health centers, and time; our study was designed to examine these dimensions to better understand the quality of TB data in this setting.

Study setting and population

Our study was conducted in Uganda, one of WHO's high HIV and TB burden countries,[25] with an estimated TB prevalence of 253 per 100,000 population.[26] TB diagnostic and treatment services are overseen by the Ministry of Health's (MOH's) National Tuberculosis and Leprosy Programme (NTLP) and provided free of charge in primary health centers. Our study included 32 of these facilities from 18 urban, semi-urban, and rural districts in the Central and Eastern regions of Uganda. We included all

XPEL TB study sites that participated in the baseline assessment and/or main trial (2017 and 2019); all sites were chosen because they had a high volume of smear examinations (>150) and smear-positive diagnoses (>15) per year.[22] Our analyses included data from January 1 through December 31, 2017 and January 1 through December 31, 2019; data for 2018 was not available for the research study.

The XPEL-TB study included all adults and children undergoing evaluation for possible TB, defined as having ≥1 sputum sent for smear or Xpert testing. For our analyses including surveillance data, we followed these inclusion criteria as closely as possible, as described below in "Measurements."

Data sources and recording practices

Surveillance data: In Uganda, all hospitals and health centers that treat TB patients report surveillance data on a quarterly basis through a national reporting system using DHIS2 software, a widely-used, open-source, health management information system that was implemented in Uganda in 2012, began collecting TB data in 2017, and fully adopted for TB reporting in 2018.[27] Reporting follows a series of steps. First, a trained staff member at each facility reviews handwritten TB laboratory and treatment registers quarterly and counts the number of new laboratory tests performed, laboratory test results, and case notifications. Second, the staff member records these aggregated counts on a standardized paper reporting form within pre-specified strata for case notifications (e.g., prior treatment status, disease type) and laboratory tests (smear microscopy, GeneXpert). Finally, either a facility-based or a district-level data officer reviews the reporting form and enters the data into the DHIS2 database. For this study,

we extracted annual, facility-level data on diagnoses and treatment initiations from these quarterly reports.

High-fidelity research data: In the XPEL-TB study, trained facility staff photographed handwritten TB laboratory and treatment registers and uploaded them to a secure server monthly. Study staff then entered the data into a patient-level database and conduct quality assurance activities to ensure accuracy, including resolving missing data and other discrepancies with health facility staff.[22] The final dataset included patient results and dates for all steps of TB evaluation and treatment. To make direct comparisons to the surveillance dataset, we aggregated individual patient data by year and health center using the same strata reported in the DHIS2 system.

Measurements

We selected a total of six measurements to compare between surveillance and research data. Four of these were TB care cascade measurements that were available in both the research dataset and quarterly surveillance reports:[16] smear-positive diagnoses (Smear positive), GeneXpert-positive diagnoses (Xpert positive), bacteriologically confirmed treatment initiations (BC treated), and clinically diagnosed treatment initiations (CD treated). BC treated included smear- and Xpert-positive patients who initiated TB treatment, while CD treated included those who were started on TB treatment without a confirmed diagnosis because they were deemed to have a high probability of pulmonary TB. We excluded the following from the BC and CD treated surveillance measurements: those previously treated for TB, those diagnosed with extra-pulmonary TB, those with evidence of drug-resistant TB, and those who transferred in from other health centers.

Finally, we included two measurements specific to people living with HIV (PLHIV). Among those initiating treatment for TB, we compared the number who were also PLHIV and the number who were taking antiretroviral therapy (ART) between the two data sources.

Statistical Analyses

First, we used descriptive statistics (median, interquartile range) and plots to summarize the distribution of data for each measurement in 2017 and 2019. We then used previously described methods[28–30] to calculate metrics of agreement and further characterize the relationship between surveillance and research data (described in Table 1.1).

Table 1.1. Agreement metrics, equations, and interpretations

Statistic	Definition	Interpretation
Average Ratio	Average ratio of surveillance counts to research counts.	Overall agreement across health facilities. If <1, indicates underreporting in surveillance data relative to research data; if >1, indicates overreporting.
95% Limits of Agreement (LOA)	Upper and lower bounds for the average ratio within which 95% of ratios are expected to fall.	Expected range of agreement at the health facility level.
Concordance Correlation Coefficient (CCC)	Proportion of variation in counts attributable to facility, *assuming a fixed effect of data type*, ranging from 0 (none) to 1 (all).	Agreement was defined as high (CCC>0.75), moderate (0.50<CCC<0.75), or low (CCC<0.50). The CCC is equivalent to the intraclass correlation coefficient (ICC) for agreement.

For each of the six measurements, we calculated the average ratio of surveillance counts to research counts and the 95% Limits of Agreement (LOA) using the linear mixed model (Equation S1.1) and the calculations (Table S1.1) described in the Supplement. The 95%

LOA provide a wider range than 95% confidence intervals because they also incorporate the variance contributed by health center differences; the 95% LOA can be interpreted as the expected range of health center-level agreement. Next, we calculated Concordance Correlation Coefficients (CCCs) using a variance components approach[28,31] using the linear mixed model (Equation S1.2) and the calculations (Table S1.1) described in the Supplement. The CCC is equivalent to the Intraclass Correlation Coefficient (ICC) for agreement, measuring the proportion of variation in a measurement that is attributable to health facility differences adjusted for the effect of data type on the measurement; similar to ICC, the CCC ranges from 0 to 1 with 1 indicating perfect agreement between data types.

Second, we wanted to evaluate whether agreement between surveillance and research data changed over time, to 1) determine the suitability of surveillance data for monitoring performance trends and 2) identify possible changes in data quality after the full adoption of the DHIS2 system for TB reporting in 2018. To do this, we used the uncontrolled pre-post model described in Equation S1.1 with year (2017 vs. 2019) as a fixed effect. In addition, we used plots visually assess whether health facility-level agreement was consistent over time.

Finally, we sought to identify possible factors associated with agreement between research and surveillance data, including TB testing volume (measured as the total number of smear examinations), health facility level (subcounty or county), and location (Eastern or Central region). We included these characteristics as fixed effects in linear mixed models (see Equation S1.3) predicting the magnitude of the difference between paired observations of surveillance and research counts in 2017 and 2019. Covariates

were obtained from the surveillance database (DHIS2), the Ministry of Health's master list of health facilities,[32] and the Uganda Bureau of Statistics website.[33]

Ethical Considerations

This study was determined to be exempt as not human subjects research by institutional review boards at Yale University and the Makerere University School of Public Health.

Results

Description of study sites and variables

The study sample included 32 government primary health centers, of which 24 were from the 2017 XPEL-TB baseline assessment, 20 were from the 2019 main trial, and 12 were included in both. 16 (50%) were Health Centre IIIs (subcounty-level) and 16 (50%) were Health Centre IVs (county-level), all located in 19 districts within 150 km of Kampala (Figure S1.1). According to the surveillance data for 2017 and 2019, these health centers had a median of 17.5 (IQR 9.0, 12.25) smear positive and 2.0 (IQR 0, 13.0) Xpert positive TB patients per year. A median of 24.0 (IQR 17.5, 31.25) bacteriologically confirmed TB patients and 14.0 (IQR 8.0, 25.0) clinically diagnosed TB patients initiated treatment at these sites. Of those who initiated treatment, a median of 14.5 (IQR 9.0, 26.0) were PLHIV, and a median of 14.0 (5.0, 24.5) were also taking ART (Table 1.2). Scatterplots in Figure 1.1 show the relationships between surveillance and research counts for each measurement; while all appear to be correlated, each measurement shows some variation from perfect agreement.

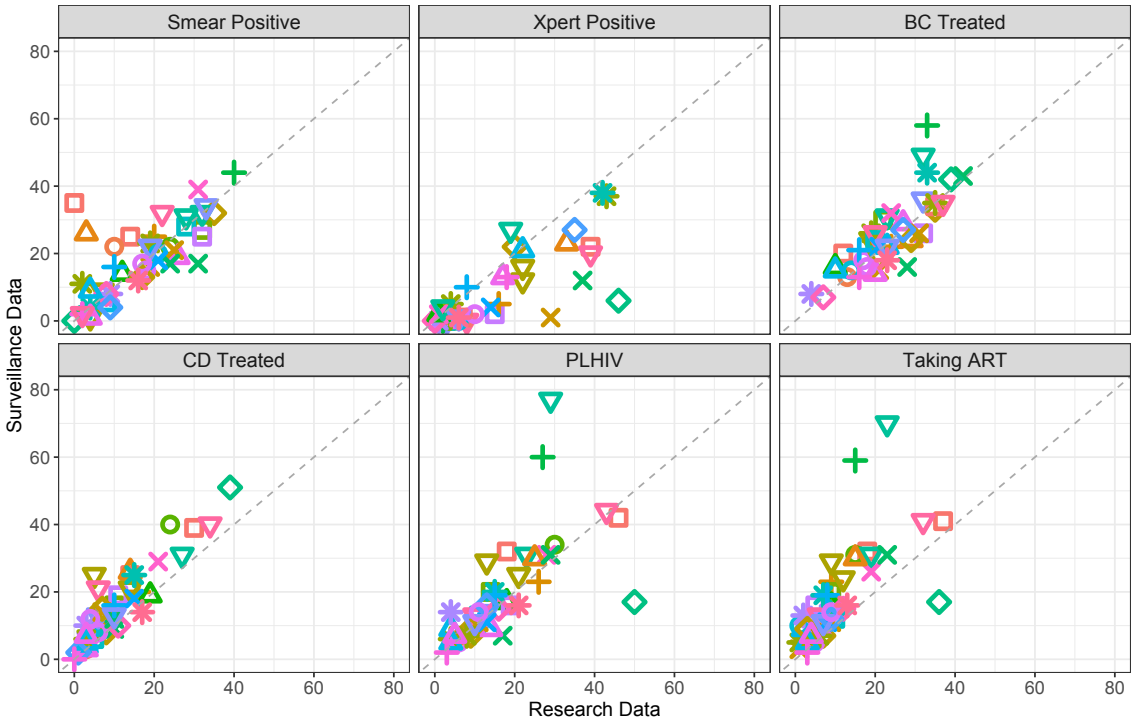

Figure 1.1. Scatterplots showing the relationship between research data (x-axis) and surveillance data (y-axis) counts for six measurements. Each of the 32 facilities is represented by a unique color and shape combination that is consistent across measurements. Two outliers with surveillance data counts >80 are not shown (both from CD Treated measurement).

For all six measurements, results of analyses assessing average agreement (ratio of surveillance counts to research counts), expected range of agreement (95% LOA), and agreement between data sources (CCC) are shown in Table 1.2 and Figure 1.2.

Table 1.2. Distribution and metrics of agreement comparing surveillance data counts to research data counts

Measurement	Surveillance Data Median (IQR)	Research Data Median (IQR)	Avg. Ratio (95% LOA)	CCC
Smear Positive*	17 (9.0, 25.0)	18 (8.0, 25.5)	1.04 (0.38, 2.82)	0.783
Xpert Positive	2.0 (0, 13.0)	7.5 (3.0, 22.0)	0.45 (0.099, 2.07)	0.361
BC Treated	24.0 (17.5, 31.25)	23.0 (18.75, 31.25)	1.07 (0.67, 1.70)	0.816
CD Treated	14.0 (8.0, 25.0)	10.0 (4.0, 15.25)	1.52 (0.71, 3.26)	0.822
PLHIV	14.5 (9.0, 26.0)	13.5 (9.0, 21.5)	1.11 (0.51, 2.41)	0.818
Taking ART	14.0 (5.0, 24.5)	9.0 (5.0, 13.5)	1.71 (0.71, 4.12)	0.616

Abbreviations: IQR = interquartile range, LOA = limits of agreement, CCC = concordance correlation coefficient, BC = bacteriologically confirmed, CD = clinically diagnosed, PLHIV = people living with HIV, ART = antiretroviral therapy, * = one outlier excluded.

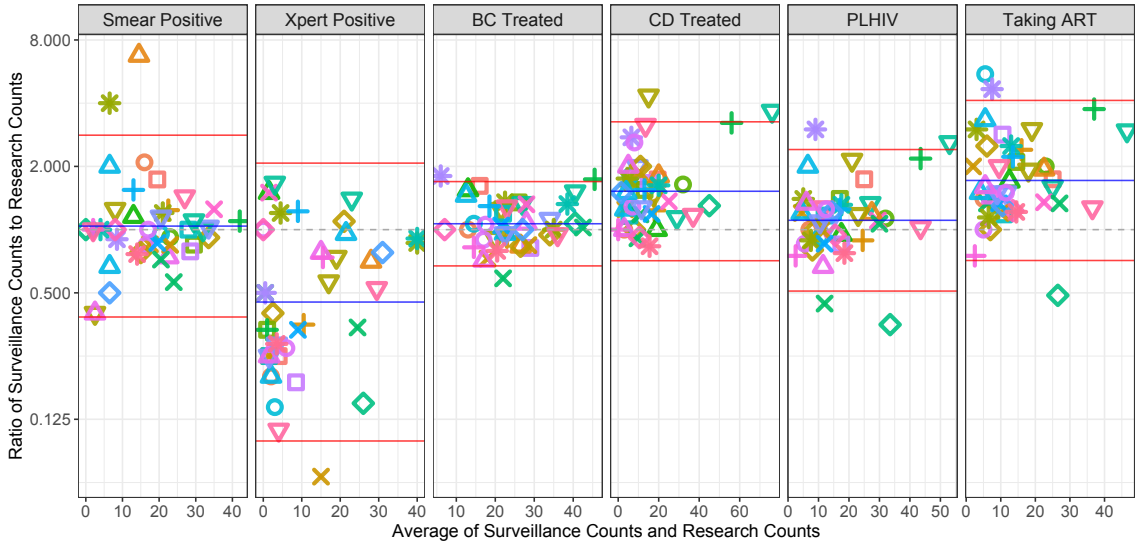

Figure 1.2. Bland-Altman plots showing the relationship between the average count and the ratio. For each measurement, the average of surveillance and research data counts (x-axis) versus the ratio of surveillance to research data counts (y-axis, log base 2 scale) in both 2017 and 2019 combined.[34] Gray dashed lines represent perfect agreement (ratio of 1), blue lines represent systematic agreement (average ratio), and red lines represent the expected range (95% LOA). Each facility is represented by a unique color and shape combination that is consistent across years and measurements.

Smear positive diagnoses

For the smear positive measurement, there was good agreement between surveillance and research data overall (average ratio=1.04, CCC=0.783). However, the 95% LOA revealed some facility-level variation; surveillance data measurements could be expected to be 62% lower to 180% higher than research data measurements.

Xpert positive diagnoses

Xpert positive diagnoses showed poor agreement between surveillance and research data; they were counted on average 55% lower in the surveillance data with a wide range of expected facility-level agreement (mean ratio 0.45, 95% LOA 0.099-2.07). A low CCC below 0.500 indicated that between-data source differences, rather than between-facility differences, contributed much of the variation in Xpert positive measurements.

Bacteriologically confirmed treatment initiations

BC treatment initiation counts showed good overall agreement between the two data sources (mean ratio=1.07, CCC=0.816). There was a moderate range in the expected agreement ratio at the facility level (95% LOA 0.67-1.70).

Clinically diagnosed treatment initiations

For CD treatment initiations, surveillance data systematically overcounted relative to research data by an average of 52%; there was also a wide range of expected facility-level agreement (95% LOA 0.71-3.26). The CCC was high (CCC=0.822), suggesting that most of the differences in this measurement were due to variation between health

facilities; however, this measurement had particularly high variance contributed by both health facility and data source.

People living with HIV

The number of people treated for TB who were PLHIV had good overall agreement between data sources with a wide range of facility-level agreement (average ratio=1.11, 95% LOA=0.51, 2.41) and a high CCC (0.818).

People taking ART

The number of people treated for TB who were PLHIV taking ART was systematically overcounted in surveillance data relative to research data, with a wide range of expected facility-level agreement (average ratio=1.71, 95% LOA=0.71-4.12). A moderate CCC of 0.616 indicated that variance in this measurement came from both data sources and health facilities.

Trends over time and sources of variation

Comparing 2019 results to those from 2017, we saw that the systematic agreement between surveillance and research data did not differ substantially between the two years. In the unadjusted pre-post analysis, year was not a statistically significant predictor of agreement for any measurements except BC Treated and Taking ART; even for these measurements, changes in point estimates for the average ratios from 2017 to 2019 were qualitatively small, remaining close to 1 for BC treated and between 1.45 and 2.0 for Taking ART (Table 1.3). However, there was evidence that small changes in average agreement might mask underlying fluctuations in facility-level agreement, as shown by plotting changes in facility-level agreement ratios between 2017 and 2019

(Figure 1.3). Results were similar when restricted to include only those facilities present in both the 2017 and 2019 datasets (see Supplement).

Table 1.3. Results of analyses examining trends in agreement between surveillance and research data over time: metrics of agreement and pre-post analysis for 2017 (N=24) and 2019 (N=19).

Measurement	Average Ratio (95% LOA)		Effect of year on avg. ratio (p-value)		CCC	
	2017	2019	2017	2019	2017	2019
Smear Positive	1.02 (0.25, 4.16)	1.05 (0.07, 17)	ref.	1.24 (0.29)	0.837	0.760
Xpert Positive	0.40 (0.05, 3.54)	0.52 (0.05, 5.22)	ref.	1.31 (0.23)	0.300	0.447
BC Treated	1.15 (0.31, 4.19)	0.97 (0.39, 2.44)	ref.	0.85 (0.02)*	0.801	0.848
CD Treated	1.51 (0.20, 11.2)	1.54 (0.09, 25.4)	ref.	1.02 (0.88)	0.714	0.869
PLHIV	1.16 (0.21, 6.32)	1.05 (0.13, 8.19)	ref.	0.90 (0.38)	0.749	0.878
Taking ART	1.97 (0.29, 13.5)	1.45 (0.19, 11.0)	ref.	0.73 (0.03)*	0.524	0.748

Legend: * = significant at P<0.05 level

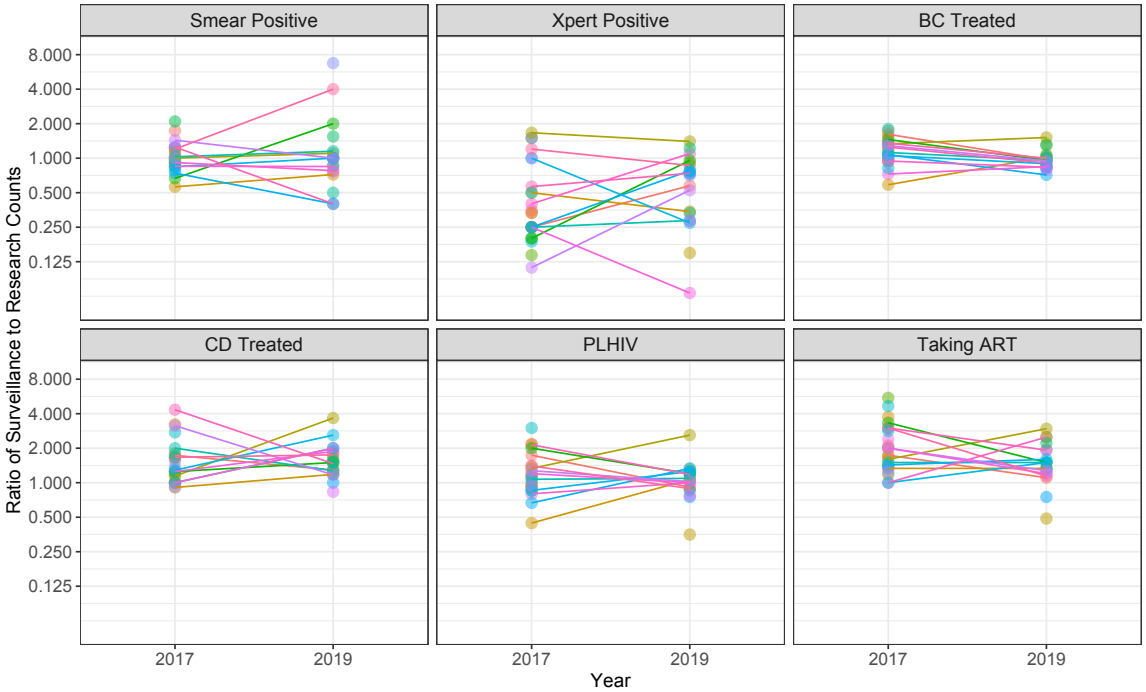

Figure 1.3. Change in facility-level agreement ratios between 2017 and 2019.

Finally, there were no significant associations between health facilities' TB testing volume, level, or region with the magnitude of agreement between surveillance and research data (Supplementary Table S1.2).

Discussion

As quality of care takes on greater priority in global TB control and elimination efforts, there is a need for timely and accurate data to monitor the quality of TB care and drive public health decision-making.[2,35] The ready availability of surveillance data makes it attractive for this purpose, but it remains underused compared to research data. In this study from Uganda in 2017 and 2019, we found that these two types of data did not reliably agree, with variation occurring across measurements, between health facilities, and within facilities over time. Importantly, we saw that even variables with good systematic agreement overall, as measured by average ratios or CCCs, may have moderate to substantial underlying variability at the facility level. These findings suggest that data collection and reporting practices occurring at the facility level may be important drivers of data quality and, further, that systems should evaluate data quality in real time.

Understanding the sources of discrepancies in routine data is critical to correcting them, with the goal of ensuring high-quality data and enabling confidence in data use.[36] Previous research in multiple settings (e.g. TB inventory studies, which estimate TB incidence and reporting rates by linking patient records across multiple sources) has identified undercounting of health outcomes in routine data due to both low case ascertainment and under-reporting, and proposed methods for adjustment.[10–12] Our study was designed to evaluate underreporting among those patients who did seek TB care

services. We expected to find that the surveillance data would either agree with or undercount diagnoses and treatment initiations compared to research data; however, we also found overreporting in some cases. Smear positive diagnoses and bacteriologically confirmed diagnoses had good overall agreement with research data. These two data elements have been the targets of NTLP quality assurance programs, are recorded in a centralized location on the original handwritten records, and represent the majority of TB patients in this setting.[26] Likewise, there are several possible explanations for the systematic undercounting of GeneXpert positive diagnoses in surveillance data relative to research data. In our study setting, delays in GeneXpert testing results, the lack of a dedicated register for this information, and the presence of multiple data collection tools are known challenges that could have contributed to under-recording of test results in the treatment registers.[37] However, we also found that clinically diagnosed TB treatment initiations were systematically higher in surveillance data compared to research data. While this was unexpected, it is similar to findings of overreporting of immunization data in quarterly reports compared to source documents, suggesting under-recording in the original source documents compared to other data tools.[21,38] The quality assurance procedures in the research study may have led to the reclassification of some of these "clinically diagnosed" TB patients that appeared in the original handwritten records as bacteriologically confirmed.

For quality improvement programs, which aim to identify and act upon gaps in health system performance, some level of disagreement between surveillance and research data could be allowable if they are consistent over time and across settings. However, a major finding of this study was a great deal of underlying heterogeneity that

could only partially be explained by health facility and time. Other studies in Uganda and Zimbabwe have found that staffing, supervision, and local use of data are associated with improved data quality.[38,39] Although we did not identify statistically significant predictors of data agreement and the availability of these factors was limited by the retrospective study design, our approach proved feasible and could be adapted to other settings to identify factors associated with data quality. This approach also extends current WHO guidance[36] for assessing internal and external consistency of data over time by enabling the identification of factors associated with data consistency over time.

This study adds to a growing literature on the usefulness of routine data sources, such as public health surveillance data, for addressing gaps in the quality of TB care. However, most widely used methods, such as TB inventory studies and studies that generated national- and sub-national TB care cascades, have relied on routine data at the level of the individual patient, rather than the aggregated data that is available in many high-TB burden settings. In order for high-quality measurements to be available to program managers in real time in settings that collect only aggregated data, they need data that is reliable over time and accurately represents the care that is being provided. Strategies such as data audits with feedback to frontline health workers have been shown to improve both the quality of the recorded data and of the care provided.[40] Our study identifies some potential targets for these and other data quality improvement efforts, such as facilities with consistently poor reporting or data elements with higher inaccuracy. However, in order to fully address variability in the quality of routine data and increase confidence in its use, future research should seek to identify the underlying mechanisms for this variation. Qualitative and mixed-methods may be especially suited

to answer these questions by characterizing the experiences and characteristics of those who record and compile routine data to inform efforts to improve the reliability of data collection.[41]

Our study has several limitations. First, while we were very careful to match the study population and measurement definitions between the two data sources as closely as possible, it was not possible to achieve a perfect match for diagnoses, which are not stratified in the surveillance data to enable exclusion of patients believed to have a drug-resistant TB, who transferred from another facility, or who had previously been treated for TB in the past year. However, these groups represent a small minority of the patient population receiving TB care in Uganda: less than 10% of TB patients have been previously treated,[42] and of that small proportion, an estimated 12% have evidence of drug resistance.[43] Thus, only 1% of new TB cases are likely previously treated with drug resistant TB, and unlikely to bias our results. Second, data on treatment outcomes was not available for the research study and data on possible TB patients was not available in the quarterly surveillance dataset; we were not able to examine these important measurements in our analysis. Finally, this study used a convenience sample of twelve health centers in Central and Eastern Uganda; while this sample is representative of Uganda, further insights may be gained by assessing agreement between data sources in a larger sample, including additional countries.

Our study also has strengths. First and foremost, our approach could be broadly applicable in high TB burden settings as they continue to develop analytical approaches to monitor the quality of their surveillance data. We used an innovative approach to collect data from source documents as a reference against which to compare routinely

reported data. This strategy could be incorporated into a quality assurance system, using a representative sample to estimate data accuracy without relying on comprehensive, prospective data collection. This approach would be similar to lot quality assurance sampling, which is widely used for monitoring the performance of smear microscopy centers.[44] In addition, assessing agreement across locations, measurements, and time provides the opportunity to identify many different sources of variation in surveillance data, which may be highly specific to a particular context. Finally, our methods are suitable to be used with the aggregated count data available in many settings.

Conclusions

Our study found substantial variability in the agreement of TB surveillance data with high-fidelity research data in a high-burden setting; agreement was best for smear positive diagnoses and bacteriologically confirmed treatment initiations and worse for Xpert positive diagnoses and clinically diagnosed treatment initiations. This study provides an example of how to use an analytical approach to identify sources of inaccuracy on the local scale, and could be replicated on regional and national scales. Incorporating this approach as part of a regular quality assurance program would promote trust in routine TB data, ultimately enabling its use as part of a data-driven public health approach to ensuring high-quality care for people with TB.

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Chapter 1 Supplementary Materials

Study Setting

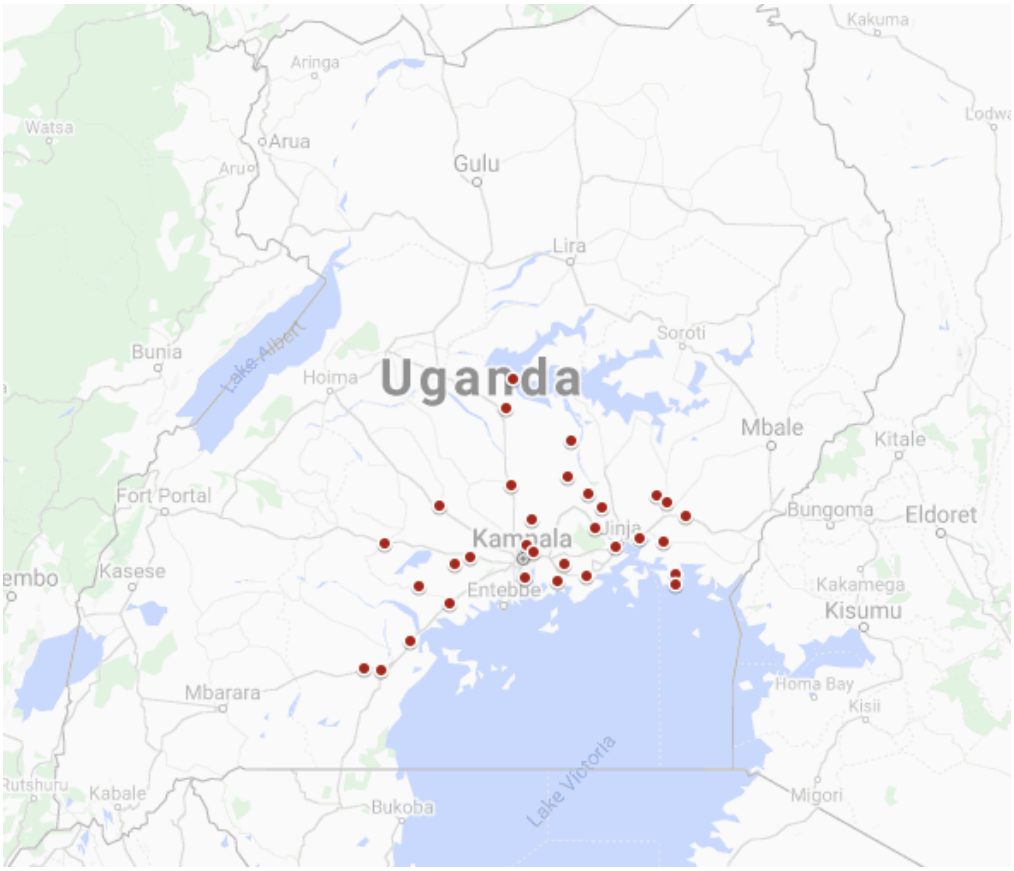

Figure S1.1. Map of 32 facilities included in analysis (Source: Google Maps)

Metrics of Agreement

Equation S1.1.

$$Y_{it} = \mu + \alpha_i + \gamma_t + e_{it}$$

Y_{it} = difference in log-transformed counts (surveillance data – research data)
μ = overall mean
α_i = random health facility effect
γ_t = fixed year effect
e_{it} = random error effect

Equation S1.2.

$$Y_{ijt} = \mu + \alpha_i + \beta_j + \gamma_t + \alpha\beta_{ij} + \alpha\gamma_{it} + \beta\gamma_{jt} + e_{ijt}$$

Y_{ijt} = log-transformed count
μ = overall mean
α_i = random health facility effect

β_j = fixed data source effect
γ_t = fixed year effect
$\alpha\beta_{ij}$ = random health facility-data source interaction effect
$\alpha\gamma_{it}$ = random health facility-year interaction effect
$\beta\gamma_{jt}$ = fixed data source-year interaction effect
e_{ijt} = random error effect

Table S1.1. Formulas for metrics of agreement.[28]

Statistic	Equation	Calculations	Definitions
Average ratio	S1	$exp(\mu)$	β_0: average difference between log-transformed surveillance and research counts SD_{total}: total standard deviation σ_α^2: health facility variance σ_ε^2: residual variance
95% Limits of Agreement (LOA)	S1	$exp(\mu \pm 1.96 * SD_{total})$ $SD_{total} = \sqrt{\sigma_\alpha^2 + \sigma_\varepsilon^2}$	
Concordance Correlation Coefficient (CCC)	S2	$\frac{\sigma_\alpha^2 + \sigma_{\alpha\gamma}^2}{\sigma_\alpha^2 + \sigma_{\alpha\gamma}^2 + \sigma_{\alpha\beta}^2 + \beta_\gamma^2 + \sigma_\varepsilon^2}$ $\beta_\gamma^2 = \frac{1}{2p}\sum_{t=1}^{p}(\hat{u}_{1t} - \hat{u}_{2t})^2 - \frac{\sigma_{\alpha\beta}^2 + \sigma_e^2}{n}$	σ_α^2: health facility variance $\sigma_{\alpha\gamma}^2$: health facility:year variance $\sigma_{\alpha\beta}^2$: health facility:data variance σ_ε^2: residual variance β_γ^2: data fixed effect, corrected for repeated measures p: number of time points $\hat{u}_{1t} - \hat{u}_{2t}$: fixed effect of time point t n: number of facilities

Associations with Time and Facility Characteristics

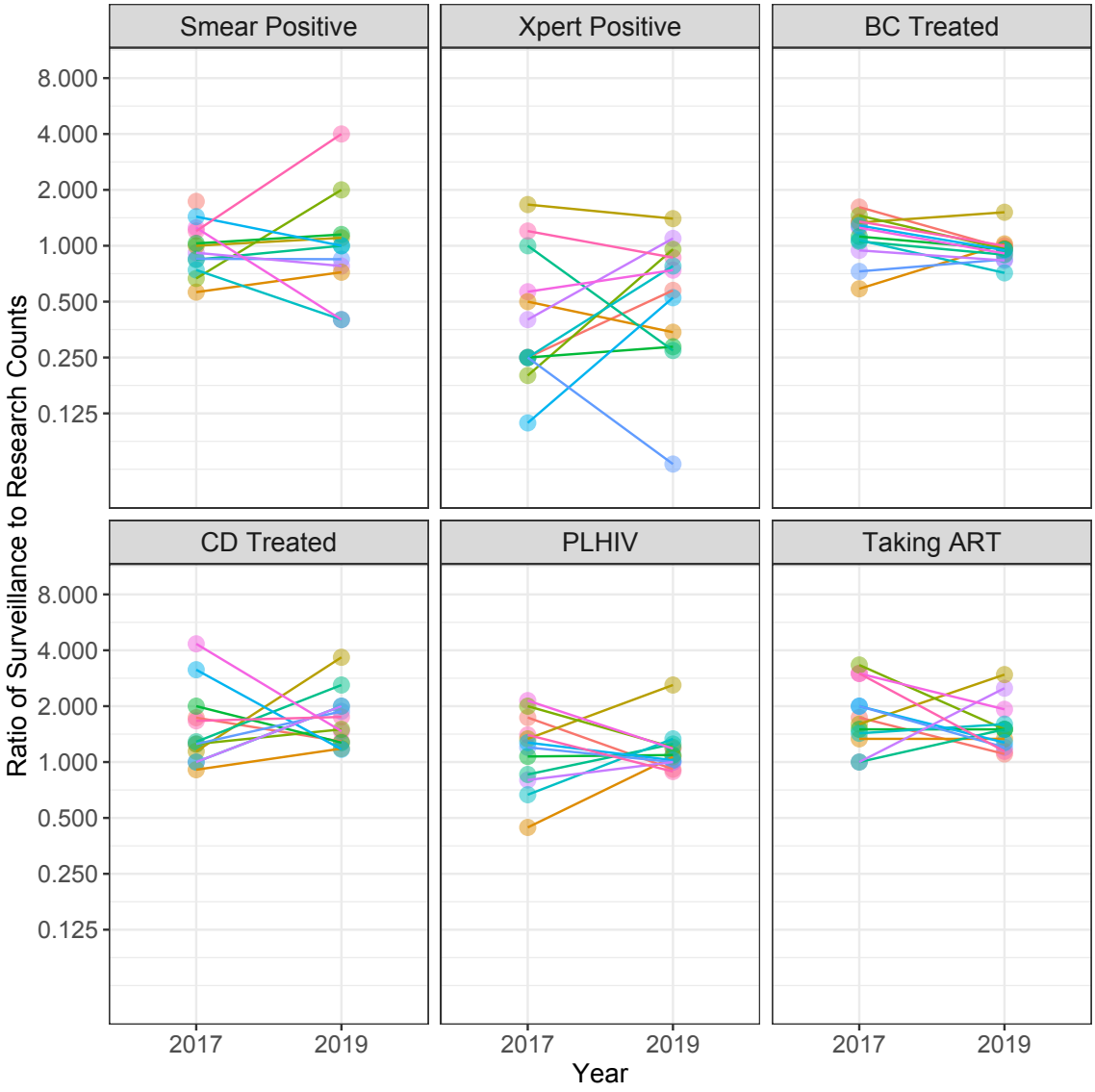

Figure S1.2. Change in facility-level agreement ratios for 12 health facilities included in both 2017 and 2019 datasets. Similar to the full set of health facilities, changes in agreement ratios over time do not follow a consistent pattern; BC treated and PLHIV may show general improvement, with the exception of one health facility.

Equation S1.3.

$$Y_{it} = \mu + \alpha_i + \gamma_t + \rho_{it} + e_{it}$$

Y_{it} = difference in log-transformed counts (surveillance data – research data)
μ = overall mean
α_i = random health facility effect

γ_t = fixed year effect (*note that this term was only included in models for BC treated and Taking ART*)
ρ_{it} = fixed effect for one of the following: Health facility level (County vs. Subcounty [ref.]), Region (Eastern vs. Central [ref.]), or TB testing volume (number of smear examinations at facility *j* in year *i*)
e_{it} = random error effect

Table S1.2. Associations between health center characteristics and agreement between data sources (ratio).

	Smear Positive	**Xpert Positive**	**BC Treated**	**CD Treated**	**PLHIV**	**Taking ART**
	Coefficient (p-value)	Coefficient (p-value)	Coefficient (p-value)	Coefficient (p-value)	Coefficient (p-value)	Coefficient (p-value)
Health Center Level						
County	0.19 (0.43)	0.079 (0.74)	-.052 (0.52)	-0.017 (0.88)	0.013 (0.92)	0.24 (0.11)
Sub-county	(ref.)	(ref.)	(ref.)	(ref.)	(ref.)	(ref.)
Region						
Eastern	-0.27 (0.29)	0.23 (0.37)	-0.10 (0.23)	-0.018 (0.89)	-0.11 (0.41)	-0.16 (0.32)
Central	(ref.)	(ref.)	(ref.)	(ref.)	(ref.)	(ref.)
TB testing volume	0.0001 (0.19)	4.8e-05 (0.95)	0.0005 (0.09)	5.5e-04 (0.18)	0.0004 (0.26)	7.199e-04 (0.15)

Chapter 2

"Data can only improve if it's used:" a qualitative study of tuberculosis data collection, reporting, and use in Uganda

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Introduction

Gaps in case detection, treatment initiation, and cure for tuberculosis (TB) contribute to unacceptably slow declines in incidence and mortality.[1] Moreover, a lack of routine data that is timely, accurate, and reliable hinders the ability of TB programs to quickly measure and address these gaps. The World Health Organization (WHO) END TB strategy and the Lancet Commission on Quality[2] have identified high-quality data on both outcomes and processes of care, as a priority for evaluating and improving the quality of patient care in low- and middle-income countries. WHO even provides a toolkit to assess the quality of routine TB data.[3] Yet, routine health data for TB continue to be underutilized for such purposes, despite the ready availability and potential of such data to answer many questions about quality of care.[4,5]

Historically, routine health data has been unreliable because of a lack of completeness, accuracy, and timeliness across settings and health contexts, especially in low- and middle-income countries.[6] For TB, under-detection and under-reporting of cases have been widespread,[7] requiring innovative methods to produce estimates of TB burden, treatment processes, and patient outcomes.[8,9] A previous analysis from our group found that variability in the accuracy of routine TB data in Uganda included both under- and over-reporting that varied across health facilities, data elements, and time.[10] Low-quality TB data has been shown to be associated with the use of multiple source documents.[11,12] In contrast, local use of data[13] and feedback of data to frontline workers in the context of performance audits[14] have been shown to improve the quality of routine TB data in Uganda and Zimbabwe, respectively. Despite these associations, suboptimal data quality persists. In order to guide efforts to improve the accuracy and reliability of routine TB

data, a detailed understanding is needed of the processes, experiences, and perspectives of those who collect and report it.

In this study, we sought to understand sources of variation in the quality of routine TB data in Uganda by characterizing the experiences, processes, and perspectives of TB data collectors and users through semi-structured interviews. Uganda is a high HIV-TB burden setting,[15,16] and its National Tuberculosis and Leprosy Programme (NTLP) has been highly engaged in improving its TB data. Because the NTLP is in the process of transitioning from an aggregated, paper-based reporting system to a case-based, electronic system (eCBSS), this study also explored best practices to carry forward with the new electronic system. Qualitative methods are especially suited to address these questions, allowing us to contextualize data quality and use through interviews with key stakeholders involved in these processes. By interviewing those who regularly collect and use, this data, we sought to identify challenges with the data system, as well as solutions to enhance data quality.

Methods

Conceptual Framework

We used the Performance of Routine Information System Management (PRISM) framework, a logic model[17] developed by the MEASURE Evaluation group and validated in Uganda to assess the performance of routine data systems in the healthcare context (Figure 2.1).[18–20] PRISM describes how a data system's technical factors (e.g. forms, software), organizational factors (e.g. resources, training, financing), and behavioral factors (e.g. skills, knowledge, motivation) influence data system processes and, ultimately, data system outputs (e.g. data quality, use of information). This framework

has been previously applied by researchers in the maternal, child, and newborn health field in Tanzania,[21] but to our knowledge, not for TB data in Uganda.

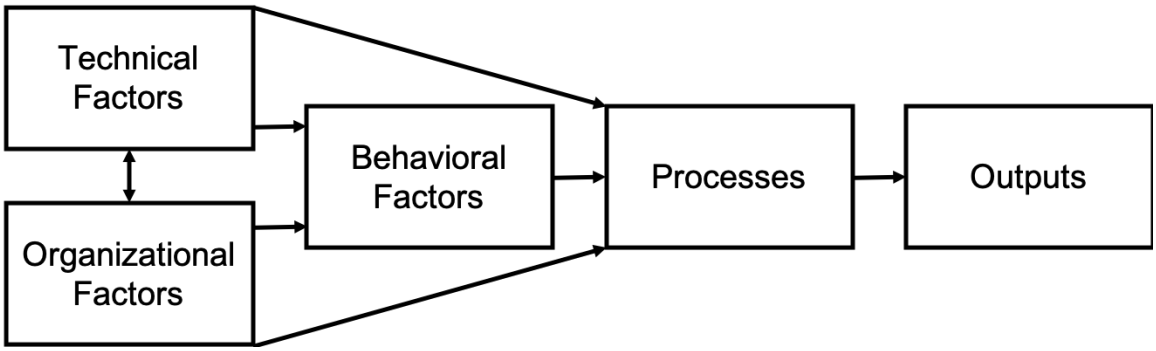

Figure 2.1. A modified Performance of Routine Information System Management (PRISM) Framework, adapted from Aqil et al. (2009). The framework theorizes that interacting technical, organizational, and behavioral factors affect the processes of collecting routine health data, which in turn influence data system performance such as data quality and use.

Setting

We conducted our study in three districts in Central Uganda: the capital city (Kampala) and two adjacent districts spanning urban, semi-urban, and rural settings (Wakiso and Mukono). In Uganda, all routine TB data is collected by frontline health workers and recorded by hand in paper registers at each health facility. Facility staff aggregate and compile this data into standardized reporting forms, which require certain data elements at weekly, monthly, or quarterly intervals. The forms are then entered by a data officer into a District Health Information Systems 2 (DHIS2) database, an open-source web-based platform that is used widely in LMICs. DHIS2 was first introduced in Uganda in 2012 and expanded to the TB program in 2016.[22] The Monitoring and Evaluation (M&E) team at the Uganda tracks data completeness (e.g., percent of sites reporting), timeliness (e.g., percent of sites reporting within 15 days of the end of the quarter), and performs data quality assessments of data in the DHIS2 database.

Sampling and Participants

We sampled two stakeholder groups: 1) programmatic stakeholders who oversee and use the TB data system, and 2) facility-based stakeholders who collect the data. To recruit programmatic stakeholders, a senior study team member (AK) and an NTLP collaborator (RKM), both of whom have longstanding relationships with TB leadership in Uganda, used snowball sampling to identify participants from the NTLP, the Ministry of Health (MOH), and implementing partner organizations (i.e., non-governmental organizations providing technical and operational support for NTLP activities). We contacted these stakeholders via email to introduce the study and invite them to participate, and then asked stakeholders to refer others with experience overseeing or using the TB surveillance data or the DHIS2 system.

To recruit facility-based stakeholders, we first included all health centers in the three study districts that reported ≥20 TB patients to the DHIS2 system in 2019, the most recent year with complete data not affected by interruptions in service delivery due to COVID-19. We excluded referral hospitals because they usually have additional dedicated staff and workstations for data compilation and submission compared with lower level health centers; military, police, and prison facilities with particular patient populations; and facilities that could not be matched to MOH's National Health Facility Master List.[23] We then employed stratified purposeful sampling procedures[24] to maximize variation with respect to health center level (hospital, county, or subcounty), ownership (public, private not for profit [PNFP], or private for profit [PFP]), TB patient volume, and data quality. We characterized data quality using the WHO's quality benchmarks for national TB data and stratified sites as having above-average, average, or

below-average data quality based on whether they always, sometimes, or never met these benchmarks (see Supplement). For each sampled health facility, we identified TB clinicians and data officers to participate in the interviews through in-person site visits.

Data Collection

The interview team, consisting of one female U.S.-based doctoral student (EBW) with previous field experience in Uganda and two male Ugandan researchers (JG and NK), developed two semi-structured interview guides, one for programmatic and another for facility-level stakeholders (Supplement). Interview guides were designed to elicit respondents' roles and responsibilities, experiences, challenges, perspectives, and recommendations related to routine TB data collection, reporting, and use. We piloted the interview guide on a Ugandan researcher who had familiarity with Uganda's routine TB data system and incorporated the suggested revisions for clarity. Health facility interviews were conducted in-person, and programmatic stakeholder interviews were conducted on an online, video-conferencing platform. All interviews were conducted in English and were led by one of the Ugandan social scientists (JG or NK), with another team member (EBW) serving as a secondary interviewer and notetaker. At the beginning of each interview, we collected data on demographics and work history and experience (Supplement). Interviews occurred between September-December 2021 and were audio-recorded and transcribed verbatim. We set our target sample size based on guidelines for thematic saturation, or the point at which no new themes emerged from subsequent interviews;[25] we evaluated for saturation midway through and at the end of the interview period, at which time the team agreed that saturation had been reached.

Data Analysis

We uploaded all transcripts to Dedoose. We developed an initial deductive codebook based on PRISM to identify important themes related to the organizational, technical, and behavioral factors underlying health system processes and outputs. Three researchers (EBW, NK, and JG) independently applied these codes to an initial set of transcripts (two researchers per transcript) and inductively identified codes that were not captured by PRISM. After the group reached consensus on a final codebook and code application, a single team member (EBW, NK, or JG) coded the remaining transcripts. One team member (EBW) reviewed all coded transcripts to ensure that codes were applied consistently. Next, we conducted a thematic analysis to identify how factors from the PRISM framework worked together to affect data quality and use in this setting. We also compared themes between programmatic stakeholders and health facility staff, above-average and below-average data quality sites, and TB clinical staff and data officers, in order to identify any differences in perspectives based on these participant and site characteristics.

Ethical Considerations and Reporting

With each participant, we introduced the study team, explained the research objectives, and obtained verbal consent, including consent specifically for audio recording, prior to beginning the interview. The study was approved as a minimal risk protocol by institutional review boards at Yale University and Makerere University School of Public Health, as well as the Uganda National Council for Science and Technology (UNCST). Both IRBs and the UNCST also approved our COVID-19 mitigation plans for in-person interviews. Finally, we established relationships with and

obtained permission from the relevant district- and facility-level authorities before approaching individuals for interviews. We used the Consolidated Criteria for Reporting Qualitative Research (COREQ) to guide study reporting (Supplement).

Results

Health Facility and Participant Characteristics

Of the 71 eligible sites, we identified 15 sites to approach for interviews. Thirteen (87%) sites agreed to participate; two sites were unable to participate due to schedule conflicts involving the target staff members. Of the 13 participating sites, six (46%) were in Kampala, four (31%) in Wakiso, and three (23%) in Mukono (Table 2.1). Five (38%) facilities were subcounty-level, six (46%) were county-level, one (8%) was a special clinic, and one (8%) was a hospital. Eight (62%) were public, government-run facilities, three (23%) were PNFP, and two (15%) were PFP (Table 2.1). Six (46%) had a TB patient volume above 100 in 2019, and together the 13 sites covered 18% of the 11,589 pulmonary TB patients reported in the study region in 2019. Five (38%) sites had above-average data quality, three (23%) had average data quality, and five (38%) had below-average data quality (Table 2.1). An itemized list of participating facilities and their characteristics is provided in the Supplementary Material.

Table 2.1. Characteristics of participating health facilities.

	Participating health facilities (n=13)
	n (%)
District	
Kampala	6 (46)
Wakiso	4 (31)
Mukono	3 (23)
Health facility level	
Hospital	1 (8)
County	6 (46)
Sub-county	5 (38)
Clinic	1 (8)
Ownership	
MoH	8 (62)
PNFP	3 (23)
PFP	2 (15)
TB patient volume	
High[*]	6 (46)
Low	7 (54)
Data quality	
Above-average	5 (38)
Average	3 (23)
Below-average	5 (38)

Notes: MoH: Ministry of Health; PNFP: private-not-for-profit; PFP: private-for-profit; percentages are by row.
[*]>100 patients in 2019

We interviewed 31 health facility staff and 10 programmatic stakeholders (Table 2.2) through 29 semi-structured interviews. The 21 health facility interviews had a median length of 39 (range 8-75) minutes, and the 8 stakeholder interviews had a median length of 37 (range 9-48) minutes. The majority (22/29) of interviews were with a single participant, and the remainder (7/29) were conducted with two to four participants who shared similar professional roles. Health facility staff included 9/31 (29%) TB focal persons, 7/31 (23%) other clinical staff, and 15/31 (48%) data officers. Among all health facility staff interviewed, 14/31 (48%) were female, the median age was 33 years (IQR 28, 40), and staff had a median of 5 years (IQR 3.5, 8.5) of experience in their current professional role. Among programmatic stakeholders, 5/10 (50%) were employed by the

NTLP, 2 (20%) by the Information Communication Technology department of the Uganda Ministry of Health MOH, and 3 (30%) by implementing partners. Eight (80%) of the programmatic stakeholders interviewed were male. Professional departments included monitoring and evaluation, program management, and technical advising.

Table 2.2: Qualitative interview participant characteristics

Characteristic	**Health facility stakeholders (n=31)**
Female sex, n (%)	14 (48)
Age, median years (IQR)	33 (28, 40)
Professional experience, median years (IQR)	5 (3.5, 8.5)
Professional category, n (%)	
Data personnel	15 (48)
TB focal person	9 (29)
Other clinical staff	7 (23)
	Programmatic stakeholders (n=10)
Female sex, n (%)	2 (20)
Employer, n (%)	
National Tuberculosis and Leprosy Programme	5 (50)
Ministry of Health	2 (20)
Implementing partner organization	3 (30)

Overview

Interview respondents discussed their professional roles and responsibilities, experiences, challenges, good practices, and desired changes related to routine TB data collection and reporting. Health facility stakeholders described three crucial data processes: documentation, report compilation, and report submission. Documentation of patient data requires several paper registers (e.g., outpatient, presumptive TB, laboratory, and TB treatment) and is carried out by clinical staff. Report compilation and submission were primarily done by a data officer, with TB clinical staff involved in compilation at some facilities. At the national level, the NTLP is primarily responsible for data cleaning.

During preliminary coding based on the PRISM framework, we identified important technical, organizational, and behavioral factors that influenced these processes and data system outputs (data quality and use). Through thematic analysis, we identified four cross-cutting themes, depicted in Figure 2.2 and described in detail below.

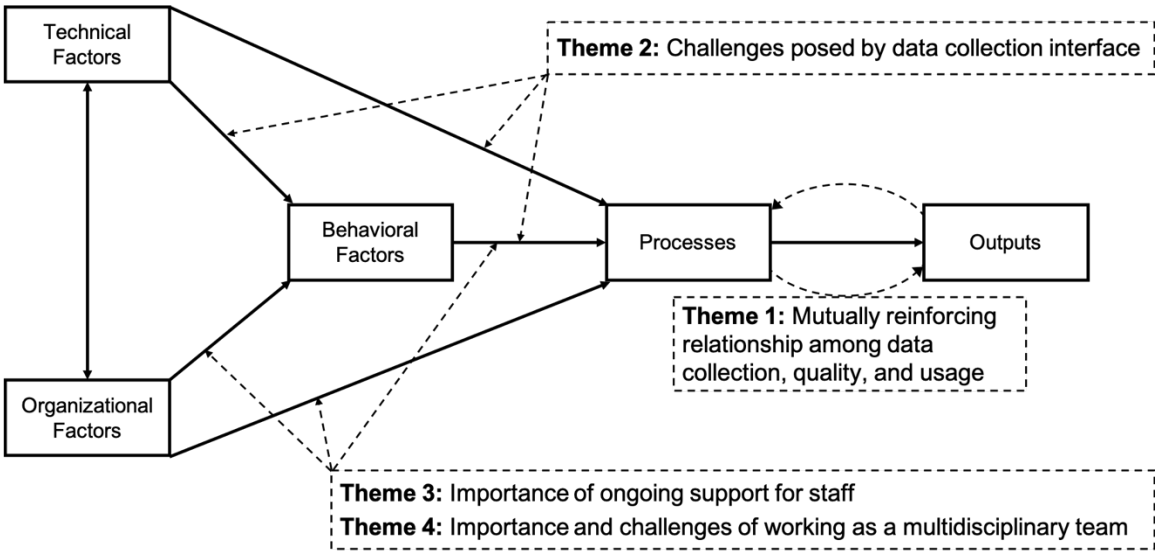

Figure 2.2. Conceptual model illustrating how the four emergent themes (dashed boxes and arrows) describe relationships between PRISM domains (solid boxes and arrows).

Theme 1: Mutually reinforcing relationship among data collection, quality, and usage

Many interview respondents, particularly programmatic stakeholders but also some health facility staff, emphasized that the best way to improve the quality of collected data is by using it. National-level stakeholders from NTLP and MOH described how they have increasingly promoted data use in recent years (2019-2021) for monitoring program performance, evaluating the impact of new initiatives, and providing accountability to national and international bodies. Data quality assessments, which have been conducted more frequently since 2019, have shown improved data completeness, timeliness, and accuracy during this time. These assessments have also repeatedly shown that data use reinforces data quality.

"The number one driver of accuracy was data use. That is what we saw. The fact that we realized facilities that had the best quality in terms of data for TB were actually holding performance reviews, they display this data openly to generate discussions around it." – Stakeholder 7, Implementing Partner

However, data usage has not been achieved in the same way at the health facility level. All stakeholders from health facilities reported using their TB data to some degree, but not all of them used it in the ideal manner described by the stakeholder in the quote above. The most commonly reported purposes were for estimating inventories of drugs and other supplies, conducting targeted community outreach, and accountability to accrediting bodies. Some sites, especially higher data quality sites, did describe using their data for QI initiatives, stating that implementing partners have been instrumental in promoting QI at the facility level.

"On the ground, we always use our data before others use. Now we always own our data using QI, so that it helps us to identify gaps and we correct them, we use them in opening up QI projects. And here, when we use our data, it helps us to identify gaps. Then other people use our data like when we're doing performance review meetings with other facilities, they know, here this is what these people did and what they achieved." – Data officer, high data quality facility (ID F-F4)

Together, interviews highlighted universal agreement about the importance of TB data. They also demonstrated that data use has been a priority at the national level but less so at the facility level, although many facility-based staff were eager to learn.

Theme 2: Challenges posed by data collection interface

Stakeholders at all levels reported that the numerous, complex paper registers required for documentation and compilation of TB data were a major obstacle to collecting high-quality data. Many health facility staff described having limited time for documentation due to patient care duties, the large number of patients, and the large number of data fields requested for each patient.

"At times I find it is so tiresome to write in four registers, and the file, and the book, and you are [only] one person." – Nurse, low data quality facility (ID F-E1)

Participants also reported challenges with missing or incomplete data for each of the registers. However, the presumptive register posed a particular challenge because there were different registers located in each specialty clinic (e.g., maternity, ART), not all of which prioritized screening for TB. For the TB treatment register, clinical staff described going to great lengths to fill in missing data, especially for variables that were important for patient follow-up, such as contact information. Registers also sometimes went missing, lost pages, or had indecipherable handwriting, preventing or greatly inhibiting accurate reporting. Importantly, several respondents in higher-data quality sites described how their TB focal person was able to improve documentation by taking initiative to coordinate across staff and departments, train others within the TB clinic, and personally ensure data completeness in the many registers.

"But ever since we got someone who is coordinating the TB unit, these days these errors have been minimized. He has given time at the TB unit, he has mentored the rest of the staff in the clinic, at least we are moving on. The errors have been minimized." – Data officer, average data quality facility (ID F-D2)

Participants reported that the standardized reporting forms, requiring counts of TB-specific indicators, were a critical factor during the next steps of data compilation and submission. However, several data officers said they lacked the knowledge required to compile or verify certain indicators into the reporting forms. Many participants described how implementing partners, while critically important for supporting data collection on the ground, often have a specific emphasis on particular types of data over others, affecting both the training received by staff and the attention they gave to those data elements. HIV-related variables were frequently mentioned as an example of this.

"Now that different IPs [implementing partners] have different interests, and the more emphasis they put the more the errors they are reducing […] Because if I know someone is going to check on the piece I've done, I will be more keen on that piece." – Data officer, high data quality facility (ID F-C2)

"For example the ART [HIV treatment] program has been under [a nonprofit agency]. So they have been sending support teams, at times inviting us for trainings in line to HIV and HMIS-105 [reporting form] guidelines. […] At times, they send TB treatment guidelines." – Data officer, low data quality facility (ID F-I2)

In addition, they talked about challenges compiling, verifying, and submitting forms before the deadline, which comes only two weeks after the end of the reporting period. Some data officers addressed this issue by asking colleagues to complete their reports at least a week before the deadline. They also provided mentorship in how to compile the reports or simply compiled the report themselves. Despite these efforts, data officers sometimes had to omit certain data with major inconsistencies that could not be resolved, and sometimes made counting or data entry errors in their haste to submit the forms on time.

Participants at all levels reported a major challenge that arose in 2020 when the NTLP revised the format of the paper tools: months-long delays in delivering the new tools to facilities, exacerbated by pandemic-related supply chain and budget challenges. In the meantime, facility staff described making their reports using outdated tools, causing delays in documentation and improvisation or omission of newer indicators. Once they received the new tools, facility staff generally said that they found the new registers to be more streamlined but the new reporting forms to be more difficult, due to the number of new strata and indicators.

For the final step, report submission, participants emphasized the need for a computer and internet connection to access the DHIS2 web-based system. However, they

also described challenges due to unreliable internet connection, insufficient mobile data, lack of a dedicated computer, and outages in the DHIS2 system itself at critical times:

"Then there are times the system is off, there could be many users, and remember when you are trying to beat the deadline, because you are expected to have entered this information by 15th…yeah so if you had not planned well your time, and you want to enter, towards 15th, then you might not be able to do so because of the pretty huge number that is using the system." – Data officer, high data quality facility (ID F-B1)

In summary, paper registers, reporting forms, and computers are crucial technical elements of the TB data system, and they require time, knowledge, and consistent availability in order for the reported data to be accurate and usable.

Theme 3: Need for ongoing support for staff

All stakeholders described the importance of formal training, performance reviews, supportive supervision, and feedback for maintaining skills and motivation to collect and use TB data. However, these opportunities were described as being offered inconsistently or ineffectively, often due to shortages of key resources.

Clinical and data officers who document and compile TB data described the value of initial training on how to calculate TB indicators, use DHIS2 for data analysis, and conduct performance feedback, as well as ongoing training in the form of performance review meetings, supportive supervision, and feedback. Performance reviews, in which staff from multiple facilities come together to review their data and share best practices, served as an especially important venue for both imparting knowledge and providing peer-to-peer support, as described by this data officer:

"Because if you come and tell me, 'Facility A is very good,' I will say, 'You're telling me because you want me to do what, to change.' But if people meet and someone from that facility comes out, he speaks out, 'For us, we do this and this and this, that is why our facility is at the top.' Even this person who is down will get in touch with the one doing well, and they will all rise." – Data officer, high data quality facility (ID F-F4)

In practice, however, these trainings were not carried out consistently, with some facility staff reporting waiting months after being hired to be trained in data processes. National-level stakeholders acknowledged this issue, and described how human resource shortages limited some district-level biostatisticians time to train staff at the health facilities in their jurisdictions. In addition, high staff turnover at health facilities resulted in frequent departures of highly skilled colleagues who were then replaced by new hires with less training in data collection, reporting, or use.

"But you always get also a challenge that you train someone today, the following day he gets a transfer. When someone is on transfer, he doesn't get time of mentoring someone who has replaced. He will be in a transfer mode; he just goes. So when it comes to reporting, someone who has been transferred in is the one handling the reports. So you find that most of these errors are carried forward." – Data officer, average data quality facility (ID F-D2)

Funding gaps were also described by both national and facility-level stakeholders as challenges in carrying out supportive practices. At the national and district level, low donor or implementing partner funding for TB relative to HIV led to performance reviews and trainings with little specific focus on TB data. In addition, salary cuts for public servants were de-motivating to some clinical and data officers, who considered data collection to be uncompensated "extra work" on top of their other responsibilities. At the facility level, supportive supervision sometimes did not occur due to insufficient funds for transport and mobile data. These resources were especially needed by data officers, who have the responsibility to mentor lower-level facilities in their health subdistricts on data collection and use. Without the funds to travel to or communicate with those other sites, participants described a persistent cycle of training gaps, low-quality data collection, and suboptimal data use.

"Yeah I think if I had support to support others in the lower facilities, because this is an HSD [health sub-district] level. I have other facilities, lower facilities that report to me. I feel like to mentor them, but I have no capacity. We have no transport, we have no financial support, and I feel many of these errors would be eradicated or minimized if we had capacity to go to these lower facilities and show them exactly what is supposed to be done, how it supposed to be done." – Data officer, average data quality facility (ID F-D2)

Beyond knowledge and skills, the motivation of facility staff to participate in routine data processes also suffered as a result of these gaps in engagement. Importantly, lack of feedback from stakeholders from MOH or the NTLP was a major contributor to low motivation, with many staff reporting only hearing feedback about their data when there was a problem. In addition, some individuals noted that low engagement between programmatic leadership and staff on the ground led to unrealistic expectations of how much work one person should be able to accomplish.

"Sometimes I see Ministry of Health just rolls out programs but they don't assess, how much does this take one record officer to do this work? They've brought COVID issues here, there's Defeat TB program, HIV management, NCDs [non-communicable diseases], there's DHIS2 reporting. So a lot of work on the ground, but they don't want to come and find out, "Are you really okay with this workload?" And we just burn with the work like that." – Data officer, high data quality facility (ID F-N1)

Stakeholders acknowledged this problem as well.

"The other problem that I'm seeing and that is causing a quality problem is […] we do not have a good system for providing feedback to the people that are collecting this data. In most cases me, who is a supervisor, I go to the facility maybe once a quarter, and once I've talked to a health worker, then I allow that health worker to collect the data. The next time I see the data is in DHIS2. I do not have time to go back to the facility and maybe congratulate this health worker upon abstracting a good report or share feedback on the quality of the data." – Stakeholder 1, Implementing Partner

Overall, participants described inconsistent opportunities to participate in training, supportive supervision, feedback, and performance review, which negatively impacted the development of their knowledge, skills, and motivation.

Theme 4: Importance and challenges of working as a multidisciplinary team

According to several TB focal persons and data officers, teamwork was a key factor facilitating data collection and reporting processes. Collaboration across departments is required to ensure thorough TB screening, evaluation, and documentation in the presumptive register. Critically, collaboration between the TB focal person and the data officer is necessary to review the data report, identify any errors, and make corrections prior to screening. In the most collaborative facilities, staff reported that data reviews were held regularly—weekly or monthly—and involved the entire TB and data departments. For high data quality sites that reported engaging in QI activities, teamwork was described as an essential component that allowed the identification of performance gaps and solutions.

"So after we've compiled our reports, we've identified the gaps, I've actually gone that extra mile let the team know, "You know we have not met the target of screening, what could be the challenges, what went wrong?" And we forge our way forward together as a team." – Data officer, high data quality facility (ID F-B1)

However, in the hectic and high-workload setting of the TB clinic, teamwork was sometimes described as difficult to achieve. Many facility staff perceived that their colleagues had a poor attitude toward data work, resulting in incomplete tasks and an increased burden on others. Some respondents said that tasks like documentation in the TB register were seen as the sole responsibility of the TB focal person; when that person was not at the clinic, documentation did not occur. Some facilities solved this problem by ensuring that everyone in the TB clinic had the knowledge and skills to contribute to documentation. In addition, some data officers observed that their mentees at lower-level facilities had become so reliant on supportive supervisions that reports would not be compiled without them. Others reported that the data officer, who is responsible for all

departments' data in addition to TB, is too busy to consult with them before submitting a report; they only review the data together if someone recognizes an error.

"The data officer, at times somehow he is busy, because he has a lot of work. He is only one person and he has to deal with all the facility data. So I usually sit with the team, the other team, leaving him." – TB focal person, high data quality facility (ID F-C1)

Overall, teamwork within and across departments was described as crucial for documentation and compilation of high-quality TB data, as well as data use for QI. However, high workloads, staff shortages, and individual attitudes sometimes impeded teamwork, negatively affecting data quality and use.

Implications for "going digital": transition to an electronic, case-based surveillance system

Each of the four themes above has implications for Uganda's ongoing transition to a fully electronic, case-based surveillance system (eCBSS) for TB. Stakeholders from the NTLP explained that the new system will eventually eliminate paper registers and reporting forms, allowing for documentation of patient data directly into a reconfigured, patient-level DHIS2 web interface. eCBSS will automatically compile and submit reports, and patient data will be available to stakeholders in real time. At the time of these interviews (September-December 2021), many clinical and data staff reported that eCBSS had been introduced at their health facility but was not yet operational for reporting. They described this transitional period itself as posing specific challenges, including back-entering previous years' patients into the new system and double-entering current patients into both the old and new systems. Nonetheless, enthusiasm for eCBSS and its potential benefits was high among all stakeholders.

Regarding the mutually reinforcing relationship between data quality and data use (Theme 1), programmatic stakeholders saw two main advantages of eCBSS. First, the system will provide continuous access to individual patient data, rather than aggregate counts, allowing them to monitor progress toward performance targets without having to wait until the end of a reporting period. Second, eCBSS was seen as a more sustainable approach to promoting data use at the facility level than the current system, which requires a great deal of time and attention to documentation and compiling reports at the expense of data use.

"But if we continue with our paper-based processes, the biostatisticians and record people they will continue using their time in data entry. If we made these processes digital, the data entry will be continuous and ongoing and it will allow these records officers and biostatisticians to spend more time interrogating the data and therefore flagging some of these issues." — Stakeholder 9, MOH

Another advantage of eCBSS noted by facility-level stakeholders is that it will eventually replace the paper tools, not only making documentation and compilation of TB reports faster and easier, but also eliminating major sources of data errors (as discussed in Theme 2). At this time however, facility staff said that they could not rely fully on eCBSS because it exhibits many of the same challenges as the old DHIS2 system, including continuous lags and blackouts near the reporting deadline.

"With regards to the electronic, the new system is a little bit challenging. While using the laptop, the system lags behind a lot. It is too slow, there are times you want to check for a patient and it's not functioning. So there's still a lot of challenges in the system." – TB clinical staff, high data quality site (F-N3)

In addition, stakeholders recognized that eCBSS will heighten the need for all facilities to have reliable access to computers, internet, and sufficient staff.

"My fear with that kind of suggestion is that we are not yet enrolled with internet in the country, we are not yet enrolled with the human resource. We still have human resource gaps like I mentioned at the beginning. So when somebody's thinking about a case based

management system, would need to first of all put in place infrastructure for a case-based." – Stakeholder 1, Implementing Partner

Finally, as was noted by another stakeholder, the ability of eCBSS to become a sustainable source of high-quality TB data will depend on facilities successfully adopting the new system as routine. They emphasized the need for continuous trainings and financial support (Theme 3) to promote adoption of eCBSS and facilitate better teamwork (Theme 4) as eCBSS becomes a routine part of TB clinic work.

"So yeah so currently what we see is again the need to push these facilities to take it as a routine thing. Initially, what has been happening is we've of course we've done the trainings at regional levels, district levels, and then pilot facilities are onboarded, but what you see is after these trainings there's very little effort on part of these facilities to actually ensure that these data are captured as is required. And what we've done right now is the beginning was to provide some funds in terms of maybe a facilitation to really clear the backlog of 2020, we decided to start from January 2020. But now, even for 2021 where we expect facilities to adopt it as a routine function of the facilities to update the eCBSS for TB, we're not seeing that come through very quickly." –Stakeholder 7, Implementing Partner

In summary, the transition to eCBSS promises many improvements, including easier data collection, access to real-time individual patient data, and more opportunity for data use at facilities. However, many ongoing and new challenges persist, including human resource gaps, training gaps, and infrastructure.

Discussion

A detailed understanding of the many factors that influence the quality and use of routine TB data is needed to improve its reliability for local and national decision-making. To that end, in this study we conducted semi-structured interviews to characterize the experiences, processes, and perspectives of health facility and programmatic stakeholders in Uganda's TB data system. Using the PRISM framework, we identified four themes that explained how technical, organizational, and behavioral

factors interact to influence data system processes and outcomes. We found that the mutually reinforcing relationship between data quality and data use relies on adequate availability of technical components, data knowledge and skill, ongoing training and engagement, and teamwork. As Uganda transitions to an electronic, case-based surveillance system for TB, addressing ongoing technical, organizational, and behavioral challenges will be key to ensuring that the new system produces data that is feasible for routine use.

Previous research has highlighted low facility-level demand for and use of data to be a key barrier to achieving high quality routine health data in Uganda[26–29] and other sub-Saharan LMICs.[4,21,30–32] Our study was among the first to investigate these questions specifically for TB data. We similarly found that the routine use of TB data has been prioritized by stakeholders at the NTLP, MOH, and implementing partners, but unevenly realized at the facility level. However, our study also provides evidence that facility-level staff are increasingly interested and experienced in using their data, both for formal QI and informal performance evaluation. This developing culture of data use has been achieved largely through the support and mentorship of implementing partners. In order to strengthen the mutually reinforcing relationship between data use and data quality, it will be important for these partnerships to continue emphasizing QI within health facilities. Data use workshops, in which staff meet regularly to review and learn from their data, have also been successful at improving routine health data quality and use in Tanzania.[31] These workshops were similar to the performance review meetings already held in Uganda, suggesting that improving the regularity of these meetings may be a

practical way of improving data quality. To maximize their impact, these reviews should include TB-specific indicators and data processes, in addition to HIV.

We also identified several technical and organizational factors that hindered the collection and use of high-quality TB data in this setting. Reliance on paper tools, resource constraints, and inconsistent opportunities for engagement with programmatic stakeholders negatively impacted facility staff's knowledge, skills, and motivation. These challenges are not unique to TB data or Uganda, and have also been identified in the context of routine health data for family planning, immunization, and maternal and child health.[21,27,28] Furthermore, these challenges limited the frequency and effectiveness of supportive supervision, performance reviews, and feedback, key practices that served as important venues for both capacity building and peer-to-peer support for facility staff. A comparison of implementation strategies for enhancing health information system performance across five sub-Saharan African countries likewise found that training in data processes alone is not enough; stakeholder meetings, mentorship, and guided use of data for decision-making were necessary to engage facility staff to collect and use high-quality data.[30] Therefore, addressing technical and organizational challenges will help strengthen these important engagement opportunities, addressing gaps in data quality while also enhancing health worker motivation to adopt data work into routine practice.

Electronic data collection offers great potential to remove many of the technical inefficiencies of the current data collection system, such as time spent on documentation and report compilation and reliance on paper tools. However, at this early stage of implementation the system also presents challenges, including the burden of double data entry and frequent outages in the electronic system. In the absence of systemic changes,

many barriers to data quality and use identified by stakeholders in this study are likely to persist, such as gaps in training, low staff motivation, human resource shortages, and technology challenges. These barriers have been observed in other settings transitioning from paper to electronic systems for TB, such as Kenya,[33] South Africa,[34] and Ireland,[35] leading to incomplete and inconsistent data. Likewise, a recent systematic review of interventions to improve routine data system performance found that interventions using technology alone are unlikely to result in great improvements in data quality, data use, or service delivery.[36] Interventions combining technology with other components, such as capacity building, may be more successful at ensuring high data quality.[37] As the rollout of Uganda's electronic system continues, an implementation strategy that incorporates user-centered design principles including continuous feedback from end-users,[38] similar to the process undertaken in Tanzania's transition from a paper to electronic health information system,[39] will be crucial to identify where that capacity is needed and to motivate users by fostering a sense of ownership of TB data.

Our study has a few limitations. First, the research team and the NTLP had an established partnership before the study began, which could have introduced social desirability bias insofar that participants may have over-reported good practices and under-reported criticism to avoid negative consequences. To mitigate this, our informed consent process included assurance that participants would not be evaluated and that we valued their honest opinions and experiences, positive or negative. Second, our study was conducted in only three (out of 136) Ugandan districts centered around the capital city, among sites that reported >20 TB patients in 2019, limiting generalizability and possibly excluding sites with severe under-reporting. However, we know from our previous

studies that under-reporting of TB data is a widespread issue among facilities of any size in this setting;[10] thus our exclusion of the smallest sites likely did not introduce substantial bias.

Our study also has several strengths. First, our use of a stratified purposeful sampling design maximized variation among interview participants across the spectra of health facility location, size, governance, and data quality. This sampling strategy used readily available public health information, such as facility lists and notification data, that could be easily replicated in other settings to avoid biases associated with convenience sampling. Second, we included both health facility staff and programmatic stakeholders in our qualitative interviews, which allowed us to triangulate data from different perspectives and contributed to the rigor of our study. Third, our qualitative approach is innovative for this topic in the way we applied principles of community engagement to understand barriers, facilitators, and possible solutions from the perspective of the people who use the data system. This approach has, to our knowledge, not previously been used to characterize routine health data systems specifically for TB.

In conclusion, our study identified technical, organizational, and behavioral factors that influenced data collection processes, data quality, and data use for TB in Uganda. A key finding was the wide acknowledgement, but uneven progress, in using data to improve care delivery through QI. Meanwhile, the use of paper registers and forms, gaps in training, low staff motivation, and resource constraints inhibited data collection and use for TB. Uganda's NTLP and MOH, enthusiastic proponents of high data quality and data use, are already aiming to address many of these issues through the

rollout of an electronic system; with careful attention to end-users' perspectives and needs, even greater strides toward high-quality TB data can be made.

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Supplementary Materials

Description of Data Quality Analysis and Stratified Purposeful Sampling

We assessed the quality of routine TB data for all eligible sites. First, we identified WHO benchmarks for high-quality national TB data that could be replicated on the facility level, including internal consistency, external validity, and completeness.[3] These benchmarks and how we operationalized them are described in detail in Table S2.1. Next, we extracted quarterly data on diagnosis, treatment initiation, HIV status, and drug susceptibility testing from the DHIS2 database from 2017-2019 and created time series plots to examine trends. For internal consistency and external validity benchmarks, we primarily relied on ratios to determine whether the benchmark was met; to account for small patient counts at some facilities, we examined raw counts in addition to ratios. For completeness, we looked at raw counts. We separated the sites into three groups of above-average, average, and below-average data quality based on whether they always, sometimes, or rarely met our operational benchmark of this ratio.

Table S2.1. WHO Benchmarks used to assess data quality in the quantitative analysis.

Dimension	WHO Benchmark	Operational Benchmark
Internal consistency over time	B1.7. Evidence of internal consistency over the previous five years for the ratio of male to female TB cases	Evidence of internal consistency over the previous three* years for the ratio of male to female TB cases; supplemented with raw counts for small facilities
	B1.7. Evidence of internal consistency over the previous five years for the proportion of childhood TB cases out of all TB cases	Evidence of internal consistency over the previous three* years for the proportion of children ≤15 years of age among all TB cases; supplemented with raw counts for small facilities
	B1.7. Evidence of internal consistency over the previous five years for year-to-year change in case notifications for new TB cases	Evidence of internal consistency over the previous three* years for year-to-year change in case notifications for new TB cases
External Validity	B1.6. Among new TB cases, the percentage who are children diagnosed with TB is between 5–15%	Among new TB cases, the percentage who are children diagnosed with TB is between 5–15%
Completeness	B2.1. Rifampicin susceptibility status (Positive/Negative) documented for ≥75% of new pulmonary TB cases	Evidence of documentation of drug susceptibility testing among previously lost to follow-up, relapse, or treatment failure cases
	B2.2. HIV status (Positive/ Negative) is documented for ≥80% of all notified TB cases	Evidence of documentation of HIV status by comparing percent of HIV/TB cases among all TB cases to the Uganda national estimate of 45%[17]

*WHO Benchmark calls for five years, but only three years of data (2017-2019) were available in DHIS2

Data Quality and Other Characteristics of Study Sites

We identified 150 health facilities that reported any TB cases in DHIS2 between 2017 and 2019. Of those, 71 (47%) were eligible for inclusion in our data quality analysis; most excluded sites reported fewer than 20 cases in 2019 (Figure S2.1).

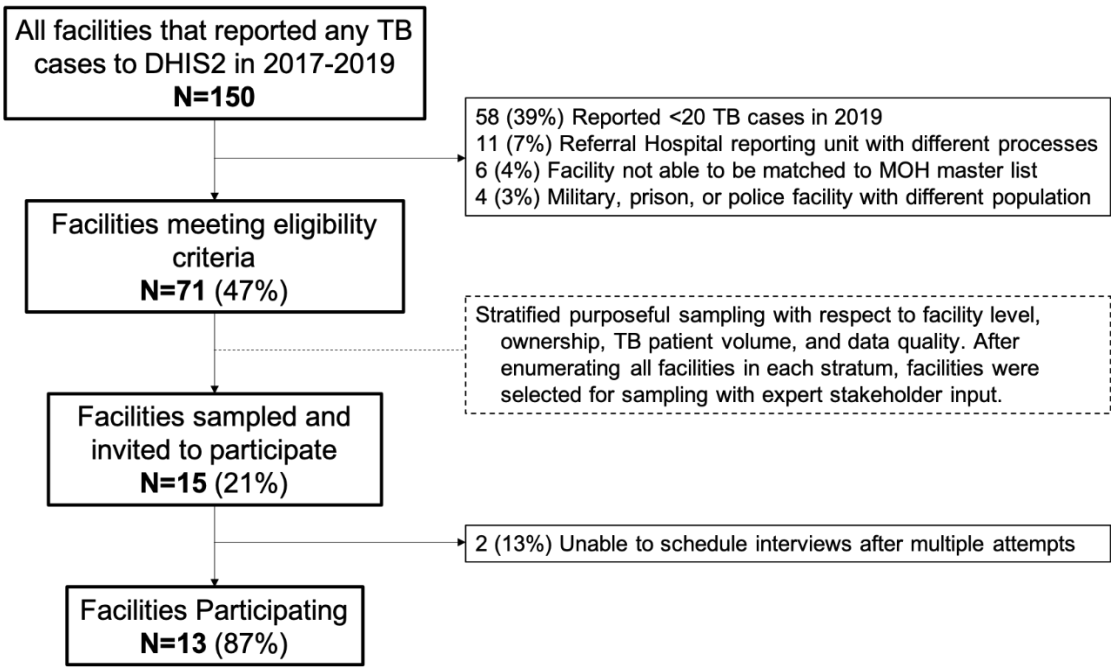

Figure S2.1. Flow diagram describing health facility eligibility, and participation, and characteristics.

Among the benchmarks used, the criteria for internal consistency were met most frequently, while the completeness and external validity were less consistently achieved. A majority of hospitals (60%) had above-average data quality, a majority of county-level facilities (60%) had average data quality, and a majority of sub-county level facilities (50%) had below-average data quality (Table S2.2). Data quality was also higher in high-TB patient volume clinics. Almost all private-for-profit facilities had below-average data quality (83%). All three districts included in the analysis had a range of higher, average, and lower data quality sites, with Kampala having the greatest proportion of higher data quality sites.

Table S2.2. Description of facility characteristics and data quality

			Data Quality	
n (%)	**Total**	**Above-average**	**Average**	**Below-average**
District				
Kampala	28	13 (46)	8 (29)	7 (25)
Wakiso	29	10 (34)	7 (24)	12 (41)
Mukono	14	4 (29)	4 (29)	6 (43)
Health facility level				
Hospital	10	6 (60)	1 (10)	3 (30)
County	10	4 (40)	6 (60)	0 (0)
Sub-county	38	12 (32)	7 (18)	19 (50)
Clinic	13	5 (38)	5 (38)	3 (23)
Ownership				
MOH	36	15 (42)	9 (25)	12 (33)
PNFP	29	11 (38)	10 (34)	8 (28)
PFP	6	1 (17)	0 (0)	5 (83)
TB patient volume				
High[*]	24	18 (75)	5 (21)	1 (4)
Low	47	9 (19)	14 (30)	24 (51)

Notes: MOH: Ministry of Health; PNFP: private-not-for-profit; PFP: private-for-profit; percentages are by row. [*]>100 patients in 2019

Table S2.3. Itemized list of sites chosen for qualitative interviews. To select sites, the characteristics in strata (1) through (5) were decided by the study team, all eligible sites fitting those characteristics were enumerated, and one site was chosen in consultation with expert stakeholders.

(1) District	**(2) Level**	**(3) Governance**	**(4) TB patient volume 2019**	**(5) Data quality**	**Participated?**
Kampala	H	PFP	Low	Low	Yes
Kampala	IV	MOH	High	Average	Yes
Kampala	III	MOH	High	High	Yes
Kampala	III	PFP	Low	Low	Yes
Kampala	III	PNFP	Low	Low	Yes
Kampala	III	PNFP	Low	Low	Yes
Kampala	C	PNFP	High	High	No
Wakiso	IV	MOH	Low	High	Yes
Wakiso	IV	MOH	High	High	Yes
Wakiso	IV	MOH	High	Average	Yes
Wakiso	III	PNFP	Low	High	Yes
Wakiso	C	PFP	Low	Low	No
Mukono	IV	MOH	High	High	Yes
Mukono	IV	MOH	High	Average	Yes
Mukono	III	MOH	Low	Low	Yes

Abbreviations: (2) H: hospital, IV: county (level IV) health center, III: subcounty (level III) health center, C: clinic; (3) PFP: private-for-profit, MOH: Ministry of Health, PNFP: private-not-for-profit.

Consolidated criteria for reporting qualitative research[1]

1. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International journal for quality in health care. 2007 Dec 1;19(6):349-57.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	44
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	44
3. Occupation	What was their occupation at the time of the study?	44
4. Gender	Was the researcher male or female?	44
5. Experience and training	What experience or training did the researcher have?	44
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	43, 45-46
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	45
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	44
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	41, 45
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	43
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	43
12. Sample size	How many participants were in the study?	46-47
13. Non-participation	How many people refused to participate or dropped out? Reasons?	46-47
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	44
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	44
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	48
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	44
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	44
20. Field notes	Were field notes made during and/or after the interview or focus group?	44
21. Duration	What was the duration of the interviews or focus group?	47
22. Data saturation	Was data saturation discussed?	44
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	45
25. Description of the coding tree	Did authors provide a description of the coding tree?	45
26. Derivation of themes	Were themes identified in advance or derived from the data?	45
27. Software	What software, if applicable, was used to manage the data?	45
28. Participant checking	Did participants provide feedback on the findings?	No
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number	Yes
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31. Clarity of major themes	Were major themes clearly presented in the findings?	49-59
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	All themes were discussed, even minor ones.

Feasibility, acceptability, and adoption of digital fingerprinting during contact investigation for tuberculosis in Kampala, Uganda: A parallel-convergent, mixed-methods analysis

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 White EB, Meyer AJ, Ggita JM, et al. Feasibility, Acceptability, and Adoption of Digital Fingerprinting During Contact Investigation for Tuberculosis in Kampala, Uganda: A Parallel-Convergent Mixed-Methods Analysis. *J Med Internet Res*. 2018;20(11):e11541. doi:10.2196/11541

Abstract

In resource-constrained settings, challenges with unique patient identification may limit continuity of care, monitoring and evaluation, and data integrity. Biometrics offer an appealing but understudied potential solution. We conducted a mixed-methods study to understand feasibility, acceptability, and adoption of digital fingerprinting for patient identification in a study of household TB contact investigation in Kampala, Uganda. We tested associations between demographic, clinical, and temporal characteristics and failure to capture a digital fingerprint, and evaluated clustering of outcomes by household and community health worker (CHW). To understand determinants of intended and actual use of fingerprinting technology, we conducted fifteen in-depth interviews with CHWs and applied the Technology Acceptance Model 2 (TAM2). Digital fingerprints were captured for 515 (74%) of eligible participants, with extensive clustering of failures by household (ICC=0.99) arising from software (60.3%) and hardware (36.3%) failures. The proportion of households with all members successfully fingerprinted declined over time (Spearman's rho = 0.30, $P < .001$). In interviews, we found digital fingerprinting to be feasible and acceptable for individual identification, but failures lowered CHWs' perceptions of the quality of the technology, threatened their social image as competent health workers, and made the technology difficult to use. We emphasize the need for routine process evaluation of digital technologies in resource-constrained settings to assess implementation effectiveness and guide improvement of delivery.

Introduction

The ability to uniquely identify individuals in health care settings is important for patient care, health system monitoring, and health research. For patients, unique identifiers may facilitate continuity of care, linking of encounters into a longitudinal health record, and prevention of errors during treatment. For health systems, these linkages provide richer evidence for monitoring and evaluation than aggregated data.[1] In clinical and public health research, unique identification helps preserve the integrity of data and protects against misclassification.[2] In resource-constrained settings, however, there are many barriers to unique patient identification: lack of national identification systems, inconsistent spelling of names, uncertainty about date of birth, continually changing phone numbers, a lack of street addresses, and intentional avoidance of identification procedures in order to escape stigma. A reliable identification method that circumvents these barriers could improve data accuracy and patient retention in care in resource-constrained settings.

Biometric identification techniques offer a novel and appealing solution to these challenges in settings where other identification methods are not feasible or acceptable. Biometric methods rely on an individual's physical characteristics such as fingerprints, facial structure, iris geometry, or actions including handwriting or gait pattern.[3] A number of biometric identifiers, including fingerprint and ocular characteristics, have demonstrated technical feasibility in a variety of studies.[4] However, fingerprint scanning has become the most widely used because of the development and widespread availability of portable, low-cost technologies for digital capture[2] and its high sensitivity and specificity for verification.[5] Others have reported that fingerprinting is feasible[2,5-9]

and acceptable.[9,10] However, there are few published reports regarding actual use of fingerprinting technologies in resource-constrained settings. Therefore, we sought to perform a detailed process evaluation of digital fingerprint scanning by community health workers (CHWs) in urban Uganda in order to understand the feasibility, acceptability, and adoption of this technology for patient identification.[11] Additionally, we sought to better understand the determinants of CHWs' intended and actual use of fingerprint scanning technology by applying a widely used conceptual framework, the Technology Acceptance Model 2 (TAM2).[12]

Methods

Study Design, Objectives, Setting, and Population

We conducted a parallel-convergent, mixed-methods study of digital fingerprinting in the context of a household-randomized trial of enhanced tuberculosis (TB) contact investigation. Specifically, the trial (called the parent study) sought to evaluate the effects of home sputum collection and SMS messaging on completion of evaluation for TB among household contacts living with index TB patients. This sub-study sought to determine the *feasibility* of digital fingerprinting as measured by the proportion of participants and households successfully identified via fingerprint at baseline and follow-up; to describe the reasons for not capturing fingerprints; and to ascertain the technology's *acceptability* in principle and *adoption* in practice among health workers with experience using it.

The parent study took place in Kampala, Uganda from July 2016 to July 2017. In the parent study, we employed digital fingerprinting to avoid duplicate registrations of index patients and contacts and to verify follow-up visits at clinics for those needing

additional evaluation. In this sub-study, we analyzed quantitative data from participants enrolled in the parent study and qualitative data from interviews with CHWs who carried out digital fingerprinting and other study procedures. Children under the age of 5 were not eligible for scanning because digital fingerprints are difficult to capture and less accurate in young children.[13,14]

Study Procedures

Prior to implementation, all CHWs completed a course introducing the rationale for the use of fingerprints as biometric identifiers, describing different fingerprint patterns, and training them to capture high-quality fingerprints using a digital scanner. CHWs participated in hands-on training, including "role-play" sessions that allowed them to practice acquiring good quality fingerprints and troubleshooting commonly encountered problems with fingerprint scanning. All CHWs were trained in infection control practices prior to initiating their work and provided disposable personal protective equipment to protect them during patient encounters. CHWs performed digital fingerprinting and collected individual age, sex, and self-reported HIV status from household members during contact investigation visits. Fingerprinting was performed using multi-spectral fingerprint scanners (Lumidigm M301, HID Global, Austin, Texas) linked to embedded matching software (Biometrac, Louisville, KY). Matching was available offline and fully integrated as an application programming interface (API) within a customized survey application (CommCare, Dimagi, Boston, MA, USA). The application logged each health worker and time-stamped each encounter. Data were uploaded to a cloud-based server (CommCareHQ, Dimagi, Boston, MA, USA).

Fingerprint images were not stored but instead recorded as a series of unique characters decipherable only using a secured, proprietary algorithm.

Quantitative Analysis

For individual contacts, the outcome of interest was failure to record a complete fingerprint scan in the database, categorized as a binary outcome. A complete scan required successful imaging of the fingerprint with sufficient clarity and resolution to allow adequate feature extraction; scans failing to meet quality criteria (e.g. because of degraded ridges, dirt, or fingerpad placement excluding the fingerprint core) were immediately rejected. A complete scan required capture of right and left thumbprints, followed by right and left index fingerprints; any scan that failed to capture all four fingerprints was deemed unsuccessful. Although fingerprinting is an individual procedure, it is frequently offered to multiple household members on a single hardware device during a household visit for contact investigation. To reflect these conditions, we also defined failure at the level of the household encounter; any encounter that did not capture fingerprints from all present household contacts was deemed unsuccessful. If a household required multiple visits in order to enroll all contacts, we included only the first household encounter in our analyses. Two investigators (EBW, DB) independently reviewed free text explanations from CHWs for fingerprinting failures and classified each as a hardware problem, a software problem, or as another unclassified problem.

We described the population characteristics of individual study participants, including age, sex, and HIV status, as well as characteristics of households, including which CHW captured fingerprints and the time period of enrollment. We examined differences in success by age, using the standard categories employed by the WHO Stop

TB Department (5-14 years and ≥15 years); sex; and HIV status. We examined the trend in fingerprinting success over time by quarter of study enrollment by calculating Spearman's rho. We examined differences in household-level fingerprinting success by CHW using a chi-squared test. To test associations between individual characteristics and fingerprinting success, we fit bivariate logistic regression models using generalized estimating equations and a robust covariance estimator to account for clustering by household. We report p-values based on cluster-robust standard errors. To estimate the extent of clustering of outcomes by household and CHW, we calculated intra-class correlation coefficients (ICC).

Qualitative Interview Procedures

During the last two months of the study, we carried out parallel in-depth interviews with each of the fifteen CHWs who conducted study procedures using a semi-structured interview guide. We developed the guide to elicit responses related to three overarching topics: the CHWs' first interactions with digital fingerprinting; their experiences using digital fingerprinting during the study; and their opinions regarding the usability of digital fingerprinting. The guide was developed in English and is reported in Multimedia Appendix 1. One English-speaking investigator (EBW) interviewed all fifteen CHWs who conducted study procedures. All but one reported feeling comfortable completing the interview in English. A native Luganda-speaking investigator (JG) re-interviewed this CHW in Luganda to give the respondent the opportunity to elaborate on experiences and opinions in their native language. During the interview, each CHW was also asked to mock-fingerprint the interviewer as a means of eliciting the user's experiences and interactions with digital fingerprinting. All interviews were recorded,

transcribed, and uploaded to a secure online server for qualitative data analysis (Dedoose, Manhattan Beach, CA). In addition, interviewers used a structured debriefing form (Multimedia Appendix 2) to organize emergent themes immediately following each interview. Additional details were added iteratively after reviewing interview recordings and transcripts.

Qualitative Analysis

We carried out the qualitative analysis using the debriefing forms to identify key themes.[15] Using the TAM2 framework, one investigator (EBW) categorized themes into pre-specified antecedents of "behavioral intention" to use fingerprinting technology (Figure 3.1). TAM2 theorizes that behavioral intention precedes and predicts actual use. Behavioral intentions are influenced by perceptions of the technology's usefulness and ease of use. Five domains independently contribute to the perceived usefulness of a technology: the perception that important others expect one to use the technology (*subjective norm*); the perception that social status is enhanced through its use (*image*); the perception that the technology supports an important job function (*job relevance*); the performance of the technology (*output quality*); and tangible results of its use (*result demonstrability*).[12,16-19]

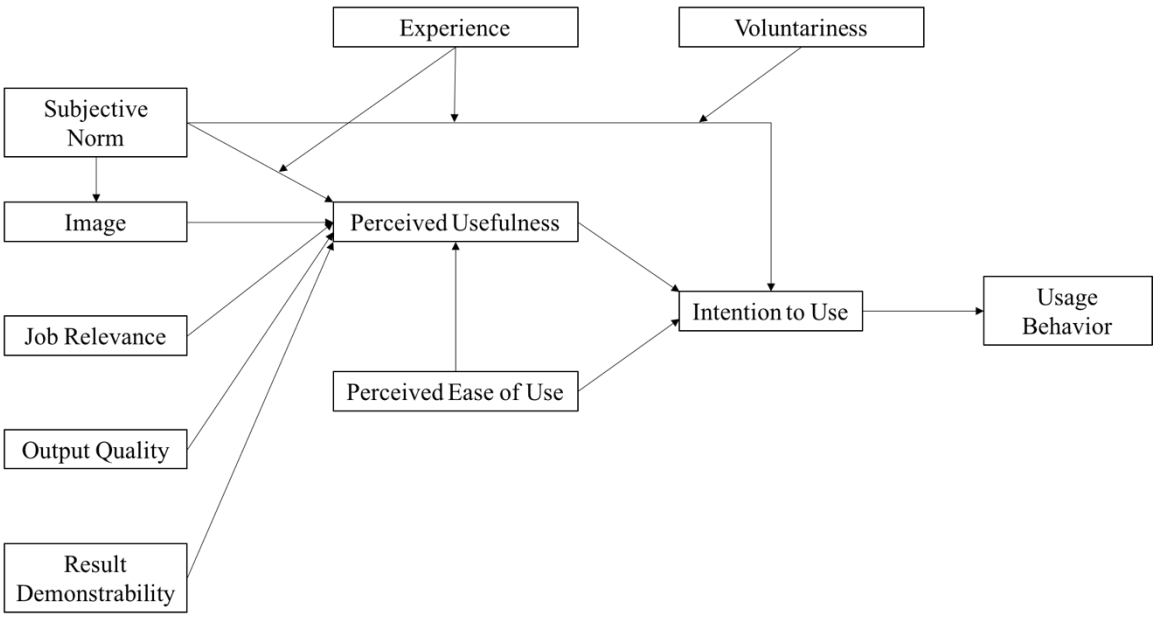

Figure 3.1 Technology Acceptance Model 2 (TAM2), Adapted from Venkatesh and Davis 2000

Human Subjects Considerations

Each participant or the parent/guardian of minors provided written informed consent as part of the parent study. Participants aged 8-17 years old also provided written assent. For this sub-study, CHWs provided verbal consent prior to the interview. Institutional review boards at the Makerere College of Health Sciences, the Uganda National Council for Science and Technology, and Yale University approved the study protocol.

Results

Study Population and Results of Quantitative Analysis

Of the 919 household contacts eligible for the parent study, 694 (75.5%) individuals aged 5 and above were eligible for digital fingerprinting (Figure 3.2). Of those eligible, 515 (74.2%) had a successful fingerprint scan during the household visit. Of the 179 contacts without successful fingerprint scans during the household visit, 108

(60.3%) fingerprint scan failures were classified as software problems, 65 (36.3%) as hardware problems, and 6 (3.4%) as unclassified problems. None were classified as refusals. We found similar baseline fingerprinting success rates and failure reasons among index patients; because these were individual data collected separately and in a clinic setting, we report them separately in Multimedia Appendix 3. Only 1 (3%) of the contacts fingerprinted at the household visit and referred to the clinic for evaluation was identified via fingerprint at the follow-up visit. Among individual contacts, clustering of unsuccessful scans by household was extensive (ICC = 0.99). Household contacts who were not successfully fingerprinted did not differ significantly with respect to sex, age, or HIV status from those who were successfully fingerprinted (Table 3.1).

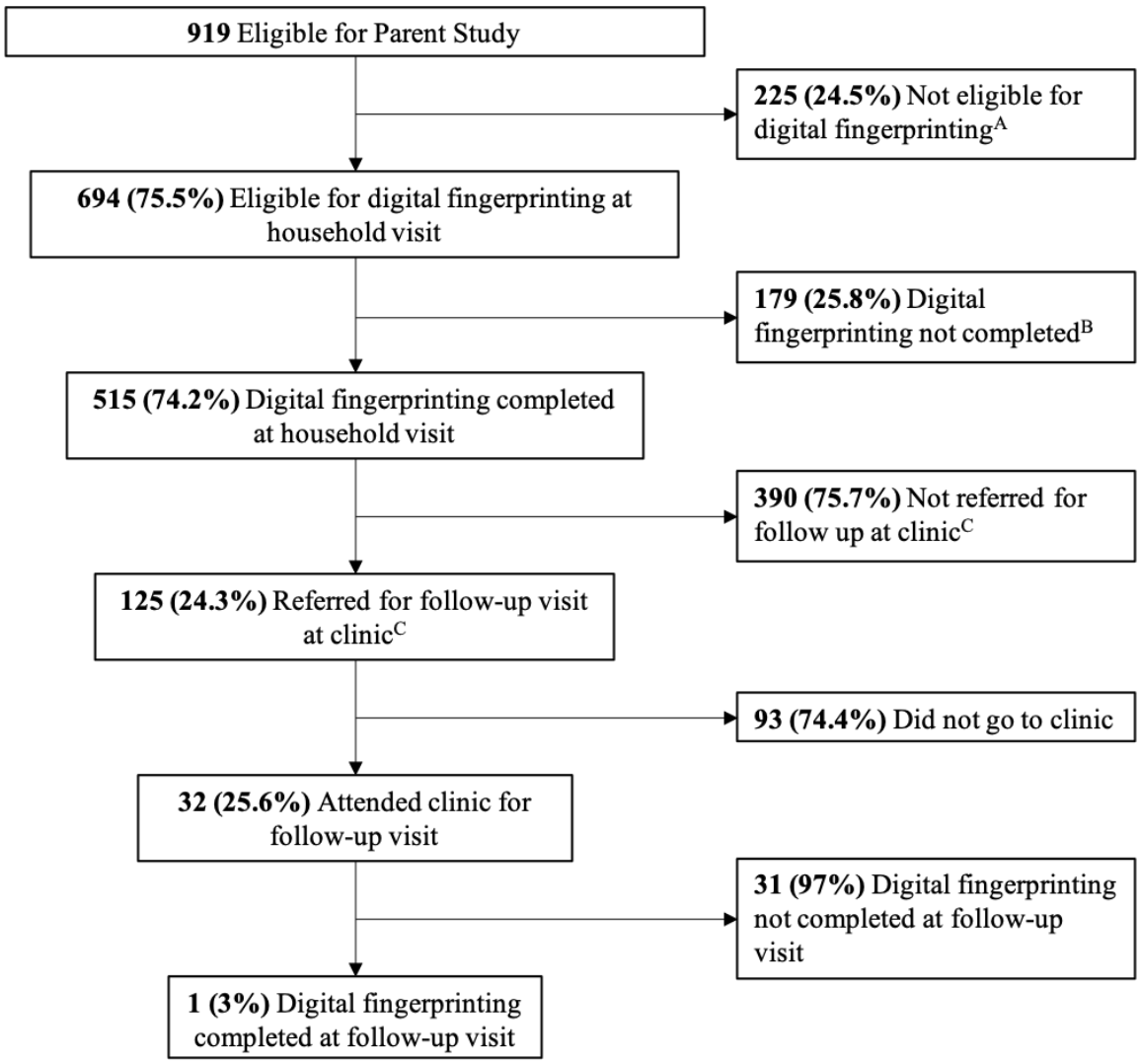

Figure 3.2 Flow diagram showing enrollment of household contacts

Legend:

[A] Children under the age of 5 were not eligible for digital fingerprinting.

[B] 108 (60.3%) fingerprint scan failures were classified as software problems, 65 (36.3%) as hardware problems, and 6 (3.4%) as unclassified problems.

[C] Those referred for follow up evaluation at the clinic included contacts who were persons living with HIV; contacts who had TB symptoms but did not produce a sputum sample at the household visit; and those who had an inconclusive diagnostic result for sputum collected during the home visit. All others were not referred for a follow-up visit.

Table 3.1 Characteristics of study participants (n=694)

Characteristic **n (%)**	**Fingerprint Scan (n=515)**	**No Fingerprint Scan (n=179)**	***P*-value[A]**
Age			
Children 5-14 years	162 (31.5)	59 (33.0)	.56
Adults 15 and older	353 (68.5)	120 (67.0)	
Sex (%)			
Female	336 (65.2)	108 (60.3)	.83
Male	179 (34.8)	71 (39.7)	
Proportion living with HIV (%)			
Positive	41 (8.0)	17 (9.5)	.87
Negative or Unknown	474 (92.0)	162 (90.5)	

Legend: [A]Corrected for clustering of fingerprint scan outcomes by household with robust standard errors.

CHWs successfully fingerprinted all consenting contacts in 213 (70.0%) households. Among households, clustering of fingerprint scan outcomes by CHW was modest (ICC = 0.18). The frequency of successfully fingerprinting all contacts in a household by CHW ranged from 45% to 97%, with a median of 71% ($P < .001$). The proportion of households where all contacts were successfully fingerprinted decreased over time: 87% in Quarter 1, 77% in Quarter 2, 68% in Quarter 3, and 51% in Quarter 4 (Spearman's rho = 0.30, $P < .001$).

Qualitative Interviews

The CHWs involved in the parent study were recruited based on their high level of previous work experience and their ability to speak both English and Luganda. All fifteen CHWs who carried out fingerprint scans were interviewed. The median interview length was 37 minutes (IQR: 33.5-42 minutes). CHWs ranged in age from 24 to 54 years with a median of 33 years, and 12 (80%) were female. Most (13, 87%) had completed ordinary secondary education (O-Level) or higher, and a few (3, 20%) had completed

university-level education. Most of the CHWs had prior experience using information technology, including smartphones (14, 93%); fewer had previously used computers (8, 53%), or tablets (5, 33%). All fifteen CHWs had worked in a lay health worker role prior to joining the study.

In the interviews, CHWs emphasized how specific experiences with the fingerprinting technology affected their sense of identity, their interactions with household contacts, and their ability to carry out their work. These experiences informed CHWs' perceptions of the fingerprinting technology's ease of use and usefulness, two key determinants of intention to use, or acceptance, in the TAM2 model.

Idealized views of fingerprinting

CHWs described the usefulness of fingerprinting in an idealized way, reflecting many of the potential applications of fingerprinting that were introduced during training. CHWs consistently said they believed that fingerprinting would prevent duplicate enrollment and help identify patients who came for follow-up, even if they visited a different study facility.

"It's useful. I get to know exactly I am with the right patient. And if he has ever, for example you have so many facilities, maybe that patient has ever been to [a different health center], and they have ever scanned, so the scanner will refuse or it will tell me already the patient is in the system."- Female (CHW6)

Even while acknowledging that the technology did not work perfectly, many CHWs said they believed that fingerprinting could be useful and should continue.

"Me I just wish [the use of fingerprinting] would continue and it could be stable, it could not stop, you know you go to the field and it stops, and you have to do restart, do things, it takes a lot of time. […] So me, I just wish in case [fingerprinting] continues, let us do those challenges so we can remove those." – Female (CHW8)

By expressing a desire for fingerprinting to continue, despite substantial challenges with the technology, the CHWs revealed how much their perceptions of its potential usefulness were driven by their optimism to make it work.

Positive and negative consequences of digital fingerprinting for the self-image of CHWs

The CHWs described their role in the community with pride. They said they felt that they were providing important services to their patients, whom they often referred to as "clients". However, fingerprint scanning had complicated implications for CHWs' self-image. CHWs explained that the technology could both elevate and threaten their social status. On one hand, fingerprint scanning represented an additional service they could offer to their clients, which elevated the capabilities they projected as CHWs. They perceived digital fingerprinting to be an important technology because it is associated with registering for a National ID and for identification at commercial banks. The excitement of getting to use this important technology in their work helped motivate the CHWs to learn and implement fingerprint scanning.

"So I was so excited, and I even asked myself, "Who am I, to be in this?" So, I put on my brains in there to really understand what is going to be done. And it took me only two days to get everything in the tablet because I was so attached to it, I wanted it so much."- Female (CHW12)

On the other hand, when the CHWs struggled to use the fingerprinting technology in front of clients, they felt that their credibility was diminished.

"When you're 'printing someone and it fails? They just look at you like you don't know what you're doing."- Female (CHW13)

CHWs placed high importance on their competence in carrying out contact investigation, and a failed fingerprinting attempt could damage one's credibility. Thus, CHWs

perceived that the technology enhanced their social and professional status when it worked smoothly but threatened their status when it failed in the presence of a client.

Variable views on the need and appropriateness of digital fingerprinting

While CHWs generally acknowledged the need for some way to identify patients and contacts in order to carry out contact investigation, views were mixed regarding whether fingerprinting was necessary. These mixed opinions arose from different perceptions of the job relevance of fingerprinting, or the belief that fingerprinting is important to contact investigation. Some CHWs thought that fingerprinting could be the best way to uniquely identify people:

"[…] even if you give three names, someone might come with, another person might come with three names which are the same. Yet here the fingerprints identify the very person you want." – Female (CHW3)

However, others suggested that the name, health center, patient identification number, signatures, photos, or voice recordings would suffice as alternatives. In practice, most CHWs described using some combination of name and other identifiers to identify contacts at follow-up, rather than using the fingerprint. One CHW distinguished between the usefulness of fingerprinting for identifying contacts versus index patients. He said that it was more useful for contacts, who are numerous and who come to the clinic months after the CHW meets them. Because index patients are fewer in number, sicker when the CHW meets them, and come back to the clinic often, the CHW felt that they were more memorable and that there was no need to rely on a fingerprint to identify them.

Impact of failures to capture fingerprints digitally

Even before interviewers asked about technology failures that prevented the successful capture of fingerprints, the CHWs repeatedly turned the discussion toward their experiences with technology failure. The CHWs linked the output quality, or how well the technology performed, to their perceptions of its usefulness. A small number of CHWs who reported never having issues with the technology described fingerprinting as being useful. Most CHWs, however, described an increase in technology failures over time, preventing them from capturing fingerprints and adding unnecessary time to the study procedures. When asked whether fingerprinting was useful and should continue in the future, almost all of these CHWs still responded yes, but only if it worked consistently and did not take too much time.

"It would be good, like I've told you, but the technical issues around it can make the work difficult." – Female (CHW9)

Thus, the perceived usefulness of digital fingerprinting depended on it being reliable, fast, and free from technology problems.

Voluntary abandonment of digital fingerprinting

Most CHWs described instances when they chose to "bypass" the fingerprint scan during contact investigation enrollment; this option was built into the software to allow them to continue with the encounter even when fingerprint scanning failed. They did not indicate any negative impacts of failing to capture a fingerprint on contact investigation procedures. These descriptions suggest that result demonstrability was low and the effect of capturing a fingerprint was not tangible to the CHW.

"When it has refused. That's when I decide to go back and I bypass the fingerprint scanner, and I continue with my patients. I jump it and go to the next question." – Female (CHW5)

CHWs described troubleshooting measures that they used when the fingerprint scanner failed: disconnecting and reconnecting the cable linking the scanner to the tablet, powering the tablet off and back on again, and asking a colleague for help. However, most CHWs said that they only attempted to troubleshoot one to three times – or sometimes not at all – before bypassing the fingerprint scan altogether. Whether a fingerprint was successfully captured or not did not seem to change the contact investigation procedures, in the view of CHWs.

Variable confidence in using the technology

CHWs differed in their perceptions of the ease of use of the technology, including the scanner itself and the tablet that they used to control the scanner. Some said that it was consistently easy to navigate through the application on the tablet and obtain a fingerprint using the scanner. Others described relying on colleagues or study staff for support when they had problems, which were frequent and which they came to anticipate.

"I'm expecting I will go and then I will call [the technology support officer] that this thing has blacked out. So it's expected. […] I don't think I'm the only one complaining about the scanner. They disturb us a lot." – Female (CHW9)

This range of comfort with the technology was also reflected during the interview prompt exercise in which the CHWs demonstrated the fingerprinting process. Some worked quickly while others were hesitant when navigating through the application; some were able to describe the process in their own words while others read directly from the text on the screen. Individuals' confidence using the tablet and scanner varied greatly.

Personal risks to health workers

CHWs described two forms of risk that they associated with digital fingerprinting and that influenced their perceptions of its ease of use. First, some CHWs worried about risk of infection through close contact with patients during the fingerprinting procedure, exacerbated by lack of adequate space and ventilation while performing fingerprinting.

When you're doing this and this [demonstrating placing fingers on the scanner], you're kind of getting closer to the patient who is HIV – I mean TB positive, so somehow you are risking. Just try to demonstrate, just try to put your finger here [on the scanner]. So as I'm a community health worker and you have to get closer to me, I'm also breathing in. – Female (CHW9)

Second, CHWs said they worried about personal security when carrying the tablet and scanner to household visits.

When we move, some of our places are not in…they are not easy to go there alone. Because you have slums, very dangerous to go with the gadget. […] And TB is mostly in those places. – Female (CHW7)

The risk of infection and lack of personal security introduced psychological and logistical challenges that the CHWs had to overcome in order to carry out fingerprinting.

Discussion

The inability to uniquely and accurately identify individuals in resource-constrained settings remains a major barrier to improving the quality of health information management and public health research. We found that digital fingerprint scanning was feasible but not reliable – failing to capture fingerprints in about one-quarter of cases – during household contact investigation for TB. Importantly, we found evidence that failures were tightly clustered by household, that they increased substantially over the course of the study, and that there were no systematic differences by clinical or demographic factors. The low rate of fingerprinting at follow-up suggests

that CHWs saw little value in the digital fingerprinting system's usefulness as a verification tool. A systematic qualitative analysis indicated that CHWs continued to find digital fingerprinting acceptable in principle despite the technology's inconsistent reliability and an accumulating experience with technology failures that decreased their confidence in its usefulness in this setting.

The patterns of fingerprinting failures during the household visit pointed towards problems with the implementation of both software and hardware. Fingerprinting outcomes were almost completely clustered at the household level, suggesting that rather than being driven by sporadic, individual-level failures or refusals, the fingerprinting technology either worked or did not work on a given visit to a household. We identified no individual patient characteristics associated with failure, including age and sex, which argues against degraded individual fingerprints as a cause of failure, as might be expected among adult manual laborers. Furthermore, the predominance of software and hardware problems as explanations for failure and the modest clustering by CHW implies that technology failures were responsible rather than the skills of individual health workers. Finally, the significantly increasing trend of fingerprinting failures reflects the declining usefulness of the technology over time, whether due to health worker disengagement from the technology, software issues, hardware issues – or perhaps all three.

Previous studies have shown that CHWs without prior experience with digital fingerprinting describe the technology as acceptable in principle.[10] However, we observed that CHWs' assessments of fingerprint scanning can change as they gain experience with the technology. We found that the TAM2 domains of image, job relevance, output quality were especially relevant to CHWs' perceptions of the usefulness

of digital fingerprinting in the study. Technology failures lowered CHWs' perception of the quality of the system, threatened CHWs' social image, and made the technology more difficult for CHWs to use. Although the technology worked as intended in the majority of interactions, workarounds and a lack of a tangible benefit of fingerprinting ultimately limited its job relevance and perceived usefulness among CHWs. After regular use, CHWs continued to express enthusiasm for fingerprint scanning in principle, but their intention to use the technology was tempered by perceptions that it was inconsistent and of questionable value, ultimately undermining their intention and usage behaviors.

Our findings add to a relatively limited literature on the use of digital fingerprinting for public health applications in sub-Saharan Africa. Our findings differ from a study of the same technology among female sex workers in Zambia, where digital fingerprinting was feasible for and acceptable to clients in the clinic setting, but not acceptable to clients in the field.[5] Perhaps because participants were at greater risk for stigma or arrest and prosecution, the most common reasons for refusal related to clients' concerns about a potential loss of confidentiality and/or privacy. In contrast, we found that a majority of community members underwent fingerprinting during study registration without differences by demographic or clinical characteristics or documented refusals. Similar to a previous study of a mobile health tool for reporting adverse effects of treatments for drug-resistant TB in South Africa, we found that reported enthusiasm for technology – fingerprinting, in this case – did not translate into usage.[20] The acceptance of fingerprinting technology among CHWs serving these clients may decline if they experience technology failures during their work and may be more impactful in terms of its use than the perceived acceptability by community members. There may be a role of

the use of Communities of Practice – learning and peer support networks established to facilitate continuous quality improvement – as patient identification technology is being introduced to help address these challenges.[21-23]

Finally, the almost universal failure of lay health workers in our study to use digital fingerprinting at follow-up contrasts with the findings of a study of a biometric identification system for monitoring TB treatment in rural Uganda, which found that fingerprinting improved follow-up among patients engaged in daily directly-observed therapy at the clinic.[24] A low background rate of clinic follow-up in our study limited opportunities for digital fingerprinting in this context, and perhaps therefore its utility. In settings where digital fingerprinting has been shown to be feasible and acceptable, researchers should conduct larger, well-controlled studies to assess whether fingerprinting is an effective tool for monitoring and improving adherence to follow-up visits in combination with feedback communications. Finally, a limitation of digital fingerprinting is that it is unable to reliably capture fingerprints of children under five years of age,[14] resulting in their exclusion from the analysis. Further studies should evaluate whether newer technologies ca accurately capture fingerprints for children under five. Future studies could also include interviews with household contacts in order to gain a more comprehensive understanding of the acceptability and challenges of fingerprinting from the perspective of contacts.

This study had a few limitations. First, we had limited data on the technical reasons for each fingerprinting failure. While we were able to categorize failures broadly as related to hardware or software problems, these groupings are not specific enough to guide improvement strategies. Detailed logs itemizing the circumstances of each

fingerprinting failure should be included in future evaluations. Second, incomplete data for household-level covariates such as income limited our ability to identify predictors of failure to capture fingerprints digitally, although the lack of reported refusals and the very small number of unattributable explanations for failure make patient factors an unlikely explanation.

This study also had several strengths. First, the mixed-methods design enabled complementary analyses of the use of fingerprint scanning during household contact investigation for TB. The quantitative analysis revealed evidence of extensive clustering of failures within household encounters, while the qualitative analysis showed the influence of these failures on CHWs' perceptions of the technology's usefulness. Second, we organized key themes offered by CHWs into TAM2 sub-domains such as image, job relevance, and output quality, showing how these perceptions shape CHWs' evolving understanding of the usefulness of fingerprinting technology. Third, we were able to interview the entire CHW population involved in the study rather than relying on a sample. Finally, we evaluated a multi-spectral fingerprinting technology integrated with and offered as a standard commercial product by a leading global health software platform, increasing generalizability.

The ability to accurately collect and link individual data to preserve privacy and enhance the generation of quality measures for patients moving through complex care pathways should be a major global health priority.[25] Despite the feasibility and acceptability of biometric identification methods as a means of bringing unique patient identification to resource-constrained settings, the technology we evaluated was not widely adopted by the health professionals tasked with using it. As biometric

technologies are increasingly introduced in resource-constrained health contexts, our findings point to the importance of theory-informed, mixed-methods evaluation of adoption of these technologies. Mixed-methods data may guide iterative improvements to hardware, software, and the user interface to ensure that the technology aligns with tasks that users find useful and important, and engages health workers so that they voluntarily apply the technology to improve the experience of patients. Future studies should also consider whether detailed process evaluation using mixed methods can be applied to other biometric technologies.

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Supplementary Material

I. Fingerprinting Interview Guide

Introduction to the interview:

- Introductions between interviewer and CHW
- Explanation that the purpose of the interview is to hear about the CHW's experiences using digital fingerprinting in the mHealth study; that there are no right or wrong answers; that if any question is unclear they should feel free to ask for an explanation.

Consent:

- CHWs were asked for verbal consent to have the interview recorded.
- CHWs were asked for verbal consent for their de-identified responses to be used as part of a research project on digital fingerprinting.

Introducing question: To begin, can you walk me through the fingerprint scanning process?

<u>First interactions of CHW with fingerprinting technology</u>

Introducing question: Think back to the beginning of the mHealth study. what did you think about the idea of fingerprint scanning when it was first explained to you?

Specifying questions:

- What was it like learning to use the fingerprint scanner?
- If you took time off work, for example, if you took time off for Christmas and then came back to work after a week or two, what was it like starting to use the fingerprint scanner again?

<u>Use of fingerprint scanning during study activities</u>

Introducing question: What is it like using fingerprint scanning with study participants?

Specifying questions:

- What has it been like explaining the fingerprint scanner to study participants? (What has it been like telling the participant about the scanner and why we need to use it?)
    - **Probes:**
        - What is challenging about explaining the fingerprint scanner?

        - What has worked well in explaining the fingerprint scanning process?
        - What do you do when a participant is reluctant to provide a fingerprint?

- What is it like explaining to participants how to place their finger to give a proper fingerprint scan?
    - **Probes:**
        - What part of the fingerprinting process is most challenging?
        - What part of the fingerprinting process works well?
- How do you compare fingerprint scanning at home and at the clinic?
    - **Probe:** Are there differences or is it the same?
- Does the fingerprint scanner ever fail?
    - **Probes:**
        - How does it fail? (What happens when it fails?)
        - What do you do when it fails?

<u>Future use of fingerprint scanning</u>

Introducing question: Moving forward, what do you think about fingerprint scanning in the mHealth study?
Specifying questions:

- What do you think about using fingerprint scanning when you carry out the contact interview?
    - **Probes:**
        - Is it worth using?
        - What alternatives to fingerprint scanning could be used?
- How helpful has FPS been in identifying patients who come back for subsequent visits?
- How would you feel about using fingerprint scanning in general clinic activities?
- Has your opinion of fingerprint scanning changed over time; from the time you first used it to now?

Is there anything else that you find important about fingerprint scanning that we haven't discussed yet?

Do you have any final comments about fingerprint scanning before we finish our discussion?

Have respondent complete the cover sheet

II. Community Health Worker Interview Cover Sheet

Interviewer ID: _____ Respondent ID: _____
Health Center ID: _____ Initial recruitment contact date: _____
Follow-up #1 (if applicable): _____Follow-up #2 (if applicable): _____
Scheduled interview date and time: _____
Scheduled interview location: _____

Respondent information:
Gender: _____ Age: _____ Level of education: _____
Length of time involved with mHealth study: _____ ☐ years _____ ☐ months
Previous experience using technology (check all that apply):
☐ Computers ☐ Tablets ☐ Smartphone ☐ Other: _____

If YES to previous computer experience:
☐ Personal use ☐ Professional use
Describe: _____
Length of previous computer experience: _____ ☐ years _____ ☐ months
If YES to previous tablet experience:
☐ Personal use ☐ Professional use
Describe:
_____
Length of previous tablet experience: _____ ☐ years _____ ☐ months
If YES to previous smartphone experience:
☐ Personal use ☐ Professional use
Describe:
_____
Length of previous smartphone experience: _____ ☐ years ____ ☐ months
If YES to other previous technology experience:
☐ Personal use ☐ Professional use
Describe:
_____
Length of other previous technology experience: ___ ☐ years ___ ☐ months

Work position right before mHealth study: _____

Recruitment notes
Please use this space to briefly describe how you invited the respondent to be interviewed.

Interview setting notes
Please use this space to briefly describe the setting of the interview.

Field notes
Please use this space and the back of this paper to note any details about the interview that may not be obvious from the recording.

III. mHealth Fingerprinting Interview Debriefing Tool

Basic Information	
Interview participant: **Date:** **Location:**	**Interviewer:**

Debriefing

1. A.) What were your impressions of the discussion?

   B.) Were there topics the CHW seemed uncomfortable discussing or especially passionate about?

   C.) Were there topics the CHW returned to unprompted?

2. What were the most important themes in the discussion?

3. First interactions with fingerprint scanning:
   A.) Explaining the process

   B.) Learning

   C.) Retaining

4.) Use of fingerprint scanning in mHealth study:

A.) Introducing the scanner to participants

B.) Physically using the scanner

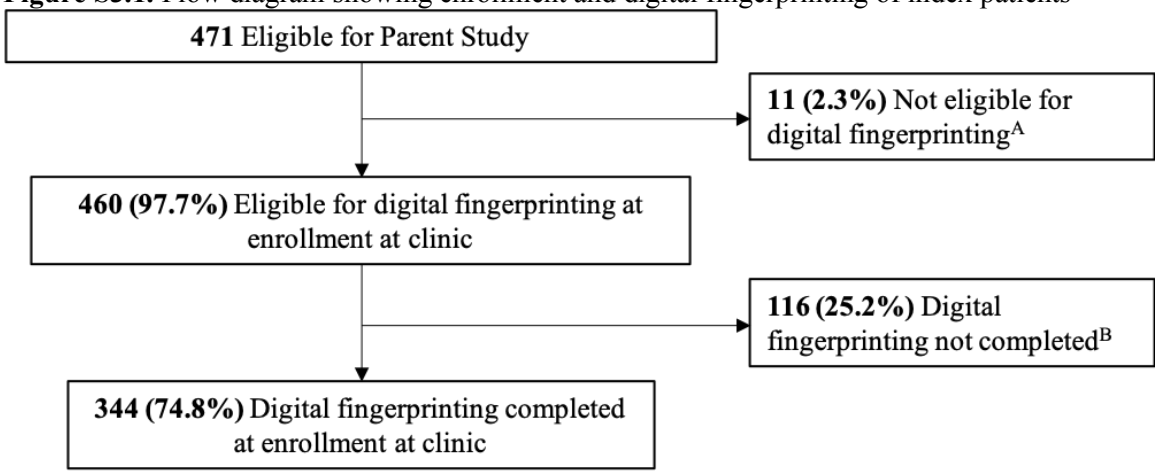
C.) Clinic versus home

5. Future use of fingerprint scanning:

6. Were there any unexpected themes?

IV. Index Patient Results

Figure S3.1. Flow diagram showing enrollment and digital fingerprinting of index patients



[A] Children under the age of 5 were not eligible for digital fingerprinting.
[B] 64 (55.2%) fingerprint scan failures were classified as software problems, 47 (40.5%) as hardware problems, and 5 (4.3%) as unclassified problems.

Table S3.1. Characteristics of index patients

Characteristic	**Digital Fingerprint**	**No Digital Fingerprint**	***P*-value[A,B]**
n (%)	**(n=344)**	**(n=116)**	
Age			
Children 5-14 years	10 (2.9)	3 (2.6)	.86
Adults 15 and older	334 (97.1)	113 (97.4)	
Sex (%)			
Female	144 (41.9)	51 (44.0)	.69
Male	200 (58.2)	65 (56.0)	
Proportion living with HIV (%)			
Positive	218 (63.4)	74 (63.8)	.94
Negative or Unknown	126 (36.6)	42 (36.2)	

[A] Chi square test of significance used
[B] *P*-values were not adjusted for clustering by CHW, as clustering was found to be modest (ICC=0.22)

V. Fingerprinting Success by CHW Over Time

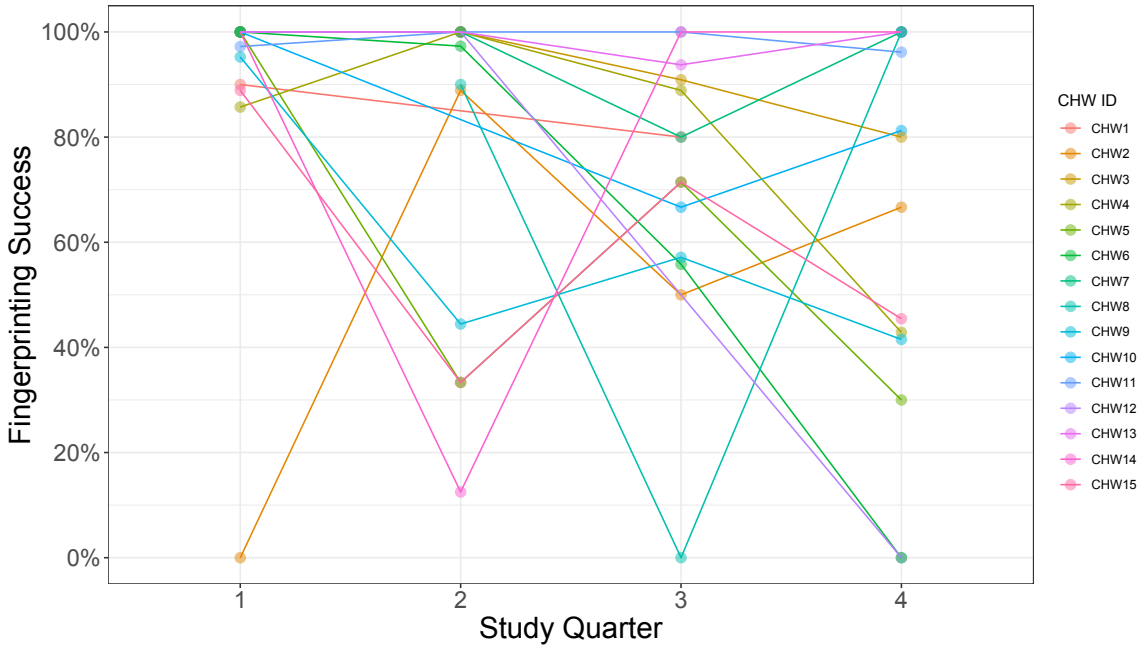


Figure S.3.2. Fingerprinting success by CHW over time. In Q1 of the study, fingerprinting success was >80% for all but one CHW. Beginning in Q2 and continuing throughout Q3 and Q4, fingerprinting success was much less consistent, with variation across CHWs and over time. Importantly, there were not specific CHWs who exhibited especially poor performance with digital fingerprinting; many CHWs showed declines or fluctuations in performance over time. The relationship between fingerprinting success and CHW was formally quantified using the intraclass correlation coefficient (ICC), as described in the main text. The ICC (presented in main text of Chapter 3) confirmed that clustering of fingerprint outcomes by CHW was modest.

Conclusions

Collecting actionable data to guide public health responses has been a longstanding challenge in many settings and disease contexts. This dissertation aimed to examine these challenges and identify potential solutions in the context of TB in Uganda. In this context, reliable and timely data is especially needed to improve the quality of care provided to TB patients; currently, low-quality care in high-burden settings contributes to the slow annual declines in global TB incidence (2%) and mortality (3%).[1,2] As countries like Uganda monitor progress toward achieving high-quality care and the WHO End TB goals, they must have the capacity to collect and utilize accurate data.[3] This dissertation combined quantitative and qualitative methods to understand the quality of routine TB data in Uganda, identify sources of variation in its quality, and assess the implementation of a technological approach for unique patient identification.

In Chapter 1, I used a quantitative approach to evaluate the potential of Uganda's routine TB data to be used as a quality improvement tool. Comparing routine TB data from 2017-2019 to a research dataset, I found that, on average, some variables (e.g., bacteriologically confirmed treatment initiations) agreed more closely than others (e.g., GeneXpert positive diagnoses). However, all variables in the analysis showed a considerable range in agreement between health facilities and over time, limiting the use of this data to monitor trends in the quality of care. Chapter 1 provides important considerations for future programmatic or research assessments focused on data quality in Uganda or other high TB burden settings. First, using a metric such as the limits of agreement, in addition to average measures, is important to quantify variation in data quality and identify priority areas for improvement. Second, we highlight the importance

of examining data quality on a facility-by-facility basis, as national or regional trends can obscure underlying differences. Third, while research studies or register audits to assemble a reference dataset can be time- and resource-intensive, future studies should take a pragmatic approach by focusing on a subset of variables; we included variables rooted in the TB care cascade, but other studies could answer questions about the quality of TB data for children, specific age groups, or populations including PLHIV.

Chapter 2 built upon the findings from Chapter 1 by delving further into sources of variation in the quality of routine TB data. We conducted a qualitative study in three urban and peri-urban districts of Uganda and used the PRISM framework to identify four themes that explained how technical, organizational, and behavioral factors worked together to influence data system processes and outcomes, including data quality. Some of the important barriers to collecting high-quality TB data included variable adherence to data system processes, resource shortages that reduced the ability to carry out best practices, and low motivation among facility staff that negatively affected their attitude toward work. Importantly, interview participants recognized regular data use as the most important facilitator of data quality. In the context of Uganda's transition to an electronic, case-based reporting system, we recommend incorporating regular end-user feedback as an essential element of the implementation strategy in order to mitigate these existing barriers, identify emerging ones, and promote best practices in data collection and use.

One important use of data to monitor quality of TB care, and a major motivation for this work, is constructing TB care cascades that describe progress and patient drop-off along the process of diagnosis, treatment, and cure. Chapters 1 and 2 highlight many of the challenges accomplishing this with aggregate data at subnational levels in this setting.

Without linkage between patient diagnoses, treatment, and outcomes, constructing care cascades requires making many epidemiological assumptions, themselves relying on parameters often estimated from limited research studies or infrequent, costly prevalence surveys. In addition to the benefits and challenges of the Uganda NTLP's new electronic data system highlighted in Chapter 2, the ability to construct national and sub-national care cascades from individual patient data is a major future opportunity for this data source. In order to do this, however, a new challenge not encountered in the current aggregate data system will be the ability to uniquely identify and link patient records.

Chapter 3 evaluated one technological approach to addressing this challenge: digital fingerprinting. In the context of a study of a mobile health intervention to improve rates of household TB contact investigation in Kampala, digital fingerprinting had been used to identify participants, with mixed results. We conducted a process evaluation of the implementation of the technology using a parallel-convergent mixed methods approach. In the quantitative analysis, we found that failures to capture a digital fingerprint were almost completely clustered by household and declined over the course of the study. Through qualitative interviews with community health workers, we found that while using the technology was acceptable and feasible in principle, failures reduced trust in the technology, damaged their self-image as competent health workers, and led to their voluntary abandonment of the technology. Together, these findings highlight the importance of detailed implementation assessments for new technologies, including biometrics, as they move from proof-of-concept to real-world use.

This dissertation provides a detailed analysis of data systems for TB in one high-burden setting, but it also highlights important themes for other settings aiming to use

routine health data or new technologies to assess quality of care or for decision-making. First, data quality can be highly variable across location, data elements, and time; our approach of using linear mixed models would allow others to identify gaps in and determinants of data quality that are specific to their setting. Second, as health systems introduce new data systems, technologies, or other complex interventions, process evaluations will be essential to identify challenges in implementation and develop solutions. Third, engaging stakeholders at all levels, from national decision-makers to local facility-level staff to use their data in meaningful ways is key to improving or maintaining data quality. Finally, mixed methods provide a richer understanding than quantitative methods alone, by not only identifying gaps in quality or implementation, but also characterizing the reasons behind them.

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