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Assessing the effect of health system resources on HIV and tuberculosis programmes in Malawi: a modelling study

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Summary

Background Malawi is progressing towards UNAIDS and WHO End TB Strategy targets to eliminate HIV/AIDS and tuberculosis. We aimed to assess the prospective effect of achieving these goals on the health and health system of the country and the influence of consumable constraints.

Methods In this modelling study, we used the Thanzi la Onse (Health for All) model, which is an individual-based multi-disease simulation model that simulates HIV and tuberculosis transmission, alongside other diseases (eg, malaria, non-communicable diseases, and maternal diseases), and gates access to essential medicines according to empirical estimates of availability. The model integrates dynamic disease modelling with health system engagement behaviour, health system use, and capabilities (ie, personnel and consumables). We used 2018 data on the availability of HIV and tuberculosis consumables (for testing, treatment, and prevention) across all facility levels of the country to model three scenarios of HIV and tuberculosis programme scale-up from Jan 1, 2023, to Dec 31, 2033: a baseline scenario, when coverage remains static using existing consumable constraints; a constrained scenario, in which prioritised interventions are scaled up with fixed consumable constraints; and an unconstrained scenario, in which prioritised interventions are scaled up with maximum availability of all consumables related to HIV and tuberculosis care.

Findings With uninterrupted medical supplies, in Malawi, we projected HIV and tuberculosis incidence to decrease to 26 (95% uncertainty interval [UI] 19–35) cases and 55 (23–74) cases per 100 000 person-years by 2033 (from 152 [98–195] cases and 123 [99–160] cases per 100 000 person-years in 2023), respectively, with programme scale-up, averting a total of 12·21 million (95% UI 11·39–14·16) disability-adjusted life-years. However, the effect was compromised by restricted access to key medicines, resulting in approximately 58 700 additional deaths (33 400 [95% UI 22 000–41 000] due to AIDS and 25 300 [19 300–30 400] due to tuberculosis) compared with the unconstrained scenario. Between 2023 and 2033, eliminating HIV treatment stockouts could avert an estimated 12 100 deaths compared with the baseline scenario, and improved access to tuberculosis prevention medications could prevent 5600 deaths in addition to those achieved through programme scale-up alone. With programme scale-up under the constrained scenario, consumable stockouts are projected to require an estimated 14·3 million extra patient-facing hours between 2023 and 2033, mostly from clinical or nursing staff, compared with the unconstrained scenario. In 2033, with enhanced screening, 188 000 (81%) of 232 900 individuals projected to present with active tuberculosis could start tuberculosis treatment within 2 weeks of initial presentation if all required consumables were available, but only 8600 (57%) of 15 100 presenting under the baseline scenario.

Interpretation Ignoring frailties in the health-care system, in particular the potential non-availability of consumables, in projections of HIV and tuberculosis programme scale-up might risk overestimating potential health impacts and underestimating required health system resources. Simultaneous health system strengthening alongside programme scale-up is crucial, and should yield greater benefits to population health while mitigating the strain on a heavily constrained health-care system.

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Introduction

Global commitment to the UN Sustainable Development Goals (SDGs), particularly the third SDG focusing on universal health coverage, is pivotal in addressing challenges such as poverty, health, and education.[1] Infectious diseases—notably, HIV/AIDS and tuberculosis—substantially impede achievements towards SDG 3 and comprise a considerable burden of disease in low-income countries with limited resources and fragile health-care infrastructures. In combating these epidemics, UNAIDS and WHO have set ambitious targets for prevention, testing, and treatment.[2,3] However, insufficient funding, health-care workforce shortages, and restricted access to diagnostics and treatment pose barriers for countries with scarce resources. Not considering these challenges might overestimate the

Research in context

Evidence before this study

UNAIDS and WHO have developed ambitious targets aimed at reducing the incidence of HIV and tuberculosis to below the threshold for elimination. Many modelling studies have supported these strategies, demonstrating substantial effects in terms of population health. To our knowledge, no studies to date have considered the costs (in terms of health and health system demands) of frailties in the health system. We searched PubMed and Google Scholar on Jan 5, 2023, with no language or date restrictions, using the terms ((tuberculosis) OR (HIV)) AND ((UNAIDS) OR (WHO)) AND ((health system) OR (constraints) OR (consumables)). We found no studies estimating the potential effect of stockouts of essential medicines in reaching HIV or tuberculosis programme targets. Furthermore, studies have largely used single-disease models to evaluate programme impacts. Existing modelling studies have found consistent potential for disease elimination with widespread programme scale-up. Separately, several studies have cited factors contributing to supply constraints for HIV and tuberculosis in low-income countries, such as low funding, weak health system infrastructure, and political instability; however, none have systematically quantified the effects on health or health systems of these constraints.

Added value of this study

We used individual-based modelling to estimate the projected effect of scaling up the HIV and tuberculosis programmes in Malawi and considered the effect that stockouts of key medicines could have on population health and health system use. This study quantifies the demands for health-care worker time required for programme scale-up and the costs of potential inefficiencies in the health system.

Implications of all the available evidence

Existing models projecting HIV and tuberculosis programmes in low-income settings often underestimate the complexities and potential demands on health systems. We address this gap by developing a novel modelling framework that incorporates resource limitations, particularly restricted access to essential consumables and the effect on diagnosis and treatment delays. We found that ambitious scale-up plans, although potentially impactful, can disproportionately strain resource-limited health-care systems if key considerations such as medicine and diagnostic availability are neglected. This can lead to substantial increases in system demand without commensurate improvements in population health. Our framework provides a practical tool for programme planners and policy makers. By explicitly accounting for potential stockouts of consumables and interdependencies between diseases and interventions, it informs resource allocation strategies that maximise health benefits while minimising health system strain. These insights extend beyond HIV and tuberculosis, informing diverse disease programmes facing rapid scale-up challenges in low-income countries. Ultimately, our study underscores the importance of integrating health system strengthening into the core of programme design.

impact of target-focused scaling of programmes towards UNAIDS and WHO goals, as overburdened health-care systems struggle to deliver comprehensive services.

Previous analyses of scale-up of programmes for HIV/AIDS and tuberculosis prevention and treatment have tended to overlook the commodity and health system requirements that are essential for effective service delivery,[4,5] and the analyses that have quantified allocative efficiency have only considered the diseases directly targeted by interventions.[6,7] However, the consequences of policy changes on health systems involve many interdependencies, fluctuations in patient behaviour, feedback loops, and capacity constraints that differ across the tiers of the health system. The dynamics of interactions between infectious and non-communicable diseases, plus the resulting changes in health system use through each policy change, are not yet well characterised and could change the way we evaluate interventions. Innovative health systems modelling is needed to capture disease dynamics combined with a realistic representation of the health-care workforce, health system structure, and availability of consumables.[8]

In Malawi, during 2019, HIV/AIDS and tuberculosis jointly caused 19% of deaths and 16% of all disability-adjusted life-years (DALYs) incurred, contributing as risk factors for several other health conditions, including diarrhoea, acute lower respiratory infections, and anaemia.[9] In 2022, 93% of people living with HIV in Malawi knew their HIV status, 97% of whom were on antiretroviral therapy (ART), and 93% of people on ART were virally suppressed.[10] This is a substantial improvement from 2010, when only 69% of people living with HIV knew their status, and brings Malawi close to achieving the UNAIDS targets of 95% of people with HIV to know their status, 95% of those diagnosed to be on treatment, and 95% of those on treatment having viral suppression. By 2021, 56% of people estimated to have active tuberculosis were on treatment, a substantial increase from 46% in 2011. Of those receiving treatment for tuberculosis in 2021, 36% were co-infected with HIV.[11] These gains have been made despite occasional stockouts of diagnostics and essential medicines that can delay treatment and cause congestion in the health system.[12] Although research indicates that Malawi is poised to eradicate the AIDS epidemic by 2030, the current rate of decline, and simultaneous allocation and use of resources, pose challenges for achieving tuberculosis elimination within the same timeframe.[13,14]

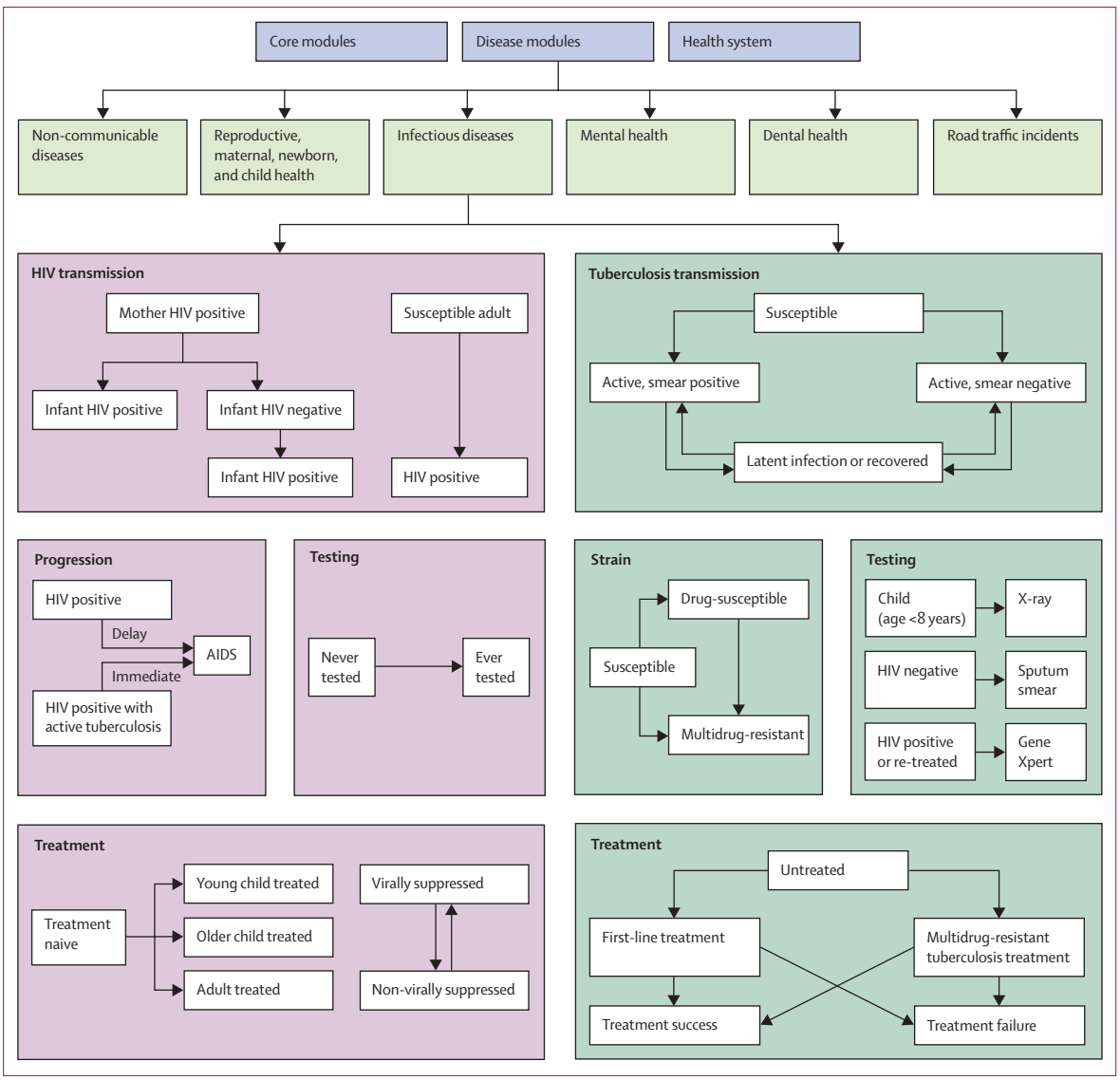

Figure 1: **Schematic of the Thanzi la Onse model with HIV and tuberculosis transmission models**

As HIV and tuberculosis programmes rapidly expand in Malawi, the broader impact of these health-care initiatives needs to be evaluated. This evaluation should consider not only the effectiveness for each disease individually but also how these programmes influence the overall health system. We aimed to do such an evaluation for Malawi using a model that projects target-focused programme scale-up under a range of scenarios to quantify the health system demands to achieve the UNAIDS and WHO targets and the consequences that existing constraints have on the health impact that can be achieved.

Methods

Study design

The Thanzi la Onse (Health for All) model is an individual-based simulation that explicitly tracks a representative population of Malawi and their health over time, incorporating both the demands on the health system and supply constraints (unpublished).The model explicitly represents health conditions accounting for over 80% of DALYs incurred in Malawi through a framework of interacting modules, describing the need for health care (eg, due to infectious and non-communicable diseases and mental health or maternal health conditions), the individual propensity to seek care[15] and the effect of health-care accounting for any frailties in the health system, such as stockouts of key medicines (figure 1). Some diseases can predispose an individual to other health risks (eg, HIV infection will increase risk of active tuberculosis and acute lower respiratory illness) and interactions with the health system can have implications on more than one health

For more on the **Thanzi la Onse model** see https://www.tlomodel.org/index.html

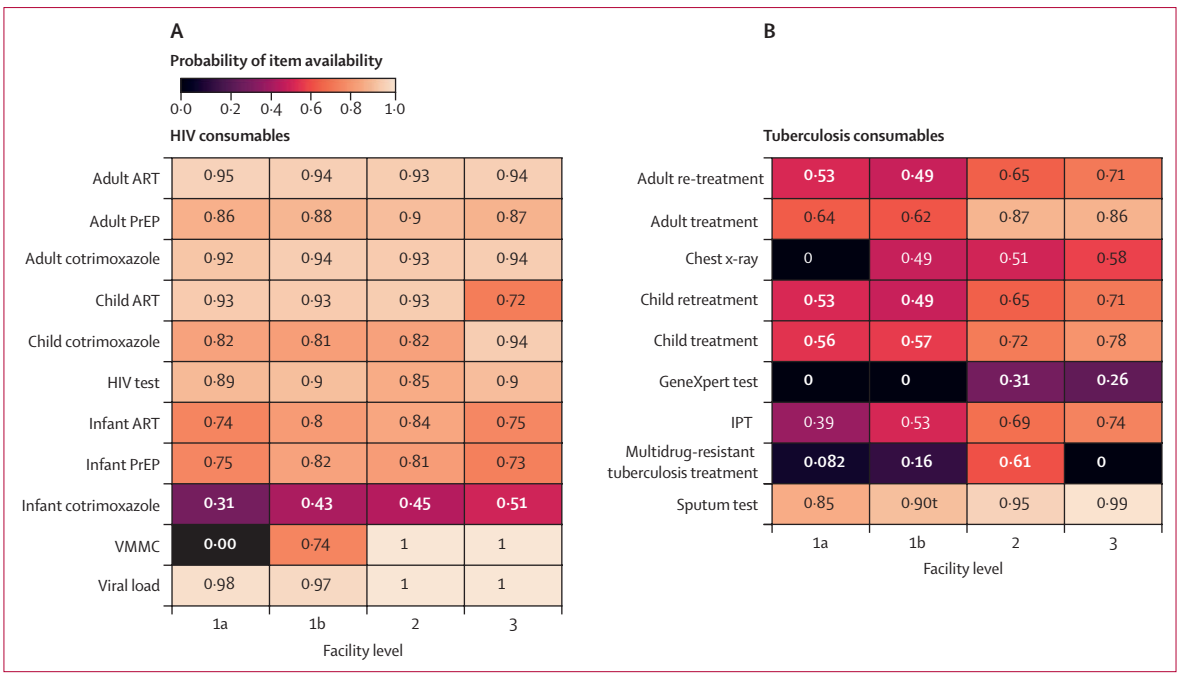

Figure 2: **Mean probability of availability of individual consumables in each facility level related to HIV (A) and tuberculosis (B) services reported through OpenLMIS in 2018**

Values are averaged across each month of 2018 for every facility within each facility level. Values of 0 indicate that the item was never available at that facility level and values of 1 indicates the item was always available at that facility level. ART= antiretroviral therapy. IPT=isoniazid preventive therapy. PrEP=pre-exposure prophylaxis. VMMC=voluntary male medical circumcision.

See Online for appendix 1

condition (appendix 1 p 14). The model follows a granular yet parsimonious structure, incorporating only the processes and determinants of health considered to be most important, as determined via consultation with country experts, modelling teams, and clinicians. Relevant modules are described in detail in appendix 1 (pp 2–13) and the full source code with documentation is available online. We used data on individual facilities in Malawi, including their location, available services, and consumables, to project health system use over a 10-year period, varying the availability of consumables and projecting the expansion of HIV and tuberculosis programmes.

For **full source code documentation** see https://github.com/UCL/TLOmodel

This study was approved by the College of Medicine Research Committee (COMREC) in Blantyre, Malawi (protocol number P.10/19/2820). Because this study used secondary anonymised and aggregated data, individual-level informed consent was not required. Permission for use of these data was obtained from the Ministry of Health, Malawi.

Consumables

The Malawi Ministry of Health uses an Open Logistics Management Information System (OpenLMIS) to manage and track consumables in the health-care system. Each month, real-time use and stockouts of all health commodities (including medicines and other essential supplies) are reported by over 95% of facilities, with reporting rates averaging 90%.[16] We incorporated OpenLMIS data for all consumables used across health-care facilities from Jan 1 to Dec 31, 2018 into the model, providing a monthly probability of item availability at each facility level (figure 2).

The probability of item availability was calculated as 1 minus the proportion of days in a month when the consumable was reported as out of stock by a facility. Average availability was determined for each consumable at the facility level for every district. In Malawi, facility levels are split into four groups: level 1a includes rural and urban health centres, level 1b includes community and rural hospitals, level 2 includes district hospitals, and level 3 includes regional central hospitals. Facilities at levels 1a, 1b, and 2 are pooled within each district in the model.

Access to health care is gated by the availability of consumables, and if items are not available the individual seeking help would be assumed to receive an alternative, return to the same facility for a repeat visit, or discontinue care (appendix 1 pp 16–17). In situations when treatment packages are recommended (eg, ART with cotrimoxazole or isoniazid preventive therapy), the availability of each component in the simulation was assessed separately. Treatment can commence if any of the essential components are available (eg, ART) and will not be forestalled if an optional component is not (eg, cotrimoxazole). Repeat health-care-seeking appointments that require only drug dispensation will incur a pharmacy appointment only,

requiring a pharmacist's time, and are not recorded as full treatment appointments.

Disease modules

As described on the Thanzi la Onse model website, the disease modules comprise mechanistic and non-mechanistic models of the causes of death and disability in Malawi. The disease models can interact with one another, allowing for single risk factors to influence the likelihood of multiple diseases, or for one disease to potentially heighten the risk or severity of another. We present here the methods for the HIV and tuberculosis disease modules, which interact extensively. These modules determine the health burden, mortality, and the effects of any interventions relating to these conditions.

The HIV transmission model describes the risk of infection through mother-to-child transmission or through sexual contact in people aged 15 years and older. A person's risk of acquisition is dependent on their characteristics, such as age, sex, education, wealth, and risk behaviours (eg, sex work). The risk of transmission to women is a function of the prevalence of untreated (or treated but not virally suppressed) infections in men and vice versa.

To determine the health burden and mortality associated with HIV, HIV is simplified into pre-AIDS and AIDS, each of which have associated disability weights (appendix 1 p 1). In the case of comorbidity, the disability weights for each condition are summed with a maximum value of 1.[17] After infection, age-dependent survival times are drawn from probability distributions and a person will die due to AIDS unless treatment is commenced. The time from AIDS onset to death is exponentially distributed, with a mean time of 18 months, unless the individual is younger than 5 years, in which case AIDS onset occurs at infection.[18] The symptoms that occur at the time of AIDS onset are assumed to increase a person's propensity to seek health care.

HIV-related interventions included in the model are HIV tests conducted for individuals aged 15 years and older (hereafter referred to as adults) seeking testing voluntarily, those with AIDS symptoms seeking care, through routine appointments (eg, tuberculosis or antenatal services), and for infants (aged 0–18 months) born to diagnosed HIV-positive mothers.[19] After an HIV test, individuals can present for further health services, such as treatment (if HIV positive), voluntary male medical circumcision (if HIV negative and male), behaviour change counselling (if HIV negative and an adult), pre-exposure prophylaxis (PrEP; if HIV negative and eligible according to policy), or repeat test. The numbers of tests and referrals each year are age-specific and calibrated to match Ministry of Health reports.

If ART is available, the probability of viral suppression is derived from the annual reported data by age and sex.[10] First-line ART regimens for adults and children (age 0–14 years) also include cotrimoxazole and isoniazid preventive therapy dispensation if available. If a person is virally suppressed, the model will assume that any existing HIV-related symptoms are resolved and AIDS onset or death will not occur. Follow-up appointments for those on ART occur every 3 months and continuation depends on the reported probability of retention. If continued, viral load monitoring is scheduled with ART dispensation. If the required drugs are not available at that time, the person can seek another appointment and the consumables checks will run again. If a person discontinues treatment, the disease will progress unless the person re-enters care at a later date.

The tuberculosis module simulates incidence, mortality and the effects of BCG, isoniazid preventive therapy, and tuberculosis treatment across all age groups. The tuberculosis fixed incidence model uses WHO estimates of incidence scaled to represent the incidence of active disease in the absence of any interventions.[20] The risk of active tuberculosis is a function of this scaled population-level risk and the individual risk, determined by characteristics such as BCG vaccination (on childhood risk), obesity, smoking, and untreated HIV infection. Latent tuberculosis is not modelled explicitly; instead the risk of disease is modelled, that can then resolve to a latent (ie, asymptomatic) infection. Drug-susceptible and multidrug-resistant tuberculosis are modelled separately.

At onset of active tuberculosis, each person experiences a set of symptoms that will determine whether they seek health care. If a person is HIV positive, the onset of active tuberculosis also indicates the onset of AIDS. Death due to active tuberculosis is dependent on age, smear status, HIV status, and treatment, occurring 1–6 months after *Mycobacterium tuberculosis* infection.[11,21] Symptoms can resolve without treatment after 3 years if HIV negative (or if HIV positive and virally suppressed), after which the person becomes latently infected and could relapse or become reinfected.

Tuberculosis interventions include individuals with tuberculosis-related symptoms being screened at health facilities and referred through the diagnostic algorithm to the appropriate tuberculosis test (appendix 1 p 13).[22,23] Additionally, we assume that a further sample of the general population with no tuberculosis-related symptoms is randomly screened, to account for the additional testing offered for individuals at high risk, periodic mass screening programmes, or routine screening, matching the overall reports of screening appointments recorded in Malawi each year. People newly diagnosed with HIV are routinely referred for tuberculosis screening, per WHO guidelines. The appropriate first-line diagnostic test is based on the individual's characteristics—for example, the GeneXpert test is used if the person has HIV or a chest x-ray is used if they are younger than 5 years. Sensitivity and specificity vary by test. If the specified test is not available, the person is

referred for an alternative test or relies on a clinical diagnosis (appendix 1 pp 12–13). First-line tuberculosis treatment is given for all primary infections and longer re-treatment regimens or multidrug-resistant tuberculosis treatments are reserved for those with previous infections or verified multidrug-resistant tuberculosis.

Isoniazid preventive therapy is offered to eligible individuals who have been in contact with individuals with confirmed active tuberculosis, identified in the simulation as a random sample of people from the same district from 2014 onwards, and to people with HIV or infants born to mothers with smear-positive tuberculosis from 2018 onwards. The protective efficacy varies by age and HIV status and lasts for the duration of treatment.

Model calibration and projections

Where possible, parameters are estimated directly from data obtained from Malawi, through surveillance programmes, census data, or health information systems (unpublished; and available on Thanzi la Onse model website). Parameters describing the natural history of diseases have been drawn from the scientific literature or through consultations with clinical experts. Most parameters are fixed, either throughout the simulation or as time-varying values. HIV transmission rate and tuberculosis scaling factor are sampled through Latin hypercube sampling then calibrated using approximate Bayesian computation (appendix 1 pp 20–21).[24] Distortions in mortality rates due to COVID-19 are not incorporated in the model.

For the current analysis, we considered three scenarios: (1) the baseline scenario, in which programme coverage remains static with existing consumable constraints; (2) constrained programme scale-up, in which prioritised interventions are scaled up to reach programme targets with fixed consumable constraints; and (3) unconstrained programme scale-up, in which prioritised interventions are scaled up with maximum availability of all consumables related to HIV and tuberculosis care.

The interventions prioritised for scenarios 2 and 3 are detailed in the panel. The target coverage for each intervention follows the UNAIDS 95–95–95 targets for HIV (95% of people living with HIV knowing their status, of whom 95% have initiated treatment, and 95% of people living with HIV on treatment becoming virally suppressed, plus services for prevention of vertical transmission reaching 95% coverage) and the 90–90–90 WHO End TB Strategy (reach at least 90% of all people in need of tuberculosis treatment and prevention, reaching at least 90% of people in key populations, and achieving at least 90% treatment success).[2,3]

The scenarios were implemented on simulation date Jan 1, 2023, as immediate changes in health system use and maintained throughout a 10-year projection period up to Dec 31, 2033. Five sets of model draws were constructed using the calibrated rates with five model runs per draw, resulting in 25 model runs per scenario.

A representative simulated population, scaled at a ratio of 1 to 145 (simulated population of 100 000), was initialised at baseline and proportionally distributed

Panel: **Interventions included in the two simulations of programme scale-up, including target and baseline coverage**

HIV programme

Prevention

- Reduction in population-level risk of HIV acquisition relating to implementation of behaviour change programmes, including condom use (target 10%)
- Probability of initiating PrEP for female sex workers after negative HIV test (target 50%; baseline 5%)
- Annual probability of initiating PrEP for adolescent girls and young women at highest risk (defined as those with the highest risks of acquisition determined by education, wealth, and risk behaviours; target 10%; baseline 0%)
- Probability of retention on PrEP every 3 months (target 75%; baseline 50%)
- Probability that an uncircumcised man is referred for VMMC after receiving a negative HIV test (target 25%; baseline 5%)

Testing

- Annual HIV testing rate for adults (target 30%; baseline is time-varying)
- Probability of HIV test for undiagnosed mothers through antenatal clinic (target 95%; baseline 95%)
- Probability of HIV test for infants born to mothers with diagnosed HIV (target 95%; baseline 95%)

Treatment

- Probability of initiating ART after positive HIV test (target 95%; baseline value is time-varying)
- Probability of viral suppression (target 95%; baseline value is time-varying)

Tuberculosis programme

Prevention

- Coverage of IPT for people living with HIV (target 90%; baseline is time-varying)
- Coverage of IPT for child contacts of people with active tuberculosis (target 90%; baseline is time-varying)

Testing

- Switch to GeneXpert MTB/RIF for first-line diagnostic testing (NA)

Treatment

- Tuberculosis treatment coverage for active tuberculosis (target 90%; baseline is time-varying)
- Tuberculosis treatment success rates for all treatment regimens (target 90%; baseline varies by regimen)

ART=antiretroviral therapy. IPT=isoniazid preventive therapy. NA=not applicable. PrEP=pre-exposure prophylaxis. VMMC=voluntary male medical circumcision.

across the districts, with demographic and lifestyle characteristics assigned to reflect the true distribution among the full population of Malawi. Population growth was calibrated to the World Population Prospects Medium Variant Estimates,[25] such that for 2023, the population of 21·1 million individuals was simulated using a population of 145 400 individuals. By 2033, the projected population was 27·2 million, represented by 187 400 simulated individuals. A detailed logger recorded the outputs of interest each year (eg, incidence, deaths, and health system use). The median of each output and the 95% uncertainty intervals (UIs; ie, 2·5th and 97·5th percentiles) were derived from the scenario sets and all results for counts are shown rounded to the nearest 100. Outputs from the simulated population were scaled linearly to represent the full population.

We did a sub-analysis that built on scenario 3 by varying availability of specific packages of HIV and tuberculosis prevention and treatment to estimate the relative effects of stockouts for each intervention package.

We did sensitivity analyses to test our assumptions of persistence in health-seeking behaviour, in which no repeat appointments were permitted, and constraints on health-care worker time, in which daily health-care worker time was capped at the reported limits (using the Malawi Human Resources for Health Strategic Plan 2018–2022).[26,27] Appointments require a fixed amount of health-care worker time and in this second sensitivity analysis, appointments that cannot be delivered are queued for the following day; after 7 days, if an individual has not had their scheduled appointment, they are lost to follow-up.

All analyses we done using Python (version 3.8).

Role of the funding source

The funders had no role in the study design, data collection, data analysis, data interpretation, or writing of the manuscript.

Results

Projections of incidence and mortality due to HIV and tuberculosis under each of the three scenarios are shown in figure 3. Under an unconstrained scenario, with unlimited availability of consumables, achieving the UNAIDS 95–95–95 goals would reduce HIV incidence rates from 152 cases (95% UI 98–195) per 100 000 person-years in 2023 to 26 cases (19–35) per 100 000 person-years in 2033 and would reduce AIDS-related mortality from 72 deaths (95% UI 58–85) per 100 000 person-years in 2023 to 21 (16–27) per 100 000 person-years in 2033, corresponding to a decrease from approximately 13 400 AIDS deaths (95% UI 10 500–15 800) in 2023 to approximately 5600 (4400–7200) AIDS deaths in 2033 (figure 3). Likewise, under this scenario, attaining the 90–90–90 WHO End TB Strategy goals is estimated to reduce tuberculosis incidence rates from 123 cases (95% UI 99–160) per 100 000 person-years in 2023 to 55 cases (23–74) per 100 000 person-years in 2033. Tuberculosis mortality rates are estimated to reduce from 20 deaths (95% UI 13–28) per 100 000 person-years in 2023 to 5 deaths (3–10) per 100 000 person-years in 2033. However, the effects of both programmes are mitigated by the availability of key medicines. The constrained scenario, with limited access to consumables for prevention, diagnostics, and treatment, would result in approximately 58 700 additional deaths (33 400 [95% UI 28 000–41 000] AIDS-related deaths and 25 300 [19 300–30 400] tuberculosis-related deaths) and approximately 11·7 million (95% UI 10·7–12·9) additional DALYs compared with the unconstrained scenario over the projected time period (table).

Between 2023 and 2033, eliminating stockouts in HIV treatment alone could avert an estimated 19 000 (95% UI 13 300–29 300) AIDS deaths compared with the baseline scenario (figure 2A; appendix 1 pp 31–32), despite ART availability consistently exceeding 90%. Strengthening supply chains for HIV prevention or tuberculosis treatment individually is projected to show little effect on

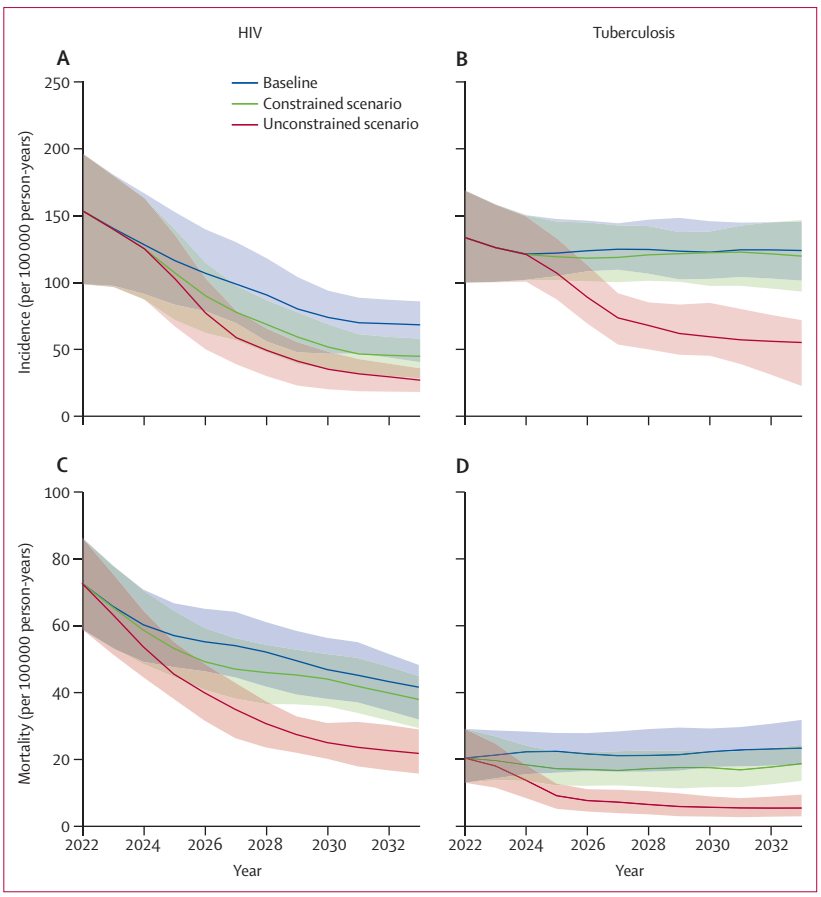

Figure 3: **Projected incidence rates for HIV in individuals aged 15–49 years and tuberculosis in all ages (A, B) and AIDS-related and tuberculosis-related mortality (C, D) under each scenario, 2023–33**
Solid lines show the median estimates and the shaded areas show 95% uncertainty interval.

	Health-care workforce time required, h (in millions)				DALYs averted *vs* baseline (in millions)		
	Clinical	Nursing	Pharmacy	Radiography	AIDS	Tuberculosis	Total
Baseline (scenario 1)	67·44	67·52	24·85	0·12	0 (ref)	0 (ref)	0 (ref)
Constrained scenario (scenario 2)	72·12	73·66	26·42	0·12	0·48 (0·22 to 0·73)	0·46 (0·27 to 0·59)	0·64 (–0·65 to 2·29)
Unconstrained scenario (scenario 3)	66·34	67·02	24·57	0·08	1·26 (1·06 to 1·56)	1·38 (1·19 to 1·65)	12·21 (11·39 to 14·16)

Data in parentheses are 95% uncertainty intervals. Total DALYs averted represents DALYs averted due to all causes. DALYs=disability-adjusted life-years.

Table: **Projected patient-facing time required by each health-care workforce cadre for delivery of HIV-related and tuberculosis-related services, and DALYs averted *vs* the baseline scenario, for 2023–33**

incidence and mortality (appendix 1 pp 31–32). However, the cumulative DALYs averted by concurrently strengthening both HIV and tuberculosis supply chains exceed those directly associated with HIV and tuberculosis individually, indicating substantial indirect health benefits (table).

The constrained scenario is projected to result in increased demands on the health-care system due to repeated health-care seeking; 14·3 million additional hours of patient-facing time are required compared with the unconstrained scenario, with most of this time delivered by clinical or nursing staff (table). Additionally, the increased demand for HIV or tuberculosis testing under the constrained scenario does not translate into higher treatment coverage because diagnosis and treatment are limited by availability of consumables. An additional 17 900–37 000 tuberculosis treatment appointments are projected to be required to meet the targets between 2023 and 2033 compared with the unconstrained scenario (figure 4; appendix 1 p 30). Scale-up of preventive services, such as PrEP, voluntary medical male circumcision, and isoniazid preventive therapy, would require approximately 20·2 million additional appointments to be delivered between 2023 and 2033 to meet targets, decreasing to 9·6 million appointments in the unconstrained scenario.

With current stock availability and enhanced screening (ie, the constrained scenario), 8600 (57%) of 15 100 individuals projected to seek health care with active tuberculosis in 2033 would be able to initiate treatment within 2 weeks of disease onset compared with 188 000 (81%) of 232 900 if consumables supplies were uninterrupted (ie, the unconstrained scenario; appendix 1 p 30). The switch to GeneXpert as a first-line diagnostic test is estimated to reduce the levels of misdiagnosis of tuberculosis in adults in 2033 from 9% (95% UI 6–15) under the baseline scenario to 2% (1–4) under the constrained scenario, increasing slightly to 6% (2–12) with increased access to all diagnostic tests including x-ray and sputum smear microscopy, which have lower specificity, under the unconstrained scenario (appendix 1 p 32).

In our sensitivity analyses, we found that the projected effect of stockouts was mitigated by the repeated health-care-seeking behaviour assumed in the main analysis. By disallowing repeat health facility visits, the magnitude of the effect increased, with 76 700 (95% UI 62 300–81 600) additional AIDS-related deaths and 58 300 (51 600–68 200) tuberculosis deaths occurring in the constrained scenario in the period 2023–33 compared with the unconstrained scenario (appendix 1 p 33). The most probable future situation is likely to lie somewhere in between these two assumptions.

In a further sensitivity analysis, assuming fixed capacity of health-care workers, the effects of consumables stockouts were again increased, with an additional 50 800 (95% UI 46 900–58 400) AIDS deaths and 31 200 (26 800–34 700) tuberculosis deaths compared with the unconstrained scenario (appendix 1 p 37).

The proportional changes in health-care worker hours show consistency across these scenarios, suggesting an approximate addition of 5 million clinical hours with HIV and tuberculosis programme scale-up in the constrained scenario across 2023–33 (appendix 1 p 38). Notably, the combined effects of constraints on health-care worker capacity and consumables on incidence and mortality of HIV and tuberculosis closely resemble those of consumables constraints alone (appendix 1 p 37).

Discussion

We projected that the HIV and tuberculosis scale-up programmes could, in a perfect health system, reach specified targets and achieve elimination in line with other model predictions.[6,28] Under the unconstrained scenario, reaching elimination would not incur substantial net health system costs over the 10-year projection period in terms of patient-facing time compared with the baseline scenario and could avert approximately 12 million DALYs. However, incorporating realistic availability of consumables resulted in treatment delays and increased health system demands, and, hence, a lower projected impact.

Consistent with other modelling studies, we found that small interruptions in ART delivery could translate into large effects on population health.[29] A backlog of repeat appointments for individuals requiring multiple clinic visits before initiating treatment would yield longer episodes of poor health, translating into higher cumulative disability weights, and feed back into an increased risk of transmission to others. Reported

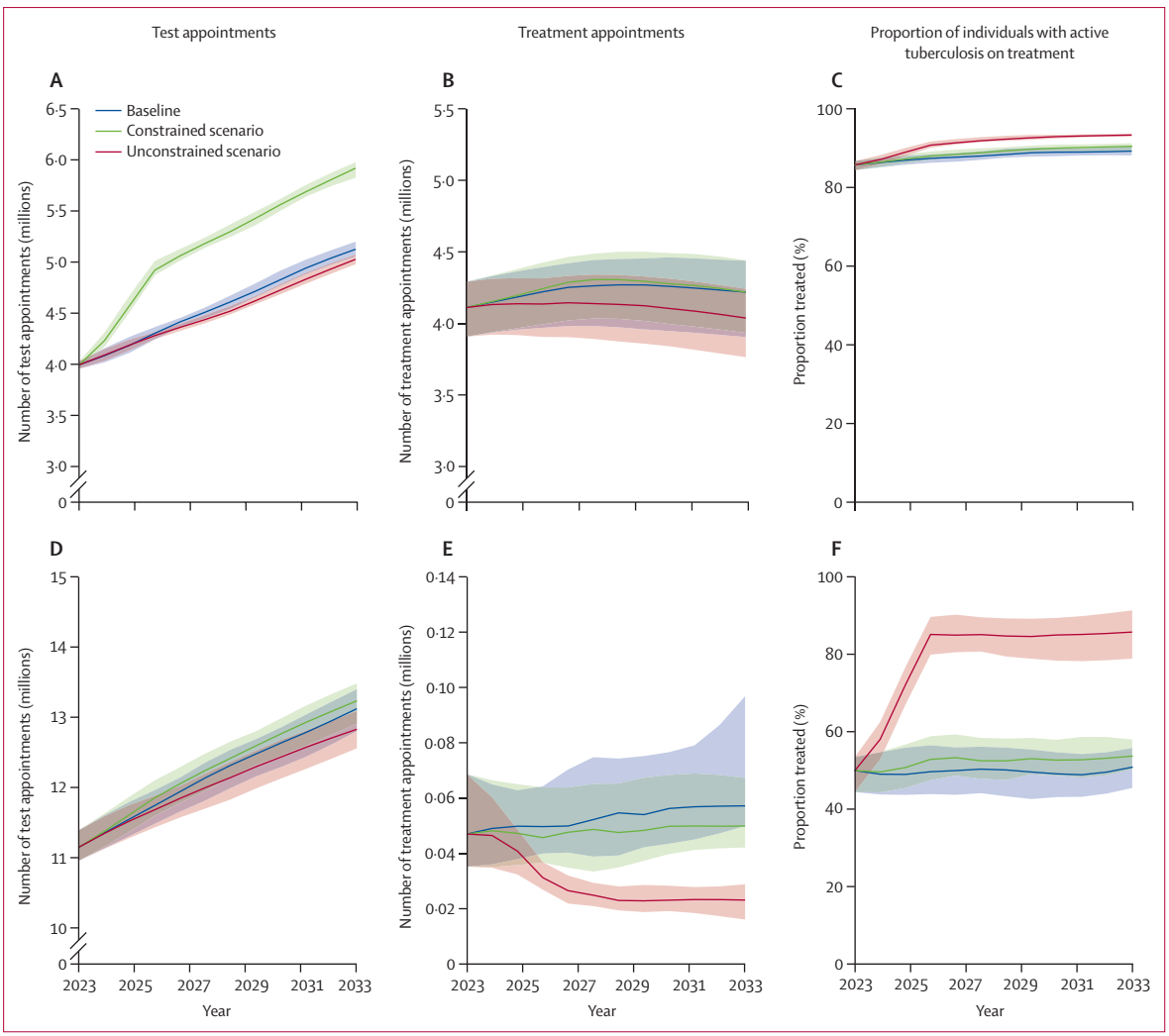

Figure 4: **Projected health system use and associated treatment coverage for HIV (A–C) and tuberculosis (D–F), 2023–33**
Tuberculosis test appointments include routine clinical screening and diagnostic tests. Treatment appointments are counted only if they include medicine dispensation (ie, routine follow-up appointments are not included). Proportion treated is the number currently on appropriate treatment divided by the estimated number currently infected.

supply issues in HIV-related and tuberculosis-related services could require an additional 14·3 million hours of patient-facing time provided by health-care workers each year in an already highly constrained health system. Prioritising preventive measures, such as voluntary male medical circumcision, PrEP, and isoniazid preventive therapy, demands careful consideration, with an estimated 20·2 million additional preventive appointments (or 9·6 million with uninterrupted supplies) required to meet targets by 2033. The impact of consumables stockouts is exacerbated when we impose constraints on health-care worker capacity, reflecting the realistic situation in which clinics frequently operate at full capacity and still have delayed appointments.[26]

With limited personnel, the decline in population health stems primarily from delays or absence of care for lower respiratory infections, malaria, and neonatal disorders because appointments for these conditions are overshadowed by prioritised HIV and tuberculosis services, underscoring the downstream effect of constrained personnel time on the provision of care for various disorders. The effect of these competing priorities could be somewhat mitigated by reductions in the time taken for appointments, task-shifting, and working longer hours.[30]

A previous study found an 8-week median health system delay for new patients with tuberculosis in Malawi, greatly exceeding the 2-week delay attributed to patient health-care-seeking behaviour.[31] In the current study, health system delays stemming from consumables stockouts were projected to result in 25 300 additional tuberculosis-related deaths across the projected study period, and were further increased when considering personnel constraints. Moderate scale-up of use

of GeneXpert as a primary diagnostic tool would curtail delays, minimising tuberculosis overdiagnosis and enhancing the detection and treatment of multidrug-resistant tuberculosis.[32,33] Aligned with Malawi Ministry of Health guidelines, our model targets tuberculosis testing for symptomatic individuals while also identifying asymptomatic cases through routine community screening for both symptomatic and asymptomatic individuals. The health-care-seeking behaviour of individuals with tuberculosis is influenced by symptom prevalence, which is dependent on smear status.[15] However, we acknowledge that relying on specific symptoms for testing referrals is a limitation, as has been shown in African prevalence survey data that indicate up to 50% of patients with culture-confirmed tuberculosis do not report symptoms and would only be identified through non-symptom-led routine screening programmes.[34]

We modelled a representative subset of the population, scaling disease burden and health system use to reflect the full population; however, we acknowledge that non-linearities in transmission dynamics and health-care-seeking behaviour might be present in larger populations and when facilities reach capacity. Although acknowledging potential complexities introduced by the COVID-19 pandemic to the health system, we intentionally omitted pandemic-related distortions in health system use in our study, focusing on the broader challenges associated with delivering essential services within existing health system constraints.[29] We did not explicitly model HIV transmission among men who have sex with men because data on the size of this population in Malawi are scarce, and we also assumed that intravenous drug use as a risk factor for HIV acquisition is not widespread in Malawi.

OpenLMIS is the most up to date and reliable source for consumable stockout data and might vary compared with other census data. Notably, OpenLMIS data can be subject to misreporting and potentially underestimating or overestimating availability of some supplies, particularly for newer diagnostics and treatment; as such, the effect of restricted access to consumables would lie somewhere between our constrained scenario and the unconstrained scenario. In the absence of data describing temporal changes in consumable availability in Malawi, we opted to maintain a fixed availability consistent with observed data. In reality, temporary supply shortages might be mitigated by rationing (eg, patients are given 1 month or 3 months of supplies instead of 6 months).

See Online for appendix 2

The Thanzi la Onse model adheres to recommended clinical practice that might not always occur.[35] Additional services such as HIV self-testing, tuberculosis contact tracing, and mobile outreach tuberculosis clinics are not currently included in the model. While facilities, personnel, and consumables are district-level factors, application of disease risks is done uniformly across the country, which might restrict capturing localised factors influencing disease prevalence and intervention effectiveness.

The tuberculosis model incorporates reduced disease risk with increased treatment coverage but does not capture evolving dynamics between multidrug-resistant tuberculosis and drug-sensitive strains. The current prevalence of multidrug-resistant tuberculosis in patients who have been previously treated suggests that treatment failure could become more common. The potential benefits of switching to GeneXpert for first-line testing, such as reducing transmission pressure and treatment failure, might be underestimated in our analysis—for instance, the need for longer and costlier drug regimens would be reduced.

The model's adaptability beyond Malawi is evident in its incorporation of generalisable disease dynamics, adaptable health system components, sensitivity to contextual factors, scenario-specific adaptability, and a collaborative approach involving stakeholders. Although our study sheds light on the effect of constraints on consumables on HIV and tuberculosis programmes in Malawi, we emphasise the model's potential for broader application, highlighting the need for future collaborative efforts to adapt and validate it in diverse global settings. Furthermore, although our study highlights specific challenges within the Malawian health system, it underscores the necessity of a nuanced understanding of real-world constraints in health-care delivery. While advocating for a comprehensive approach to programme planning, we stress the importance of aligning projections with the actual demands and limitations of the health system.

Contributors

TDM and TBH conceived the study. TDM, SM, TC, JHC, AJ, EJ, ILL, RMS, EM, MM, TEM, DN, BS, ANP, JM-B, and TBH contributed to data collection and processing. TDM, SM, TC, JHC, MG, AJ, EJ, ILL, RMS, EM, MM, TEM, DN, BS, AT, PR, ANP, JM-B, and TBH developed the study design and methods. TDM and TBH did the formal analysis. TDM, AJ, TEM, DN, ANP, JM-B, and TBH advised on analysis and interpretation of the data and model outputs. TDM and TBH drafted the manuscript and all authors contributed to writing the version for submission. TDM, DN, JM-B and TBH accessed and verified all underlying data. All authors had full access to data and code used for this analysis, read and approved the final version of the manuscript, and had final responsibility for the decision to submit for publication.

Equitable partnership declaration

The authors of this paper have submitted an equitable partnership declaration (appendix 2). This statement allows researchers to describe how their work engages with researchers, communities, and environments in the countries of study. This statement is part of *The Lancet Global Health*'s broader goal to decolonise global health research.

Declaration of interests

TC has received consulting fees from the UN Economic Commission for Africa and has participated on the Trial Steering Committee for adolescent mental health in Nepal. SM has received consultancy fees from The Global Fund to Fight AIDS, Tuberculosis and Malaria. ANP has received consultancy fees from the Bill & Melinda Gates Foundation. All other authors declare no competing interests.

Data sharing

All data used in this study were shared with the authors in an anonymised and aggregated format. The aggregated data, source code required to run the simulations, and supporting documentation are available online at www.tlomodel.org. All publicly available data sources have been cited.

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