GLOHRA Reporting Template (finished projects)

Project data

Full title and short title/acronym:

Full title: Development of a novel, easy-to-use digital tuberculosis screening tool informed by machine learning approaches

Short title: AI TB Screening Tool

Project type

☐ interdisciplinary pilot project ☒ cross-sector project ☐ global health postdoc fellowship

Research areas involved (check all that apply)

☒ Biomedical sciences ☒ Public health
☐ Social sciences and humanities ☐ Engineering and other sciences

Project duration

June 2022–June 2024

Project team[1]

Name	Organization	Discipline(s)	Contact e-mail	Main contact[2] (Yes/No)
Claudia Denkinger	Heidelberg University	TB diagnostics development & evaluation	Claudia.Denkinger@uni-heidelberg.de	Yes
Lena Maier-Hein	Heidelberg University	Machine learning	l.maier-hein@dkfz-heidelberg.de	No
Alexandra Zimmer	Heidelberg University	TB diagnostics, data management, data analysis	Alexandra.zimmer@uni-heidelberg.de	No
Lisa Koeppel	Heidelberg University	Data management, data analysis	l.koeppel@uni-heidelberg.de	No
Seda Yerlikaya	Heidelberg University	Project management	seda.yerlikaya@uni-heidelberg.de	No
Henry Loharja	Heidelberg University	Data analysis, AI	henry.loharja@uni-heidelberg.de	No

[1] This list may differ from your original application and will appear in the report on our website. Please include all core team members, including (if applicable) international and/or cross-sector partners.
[2] Please indicate **one** primary contact person **per organization**. Email addresses will not be public.

Eva Christodoulou	Heidelberg University	Machine learning	evangelia.christodoulou@dkfz-heidelberg.de	No
Maria del Mar Castro Noriega	Heidelberg University	Qualitative research, Implementation science	maria.castro@uni-heidelberg.de	No
Monde Muyoyeta	Center for Infectious Disease Research in Zambia (CIDRZ)	TB diagnostics, TB case-finding strategies	monde.muyoyeta@cidrz.org	Yes
Minyoi Maimbolwa	Center for Infectious Disease Research in Zambia (CIDRZ)	TB diagnostics, TB case-finding strategies	Minyoi.Maimbolwa@cidrz.org	No
Chris Isaacs	Connected Diagnostics	App development	chris.isaacs@connected-dx.com	Yes
Andrew Kerkhoff	University of California, San Francisco	TB diagnostics, evaluation, implementation science	Andrew.Kerkhoff@ucsf.edu	Yes
Irwin Law	World Health Organization	Country prevalence surveys	lawir@who.int	Yes

1. Project Results and Deliverables

Deliverables

Did your project produce tangible deliverables? Deliverables of your project may refer to

a) your research results, e.g. scientific publications[3], documents, guidelines, reports, databases or data analysis techniques, preventive, diagnostic or therapeutic interventions, tools for management of conditions and diseases, health and social care services, support tools for fundamental research or medical interventions, incl. potential for transfer to other settings

☒ Yes ☐ No

If "yes", please provide details on the deliverables related to your project results.

Date	Title	Description	Link (available where/ how)?

[3] If not yet published, please note the (intended) date of submission.

10/2024	Report on the performance of machine learning algorithm (WP1)	An internal report detailing the methodology and performance of the machine learning algorithm for TB risk prediction.	Internal
10/2024	Proof of concept application (mTBScreenb) (WP2.1)	In partnership with Connected Diagnostics, a proof-of-concept smartphone application called "mTBScreen" was developed	Internal
10/2024	Usability assessment manuscript (WP2.2)	A manuscript that summarizes the findings of the usability of the mTBScreen application in Zambia	In progress
05/2024	mTBScreen connectivity and interoperability compatibility assessment (WP3)	A series of four internal reports drafted by Connected Diagnostics on the connectivity and interoperability of the mTBScreen application	Internal, available upon request

b) the uptake/ use of your research results in policy and practice, e.g. circular/rapid advice/letter to the Ministry of Health, training curriculum for practitioners or researchers, (contribution to) clinical guidelines or reviews, policy documents or government reviews, citation in systematic reviews, membership of a guidance committee, participation in a national consultation, participation in advisory committee, etc.

☐ Yes ☒ No

If "yes", please provide details on the deliverables of your project related to the uptake/use of your research results in policy and practice.

c) Funding: Has the project team (or have individual members of the project team) already attracted further funding for follow-up research projects or for transfer activities? Please, also consider applications pending and applications in preparation.

☒ Yes ☐ No

If "yes", please provide details on the funding attracted (including applications pending and applications in preparation)

Source of funding / funding agency	Project	Funding (Euros)	Already granted	Pending / in preparation
European Research Council (ERC) / European Commission	FIND-TB: Developing and Validating a Novel Digital App-based Tool to Improve Tuberculosis Diagnosis in Children in Resource-Limited Settings	1698683,55	☒	☐

Deutsche Forschungsgemeinschaft (DFG)	A hybrid effectiveness-implementation trial of innovative digital diagnostic solutions for tuberculosis in low- and middle-income countries	473554	☒	☐

2. Impact

How would you rate the impact of your project in relation to the following dimensions:

Dimension	no impact		↔		very high impact
Extend the networks of the project team members with global health researchers in Germany	☐	☐	☒	☐	☐
Increase interdisciplinary collaboration of the project team members with researchers from other fields	☐	☐	☐	☐	☒
Extend the networks of the project team members to global health researchers abroad	☐	☐	☐	☐	☒
Extend the networks of the project team members to global health practitioners and policy makers abroad	☐	☐	☐	☒	☐
Transfer research results to global health policy makers and practitioners	☐	☒	☐	☐	☐
Contribute to high quality training of early career researchers among the project team members	☐	☐	☐	☐	☒
Improve the career opportunities for early career researchers among the project team members	☐	☐	☐	☒	☐
Increase the visibility of German global health research in academia internationally	☐	☐	☐	☒	☐
Increase the visibility of German global health research among policy makers abroad	☐	☐	☒	☐	☐

Please indicate which SDG 3 targets your project specifically contributed to.

SDG 3 targets	**Contribution?**	**By means of**
	Yes	
Reduce maternal mortality	☐	

Reduce neonatal and child mortality	☐	
End epidemics in infectious diseases	☒	The project developed an algorithm for TB screening. TB is a leading infectious disease killer globally and relevant to SDG 3.3.
Reduce noncommunicable diseases	☐	
Prevent and treat substance abuse	☐	
Reduce deaths and injuries from road traffic accidents	☐	
Ensure universal access to sexual and reproductive health	☐	
Achieve universal health coverage	☐	
Reduce death and illnesses from hazardous chemicals, pollution and contamination	☐	

3. Publishable project case study (ca. 1 page)

Please address each of the following points, keeping in mind a general readership:

a) a brief introduction to the background of your project
b) a brief summary of your project/intervention
c) a summary of your findings
d) any lessons learnt that may be useful for the GLOHRA or wider global health community

Please include:

- a list of materials and publications produced that may be of interest to the GLOHRA and wider global health community (including links if available)
- picture(s) which we have permission to use in public communications, sent as separate files with copyright information where applicable
- a contact e-mail address

Introduction: Tuberculosis (TB) remains the leading infectious cause of death globally. The WHO's current symptom screen lacks specificity, while other screening methods like chest X-rays are resource-intensive and inaccessible. To achieve SDG3, there's an urgent need for strategies that rapidly and accurately identify TB cases for prompt treatment initiation. Clinical risk scores and prediction models offer a promising approach to systematic TB screening. This project aimed to develop a risk score prediction algorithm and embed the algorithm within a user-friendly mobile app that combines clinical, demographic, and epidemiological data to generate individualized TB risk scores. The specific research objectives were:

Objective 1. Develop and validate a predictive risk model for active TB disease using machine learning.
Objective 2. Design a digital TB screening tool incorporating a machine learning-derived TB predictive risk model for use in resource-limited settings.
Objective 3. Facilitate interoperability and integration of the digital TB screening tool into relevant information systems.

Project activities:

Objective 1: We compiled a large, geographically diverse dataset from prevalence surveys obtained through WHO and independent community-based studies. The harmonized dataset included individuals aged ≥15 years, totaling over 900,000 entries. Using this data, we developed and trained various algorithms, including machine learning and Bayesian methods, to predict individual TB risk.

Objective 2: We developed 'mTBScreen', a mobile app that will incorporate the TB risk algorithm from Objective 1, in partnership with Connected Diagnostics. To evaluate its usability and acceptability, healthcare providers in Zambia tested data entry with the app using clinical patient vignettes. Their feedback was collected through interviews and used to refine the app's user interface.

Objective 3: Connected Diagnostics mapped electronic TB tools and databases in High Burden TB countries, ranking their API capabilities. This informed potential data flow between the mTBScreen app and TB databases. Additionally, regulatory needs for the mTBScreen app were explored.

Findings:

Objective 1: A preliminary algorithm was developed using machine learning. Validation of the algorithm has only been performed using the secondary prevalence survey data, achieving a balanced accuracy of approximately 60%. Further training and validation are underway.

Objective 2: A proof-of-concept mTBScreen app was developed (**Figure 1**), incorporating demographic, clinical, and epidemiological inputs for the TB risk algorithm. A usability study with 30 Zambian health workers found the app acceptable and comparable to routine screening procedures. Users expressed motivation to transition from paper-based to digital solutions. Usability varied among different user types, with community health workers taking longer to enter data than clinical officers and nurses.

Objective 3: The TB database mapping revealed potential for streamlined operations through data integration, but highlighted challenges due to varying API capabilities across systems. This emphasizes the need for careful planning and customized integration design to ensure seamless interoperability. mTBScreen requirements and architecture documentation was created, including exploration of ISO IEC 62304 Medical Device Data Systems compliance.

Lessons learnt: Working with prevalence survey data presents significant challenges. While these large datasets appropriately target community-based populations in high TB burden settings, the data quality varies considerably between surveys. This variability creates downstream difficulties when developing models using harmonized datasets, particularly due to inconsistencies in variables across individual datasets. Regarding the mTBScreen app development, early engagement with end users proved crucial. Obtaining feedback on usability and acceptability not only provided insights into potential downstream uptake but also guided the refinement of the user interface. This iterative process was instrumental in creating a user-friendly product that meets the needs of healthcare providers in the field.

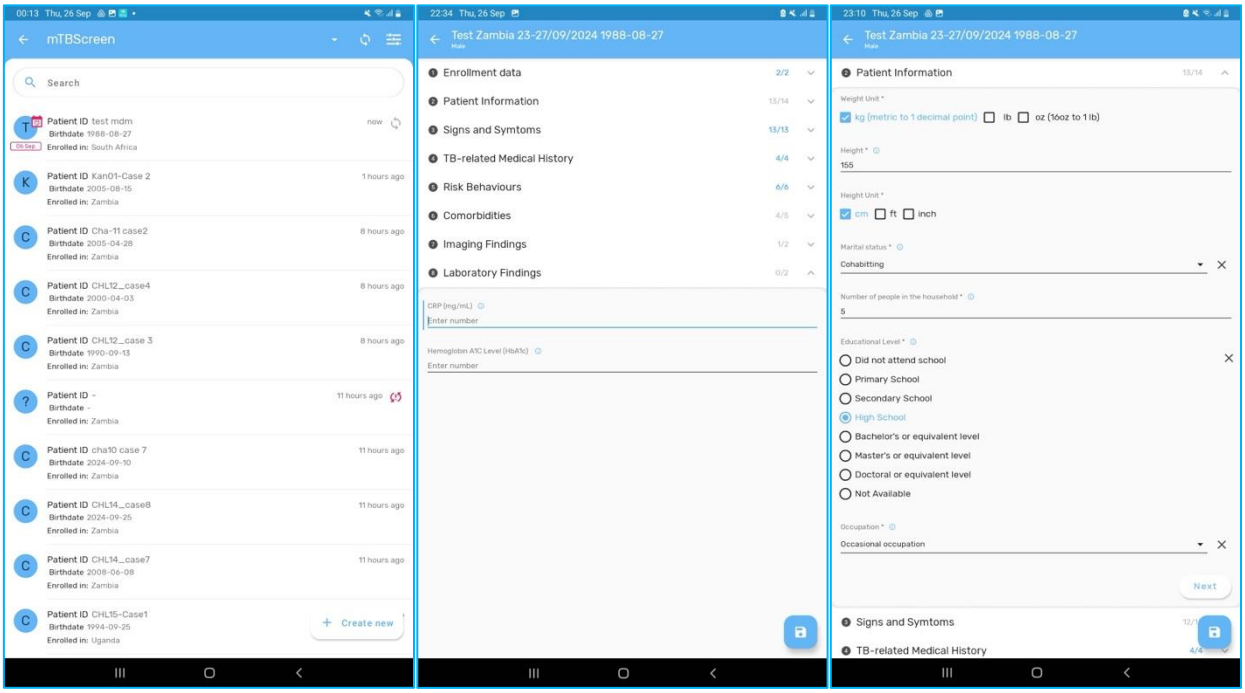

Figure 1. User interface pages of the mTBScreen mobile application. All information presented belongs to generated clinical vignettes and is not from a real patient. Left) Overview of different patient profiles that have been entered into the app. Middle) Overview of the different fields used for data entry. Right) Example of data entry for a clinical vignette.

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