RESEARCH ARTICLE

Comparing the usability of the World Health Organization's conventional tuberculosis guidelines to the eTB recommendations map: A two-arm superiority randomised controlled trial

Micayla Matthews[1,2], **Tamara Lotfi**[1,2], **Nancy Santesso**[1,2], **Mark Loeb**[1,2], **Dominik Mertz**[1,3], **Zain Chagla**[1,3], **Anisa Hajizadeh**[1,4], **Thomas Piggott**[1], **Bart Dietl**[5], **Holger J. Schünemann**[1,2,6]*

1 McMaster University Department of Health Research Methods, Evidence and Impact, Hamilton, Ontario, Canada, 2 McMaster University Michael G. DeGroote Cochrane Canada and GRADE Centre, Hamilton, Ontario, Canada, 3 Department of Medicine, McMaster University, Hamilton, Ontario, Canada, 4 Department of Primary Care, Oxford University, Oxford, United Kingdom, 5 Evidence Prime Incorporated, Hamilton, Ontario, Canada, 6 Department of Biomedical Sciences, Humanitas University, Milano, Italy

* schuneh@mcmaster.ca

Abstract

Best practices for the dissemination of global health guidelines has not undergone rigorous research. We used a new approach to digitizing World Health Organization (WHO) global tuberculosis guideline recommendations (eTB RecMap) and compared its usability to the conventional method of accessing TB recommendations using the WHO website. We conducted a two-arm superiority randomised controlled trial using a survey among global stakeholders who were past or planned future users of TB guidelines, recommendations, or policy advice. We assigned participants randomly (1:1) to complete an activity using the WHO eTB RecMap or the conventional website. The primary outcome was the accessibility of information and secondary outcomes understanding, satisfaction, and preference for one of the two formats. Between February 26 and August 29, 2021, we received 478 responses from stakeholders, of whom 244 (122 per group) were eligible and provided analysable results. Participants rated the eTB RecMap as more accessible, on average, when compared to the conventional website (on a seven-point scale, the mean difference {MD} was 0.9; 95% confidence interval {CI}: 0.6, 1.2; p < 0.001) and were more likely to correctly answer understanding questions. This is the first trial comparing digitized dissemination formats of health guideline recommendations. Stakeholders rated the WHO eTB RecMap as more accessible than the conventional WHO website for the tested recommendations. They also understood presented information better. The findings support better usability of TB information through the eTB RecMap and contribute to the effort to end the TB epidemic.

Trial registration: This trial was registered with ClinicalTrials.gov (NCT04745897) on February 9, 2021.

Introduction

Tuberculosis (TB) is the leading cause of death from a single infectious agent worldwide, with an estimated 10 million new cases in 2019 [1]. In a concerted effort to end the TB epidemic, the WHO Global TB Programme (WHO-GTB) has issued guidelines with recommendations on TB prevention, diagnosis, treatment, and care [2,3]. Since 2009, these guidelines have been developed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) method [3], which is a transparent, evidence-based framework for the assessment of the certainty in a body of evidence and recommendation development [4]. Specifically, GRADE assists guideline developers in question prioritization, certainty assessments, balancing benefits and risks, and considering, among other criteria, cost, equity, acceptability, and feasibility in context [4,5].

WHO TB recommendations were located in many discrete publications on the WHO website, including standard, consolidated, interim, and emergency guidelines. Given the potential challenges of navigating through guidelines to find a recommendation, ways to enhance their connectivity and accessibility should be explored like for guidelines in other fields. A mixed-methods study by Hajizadeh, et al. [6] suggested that stakeholders, including members of the WHO-GTB guideline development group (GDG), desire direct access to WHO TB recommendations and supplementary information, such as evidence to decision (EtD) tables and evidence profiles [6].

In an effort to improve usability of WHO TB recommendations, we developed the WHO eTB recommendation map (RecMap) in a collaboration between the WHO Collaborating Center for Infectious Diseases, Research Methods and Recommendations, the Michael G DeGroote Cochrane Canada Centre and the WHO-GTB Programme [6,7]. The RecMap identifies, lists, and maps WHO TB recommendations using recommendation mapping methodology. This methodology builds on the field of evidence mapping by visually organizing recommendations, thus allowing the identification of clusters and gaps [6]. Furthermore, it is anticipated to facilitate the adoption, adaptation, or de novo development of recommendations in a variety of countries and settings through an integrated linkage and access to original content on GRADEpro [8]. The approach has been used, but not tested formally, in other efforts including the eCOVID-19 RecMap to enhance access to all guidelines in general (covid19.recmap.org) and for WHO specifically (who.covid19.recomap.org).

To evaluate if organising recommendations in a recommendation map improves usability, we conducted a randomised controlled trial in users of TB recommendations to evaluate the impact of the new WHO eTB RecMap compared with the conventional method of accessing TB recommendations on accessibility, understanding and satisfaction with the new format.

Methods

Study design

This study was a two-arm randomised controlled superiority trial to compare the accessibility of the WHO eTB RecMap (WHO eTB) to the conventional method of accessing TB recommendations through the WHO publications website (WHO TB). A questionnaire was administered using SurveyMonkey (Momentive Inc., California), accessible through a link shared via email. Participants responded to demographic questions and were subsequently randomised using 1:1 allocation to access a recommendation using either WHO eTB or WHO TB (platforms). Participants completed Likert-scale and multiple-choice questions about the platform they were allocated to. After completing the key portion of the trial, they received information about the alternative platform to respond to a question on their preference.

This study was approved by the Hamilton Integrated Research Ethics Board, Hamilton, ON, Canada (7908). No data safety monitoring committee was used. This trial was registered with ClinicalTrials.gov (NCT04745897). The protocol is available in the supporting information (S1 File).

Participants

Stakeholders who considered themselves to be users or potential users of TB guidelines, recommendations, and policy advice were eligible. We defined a user as someone who responded "yes" to the question "have you ever accessed TB guidelines, recommendations or policy advice in the past?". A potential user was someone who responded "yes" to the question "do you plan on accessing TB guidelines, recommendations or policy advice in the future?". Eligible participants could be part of any group with a stake in TB, including the public, healthcare providers, policymakers, and researchers, and there were no restrictions on country of origin, level of education, or prior TB work experience. Individuals who were involved in WHO eTB development were not eligible, and thus were not invited to participate.

We used a targeted snowball recruitment strategy by emailing survey links to WHO TB Guideline Development Group (GDG) members, program managers, and other stakeholders involved in the process of using and applying TB guideline recommendations. We requested that these members disseminate the survey within their networks, which may have included healthcare providers, policymakers, researchers, and people living with TB (S2 File). Furthermore, we shared the survey link with TB, infectious disease, and guideline groups on Twitter and LinkedIn. Participants gave written informed consent upon entry to the survey.

Randomisation and masking

Participant response to a question on their role as a participant in this study was used for stratification into one of four categories described in Fig 1. Participants within each of these categories were randomly assigned in a 1:1 ratio to the WHO eTB or WHO TB arms. Participants were also randomly assigned to access one of two recommendations in a 1:1 ratio. The same two recommendations were presented for both arms and selected because they contain mostly plain language and were more accessible to non-clinical participants.
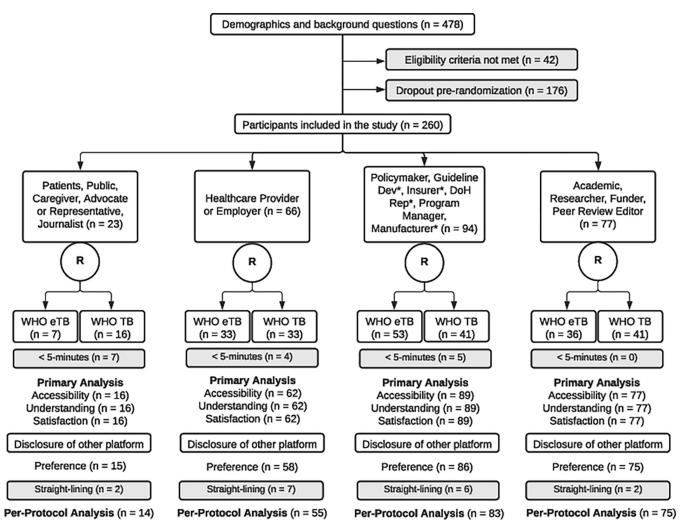
The allocation sequence was concealed using SurveyMonkey software based on a commercial, but unknown algorithm without a pre-identified sequence. Participants were not aware of their random allocation to WHO eTB or WHO TB until disclosure (Fig 1). Thus, participants in the control arm were blinded to the eTB RecMap for all outcomes except the secondary outcome of preference. Neutral language was used in both trial arms to prevent promotion of the intervention or comparison.

Procedures

In this randomised controlled superiority trial, the intervention was the new WHO eTB RecMap (WHO eTB), and the comparison was the conventional method of accessing TB recommendations using the WHO website (WHO TB). We asked survey participants to complete an activity in searching for the same recommendation using the one platform which they had been randomly allocated. Instructions and questions for both arms were worded as similarly as possible. See Table 1 for an overview of the differences between WHO eTB and WHO TB.

Outcomes

This trial used several of the outcomes that have been validated in the evaluation of GRADE Summary of Findings (SoF) tables [9–12]. The primary outcome was the accessibility of

Fig 1. This figure shows the flow of participants through the study. The following abbreviations are included: Guide Dev: Guideline developer; Insurer: Insurer of health services; DoH Rep: Department of health representative; Manufacturer: Drug or device manufacturer.

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Table 1. Description of differences between WHO TB and WHO eTB.

	WHO TB	WHO eTB
Website	WHO website	WHO eTB website
Search	PDF documents	Search bar and filters
Strength and certainty of evidence defining the recommendation	Often near recommendation with varying presentation	Always near recommendation presented with consistent language and symbols
EtD tables presenting evidence underpinning the recommendation	Found in a separate appendix	Found on the same page with a direct link to the appendix
Recommendation mapping	No	Yes

Abbreviations: WHO TB, accessing World Health Organization tuberculosis recommendations via the World Health Organization's website; eTB, the new eTB recommendations map; PDF, portable document format; EtD, evidence to decision tables.

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information available on the WHO eTB compared to WHO TB. We defined accessibility as the ability to access and use the presented information. This outcome considered the four following domains: (1) how easy it was to find the information (2) how easy it was to understand the information (3) whether the presentation facilitated decision-making (4) whether the website was easy to navigate. We used the original Likert-scale to obtain responses. We used the composite of these four outcomes as primary outcome, and the individual domains were also analyzed as secondary outcomes.

Secondary outcomes were understanding, satisfaction, and preference. We defined understanding as the correct comprehension of findings. This outcome was measured using three multiple-choice questions with five choices and one correct answer. The questions were: 'what is the recommendation strength?', 'what is the certainty of the evidence?' and 'on which page does the EtD table for this recommendation start?'. We defined satisfaction as a stakeholder's impression of platform presentation. This outcome considered the presentation of three domains: (1) home page (2) recommendation list (3) individual recommendation. We used the original Likert-scale to obtain responses. We defined preference as a greater liking of one platform over the other. All participants were provided with a short demonstration of both platforms. They were subsequently asked 'between the WHO Tuberculosis Guidelines (current website), and the WHO eTB Guidelines (alternative website), which do you prefer?'. We measured preference using a Likert-type scale to express the degree of preference with seven answer options (1 = strongly prefer WHO TB, 2 = prefer WHO TB, 3 = somewhat prefer WHO TB, 4 = same preference for WHO TB and eTB, 5 = somewhat prefer WHO eTB, 6 = prefer WHO eTB, 7 = strongly prefer WHO eTB).

Statistical analysis

For this two-sided ($\alpha = 0.05$) superiority analysis, sample size was calculated using the primary outcome of accessibility in WINPEPI (PEPI-for-Windows) version 11.65. With a sample size of 122 per arm (244 total) we would achieve 80% power to detect a difference on the Likert-scale of 0.5 with a standard deviation of 1.0 between intervention and control groups, generally considered an important change on the seven-point Likert scale and observed in previous studies measuring on GRADE SoF tables [9–13]. We assumed that 15% of those starting would not complete the survey, but we did not factor stratifying participants by stakeholder group into the calculation, as the aim of stratification was to balance participants rather than be sufficiently powered to detect subgroup effects.

We summarized participant baseline characteristics and outcomes using means and standard deviations (SD) for continuous variables, and proportions for categorical variables. We performed a primary analysis including all randomised participants, except for those who completed the survey in less than five minutes. We determined this cut-off a priori as part of the protocol because user testing determined that it would be impossible to comprehend and complete the work in that time. We conducted a second per-protocol analysis excluding participants who were flagged by pre-defined but unknown SurveyMonkey software for poor-quality responses known as straight-lining. Straight-lining is defined by SurveyMonkey as responses to questions with the same answer option or pattern. Participants flagged for straight-lining, as well as those who spent less than five minutes on the survey, were removed from the per-protocol analysis.

For the outcomes of accessibility and satisfaction, we used t-tests and mean differences 95% confidence intervals (95% CIs) to compare means and standard deviations (SDs) between the intervention and control groups. For the outcome of understanding, we used χ^2 tests and risk difference (RD) with 95% CIs to compare the proportion of correct responses between groups.

For preference, we presented preference as mean (SD) overall and for both trial arms. Skewness, Shapiro-Wilk tests, and histograms were used to evaluate whether the distribution was shifted toward the same preference in both groups. Levene's test of equal variances was used for all t-tests and degrees of freedom were adjusted for p < 0.05. We conducted the analyses using IBM SPSS (Statistical Package for Social Sciences) version 23.

We performed a pre-planned interim analysis with data collected between February 26 and March 24, 2021, based on the thesis defence date of the first author (MM). The interim analysis was not intended or used to stop the study or draw final conclusions (S3 File).

Results

Between February 26 and August 29, 2021, 478 participants enrolled in the study. Of these, 176 dropped out prior to randomisation and 42 did not satisfy the eligibility criteria. A total of 260 participants were randomised. Of these, 16 were removed for less than five-minute completion time, leaving 244 for the primary analysis. In this sample, 48% (117/244) were female, 91% (223/244) were between the ages of 26 and 65, 63% (153/244) worked or lived in a low-and-middle-income country (LMIC), 26% (63/244) in a high-income country (HIC), and 11% (26/244) in both. Most participants (79%; 193/244) held a professional or graduate degree, and at least three years (77%; 189/244) of TB-related work experience. Most participants also considered themselves to be comfortable (26%; 64/244) or very comfortable (56%; 136/244) with basic information and communication technologies. Participant strata comprised of 7% (16/244) in the patient group, 25% (62/244) in the healthcare provider group, 36% (89/244) in the policy-maker group, and 32% (77/244) in the academic group. We found no differences in study outcomes between strata on stakeholder roles, so Table 2 describes non-stratified data per group.

Across four domains, participants assigned to the new WHO eTB RecMap rated the information as more accessible compared to the conventional WHO TB website (MD on the seven-point scale: 0·9; 95% CI: 0·6, 1·2; p < 0.001). The largest mean differences were observed for the statements "it was easy to find the information" (MD 1.1; 95% CI: 0.7, 1.5; p < 0.001) and "this website was easy to navigate" (MD 1.3; 95% CI: 0.9, 1.7; p < 0·001). Participants assigned to WHO eTB also stated that it was easier to understand the information (MD 0.6; 95% CI: 0.3, 0.9; p = 0.001) and that the information was presented in a way that would help them make a decision (MD 0.7; 95% CI: 0.3, 1.0; p < 0.001, Table 3).

Participants assigned to the WHO eTB were more likely to correctly answer understanding questions: risk difference of 47% (95% CI 37, 57; p < 0.001, Table 4) for correct responses to the EtD question. There were also 20% differences (95% CI 8, 32) in correct responses to questions on recommendations strength (p = 0.002) and certainty of evidence (p = 0.001).

Participants assigned to WHO eTB were more satisfied with the presentation of the home page (MD 1.0; 95% CI: 0.7, 1.4; p < 0.001, Table 5) and individual recommendations page (MD 0.3; 95% CI: 0.002, 0.6; p = 0.048) compared to WHO TB. We observed that participants assigned to WHO eTB also appeared more satisfied with the list of recommendations page, but the difference was smaller than for the other outcomes (MD 0.2; 95% CI: -0.1, 0.5; p = 0.214).

Overall, participants (n = 234) "somewhat preferred WHO eTB" (4.8; SD 1.8), after reviewing demonstrations of both platforms. This preference was stronger in participants who were assigned to first review the WHO eTB (5.0; SD 1.6) compared to those who first reviewed the WHO TB (4.5; SD 2.0) (p = 0.044) platform. Both arms were left-skewed toward this preference (p < 0.001).

There were no differences between the primary and per-protocol analyses that excluded participants suspected of straight lining (responses to questions with the same answer option or pattern) (n = 227) (S3 File).

Table 2. Baseline characteristics of participants per group.

	WHO eTB (n = 122)	WHO TB (n = 122)
Gender: n (%)		
Female	58 (47)	59 (48)
Male	63 (52)	60 (49)
Other	-	1 (1)
Prefer not to respond	1 (1)	2 (2)
Age (years): n (%)		
< 25	3 (3)	7 (6)
26–35	41 (34)	29 (24)
36–45	37 (30)	37 (30)
46–55	25 (20)	29 (24)
56–65	10 (8)	15 (12)
66–75	4 (3)	5 (4)
Prefer not to respond	2 (2)	-
Setting: n (%)		
HIC	29 (24)	34 (28)
LMIC	76 (62)	77 (63)
HIC and LMIC	16 (13)	10 (8)
Prefer not to respond	1 (1)	1 (1)
Education: n (%)		
Primary	-	1 (1)
High school	-	2 (2)
College	2 (2)	6 (5)
Bachelor	18 (15)	21 (17)
Professional	18 (15)	27 (22)
Graduate	50 (40)	38 (31)
Professional and graduate	33 (27)	27 (22)
Prefer not to respond	1 (1)	-
TB work (years): n (%)		
< 1	6 (5)	12 (10)
1–2	14 (12)	8 (7)
3–5	20 (16)	16 (13)
6–9	17 (14)	12 (10)
> 10	59 (48)	65 (53)
Not applicable	4 (3)	5 (4)
Prefer not to respond	2 (2)	4 (3)

Abbreviations: WHO, World Health Organization; TB, Tuberculosis; HIC, high income country; LMIC, low- and middle-income country.

Discussion

The primary aim of this RCT was to determine if the WHO eTB RecMap [6,7] improved the usability of WHO TB recommendations for stakeholders of interest. Participants represented a diverse group of users and potential users of TB recommendations. Our results suggest that the WHO eTB RecMap improves the usability of these recommendations for stakeholders when compared to the conventional method. Specifically, participants found, on average, that the information presented in WHO eTB was easier to find, easier to understand, that it was

Table 3. Overall accessibility of information [mean (SD)].

	WHO eTB[a] (n = 122)	WHO TB[a] (n = 122)	MD (95% CI)[b] p value
Overall Accessibility[c]	**5.6 (1.0)**	**4.7 (1.5)**	**0.9 (0.6, 1.2)** < 0.001
It was easy to find the information	5.6 (1.1)	4.4 (1.9)	1.1 (0.7, 1.5) < 0.001
This website was easy to navigate	5.6 (1.2)	4.3 (1.8)	1.3 (0.9, 1.7) < 0.001
It was easy to understand the information	5.6 (1.0)	5.0 (1.6)	0.6 (0.3, 0.9) 0.001
The information was presented in a way that would help me make a decision	5.7 (1.0)	5.0 (1.5)	0.7 (0.3, 1.0) < 0.001

Abbreviations: SD, standard deviation; WHO, World Health Organization; TB, tuberculosis; MD, mean difference; CI, confidence interval.

[a] Likert-scale from 1 = strongly disagree to 7 = strongly agree.

[b] Equal variances could not be assumed using Levene's test, degrees of freedom adjusted.

[c] Composite of four domains (primary outcome).

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presented in a way that would help them make a decision, and that the website was easier to navigate. We sought to corroborate accessibility with the secondary outcome of understanding, and we found that the eTB RecMap improved the ability of participants to identify recommendation strength and certainty, and to access the supporting evidence and decisions underpinning the recommendation (EtD). Furthermore, stakeholders were more satisfied with the presentation of the WHO eTB home page and presentation of individual recommendations, although the effects were small. Overall, participants somewhat preferred the eTB RecMap to the conventional WHO TB website.

To our knowledge, this is the first RCT comparing stakeholder feedback on the presentation of two guideline platforms. However, several studies have explored stakeholder perceptions of guideline development and presentation, as well as the factors that influence their uptake. One qualitative study by Fearns, et al. [14] explored public perceptions of clinical practice guidelines and found that participants desired information to help them make decisions, but current numerical formats may not always be accessible to a public audience. Additionally, a content analysis by Santesso, et al. [15] found that patient versions of guidelines may not always address stakeholder needs, as they rarely include important EtD information, such as beliefs, values and preferences, accessibility, costs and feasibility. Furthermore, a realist review by Kastiner, et al. [16] which sought to identify the factors associated with guideline uptake,

Table 4. Percentage # (%) of participants who responded correctly to understanding questions.

	WHO eTB (n = 122)	WHO TB (n = 122)	Risk Difference (95% CI) p value[a]
On which page does the evidence to decision (EtD) table for this recommendation start?	66/122 (54)	9/122 (7)	47 (37, 57) < 0.001
What is the recommendation strength?	88/122 (72)	64/122 (52)	20 (8, 32) 0.002
What is the certainty of evidence?	66/122 (54)	41/122 (34)	20 (8, 32) 0.001

[a] Pearson's chi-square.

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Table 5. Satisfaction with the presentation of platform pages [mean (SD)].

	WHO eTB[a] (n = 122)	WHO TB[a] (n = 122)	MD (95% CI) p value
Home page	5.6 (1.1)	4.6 (1.8)	1.0 (0.7, 1.4)[b] < 0.001
Individual recommendation	5.6 (1.1)	5.3 (1.3)	0.3 (0.002, 0.6) 0.048
List of recommendations	5.5 (1.1)	5.3 (1.3)	0.2 (-0.1, 0.5)[b] 0.214

Abbreviations: SD, standard deviation; WHO, World Health Organization; TB, tuberculosis; MD, mean difference; SE, standard error.

[a] Likert-scale from 1 = very dissatisfied to 7 = very satisfied.

[b] Equal variances could not be assumed using Levene's test, degrees of freedom adjusted.

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found that effective communication of content, including simple, clear and persuasive language, improved the implementability of guidelines by stakeholders.

This trial expands on the methods of previous RCTs used to evaluate the presentation of guideline information, specifically, comparing new GRADE SoF tables to conventional formats. These studies also evaluated the outcomes of participant understanding, accessibility, satisfaction and preference [9,11,12]. Akl, et al. [17] found that participants demonstrated a better understanding of strength of recommendations and quality of evidence when this information was presented as symbols, rather than numbers. Carrasco-Labra, et al. [9] and Vandvik, et al. [12] identified that stakeholders preferred the presentation of risk differences over absolute risk estimates, as well as the inclusion of narrative statements to supplement numerical data. Similar, to our trial, these studies objectively evaluated perceptions of new to conventional formats to identify areas of improvement.

This study had several strengths. First, we used a randomised design reported in accordance with the CONSORT statement on randomised trials, which reduces the risk of confounding, selection and reporting bias (S1 Table) [18,19]. Second, we used several previously validated outcomes from similar trials [9–12]. Third, we gathered feedback from diverse group of stakeholders, thus improving the generalizability of findings using a carefully developed approach to presenting recommendations [6]. Nevertheless, the snowball recruitment strategy through established guideline networks may limit the generalizability in potential users. This study has some additional limitations. First, the ability to blind participants was limited, as some may have been aware of eTB development. We consider this probability to be small, as the main publication and awareness campaigns began after the majority of participants had been recruited. Our pre-planned a priori interim analysis that coincided with publication of the eTB platform did not suggest differences in the results before and after these campaigns (S3 File). Second, data were collected using an online survey and, thus, there was limited control over the environment in which the survey was performed. Third, participants often claimed to be part of more than one stakeholder group (e.g., a healthcare provider involved in research), but they were required to select just one for stratification. Fourth, we did not power our trial to conclusively evaluate results by participant strata. Fifth, some of the secondary outcomes showed mean effects that were below the minimal important difference (MID) although the CI of the effects crossed the MID. Despite these small effects, a proportion of users would still experience benefit from the eTB platform presentation related to these secondary outcomes [20]. Furthermore, to improve the presentation on the eTB platform, we have made additional changes to the final presentation on the eTB RecMap and our new eCOVID RecMap that catalogues recommendations related to COVID-19 guidelines [21].

Tuberculosis guideline recommendations developed by the WHO assist stakeholders in making evidence-informed decisions on TB prevention, diagnosis, treatment, and care [2,3]. According to the Guidelines International Network (G-I-N) and the National Institute for Health and Care Excellence (NICE), stakeholder engagement is important to ensuring that guideline products are feasible and acceptable to end-users [22,23]. This study engaged stakeholders in evaluating the presentation of recommendations through the outcomes of accessibility, understanding, and satisfaction, which are surrogates for the correct implementation of evidence in practice. Thus, our findings suggest that the new WHO eTB RecMap will help stakeholders make evidence-informed decisions on TB in support of the WHO End TB strategy [2]. This study demonstrates that RCTs may be used to compare stakeholder feedback on guideline platforms. Future studies should seek to explain the findings of this trial through qualitative and user testing techniques, such as the study by Rosenbaum, et al. for SoF tables [10]. Furthermore, additional trials should focus on specific stakeholder groups, such as patients and the public, to determine optimal ways to present recommendations. There are three trials underway that test the use of plain language recommendations presented as part of a recommendation map for COVID-19 (https://clinicaltrials.gov/ct2/show/NCT05358990).

In conclusion, the new WHO eTB RecMap [6,7] improved the usability of WHO TB recommendations and supporting evidence for stakeholders of interest. Our findings support the continued use, promotion, and quality improvement of WHO eTB. Researchers should consider the use of RCTs to evaluate stakeholder feedback on guideline presentation in the future. The RecMap approach has been used for COVID-19 (covid19.recmap.org and who.covid19.recmap.org) and is being implemented by the PanAmerican Health Organization across all guidelines that use the GRADE approach (https://bigg-rec.bvsalud.org/en). This trial provides some evidence that this may be a wise decision.

Supporting information

S1 Table. CONSORT checklist.
(PDF)

S1 File. Trial protocol.
(PDF)

S2 File. Consent, survey, and recruitment details.
(PDF)

S3 File. Interim and per-protocol analysis details.
(PDF)

Acknowledgments

Author Contributions

Conceptualization: Micayla Matthews, Tamara Lotfi, Nancy Santesso, Mark Loeb, Dominik Mertz, Holger J. Schünemann.

Formal analysis: Micayla Matthews, Tamara Lotfi.

Investigation: Thomas Piggott, Holger J. Schünemann.

Methodology: Micayla Matthews, Tamara Lotfi, Nancy Santesso, Mark Loeb, Dominik Mertz, Zain Chagla, Anisa Hajizadeh, Bart Dietl, Holger J. Schünemann.

Resources: Tamara Lotfi, Thomas Piggott, Holger J. Schünemann.

Software: Tamara Lotfi, Anisa Hajizadeh, Bart Dietl, Holger J. Schünemann.

Supervision: Nancy Santesso, Mark Loeb, Dominik Mertz, Zain Chagla, Holger J. Schünemann.

Validation: Holger J. Schünemann.

Visualization: Bart Dietl.

Writing – original draft: Micayla Matthews.

Writing – review & editing: Micayla Matthews, Tamara Lotfi, Nancy Santesso, Mark Loeb, Dominik Mertz, Zain Chagla, Anisa Hajizadeh, Thomas Piggott, Bart Dietl, Holger J. Schünemann.

References

1. World Health Organization. Global Tuberculosis Report 2020. 2020. Available from: https://www.who.int/publications/i/item/9789240013131.

2. World Health Organization. WHO End TB Strategy. 2015. Available from: https://www.who.int/teams/global-tuberculosis-programme/the-end-tb-strategy.

3. Falzon D, Schünemann HJ, Harausz E, González-Angulo L, Lienhardt C, Jaramillo E, et al. World Health Organization treatment guidelines for drug-resistant tuberculosis, 2016 update. Eur Respir J. 2017; 49(3): 1602308. https://doi.org/10.1183/13993003.02308-2016 PMID: 28331043

4. Moberg J, Oxman AD, Rosenbaum S, Schünemann HJ, Guyatt G, Flottorp, S, et al. The GRADE Evidence to Decision (EtD) framework for health system and public health decisions. Health Res Policy Syst. 2018; 16(1): 45. https://doi.org/10.1186/s12961-018-0320-2 PMID: 29843743

5. Alonso-Coello P, Oxman AD, Moberg J, Brignardello-Petersen R, Akl EA, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 2: Clinical practice guidelines. BMJ. 2016; 353: i2089 https://doi.org/10.1136/bmj.i2089 PMID: 27365494

6. Hajizadeh A, Lotfi T, Falzon D, Mertz D, Nieuwlaat R, Gebreselassie N, et al. Recommendation mapping of the World Health Organization's guidelines on tuberculosis: A new approach to digitizing and presenting recommendations. J Clin Epidemiol. 2021; 134: 138–149. https://doi.org/10.1016/j.jclinepi.2021.02.009 PMID: 33762142

7. World Health Organization. eTB Guidelines: Database of recommendations for TB prevention and care. Available from: https://tuberculosis.evidenceprime.com/.

8. Schünemann HJ, Wiercioch W, Brozek J, Etxeandia-Ikobaltzeta I, Mustafa RA, Manja V, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol. 2017; 81: 101–110. https://doi.org/10.1016/j.jclinepi.2016.09.009 PMID: 27713072

9. Carrasco-Labra A, Brignardello-Petersen R, Santesso N, Neumann I, Mustafa RA, Mbuagbaw L, et al. Comparison between the standard and a new alternative format of the Summary-of-Findings tables in Cochrane review users: study protocol for a randomized controlled trial. Trials. 2015; 16(1): 164. https://doi.org/10.1186/s13063-015-0649-6 PMID: 25873338

10. Rosenbaum SE, Glenton C, Nylund HK, Oxman AD. User testing and stakeholder feedback contributed to the development of understandable and useful Summary of Findings tables for Cochrane reviews. J Clin Epidemiol. 2010; 63(6): 607–19. https://doi.org/10.1016/j.jclinepi.2009.12.013 PMID: 20434023

11. Yepes-Nuñez JJ, Morgan RL, Mbuagbaw L, Carrasco-Labra A, Chang S, Hempel S, et al. Two alternatives versus the standard Grading of Recommendations Assessment, Development and Evaluation (GRADE) summary of findings (SoF) tables to improve understanding in the presentation of systematic review results: a three-arm, randomised, controlled, non-inferiority trial. BMJ Open. 2018; 8(1): e015623. https://doi.org/10.1136/bmjopen-2016-015623 PMID: 29362242

12. Vandvik PO, Santesso N, Akl EA, You J, Mulla S, Spencer FA, et al. Formatting modifications in GRADE evidence profiles improved guideline panelists comprehension and accessibility to information. A randomized trial. J Clin Epidemiol. 2012; 65(7): 748–55. https://doi.org/10.1016/j.jclinepi.2011.11.013 PMID: 22564503

13. Streiner DL, Norman GR. Health measurement scales: A practical guide to their development and use. Third edition. Oxford (UK): Oxford University Press; 2003. p. 209.

14. Fearns N, Kelly J, Callaghan M, Graham K, Loudon K, Harbour R, et al. What do patients and the public know about clinical practice guidelines and what do they want from them? A qualitative study. BMC Health Serv Res. 2016; 16(74). https://doi.org/10.1186/s12913-016-1319-4 PMID: 27121606

15. Santesso N, Morgano GP, Jack SM, et al. Dissemination of Clinical Practice Guidelines: A Content Analysis of Patient Versions. Med Decis Mak Int J Soc Med Decis Mak. 2016; 36(6): 692–702. https://doi.org/10.1177/0272989X16644427 PMID: 27091380

16. Kastner M, Bhattacharyya O, Hayden L, Makarski J, Estey E, Durocher L, et al. Guideline uptake is influenced by six implementability domains for creating and communicating guidelines: a realist review. J Clin Epidemiol. 2015; 68(5): 498–509. https://doi.org/10.1016/j.jclinepi.2014.12.013 PMID: 25684154

17. Akl EA, Maroun N, Guyatt G, Oxman, AD, Alonso-Coello P, Vist GE, et al. Symbols were superior to numbers for presenting strength of recommendations to health care consumers: a randomized trial. J Clin Epidemiol. 2007; 60(12): 1298–1305. https://doi.org/10.1016/j.jclinepi.2007.03.011 PMID: 17998085

18. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2010; 340: c869. https://doi.org/10.1136/bmj.c869 PMID: 20332511

19. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. Lancet. 2008; 371(9609); 281–3. https://doi.org/10.1016/S0140-6736(07)61835-2 PMID: 18221781

20. Schünemann HJ, Akl EA, Guyatt GH. Interpreting the results of patient reported outcome measures in clinical trials: The clinician's perspective. Health Qual Life Outcomes. 2006; 4(62). https://doi.org/10.1186/1477-7525-4-62 PMID: 16973000

21. Lotfi T, Stevens A, Akl EA, Falavigna M, Kredo T, Mathew JL, et al. Getting trustworthy guidelines into the hands of decision-makers and supporting their consideration of contextual factors for implementation globally: recommendation mapping of COVID-19 guidelines. J Clin Epidemiol. 2021; 135:182–186. https://doi.org/10.1016/j.jclinepi.2021.03.034 PMID: 33836255

22. Guidelines International Network. G-I-N PUBLIC Toolkit: Patient and Public Involvement in Guidelines —Guidelines International Network. Available from: https://g-i-n.net/working-groups/gin-public/toolkit.

23. Jarrett L, Patient Involvement Unit (PIU). A report on a study to evaluate patient/carer membership of the first NICE Guideline Development Groups. National Institute for Health and Care Excellence (NICE) 2004. Available from: https://www.nice.org.uk/media/default/About/NICE-Communities/Public-involvement/Public-involvement-programme/PIU-GDG-evaluation-report-2004-1.pdf.