



# People first: a participatory community approach on patient-reported outcomes in tuberculosis

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By prioritising patient-reported outcomes and involving the TB community, TB care can be transformed into a person-centred experience. This paves the way for a more comprehensive and effective approach, benefiting those impacted by the disease. <https://bit.ly/3S6HJ4m>

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## Abstract

Patient-reported outcomes (PROs) play a crucial role in understanding the impact of tuberculosis (TB) on both individuals and communities. Despite advances in TB treatment, conventional outcome definitions often overlook essential components of people with TB's experiences, leading to disparities in treatment understanding. The incorporation of PROs in TB scientific research can help bridge the gap between the health system and people's needs and expectations. PROs can offer valuable insights into non-observable constructs like health literacy, self-efficacy and overall wellbeing, contributing to the comprehensive assessment of diagnosis, treatment and research end-points. Participatory community approaches, such as Community-Based Participatory, emphasise the engagement and involvement of relevant stakeholders in designing interventions tailored to their needs. Key stakeholders, including healthcare professionals, researchers, clinical trial investigators, public health officials, and community health workers, TB survivors and people with TB, can play a vital role in promoting patient-centred care and engaging directly with the TB-affected community. An increased and cross-collaborative effort for the inclusion of PROs in TB research can entail their potential role in developing effective treatment regimens and promoting adherence, while maximising community engagement and improving outcomes for those affected by TB.

## Introduction

Tuberculosis (TB) is a leading cause of morbidity in many regions. As such, understanding its effect on quality of life and health status is essential for patient care, evaluation of novel treatments or development of preventive strategies, and health policy [1]. Although it has been effectively treated for many years, and progress has been made in prevention and care, it still represents a global health problem for which the conditions and outcomes valued by the TB community need to be better understood [2]. Identifying patient-reported outcomes (PROs) reported by people affected by TB can provide a wealth of information about the impact of the disease. Overall, conventionally used outcome definitions seem to miss crucial components of people with or affected by TB's treatment experiences and conceal significant disparities between people undergoing treatment [3].

PROs in clinical practice have become increasingly common in recent years. PROs are "... any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else." [4]. Since PROs are subjective, they can provide information about non-observable constructs such as health literacy, self-efficacy, and general health and wellbeing [5]. PROs describe the broad scope of patients' experience with their disease, which can go undetected by healthcare professionals and caregivers [6]. Their utility extends beyond information about patients and healthcare professionals. It can also be employed in assessing diagnosis, treatment, follow-up,



therapeutic outcomes and research end-points. Additionally, it evaluates cost-effectiveness and fills a crucial gap in defining a favourable outcome by capturing the aspects of quality of life that are significant to patients. These aspects often drive individuals to seek healthcare services [7, 8].

Many studies highlight the use of PROs to provide direct patient evidence of the benefits of treatment, as they measure valuable insights into the impact of a disease or treatment on patients' quality of life, symptoms, functional status and overall wellbeing [9]. Relevant and accurate information on outcomes provided by PROs can help healthcare professionals and researchers understand the entire burden of these diseases and guide treatment decisions [10]. In a study on symptomatic HIV infection, patient-reported symptoms showed higher reliability and they were more strongly associated with health-related quality of life than symptoms reported by healthcare providers [11]. This evidence demonstrates how PROs can increase the clarity and accuracy of clinical assessment.

PROs may assist clinicians and future patients to select the best treatment by providing a clearer picture of the costs and benefits of treatment and enrich our understanding of patients' experience with unique information that could not be gained from biomedical outcomes alone, as certain domains are difficult to observe (*e.g.* pain and fatigue) [12]. As a treatment evaluation tool, PROs consider different aspects simultaneously, such as symptoms, disability, health status, quality of life, utility and stigma associated with the disease [13]. Although it is known that PROs reported by people affected by a disease can provide a wealth of information about the impact of the disease on their health and wellbeing, there is no study evaluating PROs in TB-affected communities. In this context, PROs can provide additional information to improve clinical care and outcomes for people with TB as a tool with the potential to bridge the gap between the expectations of healthcare systems and the preferences and perceived needs of people with TB [14].

Approaching PROs for people with TB may enhance their quality of life. Efforts can be made to systematically address and prioritise the side-effects associated with treatments, leading to more effective interventions [15]. This approach can minimise non-adherence to TB treatment regimens by proactively managing and alleviating the impact of potential adverse outcomes that are reported by people with TB and by promoting health-related quality of life outcomes [16]. In this sense, identifying people affected by TB's reported outcomes (PROs) can provide a wealth of information about the impact of the disease. The assessment of these reported outcomes in TB may lead to an approach that encompasses and considers different key dimensions and factors that influence treatment outcomes positively.

Understanding these dimensions and factors, such as physical and psychological health, economic consequences, the patient–healthcare provider relationship, or the social impact that TB specifically has especially on the affected community, can provide a more complete understanding of the challenges faced by people with or affected by TB and develop targeted interventions to improve treatment outcomes and overall quality of life. This holistic approach recognises the interconnectedness of the physical, mental, social and economic factors that contribute to the wellbeing of individuals within the TB community.

### **Community-based participatory approaches for identifying TB community PROs**

A particular challenge in contemporary healthcare lies in delivering patient-centred care that not only respects but also responds to each person's unique preferences, needs and values during health decision making [17]. One of the three key pillars to eradicate the TB pandemic worldwide proposed by the World Health Organization (WHO) End TB Strategy is integrated patient-centred care [18]. This characteristic holds dual significance, being both intrinsically important – given that all people have the right to be treated with dignity and respect – and instrumentally important as person-centred care is associated with improved healthcare utilisation and health outcomes [19]. Although patient-centred care is at the forefront of the End TB Strategy, little is known about user (patient's) experience and patient satisfaction with TB services [20].

In light of this gap, the End TB Strategy advocates the adoption of interventions, techniques and medical approaches that not only are based on the lived experiences of the affected communities [21], as an interventional component of the clinical approach, but also foster cultural competence, tailor interventions to specific needs, build trust, improve communication, reduce disparities, promote cultural sensitivity, cobble together communities, and provide holistic care, all of which contribute to more effective and equitable healthcare delivery [22]. This goal can be achieved using community-based participatory (CBP) approaches, as it favours the involvement of affected communities at all stages of research or interventions, allowing them to co-create programmes and strategies directed at them [23]. Patient-centred outcome research is defined by the Patient-Centered Outcomes Research Institute as “research that addresses the

**TABLE 1** Responsibilities and involvement of each professional involved in tuberculosis (TB) prevention and care

Parties concerned	Responsibilities and involvement
Healthcare systems administrators and managers	Recognise and promote the importance of patients' perspectives in healthcare systems to ensure the delivery of high-quality and equitable services [24]
Healthcare researchers	Conduct studies on the impact of infectious diseases, like TB, on patients' quality of life, wellbeing, and overall health outcomes using PROs [9, 10]
Clinical trial investigators	Include PROs in clinical trials and routine care for infectious diseases and chronic conditions to understand the burden and effects of the diseases on patients' lives [10, 25]
Healthcare providers (doctors, nurses, etc.)	Use information from PROs to understand the entire burden of infectious diseases, guide treatment decisions and improve clinical care for patients [10, 11] Implement an integrated person-centred approach as proposed by WHO for effective health intervention, equity of access, responsiveness and preparedness of health services [26]
Public health officials and TB programme administrators	Recognise TB as a global health problem and advocate for the assessment of PROs in the TB-affected community to tailor patient-centred care [13, 14]
Community health workers and TB care providers	Play a crucial role in engaging the TB-affected community directly, collecting PRO data, and understanding the specific needs and concerns of TB patients for enhanced clinical treatment

PROs: patient-reported outcomes; WHO: World Health Organization.

questions and concerns most relevant to patients" ([www.pcori.org/about/about-pcori](http://www.pcori.org/about/about-pcori)). It has roots in both CBP research, which incorporates engagement with end-users of the research, and comparative effectiveness research, which focuses on identifying the best choice for individuals among several options.

CBP methodologies are a crucial component of quality healthcare and understanding the treatment priorities of TB-affected communities, while aiming to improve clinical care and providing services tailored to the specific needs and concerns of the individual and the TB-affected community. CBP approaches are essential in the creation of tools for measuring patient-centred care, seeing that people affected by the disease should be involved in their design to ensure that their experience is being accurately represented [19].

CBP approaches and techniques are also specially tailored for the assessment and implementation of PROs, given that both share a potential to transform the healthcare system and improve the quality of care by placing the patient at the epicentre of decision making [6]. In aiming to combat the lack of information regarding identification of PROs in the TB-affected community and improving patient-centred care, a collaborative approach is essential for each party involved in TB prevention and care (table 1).

### Strategies aided by PROs in TB management and care

Given the significance of identifying and measuring PROs (as illustrated in the preceding sections), it is clear how PROs could be useful in addressing current TB issues, particularly those pertaining to the development of new and more effective and tolerable treatment regimens that favour trial participants retention or strategies for promoting adherence to existing treatment regimens [27].

Regarding TB research and development, particularly TB drug development, WHO reported that 18 (64%) out of 28 drugs were new chemical entities among the drugs that were in phase I, phase II or phase III trials in 2023, representing an increase from 26% in 2022 and 8% in 2015 [28]. Additionally, WHO reported at least 29 clinical trials and implementation research studies intended to evaluate new drug regimens and models of delivery for TB preventive treatment [28].

PROs can be included in clinical trials and are increasingly recognised by regulators, clinicians and participants as valuable tools to collect patient-centred data [29]. In recent years, there has been increasing emphasis on including PROs in clinical trials and routine clinical care in various disease areas, such as chronic diseases like cancer and diabetes. For instance, a systematic review of PROs in cancer clinical trials found that patients valued outcomes related to symptom control, physical function and emotional wellbeing [25]. In the case of infectious diseases, their use in clinical trials is also expanding [10].

While there is a dearth of research on the use of PROs in TB clinical trials, what is known from other fields suggests that this could have implications on the development of drugs or regimens that consider the preferences, needs and experiences of end-users, in this case, people with TB. Given that prioritising research and quality improvement in healthcare involves a commitment to maximising patient engagement in treatment decisions and ensuring that care packages align with the needs and expectations of both patients and their households [29], PROs could be extremely useful in designing interventions to promote adherence to treatment [14, 16].

## Conclusion

In conclusion, we aim to shed light on the significance of PROs in delivering patient-centred care and emphasise the current dearth of research in the TB community regarding PROs. By engaging the TB-affected community directly, we can gain valuable insights into their priorities and needs, allowing us to enhance the clinical treatment process for individuals affected by TB. This collaborative effort can pave the way for a more comprehensive and patient-centric approach to TB care and ultimately improve outcomes for those impacted by this disease.

Conflict of interest: The authors have no conflicts of interest to declare. All co-authors have seen and agree with the manuscript's contents and there is no financial interest to report.

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