


A failure in solidarity: Ethical challenges in the development and implementation of new tuberculosis technologies

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Abstract

Prominent tuberculosis (TB) actors are invoking solidarity to motivate and justify collective action to address TB, including through intensified development and implementation (D&I) of technologies such as drugs and diagnostics. We characterize the ethical challenges associated with D&I of new TB technologies by drawing on stakeholder perspectives from 23 key informant interviews and we articulate the ethical implications of solidarity for TB technology D&I.

The fundamental ethical issue facing TB technological D&I is a failure within and beyond the TB community to stand in solidarity with persons with TB in addressing the complex sociopolitical contexts of technological D&I. The failure in solidarity relates to two further ethical challenges raised by respondents: skewed power dynamics that hinder D&I and uncertainties around weighing risks and benefits associated with new technologies. Respondents identified advocacy and participatory research practices as necessary to address such challenges and to motivate sustained collective action to accelerate toward TB elimination.

We present the first empirical examination of bioethical accounts of solidarity in public and global health. Our study suggests that solidarity allows us better to understand and address the ethical challenges that arrest the D&I of new TB technologies. Solidarity lends credence to policies and practices that address the relational nature of illness and health through collective action.

KEYWORDS

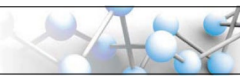
bedaquiline, delamanid, empirical bioethics, power, risks and benefits, solidarity, technology, tuberculosis

1 | INTRODUCTION

Tuberculosis (TB) has long been considered a 'disease of poverty'.¹ Social, political, and economic conditions associated with poverty

facilitate TB transmission and are associated with chronic underinvestment in the development and implementation (D&I) of innovative technologies (i.e., diagnostics, medicines, and vaccines). Responding in part to the lack of political will to address TB, the World Health Organization (WHO) introduced the End TB Strategy in 2015, with the goal of reducing the number of TB-related deaths by 95% by 2035. The End TB Strategy outlines several mechanisms to achieve

¹Degeling, C., Mayes, C., Lipworth, W., Kerridge, I., & Upshur, R. (2015). The political and ethical challenge of multi-drug resistant tuberculosis. *Journal of Bioethical Inquiry*, 12(1), 107–113.



this goal, including a call for 'intensified research and innovation'. Coupled with the efforts of other prominent international organizations, such as the Stop TB Partnership and the Global TB Caucus, there are indications that heads of states and ministers of health are finally paying heed. The Moscow Declaration to End TB, which was adopted at the WHO Global Ministerial Conference on Ending TB in November 2017, calls for a multisectoral response to TB in support of the End TB Strategy and United Nation's Sustainable Development Goals.² It will be followed by the first-ever United Nations General Assembly high-level meeting on TB in September 2018 with the aim of developing a Political Declaration on TB to secure commitments from heads of state to accelerate eradication efforts.³

Despite the advent of new antitubercular drugs and diagnostics for the first time in decades, access to essential treatments and care remains woefully inadequate in high-burden, low-income settings. If present conditions persist, the spread of drug-resistant TB is only expected to continue and ultimately undermine the End TB Strategy's aims.⁴ The D&I of new TB technologies raise many ethical issues, yet, there is little empirically informed understanding of them.

Prominent TB actors have begun appealing to solidarity to justify and motivate action for TB D&I, acknowledging that quelling the TB epidemic will require significant collective efforts globally.⁵ Indeed, the End TB Strategy was introduced with a resounding appeal for global solidarity by then-Director General of the WHO, Dr. Margaret Chan:

Everyone with TB should have access to the innovative tools and services they need for rapid diagnosis, treatment and care. This is a matter of social justice, fundamental to our goal of universal health coverage ... *I call for intensified global solidarity and action to ensure the success of this transformative End TB Strategy.*⁶

Despite being invoked as a guiding norm for TB reduction efforts, as well as in global health more generally,⁷ the exact meaning of solidarity remains unclear and its practical implications are poorly

understood with respect to TB. However, the meaning and role of solidarity has recently been subject to debate in bioethics.⁸ This discussion can be used to ensure that solidarity does not remain vague or underdetermined in discussions of TB policy.

The purpose of this article, then, is twofold: first, to describe the ethical challenges associated with D&I of new TB technologies by drawing on TB stakeholder perspectives and using solidarity as an explanatory concept, and second, to begin to articulate the ethical implications of solidarity for TB D&I. The overall conclusion is that properly developing and implementing new technologies for TB necessitates addressing the sociopolitical conditions that facilitate transmission and hinder eradication efforts. Justifying such interventions and understanding how they ought to occur requires, in part, understanding the role that solidarity plays in such arguments. We draw on two dominant bioethical accounts of solidarity, which articulate its meaning and moral significance in the context of health, to help conceptualize the ethical challenges facing TB D&I as identified by respondents.

We begin with a background on TB technology D&I followed by an outline of the theoretical accounts of solidarity that inform our analysis and interpretation of the stakeholder interviews. Then, we present the findings of our empirical investigation with an integrated conceptual discussion to address our dual objectives of developing a descriptive account and providing normative guidance with respect to the ethical challenges facing TB D&I.⁹

We note at the outset that participants never explicitly used the term 'solidarity'; instead, we interpreted their comments as being directly about solidarity, or the lack thereof, based on our understanding of ethical theory about solidarity, which we use for its explanatory power in our analysis. Similarly, despite there being two prominent articulations of solidarity in the recent bioethics literature (and despite one of the present authors, [Angus Dawson], being a co-author of one account), we remain agnostic, here, as to their relative merits; rather, we use them to interpret participant responses, which spoke to both accounts. Finally, the main aim of our paper is descriptive and any normative ethics arguments presented will be nascent in their articulations; a fully developed normative account of how solidarity may better inform TB D&I is beyond the scope of this paper.

2 | BACKGROUND

TB is an aerielly transmitted bacterial infection that caused an estimated 10.4 million incident active cases and 1.7 million deaths in 2016.¹⁰ Despite a longstanding understanding of its etiology, preventive measures, and available treatments, efforts to eradicate

²World Health Organization (WHO). (2017). *Moscow Declaration to End TB*. Available from: http://www.who.int/tb/features_archive/Moscow_Declaration_to_End_TB_final_ENGLISH.pdf [Accessed Dec 20, 2017].

³World Health Organization (WHO). (2018). *UN General Assembly High-Level Meeting on Ending TB*. Available from: http://www.who.int/tb/features_archive/UNGA_HLM_ending_TB/en/ [Accessed Feb 8, 2018].

⁴Mariandyshev, A., & Eliseev, P. (2017). Drug-resistant tuberculosis threatens WHO's End-TB Strategy. *Lancet Infectious Diseases*, 17(7), 674–675.

⁵African Union. (2012). *Roadmap on shared responsibility and global solidarity for AIDS, TB and malaria response in Africa*. Available from: <http://carmma.org/download/file/fid/767> [Accessed March 24, 2017]; Stop TB Partnership. *The red arrow - A symbol to unite us against TB*. Available from: http://www.stoptb.org/news/stories/2015/ns15_058.asp [Accessed March 4, 2017]; WHO. (2015). *End TB Strategy - Brochure*. Available from: http://www.who.int/tb/End_TB_brochure.pdf [Accessed March 6, 2017]; WHO. (2017). *Ethics guidance for the implementation of the End TB Strategy*. Available from: <http://www.who.int/tb/publications/2017/ethics-guidance/en/> [Accessed March 24, 2017].

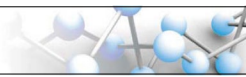
⁶WHO (2015), *op. cit.* note 5, p. 4 (emphasis added).

⁷Benatar S. R., Daar, A., & Singer, P. A. (2003). Global health ethics: The rationale for mutual caring. *International Affairs*, 79, 107–138; Frenk, J., Gómez-Dantés, O., & Moon, S. (2014). From sovereignty to solidarity: A renewed concept of global health for an era of complex interdependence. *Lancet*, 383, 94–97; Lancet. (2017). Achieving sustainable solidarity development goals. *Lancet*, 390(10113), 2605.

⁸Dawson, A., & Jennings, B. (2012). The place of solidarity in public health ethics. *Public Health Reviews*, 34(1), 65–79; Prainsack, B., & Buyx, A. (2017). *Solidarity in biomedicine and beyond*. Cambridge, UK: Cambridge University Press.

⁹Ives, J., & Draper, H. (2009). Appropriate methodologies for empirical bioethics: It's all relative. *Bioethics*, 23(4), 249–258.

¹⁰WHO. (2017). *Global tuberculosis report 2017*. Available from: <http://apps.who.int/iris/bitstream/10665/259366/1/9789241565516-eng.pdf> [Accessed March 24, 2017].



TB have been unsuccessful in part because poverty remains woefully unaddressed.¹¹ As a result, 95% of active cases of TB occur in low- and middle-income countries (LMICs). Conversely, communities with a combination of near-universal access to existing TB diagnostics, medicines, public health measures, social protections, and better socioeconomic conditions have nearly eliminated TB.¹² The poor management of TB globally is further implicated in the emergence and spread of multidrug-resistant (MDR) TB and extensively drug-resistant (XDR) TB, which have reached epidemic proportions in their own right.

Research into diagnostics and treatments for TB has historically been underfunded, so the standard of care has remained the same for decades.¹³ MDR- and XDR-TB treatment regimens last 9–24 months, result in severe adverse reactions, including hepatotoxicity, renal toxicity, and neuropathy, and are often combined with periods of isolation or inpatient care. As a result, completion rates are low when accompanying social and community supports are lacking (e.g., provision of low-cost food, care for dependants, etc.).¹⁴ Poor treatment completion rates are implicated in the development and spread of drug-resistant TB.¹⁵

Recently, two new antitubercular drugs and one diagnostic test have been introduced, albeit with controversy surrounding their safety, effectiveness, and costs. Xpert MDR/RIF is a diagnostic assay that enables earlier isolation and treatment, but its implementation and clinical impact appear to be blunted by health systems that are unequipped to treat the greater number of persons diagnosed.¹⁶ Bedaquiline and delamanid, the first antitubercular medications developed in over 40 years, were approved conditionally in 2012 and 2013, respectively. Conditional approval was granted based on phase II clinical trial data owing to the morbidity associated with MDR-TB. As phase III results would only become available several years later, there have been global calls for pharmacovigilance to evaluate the long-term safety and effectiveness of bedaquiline and delamanid.¹⁷ While observational studies have suggested improved cure rates of MDR-TB with bedaquiline and

delamanid,¹⁸ safety concerns exist.¹⁹ Most recently, results from a phase III trial for delamanid have failed to confirm its efficacy, highlighting the challenges of developing new and effective regimens for treating M/XDR-TB.²⁰

3 | THEORETICAL BACKGROUND: ETHICAL ACCOUNTS OF SOLIDARITY

Solidarity has long been used as an explanatory concept in sociology to describe existing norms, forms of action or social organization.²¹ Recently, solidarity has been garnering attention in bioethics where scholars are seeking to further its understanding by addressing its normative dimensions, including in the context of health.²² We draw primarily on two ethical conceptions of solidarity to outline a taxonomy of the normative features of solidarity as a means of interpreting our interview data.²³ Rather than assessing the relative merits of the two accounts, we indicate where the data reflect either or both accounts and aid in understanding the associated ethical implications.

Conceptions of solidarity in bioethics share several common features. Broadly, solidarity is understood as a fundamentally relational concept that comprises both descriptive and normative dimensions. Solidarity is fundamentally relational as it holds that individuals and communities are bound together, or mutually interdependent, and thus, that personal and collective well-being are intimately linked. As such, solidarity weakens the distinction between self-interest and shared interests in contrast with the primacy of individual autonomy. Similarly, solidarity calls attention to the relational nature of health; it recognizes that people, and thus health and illness, are embedded in broader social, political, and environmental contexts.²⁴ Solidarity's emphasis on mutual interdependence between peoples and the socially embedded nature of health lays the groundwork for other moral commitments and collective obligations to support and act in concert with those in need. Solidarity is also understood as being enacted in that it

¹¹Benatar, S. R., & Upshur, R. (2010). Tuberculosis and poverty: What could (and should) be done? *International Journal of Tuberculosis and Lung Disease*, 14(10), 1215–1221.

¹²Lönroth, K., Migliori, G. B., Abubakar, I., D'Ambrosio, L., de Vries, G., Diel, R., ... Raviglione, M. C. (2015). Towards tuberculosis elimination: An action framework for low-incidence countries. *European Respiratory Journal*, 45, 928–952.

¹³Frick, M., Gay, B., Gaudino, A., Harrington, M., Horn, T., Jefferys, R., ... McKenna, L. (2017). *Treatment Action Group 2017 Pipeline Report: HIV, TB & HCV*. New York, NY. Available from: <http://www.pipelinereport.org/> [Accessed Oct 24, 2017].

¹⁴WHO, *op. cit.* note 10.

¹⁵WHO. (2017). *What is multidrug-resistant tuberculosis (MDR-TB) and how do we control it?* Available from: <http://www.who.int/features/qa/79/en/> [Accessed Oct 8, 2017].

¹⁶Albert, H., Nathavitharana, R. R., Isaacs, C., Pai, M., Denkinger, C. M., & Boehme, C. C. (2016). Development, roll-out, and impact of Xpert MTB/RIF for tuberculosis: What lessons have we learnt, and how can we do better? *European Respiratory Journal*, 48, 516–525.

¹⁷WHO. (2015). *Active tuberculosis drug-safety monitoring and management: Framework for implementation*. Available from: http://apps.who.int/iris/bitstream/10665/204465/1/WHO_HTM_TB_2015.28_eng.pdf [Accessed Oct 24, 2017].

¹⁸Borisov, S. E., Dheda, K., Enwerem, M., Leyet, R. R., D'Ambrosio, L., Centis, R., ... Migliori, G. B. (2017). Effectiveness and safety of bedaquiline-containing regimens in the treatment of MDR- and XDR-TB: A multicentre study. *European Respiratory Journal*, 49(5); Hafkin, J., Hittel, N., Martin, A., & Gupta, R. (2017). Early outcomes in MDR-TB and XDR-TB patients treated with delamanid under compassionate use. *European Respiratory Journal*, 50, 1700311.

¹⁹Gler, M. T., Skripconoka, V., Sanchez-Garavito, E., Xiao, H., Cabrera-Rivero, J. L., Vargas-Vasquez, D. E., ... Wells, C. D. (2012). Delamanid for multidrug-resistant pulmonary tuberculosis. *New England Journal of Medicine*, 366, 2151–2160.

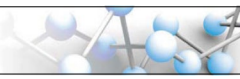
²⁰WHO. (2018). *WHO position statement on the use of delamanid for multidrug-resistant tuberculosis*. Available from: www.who.int/tb/publications/2018/WHOPositionStatementDelamanidUse.pdf?ua=1 [Accessed Feb 8, 2018].

²¹Prainsack & Buux, *op. cit.* note 8.

²²Ibid; Benatar et al., *op. cit.* note 7; Dawson & Jennings, *op. cit.* note 8; Jennings, B., & Dawson, A. (2015). Solidarity in the moral imagination of bioethics. *Hastings Center Report*, 45(5), 31–38; Meulen, R. (2015). Solidarity and justice in health care: A critical analysis of their relationship. *Diametros*, 43, 1–20.

²³Prainsack & Buux, *op. cit.* note 8; Jennings & Dawson, *op. cit.* note 22.

²⁴Ibid.



requires readiness to act and active engagement; passive empathy is insufficient.²⁵

Normative accounts of solidarity can be distinguished by the extent to which they conceptualize it as an instrumental or intrinsic value. As an instrumental value, solidarity is understood as a means to motivating the collective action of individuals or groups to bring about other important considerations (such as reducing risk of harm). For example, Prainsack and Buyx articulate an account of solidarity based on how and why people act the way they do. They conceive of solidarity as a descriptive concept with normative dimensions that aids in guiding policy and practices by drawing attention to the collective benefits that arise from solidaristic action.²⁶ They define solidarity as 'an enacted commitment to carry the "costs" (financial, social, emotional, and otherwise) to assist others with whom a person or persons recognise similarity in relevant respect'.²⁷ Instrumental solidarity hinges on the recognition of commonality as necessary to justify accepting the costs but also as a means to achieving other ends.

Extending this conception of solidarity to global health, West-Oram and Buyx articulate a more explicitly instrumental formulation of solidarity. They assert that self-interest should serve 'as a motivational *starting point* from which solidarity can be developed', such that emerging global health threats that face the rich and poor alike should motivate wealthy nations to 'expand the range of persons with whose interests they are concerned'.²⁸ Eckenwiler, Straehle, and Chung articulate a similar understanding of global solidarity where national governments may be moved to enact solidarity because of 'prudential' considerations.²⁹

Others tie solidarity's normative force to its intrinsic value; solidarity's normative force stems from the meaning of the concept itself, not how it may bring about other ends.³⁰ Jennings and Dawson describe solidarity as a fundamental descriptive and normative concept in public health ethics that functions 'as a *shaping sensibility* – a vantage point that informs other normative principles and ideals rather than supplementing or competing with them'.³¹ They define solidarity as:

a moral practice that is fundamental to the social and cultural structure of right relationship. Right recognition is a condition of moral and political membership, rights, and equality—the recognition of the moral standing and respect of each person. Right relationship is a condition of mutuality—the mutuality

of interdependence, care, and concern for others and for their relational human flourishing.³²

Jennings and Dawson claim that their conception of solidarity has greater normative force than more instrumental and incidentally cooperative notions of solidarity, such as Prainsack and Buyx's, as it is constitutive. That is, solidarity arises 'from the nature of humans as biological and social creatures' and thus centres on what *ought* to be done, rather than on individual choice or considerations of self-interest.³³ While shared humanity can also serve as the common basis for engendering solidarity on Prainsack and Buyx's account, it is neither the only nor necessarily the primary basis in the way that it is for Jennings and Dawson's intrinsic account.

To appreciate the various forms of relationality and positionality inherent in different degrees of solidarity, Jennings and Dawson articulate a taxonomy of solidarity comprising one foundational and three relational dimensions.³⁴ The foundational dimension of solidarity may be understood as 'standing up beside'. It requires active moral engagement through supporting others and standing up to the forces that oppress them.³⁵ The three relational dimensions of solidarity can be understood as stances that require progressively greater recognition of the mutuality between people along an 'arc of solidarity': standing up *for* (through assistance and advocacy, but which may not include challenging the underlying basis for a person or group's subordinate social status); standing up *with* (which requires moving beyond relating to persons as victims by appreciating the standpoint of others); and standing up *as* (the greatest degree of identification with others but without denying differences). Progressing along the arc of solidarity demands greater moral discernment and commitment, requiring a shift from 'seeing health as personal achievement or a matter of the biological lottery to seeing health (and illness) as something mutual, something that creates responsibilities of care and concern incumbent on us all'.³⁶

Although the instrumental and intrinsic accounts of solidarity have both points of convergence and divergence, rather than endorsing one account here, we employ both to interpret the full range of interviewee responses and consider the associated normative implications.

4 | METHODS

4.1 | Sampling

We interviewed a purposive sample of 23 participants from three major stakeholder groups in TB technological policy:³⁷ policy mak-

²⁵Ibid.

²⁶Prainsack & Buyx, *op. cit.* note 8.

²⁷Prainsack & Buyx, *op. cit.* note 8, p. 52.

²⁸West-Oram, P., & Buyx, A. (2016). Global health solidarity. *Public Health Ethics*, 10(2), 212–224.

²⁹Eckenwiler, L., Straehle, C., & Chung, R. (2012). Global solidarity, migration, and global health inequity. *Bioethics*, 26(7), 382–390.

³⁰Benatar et al., *op. cit.* note 7; Jennings & Dawson, *op. cit.* note 22; Meulen, *op. cit.* note 22.

³¹Jennings & Dawson, *op. cit.* note 22, pp. 31–32 (emphasis original).

³²Ibid: 32.

³³Dawson & Jennings, *op. cit.* note 8, p. 74.

³⁴Jennings & Dawson, *op. cit.* note 22.

³⁵Ibid: 35.

³⁶Ibid: 37.

³⁷Patton, M. Q. (2002). *Qualitative research and evaluation methods* (3rd ed.). Thousand Oaks, CA: Sage Publications Inc.

ers, including program administrators, bureaucrats, and employees of funding organizations, who help determine domestic and international TB policy and practice; healthcare workers, who are responsible for the care of persons with TB and whose actions are shaped by policy makers; and professional advocates, who promote the interests of persons with TB at the bedside and at the policy level. Respondents were based in Africa, Europe, North America, and South America at the time of the study, with 17 in high-income countries.

We identified potential participants based on prior, expert knowledge of the field as well as research into influential TB stakeholders. Additional participants were recruited using snowball sampling, in which respondents refer potential participants.³⁸ The principal investigator (PI) recruited participants by email. Recruitment ceased once we reached saturation and no new themes or concepts were raised in the interviews.³⁹

Research ethics approval was granted by [Simon Fraser University (study no. 2015s0433)].

4.2 | Data collection

Interviews took place between December 2015 and September 2016. They lasted approximately one hour, were conducted over the phone by the PI, and were recorded and transcribed. We developed an interview guide with open-ended questions for semi-structured interviews.⁴⁰ Initial questions asked participants to identify and explain what they considered to be ethical issues associated with new antitubercular drugs and diagnostics. Follow-up questions expanded on responses and included additional, pre-developed questions, which we modified throughout the study as we sought to deepen our understanding of topics that were not raised in earlier interviews.

4.3 | Analysis

We conducted a qualitative thematic analysis.⁴¹ We developed codes and themes from the transcripts, but were sensitized to and used bioethical concepts to inform our interpretation of participant responses during coding and thematic aggregation. One team member coded the transcripts in NVivo 11 based on a codebook that was developed jointly by the research team and to which codes were added and discussed by the team. The PI and a second team member each prepared analytic memoranda summarizing key themes and quotations for every interview. We discussed the emerging analysis through bi-weekly meetings.

Once the interviews were discussed individually and then collectively, we developed preliminary themes and reviewed them in relation to the data, codes, and each other, and then organized them into higher-level, analytic themes.⁴² We shared a document summarizing the preliminary analytic themes with the respondents, 10 of whom responded with comments, which we used as additional data. Finally, as we identified solidarity as a central moral consideration in our interpretation of participant responses in the initial thematic analysis, we looked to the bioethics literature on solidarity to inform a subsequent conceptual and normative analysis of the findings⁴³, and in particular, to understand the normative nature and implications of solidarity in the context of TB.

5 | FINDINGS AND DISCUSSION

We identified three key ethical challenges and two responses that participants raised with respect to the D&I of new TB technologies. The fundamental ethical challenge facing D&I is the failure in solidarity in TB. Solidarity features as the central concept in our analysis as it is both morally significant in its own right and underpins the remaining, interconnected ethical issues raised by participants, including power imbalances and balancing risks and benefits. Participants identified advocacy and participatory D&I, which can be understood as ways of engendering solidarity, as responses to these challenges and ways of improving TB research, prevention, and care.

5.1 | A failure in solidarity: The fundamental ethical challenge

The fundamental ethical challenge facing the D&I of new TB technologies can be understood as a failure in solidarity – a failure to identify and stand with persons and communities affected by TB and to respond to the social and political embeddedness of TB. Although participants did not explicitly use the term 'solidarity', they indicated that a lack of political will, manifest by persistent failures to address background social and political conditions, as well as insufficient attention to the needs of persons with TB and affected communities, lay at the crux of the challenges facing TB D&I. As an explanatory category, the failure in solidarity best captures the common thread across such views.

There are a lot of things that can improve, but why is it possible that a country like Cuba has managed to control TB, and it's on the path of elimination? A poor country, with limited resources, but with a political will ... So

³⁸Ibid.

³⁹Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. *Field Methods*, 18(1), 59–82.

⁴⁰Patton, *op. cit.* note 37.

⁴¹Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77–101.

⁴²Ibid.

⁴³Peter, E., Spalding, K., Kenny, N., Conrad, P., McKeever, P., & Macfarlane, A. (2007). Neither seen nor heard: Children and homecare policy in Canada. *Social Science & Medicine*, 64(8), 1624–1635.



all these arguments about lack of resources ... these are feeble excuses to hide the lack of political will. We want to make it happen, it will happen. (Interview 1)

and I think hardly addresses the patients that we should be concerned with if we think of it as a global health issue. (Interview 7)

Significantly, respondents noted that because TB largely affects persons who are impoverished, disenfranchised, and stigmatized – the ‘other’ – there is a fundamental lack of awareness about, and interest in, TB, in both low- and high-burden countries. Although participants did not explicitly invoke the notion of the ‘other’, the relationships they described mirror the process of othering inherent in us-and-them distinctions that undermine solidarity.⁴⁴

TB really seems to be – well, how do I say? Invisible to – well, not only to decision makers, but to the people who might drive decision makers. (Interview 15)

Indeed, participants attributed poor investment in TB technologies and the lack of political will to address TB to ignorance and the marginalization of those affected by TB. For example, TB was often contrasted with human immunodeficiency virus (HIV), which has been more successful in raising awareness and research funding owing to its greater visibility, especially in high-income countries:

[TB] presently predominately affects the disenfranchised, the poor, the marginalized, and they are usually voiceless communities, unlike many of the gay men who were initially afflicted by HIV, who were professionals themselves and a very active community who had to develop the lobby power in cities like San Francisco and New York. (Interview 20)

Yet, if solidarity requires identifying with persons with TB, as on more instrumental accounts of solidarity such as Prainsack and Buyx's, the invisibility – inadvertent or otherwise – of persons and communities affected by TB presents a fundamental barrier to engendering solidarity. On a more intrinsic account of solidarity, it represents a lack of mutual recognition that limits the very possibility of seeing an ethical relationship, and any associated obligations, between persons with and without TB.

Participants cautioned that, despite being central to the etiology of TB and the challenges facing technological D&I, the context of poverty and weak health, social, and governance systems surrounding TB is underappreciated and remains unaddressed. Most respondents were adamant that new TB technologies are not a panacea.

Without addressing those [socioeconomic issues], the availability of technology becomes just a privilege for a few, doesn't address the patients that we're concerned with, at least as an organization,

Furthermore, the failure to address sociopolitical factors was cited as being implicated in the M/XDR-TB epidemic:

If you have a poor program that doesn't provide treatment, care and support so that you actually cure someone, then you are going to have drug-resistant TB. And that's what we have today. (Interview 3)

Various practical challenges to the D&I of new TB technologies that participants cited have also been identified elsewhere.⁴⁵ Our findings indicate that the failure to stand in solidarity with affected persons and communities and to address broader sociopolitical challenges underpins such challenges and continues to undermine technological advancement and TB elimination efforts. Our research highlights a need for an ethical analysis of present responses to the MDR-TB epidemic with a focus on structural considerations.⁴⁶

5.1.1 | Justifying obligations: Two conceptions of solidarity

Solidarity captures differences in how respondents conceptualized obligations to address TB. When asked about whether and why high-income countries (HICs) ought to aid persons in LMICs, or why persons in positions of power in LMICs ought to aid poor and disenfranchised individuals in their own communities, participants cited two primary justifications. Some participants appealed to instrumental notions of enlightened self-interest, more akin to Prainsack and Buyx's or West-Oram and Buyx's conceptions of solidarity, as giving rise to obligations to address to TB, noting that everyone is in some way affected by or vulnerable to it.

I think everyone has a part to play in a sense because no one is not affected by TB ... The U.S. – they're one of the biggest – I think they're the number one donor for TB ... So I think there's a recognition even in the U.S. that we're not in silos anymore. Our borders are not fixed; you know? Diseases and conditions don't necessarily respect borders, especially infectious diseases. So you still have a responsibility, especially to

⁴⁴Benatar et al., *op. cit.* note 7.

⁴⁵Degeling et al., *op. cit.* note 1; WHO, *op. cit.* note 10; Albert et al., *op. cit.* note 16; Horsburgh, C.R. Haxaire-Theeuwes, M., Lienhardt, C., Wingfield, C., McNeeley, D., Pyne-Mercier, L., ... Critical Path to TB Drug Regimens' Access and Appropriate Use Workgroup. (2013). Compassionate use of and expanded access to new drugs for drug-resistant tuberculosis. *International Journal of Tuberculosis and Lung Disease*, 17(2), 146–152.

⁴⁶Degeling et al., *op. cit.* note 1.

your own population, but to help address the needs, especially if you can. (Interview 18)

Others appealed to a more fundamental sense of duty stemming from shared humanity or attention to suffering, more akin to Jennings and Dawson's articulation of solidarity as having intrinsic value.

I think that as a collective we have – everyone has a responsibility to this whether you're living in Norway or Canada and you stay far away from XDR-TB in Kwazulu-Natal. It's impacting human beings, it's causing death, and it's causing untold suffering to communities and individuals and families, and that we need to be responsive because TB is treatable and curable. (Interview 22)

Another respondent, when asked to clarify why high-income, low-burden countries have a responsibility to address TB globally, firmly dismissed self-interest as a motivating factor:

Compassion for your fellow human being ... There's nothing else that drives it. Because I think secondary gain for us is not the reason to pursue it ... We need to care because we need to care about everyone globally, that's it. (Interview 5)

Thus, as in the ethics literature, participants justified obligations of solidarity in TB both on instrumental and intrinsic grounds.

5.1.2 | Solidarity as an 'enmeshed' concept

Solidarity captures a variety of ethical concerns raised by respondents in our analysis: the social embeddedness of TB, the 'otherness' of persons and communities affected by TB, the lack of political will to address TB, and the collective responsibility of the TB community (i.e., individuals and organizations working within the field of TB, broadly construed), HICs, and even LMICs, to advocate for and aid persons and communities affected by TB to eliminate what ought to be a curable disease. However, solidarity also serves as an organizing concept that informs an understanding of, and is instrumental to, successfully addressing other ethical challenges that participants raised. The notion that solidarity informs an understanding of other ethical issues raised by respondents echoes how Jennings and Dawson describe solidarity as an "enmeshed" or "implicated" concept, a value that supports and structures the way we in fact do and ought to see other kinds of moral considerations.⁴⁷

The ways in which participants described skewed relations between TB stakeholders as impacting technological D&I, as will be discussed subsequently, suggested that they underpin other ethical concerns, including issues of justice such as inequitable access to new TB technologies. While solidarity and justice are

complementary, solidarity calls attention to reconceiving relationships on the basis of mutual recognition and interdependence,⁴⁸ such that persons with TB are no longer marginalized. As such, solidarity may serve as a precondition for considerations of justice in TB,⁴⁹ including considerations of just D&I processes and just distributions of the benefits and burdens of new technologies. Consequently, we explore the implications of the ensuing ethical issues raised by participants in light of solidarity.

5.2 | Power imbalances

Respondents described power imbalances within and beyond the TB community as ethically concerning, since powerful actors – who are seldom affected by TB – dictate whether and how D&I ought to be pursued, irrespective of local needs. Participants described how power differentials exist at many levels: globally, for example, between high- and low-income countries, which correspond to low- and high-burden countries, respectively; locally, for example, between persons with and without TB, owing to the stigma associated with the disease; and within the TB community, such as between funders and national TB programs (NTPs), or between NTPs, clinicians, and patients. Fundamentally, the present model of developing, implementing, and securing access to new TB technologies, which participants characterized as disempowering and inequitable, is indicative of a failure of mutual recognition and what can be understood as a failure in solidarity.

Participants described how the reliance of LMICs on foreign and philanthropic funding leaves persons with TB and NTPs in LMICs disempowered when accessing technologies and shaping TB technological D&I.

We are dependent on those with the money, those that can help us out of our misery and our poverty. So we are dependent and it's a modern form of slavery from a societal point of view. (Interview 6)

Moreover, the reliance on philanthropic and foreign funding stems in part from power imbalances in TB technology markets where for-profit companies are reluctant to invest in TB as they do not expect a good return on investment from a patient population that is largely poor.

Charity, however, is also predicated on a power imbalance; it is a top-down and asymmetric interaction between the donor and recipient that 'rob[s] those on the receiving end of their dignity demeaning them by forcing them to lay open their needs and vulnerabilities, and "grovel" for help'.⁵⁰ As a participant noted, NTPs in LMICs are relatively powerless and often reliant on foreign aid, leaving donors

⁴⁸Meulen, *op. cit.* note 22.

⁴⁹Krishnamurthy, M., & Herder, M. (2013). Justice in global pandemic influenza preparedness: An analysis based on the values of contribution, ownership and reciprocity. *Public Health Ethics*, 6, 272–286; Scholz, S. J. (2008). *Political solidarity*. Pennsylvania, PA: The Pennsylvania State University Press.

⁵⁰Prainsack & Buyx, *op. cit.* note 8, p. 67.

⁴⁷Jennings & Dawson, *op. cit.* note 22, p. 34.



and funding agencies to shape the TB research agenda without necessarily being attuned to local needs:

Most national TB programs that I have to deal with are not that strong and they're poorly resourced. So unfortunately they need to kind of take what they can get. (Interview 9)

Similarly, participants described mechanisms for accessing new drugs, such as donation programs from pharmaceutical companies, as inadvertently disempowering and as contributing to inequitable access to the benefits of new technologies.

Charity is not a substitute for equity or justice. And a donation program, while good for the 30,000 people who can get it in the first 4 years, doesn't solve the bigger equity issue or the fact that bedaquiline is going to be likely priced too high. (Interview 2)

Solidarity draws attention to the relationships between stakeholders, requiring those in power to stand with, but not in place of, persons with TB, affected communities, and NTPs. As Prainsack and Buyx note, carrying costs is insufficient for solidarity; solidarity must be enacted in a manner that is neither patronizing nor demeaning.⁵¹ Similarly, Jennings and Dawson note that to stand up beside, and especially to stand up as (their most involved dimension of solidarity), requires supporting the agency of those with whom we aim to act in solidarity.⁵² Rather than relying on an inherently asymmetric philanthropic model of developing and securing access to new TB technologies, solidarity challenges us to find a model that enables the TB community to stand in solidarity with, but not in place of, persons with TB and those directly charged with their care, including NTPs.

5.3 | Balancing risks and benefits

5.3.1 | Balancing risks and benefits for individual patients

Granting persons with M/XDR-TB access to drugs that have yet to undergo phase III clinical trials on compassionate grounds is ethically contentious because of the heightened uncertainty, safety concerns, and power imbalances associated with TB and last-resort treatments.⁵³ Nonetheless, respondents consistently asserted that persons with M/XDR-TB should be granted access to new drugs. Respondents cited that the potential, albeit still uncertain, benefits of bedaquiline and delamanid outweighed the known, serious risks associated with existing therapies for M/XDR-TB.

Initially the finding about the deaths [in the bedaquiline trials] that were unexplained was of concern, but then, when you put the balance on the risk and benefits, you're looking at conditions that have very high case fatalities and relatively poor outcomes because what we have to offer people with multi- and extensively drug-resistant TB is a bunch of toxic drugs with their own horrible side effects ... You're almost looking for which one is the lesser evil. Let people go untreated with MDR-TB or rely on the available lousy drugs that require long-term therapy and are associated with well known side effects. (Interview 20)

When faced with conditions of uncertainty, solidarity is instructive for understanding right relationships. Solidarity informs how we ought to relate to persons with TB as well as who and what ought to be considered when assessing risks and benefits associated with new technologies. For example, solidarity problematizes common assumptions that patients with life-threatening illnesses are willing to accept higher risks for potential benefits, which is what our participants unanimously suggested and is suggested elsewhere.⁵⁴ Solidarity also asks us to consider what might be owed to persons with M/XDR-TB even if the use of pre-approval medicines is warranted. For, not only is the burden of disease unequally distributed, disproportionately affecting persons who are poor and marginalized, so is the burden of treatment. For example, participants cited that persons with TB in high-burden, low-resource settings are doubly burdened as they are most likely to need pre-approval medicines, but live in settings that are often least able to support necessary active pharmacovigilance. The results of a phase III clinical trial indicating that delamanid is not efficacious highlight the significance of ongoing, active pharmacovigilance for risk-benefit assessments, especially for M/XDR-TB where dire need for new treatments may alter willingness to accept risks.⁵⁵ Standing with persons with TB requires mitigating the biological, financial and other risks associated with treatment, such as by supporting pharmacovigilance and providing social protections as recommended by the End TB Strategy. Furthermore, it requires attending to the broader sociopolitical contexts that shape risks and benefits, which we turn to next.

5.3.2 | Public health: Whose risk and whose benefit?

Participants were less certain as to how potential benefits associated with accessing experimental or new drugs for individual patients ought to be balanced with the potential risks to populations. In particular, some respondents were concerned that the premature administration of drugs in contexts where appropriate use could not be ensured would result in drug resistance, which could jeopardize the effectiveness of new drugs globally:

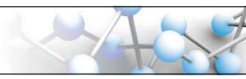
⁵¹Ibid.

⁵²Jennings & Dawson, *op. cit.* note 22.

⁵³Horsburgh et al., *op. cit.* note 45; Geffen, N. (2016). Anything to stay alive: The challenges of a campaign for an experimental drug. *Developing World Bioethics*, 16(1), 45–54.

⁵⁴Horsburgh et al., *op. cit.* note 45.

⁵⁵WHO, *op. cit.* note 20.



The biggest issue is the balance of wide-scale access against the potential of undermining the true value of [bedaquiline] ... The restricted access was really around limiting the use of the drug to ensure that it preserves the drug as an option for future treatment for the individual patient, and also from a kind of program perspective. (Interview 22)

Weak health systems and resource limitations heighten both the need for conditionally approved drugs and hinder appropriate drug use. It is precisely such conditions, which heighten tensions between individual and public well-being, that solidarity draws attention to and requires us to address. As Jennings and Dawson suggest, solidarity not only requires standing up with, but also critical reflection and standing up to oppressive agents or forces. This includes confronting the reasons underlying the failure in the TB technology market that left the technology pipeline barren for decades. Solidarity asks us to probe the underlying reasons why new medicines are so urgently required to address the M/XDR-TB epidemic. Such critical reflection was poignantly articulated by the same participant who expressed concern about balancing risks and benefits to individuals and TB programs above. The participant characterized the status quo as an 'indictment against society' that gives rise to a moral imperative to improve the quality and availability of treatments:

There is a moral imperative to find alternatives to what we currently have, and the only alternative we have thus far is the bedaquiline, which is available, but on restricted access ... But then there's also the ethical issue about - why aren't there more drugs available in the pipeline? Where are the resources for research and development of new agents? ... And, you know, it's just an indictment against society that the response to find cures, and to find better ways of treating these diseases of poverty, have really and truly been neglected. (Interview 22)

Beyond the risks and benefits associated with new technologies, some participants were concerned that persons with TB bear the brunt of the burdens associated with both the illness and treatment in an attempt to protect the public. A public health approach that emphasizes population well-being is taken with good reason in response to infectious diseases such as TB. At the same time, solidarity gives rise to a moral imperative to consider how to improve care for individual patients undergoing treatment for a disease that is itself the result of a collective failure to recognize its socially embedded nature. For example, one participant described what centering care on the patient would involve:

I call it a patient-centered approach. It's making it easy for the patient to get to clinic, to access their medicine, the education regarding around how long

treatment needs to go on, and some social supports in helping them through their care. (Interview 12)

Patient-centered care need not be antithetical to public health. Yet, the sociopolitical context of TB, including weak health systems, resource limitations, and marginalization, make personalized approaches to care that may minimize risks of developing resistance and harms to individuals undergoing treatment, difficult, if not impossible, in many settings.

There's just not that thinking of the patients' perspective and I think that's largely because it's TB, as a disease of poverty, and it's a disease that affects countries with large percentages of populations living in poverty. (Interview 17)

Solidarity draws attention to the moral significance of addressing precisely such contextual conditions that heighten tensions between individual and population risks and benefits.

5.4 | Moving forward: Engendering solidarity through advocacy and participatory practice

Respondents commonly identified two ways in which the ethical challenges facing TB D&I could be addressed, both of which we interpret as ways of enacting or engendering solidarity in TB: advocacy and concerted engagement with persons with TB and affected communities.

Participants identified increased advocacy as key to raising much-needed awareness about inadequacies in TB prevention, treatment, and care. The emphasis on advocacy echoes the notion of 'standing up for' through advocacy as an expression of solidarity.⁵⁶ Some noted that everyone in the TB community - from bench scientists and policy makers to civil society - must be actively engaged in advocating for persons with TB, and particularly those in communities of greatest disadvantage. Furthermore, some participants noted the importance of highlighting patient narratives in advocacy to facilitate identification with persons with TB - an essential element for engendering mutual recognition under a more instrumental account of solidarity such as Prainsack and Buyx's:

I think civil society can play a really powerful role in creating the demand for better diagnostics and better drugs by highlighting the personal stories ... Advocacy bringing to the forefront the human element because it's not just statistics and code numbers, but it's the human element of the suffering that becomes the fore-runner of why we need to invest in TB. (Interview 22)

In addition to advocacy, participants discussed the importance of including persons with TB and affected communities early on in D&I

⁵⁶Jennings & Dawson, *op. cit.* note 22.

so as to 'begin with the end in mind' (Interview 16) and develop technologies that are responsive to the realities and most urgent needs of high-burden contexts.

The lessons that we learned, number one, was it's not sufficient to have even a perfect diagnostic. You have to address the other landmines in the broader healthcare system that could neutralise the impact of the diagnostic ... The earlier you can engage [end-user stakeholders] in the product-development effort, the more likely you will have a more successful outcome.

(Interview 16)

Moreover, involving stakeholders who are currently marginalized in priority setting in D&I may bring attention to overlooked social contexts. For example, some respondents noted that philanthropic organizations and funders are more interested in developing new technologies than innovative ways of solving the underlying causes of TB. This is echoed in the literature.⁵⁷

It means that philanthropists or international organizations are much more interested [in] provid[ing] new technology to the big cases of tuberculosis when the disease is there. But they are not interested enough in health promotion, in health and prevention.

(Interview 13)

Existing guidelines for participatory research practices in clinical research offer a starting point for developing policies that integrate persons with TB and their communities into the technology D&I process.⁵⁸

Solidarity's emphasis on the socially embedded nature of health also raises new possibilities for collaboration and advocacy beyond TB in global health. For example, some participants noted that the syndemic interactions of TB and HIV, and relative success of HIV advocacy, present an opportunity for collaboration and collective action across diseases.

And we are building off of the HIV legacy from the late eighties, early nineties where activists really were extremely influential in a call to action. I think increasingly these kinds of activist organisations need to speak up for TB.

(Interview 16)

Such an approach echoes participants' calls for social, and not just technological, solutions to TB. It also supports fundamentally

reorienting global health policy from vertical approaches focused on individual diseases to horizontal approaches to improving global health through social and health-systems reforms.⁵⁹ Similarly, it draws attention to the synergistic effects between the TB and HIV epidemics, including how they arise from and are exacerbated by shared social, economic, environmental, and political contexts and how they interact adversely and further heighten mutual vulnerabilities.⁶⁰

6 | CONCLUSIONS

We conducted the first investigation of ethical issues related to the D&I of new TB technologies that draws on policy stakeholder perspectives. Moreover, our analysis is the first to consider how recent accounts of solidarity in bioethics may contribute to understanding the nature and significance of solidarity for TB policy, where it is increasingly being invoked as a guiding norm, as well as for global health more generally.

This analysis sheds light on four primary features of solidarity in the context of TB. First, as both a descriptive and normative concept, solidarity provides a means for understanding the ethical challenges associated with the D&I of new TB technologies. Solidarity is an issue in its own right in the D&I of new technologies, where a lack of solidaristic action is hindering D&I efforts. Moreover, solidarity informs understanding of other ethical concerns identified by participants, including power imbalances between stakeholders and balancing the risks and benefits associated with emerging technologies. Second, appeals to solidarity are instrumentally important for the D&I of new TB technologies, lending credence to policy responses that recognize and address the relational nature of health and illness through collective action. Third, solidarity is intrinsically important in TB, justifying action to attend to the suffering and needs of persons with TB and affected communities.

Finally, our analysis suggests that the challenges facing TB elimination are characterized by a key practical and ethical concern: a failure within and beyond the TB community to identify, stand, and act in concert with persons and communities affected by TB – a failure in solidarity. Fundamentally, addressing TB requires policies that both support technological advances and attend to the sociopolitical contexts that enable TB to thrive and limit technological D&I. Necessary sociopolitical changes require solidarity across and beyond the TB community. This includes raising awareness about TB through advocacy and actively engaging persons with TB and affected communities early on in technological D&I. Our findings echo the End TB Strategy and Moscow Declaration in emphasizing the importance of political will and multi-sectoral action to realize systems-level strategies for successful TB eradication and the D&I of new technologies in particular.

This investigation is limited as we did not interview persons with TB, so additional research with, and by, affected persons and communities

⁵⁷Birn, A.-E., Pillay, Y., & Holtz, T. H. (2017). Between international and global health: Contextualizing the present. In *The Textbook of Global Health* (4th ed.) (pp. 3–88). New York, NY: Oxford University Press.

⁵⁸Boulanger, R. F., Seide, S., Lessem, E., Pyne-Mercier, L., Williams, S. D., Mingote, L. R., ... Critical Path to TB Drug Regimens' Stakeholder and Community Engagement Workgroup. (2013). Engaging communities in tuberculosis research. *Lancet Infectious Diseases*, 13(6), 540–545.

⁵⁹Birn et al., *op. cit.* note 57; Farmer, P. (2000). The consumption of the poor: Tuberculosis in the 21st century. *Ethnography*, 1(2), 183–216.

⁶⁰The Lancet. (2017). Syndemics; Health in context. *Lancet*, 389(10072), 881.

is necessary to fully understand the challenges and opportunities for enacting solidarity in TB. Moreover, further conceptual work is required to identify a preferred normative account of solidarity for justifying and guiding TB policy. Notwithstanding these limitations, our findings caution that the failure to enact solidarity threatens the D&I of new TB technologies and, ultimately, global TB eradication efforts as called for in the End TB Strategy and the Sustainable Development Goals.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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