Analysis of the draft political declaration on the fight against tuberculosis

United Nations (UN) States are expected to adopt a political declaration on the fight against tuberculosis during the high-level meeting to be held in September 2023. In May 2023 the co-facilitators of the intergovernmental consultation circulated a Zero Draft for a prospective political declaration on the fight against tuberculosis. Negotiations are now underway.

A wide variety of international documents have addressed critical issues in public health, human rights, recognition of populations made vulnerable by law or policy, and access to medicines. The HIV Language Compendium (HILanguageCompendium.org) compiles "agreed language" on a set of key contentious issues – illustrating that there exists strong consensus and political settlement on many of these issues. Based on these elements from international instruments, sources, and agreements, our analysis proposes improvements that could be reflected in the final political declaration on tuberculosis to make it as bold as other declarations in selected areas.

While strong in some aspects, ongoing drafts of the political declaration do not yet reflect internationally agreed terms in some important areas. Multiple international documents have called for community-led monitoring of health responses. Contrary to these precedents, some stakeholders are opposed to recognizing the importance and commuting to implement "community-led" monitoring to improve social accountability. Some stakeholders are also opposed to language relating to health and human rights that have been widely recognized in international documents. Given that public and philanthropic institutions represent a large portion of funding for tuberculosis research and development, States should also commit to embedding strong contractual conditionalities to ensure access. States should also urge avoiding international agreements that restrict maneuvering space for implementing intellectual property flexibilities. The final political declaration would be stronger if concrete and actionable commitment to explore, support, and implement delinkage incentive models are adopted.

1. Protect proposed language relating to community leadership and monitoring

Early versions of the draft declarations have proposed language acknowledging the "value of community-led monitoring in improving social accountability." Commitments to develop and

implement "community-led monitoring" have also been proposed in early versions of the declaration. However, a handful of stakeholders in the negotiation are opposing including the phrase "community-led" monitoring in the draft declaration. Failure to recognize and call for implementing "community-led" monitoring would make the political declaration far weaker.

Community leadership has a measurable impact on the health of key populations.[1] More effective, sustainable, and equitable systems are developed when communities are directly involved at all stages of decision-making processes. These positive effects have been shown in research finding that community-led initiatives are central to equitable pandemic preparedness and response.[2] Research has also demonstrated that community leadership is more effective in settings where laws criminalize same-gender sex, sex work, or drug use.[3] It is therefore critical to acknowledge the importance of community leadership in health service delivery and responses.

Recognizing this, States have called for placing communities at the center of health service delivery and responses in multiple international agreements. In the HIV political declaration adopted in June 2011 by the UN General Assembly (UNGA), States committed "to partner with local leaders and civil society, including community-based organizations, to develop and scale up community-led HIV services and to address stigma and discrimination."[4] In the 2016 political HIV declaration, States committed to expanding "community-led service delivery to cover at least 30 per-cent of all ser-vice deliv-ery by 2030."[5] The HIV political declaration adopted by the UNGA in 2021 again called on States to implement "community-led" service delivery models.[6]

Experts have also called for community leadership in numerous reports and guidelines. The UN High Commissioner for Human Rights recently urged States to ensure that the development, implementation, and monitoring of all HIV legal and pol-icy changes and pro-gram-matic inter-ven-tions "are under-taken with the mean-ing-ful engage-ment and lead-er-ship of com-mu-nity-led orga-ni-za-tions."[7] In 2021, the Com-mis-sion on the Sta-tus of Women (CSW) of the UN Economic and Social Council (ECOSOC) encouraged States "to facil-i-tate the active engage-ment, rep-re-sen-ta-tion, and deci-sion-mak-ing of women liv-ing with, at risk of or affected by HIV and their net-works in inter-na-tional, regional, national and com-mu-nity-led

[1] https://hivlanguagecompendium.org/intergovernmental-evidence/2022-who-consolidated-guidelines-on-hiv-vh-sti-for-kps.html

[2] https://www.unaids.org/en/resources/presscentre/featurestories/2022/january/20220128_communities-first-responders

[3] 2021 WHO Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring (p. 346): https://hivlanguagecompendium.org/intergovernmental-evidence/2021-who-consolidated-guidelines-hiv-prevention-testing-treatment-monitoriong.html

[4] https://hivlanguagecompendium.org/high-level-precedent/2011-political-declaration-on-hiv-and-aids.html

[5] https://hivlanguagecompendium.org/high-level-precedent/2016-political-declaration-on-hiv-and-aids.html

[6] https://hivlanguagecompendium.org/high-level-precedent/2021-political-declaration-on-hiv-and-aids.html

[7] https://hivlanguagecompendium.org/expert-precedent/2022-ohchr-report-on-human-rights-and-hiv-aids.html

processes related to the HIV and AIDS response."[8] The 2021 WHO Consolidated Guidelines on HIV Prevention, Testing, Treatment, Service Delivery and Monitoring state that "com-mu-nity-led mon-i-tor-ing and related advo-cacy engen-ders account-abil-ity of ser-vice providers and local and national offi-cials to stan-dards of high-qual-ity health care, includ-ing the avail-abil-ity and acces-si-bil-ity of ser-vices; such account-abil-ity leads to improved health out-comes."[9]

Recommendation: Retain proposed language recognizing the "value of community-led monitoring in improving social accountability." Retaining this language would be consistent with other internationally agreed documents. Adopt clear and programmatic commitments to develop and implement "community-led monitoring" across the political declaration.

2. Protect proposed language relating to health and human rights

Early versions of the draft political declaration included proposed language recognizing that health "significantly contributes to the promotion and protection of human rights." However, this phrase has been opposed by some stakeholders participating in the negotiations.

States have previously adopted international declarations specifically stating that health "significantly contributes to the promotion and protection of human rights." Language explicitly recognizing that health "significantly contributes to the promotion and protection of human rights" was adopted, for instance, in the 2019 political declaration on universal health coverage.[10] More broadly, there is an extensive body of international agreements explicitly recognizing that health is a human right.[11] Numerous international agreements, expert comments, and guidelines also recognize that fulfillment of the right to health is necessary to protect human rights.[12]

A human-rights based approach to tuberculosis is one that is grounded in international and regional treaties, and national laws, that establish the rights of all people to life, health, nondiscrimination, privacy, participation, information, freedom of movement, housing, food, water, and to enjoy the benefits of scientific progress. This includes those living with, and vulnerable to, tuberculosis. Governments and private actors have obligations and responsibilities to protect and promote human rights, including through accountability and access to remedies for rights violations. Protecting and fulfilling the rights of people with tuberculosis, as has been demonstrated in the

[8] https://hivlanguagecompendium.org/intergovernmental-precedent/2021-csw-report-on-women-and-hiv-aids.html
[9] https://hivlanguagecompendium.org/intergovernmental-evidence/2021-who-consolidated-guidelines-hiv-prevention-testing-treatment-monitoring.html
[10] https://hivlanguagecompendium.org/high-level-precedent/2019-political-declaration-of-the-hlm-on-uhc.html
[11] https://www.ohchr.org/en/special-procedures/sr-health/about-right-health-and-human-rights
[12] The Right to Health Fact Sheet No. 31 (Stating that "Human rights are interdependent, indivisible and interrelated. This means that violating the right to health may often impair the enjoyment of other human rights, such as the rights to education or work, and vice versa.")

fight against HIV, is likely to foster sustainable interventions, improvements in treatment outcomes, and reductions in drug resistance.

In this context, early versions of the draft political declaration have included proposed language recognizing that "structural" inequity, stigma, racism, and discrimination, including against women, remains key roadblocks to ending the tuberculosis epidemic. But, some stakeholders have expressed opposition to using the term "structural" in several parts of the draft political declaration. Contrary to that opposition, recognition of "structural" inequity, including against women, have already been adopted in previous UN resolutions. Recognition of "historical and structural inequality in power relations between women and men" was adopted, for instance, in the 2020 UN resolution on violence against women migrant workers.[13] Terms like "systemic" or "structural" racism have also been recognized by governments and UN experts.[14] Furthermore, several international documents recognize the structural roots and effects of discrimination.[15]

Early versions of the draft declaration have proposed language acknowledging gender specific barriers to ending the tuberculosis epidemic, which need to be addressed through comprehensive political, legal, and programmatic actions. Gender related barriers and the need for "gender-sensitive" or "gender-responsive" approaches have also been recognized in early versions of the draft declaration. However, some stakeholders are opposed to terms recognizing gender related barriers and the need for gender-sensitive and gender-responsive approaches.

Despite such opposition, internationally agreed documents have already recognized gender inequality as a barrier to ending the tuberculosis epidemic.[16] The 2018 political declaration on the fight against tuberculosis adopted by the UNGA also recognized the need for developing "gender-responsive health services based on human rights."[17] In the 2018 political declaration on the fight against tuberculosis, States also committed to developing health services through approaches that protect and promote, among others, "gender equality and human rights."

Recommendation: Retain proposed language reaffirming that health "significantly contributes to the promotion and protection of human rights." Moreover, protect proposed language recognizing that "structural" inequity, stigma, racism, and discrimination, including against

[13] https://hivlanguagecompendium.org/high-level-precedent/2020-resolution-on-violence-against-women-migrant-workers.html
[14] https://www.ohchr.org/en/racism/agenda-towards-transformative-change-racial-justice-and-equality
also see: https://oneill.law.georgetown.edu/projects/the-oneill-lancet-commission-on-racism-structural-discrimination-and-global-health
[15] https://hivlanguagecompendium.org/stigma-and-discrimination.html
[16] https://hivlanguagecompendium.org/high-level-precedent/2018-political-declaration-of-the-hlm-on-the-fight-against-tb.html
[17] https://hivlanguagecompendium.org/high-level-precedent/2018-political-declaration-of-the-hlm-on-the-fight-against-tb.html

women, remains key roadblocks to ending the tuberculosis epidemic. Furthermore, retain proposed language recognizing gender specific barriers to ending the tuberculosis epidemic, which need to be addressed through comprehensive political, legal, and programmatic actions.

3. Commit to embedding strong equitable access terms on publicly funded research

Public and philanthropic contributions represent a significant portion of the research and development funding relating to tuberculosis. In 2021, seventy percent of tuberculosis research and development funding came from public entities, with the National Institutes of Health (NIH) in the United States providing the largest single allocation at 354 million U.S. dollars.[18] Philanthropic institutions have committed hundreds of millions of dollars toward research and development efforts relating to tuberculosis. Public and philanthropic funders, however, often fail to secure contractual terms requiring their grantees to openly share knowledge and ensure equitable access. States are starting to acknowledge and have committed to address this gap by embedding equitable access and knowledge sharing terms on publicly funded research agreements. These types of commitments have been adopted, for instance, in the pandemic preparedness and response resolution adopted by the UN General Assembly in March 2022.[19]

Drafts of the political declaration have failed to acknowledge these extensive contributions of public and philanthropic institutions in tuberculosis pharmaceutical research and development.

Recommendation: Acknowledge the extensive contributions of public and philanthropic institutions in pharmaceutical research and development for tuberculosis. Additionally, commit to ensuring that publicly funded technologies are licensed openly to promote equitable access.

4. Urge avoiding TRIPS Plus and other commitments that prevent the use of IP flexibilities

Language proposed for inclusion in the draft political declaration would reaffirm widely accepted concepts relating to the right of States to use intellectual property flexibilities "to the fullest extent." However, existing proposals for inclusion in the political declaration fail to mention the legal, political, and practical barriers that often impede the use of those provisions. Several of those barriers are imposed by preferential trade and investment agreements with international intellectual property commitments that go beyond those required by the TRIPS Agreement. These include exclusive protection to regulatory data and patent term extensions.

[18] https://www.stoptb.org/news/worldwide-tb-rd-funding-surpasses-us1-billion-falls-short-of-goals
[19] A/RES/76/257

Several international sources have acknowledged the detrimental effects of TRIPS Plus commitments on access to health technologies, including the 2021 political declaration on HIV.[20] Experts have also advised States against TRIPS Plus provisions in numerous reports. In 2009, the UN Special Rapporteur on the right to health, Anand Grover, urged developing countries to avoid TRIPS Plus commitments that impede access to health technologies.[21] Grover also warned that exerting pressure on developing countries to enter into TRIPS Plus commitments may infringe on the right to health, including access to and affordability of care.[22] The UN Special Rapporteur for cultural rights Farida Shaheed similarly urged States to refrain from adopting TRIPS Plus provisions that impede the use of "exclusions, exceptions and flexibilities and thus from reconciling patent protection with human rights."[23] The final report of the UN Secretary-General's High-Level Panel on Access to Medicines found that commitments beyond the TRIPS agreement "may impede access to health technologies."[24] Given these effects, the High-Level Panel on Access to Medicines urged States to avoid TRIPS Plus commitments.

Recommendation: Urge States to refrain from entering into TRIPS Plus commitments in preferential trade or investment agreements, which would severely undermine their ability to fulfill the right to health and fight tuberculosis by restricting access to health technologies.

5. Commit to collaborating on delinking research and development incentives models

Early versions of the draft declaration include language proposing commitments "to continue to support existing initiatives and incentive mechanisms that separate the cost of investment in research and development from the price and volume of sales, to facilitate equitable and affordable access to new tools and other results to be gained through research and development."
Recognition of the need for exploring delinkage models is welcomed. However, the proposed language only provides a limited commitment to "support" "existing" initiatives. This fails to state concrete and actionable commitments for how to "support" "existing" initiatives. Moreover, this fails to recognize the need for international collaboration to advance delinkage models.

Cooperating towards delinkage models have been recognized as a priority by several international authorities for their potential to promote human rights by ensuring access to health technologies for all who need them. States have also acknowledged the importance of international collaboration toward delinkage to address specific health needs. The 2021 UNGA political declaration on HIV recognized the need to continue exploring delinkage research and development

[20] A/RES/75/284 (calling States to ensure "that intellectual property rights provisions in trade agreements do not undermine [access to health technologies])."
[21] https://hivlanguagecompendium.org/expert-precedent/2009-special-rapporteur-on-the-right-to-health.html
[22] Id.
[23] A/70/279
[24] http://www.unsgaccessmeds.org/final-report

models "where rewards for innovation are independent from rights to market exclusivity."[25] In 2018, the UNGA also recognized the need for incentives that avoid reliance on high prices specifically for health products to fight against tuberculosis.[26] In 2016, the UNGA acknowledged the need for international collaboration on delinkage models to decouple antimicrobial resistance research and development from prices and volumes of sales.[27]

Several international authorities have specifically called on States to further explore and collaborate toward delinkage models. In 2015, for instance, the WHO Executive Board called upon Member States to "collaborate" on delinkage incentive models to combat Ebola.[28] Furthermore, in July 2022, the HRC called upon States to "collaborate" "on models and approaches that support the delinkage of the cost of new research and development from the prices of medicines, vaccines and diagnostics."[29] The HRC has also called on States to "collaborate" on delinkage incentive models to ensure "sustained accessibility, affordability and availability and to support access to treatment for all those in need."[30] Similar language calling upon States to collaborate on delinkage incentives models to ensure access to health technologies for all those in need features in HRC resolutions adopted in 2021,[31] 2019,[32] 2016,[33] and 2013.[34]

Recommendation: Adopt concrete and actionable commitments directed towards exploring, supporting, and implementing incentive models that delink pharmaceutical research and development costs from the price of products. The declaration should reflect commitments to engage in international collaboration efforts to explore, support, and implement delinkage.

6. Acknowledge and commit to address digital health governance gaps

Early versions of the draft political declaration have called for strengthening notification "of all people diagnosed with tuberculosis, as appropriate by public, private and community-based health care providers to national health information systems." Earlier versions have also called for expanding the "use of secure, confidential and human-rights based digital case-based surveillance, in line with applicable standards and data privacy laws." Although early drafts have briefly

[25] A/RES/75/284
[26] A/RES/73/3
[27] A/RES/71/3
[28] https://oneill.law.georgetown.edu/five-observations-ebola-special-session-resolution/
[29] A/HRC/50/L.13/Rev.1
[30] A/HRC/RES/49/25
[31] A/HRC/RES/46/14
[32] A/HRC/41/L.13
[33] A/HRC/32/L.23/Rev.1
[34] A/HRC/23/L.10/Rev.1

mentioned human-rights based approaches and data privacy laws, they have generally called for expanding the use of digital technologies without fully acknowledging their risks.

Global governance of data and digital technologies is currently inadequate for safeguarding human rights. While digital health technologies can address challenges in terms of notification of tuberculosis infections, the threats to privacy and confidentiality can lead to violence, discrimination, and violations of key human rights including housing, employment, expression, freedom of assembly, protection from arbitrary detention, bodily autonomy, and security.

Multiple international sources have recognized this. Affirming "that the same rights that people have offline must also be protected online,"[35] the Human Rights Council (HRC) has for instance called States to consider "adopting or reviewing legislation, regulations or policies to ensure that business enterprises fully incorporate the right to privacy and other relevant human rights into the design, development, deployment and evaluation of technologies, including artificial intelligence."[36] States have also stressed the need to ensure "the use of technology to monitor and contain the spread of infectious diseases, are in full compliance with the obligations of States under international human rights law."[37] Privacy must be protected "when designing, developing or deploying technological means in response to disasters, epidemics and pandemics."[38]

Recommendation: Include a new OP specifically recognizing the need to protect human rights in digital environments, including privacy and non-discrimination. This new OP should read: "Recognise the need to adopt or review legislation, regulations or policies that strengthen and enforce the governance of data and digital technologies to ensure the protection of human rights, including the right to privacy and non-discrimination, into the design, development, development and evaluation of technologies, including artificial intelligence."

[35] A/HRC/RES/42/15
[36] A/HRC/RES/42/15
[37] A/RES/75/176
[38] A/RES/75/176
https://www.ohchr.org/en/documents/thematic-reports/ahrc5365-digital-innovation-technologies-and-right-health