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Where Public Health Meets Human Rights: Integrating Human Rights into the Validation of the Elimination of Mother-to-Child Transmission of HIV and Syphilis

ESZTER KISMÖDI, KARUSA KIRAGU, OLGA SAWICKI, SALLY SMITH, SOPHIE BRION, ADITI SHARMA, LILIAN MWOREKO, AND ALEXANDRINA IOVITA

Abstract

In 2014, the World Health Organization (WHO) initiated a process for validation of the elimination of mother-to-child transmission (EMTCT) of HIV and syphilis by countries. For the first time in such a process for the validation of disease elimination, WHO introduced norms and approaches that are grounded in human rights, gender equality, and community engagement. This human rights-based validation process can serve as a key opportunity to enhance accountability for human rights protection by evaluating EMTCT programs against human rights norms and standards, including in relation to gender equality and by ensuring the provision of discrimination-free quality services. The rights-based validation process also involves the assessment of participation of affected communities in EMTCT program development, implementation, and monitoring and evaluation. It brings awareness to the types of human rights abuses and inequalities faced by women living with, at risk of, or affected by HIV and syphilis, and commits governments to eliminate those barriers. This process demonstrates the importance and feasibility of integrating human rights, gender, and community into key public health interventions in a manner that improves health outcomes, legitimizes the participation of affected communities, and advances the human rights of women living with HIV.

Eszter Kismödi, JD, LLM, is an international human rights lawyer in Geneva, Switzerland, and a visiting scholar at Yale Law School and School of Public Health, New Haven, CT, USA.

Karusa Kiragu, MPH, PhD, is UNAIDS Country Director, Uganda.

Olga Sawicki, MD, MPH, is Carlo Schmid Fellow at UNAIDS, Geneva, Switzerland.

Sally Smith, MSc, is senior adviser, Community and Faith Engagement, UNAIDS, Geneva, Switzerland.

Sophie Brion, JD, MPP, is a human rights attorney for the International Community of Women Living with HIV Global Office, Washington, DC, USA.

Aditi Sharma is consultant for the Global Network of People Living with HIV, Brighton, UK.

Lilian Mworeko is executive director of International Community of Women Living with HIV Eastern Africa, Kampala, Uganda.

Alexandrina Iovita, MPH, PhD, is human rights and law adviser at UNAIDS, Geneva, Switzerland.

Please address correspondence to Eszter Kismödi. Email: eszter.kismodi@gmail.com.

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Introduction

In 2015, Cuba became the first country to be officially validated by the World Health Organization (WHO) for the successful elimination of mother-to-child transmission (EMTCT) of HIV and syphilis.[1] Since then, several other countries and territories have been successfully validated, including Thailand, Belarus, Anguilla, Montserrat, Cayman Islands, Bermuda, St. Kitts and Nevis, and Antigua and Barbuda for dual elimination, Armenia for EMTCT of HIV, and Moldova for elimination of syphilis. Over 80 countries are considering applying for, or are in the advanced stages of validation.[1]

The WHO-led process of EMTCT validation is a unique disease elimination certification process that proves the feasibility and value of the integration of human rights standards and community participation into public health interventions.

From both public health and human rights perspectives, this WHO EMTCT validation process is remarkable for several reasons. First, validation involves the fulfillment of epidemiological and public health criteria that illustrate the successes of global and national efforts to address vertical transmission of HIV and syphilis. This biomedical criterion relates to the reduction in the number of new babies born with HIV below a threshold low enough that it no longer constitutes a public health problem.[2] This criterion is also being applied to EMTCT of syphilis, which can be prevented through simple, low-cost screening and treatment of pregnant women. Since the antenatal services to prevent mother-to-child transmission of HIV and syphilis are similar, dual elimination is being pursued to harmonize improvements in maternal and child health.[3]

Second, EMTCT certification also includes—for the first time in history—human rights, gender equality, and meaningful community engagement as key factors in evaluating whether a country should receive certification for a health achievement. The inclusion of these factors among the validation criteria is a reflection of the increased understanding that the realization of human rights can foster the achievement of public health goals. It also signals that the respect and fulfillment of these principles are critical goals in themselves.

Historically, public health approaches to disease control and elimination have focused on biomedical and technical approaches rather than addressing human rights and social determinants of health.[4] However, in the context of HIV, networks of people living with HIV, and particularly, networks of women living with HIV have consistently identified gender inequality and human rights abuses, including discrimination, as obstacles to treatment, care, and support, and have called for greater focus on human rights, gender equality, and community engagement.[5]

These efforts recognize that human rights, gender equality, and community engagement are essential factors that influence: how health systems are shaped both at community and country level; the national and international legal and policy environment within which these systems operate; and the overall social and economic context of people's access to and use of these services.[6]

Earlier in the HIV epidemic, access to medicines for EMTCT came to epitomize the struggle for human rights in the context of HIV in South Africa and globally.[7] The refusal of the South African government to provide access to antiretroviral treatment for EMTCT was challenged before the court by civil society. In a landmark ruling, the Constitutional Court of South Africa held that the constitutional rights of pregnant women living with HIV were being violated by the failure to provide them with anti-retroviral medicines.[8]

While countries across the world have been implementing EMTCT programs since the late 1990s to early 2000s, global efforts to accelerate the elimination of vertical transmission of HIV gained momentum in middle- and low-income countries around 2009, when UNAIDS published its Business Case as part of the Outcome Framework.[9] This joint publication with WHO, UNICEF, and UNFPA laid the groundwork for the elimination of vertical transmission, including its definition and its indicators. The biggest impetus for the development of rights-based validation of EMTCT was the launch of the Global Plan Towards the Elimination

of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive ("Global Plan"), initiated by UNAIDS and PEPFAR. The Global Plan was launched in July 2011 at the United Nations General Assembly High-Level Meeting on AIDS in New York. It prioritizes 22 countries with the highest number of pregnant women living with HIV in need of services. These countries are Angola, Botswana, Burundi, Cameroon, Chad, Côte d'Ivoire, the Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Swaziland, Uganda, the United Republic of Tanzania, Zambia, and Zimbabwe. Together, these countries accounted for 90% of the total number of pregnant women living with HIV that needed services to prevent mother-to-child transmission of HIV in 2009. The goals of the Global Plan were to reduce the number of new HIV infections among children by 90%, and to reduce the number of AIDS-related pediatric and maternal deaths by 50%. This plan was "global" in nature, and it galvanized leadership, engaged front-line communities, and stimulated innovative approaches and new technologies to prevent, diagnose, and treat HIV.[10] It called for the respect and fulfillment of the rights of women living with HIV, and for community empowerment and engagement.[10] It brought together a diverse set of stakeholders, including governments, funders, the private sector, networks of women living with HIV, civil society, and many more; seized political momentum for planning and action; and set bold targets enabling accountability.[11]

Countries which had reduced vertical transmission of HIV to negligible levels seized the momentum generated by the Global Plan to ask for avenues to officially recognize their achievements. WHO understood the potential of such process not only for recognizing achievements but also for maintaining and encouraging continuous efforts towards EMTCT. In response to these calls, WHO thus developed a process through which countries could be validated as having eliminated vertical transmission of either HIV, syphilis, or both. Tools to guide the validation process and to conduct country assessments were developed and a governance mechanism at global, regional, and country levels was formulated. In light of the serious human rights violations that have been reported in maternal and child health care settings, including rampant discrimination and involuntary sterilization, networks of women living with HIV and UNAIDS advocated the inclusion of rights-based elements to be integrated into EMTCT validation criteria and processes.[12]

This article describes the human rights, gender equality, and community mobilization principles, norms, and approaches that are included in the EMTCT validation tools and process. It also provides insights into the implementation of these principles, norms, and approaches during the validation process. Finally, the article reflects on the benefit and impact of this first-ever rights-based process for the validation of disease elimination.

Conceptual elements of the rights-based validation process

The criteria to validate EMTCT of HIV and syphilis were developed to apply across a wide range of epidemiological and programmatic contexts, including the assessment and evaluation of appropriate health services infrastructure, staff capacity and training, laboratory preparedness, and high quality monitoring and surveillance systems.[13] In addition to these, rights-based conceptual elements of the validation entail the inclusion of human rights, gender equality, and community engagement among the required validation criteria through such elements as informed consent, respect for privacy, confidentiality and autonomy, and decriminalization of HIV non-disclosure, exposure, and transmission. It also includes the manifestation of these principles in the validation process itself, such as inclusion of human rights experts in the validation committees, as well as participation of women living with HIV in each step of the process.

These key elements of the validation are outlined in "Global Guidance on Criteria and Processes for Validation of Elimination of Mother-to-Child Transmission of HIV and Syphilis," which describes the minimum global processes and criteria that countries should present to achieve valida-

tion of EMTCT, and is intended for national and regional validation committees as they prepare or review national submissions requesting validation. While the human rights, community engagement, and gender equality validation process requires the engagement of specific actors and expertise, and collection of particular information, it is seen as an integral part of the overall validation process. The first edition of this global EMTCT guidance document was released in 2014 by WHO, while the second edition was developed by WHO and the Global Validation Advisory Committee (GVAC) in 2017.[14] While both editions are inclusive of rights-based principles, the second edition is much more comprehensive and explanatory in regard to the operationalization of human rights, gender equality, and community engagement principles.[15]

Consistency with international, regional, and national human rights standards

Besides the various health system criteria, a key consideration for the validation of a country is that the interventions to reach the targets have been implemented in a manner consistent with international, regional, and national human rights standards.[11] The rights-based elements and requirements of the validation process are captured in the tool and guidance on Elimination of Mother-to-Child Transmission of HIV and Congenital Syphilis: Assessment of Human Rights, Gender Equality and Community Engagement Dimensions of National Programmes, which was developed in collaboration with the International Community of Women Living with HIV (ICW) and Global Network of People Living with HIV/AIDS (GNP+).[16] They were invited into this process to develop a clear framework and criteria for human rights, gender equality, and community engagement standards by which to evaluate EMTCT programs for validation. The standards were developed in direct consultation with networks of women living with HIV and other experts on human rights, gender equality, and community engagement.

This tool and guidance is one of four core assessment tools to be used by all EMTCT stakeholders throughout the validation process; the others include the evaluation of national programmatic elements, the laboratory services, and the quality of data. Human rights issues being investigated and evaluated through the validation process include: whether or not vertical transmission of HIV is criminalized; whether health care settings are free from mandatory or coerced testing and treatment, forced and coerced abortion, contraception and/or sterilization; and whether informed consent, confidentiality and privacy, and equality and non-discrimination are respected, protected, and fulfilled. The validation process also recognizes inclusion and meaningful participation as a human rights concept in programmatic efforts. As an illustration, the process investigates whether certain population groups, such as migrants or sex workers are systematically included in EMTCT programs and the provision of services.

Gender equality

The criteria for EMTCT validation also include a gender equality-related component, which recognizes that gender norms and practices can significantly shape sexual and reproductive health and rights of women, and health outcomes for their children. In particular, it recognizes that the promotion and achievement of gender equality can significantly influence the opportunities of women and girls to access necessary information and services, make autonomous decisions about their sexuality and reproduction, and protect themselves against HIV and sexually transmitted infections (STIs). The assessment of this gender equality criteria includes the investigation of the steps taken by the state to address gender-based violence and to ensure adequate access to justice, remedies, and redress for women, including in the context of EMTCT.

Community engagement

The validation process aims to give significant recognition to the content and meaning of the right to participation and to the principle of "Greater involvement of people living with HIV" (GIPA).[17] This principle recognizes that meaningful participation of people living with HIV, and

in particular, women living with HIV, affects the exercise of their right to health and well-being. Meaningful participation helps to ensure that women living with HIV and infected with syphilis get the treatment they need to keep themselves well and their children free from infection; it also results in better, more effective programs.[18] This validation criteria hence investigates whether the involvement of women, in particular women living with HIV, is multi-dimensional, and includes their participation in the formulation of health laws and policies, program development, and implementation, service delivery, and advocacy.

Progressive realization

In the revised validation process, which incorporates lessons learned from practical implementations, WHO proposes criteria for validation of three levels of achievement—bronze, silver, and gold—on the path to elimination. The term "validation" is used to attest that a country has successfully met criteria for EMTCT or for one of the three levels of achievement on the path to EMTCT of HIV and/or syphilis. This second edition of the global guidance presents a new approach to recognizing high-burden countries that may not have reached elimination targets but are on the path to elimination.[19] The path to elimination comprises three tiers of accomplishment, each with its own set of process and outcome indicators. These three levels are designed for countries with a high prevalence of HIV and/or syphilis that have made tremendous strides in preventing MTCT but cannot as yet reach elimination targets due to the high prevalence of HIV and syphilis in antenatal care attendees. Moving to a higher tier brings a country progressively closer to meeting the WHO criteria for achievement of elimination.[20]

This approach is easily translatable to the principle of "progressive realization" of socioeconomic rights that recognizes that states will be in a position to immediately and completely fulfill all these rights. This principle, however, implies that steps toward the full realization of socioeconomic rights, including the right to the highest attainable standard of health, which relates directly to EMTCT, must be deliberate, concrete, and targeted as clearly as possible toward meeting a state's human rights obligations "to the maximum of its available resources."[21] It thus requires all countries to show concrete efforts in moving toward full realization of rights within their means and without deliberate backsliding.

Due diligence

States have an obligation to exercise due diligence to prevent, investigate, and, in accordance with national legislation, punish acts that violate human rights, whether those acts are perpetrated by the state or by private persons. In the context of EMTCT, this can be of vital importance—where, for example, discrimination or violence render some individuals unable to realize their rights on an equal basis with others, including those women living with HIV, or women engaging in sex work.[22] The due diligence standard has been also applied increasingly in the context of elimination of gender stereotypes, as well as in the context of provision of health care for marginalized populations, such as migrants and refugees, that can have a great relevance when countries are applying for validation.

Rights-based procedural elements of the validation

A rights-based approach to health interventions is not only grounded in the content but also essential to the process by which validation is granted. The EMTCT validation provides an important and innovative platform for interrogating and addressing human rights issues, in particular during the in-country assessment missions and during the final consideration of the validation report and findings.

Such procedural elements are related to:

- operationalizing of human rights in country reviews, through a systematic and analytical inclusion of the human rights-based criteria into the validation reports;
- inclusion of human rights expertise and civil society representation in national-, regional-,

and global-level program and data reviews and within the validation committees, including the national and Regional Validation Committees (RVC), where such mechanisms exist, and in the Global Validation Committee (GVAC).

- strong community engagement throughout the validation assessment; and
- integration of human rights into the maintenance of the validation.

Operationalizing of human rights in country reviews

The methodology for the human rights assessment of country validation includes three complementary processes: 1) a desk review to assess national legal framework relating to EMTCT against applicable international and regional human rights and gender equality standards; 2) semi-structured interviews with women living with HIV, key officials with human rights, gender equality and community engagement functions, civil society and community-based organizations representatives, and HIV and EMTCT program managers and service providers; and 3) invitation of shadow reports by civil society organizations, including networks or groups of women living with HIV who use EMTCT services to provide their views on human rights, gender equality, and community involvement issues. Findings from the desk review, interviews, and shadow reports are compiled into a report. The drafters of the report, who may be from ministries of health or EMTCT programs, are encouraged to document how they have engaged and consulted community in the collection and preliminary examination of data, particularly around human rights, gender equality, and community engagement. However, not only the drafters of the report need to demonstrate thorough investigation of the fulfillment of human rights standards. The RVC, where such mechanisms exist, and the GVAC must also evaluate the content of the report from a human rights perspective and where possible embody the core principles of GIPA and gender equality.[18] WHO Headquarters and Regional Offices function as validation secretariats for these Committees, in partnership with UNAIDS, UNFPA and UNICEF.[23] For example, it is recommended for the validation team assessing the country report to arrange to meet independently with human rights experts and networks of women living with HIV at the country level in order to evaluate the claims in the report. Critically, these bodies need to provide clear rights-based feedback to countries about required areas of improvement and, where necessary, encourage them to take specific steps to remedy laws, policy, and practices which have resulted in human rights violations. They are also expected to call countries to demonstrate progressive improvements on key issues related to gender equality and community engagement in order to achieve validation or alternatively to maintain the validation once achieved.

Inclusion of human rights expertise and civil society representation in the validation committees

The validation process consists of a series of national-, regional-, and global-level program and data reviews. Once the reports prepared at the country level are submitted to the RVC, the RVC convenes a team to undertake an initial assessment of whether the report confirms that the country has met with the fundamental requirements for validation across the four assessment tools. Once the report passes the RVC assessment, it is submitted to the GVAC along with the RVC assessment. The GVAC then prepares a global validation report based on a critical review and assessment of the information, outcomes, processes, and recommendations identified in the regional report. Ultimately, it is the WHO global secretariat, in collaboration with UNAIDS, UNFPA, and UNICEF who reviews the GVAC's critical assessment and recommendations and make the final determination on whether the country has achieved validation of EMTCT of HIV and/or syphilis including recommended follow-up actions for maintenance of EMTCT validation status. Subsequently, WHO headquarters monitors maintenance of EMTCT of HIV and syphilis annually through routine global reporting mechanisms already in place, and with additional reports

from validated countries. As a result, not only the drafters of the initial report need to demonstrate thorough investigation of the fulfillment of human rights standards, but the RVC (where applicable) and the GVAC must also evaluate the contents of the report from a human rights perspective and, where possible, embody the core principles of GIPA and gender equality.[24]

A rights-based consideration of the validation reports requires that the membership of the national, regional, and global validation committees consist of independent and multidisciplinary experts, including human rights experts, representatives of networks of women living with HIV, as well as advocates from civil society that work with at-risk and vulnerable groups.[25]

In practice, however, resource limitations may jeopardize consistent use of in-country evaluation teams, and in some cases the assessment may need to be conducted remotely by members of the GVAC.[26] This may lead to limitations on the involvement of human rights and community experts in the validation process, which may influence the final findings of the report. There are countries, however, where significant efforts have been made to provide meaningful participation of human rights expertise and communities in the process. In Cuba, for example, five municipalities were selected for site visits, which included visits to civil society organizations, including networks of people living with HIV. Three members of the validation team were specialists in human rights, and community engagement and civil society representatives were included in meetings with national ministry of health officials at the beginning of the validation process. The inclusion of human rights experts and community members ensured that human rights issues, such as adolescents' access to services and institutionalization practices and community participation in program development, were raised and adequately addressed.[27]

Ensuring community engagement throughout the validation assessment

The validation process requires countries to ensure that representatives of civil society, including women living with HIV, are involved in each level of the validation process. This element of the process can serve as an important accountability mechanism for comprehensively evaluating human rights concerns in the context of EMTCT in the country. Furthermore, the procedural criteria of community engagement can encourage governments to systematically involve communities in the process, that can create previously non-existent mechanisms for monitoring and multi-stakeholder discussions on human rights and gender equality in relation to EMTCT. In Thailand, for example, strong success with community engagement became one of the key factors that enabled the country's success in validation.[28]

At the national level, community consultations, focus group discussions, and other methods such as interviews with key community members and human rights experts creates the community engagement element of the process. In addition, the possibility of submission of shadow reports to the RVC or the gathering of their own data around key issues, by community groups, including networks of women living with HIV, provide independent input to the validation process.

Although only a few countries have gone through the nascent process of validation, it is clear that the process would benefit from the establishment and requirement of minimum standards of community engagement within the process to further guide and encourage countries to gather data and feedback from community groups in the preparation of their reports. Such minimum standards could include ensuring that community-based organizations and networks of people living with HIV are not tokenized within the process of report preparation, and that their concerns, voices and lived experiences are heard.

Integrating human rights in the maintenance of the validation

The validation criteria also include the demonstration that the country is committed to maintain the validation status of EMTCT of HIV and/or syphilis, including through sustained attention to respecting, protecting, and fulfilling human rights

as part of EMTCT efforts. This includes ensuring that the incidence of vertical transmission remains low, health systems continue to be maintained and strengthened, human rights and gender equality barriers are addressed and community engagement sustained.[29]

Countries need to show evidence that they are consistently meeting the EMTCT criteria over time, and that they are addressing the recommendations received. For example, in at least three of the validated countries, urgent timelines were set for removal of laws criminalizing HIV non-disclosure, exposure, and transmission, and for ensuring access to HIV services for adolescents. A country may have their validation rescinded if they do not comply with recommendations.

Greater transparency around the specific recommendations issued by the GVAC in this process—for example, making the recommendations public or sharing them with all involved in the validation process, including community-led groups—would strengthen accountability within this mechanism and empower community and advocacy groups to hold EMTCT programs accountable at the country level.

Benefits and impact

Adequate attention to human rights, gender equality, and community engagement considerations has the potential to serve as an important tool for community-led accountability dialogues and advocacy to challenge human rights violations and improve program quality. The validation process can provide a critical point of engagement for women living with HIV to advocate for stopping practices that violate human rights. These human rights considerations, based on recommendations considered in final country decisions, include:

- addressing criminalization of HIV non-disclosure, exposure, and transmission, and its impact on EMTCT efforts,
- removing age-related legal barriers to services by acknowledging adolescents' rights to make decisions according to their evolving capacity and best interest,
- removing mandatory testing and treatment requirements,
- safeguarding privacy and confidentiality,
- eliminating stigma and discrimination in health care settings, and
- ensuring systematic and sustained community engagement in EMTCT.

GVAC chooses from the following options: 1) unqualified endorsement of the EMTCT programs and services, 2) endorsement of the programs and services with clear recommendations for strengthening of components that might pose a current or future threat, or c) determination of insufficiencies that preclude EMTCT validation or which must be remedied before reapplication or revalidation. Recognition that countries may achieve process and target indicators for EMTCT and still not be validated if there are grave or systematic recent or ongoing human rights violations is an important motivator for due diligence in pre-empting and addressing such violations.[30]

Importantly, the mere inclusion of human rights in the EMTCT validation demonstrates clear commitment to realizing that long-term public health benefits can only be achieved if rights are upheld, and those most affected are meaningfully engaged as partners in promoting their own and community health.[31]

In addition, the EMTCT validation process requires assessment of whether the least-performing geographic unit meets the criteria of providing access to EMTCT services for all, including the most vulnerable and marginalized. Challenges related to access of key and vulnerable populations to services are taken into consideration during validation missions and case reviews to ensure that the validation process and tools are applied in a manner that is consistent with the guidance. Among the countries that applied for validation, many faced challenges in ensuring equitable access to antenatal care to undocumented internally displaced people, external migrants, refugees, or ethnic minority groups. The importance of leaving no one behind in EMTCT

program efforts was a key feature in each of the validated countries, many of which demonstrated the provision of free antenatal (inclusive of HIV and syphilis screening and treatment) and outreach services to these populations.[32]

Another vital benefit of the process is that it galvanizes the direct engagement of women living with HIV.[33] As countries undertake initial self-assessment as they prepare an application for validation, the data-gathering tool and process encourages both self-reflection and information gathering from community-led organizations and feedback from EMTCT program participants. This process has the potential to open new dialogue or strengthen existing dialogue and collaboration between service providers and community-led organizations, which can lead to the establishment of people-centered, quality services.

Conclusively, one of the most important benefits is that the validation process and the recommendations from the GVAC can create a de facto accountability mechanism through which community-led organizations can hold programs accountable. Reporting back to the GVAC on upholding such recommendations is an important precursor for action, and creates the space for human rights activists and communities to engage in advancing human rights and removing some of the barriers to the full realization of the right to health.

As more countries achieve validation, the expected impacts will multiply and include rights-based approaches to responding to diseases, and ensuring equitable access to services that are acceptable and of good quality, for all, most marginalized and key communities included. The validation of EMTCT of HIV and syphilis may be expanded in the near future to include elimination of other diseases, as hepatitis B, further amplifying the potential benefits and impacts beyond the HIV and STI responses.

However, as an increasing number of countries apply for validation, there is a risk that human rights, gender equality, and community participation criteria might be seen as secondary to biomedical and epidemiological data on elimination. Therefore, maintaining and strengthening a rights-based EMTCT validation for the future will require continued commitment by WHO, UNAIDS, and states, as well as vigilance from civil society to protect the uniqueness of this process.

Conclusion

The WHO-led EMTCT validation is a unique and innovative channel to engage governments in addressing human rights violations and barriers in their countries, and fulfill their public health and human rights commitments towards HIV, particularly addressing the rights and health of women and children. It is a singular tool for creating important dialogue among various stakeholders within the country, and ensuring the meaningful participation of affected populations in program monitoring and evaluation. The inclusion of validation and sustainability criteria in relation to human rights, gender equality, and community participation in the EMTCT validation process allows for an ongoing dialogue, encourages and assesses advances, and ensures guarantees about no retrogression. It represents an important innovation in disease elimination validation and is already providing important lessons for other disease elimination efforts, including hepatitis, Zika, and Ebola.

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