

Treatment

Human Rights and HIV/AIDS in Brazil

Kelly Safreed-Harmon

Specific legal obligations and general human rights principles have helped shape AIDS policies in many countries, and have influenced the way HIV-infected and -affected people are treated in various aspects of their lives. This article examines how human rights principles and laws have informed the national response to HIV/AIDS in Brazil, where effective public health strategies are credited with reducing the overall impact of HIV/AIDS. One central element of Brazil's national AIDS plan is an ongoing government-led campaign against HIV-related stigma and discrimination; another is free universal distribution of antiretroviral drugs to everyone who needs them. The following analysis of these issues is prefaced with an overview of the human rights models that are central to a discussion of the Brazilian experience.

international human rights treaties, and stands today as the touchstone of the modern human rights movement. UDHR was intended to define the full body of fundamental human rights principles, among them “the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services.”

In 1966, the UN General Assembly adopted two treaties that elaborate on many aspects of UDHR: the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). These treaties bestow specific responsibilities upon ratifying parties under international law. That is, countries are legally obligated to ensure that their citizens enjoy the rights named in the treaties. To date, 160 countries have ratified ICCPR, and 157, ICESCR. Brazil is a party to both.

It is commonly understood that some rights cannot be implemented in absolute terms. A government's commitment to the right of its people to medical care, for example, does not translate into an economically untenable obligation to immediately build and staff health clinics in all under-resourced

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Health and human rights

The conceptual and legal framework for considering HIV/AIDS and other health problems as human rights issues has evolved largely through the work of the United Nations (UN).

The Universal Declaration of Human Rights (UDHR), adopted by the UN General Assembly in 1948, became the foundation for the subsequent body of

communities. States are, however, obligated to make measurable ongoing progress on those issues, a concept known as the progressive realization of rights.

Two rights that have great significance in the field of health are the right to participate in decision-making processes that affect one's well-being and the right to be free from discrimination. Thus, a state's efforts to realize its citizens' right to health should be characterized by the participation of community representatives at national and local planning levels, and by the enactment of interventions that serve all groups of citizens equally.

Background: HIV/AIDS in Brazil

In 1994, the World Bank estimated that Brazil would have almost 1.2 million cases of HIV infection by 2002. The caseload even now is little more than half that number. This can be attributed to two major factors: the strong commitment of the Brazilian government to implementing a comprehensive multifaceted national AIDS plan, and the deep involvement of civil society in many aspects of HIV/AIDS prevention, care and treatment.

Treatment is one of the most widely discussed components of Brazil's national AIDS plan. Since 1996, the government has distributed combination antiretroviral therapy for free through the national health system. Brazil's position as one of the few developing countries with a domestic pharmaceutical industry has contributed to the economic feasibility of this policy, with Brazilian companies manufacturing generic versions of earlier antiretrovirals. The government has negotiated with the pharmaceutical industry for discounts on more recent antiretrovirals that cannot be copied because of patent laws. However, as demand grows for second- and third-line antiretroviral regimens that include imported drugs, the cost of sustaining the treatment program looms as one of Brazil's biggest AIDS-related challenges.

Conditions supporting a rights-based response in Brazil

Beginning in 1964, a series of military dictatorships ruled Brazil. Widespread opposition to this system of governance led to a gradual "redemocratization" process throughout much of the 1980s, driven by a broad-based political and social movement with a strong human rights element. The diverse elements of Brazilian society that banded

together to bring about this transition included the sanitary reform movement—an informal coalition of health professionals, academics, and others "who demanded a public health system responsive to and controlled by the public and who defended the right to health as a fundamental human right to be guaranteed by the constitution."¹

Brazil had become a party to ICESCR in 1992. When its new constitution was enacted in 1998, it included significant human rights protections for

Since 1996, the government has distributed combination antiretroviral therapy for free through the national health system.

Brazilian citizens, including the right to health. Enshrining the right to health in its constitution could thus be viewed as a significant step in the progressive realization of the right to health as called for in the treaty because this established an important point of reference for all of the country's future health-related legislation.

Well before the new constitution was in place, the human rights dimension of the democracy movement had already greatly informed early efforts to address HIV/AIDS. In the early 1980s, human rights activists and gay rights activists joined forces to quickly mobilize an organized response to the epidemic taking hold in the state of Sao Paulo. This community-based coalition found allies in the municipal and state public health agencies. It was here that the sanitary reform movement had helped instill a strong human rights-oriented perspective in the government's conception of its health-related responsibilities.^{2,3,4} Thus, the HIV/AIDS policies and programs that emerged in Sao Paulo State—which became a model for other states and later for the national AIDS program—embodied a sophisticated understanding of the relationship between health and human rights. This relationship had significant bearing on stigma and discrimination, and on access to medicines.

Stigma and discrimination

The prominence of human rights perspectives has contributed to widespread opposition to HIV-related stigma and discrimination since very early in the Brazilian AIDS epidemic. According to Dr. Alan

Berkman and his collaborators, “A critical number of gay men and human rights activists, as well as men and women infected or affected by HIV, openly confronted the stigma, demanding that the rights of people living with AIDS be respected by the government and by their fellow citizens.”⁵

In the state of Sao Paulo, community leaders found that this stance resonated with the State Department of Health, which recognized that countering stigma and discrimination would be an important part of the fight against AIDS. Health officials, in fact, drew parallels between the social responses to HIV and Hansen’s disease (leprosy). The first person to head the state AIDS program, in 1983, later wrote:

From the beginning, the Sao Paulo AIDS Program was organized with all the components still existent today, including prevention, epidemiological surveillance, treatment and human rights, in addition to a strong component of linkage with[community organizations]. . . . It was significant that the State Dermatology Division already had multidisciplinary [Hansen’s disease] team emphasizing community involvement and the struggle for the rights of affected individuals. The longstanding experience with Hansen’s disease both supported and provided the initial structure needed to set up the AIDS Program. At the time, there was a strong link between AIDS and homosexuality, which also proved problematic. If there had not been a team in place to deal with the issues pertaining to rights, stigma and minorities as a government commitment and responsibility, it might have been much more difficult to create an AIDS Program with the above-mentioned characteristics.⁶

The Sao Paulo effort to counter stigma and discrimination was recognized by other states and later by the national program as an essential component of an effective HIV/AIDS plan. Meanwhile, by the late 1980s, community-based NGOs were taking their human rights-based campaign into the legal realm. NGOs filed lawsuits seeking to defend HIV-positive people from discrimination in housing, education, the workplace, and elsewhere. They also used lawsuits to challenge policies that required people to undergo HIV tests in order to qualify for jobs and be admitted to public exams.⁷

Legislative initiatives emerged to reinforce the courts’ often favorable rulings. A 1988 law requires employers to extend workplace disability protection to HIV-positive employees. Laws also prohibit HIV-related discrimination in the workplace, in health care and in access to public facilities, and forbid medical personnel from revealing confidential med-

ical information about HIV-positive people.⁸ NGOs provide legal aid to HIV-positive people as part of their ongoing efforts to have the anti-discrimination laws upheld. A 2003 article reported that an estimated 36 NGO legal projects, located throughout the country, were then receiving funds from the Ministry of Health.⁹

Access to medicines

The Brazilian movement to provide access to AIDS medicines has also been driven in part by human rights-based arguments put forth by community members and health officials. A landmark 1996 law requiring free distribution of antiretroviral drugs through the public health system had its roots in actions that both of those groups had taken in the 1980s.

As one source explains, “The passing of this law reflected in part the efforts of community groups which had filed lawsuits, beginning in 1988, against state and local governments to guarantee assistance to people with AIDS and treatment with medication for AIDS-related opportunistic infections.”¹⁰ Although the government was the target of the lawsuits, this did not mean government entities necessarily opposed the campaign for universal treatment. Berkman and his colleagues state:

Integral care was a core concept of the sanitary reform movement in Brazil before the debate about the need for linking treatment and prevention emerged within the international AIDS movement. Integrality . . . asserts that prevention must be integrated with care and treatment. The right to health extends to those already ill and in need of treatment, and there is recognition that having people access the health system will improve the whole range of public health initiatives. Integrality also is based on a commitment to the human rights of those afflicted: a prevention-only approach to health violates those rights and the dignity of those in need of care, devalues their lives and adds to the stigma that may accompany illness.¹¹

The director of Sao Paulo State’s first AIDS program suggests that his agency even deliberately helped spur the universal access campaign by purchasing the small amount of AZT that it did in 1989, initially only enough to treat seven percent of people in need of treatment.

It was a deliberate initiative as part of a strategy to create need, to generate demands and to spark involvement by society on the issue of antiretroviral treatment in Brazil. . . . These initiatives helped mobilize public opinion and the community, and in 1990 the Ministry of Health decided to begin purchasing all the AIDS drugs

available on the market, including . . . medicines for opportunistic infections.¹²

The Sao Paulo State Department of Health set a similar precedent by beginning to distribute protease inhibitors as part of triple combination antiretroviral therapy in 1995. The national AIDS program followed suit in 1996. In November 1996, Brazil's president signed Law 9313, which required the federal government to provide free AIDS medicines through the public health system to all people who needed them. Human rights arguments provided an important rationale for the enactment of the legislation.

The human rights frame has continued to shape the judiciary's interpretation of the government's treatment-related obligations in significant ways. For example, community advocates sued the federal government in 2000 to challenge the public health system's policy of providing genotyping tests only to patients who were taking protease inhibitors. The judge who heard the case ultimately agreed with the advocates' argument that access to genotyping tests and should be extended to people taking all forms of antiretroviral regimens. The judge's explanation for his ruling made reference to "all principles that guide the health program, in particular the right to life, as established in the preamble to Article 5 of the Federal Constitution."¹³

Conclusion

There has been much discussion about how "the Brazilian model" might provide guidance for other developing countries where AIDS is a major health crisis. Of course the extent to which that model is taken up elsewhere depends in part on factors utterly beyond the control of any single individual or group. As Berkman and his associates observed, "The political crisis of military rule that precipitated the social mobilization of large numbers of Brazilians cannot be artificially recreated in other countries." Likewise, the centrality of human rights principles in the government and civil society response to HIV/AIDS in Brazil reflects a unique convergence of circumstances.

Nonetheless, those seeking to influence how government and civil society address AIDS in other hard-hit countries might still draw powerful lessons from what has happened in Brazil. When various players invoke human rights, they are bringing more than philosophical arguments to bear on the challenges they are facing. The Brazilian govern-

ment has a legal mandate to honor the right to health and other human rights, and this mandate has particularly influenced responses to HIV-related stigma and discrimination and to the treatment needs of HIV-positive people.

Many countries have the same health-related treaty obligations as Brazil, yet have failed to operationalize the right to health to the same extent as Brazil. What sets Brazil apart? Brazil's executive and legislative branches have developed a body of law that provides clear direction on how the right to health is to be actualized. The judiciary has provided critical guidance on implementation through rulings that address many different HIV-related issues from a human rights perspective. Finally, a strong community-based movement has conceptualized its objectives in terms of human rights principles.

Community advocates recognized that opposing HIV-related stigma and discrimination on human rights grounds was imperative. They also asserted that the right to health implies the right to treatment with the best available drugs. While civil society representatives engaged in dialogue with government agencies, they also pursued their rights-based goals through the legal system. Ultimately, the forces of government and civil society working together have shaped a strategy that demonstrates, through its success, both the moral and practical relevance of human rights in the global fight against AIDS.

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AIDS Vaccine Update: Questions after candidate fails in the STEP study

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The HIV vaccine research field suffered a blow last fall with the announcement that Merck's promising HIV vaccine candidate was not effective and may have even increased susceptibility to acquiring HIV. The candidate, known as MRK-Ad5, used a disabled version of a common cold virus, known as adenovirus-5, to carry synthetic fragments of HIV genetic material. The vaccine was designed to induce immune responses that developers hoped would either prevent infection and/or reduce viral load in HIV negative people who received the vaccine and went on to become infected with HIV through high risk exposure.

The vaccine failed to show efficacy in two large trials, known as STEP and Phambili. In the STEP study, volunteers who received the vaccine were more likely to acquire HIV as compared to volunteers who received the placebo. This effect was strongest in volunteers who had been exposed to cold-causing adenovirus prior to receiving the vaccine.

The lack of efficacy and the possibility of vaccine-related enhancement of susceptibility to HIV infection have raised serious questions for AIDS vaccine researchers and prevention advocates: Why did the vaccine fail to reduce viral load setpoint or the risk of infection? What is the explanation for the apparent increase in susceptibility to HIV infection? Were the unexpected results a fatal knockout to all Ad5-vector vaccines, or a knockdown punch to a single candidate? And finally, how do prevention advocates respond to the crisis?

What happened

After extensive preclinical testing and several prior studies in humans, MRK-Ad5 was being tested in STEP (which enrolled MSM and heterosexual women in the US, Latin America and the Caribbean and Australia) and Phambili (which enrolled heterosexual men and women in South Africa). Both

studies were jointly conducted by Merck & Co., and the HIV Vaccine Trials Network (HVTN) which is funded by the National Institutes of Health (NIH).

The vaccine candidate was designed to elicit T-cell based immunity. There is strong evidence that this type of "cell-mediated" immunity can play a role in control of HIV.

The STEP and Phambili trials involved participants who were HIV negative but at high risk for infection. All of the volunteers received ongoing risk reduction counseling, condoms, and STD treatment. During the informed consent process and the follow-up study visits, volunteers were counseled not to assume that they had received the vaccine, and not to assume that the vaccine provided any protection. All volunteers were urged to practice safe sex and other risk reduction strategies.

In September 2007, the Data and Safety Monitoring Board (DSMB) for the STEP study recommended that the trial halt immunizations after a scheduled data analysis showed "futility," meaning that there was no possibility that the vaccine would prove efficacious for either preventing infection or reducing viral load. Out of 1,850 men in the trial, there were 49 seroconversions in those who received the vaccine, compared with 33 in those who received the placebo. There was only one HIV infection in STEP's cohort of 1,150 women. This was not evidence that the vaccine worked better in women, since there were almost no infections among women in either the vaccine or the placebo arm. All subsequent analysis of STEP data related to vaccine effects focused on the male volunteers.

Immediately after the STEP DSMB recommendation that immunizations be halted, the Phambili trial also halted immunizations. Within three weeks, the DSMB for that study recommended that volunteers be unblinded, meaning that they were informed about whether they had received the vaccine or the placebo. The DSMB also recommended that they be counseled that receiving the vaccine might have increased their risk of HIV infection.

Understanding the data

The primary finding from the STEP study is of great concern; it is also quite confusing. While there were more infections among male volunteers who received the vaccine, as compared to male volunteers who received the placebo, scientists have yet to come up with an explanation for this apparent effect, which

was most pronounced in volunteers who had levels of pre-existing immunity to adenovirus.

As part of ongoing research to try to understand the mechanism which might explain the finding, researchers are looking at samples stored from STEP participants. They are asking all volunteers from both STEP and Phambili to continue coming for study visits, where additional, intensified risk-reduction counseling is being made available.

Among other things, scientists are trying to understand whether and how pre-existing immunity to adenovirus might have affected vaccine-induced immune responses and subsequent susceptibility to HIV infection. They are also looking at other variables like circumcision status, HSV-2 status (whether or not volunteers had herpes simplex virus type 2) and other issues, which might explain the difference.

One reason for this is that there were noteworthy differences in some of the demographic characteristics of men in the high and low Ad5 titer groups. For example, there were considerably more non-white, non-US men in the high Ad5 titer group. This group also had significantly more uncircumcised men and more men under the age of 30. However, in the analyses that have been conducted to date, none of these demographic differences explain the observed trend towards increased rates of infection in vaccine recipients.

In discussions of this data analysis, scientists have emphasized repeatedly that it is quite possible that there may never be a clear answer about what happened in the STEP study.

Where to from here?

What is the best way to move forward in the context of such great disappointment and uncertainty? The reality is that for any drug or vaccine which reaches the market, there are many, many candidates which fail. The fact that MRK-Ad5 failed to provide any protection is hugely disappointing, but its failure is part of the product development pathway.

While there are many questions, there are also some clear lessons from the STEP data, particularly about the animal models that are used to evaluate future candidates. MRK-Ad5, like all candidate vaccines, was advanced into human trials after extensive pre-clinical testing and studies in non-human primates. In the primary non-human pri-

mate study that showed vaccine-related benefit, monkeys were given a candidate vaccine closely resembling MRK-Ad5 and challenged with a viral strain called SHIV 89.6p. Monkeys that received the vaccine had lower viral loads than those that did not get the vaccine. Based on the subsequent failure

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of the candidate in human clinical trials, there is a strong sense that animal model challenge experiments using SHIV 89.6p should not be used as the basis for advancing candidates.

The extremely low rate of HIV infections in women enrolled in the STEP study is also prompting some hard thinking. The fact that women in the STEP study got infected at much lower rates than men could have something to do with the prevention package provided at the trial sites; it could be that the criteria used to classify women as 'high risk' for HIV infection did not identify women who fit into this category. Going forward, it is critical to understand how to reach and engage with high risk women, both for prevention research and for prevention services in general.

In terms of next steps for HIV vaccine development, one of the major questions facing the field is whether or not to proceed with an efficacy trial of a vaccine strategy developed by the US NIH's Vaccine Research Center. This strategy combines two types of vaccines in a prime-boost strategy—the priming vaccine is a DNA-based vaccine candidate and the boosting vaccine uses an adenovirus-5 vector which is similar, though not identical, to the MRK-Ad5 candidate.

An efficacy trial known as PAVE 100 of this vaccine combination strategy was scheduled to start in late 2007, and was put on hold after the STEP results were announced. Subsequent discussion has led to consensus in the scientific community that this strategy could only be tested in people who have no pre-existing immunity to adenovirus. This is a critical safety precaution, given the apparent trend towards increased susceptibility in people with pre-existing Ad5 immunity in the STEP trial.

Conducting a trial of the VRC strategy in “Ad5 seronegatives” could provide an answer about whether a different strategy (combining two vaccines, aiming at different qualities of immune responses) could have better results than the MRK-Ad5 product. However, at this time, it is difficult to imagine that an Ad5-vectored candidate could be taken through the full series of efficacy evaluations and licensed for use, given the safety concerns raised by the STEP data.

While this could change, we must acknowledge the many unknowns that surround the STEP data and all Ad5-vectored candidates at this time. The AIDS Vaccine Advocacy Coalition (AVAC) has argued that the PAVE collaborators moving ahead with a redesigned PAVE 100 should have a clear agenda for next steps should the study show any benefit.

Discussions about whether and how to proceed with a redesigned PAVE 100 study are ongoing. AVAC and other advocates have emphasized that input from communities that will be asked to participate in the studies is absolutely essential before any decision to proceed with the study is made.

The STEP and Phambili trials have led to a moment of disappointment and confusion in the AIDS vaccine field and in the broader field of prevention research, where trials of candidate microbicides and the diaphragm have also failed to show efficacy in the last 12 months. In this context, it is as important as it has ever been that communities convey clear, accurate messages about what is known and what is not known, both about specific products and about the overall effort to find additional, new interventions to prevent HIV infections.

Results are due from a trial which looks at herpes treatment as a strategy for reducing susceptibility to HIV infection. Some data on pre-exposure prophylaxis (PrEP) is expected beginning in the next 12–18 months. These trials could bring positive news, or additional setbacks. Whatever happens, prevention research must continue to be a priority as part of a comprehensive response to the epidemic. This means providing full access to what prevention and treatment options are available today, and continuing to search for additional strategies that can help save lives tomorrow.

For more information visit www.avac.org and www.aidsvaccineclearinghouse.org

Migration and HIV in Africa: Challenges and recommendations

Anthony Rutabanzibwa

Increasingly, global responses to migration and to migrants are influencing responses to the HIV/AIDS epidemic itself. African migrants in particular have borne the brunt of xenophobia and discrimination directed toward outsiders. Those who are undocumented have little or no legal protections and limited access to basic health and social services that are fundamental to successful integration into a foreign environment. These barriers, coupled with the complex social, behavior and psychological dynamics of migrancy form a constellation of risk factors that heightens vulnerability for contracting HIV/AIDS.

The African population has always been extremely mobile. Pre-colonial migratory patterns occurred without barriers or legal restraint, driven by agricultural resources, trade and labor. Similarly, in the post-colonial period migration has become a vehicle for economic betterment as well as an escape valve to overwhelming tensions caused by displacement, conflict, poverty, and resource deprivation. Today, international labor migration is commonplace.

According to the International Labor Organization (ILO), over 20 million African men and women are migrant workers and the World Bank reports that remittances by Africans working abroad now account for a substantial portion of the gross domestic product of Lesotho, Senegal, Uganda and Nigeria. In spite of the critical role they play in the economic development of their adoptive countries, these workers are, at best, treated as second class citizens. The international community has sought ways of achieving justice via the creation of international migrant worker rights conventions, including the Migration for Employment Convention (Revised) of 1949; the Migrant Workers (Supplementary Provisions) Convention of 1975; and the United Nations Convention on the Protection of the Rights of Migrant workers and their Families, adopted by the United Nations General Assembly in 1990. These legal instruments created principles for the establishment of national laws and judicial and administrative procedures related to human rights (such as equal treatment in employment, social secu-

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is published by GMHC, Inc.

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GMHC Treatment Issues

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119 W. 24th Street, New York, NY 10011

Fax: (212) 367-1235

www.gmhc.org

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Support for *GMHC Treatment Issues*
was made possible through educational grants
or charitable contributions from the following:

Gilead Sciences, Inc.

GlaxoSmithKline

M·A·C AIDS Fund

Roche and Trimeris

The Shelley & Donald Rubin Foundation

Tibotec Therapeutics

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ity, non-discrimination and anti-trafficking activities). It is important to note that the US and most of western European countries that receive migrant workers have yet to ratify or adopt any international convention protecting their rights.

AIDS in Africa is a pandemic—affecting the lives of over 22.5 million people in sub-Saharan Africa alone. In popular lore, migration and HIV/AIDS are often described as associated phenomena, with the migrant commonly considered the host and vector of HIV/AIDS. Despite the prevailing myth that migrants, refugees and other mobile populations spread HIV/AIDS, studies have shown that they have significantly lower prevalence rates than the surrounding communities wherein they reside. In no less than 60 countries, African

migrants are forced to undergo mandatory HIV testing as a pre-condition for work permits and immigrant visas. In other countries, mandatory testing is a condition precedent for being granted an extension of work permits. A positive HIV test often leads to repatriation or denial of a visa or work permit for migrants. Mandatory HIV testing for purposes of exclusion should be discouraged; however HIV testing accompanied by assurances of access to appropriate treatment and care following a positive diagnoses should be made available.

In many African countries, regulatory frameworks are being revised with the objective of integrating HIV/AIDS-related human rights principles into a national legal fabric. Some countries are going as far as drafting provisions in the law that clearly stipulate that HIV positive people entering or returning will enjoy the same rights as non-infected persons, reaffirming that one's HIV status will have no bearing on the right of entry, freedom of movement or freedom to work. For example, the economically integrated regional trading blocs in Africa, known as the Regional Economic Communities (RECs), have subscribed to the commitments laid out in the 2001 United Nations General Assembly Special Session on HIV/AIDS Declaration. The declaration stipulates that RECs should develop and implement strategies that incorporate HIV/AIDS awareness, prevention, care and treatment into emergency response and national assistance programs that target refugees, internally displaced persons, and migrants. It is within this context that some African countries, already overburdened with the HIV/AIDS epidemic of their own nationals, have restructured their health systems so as to benefit foreign migrants by providing free HIV/AIDS-related medical services.

Governments have an obligation to assure that human rights are protected for all people, irrespective of HIV status. As such, a strategic consciousness-raising and advocacy campaign needs to be undertaken to change worldwide perception on migrant populations. Restrictions imposed on travel, entry and procedures related to immigration and asylum based on one's HIV/AIDS status are a violation of the right to equality of treatment before the law. National governments have an obligation to ensure that such rights do not disappear once a migrant leaves his or her country of origin.