

Neglected Population, Neglected Right: Children Living with HIV and the Right to Science

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Abstract

The laws, language, and tools of human rights have been instrumental in expanding access to lifesaving treatment for people living with HIV. Children, however, remain a neglected population, as evidenced by inadequate child-specific and child-friendly HIV treatment options. In this article, we explore the right to science, a potentially powerful but underdeveloped right in international law, and its application to research and development for pediatric HIV treatment. Drawing on reports of human rights bodies and scholars and applying the human rights typology of state obligations to respect, protect, and fulfill, we argue that states have five core obligations related to research and development for child-specific and child-friendly treatment: (1) adopting a public goods approach to science and science policy; (2) including and protecting children in research activities; (3) adopting legal and policy frameworks to support research and development through public funding and private sector incentives; (4) promoting international cooperation and assistance; and (5) ensuring the participation of marginalized communities in decision-making processes. In concluding, we make a number of recommendations for states, human rights bodies, international organizations, civil society, and private industry to further develop and implement the right to science.

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Introduction

An estimated 1.8 million children under the age of 15 are living with HIV—over 90% of whom reside in sub-Saharan Africa—and 150,000 are newly infected each year.¹ Strikingly, HIV is the second leading cause of death globally among older children (10 to 19 years of age) and the leading cause of death in sub-Saharan Africa.² While AIDS-related deaths fell in all other age groups between 2005 and 2013, they increased by 50% among older children.³ Treatment for children living with HIV, particularly for those under the age of five, lags behind treatment for adults; there are fewer child-specific and child-friendly treatment options, fewer data on the safety and efficacy of existing medicines to inform treatment guidelines, and insufficient drug pipelines for new treatments.⁴ This has prompted some experts to refer to pediatric HIV as a “neglected disease,” defined as a disease that predominately affects populations in the developing world and that is typically overlooked by drug developers.⁵

The laws, language, and tools of human rights have been instrumental in responses to the HIV epidemic, particularly in supporting access to expensive lifesaving treatment for millions of people in the developing world.⁶ Human rights approaches, however, are underutilized in terms of promoting the need for new and better HIV treatment options for children. The right to enjoy the benefits of scientific progress and its applications (hereinafter abbreviated as “the right to science”) is a little known but potentially powerful human right that is explicitly recognized in both the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights (ICESCR).⁷ While the specific obligations of states under the right to science remain underdeveloped, there is an emerging consensus among human rights bodies and scholars that the right to science obliges states to take specific actions, both domestically and internationally, to ensure that scientific research, funding, and policy address the rights and unmet health needs of all, particularly marginalized populations.

In this article, we develop a framework to identify state obligations under the right to science,

specifically obligations related to research and development (R&D) in areas such as pediatric HIV treatment. Using this framework, we show that many of the obligations laid out under the right to science address (either directly or indirectly) key shortcomings in the current R&D environment that ignore the needs of vulnerable populations around the world. Thus, we provide a novel rights-based perspective on why and how states and other actors should adopt a more just and equitable approach to biomedical R&D and scientific progress as a whole.

Following this introduction, we review the current state of pediatric HIV treatment to show that children living with HIV, particularly those in low-income countries, have had and continue to have fewer treatment options compared to adults. The next section of the article locates the right to science in human rights law and presents a framework on the normative content of the right to science and state obligations. Then, we apply this framework to analyze the obligations of states to respect, protect, and fulfill the right to science, focusing specifically on those obligations related to R&D on pediatric HIV treatment. The final section makes five recommendations to support the development of the right to science and its implementation.

Children living with HIV: A neglected population

Since the beginning of the HIV epidemic, children have had fewer treatment options and faced worse outcomes than adults, due in large part to insufficient pediatric-specific R&D.⁸ In 2015, the World Health Organization (WHO) recommended for the first time that everyone diagnosed with HIV, including children, should immediately initiate lifelong treatment regardless of symptoms or clinical stage. Today, however, only 49% of children living with HIV are on treatment.⁹ In the absence of treatment, children born with HIV experience significantly faster progression to AIDS-defining illness and death compared to adults; more than half of children born with HIV will die within two years without treatment.¹⁰ Moreover, even children on treatment have lower rates of viral suppression

(a clinical indicator of successful HIV treatment) compared to adults, which puts children at higher risk for drug resistance and HIV-related morbidity and mortality.¹¹

Poorer viral suppression among children is at least partly attributable to a lack of child-specific and child-friendly treatment options, which leads to suboptimal efficacy, side effects, non-adherence to treatment, and dropping out of care.¹² Many children require that their HIV drugs in pill form be cut in half or quarters to achieve proper dosing (in other words, these drugs are not child-specific), while other children are forced to ingest unpalatable alcohol-based syrups that sometimes require refrigeration (in other words, they are not child-friendly). Fixed-dose combinations in which multiple drugs are combined into a single pill to reduce pill burden are less likely to be available to children compared to adults.¹³ Younger children have even fewer treatment options, and only one drug (zidovudine) is currently approved for use in preterm infants and available for intravenous delivery.¹⁴ Second- and third-line regimens, which are increasingly needed for children, are expensive.¹⁵ The relative lack of pharmacokinetic data (data on the absorption, distribution, metabolism, and excretion of HIV drugs) for children results in less evidence-based treatment guidelines for specific dosing of different drugs, their potential side effects, and drug-drug interactions.¹⁶ An estimated 40% of children on treatment are not on optimal regimens.¹⁷ Children urgently need additional child-specific and child-friendly HIV treatment options, and this requires increased levels of pediatric-specific R&D.¹⁸

The human right to science: A neglected right

The right to science is recognized as a component of cultural rights in both article 27 of the Universal Declaration of Human Rights and article 15 of the ICESCR. Similar provisions on the right to science are also in the Revised Arab Charter on Human Rights and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.¹⁹ Address-

ing health specifically, the Convention on Human Rights and Biomedicine of the Council of Europe identifies “the need for international cooperation so that all humanity may enjoy the benefits of biology and medicine.”²⁰ Additionally, a general comment from the African Commission on Human and Peoples’ Rights references article 15(1)(b) of the ICESCR in stating that women’s lack of access to safe abortion services is a violation of the right of access to scientific progress and its applications.²¹ Despite all these provisions, the right to science is still an “emergent right,” as its recognition in international human rights law is relatively recent; however, its standing and legitimacy is growing, and its interpretation and related obligations are gradually developing.²²

In this article, we focus on article 15(1)(b) of the ICESCR, which is the most widely applicable international legal provision on the right to science, as it applies in all 165 countries that have ratified the ICESCR.²³ Article 15(1)(b) guarantees the right of everyone “to enjoy the benefits of scientific progress and its applications.”²⁴ Former United Nations (UN) Special Rapporteur in the field of cultural rights Farida Shaheed has identified three elements of this right: (1) the right of everyone to access the benefits of science without discrimination; (2) the right of everyone to have opportunities to contribute to the advancement of science, and the right to the freedom necessary to do this research; and (3) the right of individuals, communities, and peoples to participate in science-related decision making.²⁵ Importantly, non-discriminatory access to the benefits of science refers broadly to access to scientific knowledge, information, and processes (such as R&D)—in other words, access to “science as a whole, not only to specific scientific outcomes or applications.”²⁶

Following subsection (1)(b) of article 15 of the ICESCR, which recognizes the right to science, subsection (2) sets forth the corresponding obligations of the parties. Subsection (2) mandates that states take steps “necessary for the conservation, the development, and the diffusion of science and culture.”²⁷ While “conservation” involves safeguarding scientific knowledge and “diffusion”

means disseminating that knowledge, including through publishing, “development”

*demands an explicit commitment to the development of science and technology for human benefit by, for example, developing national plans of action. Usually, this implies the adoption of programmes to support and strengthen publicly funded research, to develop partnerships with private enterprises and other actors, ... and to promote freedom of scientific research.*²⁸

Finally, subsection (4) of article 15 obliges states to “recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.” Thus, the right to science also includes an international dimension that goes beyond the general requirement for “international assistance and cooperation” in article 2(1) of the ICESCR, which applies to all economic, social, and cultural rights. The UN Committee on Economic, Social and Cultural Rights, which is responsible for monitoring states’ implementation of the ICESCR, in its 2014 concluding observations to El Salvador, stated:

*The Committee urges the State party to work with neighboring countries, international bodies ... and increase scientific resources needed to carry out independent research into [chronic kidney failure] and its causes and then to use that knowledge to prevent and cure it, thereby enabling those affected to enjoy the benefits of scientific progress.*²⁹

The committee recognizes R&D as a vital element of the right to science and, therefore, obliges states to provide resources for research to understand the causes and develop treatments for diseases; to do independent research to address health issues in national contexts; and to collaborate with international bodies and other countries on this research.

To date, the Committee on Economic, Social and Cultural Rights has not released a general comment on article 15(1)(b) to elaborate more fully on the normative content and related obligations of states under the right to science. Preliminary work to inform a general comment through multi-stakeholder discussions was undertaken by the United

Nations Educational, Scientific and Cultural Organization (culminating in the 2009 Venice Statement) and the Office of the United Nations High Commissioner for Human Rights (summarized in a report by the office in 2014).³⁰ Further, the American Association for the Advancement of Science (AAAS) actively supports the development of the right to science, including surveying the views of scientists, engineers, and health professionals on the right to science; collecting and analyzing state reporting on the right to science in states’ periodic reports to the Committee on Economic, Social and Cultural Rights; and organizing briefings for the committee to inform a general comment.³¹ Finally, several academics, most notably Audrey Chapman and Lea Shaver, have published pioneering articles to assist in unpacking the content of the right to science.³²

Drawing on these sources, we investigate state obligations under the right to science to ensure that adequate and appropriate R&D is conducted in the area of pediatric HIV treatment. To do so, we employ the Committee on Economic, Social and Cultural Rights’ typology of state obligations to respect, protect, and fulfill the entitlement relating to R&D as a component of the right to science.³³ The obligation to respect means that states must ensure that their actions, through laws and policies, are consistent (and do not interfere) with an enabling environment for R&D, while the obligation to protect means that states must prevent third parties from engaging in R&D to the detriment of human rights and protect the human rights of people participating in research activities essential to drug development. The obligation to fulfill requires states to take proactive measures, including adopting and implementing laws, policies, and programs to promote R&D in neglected areas.³⁴ This tripartite typology provides a useful starting point to analyze state obligations related to R&D as a component of the right to science.

State obligations related to R&D on pediatric HIV treatment

Obligation to respect

The obligation to respect requires first that state

laws and policies do not interfere with or create barriers to R&D on pediatric HIV treatments. At the time that the General Assembly adopted article 27 of the Universal Declaration of Human Rights (1948) and article 15 of the ICESCR (1966), science was broadly understood to be a public good from which everyone should benefit.³⁵ Since then, there have been two important changes in state governance of R&D, which have negatively affected the right to science: national laws have privatized the products of publicly funded research, and international agreements have forced this model of R&D on low- and middle-income countries.³⁶

First, starting in the 1970s, many states moved away from the public goods approach to an increasingly commercialized and profit-driven approach to R&D.³⁷ In the United States, for example, the 1980 Bayh-Dole Act allowed, for the first time, scientists in universities and the private sector to patent discoveries from publicly funded research. The subsequent proliferation of patents created a “tragedy of the anticommons” by impeding the cooperation needed for innovation, particularly in biomedical R&D.³⁸ In the case of HIV medicines for children, the current system introduces both “horizontal” patent gridlock in developing new fixed-dose combinations, as each pill contains multiple drugs often patented by different companies, and “vertical” patent gridlock in which upstream patents limit their use in downstream drug development.³⁹ As noted by the Pediatric HIV Treatment Initiative, a multi-stakeholder initiative to increase R&D for pediatric treatments, “the development of new adapted pediatric formulations requires collaboration of each patent holder to pool [intellectual property], data, and know-how.”⁴⁰ Under their obligation to respect, states have a duty to revisit these laws to ensure that they are consistent with an enabling environment for R&D and to avoid adopting laws that create barriers to R&D for pediatric HIV medicines.

Second, states must ensure that their agreements with other states, international organizations, and multinational corporations do not create barriers to R&D, particularly in areas affecting neglected populations.⁴¹ The laws governing

science and technology are increasingly globalized, introducing important concerns about their impact on international cooperation. High-income countries often push strict intellectual property and patent protections on developing countries through international agreements and organizations. For example, the World Trade Organization’s 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights and “TRIPS-Plus” provisions in bilateral and regional free trade agreements define global standards for a more commercialized approach to science.⁴² The right of states to adopt flexibilities in intellectual property to protect public health is enshrined in the 2001 Doha Declaration, but these flexibilities often do not address the more upstream limitations of privatized, for-profit R&D. As Shaver pointedly argues, “[b]y overwhelmingly promoting the privatization of knowledge, we rob individuals of opportunities to take part in cultural life and enjoy the fruits of scientific progress.”⁴³

Obligation to protect

States have an obligation to protect the rights of individuals, particularly vulnerable populations, who participate in clinical trials and other research activities conducted by third parties.⁴⁴ Protection is often ensured through accredited institutional review boards, which may be well developed in high-income countries but are less robust in resource-limited settings, where much research into neglected areas takes place. Moreover, there is actually little evidence that institutional review boards are doing their job effectively—that is, protecting human subjects—given the lack of accountability systems.⁴⁵ A 2008 report by the Center for Research on Multinational Corporations investigated numerous undisclosed harms to research participants in clinical trials conducted by US and European pharmaceutical companies, mostly in the developing world.⁴⁶ Under the obligation to protect, states need to revisit their oversight policies of third parties, particularly private industry, and work collaboratively with other states to develop complementary research protection policies that do not allow third parties to skirt their responsibilities. Children living with HIV may be especially

vulnerable in clinical research because researchers are often not from the host community.⁴⁷ To address these issues, states, alongside those in the research community (universities, nonprofits, and private industry), should promote community participation in the development of research protocols, including defining risks and benefits for children in research that meets both international and local ethical standards.⁴⁸ The obligation to protect further means that states should take effective measures to prevent and redress infringements to the enjoyment of the right to science, including the benefit of R&D.

Obligation to fulfill

The obligation to fulfill requires that states enact and implement laws and policies to support R&D.⁴⁹ According to the Venice Statement, the obligation to fulfill requires states, among other things, to

1. adopt a legal and policy framework and to establish institutions to promote the development and diffusion of science and technology in a manner consistent with fundamental human rights;
2. promote access to the benefits of science and its applications on a nondiscriminatory basis, including measures necessary to address the needs of disadvantaged and marginalized groups;
3. take measures to encourage and strengthen international cooperation and assistance in science and technology to the benefit of all people and to comply in this regard with the States' obligations under international law;
4. provide opportunities for public engagement in decision-making about science and technology and their development.⁵⁰

First, states must adopt a legal and policy framework, as well as a national plan of action, that promotes the development and diffusion of science in a manner that respects human rights. The national plan of action should include benchmarks and indicators to measure progress over time, and the state must provide the funding and other resources necessary to implement and monitor

the national R&D plan. Transparent reporting on progress is also required so people may hold their government accountable.

Second, states must ensure that their national plans are non-discriminatory and address the needs of disadvantaged and marginalized groups, particularly in areas neglected by the private sector. For neglected areas such as pediatric HIV, states must step in through both “push” (direct public funding) and “pull” (incentives to third parties to invest in key areas) mechanisms.⁵¹

Publicly funded research remains essential for drug discovery, particularly for infectious diseases.⁵² While public and philanthropic donors in high-income countries are responsible for about 40% of all health R&D funding, they are responsible for more than 80% of funding for neglected diseases.⁵³ Data on R&D expenditures in low- and middle-income countries are less accessible but suggest that R&D spending is more likely to be public, particularly in sub-Saharan Africa, where up to 70% of health R&D is funded by the public sector.⁵⁴ Since many states lack the capacity to conduct R&D or have ceded responsibility for R&D to the private sector, public funding is often directed through domestic and global product development partnerships between the public sector, academia, and private industry to target the development of technologies in specific areas.⁵⁵ For example, the Pediatric HIV Treatment Initiative was launched in 2014 as a joint initiative between Unitaid, the Drugs for Neglected Diseases Initiative, and the Medicines Patent Pool, in coordination with WHO and pharmaceutical companies. The initiative's goal is to “catalyze development of, and accelerate access to new, better-adapted pediatric [drugs] and formulations to improve treatment for all children living with HIV.”⁵⁶ Unfortunately, an analysis of government funding for R&D on neglected diseases from 2007 to 2012 shows decreasing support for product development in favor of basic research, which will lead to further delays for pipeline drugs awaiting evaluation in clinical trials.⁵⁷

States can (and *should*) use a variety of pull mechanisms to incentivize third party actors to invest in R&D in areas affecting vulnerable pop-

ulations. Pediatric patent extensions (awarded to firms that conduct pediatric studies on certain new or existing drugs) and priority review vouchers (awarded to firms that conduct R&D in high-priority areas, entitling them to speedy reviews of other pipeline products) are employed in a number of countries; however, these programs are inefficient (because the incentive is not directly tied to the innovation) and short-sighted (because they do not lead to sustained private sector R&D).⁵⁸ Moreover, generic firms that are essential to producing new fixed-dose combinations for children are often excluded from these incentive mechanisms. Laws such as the US Best Pharmaceutical for Children Act of 2002 and the Pediatric Research Equity Act of 2003 actually require drug companies (under certain circumstances) to study their products in children. These acts have led to increases in pediatric clinical trials, but loopholes allow companies to delay conducting these studies, and their drugs are often not targeting neglected groups of children, such as those living with HIV.⁵⁹ Patent pools are another potential tool to encourage R&D in neglected areas, and states should consider policies to incentivize companies to join them.⁶⁰ The Medicines Patent Pool, a UN-backed multi-stakeholder initiative funded by Unitaid, works in part by partnering with pharmaceutical companies to license patented drugs for generic production and promote R&D on new child-specific HIV formulations. Finally, various prize-based approaches have been proposed whereby companies receive awards from the state, monetary or otherwise, on par with a desirable outcome that their innovation achieves (for example, lives saved).⁶¹ States need to decide which of these policies (among others) are most appropriate for them, but the right to science mandates that states adopt a legal and policy framework that both pushes public funds and pulls private industry to ensure that R&D is conducted on a non-discriminatory basis and addresses the needs of vulnerable populations.

Third, states are required to encourage and strengthen international cooperation and assistance as an essential component of the right to science. This includes providing direct bilateral and

multilateral aid, supporting international organizations, and promoting technology transfers. Despite unprecedented international assistance, funding for HIV will remain far below the estimated US\$36 billion needed annually to achieve Target 3.3 of the Sustainable Development Goals, which seeks to end the AIDS epidemic by 2030.⁶² Moreover, international assistance is often ad hoc and does not necessarily address developing countries' needs nor support the development of domestic R&D capacity.⁶³ In 2012, WHO's Consultative Expert Working Group on Research and Development highlighted the ongoing needs of developing countries both for new medicines, vaccines, and diagnostics, and for new and innovative sources of international aid. The group's principal recommendation was that all states should commit to spend at least 0.01% of their GDPs on government-funded R&D to meet the health needs of developing countries.⁶⁴ These commitments could be pursued through a global binding instrument (such as an international convention on cooperation for R&D) or mandatory minimum financial contributions.⁶⁵ The right to science contributes to the human rights grounds for such a treaty and should inform its content.

Innovative global public financing mechanisms offer potential alternatives to traditional bilateral and multilateral aid.⁶⁶ For example, Unitaid, established in 2006, is an initiative by Brazil, Chile, France, Norway, and the United Kingdom to fund underserved health product markets, including pediatric HIV treatment, through a levy on airline tickets. Between 2007 and 2014, Unitaid raised US\$2.4 billion, which assists in funding pediatric HIV R&D through patent pools, direct negotiations, and product development with partner organizations and pharmaceutical companies.⁶⁷ States' support for initiatives such as Unitaid has been cited by the UN Special Rapporteur as consistent with the obligations under the right to science requiring international cooperation that targets the needs of disadvantaged groups, such as children living with HIV.⁶⁸

In addition to financial assistance, the obligation to strengthen international cooperation requires that states enhance collaboration on R&D

activities, particularly in neglected areas. Cooperation through transfers of scientific knowledge, processes, and applications (often referred to broadly as “technology transfer”) from high-income countries to low-income ones is consistent with this obligation and reflects a commitment by states made in the Sustainable Development Goals.⁶⁹ Many low-income countries have some R&D capacity both in the public and private sectors, including for pediatric HIV medicines, but these sectors are underdeveloped and face stiff competition from high-income and some middle-income countries.⁷⁰ The case of South Africa illustrates how a rights-based commitment to universal HIV treatment can inform regulatory and investment policies to develop domestic pharmaceutical capacity through tax relief, investment credits, and technology transfers with international partners.⁷¹ As international commitments for technology transfer develop, greater consideration of the human rights dimensions of these policies and their impact on R&D for diseases affecting vulnerable populations is needed.

Finally, states are required to support the participation of everyone, particularly vulnerable communities, in science-related decision making to ensure that R&D addresses their priority needs. Shaheed explains, “major decisions regarding funding and research priorities, science policies, emerging areas of research, and new technological applications should entail a participatory process.”⁷² In other words, participation goes beyond enrollment in clinical trials and should be an empowering process for communities.⁷³ States must create public forums and proactively ensure the participation of disadvantaged groups when discussing and deciding on R&D priority setting and public funding. Further attention must be paid to children’s participation in these processes, as their rights to seek and impart information and to freely express their views in all matters affecting them is guaranteed under the Convention on the Rights of the Child.⁷⁴ Under the obligation to fulfill, states should ensure that children, their families, and affected communities have a voice in this research, as well as in access to its benefits.⁷⁵

Recommendations

Under the right to science, states have obligations to respect, protect, and fulfill. In the context of R&D on pediatric HIV and other neglected areas, these obligations include shifting the pendulum back toward a public goods approach to R&D both domestically and in agreements with other states to ensure that R&D addresses the priority health needs of the population, including marginalized groups; protecting the human rights of individuals involved in research; adopting a legal and policy framework to support R&D through push and pull mechanisms; strengthening international cooperation and assistance for R&D; and ensuring the participation of marginalized communities in decision-making processes. To further develop the right to science so that more specific obligations are developed to support R&D in neglected areas, we have five key recommendations.

First, the Committee on Economic, Social and Cultural Rights should urgently elaborate the normative content of the right to science and states’ minimum core obligations in a general comment.⁷⁶ To assist the committee, the Human Rights Council should request that the Office of the United Nations High Commissioner for Human Rights convene another seminar (the first was held in 2013) so that states, the Special Rapporteur, and other relevant stakeholders can reach a consensus on its normative content and the obligations of states, providing a basis for the general comment.⁷⁷ Additionally, authoritative bodies in the public health arena should voice their support for developing and subsequently implementing the specific obligations under the right to science. For example, key international organizations working on HIV, health, and access to medicines—such as UNAIDS and the United Nations Development Programme—should play a stronger role in forums and debates on the right to science. WHO has been involved in these forums but thus far has not incorporated the right to science in recent reports on global health R&D. For example, WHO’s 2012 report *Research and Development to Meet Health Needs in Developing Countries* frequently references the right to health to bolster its arguments but does not mention the

right to science.⁷⁸ However, a 2016 report of the UN High-Level Panel on Access to Medicines refers several times to the right to science, suggesting that this right might be gaining greater awareness in public health circles.⁷⁹

Second, authoritative bodies and scholars should clarify the overlap of the right to science with other human rights.⁸⁰ Former UN Special Rapporteur on the right to health Paul Hunt has cited the right to science as both potentially overlapping and complementary to the right to health in protecting the rights of people living with neglected diseases.⁸¹ In a recent article exploring the rights to science and health in the context of multidrug-resistant tuberculosis, Leslie London and colleagues argue that while the right to health requires access to essential drugs, the right to science “can potentially take this further and suggest that essential drugs need to be ‘created’ through scientific research and development in addition to being made accessible.”⁸² Still, as Yvonne Donders points out, the normative content and obligations of states under the right to science in relation to health-related R&D are vague, which undermines its potential to be employed alongside the right to health.⁸³ Additionally, while children have special status in human rights law, the Convention on the Rights of the Child does not specifically mention a child’s right to science; however, a general comment of the Committee on the Rights of the Child cites children’s right to “drugs [that] are scientifically approved ... [and] child-specific (when necessary)” and encourages states to allow children to participate and express their views, according to age and maturity, on matters regarding health, including research.⁸⁴

Third, states must monitor their implementation of the right to science and report to the Committee on Economic, Social and Cultural Rights and other human rights mechanisms on their progress and achievements. Standard reporting efforts are critical for developing implementation and monitoring frameworks that include indicators on the right to science.⁸⁵ These reports should specifically refer to a right-to-science “national plan of action with a timetable and goals to rectify existing inadequacies and a monitoring strategy to evaluate

the extent to which these milestones are being realized.”⁸⁶ Amrei Müller argues that “the reporting process before the [Committee on Economic, Social and Cultural Rights] could become a catalyst through which, first, the obligations set out in the Venice Statement can be tested and clarified; and second, the priorities for their implementation in different countries and contexts can be identified.”⁸⁷ Indeed, the committee has repeatedly requested that states include more information on the implementation of the right to science in their periodic reports.⁸⁸

Fourth, members of civil society—including adults and young people living with HIV, human rights activists, professional associations of scientists, and medical researchers—should ramp up efforts to educate government officials and the public on the spirit of the right to science and on commitments made in recognizing this right. As noted earlier, the AAAS has been a leader in this area through its Science and Human Rights Coalition, which organized a two-day meeting on the right to science in July 2017 involving human rights scholars, public health experts, and representatives from the Committee on Economic, Social and Cultural Rights.⁸⁹ AAAS’ Article 15 Project has compiled a database of state reports on implementing article 15 of the ICESCR and exemplar cases to illustrate different aspects of the right to science in practice.⁹⁰ Civil society efforts to monitor states’ investment in R&D can also help, particularly in supporting accountability mechanisms. For example, the Global Funding of Innovation for Neglected Diseases tracks global R&D funding and investments for 35 neglected diseases from public, private, and philanthropic sources.⁹¹ These data now support the recently launched Global Observatory on Health R&D housed at WHO, whose goal is to monitor, benchmark, and create standardized indicators for global health R&D.⁹²

Fifth, states and international organizations should further engage with non-state actors, particularly private industry, to develop cooperative approaches to meeting obligations under the right to science for more equitable R&D. Hunt’s pioneering work *Human Rights Guidelines for Pharmaceuti-*

cal Companies argues that these companies have human rights-based responsibilities to “in-house research and development for neglected diseases, or support [of] external research and development for neglected diseases, or both.”⁹³ As we have shown, there are several examples of multi-stakeholder models, including those involving pharmaceutical companies and other non-state actors, that are consistent with human rights principles; however, these efforts are underfunded and insufficient to meet the needs of the vast majority of poorer and marginalized populations throughout the world.

Finally, important shifts have also occurred in how scientific research is disseminated and who has access to it. Scientific publishing houses often require expensive subscription fees that create barriers to the flow of scientific information, and these thus deserve human rights scrutiny.⁹⁴ The “open access movement” driven by a loose coalition of civil society organizations and initiatives, with the support of some states, has recently made positive steps in pushing states to adopt open access policies consistent with the right to the benefits of science while respecting authors’ rights to protect their material and moral interests.⁹⁵

Conclusion

The right to science obliges states to adopt legal and policy frameworks that enable and promote R&D in a manner consistent with fundamental human rights. This makes the right to science a potentially powerful tool for human rights practitioners and activists working to protect the rights of children living with HIV and for people all over the world suffering from neglected diseases. The fact that we are in the fourth decade of the HIV epidemic yet lack sufficient treatments for children powerfully illustrates the profound inadequacies of the current approach to advancing medical science. It also raises the core equity question of *cui bono?*, or who benefits from science? Increased and sustained engagement by the human rights community is necessary to address these inadequacies—inadequacies which can, in part, be rectified through the development and implementation of the right to science.

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References

1. UNAIDS, *Children and HIV fact sheet* (Geneva: UNAIDS, 2016). Available at http://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf.
2. UNICEF, *Children and AIDS* (New York: UNICEF, 2016). Available at http://childrenandaids.org/sites/default/files/Stats_Exec_Summary_IAS_July_2016.pdf.
3. P. Piot, S. Karim, R. Hecht, et al., “Defeating AIDS—advancing global health,” *Lancet* 386/9989 (2015), pp. 171–218.
4. M. Davies and J. Pinto, “Targeting 90-90-90: Don’t leave children and adolescents behind,” *Journal of the International AIDS Society* 18/Suppl 6 (2015), p. 20745.
5. M. Lallemand, S. Chang, R. Cohen, and B. Pecoul, “Pediatric HIV: A neglected disease?” *New England Journal of Medicine* 365 (2011), pp. 581–583.
6. M. Heywood, “South Africa’s Treatment Action Campaign: Combining law and social mobilization to realize the right to health,” *Journal of Human Rights Practice* 1/1 (2009), pp. 14–36.
7. A. Chapman and J. Wyndham, “A human right to science,” *Science* 340 (2013), p. 1291.
8. M. Penazzato, “Themed discussion: New drugs for kids: what’s taking so long?” (presentation at the Conference on Retroviruses and Opportunist Infections, Boston, MA, February 22–25, 2016).
9. UNAIDS (see note 1).
10. M. Newell, H. Coovadia, M. Cortina-Borja, et al., “Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis,” *Lancet* 364/9441 (2004), pp. 1236–1243.
11. R. Boerma, T. Boender, A. Bussink, et al., “Suboptimal viral suppression rates among HIV-infected children in low- and middle-income countries: A meta-analysis,” *Clinical Infectious Diseases* 63/12 (2016), pp. 1645–1654; L. Muri, A. Garmell, A. Ntamatungiro, et al., “Development of HIV drug resistance and therapeutic failure in children and adolescents in rural Tanzania: An emerging public health concern,” *AIDS* 31/1 (2017), pp. 61–70.
12. A. Schlatter, A. Deathe, and R. Vreeman, “The need for pediatric formulations to treat children with HIV,” *AIDS Research and Treatment* 2016/1654938 (2016), pp. 1–8.
13. *Ibid.*
14. M. Cotton, S. Holgate, A. Nelson, et al., “The last and first frontier: Emerging challenges for HIV treatment

and prevention in the first week of life with emphasis on premature and low birth weight infants,” *Journal of the International AIDS Society* 18/Suppl 6 (2015), p. 20271.

15. R. Hazra, G. Siberry, and L. Mofenson, “Growing up with HIV: Children, adolescents, and young adults with perinatally acquired HIV infection,” *Annual Review of Medicine* 61 (2010), pp. 169–185.

16. M. Penazzato, J. Lee, E. Capparelli, et al., “Optimizing drugs to reach treatment targets for children and adolescents living with HIV,” *Journal of the International AIDS Society* 18/Suppl 6 (2015), p. 20270.

17. P. Clayden, “The pediatric antiretroviral pipeline,” in P. Clayden, S. Collins, M. Frick, et al., *2016 pipeline report* (New York: HIV i-Base/Treatment Action Group, 2016), pp. 63–81.

18. Penazzato (see note 8).

19. Arab Charter on Human Rights (2004), art. 42; Additional Protocol to the American Convention on Human Rights in Area of Economic, Social and Cultural Rights, OAS Treaty Series No. 69 (1988), art. 14.

20. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, European Treaty Series No. 164 (1997), preamble.

21. African Commission on Human and People’s Rights, General Comment No. 2 on Article 14.1(a), (b), (c) and (f) and Article 14.2(a) and (c) of the Protocol to the African Charter on Human and People’s Rights on the Rights of Women in Africa, (2014), para. 33.

22. A. Chapman, *Global health, human rights and the challenges of neoliberal policies* (Cambridge: Cambridge University Press, 2016), p. 3.

23. United Nations Treaty Collection, *Chapter IV: Human Rights, International Covenant on Economic, Social and Cultural Rights*. Available at https://treaties.un.org/PAGES/ViewDetails.aspx?src=TREATY&mtsg_no=IV-3&chapter=4&clang=_en.

24. International Covenant on Economic, Social and Cultural Rights (ICESCR), G.A. Res. 2200A (XXI) (1966), art. 15(1)(b).

25. F. Shaheed, Report of the Special Rapporteur in the field of cultural rights, UN Doc. A/HRC/20/26 (2012), para. 25.

26. *Ibid.*, para. 26.

27. ICESCR (see note 24), art. 15(2).

28. Shaheed (see note 25), para. 47.

29. Committee on Economic, Social and Cultural Rights, Concluding observations on the combined third, fourth and fifth periodic reports of El Salvador, UN Doc. E/C.12/SLV/CO/3-5 (2014), para. 28.

30. UNESCO, *Venice Statement on the right to enjoy the benefits of scientific progress and its applications* (Geneva: UNESCO, 2014); Human Rights Council, Report of the United Nations High Commissioner for Human Rights, Report on the seminar on the right to enjoy the benefits

of scientific progress and its applications, UN Doc. A/HRC/26/19 (2014).

31. American Association for the Advancement of Science (AAAS), *Defining the right to enjoy the benefits of scientific progress and its applications: American scientists’ perspectives* (Washington, DC: AAAS, 2013); J. Wyndham, M. Vitullo, K. Kraska, et al., *Giving meaning to the right to science: A global and multidisciplinary approach* (Washington, DC: AAAS, 2017).

32. A. Chapman, “Towards an understanding of the right to enjoy the benefits of scientific progress and its applications,” *Journal of Human Rights* 8/1 (2009), pp. 1–36; L. Shaver, “The right to science and culture,” *Wisconsin Law Review* 1 (2010), p. 128; see also Y. Donders, “The right to enjoy the benefits of scientific progress: In search of state obligations in relation to health,” *Medicine, Health Care and Philosophy* 14/4 (2011), pp. 371–381.

33. See, for example, Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health, UN Doc. E/C.12.2/200/4 (2000), paras. 34–37.

34. UNESCO (see note 30), paras. 14–16.

35. Chapman (see note 32), p. 8.

36. *Ibid.*

37. *Ibid.* See also Shaver (see note 32), pp. 131–133.

38. M. Heller and R. Eisenberg, “Can patents deter innovation? The anticommens in biomedical research,” *Science* 280/5364 (1998), pp. 698–701; J. Lexchin, “One step forward, one step sideways? Expanding research capacity for neglected diseases,” *BMC International Health and Human Rights* 10/20 (2010), pp. 1–10.

39. M. Mattioli, “Communities of innovation,” *Northwestern University Law Review* 106/1 (2012), pp. 103–156.

40. Pediatric HIV Treatment Initiative, *Closing the treatment gap through innovation* (Geneva: Unitaid, 2014), p. 4.

41. O. De Schutter, Report of the Special Rapporteur on the right to food: Guiding principles on human rights impact assessments of trade and investment agreements, UN Doc. A/HRC/19/59/Add.5 (2011), Addendum, para. 1.1; see also Committee on Economic, Social and Cultural Rights, General Comment No. 14 (see note 33), para. 50.

42. R. Lopert and D. Gleeson, “The high price of ‘free’ trade: US trade agreements and access to medicines,” *Journal of Law, Medicine and Ethics* 41/1 (2013), pp. 199–223.

43. Shaver (see note 32), p. 163.

44. UNESCO (see note 30), para. 15.

45. C. Coleman and M. Bouësseau, “How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review,” *BMC Medical Ethics* 9/6 (2008), pp. 1–7

46. F. Weyzig and I. Schnipper, *SOMO briefing paper on ethics in clinical trials: Examples of unethical trials* (Amsterdam: Centre for Research on Multinational Corporations, 2008).

47. M. Angell, "The ethics of clinical research in the Third World," *New England Journal of Medicine* 337/12 (1997), pp. 847-849.
48. R. Dal-Ré, P. Ndebele, E. Higgs, et al., "Protections for clinical trials in low and middle income countries need strengthening not weakening," *British Medical Journal* 349 (2014), p. 4254; R. Vreeman, E. Kamaara, A. Kamananda, et al., "Community perspectives on research consent involving vulnerable children in western Kenya," *Journal of Empirical Research on Human Research Ethics* 7/4 (2012), pp. 44-55.
49. Shaheed (see note 25), paras. 33, 70-73.
50. UNESCO (see note 30), para. 16.
51. F. Mueller-Langer, "Neglected infectious diseases: Are push and pull incentive mechanisms suitable for promoting drug development research?" *Health Economics, Policy and Law* 8/2 (2013), pp. 185-208.
52. A. Stevens, J. Jensen, K. Wyller, et al., "The role of public-sector research in the discovery of drugs and vaccines," *New England Journal of Medicine* 364 (2011), pp. 535-541.
53. R. Viergever, "The mismatch between the health research and development (R&D) that is needed and the R&D that is undertaken: an overview of the problem, the causes, and solutions," *Global Health Action* 6 (2013), p. 22450.
54. D. Kebede, C. Zielinski, P. Mbondji, et al., "Expenditures on health research in sub-Saharan African countries: results of a questionnaire-based survey," *Journal of the Royal Society of Medicine* 107/Suppl 1 (2014), pp. 77-84.
55. Mueller-Lander (see note 51).
56. Pediatric HIV Treatment Initiative (see note 40).
57. G-FINDER, *Government funding for neglected diseases: Why it doesn't add up* (Sydney: Policy Cures and G-FINDER, 2014).
58. K. Hoppu, G. Anabwani, F. Garcia-Bournissen, et al., "The status of paediatric medicines initiatives around the world: What has happened and what has not?" *European Journal of Clinical Pharmacology* 68/1 (2012), pp. 1-10; A. Kesselheim, "Drug development for neglected diseases: The trouble with FDA review vouchers," *New England Journal of Medicine* 359 (2008), pp. 1981-1983.
59. L. Jerles, "The Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act: Helping or hurting American's children?" *Cardoza Public Law, Policy and Ethics Journal* 6 (2008), pp. 515-545.
60. Shaheed (see note 25), para. 74(l).
61. J. Love and T. Hubbard, "The big idea: Prizes to stimulate R&D for new medicines," *Chicago-Kent Law Review* 82/3 (2007), pp. 1519-1554.
62. P. Piot, S. Karim, R. Hecht, et al., "Defeating AIDS-advancing global health," *Lancet* 386/9989 (2015), pp. 171-218.
63. Viergever, R., "Aid alignment for global health research: The role of HIROs," *Health Research Policy and Systems* 9/12 (2011), pp. 1-3.
64. Consultative Expert Working Group on Research and Development, *Research and development to meet health needs in developing countries: Strengthening global financing and coordination* (Geneva: WHO, April 2012).
65. S. Moon, J. Bermudez, and E. 't Hoen, "Innovation and access to medicines for neglected populations: Could a treaty address a broken pharmaceutical R&D system?" *PLoS Medicine* 9/5 (2012), p. e1001218; J-A Røttingen, C. Chamas, L. Goyal, et al., "Securing the public good of health research and development for developing countries," *Bulletin of the World Health Organization* 90/5 (2012), pp. 398-400.
66. D. Gartner, "Innovative financing and sustainable development: lessons from global health," *Washington International Law Journal* 23/3 (2015), pp. 495-515.
67. Unitaid, *Audited financial report* (Geneva: Unitaid, 2014); Unitaid, *Paediatric HIV/AIDS project*. Available at <http://www.unitaid.eu/en/paediatrics>.
68. Shaheed (see note 25), paras. 35, 62.
69. Ibid., para. 74(k); UN, *Sustainable Development Goals*. Available at <https://sustainabledevelopment.un.org/sdgs>.
70. E. Santos Pinheiro, K. Brüning, M. Macedo, and A. Siani, "Production of antiretroviral drugs in middle- and low-income countries," *Antiviral Therapy* 19/6 (2014), pp. 49-55; M. Mackintosh, G. Banda, P. Tibandebage, and W. Wamae (eds), *Making medicines in Africa* (London: Palgrave Macmillan, 2016).
71. C. Sprague and S. Woolman, "Moral luck: Exploiting South Africa's policy environment to produce a domestic supply of antiretroviral medicine for a sustainable national antiretroviral treatment programme," *South African Journal of Human Rights* 22 (2006), pp. 337-379.
72. Shaheed (see note 25), para. 43.
73. L. Swartz and A. Kagee, "Community participation in AIDS vaccine trials: empowerment or science?" *Social Science & Medicine* 63/5 (2006), pp. 1143-1146.
74. Convention on the Rights of the Child, G.A. Res. 44/25 (1989), arts. 12-13.
75. B. Meier, A. Gelpi, M. Kavanagh, L. Forman, J. Amon, "Employing human rights frameworks to realize access to an HIV cure," *Journal of the International AIDS Society* 18/1 (2015), p. 20305.
76. Shaheed (see note 25), para. 75(b).
77. Human Rights Council (see note 30).
78. Consultative Expert Working Group on Research and Development (see note 64).
79. UN Secretary General's High-Level Panel on Access to Medicines, *Promoting innovation and access to health technologies* (Geneva: UN, 2016).
80. See, for example, O. De Schutter, "The right of everyone to enjoy the benefits of scientific progress and the right to food: From conflict to complementarity," *Human Rights*

Quarterly 33/2 (2011), pp. 304–350.

81. P. Hunt, *Neglected diseases: A human rights analysis* (Geneva: WHO, 2007), p. 38.

82. L. London, H. Cox, and F. Coomans, “Multidrug-resistant TB: Implementing the right to health through the right to enjoy the benefits of scientific progress,” *Health and Human Rights Journal* 18/1 (2016), pp. 25–41.

83. Donders (see note 32).

84. Committee on the Rights of the Child, General Comment No. 15, The Right of the Child to the Enjoyment of the Highest Attainable Standard of Health (Art. 24), UN Doc. CRC/C/GC/15 (2013), paras. 19, 116.

85. A. Chapman, “Development of indicators for economic, social and cultural rights: The rights to education, participation in cultural life and access to the benefits of science,” in Y. Donders and V. Volodin (eds), *Human rights in education, science and culture: Legal developments and challenges* (Aldershot: Ashgate, 2007), pp. 111–152.

86. Chapman (see note 32), p. 25.

87. A. Müller, “Remarks on the Venice Statement on the right to enjoy the benefits of scientific progress and its applications (Article 15(1)(b) ICESCR),” *Human Rights Law Review* 10/4 (2010), pp. 765–784.

88. See, for example, Committee on Economic, Social and Cultural Rights, Consideration of reports submitted by States parties under articles 16 and 17 of the Covenant, UN Doc. E/C.12/ARG/CO/3 (2011), para. 25.

89. AAAS Science and Human Rights Coalition Meeting, Agenda, July 27–28, 2017 (Washington, DC: AAAS, 2017). Available at https://mcmprodaaas.s3.amazonaws.com/s3fs-public/content_files/July%20Meeting%20Agenda_Final_o.pdf.

90. American Association for the Advancement of Science, *Article 15 Project: Human Right to Science*. Available at <https://www.aaas.org/page/science-human-right-article-15>.

91. M. Moran, J. Guzman, K. Henderson, et al, *Neglected disease research and development: A five-year review* (Sydney: Policy Cures and G-FINDER, 2012).

92. R. Terry, J. Salm Jr., C. Nannei, and C. Dye, “Creating a global observatory for health R&D,” *Science* 345/6202 (2014), pp. 1302–1304.

93. P. Hunt, Human rights guidelines for pharmaceutical companies in relation to access to medicines, Report of the Special Rapporteur on the right to health, UN Doc. A/63/263 (2008), paras. 23–25.

94. G. Yamey, “Excluding the poor from accessing biomedical literature: A rights violation that impedes global health,” *Health and Human Rights Journal* 10/1 (2008), pp. 21–42.

95. A. Skre and A. Eide, “The human right to benefit from advances in science and promotion of openly accessible publications,” *Nordic Journal of Human Rights* 31/3 (2013), pp. 427–453.

