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## HIV testing and human rights: the right to the right test

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In September, 2015, Stefano Vella published an important commentary in *The Lancet HIV* on addressing barriers to end the HIV epidemic by 2030.<sup>1</sup> An additional barrier that needs to be addressed is to ensure the quality of HIV diagnostic testing as programmes are scaled up. About 150 million children and adults in 129 low-income and middle-income countries reportedly received HIV testing services in 2014.<sup>2</sup> Optimistically assuming a 1% error rate (ie, 99% accuracy), a large number of individuals could be wrongly initiated on (ART) as we enter the test-and-treat era while others who need therapy would not receive it. In fact, although diagnostic tests have high sensitivity and specificity, some studies have reported misdiagnosis rates of 2·6–4·8% that occur in HIV testing programme settings.<sup>3,4</sup>

Almost 20 years ago, in 1998, the Office of the High Commissioner for Human Rights (OHCHR) and the Joint UN Programme on HIV/AIDS (UNAIDS) issued the International Guidelines on HIV/AIDS and Human Rights.<sup>5</sup> The guidelines emphasised the need for countries to take steps to protect human rights in the context of HIV/AIDS. The epidemic is ever evolving at a rapid pace, and much has happened since the guidelines were adopted: at the time, fewer than 50 000 people with HIV were receiving life-saving ART in developing countries, now more than 17 million are estimated to be on treatment.<sup>6</sup> As the global community responds to the prospects of ending the HIV/AIDS epidemic by 2030, UNAIDS has set an ambitious target of 90% of infected individuals being diagnosed, 90% of those being on ART, and 90% of those achieving viral load suppression by 2020.<sup>7</sup>

The rights to accurate diagnostics have received little attention. The international guidelines<sup>5</sup> urge countries to regulate the quality of HIV testing, to guarantee the quality assurance and control of HIV-related products, to ensure that diagnostics and related technologies are safe and effective through legislative or other measures, and to enact laws or regulations that ensure quality and accuracy of HIV counselling and testing.

Very few countries, especially developing countries, have enacted laws or regulations to ensure the quality of HIV testing. However, the urgent need for access to accurate and reliable HIV test results is beginning to be recognised at a regional level. In a historic move, in October, 2014, 16 Caribbean countries issued a call to action to make the quality of HIV testing a human right entitlement;<sup>8</sup> and in July 2015, member states in the southeast Asia and the western Pacific regions, in collaboration with WHO and partners, at a meeting

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in Cambodia, issued the Phnom Penh Statement on improving the quality of HIV-related diagnostics in the Asia-Pacific, linking access to accurate diagnostics a human rights issue.<sup>9</sup> Achieving the first 90 of the 90–90–90 goals will require that HIV testing is scaled up substantially. As such, ensuring that documents and commitments like the Caribbean call to action and the Phnom Penh Statement are fully implemented will be crucial as HIV testing is scaled up.

Accurate and reliable HIV test results are essential to initiating life-saving ART. Misdiagnosis of individuals as either HIV positive or negative has huge consequences:<sup>10</sup> violence, psychosocial strains, disruption in family settings, undermining of treatment programmes, unnecessary initiation of ART, ongoing transmission potential of HIV for false-negative people, and a missed opportunity to initiate ART.

In implementing the various calls to action or statements on quality-assured HIV testing, countries could enact laws and regulations on testing with a comprehensive approach as outlined in the recently published *WHO Handbook on Ensuring the Accuracy and Reliability of HIV-related Point of Care Testing*.<sup>11</sup> Key features of such laws and regulations could include establishing or updating policies to ensure quality-assured HIV testing; committing resources and empowering national public health or reference laboratories to enforce the regulations; supporting surveillance of test kits before and after their approval; requiring testers and testing sites to be certified, particularly since task sharing has diversified the testing workforce, adopting innovative approaches to ensure coverage and uptake of quality assurance materials, and taking timely corrective actions. As donors and partners work with developing countries to achieve the 90–90–90 goals, support of states to implement regulations for quality-assured HIV testing is of crucial importance. Countries, donors, and partners must continue to find ways to operationalise commitments of the call to actions and statements to ensure that quality-assured HIV test results are issued to patients as we strive to end the epidemic. Along that line, in March 2016, WHO and other key stakeholders, hosted a meeting on *The social, public health, human rights, ethical, and legal implications of the misdiagnosis of HIV status* in Geneva that highlighted reports and implications of HIV misdiagnosis and ways to improve accuracy of HIV testing.<sup>12</sup>

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