

Desperately seeking targets: the ethics of routine HIV testing in low-income countries

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Abstract The human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) pandemic, and responses to it, have exposed clear political, social and economic inequities between and within nations. The most striking manifestations of this inequity is access to AIDS treatment. In affluent nations, antiretroviral treatment is becoming the standard of care for those with AIDS, while the same treatment is currently only available for a privileged few in most resource-poor countries. Patients without sufficient financial and social capital — i.e., most people with AIDS — die each day by the thousands. Recent AIDS treatment initiatives such as the UNAIDS and WHO “3 by 5” programme aim to rectify this symptom of global injustice. However, the success of these initiatives depends on the identification of people in need of treatment through a rapid and massive scale-up of HIV testing. In this paper, we briefly explore key ethical challenges raised by the acceleration of HIV testing in resource-poor countries, focusing on the 2004 policy of routine (“opt-out”) HIV testing recommended by UNAIDS and WHO. We suggest that in settings marked by poverty, weak health-care and civil society infrastructures, gender inequalities, and persistent stigmatization of people with HIV/AIDS, opt-out HIV-testing policies may become disconnected from the human rights ideals that first motivated calls for universal access to AIDS treatment. We leave open the ethical question of whether opt-out policies should be implemented, but we recommend that whenever routine HIV-testing policies are introduced in resource-poor countries, that their effect on individuals and communities should be the subject of empirical research, human-rights monitoring and ethical scrutiny.

Keywords HIV infections/diagnosis; Acquired immunodeficiency syndrome/diagnosis; Ethics, Medical; Human rights; Informed consent; Developing countries; Botswana (*source: MeSH, NLM*).

Mots clés Infection à VIH/diagnostic; SIDA/diagnostic; Ethique médicale; Droits homme; Consentement éclairé; Pays en développement; Botswana (*source: MeSH, INSERM*).

Palabras clave Infecciones por VIH/diagnóstico; Síndrome de inmunodeficiencia adquirida/diagnóstico; Ética médica; Derechos humanos; Consentimiento consciente; Países en desarrollo; Botswana (*fuentes: DeCS, BIREME*).

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Voir page 55 le résumé en français. En la página 56 figura un resumen en español.

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Introduction

Only a few years ago, the question “should AIDS treatment programmes be implemented in low-income countries?” was a matter of heated debate among AIDS activists, health economists, bio-ethicists, and epidemiologists. Recent initiatives such as the WHO and UNAIDS “3 by 5” programme have addressed this issue, only to replace it with a daunting new question: how can the ambitious and costly global AIDS treatment programmes be implemented in ways that

are swift, affordable, feasible, efficient and ethically sound in the resource-poor countries most burdened by HIV/AIDS? While there seems to be consensus on the egalitarian goal of “treatment access for all”, strong disagreement remains about how best to achieve it.

One key area of dispute concerns policies on HIV testing. Testing is increasingly viewed as the “critical gateway” to HIV treatment and prevention.¹ For more patients to receive treatment, more people must be tested for HIV: very many more. To meet the 3 by 5 target,

according to one estimate, 5000 people would have to commence treatment every day from the time of the XV International AIDS Conference in Bangkok in July 2004 to the end of 2005. If we assume a 10% HIV prevalence, and assume that 10% of those who test positive will be in need of treatment, 500 000 patients will have to be tested each day to meet the 3 by 5 goal.² Looking beyond 2005, WHO has estimated that up to 180 million people will be in need of HIV testing and counselling every year.³

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To sharply increase the number of people being tested for HIV, a departure from the traditional voluntary counseling and testing (VCT) model would be required. As the name suggests, VCT involves people self-presenting for testing at their local medical facilities if they believe they have been exposed to HIV. Poor uptake of VCT, despite decades of AIDS education campaigns, is reflected in estimates that the vast majority (>90%) of HIV-positive people in low-income countries do not know they are infected.⁴ The successful meeting of treatment targets will require not only more aggressive testing than VCT, but also other preconditions of successful testing scale-up, such as availability of affordable testing kits and competent health-care staff.⁵

The Botswanan example

With one of the world's highest HIV/AIDS burdens — HIV prevalence in pregnant women stands at 35–37% — Botswana has been at the forefront of reforms to HIV-testing policy in the developing world in the past two years. On 13 September 2003, 70 participants from legal, medical, academic and civil society backgrounds met in Gaborone to discuss the advantages and disadvantages of changing Botswana's national HIV-testing policy from VCT to one of routine (or "opt-out") testing.⁶ With routine testing, all patients in a clinical setting are informed that they will be tested for HIV unless they explicitly refuse. Discussions about routine testing revolved around the tension between the protection of human rights and the pursuit of public health goals, and the consideration of potential benefits and risks for individuals and populations.

Speakers at the meeting stressed the benefits of HIV testing. For example, timely diagnosis of HIV infection can allow access to important treatment opportunities including antiretrovirals, multivitamins, treatment for opportunistic infections or longitudinal care. Horizontal HIV transmission can be prevented through knowledge of HIV status and behaviour change, and vertical HIV transmission can be reduced through screening and subsequent interventions with HIV-positive pregnant women. Furthermore, HIV/AIDS awareness and risk reduction may result in those who test HIV-negative.

Despite these important potential benefits, the meeting reached the consensus that compulsory HIV testing, even in a high-prevalence country like Botswana, is ethically unacceptable. However, in weighing up the perceived risks and benefits, the discussion group concluded that routine testing for HIV/AIDS in the context of an overwhelming public health emergency is ethically defensible on the condition that individual rights are protected and negative consequences of being tested (and found HIV-positive) are minimized by appropriate social and institutional support services.

The Gaborone meeting transformed Botswana's national HIV-testing policy. By January 2004, to increase use of free national "Prevention of mother-to-child transmission (PMTCT) programmes and antiretroviral treatment programmes, the Botswana Government began routine, opt-out HIV testing in antenatal and other health-care settings.

Promoting health and protecting rights

But the ethical calculus from the Gaborone meeting had a wider effect, as similar changes to HIV-testing policy soon followed on an international level. By June 2004, WHO released a similar policy (Box 1), recommending the use of routine HIV testing in certain circumstances and for certain reasons.

According to WHO, routine HIV testing is justified in these circumscribed situations on clinical and public health grounds. But the policy clearly states that these uses of routine testing are only *ethically* legitimate under the conditions shown in Appendix 1 ("Ensuring a rights based approach") of the WHO/UNAIDS HIV-testing policy, crafted by the new UNAIDS Global Reference Group on HIV/AIDS and Human Rights (reproduced in Box 2).

Like the Botswana policy, the UNAIDS/WHO policy clearly aims to produce a win-win situation in which governments can more aggressively pursue public health goals without compromising the rights of individuals. But the difficulties and complexities associated with a genuine consideration of human rights, particularly in resource-poor countries, are often downplayed by advocates of the new routine testing policies.

Ethical obstacles

Take, for example, the key idea that voluntariness must be central to all HIV policies. Some advocates suggest this condition is fulfilled simply by offering the patient the right to refuse: "... informed right of refusal or [the] opt-out approach ... balances autonomy with usual medical practice and meets ethical standards of informed consent".⁸ However, refusing to be tested (opting out) is ethically equivalent to affirmative consent (opting in) only if the refusal is adequately informed and if the patient has sufficient liberty to say no. However, in discussions about the ethics of biomedical research in the developing world, the quality of the informational and volitional elements of informed consent has been repeatedly questioned over the past decade.^{9,10} Uncertainty remains about whether (and to what extent) consent in resource-poor nations is more compromised than that in industrialized countries.¹¹ Factors that weaken or hinder informed consent in biomedical research are also likely to be relevant in a patient's acceptance or refusal of routine HIV testing.

For example, take policy communication. Ideally, those who present at hospitals and clinics (for health conditions other than HIV/AIDS) should have prior knowledge of the routine HIV-testing policy. But there are many barriers to effective health communication in

Box 1. UNAIDS/WHO policy on routine offers of HIV testing, 2004⁷

A routine offer of HIV testing by health-care providers should be made to all patients being:

- assessed in a **sexually transmitted infection** clinic or elsewhere for a sexually transmitted infection — to facilitate tailored counselling based on knowledge of HIV status
- seen in the context of pregnancy — to facilitate an offer of **antiretroviral prevention of mother-to-child transmission**
- seen in clinical and community-based health service settings where HIV is prevalent and antiretroviral treatment is available (injecting drug use treatment services, hospital emergencies, internal medicine hospital wards, consultations etc.) but who are **asymptomatic**.

resource-poor countries, such as a small number of media outlets, the power of health-related rumours, unfamiliarity with biomedical concepts, large distances between local communities and health centres, and low rates of literacy. Patients may first learn of the policy from doctors, nurses and other health-care workers in clinical settings. But communication of the opt-out policy within a clinical context poses ethical challenges of its own.

In their interaction with patients, health-care professionals must delicately balance the public health and clinical benefits of testing with the individual's right to refuse testing. Trained to promote health, health professionals may (consciously or unconsciously) be tempted to "sell" the clinical and public health benefits of HIV testing while playing down the right to refuse and glossing over the possible negative consequences of receiving a HIV-positive test result.

By contrast, an emphasis on the right to refuse may also send the wrong message — i.e., that testing is unimportant and has no benefits. Negotiation of a responsible path between health benefits and patient rights in the face-to-face process of policy communication may be even more demanding when (faced by staff shortages) little time can be devoted to pretest counselling.

Furthermore, the voluntary element of consent may be compromised if patients are informed about the opt-out policy by health-care professionals. Given the high social status of medical professionals, the scarcity of health care, and the arguably universal psychological tendency to obey authority,¹² patients may be unlikely to oppose the recommendations of physicians and health-care institutions. The very establishment of any opt-out testing policy (not only in health care) sends a powerful normative message: it appears as an institutionally sanctioned judgment that being tested for HIV is the correct thing to do.¹³ Patients may not opt-out of testing because they believe that their doctor will react negatively to their refusal and/or fear they will receive inferior care as a result of their "incorrect" decision. The WHO HIV-testing policy acknowledges HIV/AIDS-related discrimination and stigma in health-care settings, but not the possibility that patients will be discriminated against for refusing an HIV test.

In short, against this background of complex social, institutional and psychological dynamics, a failure to opt-out of HIV testing may be symptomatic of

Box 2. Ensuring a rights-based approach⁷

The global scaling up of the response to AIDS, particularly in relation to HIV testing as a prerequisite to expanded access to treatment, must be grounded in sound public health practice and also respect, protection, and fulfilment of human rights norms and standards.

The voluntariness of testing must remain at the heart of all HIV policies and programmes, both to comply with human rights principles and to ensure sustained public health benefits.

The following key factors, which are mutually enforcing, should be addressed simultaneously.

1. Ensuring an ethical process for conducting the testing, including defining the purpose of the test and the benefits to the individuals being tested; and assurances of linkages between the site where the test is being conducted and relevant treatment, care and other services, in an environment that guarantees confidentiality of all medical information.
2. Addressing the implications of a positive test result, including non-discrimination and access to sustainable treatment and care for people who test positive;
3. Reducing HIV/AIDS related stigma and discrimination at all levels, notably within health care settings.
4. Ensuring a legal and policy framework within which the response is scaled up, including safeguarding the human rights of people seeking services.
5. Ensuring that the health-care infrastructure is adequate to address the above issues and that there are sufficient trained staff in the face of increased demand for testing, treatment and related services.

the disempowerment of patients rather than a reflection of considered choice. When Botswana adopted its routine testing policy, a study of antenatal clinics in Francistown showed that in the first 3 months of routine opt-out testing (February–April 2004), 90.5% of women were tested for HIV, compared with 75.3% during the final 4 months of opt-in testing (October 2003–January 2004).

However, the success of the policy was mitigated by the fact that many women failed to return for their results.¹⁴ A similar pattern of patients not returning for test results has been observed in India.¹ From a public health perspective, these data suggest a need to link the new policy with technologies that allow rapid testing. The PMTCT programme managed by the Baptist Health Convention in Cameroon has integrated rapid testing and achieved a high rate of consent for testing.¹⁵ However, the nature of the testing acceptance in the Cameroonian PMTCT programme has not been studied.

Ethically, one wonders whether the women in Botswana and India who failed to return for their test results were committed to knowing their HIV status, or whether they were channelled into testing. Qualitative and quantitative social research are needed to shed light on issues surrounding the voluntariness associated with routine testing practices in the field, a task hampered by lingering uncertainties about the meaning of the term and its measurability.^{16, 17} Preliminary data from our University of North

Carolina-Chapel Hill research group in Kinshasa (Democratic Republic of the Congo) indicate that most nurses, HIV counsellors and tuberculosis patients prefer routine, opt-out HIV testing at tuberculosis clinics over opt-in HIV testing with referrals onsite or offsite. But 41% of tuberculosis nurses and HIV counsellors believed it would be difficult for patients to opt-out of an offer of routine testing, as did 33% of patients.¹⁸ Until there is a greater body of evidence and conceptual clarity, it would be premature to assume that "voluntariness is at the heart"⁷ of routine HIV-testing practices being implemented in resource-poor settings.

Gender bias in testing

The ethics of routine testing has a conspicuous gender dimension. In the continents with the greatest HIV/AIDS burdens — Africa and Asia — women and girls are more likely to present at formal health-care services than are men, and hence are most likely to come under a routine testing policy. Women and girls are also the most likely to face stigma, violence and abuse when their HIV-positive status becomes known by their boyfriends, spouses, neighbours and community members.

Advocates of routine testing have been accused of downplaying the social consequences of a HIV-positive status for women and girls in low-income countries to make the policy look more attractive, or at least less contentious.¹⁹ Given that HIV-related stigma and violence towards women and girls is driven

by entrenched gender inequalities,²⁰ it will probably be easier in the short term to increase the numbers of tested women than it will be to protect the growing numbers of HIV-positive women from gender-based violence.

The WHO recommendation that testing must coincide with programmes and policies to reduce stigma and discrimination is laudable. However, there should be a sober recognition that while needs have been identified and policies have been formulated, many programmes to reduce stigma and provide psychosocial support for women and girls in low-income countries are currently non-existent, in the design phase, overburdened or underfunded. In the current circumstances, there is a possibility that routine HIV-testing policies could be successful from a public health perspective, while exposing women and girls to risks of significant harm.

Testing without treatment

Perhaps, as some argue, AIDS-related stigma can be reduced by increasing access to antiretroviral treatment, and by transforming HIV in the eyes of the community from a fearsome death sentence to a manageable, chronic condition.²¹ From this perspective, the WHO recommendation that individuals must be “assured that testing is linked to accessible and relevant treatment, care, and other services” seems to be a bold and positive step forward.

Botswana’s policy of routine HIV testing would be more controversial were it not backed up by a national programme to provide antiretroviral treatment free of charge. Routine antenatal testing in Canada,²⁴ UK,²³ the US,²² and has generally integrated with treatment access for HIV-positive women

since around 2000. But while treatment availability seems to help reduce HIV/AIDS-related stigma, it cannot be used as an argument in favour of implementing routine testing in African or Asian countries where antiretroviral treatment coverage is currently dismal, and where it may be years before accessible and appropriate treatment, care and other services become widely available. For example, in the Democratic Republic of the Congo, only 2% of patients with symptoms of AIDS have access to antiretroviral drugs.²⁵ How should the issue of routine HIV-testing policies be approached in such circumstances?

With little prospect of treatment availability, would a VCT approach be ethically more appropriate, even in areas of high HIV prevalence, despite the known shortcomings of VCT? To what extent does access to treatment have to be “assured” (nationally, regionally or locally) before a routine HIV-testing policy is justified on human rights grounds? In resource-poor settings, a lack of coordination and integration between routine HIV testing and treatment access threatens to sabotage the desired convergence between human rights aspirations and public health goals.

A slippery slope?

From discussions about HIV-testing policies, a related question emerges about the status of the commitment to human rights stated in the WHO policy on HIV testing: is the commitment absolute or conditional? What if routine HIV-testing practices constrained by ethical concerns do not produce sufficient numbers of tested patients? Festus Mogae, President of Botswana, has recently complained that international criticism about the

ethics of routine HIV testing has forced Botswana to create an “elaborate procedure” or “rigmarole” that, in his opinion, has negatively affected uptake of HIV testing in his country. Mogae is said to prefer compulsory testing, and plans to make HIV tests a requirement for students applying for scholarships.²⁶ Is it ethically justifiable to weaken adherence to human rights in regions of high HIV prevalence, if rights-based approaches to HIV testing have not proved sufficiently effective in the past?

The questions raised here offer a glimpse of some of the challenges and complexities for workers implementing opt-out testing in an ethical manner, in particular in settings marked by poverty, illiteracy, gender inequalities, weak health-care infrastructure and poor access to antiretroviral treatment.

It should not be forgotten that the gradual (and incomplete) process of making HIV testing a more routine part of clinical practice in industrialized countries has taken place against a background of strong civil institutions and legal protections. We urge policy-makers and health workers to reflect on the ethical significance of routine-testing policies for people in areas where such protection does not exist. Such ethical concerns are sometimes regarded as trivial in comparison with the urgency of the HIV/AIDS pandemic, or they are sometimes overlooked in the pursuit of testing targets. However, if the ethical issues surrounding HIV testing are not continuously confronted, studied, monitored and resolved, the claim that new HIV-testing practices have a human rights basis could fail to reflect the reality. ■

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Résumé

Aspects éthiques du dépistage systématique du VIH dans les pays à faibles à revenus : une définition difficile des objectifs

La pandémie de VIH/SIDA et les réponses qui lui ont été apportées ont fait apparaître des injustices claires sur le plan politique, social et économique au sein des nations et entre elles. La manifestation la plus frappante de ces injustices est l'inégalité dans l'accès au traitement du SIDA. Dans les pays riches, le traitement antirétroviral devient une référence en matière de soins pour les personnes atteintes du SIDA, alors que le même traitement est actuellement à la disposition de quelques privilégiés seulement dans les pays disposant des revenus les plus faibles. Des malades sans capital financier et social suffisant, c'est-à-dire la plupart des personnes atteintes du SIDA, meurent chaque jour par milliers. Les initiatives

récentes en matière de traitement contre le SIDA, telles que l'ONUSIDA et le Programme « 3 millions d'ici 2005 » de l'OMS, visent à corriger ce symptôme de l'injustice mondiale. Cependant, le succès de ces initiatives repose sur l'identification des personnes ayant besoin d'un traitement grâce à un dépistage rapide et à grande échelle du VIH. Le présent article examine brièvement les principales difficultés éthiques soulevées par l'accélération du dépistage du VIH dans les pays à faibles ressources, dans la ligne de la politique 2004 de dépistage systématique du VIH (« avec consentement présumé »), recommandée par l'ONUSIDA et l'OMS. L'article suggère que dans les pays caractérisés par la pauvreté, la

faiblesse des soins de santé et des infrastructures de la société civile, les inégalités hommes/femmes et la stigmatisation persistante des personnes atteintes du VIH/SIDA, les politiques de dépistage du VIH avec consentement présumé peuvent s'écarter des idéaux en matière de droit humain qui, dans les premiers temps, avaient motivé les appels à un accès universel au traitement antisida. Il

laisse ouverte la question éthique de la légitimité des politiques reposant sur le consentement présumé, mais recommande, au cas où une telle politique serait mise en place dans un pays à faibles revenus, que ses effets sur les individus et les collectivités soient soumis à une étude empirique, à une surveillance sous l'angle des droits humains et à un examen éthique approfondi.

Resumen

Ética de las pruebas sistemáticas del VIH en los países de bajos ingresos: ¿detección a cualquier precio?

La pandemia de infección por el virus de la inmunodeficiencia humana/síndrome de inmunodeficiencia adquirida (VIH/SIDA) y las respuestas a la misma han puesto de manifiesto claras desigualdades políticas, sociales y económicas entre las naciones y en cada una de ellas. La manifestación más sorprendente de esas desigualdades es la que se observa al analizar el acceso al tratamiento del SIDA. En las naciones prósperas, el tratamiento antirretroviral está convirtiéndose en la norma asistencial para las personas con SIDA, mientras que en la mayoría de los países con recursos más escasos sólo unos cuantos privilegiados pueden beneficiarse de ese tratamiento. Cada día mueren millares de pacientes que carecen del capital económico y social necesario para tratarse, situación en la que se encuentra la mayor parte de las personas con SIDA. Iniciativas recientes de tratamiento del SIDA, como el programa «tres millones para 2005» del ONUSIDA y la OMS, pretenden corregir ese síntoma de injusticia mundial. Sin embargo, para que tales iniciativas tengan éxito, es preciso identificar a las personas necesitadas de tratamiento mediante actividades de extensión rápida y masiva de las pruebas del VIH.

En este artículo analizamos brevemente algunos dilemas éticos importantes planteados por la aceleración de las pruebas del VIH en los países con pocos recursos, centrándonos en la política de fomentar las pruebas sistemáticas del VIH con posibilidad de renuncia («opt-out») recomendada en 2004 por el ONUSIDA y la OMS. Sugerimos que en los entornos caracterizados por la pobreza, unas infraestructuras de atención sanitaria y una sociedad civil débiles, las desigualdades de género y una estigmatización persistente de las personas con VIH/SIDA, las políticas de fomento de las pruebas sistemáticas del HIV con posibilidad de renuncia pueden apartarse de los ideales de derechos humanos que inspiraron al principio los llamamientos al acceso universal al tratamiento del SIDA. Dejamos abierto el dilema ético de si deben o no implementarse políticas basadas en la opción de la renuncia, pero recomendamos que, siempre que se apliquen políticas de pruebas sistemáticas del VIH en países de recursos escasos, sus efectos en los individuos y las comunidades sean objeto de investigaciones empíricas y escrutinio ético, vigilando los derechos humanos.

ملخص

البحث الدؤوب عن الأهداف: أخلاقيات الفحص الروتيني لفيروس الإيدز في البلدان المنخفضة الدخل

على السياسة التي اتبعت عام 2004 لإجراء اختبارات روتينية ينصح بها ويتغاضى عن لا يوافق على إجرائها لكشف الإيدز والتي يوصى بها برنامج الأمم المتحدة المشترك لمكافحة الإيدز ومنظمة الصحة العالمية. وفي المواقع التي تتسم بالفقر وضعف البنية الأساسية للرعاية الصحية وللمجتمع المدني، والتفاوت بين الجنسين واستمرار الوصمة في المصابين، نقتراح إمكانية فصل سياسات كشف الإيدز التي تنصح بإجراء الاختبارات لكشف الإيدز وتتغاضى عن لا يوافق على إجرائها، عن المعايير المثالية لحقوق الإنسان والتي تدعو لإتاحة شاملة للمعالجة المضادة للإيدز. وقد طرحنا السؤال الأخلاقي عما إذا كانت السياسات التي تنصح بإجراء الاختبارات لكشف الإيدز وتتغاضى عن لا يوافق على إجرائها، ينبغي أن تنفذ، ولكننا أوصينا بإدخال سياسات اختبار كشف الإيدز في البلدان الفقيرة الموارد، مع إدراج تأثير ذلك على الأفراد والمجتمعات في بحوث مرتكزة على الخبرة وعلى مراقبة حقوق الإنسان والتدقيق بالأخلاقيات.

الملخص: لقد أظهرت جائحة الإيدز والعدوى بفيروسه والاستجابة لها مدى التفاوت الواضح في العدالة بين البلدان وضمن البلد الواحد. إن أهم التظاهرات الملفتة للنظر لهذا التفاوت هو إتاحة المعالجة المضادة للإيدز. ففي حين أصبح توافر المعالجة المضادة للإيدز هو المعيار لرعاية المصابين بالإيدز في الأمم المرفهة، لا تتوافر مثل هذه المعالجة إلا لفتنة قليلة في معظم البلدان الفقيرة الموارد؛ وكل يوم يموت آلاف المرض الذين يفتقدون الرأسمال الاقتصادي والاجتماعي، وهؤلاء يشكلون معظم المصابين بالإيدز. وتهدف المبادرة التي أطلقها مؤخراً كل من برنامج الأمم المتحدة المشترك لمكافحة الإيدز ومنظمة الصحة العالمية والتي يطلق عليها 3 في 5 لتصحيح هذا الخلل في التفاوت في العدالة على الصعيد العالمي. إلا أن نجاح هذه المبادرة يعتمد على كشف المحتاجين للمعالجة من خلال اختبارات سريعة وجموعية تحسن من كشف الإيدز. ونستكشف في هذه الورقة بإيجاز التحديات الأخلاقية الرئيسية التي أثارها تسارع إجراء الاختبارات للإيدز في البلدان الفقيرة الموارد مع التركيز

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