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EDITORIAL

The role of informed consent in tuberculosis testing and screening

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In December 2010, the World Health Organization (WHO) endorsed the use of a new DNA-based test for tuberculosis (TB), the Gene Xpert [1]. This test is expected to revolutionise the care of TB and, especially, multidrug-resistant (MDR)-TB, by providing accurate diagnoses in less than 2 h [2]. As healthcare professionals begin to incorporate rapid TB testing into clinical practice, questions about the need for informed consent will inevitably arise. Yet, despite decades of debate about informed consent to HIV testing and screening [3], informed consent to TB testing and screening has received virtually no discussion in the ethical or legal literature.

In this editorial, we argue that, in most situations, TB testing and screening does not require a specific informed consent process, but that patients should be notified about testing and given the opportunity to object. If an objection is raised, the burden should be on those proposing coercive testing to show that the expected public health benefits are sufficient to justify overriding the individual's choice. We conclude by identifying limited circumstances in which specific informed consent to TB testing should be required.

BACKGROUND

When the HIV diagnostic test was first developed, many jurisdictions enacted laws requiring written informed consent to testing [3]. The rationale was that HIV was untreatable, and individuals who tested positive faced a significant risk of stigmatisation and discrimination [3]. Moreover, because HIV was not transmissible by casual contact, the public health rationale for facilitating testing was weaker than with more easily transmissible infectious diseases.

As HIV has become more treatable and less stigmatised, policy makers have begun to shift their approach. In 2006, the US Centers for Disease Control and Prevention (USCDC) recommended that HIV testing should routinely be performed in all healthcare settings [4]. According to the USCDC, patients should be informed that they will be tested for HIV and given the opportunity to opt out, but specific informed consent to testing should not be required [4]. In the 2 yrs following the release of these recommendations, nine states changed their legislation to permit opt out HIV testing [5]. A 2007 report by WHO and the joint United Nations Programme on HIV/AIDS stopped short of recommending HIV testing without an explicit consent process, but it encouraged providers to offer HIV tests routinely and to encourage patients to consent [6]. The report also emphasised that consent to HIV testing need not be in writing [6].

In contrast to HIV, most guidelines on TB treatment, including the civil society-initiated Patient's Charter for Tuberculosis Care [7], do not even mention the issue of informed consent to testing. One exception is a 1997 document from the British General Medical Council, which stated that doctors must obtain informed consent before testing for any ''serious communicable disease,'' including TB [8]. However, following criticism [9], the document was withdrawn [10] and replaced with a more general statement on the role of informed consent in medical practice, which does not specifically mention any communicable disease [11]. While no official guidelines explicitly state that TB testing may be performed without consent, some opponents of requiring specific consent to HIV testing have pointed to TB as an example of an infectious disease for which informed consent to testing is not commonly sought [12].

A FRAMEWORK FOR INFORMED CONSENT TO TESTING AND SCREENING

In order to determine the role that informed consent should play in TB testing and screening, it is necessary to reflect on the normative bases of informed consent to diagnostic testing generally. At one extreme, one might argue that, because informed consent is grounded in the principle of bodily integrity, it applies only to physically invasive procedures. Under this view, consent might be necessary for diagnostic procedures involving bodily invasions, but not for noninvasive procedures such as sputum samples collected through expectoration. Moreover, once the patient's biological material is obtained, no further consent would be required to analyse the sample. This view has some support in the laws of particular jurisdictions; for example, in New York State (USA), a malpractice claim based on lack of informed consent is available for diagnostic procedures only if the procedure ''involved invasion or disruption of the integrity of the body'' [13, 14]. As an ethical matter, however, this position ignores the fact that the goal of informed consent is to protect the patient's autonomy, and autonomy can be violated even if no bodily invasion occurs.

At the other extreme, it might be argued that informed consent is necessary for every diagnostic intervention. Under this view, biological material could not be used for diagnostic testing unless

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the patient has been informed of the risks, benefits, and alternatives to the specific test and affirmatively agreed that the test may be performed. However, such a position would be unworkable. It would mean that, before blood is taken for routine laboratory analysis, patients would have to be informed about each of dozens of tests that will be conducted, from potassium levels to liver enzyme analyses. No reasonable patient expects, or even wants, this kind of information.

In place of these extremes, we believe that informed consent to diagnostic testing should be viewed on a continuum. At one end, there are tests for which no disclosures should be considered obligatory, not even the basic fact that the test is being performed. Potassium levels and liver enzyme analyses would fall into this category, as would other tests that involve no risk and could potentially benefit the patient. Because no reasonable patient would decline such tests given full information, consent should be deemed implicit in the patient's general agreement to undergo medical care.

At the other end of the continuum are tests that should not be conducted without the patient's specific agreement, following disclosure of the nature of the test and its risks, potential benefits, and reasonably available alternatives. This category would include physically risky procedures such as biopsies, colonoscopies or heart catheterisations, as well as tests that, although not physically risky, may produce information of dubious value, such as genetic tests (which can involve psychological or social risks with no medical benefit [15]) or prostate-specific antigen testing (which may lead to unnecessary and risky surgical interventions [16]). At the beginning of the AIDS epidemic, HIV testing fell into this category, as a positive test result offered few medical benefits but could nonetheless lead to stigmatisation and discrimination.

Between these two extremes lies a middle category: tests that should not be performed unless the patient is notified and given an opportunity to object, but for which affirmative consent is not necessary and disclosure of risks, benefits, and alternatives is not needed unless the patient specifically asks. This is the approach the USCDC has recommended for HIV testing, and it is also used by practitioners for other diagnostic tests (*e.g.* sexually transmitted disease testing). While the USCDC has characterised this notice and opt out approach as ''similar to screening for other treatable conditions,'' [4] it is in fact more demanding than screening for, say, elevated cholesterol levels, which is commonly performed without any pre-test discussion. The justification for requiring explicit notice and opt out is that, even if the risks of a test are low and the potential benefits to the patient clear, a reasonable patient might nonetheless have concerns or want to ask questions. This is especially likely with conditions that, while treatable, retain an element of stigma.

INFORMED CONSENT TO TB TESTING AND SCREENING

Under the framework outlined above, specific consent to TB testing or screening should usually not be required. The potential benefits to the patient are clear: if an active TB case is missed, the disease can be fatal, but upon diagnosis, a complete cure and curtailment of transmission are usually possible [17]. Moreover, TB testing and screening are not especially risky. Risks of stigmatisation and discrimination, while not negligible, are usually not as great as those associated with HIV in the early days of the epidemic. In some countries, TB has been common for so long that it is considered a normal part of life [18].

At the same time, TB is different from situations, such as routine blood analysis, where testing can legitimately be performed without even notifying the patient. While stigmatisation of TB is much lower than stigmatisation of HIV during the early 1980s, stigmatisation and discrimination are nonetheless real. Moreover, TB disease is reportable to public health authorities [19]. Given these factors, TB testing should generally be seen as falling into the middle ground of our framework: individuals should be notified that the test will be performed and given basic information, but they need not be given additional information unless they specifically ask. Moreover, as with the USCDC's recommended approach to HIV testing, explicit consent should not be required; consent should be presumed unless the patient objects.

Some might object that even our modest proposal to require notice and the ability to opt out of TB testing inappropriately prioritises individual autonomy over the public health interest in controlling a highly transmissible infection. However, giving individuals an opportunity to express their opposition to TB testing is not the same thing as recognising a ''right to refuse'' testing under any and all circumstances. In some cases, there may be valid public health reasons to proceed with testing despite an objection, notably, if there is a high likelihood that the person is positive (based on exposure to persons known to be infected, or on clinical signs and symptoms) and the capacity to prevent exposure to others, including through humanely administered isolation, exists. However, overriding an individual's medical decision for public health reasons generally requires compliance with a review process that gives the individual due process protections [20]. In such a process, the burden should be on those proposing coercive testing to show that the expected public health benefits are sufficient to justify overriding the individual's choice.

DRUG SUSCEPTIBILITY TESTING IN THE ABSENCE OF AVAILABLE TREATMENT

Our conclusion that full informed consent is usually not necessary for TB testing and screening is consistent with recently released WHO guidance on the ethics of TB prevention, care and control [21]. The WHO guidance document recognised only one situation in which explicit informed consent should be obtained: ''where drug susceptibility testing is offered to patients when treatment for drug-resistant TB is not available.'' This situation can arise in countries where the public sector lacks the resources to provide second-line TB treatments; in these settings, MDR-TB treatment may be ''available'' in the private sector, but its cost makes it practically unavailable to the vast majority of patients. In these ''exceptional'' situations, WHO concluded, individuals ''should be informed of the risks and benefits of testing and specifically asked if they are willing to consent even though treatment is not available to them.''

We agree with this recommendation in the context in which drug susceptibility testing is currently offered, *i.e.* as a stand-alone intervention to determine whether an individual already known to have active TB happens to be harbouring a drug-resistant strain. The rationale for requiring informed consent in these situations is that, in the absence of available treatment for

drug-resistant TB, drug susceptibility testing offers few direct benefits to the individuals being tested (the main direct benefit being the provision of information that can help patients make informed life planning decisions). We stress that the consent process does not have to involve written consent forms; as an ethical matter, what is important is that the patient be given relevant information and an opportunity to decide.

However, this recommendation should not be interpreted as requiring informed consent simply because of the possibility that information about drug susceptibility may be produced as a by-product of an initial TB diagnosis, as would be true if the Gene Xpert were used as an initial diagnostic method for individuals whose TB status is unknown. (In the near term, it is unlikely that the Gene Xpert will be widely used in this manner; given its cost, its use will probably be limited to identifying rifampicin resistance in patients already known to be sick.) Even in settings that lack access to second-line drugs, an initial diagnosis of TB offers an extremely favourable benefit-risk ratio to the individuals being tested. Requiring full informed consent to testing in settings that lack access to treatment for drug-resistant TB could create a barrier to testing in precisely those settings that stand to benefit the most. In any event, as the goal of achieving universal access to treatment for MDR-TB [22] is eventually realised, questions about testing for drug susceptibility in the absence of treatment will thankfully become moot.

SUPPORT STATEMENT

A. Reis and E. Jaramillo are staff members of the World Health Organization (WHO). The authors alone are responsible for the views expressed in this publication and they do not necessarily represent the decisions or policies of the WHO.

STATEMENT OF INTEREST

None declared.

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