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HIV testing and informed consent — ethical considerations

G. R. McLean, T. Jenkins

One of the authors (T.J.) was invited by the AIDS Advisory Group to form a widely representative committee to recommend ethical guidelines concerning the extent to which HIV testing should receive informed consent. This paper presents and argues for the recommended guidelines. The question is considered with regard to a number of distinct purposes of HIV testing: the care of a patient; research; blood, tissue and organ donation; and the protection of third parties, including the health care worker. We contend that in each case there is no good reason for the requirement of informed consent to be significantly waived.

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Does testing for HIV infection require the informed consent of the person tested? This was the question which was put, by the AIDS Advisory Group, to one of us (T.J.), who was asked to convene a broadly representative committee to recommend ethical guidelines on the matter.* The committee was able to reach unanimous agreement on a set of guidelines, and in this paper we set out the guidelines concerned with informed consent and present a case for them.

HIV testing might be done for a number of possible purposes, and there is a tendency for the debate about testing to become confused because these different purposes are confused. It is very important to distinguish the different possible purposes, and to ask, for each in turn, whether there is a case for testing without consent. Four purposes can be distinguished: the proper medical care of the person tested; research; blood, tissue and organ donation; and the protection of third parties, including the health care worker.

The discussion begins against the background of a number of generally accepted ethical principles, including the fundamental principles of beneficence, non-maleficence, justice and autonomy. In particular, there is the principle that blood testing, like anything else that involves an invasive procedure, may not, in general, be done without the informed consent of the person tested. Hence there is a clear presumption *against* the testing for HIV without informed consent. Indeed, this has been specifically stated as a requirement by the South African Medical and Dental Council in its official guidelines[1] concerning the management of HIV-positive patients, as follows:

> 'For the purpose of an invasive test such as the taking of a blood or tissue sample, the consent of the patient is mandatory. It is the duty of the practitioner to prescribe the tests to be carried out and a patient refusing to undergo a test recommended by his attending doctor or dentist, should be advised to seek a second opinion, if such a test is deemed essential to the management of the patient.'

This has been reiterated even more clearly in the latest set of guidelines[2] issued by the SAMDC:

> 'A patient should be tested for HIV infection only if he gives informed consent.'

In spite of this, allegations are being made that some medical practitioners disregard this guideline; and in fact some have stated publicly that the guideline ought to be disregarded. The question thus becomes whether there is good reason for thinking that this guideline is wrong.

There are also a number of important facts which must be borne in mind from the outset. One of these is that the repercussions of an HIV test result can be very serious indeed for the person tested. No doubt there are some respects in which it is better for an infected person to know that he is HIV-positive — not least that he thereby becomes aware of the danger that he may pose to certain other persons. But it should hardly need saying that a test may not in every way work to his benefit. Not only does a positive test result (assuming that he is informed of the result at all) present him with the knowledge that he will develop an incurable fatal illness, but the stigmatisation which can result from others' knowledge of his HIV status can have unwarranted and yet profoundly grave consequences in various aspects of his life — his relationships, his work, and so on. Testing, then, is by no means an innocuous affair. (There are, for instance, documented cases of HIV-positive persons being attacked and even killed by fearful and enraged neighbours who have happened to discover the victim's HIV status.[3])

Another significant fact is that no currently available test can conclusively ascertain that a person is *not* infected with HIV, for during that period of a few months or so before an infected person undergoes seroconversion, and during which he is in fact more infective than he will be later on (the so-called window period), a test will return a false-negative result. This is a fact which colours the whole discussion of testing, though we shall note its particular importance at a couple of points — as we shall note other important facts at relevant places.

We turn, then, to consider whether informed consent is required for testing done for any of the various possible purposes.

Department of Philosophy, University of the Witwatersrand, Johannesburg

G. R. McLean, B.A. HONS, M.A., B.PHIL., D.PHIL. (OXON.)

Department of Human Genetics, South African Institute for Medical Research and University of the Witwatersrand, Johannesburg

T. Jenkins, M.B. B.S., M.D., M.R.C.S., L.R.C.P., D.R.C.O.G., F.R.S.S.A.F.

*The Committee consisted of Dr C. Allwood, Senior Specialist Psychiatrist, Baragwanath Hospital/University of the Witwatersrand; Prof. E. Cameron, Centre for Applied Legal Studies, School of Law, Wits; Rev. M. Dandala, General Secretary, Missionary Dept, Methodist Church of Southern Africa; Prof. A. F. Fleming, Head, Dept of Haematology, Baragwanath/Wits; Prof. T. Jenkins, Head, Dept of Human Genetics, SAIMR/Wits (Chairperson); Matron L. Langley, Chief Matron, Baragwanath; Prof. H. H. Lawson, Head, Dept of Surgery, Baragwanath/Wits; Mrs D. Mokhobo, Social Worker/Health Educator, Anglo-American Corporation; Dr G. R. McLean, Dept of Philosophy, Wits; Dr J. A. McIntyre, Specialist Obstetrician and Gynaecologist, Baragwanath/Wits; and Mr N. Prinsloo, Registrar, South African Medical and Dental Council.

Care of a patient

The health care worker has a duty to provide the best possible care for the patient. Now there may well be medical conditions in which the form of the best possible care depends upon the patient's HIV status — conditions, that is, which are such that if an HIV-positive patient were treated in a way that would be best for an HIV-negative patient, then his treatment would be dangerous to him, or in some other way unsatisfactory for him; and vice versa. The identification of these conditions is, of course, an empirical matter for the medical experts. But as there is no clear evidence that every case of HIV infection is a case in which the immune system is compromised, there must be other, special grounds for the identification of a particular medical condition as a member of this class. However, whatever the conditions may be, if one of these conditions is presented then obviously the health care worker needs to know the patient's HIV status in order to be able to provide him with the best possible care. Here, then, the duty of care entails the need for a test. But, equally obviously, it does not follow that the patient may be tested without his informed consent, any more than it would follow that any other aspect of the performance of the duty of care (e.g. the taking of an X-ray, or a surgical procedure) could permissibly be carried out without that consent. There is nothing special here about the need for informed consent to HIV testing. The health care worker stands under a general duty not to treat a patient against his will, even where the patient suffers as a consequence; and the need for informed consent for an HIV test performed for the patient's own sake is simply one instance of that general duty to respect the patient's autonomy.

The general duty to gain informed consent for a medical procedure is subject to exceptions, however, when a patient is unable to give that consent. In such cases the duty of care — beneficence and non-maleficence — may override the duty to respect the patient's autonomy. But even in these cases the autonomy principle does not disappear altogether: the health care worker still has a duty to obtain the most appropriate possible vicarious consent.

Thus we derive the Committee's first guideline:

> Where the health care worker's duty to provide the best possible care for the patient necessitates establishing the ained, appropriapatient's HIV status, HIV testing, in common with other invasive procedures, must receive the patient's informed consent, whenever possible. When the patient's own informed consent cannot be obtte vicarious consent must be sought. Vicarious consent means the consent of the patient's closest available relative or, in the case of a minor, the consent of the medical superintendent in the absence of a relative. If vicarious consent cannot be obtained then a senior colleague should be asked to confirm the need for HIV testing.

Research

A fundamental ethical principle of research, and one universally accepted by responsible ethical bodies, is that, in general, research and experimentation performed upon humans require the informed consent of the subjects — especially, though not only, when the research involves any risk to the subjects. (Note the World Medical Association's Declaration of Helsinki,[4] etc.) Hence an HIV test for the purpose of research requires the informed consent of the subject tested. Again there is nothing special, here, about HIV testing: it is simply one instance embraced by the general principle that informed consent is required.

However, because of the pressing public need to track the spread of HIV infection, and because a reliable survey may well require more data than can be obtained from the aggregate of individual tests ordinarily performed with informed consent, various international ethical bodies have accepted a weakening of the informed consent principle here, holding that it is permissible to test for HIV without gaining informed consent so long as the source of any given blood sample cannot be identified, and so long as the person from whom the sample was taken did give consent to the taking of blood. This kind of testing — anonymous unlinked testing, as it is called — does seem ethically acceptable, given that it cannot have any harmful repercussions for the subject, and given the public importance of the research purpose. Thus, for instance, the general testing of blood taken in antenatal clinics might provide pretty reliable epidemiological data without undermining the interests of the persons tested.

And so we have the next recommended guideline:

> The subject's specific informed consent to HIV testing is mandatory for HIV testing for epidemiological or other research purposes of an identifiable blood sample (i.e. a sample which can be linked to the individual subject).
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> The subject's specific consent to HIV testing is not mandatory for unlinked anonymous HIV testing; but in such a case informed consent to the taking of blood is obviously mandatory.

Blood, tissue and organ donation

It would be an appalling breach of his duty of care to the recipient of a blood, tissue or organ donation if a health care worker were to fail to do his best to ensure that he does not use a donation from an HIV-positive person. So the duty of care to the recipient entails that the donated substance must be tested. Once again, however, it does not follow that the testing may be performed without the donor's informed consent. The person offering the donation retains the right to forbid the testing. But his autonomy, on the one hand, and the care of the recipient, on the other, can both be maintained in a perfectly straightforward way: if the intending donor withholds consent to the test, then a donation from him must not be used.

But here we need to remind ourselves of the complications introduced by the existence of the window period of infection. Similar complications are not unimportant in the kinds of situation previously discussed: the window period gives rise to an uncertainty that must be borne in mind in one's care of a patient, and in the survey of the incidence of infection. That uncertainty is particularly important here: a negative test result is no guarantee that a donated substance is not infective (and so in due course fatal to the recipient). Hence testing provides insufficient protection. Those responsible for the business of blood, tissue or organ donation therefore have a further duty to do their best to screen out donors who are at risk of being infective, and to use a donation only when it is really necessary, i.e. when the risk of not using it exceeds the risk of using it.

That complication having been noted, we can state the next guideline:

Protection of the recipient of blood, tissue or organ donation requires HIV testing of the donated substance. This testing must receive the informed consent of the donor; but this consent can be obtained along with the consent to the donation itself, and if consent to testing is withheld then no donation shall be received. If the prospective donor is found to be HIV-positive then he/she must receive post-test counselling.

In the case of a cadaver donor, relatives, before granting consent, must be informed that routine testing, including that for HIV, will be performed.

Protection of third parties, including the health care worker

Whether a patient needs to give informed consent to a test performed on him for the sake of the protection of the health care worker, or some other third party, is the issue which has probably caused the greatest anxiety and the most vigorous ethical head-scratching in the contemporary discussion. The issue arises because of the tension between two very powerful ethical claims. On the one hand, there is the general duty to respect the patient's autonomy, especially in this case, where there may be very harmful consequences to him of others' awareness of a positive HIV test result. But on the other hand there is the duty to protect the third party from an infection that will, eventually, be fatal. The stakes, then, especially on the health care worker's side, are very high indeed.

Here again, however, the complication introduced by the window period is very significant, because testing cannot provide full protection for the third party. The only way that full protection could be provided would be by ensuring that the third party never suffers a risky exposure to possibly infective matter from the patient.

What, then, are the risky kinds of exposure? Exposures carrying a significant risk — the high-risk exposures, as they are called — are hollow needle-stick injuries, or injuries that are more traumatic still. The ground for this claim is the evidence that approximately 0,1 ml of blood is needed to transmit the virus, and this is the amount of blood contained in an ordinary hollow needle.[5] But although this is called a high-risk exposure, it is important to bear in mind just what the degree of risk is: the probability that one of *these* exposures actually transmits infection, given that the patient involved *is* HIV-positive, is evidently approximately 0,004 (or four chances in a thousand).[6] And so the risk of the health care worker's being infected while performing some procedure on any patient could be calculated on the basis of the following formula: risk of infection = probability that the patient is HIV-positive x probability that a high-risk exposure occurs x probability that a high-risk exposure transmits the virus (i.e. 0,004). Thus, for instance, if the HIV-positive rate in a population is 1 in 50, the risk of infection to the health care worker is 1 in 12 500 per high-risk exposure.

Now whatever else is indicated by these facts, at least one very important point immediately follows, and that is the point made in the committee's first recommendation in this section:

All possible precautions must be taken to protect patients and health care workers from exposure to HIV-infective material (blood, body fluids, etc.). The best technological devices for the safe disposal of needles, for example, must be available and suitable gloves and other protective clothing must also be readily available. Health care workers must not be expected to carry out 'high-risk' procedures without such protection being available. The training of health care professionals must include appropriate instruction and attempts should be made to re-educate those who employ unsafe methods.

But of course that does not answer the question whether testing for the sake of the safety of third parties requires informed consent. How do we work out the answer to this, where so much is at stake? One way to try to do it is by concentrating on the degree of risk to the health care worker, or other third party. Using the above formula, and armed with further facts, or conjectures, about the incidence of HIV infection in a relevant population and about the likelihood of the occurrence of a high-risk exposure during a given procedure, one could work towards a calculation of the degree of risk. One could then ask whether the risk thus calculated is acceptable — that is, whether it is a risk which can, or should, be accepted without any significant alteration in standard practice, or instead a risk which in fact justifies the overriding of a patient's autonomy. And one might seek to answer this question as to the acceptability of the risk by comparing the calculated degree of risk of HIV infection with the degrees of other medical and nursing risks regarded by those professions as acceptable or unacceptable, as the case may be, and by comparing it also with the degrees of what are regarded as acceptable or unacceptable risks in other, relevantly similar professions. Now that line of enquiry introduces very important considerations. But it seems that the clearest progress in resolving the issue can be made by concentrating initially not so much on those matters as on a slightly different question, namely: what practical purpose would be served by gaining the knowledge of the patient's HIV status?

In answering this question, it is helpful to begin by making a simple distinction between what one may call the manner and the substance of some medical treatment. The substance of a treatment is being referred to when we say *what* treatment is administered (e.g. whether it is a surgical operation or some non-surgical alternative). The manner of the treatment consists in *how* the treatment is administered (e.g. whether slowly or quickly, especially carefully or with standard care, with more or fewer protective measures being taken). And this distinction helps us to give a clearer focus to the question concerning the point of HIV testing. That question now becomes: should a known test result make a difference to either the manner or the substance of the treatment administered to the tested patient?

The best way to think out the answer to this more focused question is by performing a little thought-experiment. Imagine that a health care worker has responsibility for the care of a patient who has *volunteered* for an HIV test, and has returned a positive result. (By imagining this situation, we can remove from the picture the worry as to whether the knowledge of the patient's HIV status has been ethically obtained.) And now the question can be asked in a way that is yet more clearly focused: in this imagined situation, should the health care worker's knowledge of the test result make a difference to the treatment he administers to the patient — in respect either of its manner or of its substance?

Let us start with the manner of the treatment. Are there any treatment procedures that our imagined health care worker ought to undertake in a non-standard manner (i.e. in

a manner other than that in which he would administer the treatment if he *knew* that the patient was HIV-negative), for the sake (of course) of his own or some other third party's safety? Three different answers might be given to this question.

The first answer is that there are no procedures that ought to be administered in a non-standard manner, because the degree of risk of infection is too low to warrant alteration to the standard manner of treatment. But this answer, though heroic, will not do as a general prescription. There are procedures in which there is a significant chance of a high-risk exposure; and though, even when such an exposure *does* occur, the risk of infection is low by comparison with other kinds of risk (only four chances in a thousand), it is still high enough, given what is at stake, to render it only sensible that those procedures be performed in a special manner which minimises the chance of a high-risk exposure.

The second answer is also that there are no procedures that ought to be administered in a non-standard manner. But the reason given here is different: it is not that the risk does not justify special precautions or care, but rather that special measures to guard against HIV infection ought to be taken in *every* case, not just in the cases where one knows that the patient is HIV-positive; and so these special measures *ought to become standard.* And this answer is supported by a powerful argument. We have been supposing that the standard manner of treatment is that of the treatment which would be administered to a patient *known* to be HIV-negative. But because of the window period, no one can be known, absolutely conclusively, to be HIV-negative. And so the only way to ensure the protection of third parties is by introducing the special safety measures across the board.

That argument could be faulted only by showing that the general adoption of the right kinds of safety measures is not feasible. And there does seem to be a case for saying that this is indeed so, at least at this stage in South Africa: if every procedure were performed as slowly and carefully as it would be, or with the use of every safety device that would be used, if one knew that the patient was HIV-positive, then too many medical treatments would be unduly delayed and the costs of too many treatments would be unduly high. If this is correct then it is clear that every effort ought to be made to ensure that adequate safety measures can feasibly be introduced across the board. But it also means that, as things stand, this second answer to the question cannot be accepted.

And that leaves us with the third answer, which is that given the unacceptable degree of risk in the standard manner of some particular treatments, the manner of any of those treatments ought to be altered in our imagined case.

Accepting this third answer, then, we are now able to say that the properly obtained knowledge that the patient is HIV-positive ought to make a difference to the manner in which the health care worker administers some particular treatments.

Now we turn to the substance of the treatment. Ought the test result to make a difference to the substance of the treatment, in our imagined case, for the sake of the third parties involved? (Of course it may make a proper difference for the sake of the care of the patient, but that is a separate issue, to which we have already attended.) And here there are two possible answers.

The first answer is that the knowledge should make a difference in some instances, because certain kinds of treatment involve procedures which, even when performed in as safe as possible a manner, involve unacceptable risk to the health care worker or other third party. But the response to this answer takes the form of a challenge: *what* procedures involve these unacceptable risks? And this challenge has gone unanswered. The committee was unable to identify any procedure that could not be carried out in a manner placing the degree of risk at a tolerable level. An assessment of an acceptable level of risk, here, cannot be made independently of the fact that there is a duty of care owed to the patient. For if the substance of the treatment is to be altered, not for the sake of the patient himself but for the sake of a third party, this means that for the sake of the third party the patient is to receive less than optimal treatment (for, *ex hypothesi*, he is not to receive the treatment he would receive if only *his* interests were being considered); and this can only be because the degree of risk to the third party is such that the duty to protect him overrides the duty to provide optimal treatment for the patient.

The failure to find support for the first answer leaves us, then, with its alternative — namely that, given the health care worker's duty of care to the patient, and given that any standard treatment can be administered in an adequately careful manner, there is no treatment the substance of which constitutes an unacceptable risk; and so the known positive test result ought to make no difference to the substance of the treatment administered.

Hence, as far as the safety of third parties is concerned, the properly obtained knowledge that a patient is HIV-positive ought to make a difference to the manner of some of the treatments that might be administered to him, but it ought to make no difference to the substance of any of those treatments.

This conclusion gave us our second guideline in this section:

> Protection of health care workers and other third parties cannot justify HIV-positive patients receiving treatment that is non-standard in its *substance* (i.e. is not the treatment which would be administered to HIV-negative patients), though it may justify treatment that is non-standard in its *manner* (e.g. slower, more careful treatment, involving greater protective measures).

But of course this still does not offer any answer to the question whether testing requires informed consent. However, we are now very much closer to being able to answer that question, for we are now in a position to say whether and why there is a *need to know* a given patient's HIV status (for the sake of third parties). From the fact that if one knows that a patient *is* HIV-positive one is justified in altering the manner of some treatments, does it follow that there is a need to know *whether* any given patient is HIV-positive? Not quite. For if the chance of any given patient's being HIV-positive were negligibly small, the likelihood of his posing a danger to others would just be too small to be worth bothering about, and so there would be no need to ascertain his actual HIV status. But, alas, the actual probability of a given patient's being HIV-positive is not negligibly small: it is significant, and it is rising dramatically, as the incidence of HIV infection increases. And so, in cases in which knowledge that a patient is HIV-positive would

make a difference to the manner of his treatment, there is a need to know *whether* he is HIV-positive, simply because there is a need to know whether to alter the manner of his treatment.

Now we are in a position to ask the decisive question. Does this need to know the patient's HIV status justify his being tested without his consent? Does this need to know override, or outweigh, the duty to respect the patient's autonomy and to allow him to ensure that he does not suffer unwarranted ill effects of others' knowledge of his HIV status?

There are, it seems to us, two parts to the correct answer to this question. First, what is involved in the need to know the patient's HIV status *does* carry greater moral weight than the patient's right of autonomy, for the following simple reason. There is this need to know because there is a significant danger to the life of some person other than the patient, and a danger to life bears greater moral weight than the right to privacy and the right to govern one's own treatment. Another way of bringing out this point is by noting that a patient who withholds information necessary for the protection of the life of another person who is caring for him — even when that information concerns himself, and its disclosure may be to his own cost, though not to the extent of being life-threatening — is a patient who is not acting virtuously: he is acting with insufficient regard for the life of the other person. So it follows from this that, where a patient's treatment involves danger to the life of another person, that treatment is not simply to be governed by the patient's dictates: his right to autonomy is not the overriding factor.

But, secondly, the need to know the patient's HIV status does not overturn his right to autonomy completely, because there is a way in which that right to autonomy can be respected in practice, while due heed is being paid to the force of the need to know. For, given that the knowledge that he is HIV-positive would make a difference only to the manner of his treatment, not to its substance, one can respect his right to autonomy, without prejudice to the substance of his treatment, and yet also without exposing third parties to any danger to which they need not be exposed. And one can do this simply by not testing him if he withholds consent to a test, but then treating him in the *manner* in which one would treat a patient known to be HIV-positive. Thus he retains a high degree of autonomy, in that his withholding consent to a test does prevent the test's being carried out. And his treatment is substantially unaffected. But the protection of third parties is secured *as well as it could be otherwise*, for exactly the same protective measures are being taken as would be taken if one were to know that the patient *is* HIV-positive.

So consent must be sought for testing, and consent is required for the test to be performed. When the patient's consent is sought, he must be informed that if he withholds consent to a test, then, though the test will not be carried out, he will be treated in the manner in which he would be treated if he were known to be HIV-positive, and that this may be to his own cost to some extent, e.g. because it may cause a delaying or slowing down of his treatment. It may also be the case, unfortunately, that this course of action involves a cost to other patients, e.g. because it delays their treatment. If so, then the patient must be informed of this, and in any case those adverse consequences for other patients must be minimised, if necessary at the first patient's expense, e.g. by delaying his treatment rather than theirs.

This way of proceeding, then, attaches due importance to the danger to third parties, for it ensures that their protection is uncompromised, and yet it also allows the patient a very high degree — an appropriately balanced degree — of autonomy. And thus we have the third recommendation in this section:

> HIV testing for the sake of the protection of other patients and health care workers must in all cases be undertaken with informed consent unless this is impossible, and, where this is not possible, every reasonable attempt should be made to obtain appropriate vicarious consent. Patients must be informed that if they withhold consent then they will be treated as if they are HIV-positive, and that though this will not alter the substance of the treatment, it could alter its manner, perhaps to their own cost and the cost of others.

It is worth repeating, however, that, because of the window period, this way of proceeding cannot provide *complete* protection for third parties. Nor, of course, could general testing provide any more protection. There is a case for saying that, in preserving the special manner of treatment only for those patients who are known to be HIV-positive or who withhold consent to a test, a dangerously false sense of security is promoted. But while it is not possible to introduce adequate safety measures across the board, this way of proceeding does at least lower the risk as far as possible: the greater proportion of potentially dangerous cases can be guarded against. Nevertheless, our first recommendation in this section deserves to be reinforced.

There remains the question of what may be done when a health care worker has actually received a high-risk exposure and the HIV status of the patient is not known — an issue not addressed by the SAMDC's 1989 guidelines. Does an HIV test require the patient's informed consent in this case? Here the point of testing is not, of course, to alter the procedure performed upon the patient; rather, it is to ascertain whether to take immediate prophylactic measures which may be beneficial to the health care worker. On this matter the Committee considered that there is a duty to obtain informed consent where it can be obtained, but did not consider that the obtaining of informed consent is an absolute precondition for testing — as is expounded by the following guidelines:

> Where a health care worker receives a needlestick (or other high-risk) injury, in view of the fact that immediate prophylactic measures may be beneficial the health care worker may obtain information as to the HIV status of the source patient but only in the following ways:
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> 1. Testing any existing blood specimen. This should be done with the source patient's consent, but if consent is withheld the specimen may nevertheless be tested. If, in the latter situation, the test is positive, the source patient must be counselled and, if he so requests, informed of the result.
> 2. Testing a blood specimen to be collected from the source patient. The informed consent of the patient must be obtained but, if he refuses to give it, the Medical Officer of Health should be approached for the necessary approval.
> 3. If the patient is unable to give informed consent and is likely to remain unable to do so for a significant length of time in relation to the prophylactic needs of the health care worker, then every reasonable attempt should be made to obtain appropriate vicarious consent.

These have in fact been incorporated into the SAMDC's latest set of guidelines.

So, with the exception just mentioned, the same conclusion has emerged in this section as in the previous sections: an HIV test cannot permissibly be performed without the informed consent of the person tested, in any case in which that consent can be sought.

We are most grateful to the other members of the Committee for the lively and interesting discussions that led to the formulation and unanimous acceptance of these guidelines.

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