Institute of Medical Ethics: working party report

HIV infection: the ethics of anonymised testing and of testing pregnant women

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Author's abstract

An Institute of Medical Ethics working party supports the view that explicit permission should normally be sought in the case of testing for HIV antibody. It discusses this in relation to anonymised HIV testing for epidemiological purposes, concluding that this is to be welcomed, given certain safeguards. It next argues that pregnant women may have a greater and more immediate need than others to know their HIV status. It concludes that this need does not justify testing them without their permission, but can be met by voluntary diagnostic testing on an 'opting-out' basis, supported by adequate briefing.

I

Jane, aged forty and recently divorced, was talking to Anne, her friend from schooldays, now the mother of four sons. She was telling her about Dr Smith, the gynaecologist who had reassured her that the symptoms she had been worrying about were all attributable to the stress she had been going through. Dr Smith, Jane explained, had done all sorts of tests before giving his verdict; and although she had hated having to wait for the results, it had been worth it: she had begun to feel better almost immediately after he told her, and now she felt as fit as a fiddle. Dr Smith had not explained to her what all the tests were for, Jane added, but she suspected that one of them had been for AIDS. The doctor knew, after all, that her ex-husband often worked abroad, and – well, all the reasons for the divorce.

'You didn't ask the doctor if he actually did that test then?' Anne enquired. Jane replied that she had been perfectly content to trust Dr Smith, who knew what he was doing. Anne, doubted if she would have been so happy about being tested for HIV antibody without first being asked. She was not even too sure that she liked the idea of the leaflet she had glanced at while waiting in her own doctor's surgery the other day. It had said that some people's blood samples might be

tested anonymously for HIV. Fortunately, Anne had not needed to have a blood test on that occasion. But if she had, what right had they to test her blood without specifically asking her permission? Lots of people, after all, might not have read the leaflet and thus known that they could refuse. And what if her blood had been tested and found positive? Could it really not be traced back to her? Even if it could not be, Anne thought, she disliked the idea of someone having that important information, while she remained in ignorance.

Like Anne and Jane, Caroline lived in the country, but on the other side of the Pennines. She was twenty-five and had been married for a year. The maternity hospital where her first child was being delivered did not routinely test for HIV antibody, and there was nothing in the minor problems of Caroline's medical or social history which led her doctors to suspect that she should be tested for it. She had not mentioned, and preferred to forget, her short and sad sexual encounter three years earlier with David, the young man from Scotland who, in any case, had not told her of his own brief experience of injecting heroin. Thus she was utterly unprepared to learn, even from her most sympathetic and motherly consultant, that both she and the apparently healthy baby she had just given birth to, were infected with HIV.

II

Introduction

AIDS and HIV infection pose ethical questions of special importance and difficulty. Some of these questions relate to the wider issues of sexual behaviour and social attitudes. Others are focused more narrowly on the relationship between clinicians and patients, and the central issue which this often reflects of an underlying tension between care for the individual and care for society. Few, if any, of these ethical questions are new, or unique to AIDS and HIV infection. Most have been debated in connection with, for example, such traditional concerns of medical ethics as abortion and euthanasia, or with earlier epidemics or endemic sexually transmitted diseases. But we now face many of them in a fresh and more drastic form.

Key words

HIV infection; consent; epidemiology; pregnancy; counselling; anonymised testing.

One factor contributing to this is that HIV infection has the potential for becoming pandemic. The last great pandemic was in 1918, when influenza killed twenty million people. Since that time, while accepting that some diseases remain incurable, Western society has come to expect generally better health and effective health care. The prospect of a pandemic, clearly, is frightening, and as in all the great plagues of the past, it has given rise to social prejudice and misunderstanding. These problems may be reduced or aggravated by the extensive scope which the media offer today for both popular education and public misinformation.

The advent of AIDS and HIV infection thus presents an urgent challenge. The need to resolve issues affecting the social and professional response to AIDS creates an opportunity to re-examine ethical questions with significant implications for many other areas. The urgency of the issues is underlined by the fact that several important choices, about screening, testing, health education and everyday clinical management, already have been forced on policy-makers and practitioners by the progress of the epidemic. Without a clearer understanding of the ethical principles involved, and of their application, individuals may be harmed, the good practice of health care prejudiced, and the fabric of society damaged.

IME Working Party

Guidance on some of these issues already has been produced by professional and public bodies, as well as by organisations representing patients' interests, and some philosophers and others have begun to examine related ethical questions. Recognising this, it seemed to the Institute of Medical Ethics that there would be an advantage in bringing representatives of these different perspectives together in a working party, to try to clarify, consider and report on the principal ethical questions relating to AIDS and HIV infection. This is the first of a series of discussion papers prepared by the working party on the basis of its discussions. It is intended for both a professional and a wider readership, and it discusses two issues which raise both topical and basic ethical questions:

- (a) the ethics of anonymised testing; and
- (b) the ethics of diagnostic testing of pregnant women for HIV infection.

III

Blood tests, ethics and HIV

'Blood tests' are amongst the most familiar diagnostic procedures in modern medicine. To draw blood however, is an invasive act. Ethically, it can be justified only because there is no less drastic way of averting the threat, to a patient's life or health, posed by whatever the blood test is designed to investigate. Legally, the patient's consent is required before the clinician draws blood, and this is also a matter of simple courtesy. To return to the example of Jane and Dr Smith, it is inconceivable that the doctor would not seek the

patient's permission in some way before inserting a needle into her vein. It is highly unlikely, moreover, that he would not explain, in however general terms, that his purpose was diagnostic.

But it is also highly unlikely that any clinician would explain to a patient the exact number and nature of all the diagnostic tests which could be done. At present, around five hundred diagnostic blood tests, of varying degrees of complexity, could be undertaken; and while the clinician may request specific tests, the pathologist in the laboratory may augment these, or substitute others, for the proper investigation of the constellation of symptoms indicated. In the case of a relatively simple and familiar test, the clinician has no difficulty in explaining to a diabetic patient, for example, that another blood sugar test is proposed. But it is a different matter when samples are being taken for multiple investigations.

The complexity of modern diagnostic testing makes it unreasonable to expect the clinician to seek specific permission for each individual test. On the other hand, for the patient's consent to be reasonably informed, he or she needs to know something about the general role of the tests in the clinician's diagnostic thinking. A familiar moral difficulty arises here when the clinician suspects, but is not certain about, and hopes to exclude, a diagnosis with grave implications for the patient. Is the clinician morally required to tell the patient what he suspects, out of respect for the patient's autonomy? Or should he refrain from inflicting what may turn out to be an unnecessary burden of anxiety on the patient? The nearest we can come to a general, morally satisfactory, response to this question, is by weighing probabilities: the reasons for telling the patient become more weighty in proportion to the strength and seriousness of the clinician's suspicions, and to the patient's indications of wishing to know. To detect the latter, however, the clinician must first provide adequate opportunity for, and comprehensible answers to, any questions which the patient may wish to ask; and for the patient to know what to ask, the clinician has to give some indication of the general options he is considering, using his discretion in proportion to the strength and seriousness of his suspicions.

In the case of HIV antibody testing, the balance of considerations strongly suggests that the patient should be informed. By now, it is well-known to the public that the consequences of a positive HIV antibody test are very serious. A patient whose clinician has strong reasons for requesting this test, already may well be bearing a burden of anxiety. Thus there seems every reason, from an ethical point of view, that the clinician should normally seek explicit permission in the case of HIV antibody testing. This view was taken, for example, by the General Medical Council in its 1988 statement on the subject. Against this background we shall now discuss two particular cases – that of anonymised testing, and that of testing pregnant women.

IV

Anonymised testing

HIV antibody testing may be done not just for diagnostic, but also for epidemiological, purposes and on an unattributable rather than a named basis. The recent introduction of what is termed 'unlinked anonymous HIV testing', or 'anonymised testing', is an example of unattributable testing for epidemiological purposes. The practical argument for such testing is based on the long-established utility of the unlinked anonymous test method as a seroepidemiological tool. Its benefits, in moral terms, are the good of any significant addition to scientific knowledge, in particular about the prevalence of infection, and any consequent basis this may provide for health education, the prevention and treatment of disease, and resource allocation policy.

It is still too early to say how far the more practical of these benefits will be achieved by anonymised HIV testing. But reliable estimates of the population prevalence of HIV infection seem essential in order to plan effective prevention and care. Hitherto, almost the only evidence has come from testing blood donations, and named individuals diagnostically: but those most at risk are discouraged from donating blood, and may be unwilling to provide it for diagnostic purposes. Reliable estimates require randomised sampling from a variety of settings. If AIDS were curable, this might be achieved by randomised or mass voluntary testing. But the medical and social consequences of a positive result make what has been introduced the only possible acceptable alternative. This involves testing the residue of blood given for diagnostic (but not HIV antibody diagnostic) tests. Before this epidemiological test, the residue is made anonymous by a complex system of coding and labelling, in different laboratories, which ensures that there can be no identification of its source, and by the samples being collected in large batches.

The moral aim of such testing – the public good and the health of individuals – is of great importance. It is so important indeed that some would argue not just for a policy of anonymised, but for secret anonymised testing. This would be justified by the argument that, for testing to be of the fullest value epidemiologically, there should be no possibility of those most at risk avoiding it. Despite the guarantee of anonymity, public knowledge that tests were taking place might discourage them from giving blood for other diagnostic purposes. For this argument to be morally justified however, it would have to be shown that the value to be derived from secrecy outweighed the injustice of depriving the public of its liberty to challenge, understand and influence official policy. Since many of those at risk of HIV infection may be unaware that they are at risk, or will eventually seek diagnostic testing, the need for secrecy seems insufficiently weighty. In purely practical terms, moreover, it is unlikely that secret testing could be kept secret.

But will anonymised testing be less epidemiologically useful, if it is publicly stated that people giving blood for diagnostic purposes may request that it should not subsequently be tested anonymously for epidemiological purposes, and that their wishes will be respected? Here again the fear is that those most at risk will refuse and so, by escaping the epidemiological net, invalidate the purposes of the study. This argument against the opportunity of refusal, however, has to be weighed against three others, which argue that anonymised testing itself is unethical.

The weakest of these three arguments is that randomised anonymised testing is unethical because the blood is the patient's property. This argument is questionable, because the blood remaining after diagnostic tests is legally the property of the health authority. Its moral weakness can be seen by asking what its force would be if the sample were not of blood, but of urine or saliva. On the other hand, blood does have emotional or religious significance for many people, and for some this is a highly sensitive issue. Respect for the sensitivities of individuals thus is an important ethical consideration to be weighed against denying them the possibility of refusal.

A second argument against anonymised testing is not so much a rational argument, as an attempt to express the feeling that it is wrong, in the light of the consequences for them, not to tell people whose blood has been found to be HIV antibody positive. But if there was no anonymised testing, the individual could gain this information only as a result of mandatory named testing, which is ethically unacceptable, or of voluntary diagnostic testing, which is still available to the person whose blood residue is tested anonymously. Thus to forego anonymised testing does nothing to help such people. On the contrary, they might be worse off, because the benefits of the epidemiological information would not be available to them.

The third argument is stronger. This is that anonymised testing is unethical because the blood was obtained, not for that purpose, but for other tests undertaken for the patient's benefit. The blood, that is, was obtained in the context of a clinical rather than a research contract, and on the assumed promise that it was being taken only for the benefit of the patient's diagnosis and treatment. In qualification of this argument, it should be added that, in practice, no extra blood is taken for the epidemiological purpose – only the residue is used; and that diagnostic tests always take precedence. Nevertheless, this third argument, taken with the need to respect people's sensitivities about blood, weighs heavily in the moral balance against the argument that the public good may be harmed by allowing individuals the opportunity of refusing to let their blood be tested anonymously. The possible harm to public confidence in medical research, and to individual relationships between patients and clinicians, makes it even more difficult to deny the opportunity of refusal.

With these considerations in mind, the IME working party concluded that not only were there no serious ethical objections to anonymised testing for HIV, but that its introduction should be welcomed, provided that the Government's announcement that it would 'let patients know what is happening' was adhered to. The practical implications of this were noted in a letter from the Chairman of the working party to *The Times*, published on December 4 1989. These were as follows.

1. Most people do not readily understand what anonymised testing means. It will be essential to explain clearly how a blood sample taken routinely from a patient is made anonymous.
2. Some patients will be seriously concerned about widespread HIV testing which may include their own blood. The leaflets and posters should also explain concisely the scope and purpose of the surveys.
3. Any patients who express objection to their blood sample being anonymised in a survey should be assured that their blood will not be used.
4. Parallel publicity should be given to the availability for individuals on request of HIV-testing and associated counselling.

These recommendations, the working party believes, are largely satisfied by widespread distribution of a leaflet published by the Department of Health and the Central Office of Information, also in December 1989. The leaflet (which is printed in several languages) states:

IF YOU ARE HAVING A BLOOD TEST...

The Government is measuring the spread of HIV infection (the virus which causes AIDS). The information collected will help us to plan services for the future. We hope you will be willing to participate. If you are having blood taken, a small drop of leftover blood *may* be separately tested for HIV. This drop will not have your name on it. If your blood is tested for HIV it will be impossible to trace it back to you, and participation will not affect your care, treatment, job or insurance.

If you have any questions, or object to your leftover blood being used for this, the doctor, nurse or midwife will be happy to speak to you in confidence. Your wishes will be respected.

If you are worried about HIV and want to have a personal HIV test, ask your doctor, or go to the nearest sexually transmitted disease (STD) clinic.

V

Testing pregnant women

Pregnant women attending antenatal clinics are among those whose blood may be tested anonymously for HIV, after being tested diagnostically, for example for rubella. When anonymised testing of pregnant women was proposed, it was argued that they would provide an

epidemiologically useful group: they had recently been sexually active, but were not necessarily at as high a risk of HIV infection as people attending sexually transmitted disease clinics, another major group identified as an epidemiological sample. At that early stage, it was objected that it was unjust to use pregnant women as a 'captive population'. But any substance there may have been to this objection now has less force, since anonymised testing has been introduced as a public policy.

Diagnostic HIV testing of pregnant women can raise more difficult ethical problems, however. As the case of Caroline and her baby, mentioned at the beginning, makes clear, the possibility of a positive result has serious implications for more than one individual. The risk of an HIV-positive mother transmitting the infection to her baby is currently estimated at between 10 and 50 per cent. Even if an infected baby does not go on to develop AIDS, he or she may well be orphaned at an early age, or taken into care even earlier by a social work department which registers any child of an HIV-positive mother as 'at risk'.

These possible consequences for her baby, it can be argued, make knowledge of her HIV status more urgent for a pregnant woman than for other people. One obvious reason for this is that, in the light of this knowledge, she may decide to terminate her pregnancy; and even if she decides to continue with it, the information is material to making informed choices about her own and the baby's future.

A further argument, about the importance of a pregnant woman knowing her HIV status for the sake of her own health, may be less persuasive. Pregnancy and childbirth, it has been suggested, may precipitate AIDS in an HIV-positive woman who, were her pregnancy terminated, might remain healthy for much longer. This suggestion would provide a counter-argument, in the case of pregnant women, to the argument that knowledge of one's HIV status confers no medical benefit in the absence of a cure. But the scientific basis for this suggestion is still controversial.

It remains true, however, that pregnant women may still have a greater and more immediate need than other people for knowledge of their HIV status. Because of this, when diagnostic HIV tests first became available, it was argued that it might be advisable to test all pregnant women for HIV, as a matter of antenatal routine, and without seeking explicit permission in advance. A precedent for this was available in the routine testing of pregnant women for syphilis, usually without clinicians telling them what the test was for. If asked, many clinicians would have justified this by saying that syphilis was sufficiently serious a possibility (for infants as well as mothers) to investigate, but also sufficiently rare not to merit burdening the woman with considering it as a possibility.

To follow the precedent of syphilis testing clearly goes against what we argued above – that it is ethically preferable to seek explicit permission for diagnostic

HIV testing. The reasons for this, we argued, included the relative strength and seriousness of the clinician's suspicions before asking for such a test. In the case of most pregnant women, there may be no stronger reasons for suspecting HIV infection than for suspecting syphilis. But there is a great difference in relation to seriousness: if syphilis is diagnosed nowadays, normally it can be cured, unlike HIV infection and AIDS. Not seeking explicit permission for syphilis testing, even assuming that this is ethically defensible, therefore is not a morally appropriate precedent for HIV testing.

Pregnant women may have a greater and more immediate need than others for knowledge of their HIV status. But this is not a sufficient moral argument for testing them without first asking their permission. Nor, in the view of one clinical member of the working party, does it justify routinely performing antenatal HIV antibody testing unless the woman declines. The view of this member is that the test should be offered to all women attending, on the basis that, following appropriate briefing and counselling, they may choose to have it. In some circumstances, the briefing and counselling may cause either clinician or patient to recognise the possibility of increased risk of HIV infection: this would add weight in favour of testing in that individual case. This approach, which could be described as an opting-in procedure, leaves the individual decision as an explicitly autonomous choice.

The majority of the working party, however, believe that the particular needs of pregnant women provide a sufficient argument for adopting a different approach in their case. Thus they favour a policy of routine, but voluntary, diagnostic HIV testing, on an opting-out rather than an opting-in basis. 'Opting-out', here, means that this is offered as one of the normal antenatal tests, and that it is not left to the woman to make a positive request for it. In practice, the woman is told that an HIV test is among those normally offered as part of antenatal care and, after briefing (the nature of which will be discussed below), she is asked if she does not want to have this test.

An opting-out procedure, it could be argued, may make it more difficult for a woman to say that she is not willing to have the test. In the majority view of the working party however, this risk is less than the risk that an opting-in policy may make it more difficult for the woman to request the test. Some members of the working party argued, for example, that an opting-in policy might discriminate against those who were less articulate, or lacked background knowledge of HIV infection and its associated risks. An opting-out approach, it was agreed, might mean that a woman who declined to have the test was treated, for infection-control purposes, as if she were HIV-positive. But the measures involved are those which normally should be employed whenever body fluids are present. Thus, the combination of an opting-out approach with good clinical practice should be sufficient to rebut any suggestion that women who decline to have the test are

being discriminated against. An opting-out approach to diagnostic testing, it must be emphasised, loses its moral force if it is implemented in the context of standards lower than those of good clinical practice, or for any reasons other than those of the interests of the pregnant women themselves.

The working party has heard evidence from pilot schemes adopting an opting-out policy of testing pregnant women for HIV antibody. This suggests that in practice as well as on balance of ethical principle, opting-out should be recommended at the present time.

VI

Pre-test briefing

But there remains an important aspect to this which needs to be considered. It is generally agreed that some pre-test counselling is normally essential in the case of HIV testing; and it may be argued that to provide this for all pregnant women would be prohibitively expensive. This argument would have considerable force if the pre-test counselling required was of the kind required for patients whose clinicians have strong reason to suspect the risk of a positive result. And if, in the course of her antenatal care, what a pregnant woman's clinicians learn from her provide such strong reasons, a considerable amount of counselling will be required before the woman's consent is requested. But at present this is not the case for the majority of pregnant women.

Where diagnostic HIV testing is offered on a routine, opting-out, basis to pregnant women, therefore full pre-counselling is not required. What is required rather, are two things: first, that against the background of the general education and publicity about HIV infection available to the public at large, at the opting-out stage all women being offered the test should be given sufficient briefing or information for them to understand the nature of the HIV test; and second, that intensive counselling should be available when a pregnant woman, in whom there was no good reason to suspect it, is found to be antibody positive.

The pre-test briefing envisaged here would be given to all pregnant women as part of their antenatal care. If general education and publicity about HIV infection is adequate, it is likely that most pregnant women will know something about the subject. It can then be explained that the test is being offered because of public concern about the infection, and because offering it to all pregnant women avoids any possible discrimination involved in offering it only to selected groups of women. Because an increasing number of pregnant women now are being tested, it might be added, British insurers emphasise that 'provided the result is negative, the mere fact of having an HIV test neither stops people obtaining life insurance nor causes them to pay a higher premium'.

Pre-test briefing of this kind should include information about the consequences of a positive or

negative result, and should set this in a realistic context of the degree of risk. The briefing would take the form of a conversation with a doctor or midwife involved in the woman's antenatal care. No pressure should be put on the woman to decide either way, and time should be allowed for the woman to ask any questions, including a further talk if she wanted time to think things over.

Pre-test briefing of this kind undoubtedly represents an investment of time and resources. But such an investment is not disproportionate to what is considered appropriate for antenatal care generally, or, for example, to the briefing and counselling of older parents about the particular risks of their situation. Assuming, then, that a maximum take-up is in the best interest of the pregnant women themselves, an opting-out procedure of HIV testing, with pre-test briefing of this kind, would appear to be morally appropriate – if the particular need of pregnant women for knowledge of their HIV status is to be recognised, and if their liberty to make informed choices about their own and their potential child's life is to be respected.

VII

Conclusion

Where do these arguments leave people like Jane, Anne and Caroline, whom we mentioned at the beginning? Public education is designed to reduce the risk to everyone from HIV infection, and anonymised testing should provide more reliable information about the extent of that risk. Our arguments in favour of anonymised testing may help to reassure those who share Anne's misgivings. Jane, by contrast, may be less sure that what turned out well for her will have as happy consequences for others. In Caroline's case, an opting-out policy with adequate briefing might have

forewarned her of the possibility that her baby would be HIV-positive. This would not have made her subsequent choices any easier. But informed choices might not have been denied her by the course of events.

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