

# The ethics of anonymised HIV testing of pregnant women: a reappraisal

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## Abstract

*Seroprevalence monitoring of HIV in pregnant women by anonymised unlinked testing has been widely adopted in the UK and other countries. The scientific rationale is to eliminate participation and selection bias. The ethical justification is that the public good outweighs any harm to individuals. The assumption has been that individuals have had their autonomy respected by the offer of informed consent. In the light of new scientific evidence, it is doubtful that the public good is best served by the continuation of anonymously testing women receiving antenatal care. It is submitted that it is no longer ethical for health professionals to refrain from informing pregnant women of the benefits of voluntary named testing, or to request their consent to anonymised testing. The legal and moral concept of duty of care is examined, and the abrogation of this duty through anonymisation is explained.*

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Frances is expecting her second child in 1995. She receives through the post an invitation to attend the booking clinic at her local hospital. With this, there is a leaflet which explains that she may have a drop of left-over blood tested for HIV anonymously. She is a medical journalist, and is aware of the recent research which shows that vertical transmission of HIV may be reduced if the mother refrains from breast feeding. She is also aware of research going on which shows a very significant reduction in vertical transmission if zidovudine treatment is given perinatally.

When she attends the clinic, she angrily informs the midwife that she objects to the anonymised testing. She says that she would very much like to know the result. The midwife, rather shaken, answers back that if she so wishes, she can go along to “the clinic down the road” where they would be happy to do the test. They do not counsel women for HIV testing in the antenatal clinic. Frances replies that she does not consider herself at risk, and would feel very uncomfortable going

to the venereal disease (VD) clinic. But, in the unlikely event that she was positive, she would like to know for the sake of her family, and in particular for her unborn child. She could at least take treatment and measures which would reduce the chance of her child being infected. She would alter her life plans. The midwife replies that she would be benefiting others by allowing her blood to be tested anonymously, as this would give an indication of the incidence in the area, and hence the resources needed to combat the disease. But if she does not wish to have the anonymised test, her wishes will be respected. Frances refuses, on principle.

Emma is attending the same antenatal clinic. She received the leaflet as well, but consented to the anonymised test. She did not consider herself at risk, although she had injected drugs briefly as a teenager. This is her third child. She does not know about the evidence for reducing vertical transmission. At birth her son appears to be healthy, but he becomes seriously ill when he is one year old. He is diagnosed as having a disease related to HIV infection. The whole family is subsequently tested. Her middle child and herself are also HIV-positive.

## Introduction

Both these anecdotes are based on real cases. They highlight some of the moral issues raised by anonymised testing.

Since 1990, anonymised testing for HIV has been, and still is being, carried out in many antenatal centres. This surveillance is part of the Department of Health’s Unlinked Anonymous HIV Prevalence Monitoring Programme. In 1990 the Institute of Medical Ethics set up a working party to consider the ethics of anonymised testing in general and of testing pregnant women in particular.<sup>1</sup> At that time there was no knowledge of how vertical transmission could be reduced, nor was the treatment for AIDS as effective as it is now. Since the report was written, the treatment of AIDS has been revolutionised by triple therapy.<sup>2</sup> Patients live longer and have a better quality of life. In addition, early diagnosis positively modifies

the prognosis.<sup>3</sup> It seems reasonable to suggest that those persons who consent to anonymised testing should at least be made aware of the benefits at the time of named diagnostic testing. The knowledge cannot be assumed. The recommendation for named testing would be particularly relevant to those who are at high risk, such as drug abusers. I will focus in this paper on the ethics of anonymised testing of pregnant women.

The working party recommended routine, but voluntary, diagnostic HIV testing of pregnant women on an opting-out basis, with pre-test briefing (described in the report). "Opting-out" was defined as making an offer of an HIV test as part of normal antenatal care. The woman does not have to make a positive request for it ("opting-in"). The latter was considered to have the potential to discriminate against those who were less articulate, or lacked background knowledge of HIV infection and its associated risks. In the light of the new scientific evidence, which I will now briefly describe, the ethics of anonymised testing urgently needs reappraisal.

In 1992 it was shown that by abstaining from breast feeding, women could reduce transmission of the virus to their offspring.<sup>4</sup> Since 1994, there is clear, uncontroversial evidence that perinatal treatment with zidovudine will reduce transmission yet further.<sup>4</sup> By these two measures alone transmission can be reduced from 25-30% to 5-8%.<sup>5</sup> There is therefore a clear benefit in informing women of their HIV status, since the probability of their offspring escaping infection is significantly increased, provided that women consent to the treatments and measures proposed.

### Public good against individual harm

With anonymised testing, there is an underlying tension in the perceived interests of society and the importance accorded to the individual's autonomy and welfare.

#### THE PUBLIC GOOD

The arguments in favour of anonymised testing have stressed the importance of the public good.<sup>6</sup> The advantage of anonymised testing is that it provides high uptake at low cost, in contrast to named testing. This allows accurate prevalence figures to be obtained relatively easily and cheaply. These figures, in turn, provide the basis, or justification, for allocating more resources to combat the disease, particularly in areas of high prevalence. They also provide valuable information for health educators and public health physicians in the prevention of the disease. They can provide information for policy makers as to whether the

encouragement of named, linked testing can be viewed as a desirable, cost-effective enterprise. Mass voluntary testing was considered as an alternative in 1990, but was deemed to be prohibitively expensive in terms of cost and resources. The assumption, based on some evidence, was that those most likely to be positive would be the least likely to come forward for testing (participation bias).<sup>7</sup> Pre-test counselling utilises resources.<sup>8</sup> "If the necessary HIV surveys use the universal named case finding method they will be complex, expensive and subject to participation bias".<sup>9</sup> In addition, the burden of knowledge of one's HIV status was deemed to be very high. Referring to the introduction of anonymised testing, it was said: "... the medical and social consequences of a positive result make what has been introduced the only possible acceptable alternative".<sup>7</sup> The stigma associated with the disease and the lack of a curative treatment were taken as justifications for this pragmatic approach. The disadvantages of anonymised testing were deemed to be of lesser significance than the benefits to society as a whole, and even to individuals, since the latter could benefit indirectly from the epidemiological information.

I would like to examine the assumptions underlying the public good arguments. The first of these is that with the information provided by anonymised testing, resources will be directed towards the needs that have been identified. This is not necessarily the case. Governments may still retain other priorities for resource allocation.

The second is that the benefits of anonymised testing are greater than from other methods of testing. Is this actually the case? If the Department of Health had recommended and resourced routine voluntary testing of all pregnant women from 1994, as advocated by the working party of the Institute of Medical Ethics, even in 1990, several lives might have been saved. The cost of AIDS in terms of human suffering and finance, are considerable. The Department of Health in 1994 did recommend routine voluntary antenatal testing in areas of high prevalence.<sup>8</sup> It is unfortunate that in this country, the uptake subsequent to this recommendation remains low, so many preventable infections in children are still occurring.<sup>10</sup> This is not, however, the case in many other countries.<sup>5</sup> This disturbing finding needs to be further researched so that remedies can be found. It should not be used as a defence for the continuation of anonymised testing in pregnant women.

#### JUSTICE AND RESOURCE ALLOCATION

The Department of Health considered universal HIV testing of women receiving antenatal care to

be cost-ineffective.<sup>8</sup> Clearly there would be opportunity costs for the introduction of routine antenatal screening for HIV, as there are for any antenatal screening tests. It could be argued that the money might be better spent abandoning routine syphilis testing in favour of HIV testing, even though the latter is more expensive, as the former is now extremely rare in this country. It is unfortunate and inequitable that those who live in a low prevalence area for HIV cannot benefit from the same screening policy. After all, an individual, by nature of his/her personal history may be at the same risk wherever he/she happens to live. It is unacceptable that there is a variation in the HIV-screening policy even in an area of high prevalence such as London.<sup>11</sup>

#### THE BURDENS OF NAMED, LINKED TESTING

The authors who argue in favour of anonymised testing place great emphasis on the burdens of diagnostic HIV testing.<sup>9</sup> Knowing that one is HIV-positive undoubtedly causes distress. This will be even more profound in the case of the mother-to-be. There is also the prospect of stigmatisation. Life insurance can be difficult to obtain. Employment may be put in jeopardy.

The working party raised the serious implications of a positive result for “more than one individual”. For example, the real prospect of the child being orphaned at an early age, or taken into care by social services. (We are not given any evidence that the latter is universal policy).<sup>1</sup>

Some women, if they are informed that they are HIV-positive, may wish to end the pregnancy in view of the fact that they harbour a lethal virus, albeit with an ill-defined latent period. Healthy babies may thus be aborted. It could be argued that if HIV testing is deferred until the disease manifests itself, mother and child can, for a while at least, enjoy a relationship untainted by fear and medicalisation. In addition, babies who would have escaped transmission are unnecessarily treated with zidovudine. The long term consequences of this are uncertain.<sup>12</sup>

#### **The doctor-patient relationship, autonomy and beneficence**

The doctor-patient relationship (or nurse-patient relationship) can be characterised as a fiduciary one. Within this model, beneficence cannot be isolated from patients’ autonomy. Pellegrino and Thomasma define beneficence-in-trust such that “...physicians and patients hold ‘in trust’ (Latin, *fiducia*) the goal of acting in the best interests of one another in the relationship. In the main, the patient’s fulfilment of this trust resides in carrying

out the negotiated plan for his or her health. The burden of trust more often belongs on the physician, who must act in the best interests of the patient”.<sup>13</sup> Gillon also emphasises respect for patient autonomy as integral to the relationship. “Respect for a patient’s autonomy should thus be seen as a presupposition of the doctor-patient relationship, not only because it is the underlying assumption behind any voluntary interpersonal relationship, but also because in any case such respect will probably improve the beneficent outcome that the doctor intends to produce.”<sup>14</sup>

Downie outlines the traditional view of the relationship whereby the doctor aims to benefit his patient, within a set of institutional bonds, both legal and quasi-legal “which can be united in the concept of a social role”.<sup>15</sup> He then goes on to describe a more modern rights-based model whereby duties are framed in relation to patients’ rights to medical services. The doctor-patient relationship evolves into a partnership, with patients remaining as patients, but with a “...greater awareness of their rights as consumers of health care”.<sup>16</sup>

Autonomy is accorded a high value whichever model we adopt. If we consider respect for autonomy to be a fundamental principle in health care, then we should give people the opportunity to know their HIV status so that in the event of a positive result they can change their life plans, prepare themselves for the times ahead, seek information, protect others from horizontal transmission and generally have the opportunity to take charge and “rewrite their story”.<sup>17</sup> Further, as stated earlier, pregnant women have the opportunity to reduce vertical transmission.

The belief that persons are “better off” not knowing their HIV status, is a throw-back to the old days when physicians generally did not inform patients of the diagnosis of cancer.<sup>18</sup> This paternalistic attitude is no longer considered acceptable in the new ethics, being an infringement of autonomy and contrary to the wishes of most patients.<sup>19, 20</sup> Why should HIV be treated differently? After all, there is much in common between AIDS and cancer. Given that third parties may be put at risk by transmission, the arguments in favour of truth-telling are even stronger.

The working party argued that the special position of pregnant women makes it more urgent for them to know their HIV status and to be able to exercise their reproductive choices. The women, their partners, and their children can then be treated sooner rather than later.

There is concern, however, regarding the long term consequences for HIV-positive women

receiving single-drug treatment, in view of the theoretical prospect of viral drug resistance later on, and women must also be informed of this risk.<sup>21</sup>

“OPTING-IN” TESTING AND RESPECT FOR AUTONOMY  
It could be argued that offering voluntary named testing upon request (“opting in”) respects autonomy and can be offered as an alternative to those who object to anonymised testing. Is there a morally relevant difference between this offer and that of “opting out”? The working party of the Institute of Medical Ethics considered this question, and placed the focus on the woman’s perception of risk. If HIV testing is offered routinely, as for syphilis, a woman who chooses not to opt out, need not consider herself at high risk. On the other hand, if she has to contemplate opting in and having special counselling, she places herself in the high-risk group. If, after discussion, both she and her professional adviser consider her to be at low risk, they will agree that the test is unnecessary and a waste of resources. If her adviser *agrees* to do the test, however, the woman may well then perceive herself to be in the high-risk group, and experience considerable anxiety.

If a woman considers herself at high risk prior to testing, her self-perception of risk is made much more visible. There may be strong family and socio-cultural pressures not to be identified as HIV-positive. If a woman has to take positive steps for diagnostic testing, the pressures not to be identified may prove stronger than the wish to know. This certainly seems to be borne out by research studies.<sup>12</sup> With normalisation of the test, however, a woman can feel that she is participating in normal antenatal care and may be more willing to follow medical advice, ie the recommendation to have the test. It could be argued that refusal of the test could be difficult for some women. Clearly voluntary testing must be exactly that. Women should be properly advised in a non-coercive manner.

### The doctor-patient relationship and the duty of care

The duty of care is both a moral and a legal concept, and flows from the relationship of the doctor or nurse, to the patient.

Discussion of the professional’s duty of care is strikingly absent from the literature of anonymised testing. For example, Gill *et al*, when considering the legal and ethical basis for anonymised testing, inform us that: “...No fundamental ethical principle is breached by unlinked

anonymised HIV testing”.<sup>6</sup> Reference is then made to a number of distinguished organisations in agreement with this statement. Is this true in the light of antenatal testing today?

If a woman has booked into an antenatal clinic, the assumption is that she wishes to continue with her pregnancy. The professional providing antenatal care has a duty to promote the wellbeing of both the woman and the fetus. The health professional and the woman share the same goal — the welfare of the fetus. The maternal responsibility entails consenting to treatments and measures which will benefit the unborn child, provided that the woman is not made to suffer an undue burden herself. McCullough and Chervenak explore the duty of care of the health professional towards the pregnant woman. In their analysis, the mother-to-be, as an autonomous agent, confers on the pre-viable fetus, the status of being a patient.<sup>22</sup>

Health professionals should not shy away from providing advice based on recent scientific evidence for fear of appearing coercive. They should focus on providing information which is material to women’s welfare whilst respecting their autonomy.

### Consent

Respect for autonomy is integral to the process of consent. When a patient consents to have a blood test, the implicit assumption is that the test is for information that will benefit the patient. The patient has a right to be informed of the results of the test. I have already suggested that knowing the result of an HIV test, if positive, is, on balance, of benefit to the woman and to the fetus (if he/she is not aborted). A woman attending an antenatal clinic has a strong interest in knowing the result of a test which will have profound effects on the wellbeing of her fetus as well as herself. With anonymised testing, no benefit can accrue to the mother since the result of the test cannot be traced back to her. Anonymisation deprives her of the opportunity of benefit.

This situation is analogous to non-therapeutic research, and should meet the same rigorous criteria for informed consent. The *procedure* is not important. The blood is being taken anyway for other tests (which she has presumably consented to), and only if there is some left over is it tested anonymously for HIV. It is the anonymisation of the *result* which is crucial. Since the woman is being asked voluntarily to relinquish the opportunity to learn the result, she needs to know the advantages and disadvantages of so doing. Put it another way, she needs to know the benefits and burdens of receiving the result. For her consent to

be informed, she would need to be told about the new therapies available for decreasing vertical transmission.

Without informed consent, from the Kantian perspective, women are treated solely as a means, rather than ends in themselves.<sup>23</sup>

#### CONSENT AND THE LAW

For consent to be valid in law, it must be competent, informed, and voluntary. Legal competence or capacity requires that individuals understand the nature and purpose of the medical treatment and the principal risks, benefits and alternatives. The patient needs to understand in broad terms what will be the consequences of not receiving the proposed treatment, to retain the information for long enough to make an effective decision, and to make a free choice.

#### UNDERSTANDING

Concern has been raised that some patients do not fully understand the implications of anonymisation. The Institute of Medical Ethics accepted the proposal that “most people do not readily understand what anonymised testing means”. Kahtan gives an example of a patient whose child was later diagnosed as having an HIV-related illness after she was tested prenatally, but anonymously. She was bewildered that she was not informed of the result: “...but surely, if they found something wrong they’d tell you, wouldn’t they?” The author suggests a formal study to assess what proportion of the target population understand the meaning of anonymised testing.<sup>24</sup> Kahtan’s example suggests an ingrained tendency to rely on the medical profession. Patients cannot grasp the fact that they are being asked to waive their rights, as their trust in health care professionals to protect their interests is so powerful.

#### DISCLOSURE

The landmark legal cases in the UK for informed consent consider in detail the duty to disclose the risks of procedures, not the alternatives to the contemplated treatment, including non-treatment.<sup>25</sup> This omission is addressed by Kennedy and Grubb. They take the view that the knowledge of alternatives may be as significant as the knowledge of risks, and both should be disclosed: “That this should be an intrinsic element in the duty to disclose is beyond doubt”.<sup>26</sup> They cite the Californian Supreme Court case, *Truman v Thomas* (1980) which decided that the doctor’s duty to inform, in principle, may extend to advising the patient of non-treatment and its dangers. The example given was of the failure to advise a woman of the consequences of refusing a

Pap smear. If she subsequently died from cancer of the cervix, this failure could be considered to constitute a breach of duty.

The leaflet published in 1990 by the Department of Health makes no reference to breast feeding or to treatments to reduce transmission. Any woman reading the leaflet from 1992, and especially after 1994, and receiving no other information, could be considered to be inadequately informed.

#### Informed refusal

If a woman fully understands the nature of anonymised testing and is informed of the value of a linked test she may still agree to the anonymised test. She may be putting her fetus at greater risk, but since she does not *know* if she carries the virus, it could be argued that she has not intended or been aware of causing any harm.

But what about the health professional? She has asked a patient to deprive herself of a potential benefit. It could be argued that since she does not know if the woman is HIV-positive, she also is exempt from any intentional or conscious harm and is not responsible for the outcome. She has, however, failed to fulfil her duty of care if she does not advise the woman of the benefits of diagnostic testing.

Consider a woman who is attending the family planning clinic and who is to have an intrauterine device inserted. She is asked if during the procedure (just before the coil is inserted) she would like to have a cervical smear (which we will assume, for the sake of argument, is advised under the current screening guidelines). She is then asked if she would consent to having the test done anonymously. If she has pre-cancerous cells, the result cannot be traced back to her, and she cannot receive the treatment which would normally prevent the progression to cancer. This would seem an outrageous suggestion to most people, and the doctor or midwife would be considered to have abrogated her duty of care.

Consider then the case of women possessing a gene which predisposes to cancer of the breast, such as the BRCA1 gene. A simple blood test is available to detect the gene. For those at risk a single, relatively non-toxic, drug treatment is found which, if given for a short period of time, will reduce the likelihood of breast cancer from, say, 25% to 5%. The incidence of this genotype is unknown, however, and it is considered more cost-effective to test women anonymously. Women are not informed of the benefits to them if they screen positive.

Is there a morally relevant difference between these examples and the anonymised HIV testing

of pregnant women? The only one of significance is that the main benefactor in the latter case is the fetus, not the woman, and that this benefit is dependent on the mother deciding autonomously to have the named blood test, and then, if she is HIV-positive, to consent to treatments and interventions which will benefit her future child. But in the examples given, the benefit also depends on consent to treatment. If a woman decides to continue with her pregnancy, she has declared her intention to assume responsibility for her unborn child, and to promote his/her welfare.

Can it be ethically defensible for health professionals to *ask* patients to take risks, particularly when third parties are involved? Grubb and Pearl think not: "... But the reality of a potential third party victim may lead us to conclude that public policy should deny a patient the opportunity to waive his doctor's duty to him, because of the risk that this will create to others."<sup>27</sup> Even if the fetus is not a legal person, the health professional has duties towards the mother, and, through her autonomous consent, to her unborn child as well. Any benefit to the fetus will be perceived as a benefit to her.

### Conclusion

Anonymised testing of pregnant women breaches the fundamental principles of respect for autonomy and beneficence if women are not informed of the advantages of named HIV testing. Even with fully informed consent, for health professionals actively to request women to ignore the needs of third parties, and in particular of their unborn children, distorts the duty of care and undermines the goals of medicine. Unless real efforts are made to provide "normalised" antenatal testing, at least in areas of high prevalence, such that high uptakes are achieved, the intended public health benefit of anonymised testing in this group is considerably reduced, if not eliminated. The evidence suggests that such efforts are not being made in many centres in London.<sup>11</sup> It is a poor reflection on the profession that we have been counting the number of babies at risk of infection since 1990 but have failed to protect them, even when it was in our power to do so.<sup>28</sup>

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