

# HIV NURSING

CARING FOR PEOPLE AFFECTED BY HIV

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#### **Aims and Scope**

*HIV Nursing* has been developed as a forum for those at the forefront of caring for people affected by HIV. The journal is supported by a highly respected Editorial Board drawn from a wide range of nursing specialties. This is further strengthened by an Advisory Panel who will be making regular contributions to the journal.

*HIV Nursing* is intended to provide a medium for communication on issues relating to HIV care, which will be run by the care professionals for those involved in the day to day matters affecting the lives of patients.

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# Ethical issues in HIV nursing

Jane Bruton

HIV Nurse Manager, Chelsea and Westminster Hospital, London

## Case scenario

*The following is based on an actual case, although names and some details have been changed to protect anonymity.*

I was bleeped by one of the staff nurses on a medical ward. "We have a 21-year-old female patient, from a developing country, who doesn't know she is HIV-positive. Her family don't want her to know. She is on antiretrovirals which she thinks are for a heart condition. What should we do?" she said.

My mind was working overtime: where had the patient been tested? Not another patient who has been tested without giving consent. What right do the relatives have to deny her rights? I went to the ward and when looking at the notes, I realised that the situation was more complex. This young woman, Sara, had been HIV positive for 12 years. She couldn't speak English; she was there to start medication and would be discharged in three days' time back to her own country. Her male relatives were interpreting for her and appeared to act like bodyguards.

The feelings were running high among the nursing staff and there were the concerns for her human rights and her right as an adult to know. However, there was the problem of not telling her the truth, compromising our code of conduct. There was also concern about the potential disastrous impact on her life in her own country if she knew. Who were we to judge? How could we advocate for her? There

were no easy answers. We agreed to meet to discuss the issues involved and to try to unpick our feelings regarding the best interests of the patient.

I sought the consultant involved to see if there was more to the story. It was, of course, even more complex. Sara's mother had been diagnosed positive following a blood transfusion and, subsequently, her two children were born HIV-positive, but the children were not told. They were told that they had a blood disorder. The family decided to tell Sara's older brother he was positive when he was 11 years old. He committed suicide. The family were devastated and decided not to tell Sara.

On admission, the consultant had made it clear to the family that Sara had a right to know and that she will be informed at her next appointment if they hadn't told her by then. However, on this occasion, the consultant had agreed to admit Sara to start medication to help her feel better and increase her chances of accepting the diagnosis. The consultant said "I don't think I will see Sara again as the family fear I will tell her the truth".

The discussion on the ward was enhanced with this information, but it didn't help us know what was right: only that perhaps there isn't a *right* answer and that maybe we knew what would be *right* for each of us in the same situation. Most importantly, we had all been able to express our views and concerns on this ethics issue.'

This issue of *HIV Nursing* demonstrates that HIV has challenged and continues to challenge health professionals, patients, partners and carers facing complex ethical issues. The overwhelming message from all of our authors is not to think that decisions on these matters can be taken alone. The first principle is support and collaboration: discuss the problem with colleagues; seek expert advice; and acknowledge the dilemma.

Researchers in HIV face particularly difficult issues. As Ainsley Newson concludes in her article on research ethics and HIV clinical trials, there are still opposing views on the ethical issues faced in HIV research trials, but a recognition of these ethical challenges will help projects 'to embrace all local needs and sensitivities'. Her article explores the dilemmas facing biomedical researchers in HIV,

both in the developing and developed world, and discusses the guidelines and governance that are in place to help balance conflicting interests and rights.

Research ethics committees are often challenged by proposals that involve children as research subjects. John Lambert and Margaret Clapson's article on the search for a paediatric HIV vaccine state the imperative: to be successful in developing an effective vaccine for children in the developing world. However, they recognise that considerable obstacles have to be overcome. Lambert and Clapson outline the trials conducted to date, and discuss the ethical issues around informed consent and assent in children.

Probably one of the most difficult issues facing newly diagnosed patients is whether or not to

disclose their HIV-positive status to their partner. With the recent prosecutions for transmitting the virus, the issue of non-disclosure has been raised in stark relief. Lisa Power from Terrence Higgins Trust discusses the implications of the criminalisation of people living with HIV, and the potential impact on patients, health professionals and public health. She clarifies the legal issues and the responsibility of nurses, health advisors and doctors and, again, emphasises the importance of a team approach.

Melanie Ottewill and Jonathan Roberts, both Health Advisors, share a real case scenario highlighting the dilemma of disclosure, which will be familiar to many nurses working in HIV. In their

article, Ottewill and Roberts unravel the issues to be considered in the clinical setting. They outline the UK approach to partner notification and the importance of consent and confidentiality. They conclude that there is an urgent need for agreed guidelines on partner notification to ensure consistency of care and timely interventions across the clinics.

The ethical dimensions of HIV care pose dramatic problems because of the stigma attached to the disease. There is no single, right answer, but the task of forming an ethical framework for nursing decisions demands diligent critical reflection, and shared experience.

# Disclosure, confidentiality and the law

Lisa Power

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Over the past three years, there have been several high-profile prosecutions in the UK of HIV-positive people for transmitting the virus to another person or persons. These cases have had a number of unintended effects, including an increase in the stigma felt by many people with HIV, a fear of malicious allegations and a re-evaluation of health promotion messages. Not only have people with HIV become concerned about the potential implications of these cases, but so have clinical and nursing staff.

The law that has been used to prosecute these cases (the Offences Against The Person Act, 1861) does not specify HIV, only the causing of 'grievous bodily harm'. Since this law has already been used in one case of prosecution for transmission of herpes (although subsequently dropped as a result of difficulties in determining who had infected whom), there is a potential for it being used for transmission of any serious sexually transmitted infection.

Worries about legal duties and potential liabilities resulting from this have led many staff to look more closely at the realities of confidentiality within HIV and genito-urinary medicine (GUM) services. What had seemed a comfortable public consensus that confidentiality within GUM services was absolute has been shown to be inaccurate, and there is an urgent need for clarification.

Put simply, a variety of pieces of legislation and guidance currently support clinical staff in considering the limits of confidentiality. The National Health Service (NHS) Venereal Diseases Regulations (1974) prevents disclosure of any information capable of identifying an individual, except to a medical practitioner engaged in treatment or prevention of the disease. These are the strictest regulations, and they are certainly the ones that most patients believe are in use. A recent Terrence Higgins Trust (THT) survey of patient literature found that almost every leaflet promised people complete confidentiality in the GUM setting – a promise that is clearly not able to be kept when criminal proceedings arise.

However, most clinicians we have spoken to are far more influenced by the General Medical Council (GMC) guidelines on confidentiality (Serious Communicable Diseases, 1997), and these are the ones most adhered to and quoted by GUM staff. These guidelines are slightly vague, in order to allow for exercise of individual clinical judgement as to the best course of action, but they make a useful distinction between powers and duties; there are things a doctor can do, but not that they must do. The guidelines state at paragraph 22:

*'You may disclose information about a patient, whether living or dead, in order to protect a person from risk of death or serious harm. For example, you may disclose information to a known sexual contact of a patient with HIV where you have reason to think that the patient has not informed that person and cannot be persuaded to do so. In such circumstances you should tell the patient before you make the disclosure, and you must be prepared to justify a decision to disclose information.'*

In addition to this, there are the NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000 and the NHS Code of Practice on Confidentiality. The latter code is looser in its interpretation of confidentiality but has no statutory force, whereas the Directions reinforce the 1974 Regulations.

Into this minefield of legislation steps the doctor or nurse, faced with concerns both about their own potential legal liability and about onward transmission of HIV. What should they be doing? From discussion with a wide range of experts – lawyers, the Crown Prosecution Service, police, public health professionals and of course GUM staff and people with HIV themselves – THT would recommend the following courses of action.

- Take time to have a team discussion so that all staff are aware of local prioritisation and interpretation of the various guidelines.
- Be aware that the GMC guidance only explicitly supports informing a known partner at ongoing risk, and then only after discussing it with the original patient; there is no duty as such to inform any third party and many clinicians prefer not to do so where, for example, there is a risk of domestic abuse or other violence.
- Be aware that criminal prosecutions have only proceeded where there has been a victim complainant; i.e. 'no transmission, no case' and 'no complainant, no case'.
- Think through the potential effect of breaches of confidentiality upon community trust and the willingness of patients to be tested, to tell the truth about sexual contacts and to seek help with difficulties in maintaining safer sex.
- Be clear in advance about the circumstances under which your unit would hand information over to the police, and be honest with patients about this.
- Discuss ways in which the issues can best be raised with patients in order to inform them of the

potential risks without alarming them unnecessarily and without reinforcing fears of disclosure.

- Understand that the recent prosecutions do not impose any new duty upon GUM staff, only a heightened awareness of the issue and a clearer potential for involvement in legal cases.

For most clinical staff, the paramount issue for individual and public health is likely to be how to mitigate the possible impact of these legal moves

upon an individual HIV-positive person's willingness to disclose problems and to seek help. If the impact of prosecutions is to gain retribution for a few individuals, yet causes many more to shun testing, or to fail to seek help with post-diagnosis transmission of sexually transmitted infections or contact tracing, or to fail to seek advice for difficulties with safer sex for fear of this being produced in court at a later stage, then this new use of the law will have done far more harm than good.

## Research ethics and HIV clinical trials

Ainsley J Newson

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### Introduction

**A**s the HIV pandemic enters its third decade, with over 40 million people infected, the demand for a treatment or preventive vaccine is acute. The virus has now spread to every region of the world and rates of new infections are still rising dramatically in sub-Saharan Africa, Eastern Europe and Asia. Over 25 million people have died of AIDS since 1981 [1].

The effectiveness of any putative treatment or preventive measure against HIV must, of course, be proven through research. To date, research in communities living with, or at risk of, HIV infection has enabled much to be learned about preventing the spread of the virus and maximising quality of life for those already infected. Antiretroviral medications have provided a major breakthrough, although they remain available to only a fraction of those who require them.

Investigations into the medical, epidemiological and social aspects of HIV give rise to difficult questions in research ethics. The number and location of people affected with HIV, combined with the lack of access to basic health care and stigma associated with the disease have caused significant controversy, particularly for international collaborations. This article reviews some of the significant ethical issues that arise from biomedical research into HIV and highlights the regulatory mechanisms which aim to balance complex and conflicting rights and interests in this difficult field of research.

### Research ethics and HIV

Biomedical research on HIV focuses on many different aspects of the virus, including potential vaccines [2], the use of microbicides to prevent infection [3], prevention of maternal-foetal transmission [4,5] and the preventive significance of male circumcision [6]. However, undertaking this research is not an easy task [7,8].

HIV research is subject to several 'macro' considerations. Grady, for example, highlights the issue of when to move to a large-scale efficacy trial, in light of the distinct scientific uncertainty associated with HIV, but also the public health justification for a vaccine [9]. She also cites the potential for social (as opposed to physiological) harm through research participation and the importance of not forgetting about behavioural interventions that can prevent HIV infection in the first place. Schüklenk and Hogan discuss the issue of non-compliance by research participants and the balancing of paternalism with autonomy required to solve the problem [10]. Complexity is also introduced by the nature of HIV trials, often large in scale and international in coverage, highlighting disparities in wealth, power and infrastructure between researchers and participants.

From a 'micro' ethical perspective, if a research proposal is to be reviewed by a UK National Health Service Research Ethics Committee, several aspects of the study should be examined before approval is granted [11]. These include the scientific design of the study, recruitment of participants, obtaining informed consent, care and protection of participants, ensuring participants' confidentiality and issues relevant to the participants' community.

Several policy documents and guidelines guide researchers who work in the field of HIV clinical trials. These include comprehensive guidelines produced by UNAIDS [12], the Council for International Organisations of Medical Sciences [13] and the World Medical Association (WMA) [14].

### Significant controversies in HIV research

Between these 'macro' and 'micro' issues lies a complex and interwoven web of ethical conundrums, particularly affecting research in developing countries. These various problems can

be grouped into two classes: (1) ensuring acceptable standards of care for research participants; and (2) tailoring research to meet the local needs of the community in which it is being carried out [15].

### *Ensuring acceptable standards of care for research participants*

Determining how participants in a research study should be treated is fundamental to the acceptability of any project. Two aspects of HIV research have caused particular problems: the use of placebo-controlled trials and continuance of care after a trial has ended.

In the late 1990s, controversy arose over the use of placebos in research trials. In many of the countries where HIV research is carried out, healthcare for people with the virus is virtually non-existent. Questions therefore arose as to whether it was acceptable for control participants to receive a placebo medication when an effective treatment already existed, but which was unavailable or unaffordable in the research region [8,16].

On the one hand, using placebos may lead to an ethical double-standard in which trial participants in developing countries are exploited through not receiving the same level of care as those in developed countries. However, this disparity may be rationalised by recourse to the general inequalities in the global allocation of healthcare, which is not something that HIV research can overcome [15,17].

In 2000, the WMA appeared to take the former view. When reformulating the *Declaration of Helsinki*, Article 29 was added, requiring that any new method should be tested against the best available treatment, suggesting that it was acceptable to undertake a placebo-controlled trial only when there was genuine uncertainty in the community about what constituted the preferred treatment [14]. But in the context of the developing countries, what constitutes the best treatment?

In 2002, the WMA added a note of clarification to Article 29. This states that a placebo-controlled trial may be ethically acceptable even if there is a proven therapy, if there are compelling and scientifically sound reasons why the use of a placebo is necessary to determine the safety or efficacy of a new therapeutic agent [14]. This recognises that, were it not for the permissibility of placebo-controlled trials, prospective research participants in developing countries may be denied access to research. However, argument on this issue is far from resolved.

The conduct of HIV research in developing countries has also attracted criticism as to the standards of treatment provided to trial participants after a research project has ended [15,18,19]. Although an intervention may be successful during a trial (to the great benefit of all who have received

the trial agent), resource constraints often prevent the intervention remaining available after the trial has ended, leaving participants with no continuance of care.

This outcome seems to breach the goal that all research projects must aim to improve the health of the population in which they are being carried out [20]. It may also undermine the process of informed consent, particularly given the vulnerability and desperation of many potential participants [19]. As an alternative, good-faith arrangements need to be established at the start of a research project, including provisions for ongoing clinical care after the project ends; albeit recognising the fact that this process is not always straightforward and will be subject to political intervention [8]. At the very least, however, it seems reasonable to claim that any successful trial should be used in advocacy for introducing the treatment widely, and researchers should not simply 'abandon' their study populations at the end of a project.

### *Tailoring research to meet the local needs of the community*

Given that the majority of HIV infections occur in developing countries, it makes sense to undertake research with these populations. However, it is important to avoid merely imparting western research practices and principles to these groups. Instead, it is vital to tailor the research design to the specific needs of the target community.

The first point to consider is informed consent, and here it is important to account for the cultural context of a study population. Statements to participants that may seem straightforward in developed countries may have very different connotations in developing countries. For example, framing a diagnostic HIV test as a 'benefit' of research participation may mislead vulnerable groups. Moreover, for many potential research participants, access to a trial may be the only way to obtain any kind of healthcare, which could induce participation. Additionally, local understanding on the part of the research team is vital, to ensure that consent mechanisms account for and respect local knowledge, beliefs and customs [8,18].

A related issue is the potential for research participants to conflate the research context with clinical care, or something else entirely. If certain benefits are only available to trial participants, they could enter the trial under the therapeutic misconception that they will receive individually tailored care [8,18]. This issue is not confined to the developing world – some participants in London-based HIV research projects, for example, are asylum seekers. Many in this group erroneously believe that participating in a research trial may help their application for asylum (McDonald L, Centre for Professional Ethics, Keele University, personal communication). All trial participants

should therefore be made explicitly aware that they are not receiving free healthcare or other non-research-related benefits.

Further issues arise in the context of vaccine trials. The nature of these trials is such that healthy volunteers (often women) are required. There is a danger that, without appropriate and full explanation, trial participants or their partners may harbour a false sense of security about reduced susceptibility to HIV infection [18]. By misinterpreting the safety of the vaccine intervention or placebo being trailed, they could end up much worse-off (infected with HIV) than they would have been had they not participated.

Berkley highlights another potential problem with vaccine trials: how to care for those who become infected during the trial [21]. That is, should these participants be provided with the best possible standard of care, or merely the best care available in that community?

## Conclusion

HIV research, particularly that undertaken in developing countries, raises a diverse and complex range of ethical problems. Many of these issues are ongoing, with no agreement yet reached between opposing parties. At the very least, it seems necessary that all researchers recognise and take into account the complex and interrelated challenges that can arise. This recognition should form part of a 'situational analysis' of every research project, to embrace all local needs and sensitivities.

Although a global ethic may be unattainable, the strategies, partnerships, policies and political commitments that have emerged to date are laudable. It is also important that in future projects, researchers, governments, HIV/AIDS organisations and (perhaps most importantly) participants actively collaborate on research design, implementation and follow-up. Efforts should focus on addressing these overlapping ethical issues and developing long-term solutions within a framework of global justice.

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# In search of a paediatric HIV vaccine: scientific and ethical issues

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## Introduction

**H**IV transmission from mother to child (MTCT) is the primary mode of infection of children, and occurs during pregnancy, delivery and breastfeeding [1,2]. Therefore, the interruption of MTCT is an extremely important preventive strategy. Without antiretroviral (ARV) therapy, the incidence of transmission varies from 15% to 40% [3,4], with the majority of infections occurring during or after birth. The wide range in the efficiency of vertical transmission of HIV depends on the setting in which the mother/infant pair is living, and on whether treatment and other preventative interventions are available [1–7]. The vast number of new infections occur primarily in the developing world, where antiretroviral drugs are not yet widely available and breastfeeding may be a necessary fact of life. Prevention strategies for MTCT include administration of antiretroviral agents (ARVs) to the mother and/or infant, avoidance of breastfeeding or the administration of ARVs to the mother while she continues breastfeeding. In addition, interruption of breastfeeding transmission might be achieved through the use of vaccination against HIV of the newborn. Based on the successful model of hepatitis B prevention by treatment of newborn infants, research protocols have been designed to prevent the MTCT of HIV by the administration of passive HIV-specific antibody preparations and HIV vaccines to the mother and/or infant [8].

In this article, we will discuss the development of paediatric vaccines and consider the ethical issues involved in paediatric HIV prevention.

## Paediatric HIV vaccine development

Vaccines have been the key to infection prevention in both paediatric and adult medicine. Many childhood vaccines were made using standard techniques, with either live attenuated viral vaccines or inactivated vaccines. Hepatitis B vaccine is the only paediatric vaccine for viral disease that is made from the major surface protein of a virus, the hepatitis B surface antigen. It is also the first vaccine to be made by recombinant DNA technology [9]. This technology will probably be used to develop an HIV vaccine because it is deemed the safest way to deliver HIV antigens – live attenuated or killed HIV vaccines are too risky. Historically, the usual procedure has been to test

vaccines in adults before their testing in children with the result that vaccine development in children often lags behind adults.

Of at least 110 HIV vaccine trials that have been completed, only two have included children [10]. Clearly, all of the vaccine trials in adults cannot be replicated in children. However, the neonatal and infant immune system is significantly different from their adult counterparts and, whereas safety data from adult studies are transferable to the paediatric population, it will be difficult to predict what types of immune responses will be achieved from one population to another. Dose and schedule requirements may also differ in children.

Testing of vaccines in infants and children may be a quicker way to assess the efficacy of a candidate HIV vaccine; in other words, the ability to assess the prevention/treatment of acute HIV infection may be better accomplished in a vertically HIV-infected paediatric cohort than in adults. Thus, a well-designed efficacy trial of an HIV vaccine in children could potentially result in a more rapid definitive answer.

## Clinical trials using immune-based therapy to prevent MTCT

### *Pregnant women and neonates*

A number of MTCT intervention studies have been conducted through the US National Institutes of Health AIDS Clinical Trials Group (ACTG) including: (1) a phase I study of active immunisation of HIV-infected pregnant women with an HIV glycoprotein gp120 subunit vaccine (AIDS Vaccine Evaluation Group Study 104) [11]; and (2) a phase III efficacy trial of HIV-specific immunoglobulin (HIVIG) administered to HIV-infected pregnant women and their newborn babies (Paediatric ACTG study 185) [12–14] (see Table 1).

### *Children*

Further HIV vaccine trials have been performed in HIV-exposed and HIV-infected children (see Table 1). These included a vaccine immunotherapy trial of HIV-subunit vaccines administered to asymptomatic HIV-infected children [Paediatric AIDS Clinical Trials Group (PACTG) 218] [15]. This study, utilising three recombinant subunit HIV vaccines, revealed excellent safety but poor efficacy of the vaccine. However, the safety results of this study

**Table 1: Trials of HIV vaccines and immunotherapy in pregnant women and children**

<b>Trial:</b>	<b>Reference</b>
<i>HIV-infected pregnant women</i>	
AIDS Vaccine Evaluation Group Study 104	[11]
Pediatric ACTG Study 185	[12–14]
<i>HIV-exposed and HIV-infected children</i>	
PACTG 218	[15]
PACTG 230	[16]
PACTG 326	[17–19]
<i>ACTG, AIDS Clinical Trials Group; PACTG, Pediatric AIDS Clinical Trials Group.</i>	

helped pave the way for future HIV vaccine trials in HIV-infected and non-infected newborn infants and children. Subsequently, two phase I vaccine trials have been conducted in HIV-exposed children. First, PACTG 230 [16] utilised recombinant gp 120 vaccines, engineered by Genentech and Chiron, which had previously been shown to generate CD4 but not CD8 cellular (cytotoxic T cell) responses. While the results of PACTG 230 were encouraging, with over 50% of children attaining an HIV-specific lymphoproliferative response and 87% an antibody response, these vaccines were not capable of generating cytotoxic T-cell responses, as one would have predicted. Second, PACTG 326 was a phase I study of the ALVAC canarypox viral vaccines produced by Pasteur Aventis; these immunogens had been shown to generate cytotoxic T-cell responses in a number of HIV-negative adult vaccine studies [17–19]. The vaccines in this study were safe, but immunogenicity was less than that found in adult studies [20,21]. Specifically, no antibody responses were found, lymphoproliferative responses to HIV-specific antigens were found in less than 50% of vaccine-recipients, and cytotoxic T-cell responses, although modest in nature, were seen in approximately 50%.

### Ethical issues of research involving children

The foundation of all clinical research is that it is conducted in an ethically sound manner [22]. Important principles that encompass the guidance of consent for clinical trials include: autonomy, beneficence, non-maleficence and justice [23]. These principles must be modified in the setting of the dependent child. The available options for vaccine development in children are clear: (1) first study in adults and then repeat in children; or (2) perform studies in parallel.

### Consenting process in children

The enlistment of the clinical research subject is an ever-daunting task. This is especially difficult in the paediatric population, in which others (parents/-carers) are responsible for giving consent for the child to be enrolled in research [24–26].

There are particular complexities surrounding children and their consent in HIV research. In the USA, adult HIV clinical trials permit participation of children over 13 years of age in many of their studies. However, this is not the case in the UK because there is no presumption of competence for those under the age of 16 years. A young person under 16 years of age can consent to treatment provided he/she is competent to understand the nature, purpose and possible consequences of the proposed treatment.

Both the Children Act (Department of Health 1989) and the United Nations Convention on the Rights of the Child (1989) stressed the importance of listening to children and taking their views seriously. One way to ensure this is for researchers to tailor information to the needs of the children and young people they are approaching, not only in relation to the content of the information they provide and the developmental stage for which it is intended, but also the way in which it is presented. It is not sufficient to provide identical information to parents and children who are involved in research.

Watson [22] recently stated: 'There is increasing recognition that children of all ages should receive age-appropriate information and that the individual child's competency be assessed'. Where it is not feasible to get a child's consent, more effort must be made to obtain the child's assent to the research.

The Children Act is underpinned by the principle that the child's best interests are the overriding influence; however, in reality it is also 'adult centred'. Altruistic motivations are an important factor to acknowledge when obtaining parental consent and, while undertaking research in developing countries, we must be mindful that the prevailing socio-economic environment itself will influence how consent is obtained. Historically, there has been a shortage of studies done in resource-poor countries because of the difficulties of conducting such studies in these locations, in addition to the difficult political and ethical issues that can arise [27]. However, it is imperative for the development of an HIV vaccine that studies are done in the countries hardest hit by the HIV epidemic.

### ARV therapy in MTCT

It is important to remember that ARV therapy has been extremely successful in reducing the incidence of MTCT of HIV. In fact, with appropriate identification of the pregnant woman, and treatment of her and her child, transmission rates approaching zero are possible. Even with the most successful currently licensed vaccine, efficacy is usually only in the maximal range of 95%. Additionally, the cost of ARV treatment to the mother and/or infant is likely to be much less than the cost of a genetically engineered recombinant HIV vaccine, when it is discovered. However, not all pregnant women will have access to ARV

treatment and to prenatal care, and it will be important to have a post-exposure prophylaxis strategy for treatment/prophylaxis of infection in the infant whose mother did not benefit from treatment and other interventions. The design of such a study will have to be carefully planned to ensure it is ethical and that it answers the important question of efficacy. Will it be ethical to conduct a placebo-controlled trial in such a setting? Many would argue that ARVs must be provided to the mother and child in such clinical trials. This would clearly increase the sample size required to address the question of efficacy, as few of the neonates would be HIV infected if the mothers were tested antenatally and received treatment, or if the newborn received post partum ARV treatment. However, such a strategy appears to be the most sensible and ethical way forward.

### Summary: will children be left behind?

Clearly, the challenges of HIV-vaccine development are great. HIV-vaccine development in neonates may be even more challenging, as it needs to provide protection from: (1) parenteral transfusion of HIV at labour and delivery; (2) mucosal exposure in the birth canal; and possibly (3) breastfeeding. Also, children are not 'small adults' and they may have unique immunological characteristics. Dose, schedule and measures of response may have to be modified from those tested in adult vaccine trials. Measurement of antibody responses in newborns may be difficult because of passively transferred maternal immunoglobulin G. There appears to be only a small window of opportunity when a perinatal intervention can work; perhaps just a few days to a few weeks following newborn exposure to HIV. A vaccine for neonates may need to be given in an accelerated fashion, to be capable of generating rapid and vigorous immune responses. Whether such a vaccine will also require passive antibody to be simultaneously administered at birth to maximise vaccine efficacy is an important unresolved question. Thus, awaiting the results of adult studies of HIV vaccines is not an option.

In addition to a vaccine for the HIV-exposed newborn, an HIV vaccine is needed for children and pre-adolescents so they will be protected in their sexually active years. The many issues of assent and consent in the paediatric and adolescent population need to be addressed now, in anticipation of future efficacious HIV vaccines.

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## Partner notification: dilemmas in practice

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### Case scenario

*The following is based on an actual case, although names and some details have been changed to protect anonymity.*

Michael was a 35-year-old gay man who had recently been diagnosed HIV-positive. His diagnosis came as a shock and, 3 months later, Michael was still finding it difficult to accept. The Health Adviser had discussed partner notification on several occasions, and was aware that Michael had a regular male partner. Initially, Michael had felt too traumatised to disclose his HIV status to his partner, and was still reluctant to do so for several different reasons. He said they were no longer having unprotected anal sex and asked for more time to

address the issue. It was agreed that he would disclose within the next month. The month went by and Michael still did not disclose. In the meantime, his partner, Simon, attended the clinic and was diagnosed with urethral chlamydia. Simon's sexual history revealed that he had engaged in recent unprotected anal sex with his regular partner. When asked about the status of his partner, Simon had replied that he did not know and believed he had not been tested. Simon declined HIV testing on that visit to the clinic, as he had done on several previous occasions.

How should the issue of partner notification be managed in such situations?

### Background

Partner notification (PN) is recognised as an important element in the control of sexually transmitted infections (STIs). It follows the fundamental rule of epidemiology that, if a person is found to have an infectious disease, the course of that infection must be traced and treated [1]. The process of PN involves contacting the partners of a patient diagnosed with an infection, informing them of their potential exposure, and offering access to testing and treatment. With their public health focus, Health Advisers (HAs) are responsible for PN in sexual health clinics. In the UK, PN is voluntary – both to protect an individual's right to confidentiality and on the assumption that such confidentiality will promote uptake of testing and treatment [2]. An individual diagnosed with a sexually transmitted infection must, therefore, give

consent for their relevant contacts to be informed of their potential exposure to infection. As the *Manual for Sexual Health Advisers* [3] acknowledges, the interests of the individual and the public can sometimes be in conflict, causing a problem for HAs whose aim is to promote the interests of both. Similarly, while viewing confidentiality as generally in the public interest, the General Medical Council (GMC) notes that such confidential information may, conversely, also be disclosed in the public interest – that is, if it can be justified on the grounds that it protects other people from risk of death or serious harm. In relation to the sexual contacts of a patient with HIV, the GMC states:

*You may disclose information to a known sexual contact of a patient with HIV where you have reason to think that the patient has not informed that person, and cannot be*

*persuaded to do so. In such circumstances you should tell a patient before you make the disclosure and you must be prepared to justify a decision to disclose information.*' [4]

In the case scenario above, disclosure against Michael's wishes is sanctioned – as there is a known person at risk of HIV, and very good reason to believe that the patient had not informed this sexual contact. However, whereas this may benefit the identified partner by giving him the choice of accessing testing and treatment, such disclosure is not necessarily the right course of action for that individual; although breaking confidentiality might be in the short-term public interest, it risks longer term deterioration in public health. Thus, an ethical dilemma exists for the HA.

### Exploring the dilemma

If the HA chooses to disclose to Simon without Michael's permission then Michael could lose trust in his health care provider and potentially stop accessing the service – missing out on vital monitoring and any necessary intervention. Over time, this would result in a deterioration in his health and a rise in his viral load – and therefore infectiousness – potentially putting sexual partners at increased risk of transmission. In addition, by losing contact with professionals, including HAs, opportunities for exploring risk reduction and the issue of disclosure are lost.

Thus, Simon, rather than being grateful for the information, might feel that knowledge he has repeatedly chosen 'not to know' has been forced on him because it suits the health care professional's agenda. Simon could, quite rightly, point out that, on all the occasions he has attended the clinic, he has been open about his unprotected anal sex, been offered testing, been engaged in extensive discussion regarding the pros and cons, and declined. He could also point out that he stated in clinic consultations that he didn't know his partner's HIV status and that he was aware of the risks this carried. He might rightly ask what led us to think he wanted to know and how could we justify disclosure as serving his interests rather than ours. If this was the outcome, it is conceivable that Simon would decline testing and, in common with Michael, would potentially lose trust and willingness to access services; thus, neither the patient's nor the public's interest would be promoted.

Finally, if the clinic's refusal to follow the wishes of a patient becomes widespread knowledge locally, it might well affect the community's view of, and willingness to access, that service. This may be particularly so for those from marginalised communities who are already reluctant to access services they need because of fears about loss of privacy. Although it is important to reach those who may have been at risk, some would argue that PN

is not the most effective response and that targeted HIV health promotion and education to relevant groups within the local community is a more effective and empowering strategy. For all these reasons, disclosure against the patient's wishes might, in the long run, be counterproductive.

### Criminalisation of HIV transmission

Ordinarily, the fact that a patient is HIV positive would be regarded as legally confidential. However, recent convictions for the reckless transmission of HIV in the UK raise the profile – and potential for scrutiny – of activities such as PN. For professionals, the question is whether they can be legally liable – either criminally or civilly – for failing to take steps to prevent someone transmitting HIV. In the scenario above, the question is: when it is known that an HIV-positive patient is continuing to engage in unsafe sexual practices, does the professional have a legal duty to take any action? There is normally no question of being held criminally liable for failing to prevent a crime [5]. In the case of Michael and Simon, as both are patients of the clinic, and therefore both are independently owed a duty of care, a theoretical argument can be made that *criminal* liability could attach to the professional if no action was taken to try and caution Simon about the possibility of serodiscordance. Having said this, there has not been a criminal prosecution brought against a doctor for failure to prevent the onward transmission of a STI [5]. Evidence suggests that, in justifying actions taken, it is likely that the emphasis will be on whether there were genuine attempts by the health professionals to balance conflicts of duties [5] rather than whether they ultimately chose in favour of disclosure or not.

There have been five reported cases in the English-speaking world where doctors have been held *civilly* liable for failing to prevent the onward transmission of an STI. In four of the cases, liability was found because the doctors concerned had negligently advised the HIV-positive patient. That is, they were considered to have provided inadequate information concerning the diagnosis and its implications for the patient and others. In these cases, the doctor would have fulfilled their duty if they had followed GMC guidance, explaining to the patient: 'the nature of the disease and its medical, social and occupational implications, as appropriate (and) ways of protecting others from infections' [4]. There was no question of any duty to disclose against the patient's wishes [5]. In the fifth case, there was a duty of care owed to both partners (one who was positive and one who was negative) as they were both clinic patients. Liability was found because the doctor was held to have inadequately addressed the issue of results collection. The doctor had not discussed with the couple – who attended jointly for pre-test discussion – the possibility of discordant results and

a joint results appointment to ensure each could be certain of the other's result. Hence, there was a duty to attempt to prevent onward transmission but there was no question regarding disclosure against the HIV-positive patient's wishes.

## Final decision-making

Given the complexity of issues involved in PN in cases such as Michael's, it is important that decisions are not taken unilaterally by the HA. As the *Manual for Sexual Health Advisers* [3] makes clear, decisions should be made only after discussion with senior colleagues, including a Consultant (all cases of liability have been against a doctor), and after liaison with relevant professional bodies. Although, in cases like Michael's, the GMC would seem to be supportive of breaches of confidentiality, it does not make it a duty and thus the final decision is left to individual practitioner(s). The decision in this case was made in favour of giving Michael more time and finally

Michael did tell Simon eight months later. However, Simon still chose not to test for over a year.

Current uncertainty regarding 'best practice' in such situations means decisions involving the issue of disclosure might well differ between clinics, resulting in inconsistent care. Given the importance of timely intervention, there is an urgent need to agree guidelines regarding HIV PN – both for individual lives and the nation's health.

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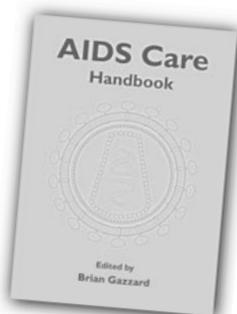
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# NHIVNA update

The plans for the 8th NHIVNA conference are now under way, so please keep the dates 29th and 30th June 2006 free in your diary. This conference will be held in Leeds and we are currently finalising the venue.

The HIV nursing competencies are progressing well and there is still time to get involved in the consultation period and assist in the writing of specific competencies. Please contact Jacqueline English at Mediscript (Jacqueline@mediscript.ltd.uk) if you would like to get involved.

In 2006, NHIVNA will be running two workshops on the topic of 'Research – how to get started'. The first workshop will be held on the 26th January 2006 in London and the second one will take place later in the year. The aim of these workshops is to encourage nurse-led research or audits, and they will provide information and support on how to get your projects started. There will also be a session on how to write an abstract.

We hope that these workshops will encourage you to submit abstracts to the 8th NHIVNA conference, and to apply for the NHIVNA and Boehringer Ingelheim (BI) grants.

The NHIVNA/BI grants and scholarships are available throughout 2006 and all submissions received will be reviewed at the quarterly NHIVNA committee meetings. For further information on these grants and scholarships, please contact Jacqueline English at Mediscript (Jacqueline@mediscript.ltd.uk).

We will also be holding a series of study days throughout 2006 and will publish the year's programme of study days and venues in the next issue of the *HIV Nursing*.

Finally, I would like to take this opportunity to wish you all a happy and peaceful festive season.

**Nicky Perry, Chair, NHIVNA, Brighton**

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