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Long-term follow-up of uninfected children born to HIV-infected women and exposed to antiretroviral therapy: survey of parents' and health professionals' views

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Abstract

~~Most~~ uninfected children born to diagnosed HIV-infected women are now exposed to antiretroviral therapy (ART) *in utero* and neonatally, and concerns have been raised over the safety of this exposure. To ~~explore~~ parents' and health professionals' views on the long-term follow-up of uninfected children two related surveys were conducted in the UK. Questionnaires were completed by 140 parents/carers and 40 health professionals. Most of the respondents in both surveys (96% overall) acknowledged that it was important to follow up children to identify possible side effects from ART exposure. Almost all respondents (99%) ~~found~~ at least one of the strategies ~~acceptable~~: follow-up through the clinic, by telephone, post or using data linkage. A third of parents and nearly half of health professionals strongly objected to at least one strategy, mostly postal and clinic contact respectively. The majority of parents (98%) thought they should be told if a potential health risk associated with ~~ART~~ exposure was identified; 73% of parents wanted any direct contact to be through ~~them~~ even when the child had grown up. Almost all respondents were supportive of the rationale for follow-up and, while expressing a preference for certain strategies, generally did not dismiss others. However, developing a single form of long-term follow-up which is both acceptable and feasible is challenging.

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Introduction

HIV-infected pregnant women in resource-rich settings routinely take antiretroviral therapy (ART) to reduce the risk of mother-to-child transmission (MTCT), and MTCT rates of less than 2% can now be achieved (European Collaborative Study 2005, Cooper *et al.* 2002). Women may also take ART during pregnancy for their own health (Hawkins *et al.* 2005). While the benefits of ART in preventing paediatric HIV infections are clear, concerns have been raised over the safety of ART exposure for uninfected children (Mofenson & Munderi 2002; Thorne & Newell 2005). Cases of mitochondrial dysfunction have been reported in exposed children (Blanche *et al.* 1999, Barret *et al.* 2003), and animal studies have suggested a risk of carcinogenesis with zidovudine exposure (Olivero *et al.* 1997). However ART exposure has not been reported to be associated with cancer in early childhood (Culnane *et al.* 1999; Brogly *et al.* 2006). As cancer and other adverse outcomes potentially associated with ART exposure may not develop for many years, it is important to put in place long-term follow-up mechanisms which are ethical, practical and acceptable to HIV-affected families and those providing their healthcare.

In the UK routine surveillance of obstetric and paediatric HIV is conducted through the National Study of HIV in Pregnancy and Childhood (NSHPC) (Townsend *et al.* 2006). Between 2002 and 2005 a consented, clinic-based follow-up study of uninfected children reported to the NSHPC was carried out to examine the logistics and feasibility of enrolling children in long-term follow-up, and to explore health outcomes in relation to type and timing of ART exposure (the CHART study). It became clear that enrolment and subsequent retention of families in this study was challenging, and in 2004/5 we therefore conducted two related questionnaire surveys

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to explore the views of parents and health professionals about this and other types of follow-up.

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Methods

Parent survey

The parent survey was conducted in 12 paediatric HIV clinics and two genitourinary clinics. Clinics were selected to provide a geographical spread (one each in Cardiff, Glasgow, Leeds, Northampton, Slough and Southampton, and eight in London).

Parents and other primary carers of ART-exposed uninfected children were

approached to take part in the survey which was conducted between October 2004

and June 2005. The study researcher attended six clinics on a total of 33 occasions,

and invited potential respondents to take part; clinic staff approached potential

respondents in the other eight clinics.

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The questionnaire was developed in collaboration with clinicians and researchers, and

piloted with parents from an HIV support group. Respondents completed the

questionnaire anonymously and provided limited personal information about their

family and their contact with health services. Respondents' views were sought on four

potential long-term follow-up strategies, chosen to provide a range of intensity of

contact from clinic-based follow-up to monitoring through data linkage (Table 1).

Questions were mostly closed-ended, but more extensive comments were invited at

the end of the questionnaire. The study was reviewed and approved by the London

Multi-centre Research Ethics Committee (ref: 04/MRE02/48).

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Health professional survey

A questionnaire and covering letter were sent to the NSHPC paediatric respondent (usually a paediatrician or paediatric specialist nurse), in 46 hospitals throughout the UK. Hospitals were included if, at least 10 uninfected children born between January 2001 and April 2004 had been reported to the NSHPC and/or at least two children had been enrolled in the CHART study (Hankin *et al.* 2004). Data collection was carried out between June and August 2005. The four follow-up strategies described in the parent questionnaire were outlined (Table 1), and respondents' views on their acceptability were sought.

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Data analysis

A Microsoft Access 2002 database was used for data entry. Data analysis was conducted using SAS statistical software (version 9.1, SAS Institute, Cary, North Carolina, USA). Univariable comparisons of categorical variables were tested with χ^2 tests.

Results

Parent survey

The study researcher approached 89 parents/carers in six clinics; 76 agreed to take part, a response rate of 85%. A further 64 parents were recruited by health professionals in the other eight clinics, giving a total of 140 respondents. For the results presented below, the denominator in parentheses relates to the number of respondents who answered the relevant question.

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The majority of respondents (91%, 127/139) were mothers, 11 were fathers, and one was an aunt with parental responsibility. Of the mothers who reported their own

country of birth, 9% (11/123) were born in the UK and 85% (105/123) in sub-Saharan Africa; four of the 11 fathers were born in the UK and the rest in sub-Saharan Africa. Most respondents (97%, 134/138) expected their children to continue living in the UK. Just over half of the respondents (53%, 74/140) cared for one child, 39 (28%) cared for two, 18 (13%) for three, and nine (6%) for four or more children. The median age of the oldest child in the family was three years (interquartile range: 1 to 6 years).

Health professional survey

Completed questionnaires were returned by 40/46 health professionals contacted, a response rate of 87%. Most respondents were paediatricians (50%, 20/40) or paediatric specialist nurses (38%, 15/40); five questionnaires were completed by other members of the clinic team (e.g. HIV physician).

Contact with general practitioners: parent survey

Almost all respondents (97%, 135/139) took their children to a general practitioner (GP) in addition to having HIV-related follow-up in the clinic. Disclosure of the family's HIV status to the GP was relatively common: 81% (109/135) reported that their GP knew about HIV in the family.

Long-term follow-up: both surveys

Nearly all parents (94%, 131/139) and all of the health professionals acknowledged that "it is important to follow up uninfected children to see if there are any side effects from anti-HIV drugs". A representative selection of respondents' comments from the questionnaires is provided in Table 2.

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Parents were asked to comment on four potential follow-up strategies (Table 1); 99% (139/140) indicated that at least one option was acceptable and 39% (55/140) more than one option. The majority (61%, 86/140) supported clinic contact, and only 4 (3%) strongly objected to it. Although only 24% (33/140) indicated that the no direct contact (data linkage) option was acceptable, only 11 (8%) strongly objected to it. Whether or not respondents approved particular options was not associated with available demographic or family characteristics, including age of their children. Most parents (77%, 105/136) did not strongly object to any of the options, but among those who did, postal contact was most unpopular (15/31) (Table 3).

All 40 health professional respondents considered at least one of the follow-up options acceptable: 70% (28/40) clinic contact, 58% (23/40) telephone contact, 55% (22/40) postal contact and 53% (21/40) the no direct contact (data linkage) option. Fifteen (38%) health professionals strongly objected to at least one option; 11 of these objected to clinic and/or telephone contact, most citing lack of clinic resources as their reason. Concerns about confidentiality and issues to do with the mobility of the families involved were also raised (see Table 2).

Future contact with the family; parent survey

Parents were asked what should happen if a potential health risk associated with exposure to a particular antiretroviral drug was identified; three respondents indicated that they would not want to be contacted under any circumstances, while 14% (19/140) felt that contact would only be appropriate if a treatment was available. The majority (84%, 118/140) however thought parents should be informed about any

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potential risk regardless of whether any treatment was available, Hypothetical ways

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by which parents might be approached, were outlined in the questionnaire: a letter

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from the clinic, a telephone call, or a letter from researchers external to the clinic, but

there was no consensus among respondents on which of these they preferred,

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It was suggested that at some stage it would be more appropriate for the clinic or

researchers to have direct contact with the young person themselves rather than with

the parent, and respondents were asked their opinion about this. Eighteen of the 105

respondents (17%) who answered this question indicated that the young person should

be contacted directly, 10 (10%) were not sure, but most (73%, 77/105) said it should

be up to the parent to decide if and when the young person could be contacted, There

was no association between parents' views about this and the age of their oldest child,

Discussion

Although almost everyone surveyed agreed that it was important to follow up

uninfected children to identify possible side effects of ART exposure, contradictory

views were expressed with respect to how contact should be maintained.

Nevertheless, it was encouraging that few respondents strongly objected to any of the

potential follow-up strategies,

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Clinic contact was preferred by both sets of respondents, but this is likely to reflect

the fact that both are familiar with it, albeit for a relatively short period in the child's

life. Some health professionals indicated that a lack of resources would make

continuing clinic-based contact difficult for them to facilitate. In a comparable survey

of parents/carers of hepatitis C infected children, most respondents also favoured

long-term clinic-based follow-up, in preference to postal or telephone contact or data linkage (Personal communication, L Pembrey, 2006).

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Health professionals and parents mentioned anxieties about confidentiality as a reason why long-term follow-up was problematic, and some parents expressed concern that it could lead to inadvertent disclosure of maternal HIV status to the child. Fear of

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Medical confidentiality is fundamental in health service provision, though the level to which individual patients want it is likely to vary (Jenkins *et al.* 2005). In a large descriptive study of views on medical privacy among patients with one or other of six chronic conditions, individuals with HIV were the least likely to report that others knew about their condition (Kass *et al.* 2004).

discrimination or isolation is likely to influence decisions about disclosure of HIV status to family and friends, as well as to health professionals (Anderson & Doyal 2004). Disclosure of parental HIV status to children has been shown to be associated with older age of the child, increased length of time since the parent's HIV diagnosis and severity of the parent's illness (Lee & Rotheram-Borus 2002, Vallerand *et al.* 2005).

Deleted: Respondents in both surveys mentioned their anxieties about confidentiality as an issue which made long-term contact and follow-up problematic. ¶

¶ Concern about long-term follow-up having the potential to lead to inadvertent disclosure of maternal HIV status to the child was raised by some parent/carer respondents. In a European multi-centre survey, around 10% of HIV-infected parents had told their children about their HIV diagnosis (Thorne *et al.* 2000).

Most respondents to the parent survey thought they should be told about any potential health risk identified as associated with ART. Nevertheless, putting this into practice would be challenging, particularly since individuals expressed inconsistent preferences about the types of follow-up they found acceptable and how they would want to be contacted about any identified risk. Furthermore, if health risks were to be identified which could be screened for or treated, this would raise the question of whether disclosure of maternal HIV status and the young person's exposure status should occur regardless of parental consent.

Deleted: The disclosure process is complex, and is likely to also involve factors such as the relationship between the parent and child, anticipated stigma and uncertainty about the future. Long-term follow-up strategies that are dependent on disclosure are likely to encounter difficulties on an individual level. If health risks to an ART-exposed individual can be screened for or treated, this raises the issue of whether disclosure of maternal HIV status and the fact that the young person was exposed to ART should occur regardless of parental consent. ¶

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Deleted: A limitation of the parent and carer survey was that most of their children were young and parents of older children may have different views (... [1])

Prophylactic ART to reduce the risk of MTCT was introduced in 1994 (Connor *et al.* 1994) and use of highly active ART (HAART) in pregnancy became widespread in the UK from 1998; consequently exposed children are still quite young. It is possible

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that parents might have different views on follow-up when their children are older.

Other factors might be associated with adverse health outcomes among children growing up in families affected by HIV: some will have been exposed to other infections and/or to non-ART drugs (prescribed or illicit) in fetal life; many will be affected by the death or illness of other family members, or other difficult family circumstances. If, during long-term follow-up, specific outcomes were recorded at a higher rate than in the general population, it would be necessary to undertake further work, such as case-control studies, to determine whether they were a direct result of exposure to ART.

Deleted: , at present the maximum age of uninfected children exposed to ART is limited, particularly for those exposed to HAART. Furthermore, families who attended their clinic appointment and agreed to take part in the survey may have had differing views from those who could not be surveyed

In the UK, there is an increasing prevalence of HIV in pregnancy coupled with high uptake of routine antenatal HIV testing. Prophylactic ART is recommended for all diagnosed HIV-infected pregnant women (Hawkins *et al.* 2005) and an increasing number of women are taking HAART for their own health when they conceive. Over 1000 uninfected infants were born to diagnosed women in the UK in 2005, and virtually all of them were exposed to ART *in utero* (NSHPC data); the annual number of exposed infants is likely to continue to increase. Despite the inherent difficulties, acceptable and practical forms of monitoring and follow-up must be developed to facilitate the identification of any substantial risk of serious adverse health effects in later life and to enable us to minimise any such risk, should it exist.

Deleted: Although the importance of long-term follow-up was accepted by almost everyone surveyed, it is unlikely that one particular long-term follow-up strategy would suit all individuals involved. Identifying the most acceptable and practical form of follow-up for these children is challenging but necessary due to the increasing use of ART in pregnancy and concerns about potential side effects.¶

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Table 1. The four follow-up options presented in the parent questionnaire**OPTION A (CLINIC CONTACT)**

- You and/or your child would be asked to come to the family or paediatric clinic once a year.
- Clinic staff would ask you general questions about your child's health.
- The answers would be put on a form and sent to us. Neither your name nor your child's name would be on the form.
- You would need to inform the clinic of any change in your contact details.

OPTION B (TELEPHONE CONTACT)

- Clinic staff would telephone you once a year and would ask you general questions about your child's health.
- The answers would be put on a form and sent to us. Neither your name nor your child's name would be on the form.
- You would not need to attend the clinic to take part, but you would need to inform the clinic of any change in your telephone number.

OPTION C (POSTAL CONTACT)

- The clinic staff would give us your contact details when your child was discharged. We would keep these in strict confidence.
- We would send you a short form about your child's health once a year, for you to complete and send back to us.
- There would be no reference to HIV on anything you were sent.
- You would need to inform us of any change in your address.

OPTION D (NO DIRECT CONTACT)

- We would not need to have any regular direct contact with you or your child and we would not know your or your child's name or address.
- Every child in the UK is given an NHS number at birth. The clinic would give us your child's NHS number which we could relate to routinely available health information.
- You would not have to keep in contact with the clinic after your child was discharged.

Note: these options were also outlined in the health professional questionnaire.

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Table 2. Comments from questionnaires

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Parent surveyDeleted: and carer

“I think it is a good idea following up these children because it shows you have their interest at heart and would like to know and help them if they do get any side effects from the drugs.” [Mother of two children (aged 1 and 7 years)]

“When you are pregnant you are worried about the virus passing to baby and not strongly about the effects of the drugs.” [Mother of one child (aged 3 months)]

“Although I strongly support research into the follow-up of children exposed to anti HIV drugs I am currently unwilling to give my permission for this to happen as I feel that my decision of when or whether to tell my child about my HIV status could be taken out of my hands. If you can assure me this won't happen I will happily comply.” [Mother of one child (aged 1 year)]

“I think that GPs must be aware of any follow-up programme. I know some families with HIV are not always comfortable with this- but personally I find it crucial to keep our family health care as ‘normal’ as possible- less explaining, and I think less stigmatised.” [Mother of one child (aged 6 years)]

“I think that when they are still young it would be important to contact the carer. But once they're more mature then it's fine to contact them without the carer there.” [Mother of two children (aged 1 and 7 years)]

“I think it should be up to the parent to tell the clinic if they can contact the young person as it would necessitate the mother's disclosure of her own HIV status and this is a very personal, individual matter.” [Mother of one child (aged 1 year)]

Health professional survey

“I think the concept of long-term follow-up needs to be raised when women are being either started on treatment or during pregnancy and then reiterated at all other visits for baby follow up i.e. birth, 6 weeks, 3 months and 18 months.”

“When parents are discharged they want to get away from us as fast as possible and start to live a ‘normal’ life.”

“There is a significant issue with respect to clinician and clinic time. As length of follow up proposed increases, number of contacts will grow. I deal with relatively low numbers but for a large patient load this is likely to become unmanageable.”

“Option C- I would be happy to ask families at last visit when uninfected but I do not think you will get good response as it is not something they can continue to feel 100% commitment to and that's what you need- other things become more important naturally over time”

“Difficulties with keeping in touch with families, often move frequently.”

Table 3. Reasons for strong objections to follow-up options (31 parents)

<u>Follow-up option(s)</u>	<u>Respondents with strong objections</u> (n)	<u>Reason given</u> (n)
<u>Clinic</u> only	2	Difficult to explain reason to child (2)
<u>Telephone</u> only	4	Someone else could hear conversation (3) Prefer eye contact (1)
<u>Postal</u> only	11	Someone else could read information (6) Do not want details to leave clinic (2) Cannot read (1) <u>None</u> (2)
<u>No direct contact</u> only	9	Want to give consent (2) Want to be seen in clinic (2) Do not want child "labelled" (1) <u>None</u> (4)
<u>Clinic + Telephone</u>	1	Do not like contact with medical professionals (1)
<u>Postal + No direct contact</u>	1	Do not want child on a "register" (1)
<u>Telephone + Postal</u>	1	Want to be seen in clinic (1)
<u>Telephone + Postal + No direct contact</u>	1	Want to be seen in clinic (1)
<u>Clinic + Telephone + Postal</u>	1	Work abroad (1)

Note: see Table 1 for a description of the follow-up options.

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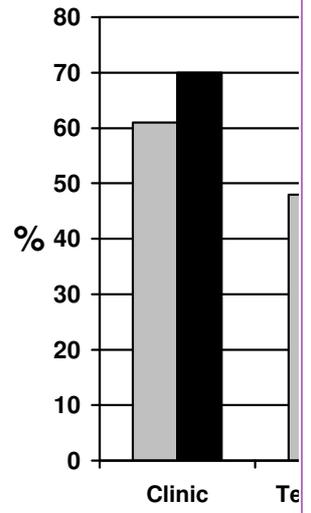
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Deleted: Figure 1. Proportion of parents/carers and health professionals who described each follow-up option as acceptable %



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A limitation of the parent and carer survey was that most of their children were young and parents of older children may have different views on follow-up. As

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