

# Opt-out HIV testing strategies

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## Executive summary/Key messages

Observational studies undertaken in the antenatal setting in Africa suggest that opt-out HIV testing strategies may increase the number of people who have an HIV test performed. We found insufficient evidence to assess whether this increase in testing translates to more people learning their status (in settings where rapid tests are not used), or if there is a subsequent increase in access to HIV preventive and treatment services.

Studies have not adequately assessed what effect HIV opt-out testing has on the popularity of the original non-HIV related service where it is introduced.

More comprehensive studies are required. The ideal study would be prospective, comparing groups offered routine opt out versus opt in testing in the same resource poor setting. Studies are required in non-pregnant populations. Outcomes to consider are the proportions accepting/declining HIV testing; proportion receiving results of the test; proportion attending further HIV related services if positive; and overall attendance rates at the health facility in question before and after the introduction of an opt-out policy.

## Introduction

HIV testing is fundamental to both prevention and treatment of HIV. Efforts to increase the coverage of HIV testing have recently extended to the provision of “opt-out” or routine HIV testing, where the healthcare provider rather than the client or patient initiates the test. We have search for evidence for the benefits and harms of such an approach in resource poor settings.

## Scope of the problem

HIV testing brings benefits through behavioural change[1] [2] and by opening access to HIV services with proven benefits: including preventing mother to child transmission,[3] and facilitating earlier access to cotrimoxazole prophylaxis[4] and highly active antiretroviral treatment (HAART).[5] Most efforts have focused on voluntary counselling and testing (VCT) as the primary means of providing testing and encouraging people to become aware of their HIV status. But coverage has been low, with the number being tested far fewer than that required to identify even those requiring HAART.[6] [7] As part of the response to the problem, the WHO has introduced opt-out testing.[8] In this scenario, HIV testing is *offered routinely* to all patients attending a particular healthcare service, such as an antenatal clinic, even though they are asymptomatic for HIV disease. The emphasis is changed from client initiated (as in VCT) to provider initiated testing. The test is still voluntary, with the option to refuse testing (opt out). Such an approach has been shown to increase uptake of testing in settings such as the USA.[9] It may also decrease the stigma associated with choosing to have a test – in as much as everyone is having it offered irrespective of perceived risk.[10]

Harms such as partner violence associated with HIV testing have also been identified, particularly

for women.[11] [12] Some may be reluctant to be tested for HIV and to adopt health behaviours that might expose their positive infection status to their partners, for example as formula feeding of their babies. Fears have been expressed that with the change in emphasis to provider initiated testing the autonomy (and the individual human right) of the patient to freely decline or accept testing could be undermined. A sense of needing to comply with the perceived authority of health staff in favour of testing, a lack of time to consider fully the information pertaining to this decision, and the strong normative message to “get tested” that universal routine testing implies may all contribute to undermining patient autonomy.[13] If clients who do not want a test perceive that they lack the freedom to decline it, when attending a service incorporating opt-out testing, they may simply not attend the service at all. Concern has also been raised that in practice a *routine offer* of HIV testing may effectively become routine HIV testing, with erosion of the pre-test counselling. It is argued that this would undermine the principles of HIV testing namely consent, counselling, and confidentiality (“the 3 Cs”) and so violate human rights.[14]

It is also to be understood that increased testing in such conditions may not translate into increased receipt of test results or uptake of HIV services. In particular, it is known that those who test HIV positive are less likely to return for their results.[15] The availability therefore of rapid HIV testing is likely to be a critical determinant of the success of opt-out testing. Those reached by the opt-out strategy who would otherwise never have opted in may still not follow up on their test.

Consequently, assessing the effectiveness of an opt-out strategy requires more than simply looking at a change in uptake of testing, although this is an important outcome in itself. Further data are also needed concerning the number of people who are counselled after testing and receive their results, the number who take up HIV related services, and the effects on the popularity of the original service that provides the opt-out testing must be gathered. We have therefore undertaken a systematic review of the available evidence that addresses these issues.

## Synthesis of current guidelines

The WHO and UNAIDS issued a joint policy statement in 2004 that introduced opt-out testing, alongside other HIV testing settings (see box 1).[8]

- 1) Voluntary counselling and testing (VCT). Client initiated HIV testing to learn HIV status provided through VCT
- 2) Diagnostic HIV testing is indicated whenever a person shows signs or symptoms that are consistent with HIV related disease or AIDS to aid clinical diagnosis and management. This includes HIV testing for all tuberculosis patients as part of their routine management
- 3) A routine offer of HIV testing by healthcare providers should be made to all patients being:
  - assessed in a sexually transmitted infection clinic or elsewhere for a sexually transmitted infection – to facilitate tailored counselling based on knowledge of HIV status
  - seen in the context of pregnancy – to facilitate an offer of antiretroviral prevention of mother to child transmission
  - seen in clinical and community based health service settings where HIV is prevalent and antiretroviral treatment is available (injecting drug use treatment services, hospital emergencies, internal medicine hospital wards, consultations etc.) but who are asymptomatic
- 4) Mandatory HIV screening. UNAIDS/WHO support mandatory screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products

The statement makes clear that opt-out testing (here referred to as “*routine offer* of HIV testing by healthcare providers”) can only take place in a setting where mechanisms exist for counselling after testing and referral for medical and psychosocial support. The pre-test counselling may be reduced (compared with VCT) but should still be sufficient to provide informed consent. Confidentiality should likewise be upheld and patients will retain the right to refuse testing.

## **Key questions relevant to resource poor settings**

- What are the benefits and harms of a switch from opt-in to opt-out HIV testing in healthcare facilities in resource poor settings?

## **Outcomes**

- Uptake of testing
- Proportion of people who return for test results
- Attendance levels at institutions offering testing

## **Methods**

The search was undertaken in April 2006. The following sources were searched for systematic reviews, RCTs, and cohort studies: Medline, Embase, Cochrane Database of Systematic Reviews, Central, Database of Reviews of Effects, HTA Database, Trip Database, AIDsearch, African Journals Online, African Index Medicus, Global Index Medicus, Lilacs, and Index Medicus for South East Asia Region. Abstracts of the studies retrieved were assessed independently by two information specialists using pre-determined criteria to identify relevant studies, and then sent to the author for further assessment of the full articles. Twenty-three papers were received for second appraisal. Of these, only four were conducted with populations in resource poor settings. Prospective or retrospective studies were included if they were of sufficient quality and compared the effects of opt-out versus opt-in (routine) testing strategies on: uptake of testing, the proportion of people tested who returned for results, the proportion of people taking up HIV treatment, and popularity of the service offering the new testing. Studies were also included if they evaluated reasons and risk factors for declining or accepting testing in an opt-out setting as described in part 3 of the WHO/UNAIDS policy document (see above).[8] Studies of voluntary counselling and testing (VCT), diagnostic counselling and testing (DCT), or mandatory HIV testing were excluded.

## **What are the benefits and harms of a switch from opt-in to opt-out HIV testing in healthcare facilities in resource poor settings?**

### ***Evidence from resource poor countries***

#### ***RCTs***

We found no RCTs.

#### ***Observational studies***

We found four studies; all conducted in the antenatal setting in Africa.[16][10][6][17]

## **Opt out versus opt in testing**

**Only one study was found that specifically compared opt-in strategies versus opt-out. It found that the uptake of HIV testing increased after introduction of an opt-out policy and with no measured change on rates of receiving results or subsequent follow up attendance. A second study retrospectively assessing testing uptake rates and rates of mother to child transmission could not establish a causal relationship between the strategy and the subsequent outcomes.**

The first study compared attendance and acceptance of HIV testing in antenatal clinics in the 4 months before and 3 months following the introduction of an opt-out strategy for HIV testing in Botswana.[16] With the new strategy, women attending the service received group education about HIV, preventing mother to child transmission, and antiretroviral therapy and were informed that blood would be drawn for an HIV test, but that they had the option to decline this if they so wished. The proportion tested increased from 381/506 (75%) women to 314/347 (91%) women ( $P < 0.001$ ). The attendance rates for antenatal services did not fall: at 114 a month (95% CI 95/month to 134/month) before to 130 a month (95% CI 97/month to 154/month) after the change. The proportion of those tested who returned (at 1 month visit) for their HIV test result did not change (29% before v 33% after;  $P = 0.29$ ). The overall rate of HIV in these cohorts was 47.9%. The strength of this study is that it looked at what happened under operational conditions. However, generalisation may be limited because the acceptance rate during the opt-in (routine) testing phase was higher than that seen elsewhere, though the authors do report logbook data from 24 health districts also showing an increase in HIV testing rates from 52% in 2003 to 69% in the first half of 2004. Other limitations of the study are that it did not report the eventual uptake of HIV treatment (treatment to prevent mother to child transmission or highly active antiretroviral treatment [HAART]) and may have ended before the impact of the new policy on uptake of services had occurred, as knowledge about the change in strategy may have taken more than 3 months to filter through to the communities.

The second study in the Ukraine showed that following the initiation of opt out, increased testing rates and a reduction in mother to child transmission occurred together. However, this association cannot be said to be causal as a trend of increasing uptake was already evident before the change in policy and the introduction of opt-out testing was only one part of a major revision and improvement of the programme.[10]

## **Attitudes to opt-out testing**

**One study surveyed the attitudes to opt-out testing of women attending an antenatal clinic. It suggested that 75% of women who do not take up opt-in (routine) testing would not refuse opt-out testing. However, expressed attitudes may not match what people do in practice.**

In a cross-sectional survey of postnatal women in six rural sites in Zimbabwe in 2004, participants were interviewed about their attitudes to opt-out testing.[6] Of 520 women, 285 (55%) had had HIV testing in the existing opt-in (routine) testing programme. Overall, 463/520 (89.0%, 95% CI 86.0% to 91.5%) said they would accept opt-out testing. This was higher in those that had already accepted an HIV test before than those who had not (97% who accepted v 76% who had not accepted). Of those who would decline opt-out, 41 (7.9%, 95% CI 5.6% to 10.4%) would still attend antenatal care but decline the test, and 4 (0.8%, 95% CI 0.2% to 2.1%) said they would go elsewhere to deliver (home or traditional birth attendant). Factors associated with increased likelihood of accepting opt-out among those who had previously declined opt-in (routine) testing were: younger age, living with a partner, secondary level or higher education, and knowledge about range and availability of services to prevent mother to child transmission. The study may overestimate uptake as subjects were recruited from 6 week follow up clinics, which are only attended by 60% of

postnatal mothers. Expressed attitudes may not match what people do in practice.

### **Effects on subsequent attendance for treatment**

**One study found weak evidence that there was no decrease in 36 week antenatal attendance rates between women in an antenatal clinic testing positive through opt-out testing and antenatal attendance rates over 1 year in all the pregnant women registered in the clinic.**

Investigators in Malawi retrospectively assessed consecutive antenatal clinic attendees in a district hospital over the year following introduction of opt-out testing, for uptake of HIV testing and subsequent attendance. A total of 2996/3135 (96%) women accepted counselling before testing and 31 of these opted-out of testing (1%).[17] As a rapid test was used, all who were tested received their results and counselling after testing. Of the 2996 women, 646 (22%) were found to be HIV positive and 288 (45%) returned at 36 weeks for nevirapine within the preventing mother to child transmission protocol. Two hundred and six women (32%) delivered in the hospital and received nevirapine and 122 (19%) returned at 6 months for postnatal follow up. There was no comparison with before the opt-out policy was introduced, but comparison was made between the 36 week antenatal attendance of the HIV positive cohort and all registered antenatal women in that hospital that year, of whom only 1112/2806 (40%) returned at 36 weeks. The authors concluded that the service was accepted for three reasons: stigma of HIV testing was reduced by the fact that everyone was offered the test routinely, the hospital had well trained and sufficient staff for counselling, and availability of services (cotrimoxazole prophylaxis, nevirapine, and counselling) made testing an entry point for services. They also concluded that poor 36 week attendance was not specific to the preventing mother to child transmission programme (including opt-out testing) as similar non-attendance was seen in the general antenatal population. Geographical distance of travel was more likely to account for the non-attendance.

### **Comment**

Little can be concluded from the few studies have been conducted in resource poor settings. However, their results are supported by evidence from resource rich settings. A number of studies from resource rich settings have found that uptake of HIV testing increases after the introduction of an opt-out policy: USA,[18] Canada,[19] Singapore,[20] Netherlands,[21] and UK.[22] Others have reported increased uptake of routine testing to be associated with low health literacy,[23] younger age, being single and when care was provided by a female, midwife, or non-obstetric specialist in the antenatal setting.[24] Declining testing was associated with a (poorly informed) perception of low risk.[25]

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