Tropical Medicine and International Health doi:10.1111/j.1365-3156.2011.02893.x

VOLUME 17 NO 1 PP 59–70 JANUARY 2012

Universal voluntary HIV testing in antenatal care settings: a review of the contribution of provider-initiated testing & counselling

Bernadette Hensen[1], Rachel Baggaley[2], Vincent J. Wong[3], Kristina L. Grabbe[4], Nathan Shaffer[2], Ying-Ru Jacqueline Lo[2] and James Hargreaves[5]

1 *Faculty of Infectious Diseases, London School of Hygiene and Tropical Medicine, London, UK*
2 *World Health Organization, HIV Department, Geneva, Switzerland*
3 *USAID, Office of HIV/AIDS, Washington, DC, USA*
4 *Division of Global HIV/AIDS, Center for Global Health, US Centers for Disease Control, Atlanta, GA, USA*
5 *Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK*

Abstract

OBJECTIVE To assess the contribution of provider-initiated testing and counselling (PITC) to achieving universal testing of pregnant women and, from available data on components of PITC, assess whether PITC adoption adheres to pre-test information, post-test counselling procedures and linkage to treatment.

METHODS Systematic review of published literature. Findings were collated and data extracted on HIV testing uptake before and after the adoption of a PITC model. Data on pre- and post-test counselling uptake and linkage to anti-retrovirals, where available, were also extracted.

RESULTS Ten eligible studies were identified. Pre-intervention testing uptake ranged from 5.5% to 78.7%. Following PITC introduction, testing uptake increased by a range of 9.9% to 65.6%, with testing uptake ≥85% in eight studies. Where reported, pre-test information was provided to between 91.5% and 100% and post-test counselling to between 82% and 99.8% of pregnant women. Linkage to ARVs for prevention of mother to child transmission (PMTCT) was reported in five studies and ranged from 53.7% to 77.2%. Where reported, PITC was considered acceptable by ANC attendees.

CONCLUSION Our review provides evidence that the adoption of PITC within ANC can facilitate progress towards universal voluntary testing of pregnant women. This is necessary to increase the coverage of PMTCT services and facilitate access to treatment and prevention interventions. We found some evidence that PITC adoption does not undermine processes inherent to good conduct of testing, with high levels of pre-test information and post-test counselling, and two studies suggesting that PITC is acceptable to ANC attendees.

keywords human immunodeficiency virus, pregnant women, prevention of mother to child transmission, diagnostic tests – routine, infection transmission – vertical

Introduction

HIV testing is a 'critical gateway' to treatment, care and support services. Knowledge of HIV status can empower individuals and couples to take measures to prevent HIV acquisition or onward transmission. For those already infected, a positive test result is necessary to access treatment and, in the case of pregnant women, to access prevention of mother to child transmission (PMTCT) services (Higgins *et al.* 1991, Coates *et al.* 2000; WHO 2003). Across communities, normalising awareness of HIV status through increasing testing could reduce HIV-related stigma and discrimination (WHO 2003).

However, progress towards universal knowledge of HIV status is inadequate (Granich *et al.* 2009). In 10 population-based surveys conducted in sub-Saharan Africa in 2007–2009, the median percentage of people living with HIV who knew their status was <40% (WHO 2010). In Africa, the estimated percentage of people who know their HIV status ranges from <10% in Sierra Leone, DRC and Liberia to 40–56% in Kenya and South Africa (WHO 2010). In 2009, an estimated 50% of pregnant women in Eastern and Southern Africa received an HIV test, up from 43% in 2008(WHO 2010).

For many years, HIV testing was delivered through a voluntary counselling and testing (VCT) model. A

client-initiated approach, VCT guidelines stressed the importance of confidentiality, expressed voluntarism and written informed consent. VCT relied on personal motivation to seek testing, which is influenced by a number of factors that might act as barriers to widespread testing (Leon *et al.* 2010b). With <10% of key populations in low- and middle-income countries who may have been exposed to HIV accessing VCT and with evidence that many opportunities to diagnose patients with HIV were lost (Seipone 2004; Fetene & Feleke 2010), VCT was increasingly seen as inadequate (Nieburg *et al.* 2005; Fetene & Feleke 2010).

To address this problem in 2007 WHO issued guidance recommending the routine offer of HIV testing in clinical settings. Termed 'provider-initiated testing and counselling' (PITC), this model supports recommending testing to all patients attending health facilities, including antenatal services, in countries with generalised epidemics and for those attending, for example, antenatal, tuberculosis and sexually transmitted infection services in non-generalised epidemiological contexts (WHO 2007). PITC eliminates the need for lengthy pre-test counselling, replacing it with pre-test information that meets the minimum standard for informed consent (WHO 2007). Opt-out PITC is recommended; however, the guidance suggests that opt-in PITC should be considered for 'highly vulnerable populations' (WHO 2007). PITC proponents highlight its potential impact on universal knowledge of HIV status, thereby its potential to reduce mother-to-child transmission (MTCT), HIV-related morbidity and mortality (Bayer & Edington 2009), and its capacity to 'normalise' HIV testing (Leon *et al.* 2010a). However, others have concerns that removing extensive pre-test counselling and written informed consent could lead to coercion and thus threatens the ethics and human rights of HIV testing (Gruskin *et al.* 2008; Bayer & Edington 2009). Prior to the WHO guidance, numerous countries had adopted the models of PITC in clinical settings, particularly in antenatal clinics (ANC) in response to evidence of the effectiveness of antiretrovirals (ARV) in reducing MTCT and the urgent need to provide access to PMTCT services to pregnant women with HIV (Seipone 2004; Centers for Disease Control & Prevention 2008).

Growing evidence suggests that adopting PITC in ANC reduces lost opportunities to test pregnant women for HIV and increases PMTCT uptake and coverage (Kharsany *et al.* 2010, Amornwichet *et al.* 2002, Weigel *et al.* 2009; Chersich & Luchters 2008). The aim of this systematic review was to determine the extent to which the adoption of guidelines for a PITC-related model in ANC contributes to achieving the goal of universal voluntary testing of pregnant women and increases the coverage of PMTCT, treatment and care services. We also aimed to assess whether PITC adheres to the standards inherent to good conduct of HIV testing, namely that it provides pre-test information and post-test counselling.

Methods

We conducted a systematic review of published literature. We searched Medline, Embase and Global Health using the following search terms: provider-initiated, routine, diagnostic, opt-out, HIV, human immunodeficiency virus, AIDS, acquired immune deficiency syndrome, counselling, counseling, testing and screening, antenatal, PMTCT, vertical transmission and prenatal care. The final full search was conducted in December 2010. BH conducted the literature search and, with support from DB and MK, determined whether full references extracted were eligible for inclusion. Studies were considered eligible for inclusion if they were conducted in ANC settings and reported on the impact of adopting a model of PITC on the primary outcome: HIV testing uptake, and were English language studies. We included randomised controlled trials (RCT) and non-randomised studies (NRS) with >1 site per arm as long as they collected both pre- and post-intervention data for each facility. We also included time series studies conducted in one facility if they had collected pre- and post-intervention data. We excluded studies conducted at population level as they provide limited information of changes within individual facilities, thus imposing greater challenges in inferring causation. Our review identified three types of intervention/comparison conditions that satisfied these criteria (Table 1).

Data extraction

BH extracted data into two data extraction forms, one for study design (Table 2) and one for data relating to HIV testing uptake and adjusted odds ratios, where reported. We also collated data on counselling and linkage to ARV. We critically appraised the quality of studies using a quality assessment tool adapted from the Effective Public Health Practice Project (EPHPP[1]). The tool included 22 questions that allowed for yes, no and cannot tell responses. Studies were not excluded on the basis of quality, but given a weak, moderate or strong quality rating (weak $n = 2$, moderate $n = 7$ and strong $n = 1$).

[1]http://www.ephpp.ca/PDF/Quality%20Assessment%20Tool_2010_2.pdf

Table 1 Comparison and intervention conditions considered eligible for inclusion

	Comparison HIV testing model	Intervention HIV testing model
A	VCT	Routine offer of testing
B	Diagnostic testing	Routine offer of testing
C	Routine offer of opt-in testing	Routine offer of opt-out testing*

*These models were defined as those where the emphasis of consent changed from one where, following a routine offer of testing, a patient explicity opted-in to a testing model where the patient had to opt-out should they choose not to test.

Defining PITC and lost opportunities

For the purpose of this review, we defined PITC as the routine offer of HIV testing, regardless of whether the emphasis of consent was opt-in or opt-out, by healthcare providers to pregnant women attending ANC settings as a standard component of clinical practice. Lost opportunities to test for HIV were defined as the difference between the reported proportion of women accepting testing and universal (100%) testing uptake. Although achieving 100% uptake of testing is an ambitious goal, universal testing is defined as such – the universal uptake of HIV testing to achieve universal knowledge of HIV status. We expected studies to report increased uptake of HIV testing after implementation of PITC; however, our primary research question was to determine the ability of PITC to achieve universal (100%; 0% lost opportunities) HIV testing in ANC. We restricted this review to studies conducted in ANC settings as the majority of studies on PITC were conducted in ANC and the majority of PITC programmes were initially implemented in ANC.

Results

We retrieved 1009 references, of which 831 were excluded following title review. Of the remaining 178, a further 158 were excluded following abstract review or retrieval of the full paper as they did not meet the inclusion criteria (Figure 1). Of the remaining 20 studies, ten targeted the population of interest (Table 2).

Studies that met the inclusion criteria

Tables 2 and 3 present the details and characteristics of the included studies. The majority were NRS (90%) comparing the period before the introduction of a routine testing guideline, implemented either through an intervention at specific clinics or through a national policy change, to the period after. We identified only one RCT (Simpson *et al.* 1998). In the studies, the number of clinics varied from 1 to 52 and sample sizes varied from 1456 to 54 429 women. Seven studies were conducted in Africa (van't

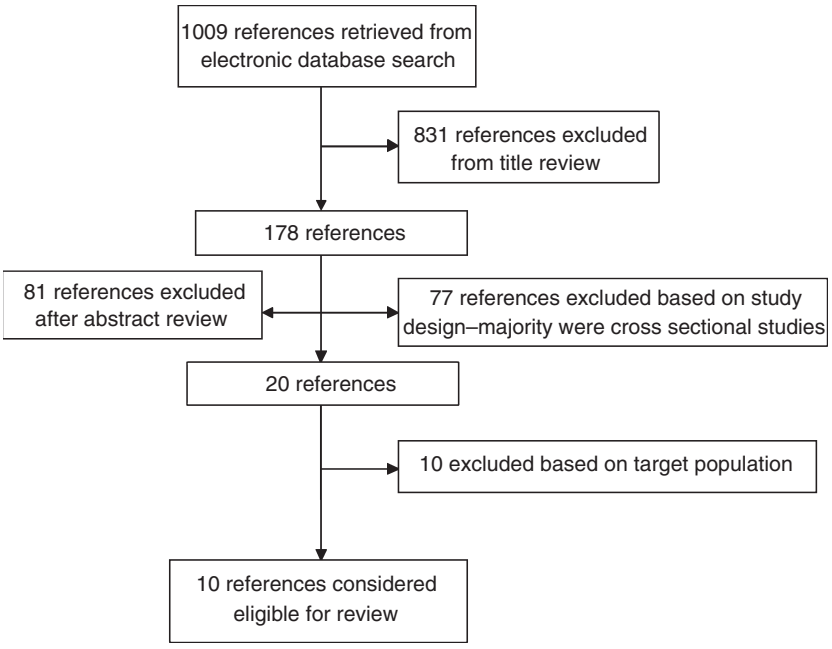

Figure 1 Inclusion flow diagram.

Table 2 Details of studies included in the review

Setting	Year of study	Study design	Study of a policy change or PITC training intervention	Comparison group	Period of follow-up	Facility setting	Num. of facilities	Population	Population size	Urban/ Rural	Outcome(s)
Scotland (Simpson *et al.* 1998)	1996–1997	RCT	RCT comparing VCT to 4 models of routine testing	Randomly selected VCT control	10 months	Hospital ANC	1	Pregnant women	3024	U	Uptake and acceptability of HIV testing, women's knowledge, satisfaction and anxiety
Scotland (Simpson *et al.* 1999)	1998	BA	Policy change	10 months prior to opt-out testing	3 months			Pregnant women	2954	U	Uptake and acceptability of HIV testing, testing-related anxiety
USA (Stringer *et al.* 2001)	1998–2000	BA	Training & policy change	Data from year before policy change	2 years	ANC	8	Pregnant women	7193	U	Uptake of opt-out testing on HIV testing rates
Kenya (van't Hoog *et al.* 2005)	2001–2003	RBA	Implementation of pilot project	Year prior to pilot project	2 years	Hospital ANC	1 (6 public health centres)	Pregnant women	8231	U	Uptake of counselling, testing and nevirapine
Botswana (Creek *et al.* 2007)	2003–2004	BA	Training & policy change	Last 5 months of VCT	1 year	ANC	4	Pregnant women	1456	U	HIV testing uptake, PMTCT intervention rates, and rates of ANC attendance
Zimbabwe (Chandisarewa *et al.* 2007)	2004–2005	BA	Training & policy change	Last 6 months of opt-in	1 year	ANC	4	Pregnant women & their partners	9423	U	HIV testing uptake, maternal HIV status; perceptions of routine testing
Malawi (Moses *et al.* 2008, Zimba *et al.* 2006*)	2002–2006	TS	Policy change	Last 9 months of opt-in	18 months	ANC	4	Pregnant women	30 092	U	Rate HIV counselled, HIV testing uptake and HIV positivity
Uganda (Byamugisha *et al.* 2010)	2002–2009	TS	Training & Policy change	Historical control – hospital records pre/post policy change	7 years	Referral Hospital	1	Pregnant women & their partners	54 429	U	Number of new ANC attendances/year, number of ANC patients counselled and tested, number that obtained a positive result, number of male partners counselled and tested and obtained positive result, HIV-positive mothers and infants that received ART prophylaxis
Ethiopia (Mirkuzie *et al.* 2010)	2004–2009	TS	Policy change	Historical control – PMTCT reports	5 years†	Public and private facilities	52 (25 private)	Pregnant women and their partners	663 603 (from 2004 to 2009)	U	Proportion of women receiving pre-test counselling, HIV testing and post-test counselling; proportion of women and babies who received ARV prophylaxis
Malawi (Kasenga *et al.* 2009)‡	2005–2007	TS	Policy change	Historical control – hospital records pre/post policy change	2 years	Hospital ANC	1	Pregnant women	2055	R	Demand for ANC, HIV testing uptake and hospital delivery

*Unpublished results from conference abstracts and presentations provided details of the study, including number of women reached, for the period 2004–2005. Results only include data from these years.

†Although 2004–2009 results are available, only 2007–2009 are included in the review as in 2007 private facilities, which are included in 2009 data, started PMTCT.

‡Results only presented for period March–December 2005, when testing was opt-in, with January–December 2006, before the implementation of free services.

RCT, randomised controlled trial; BA, before/after study; RBA, retrospective (before/after) study; TS, time series

Hoog *et al.* 2005; Chandisarewa *et al.* 2007; Creek *et al.* 2007; Moses *et al.* 2008; Kasenga *et al.* 2009; Byamugisha *et al.* 2010; Mirkuzie *et al.* 2010), two in Europe (Simpson *et al.* 1998, 1999) and one in the USA (Stringer *et al.* 2001). The outcome of HIV testing uptake was reported in all studies (Table 2).

Intervention heterogeneity

The PITC interventions under study varied in a number of ways. Some studies reported extensive healthcare worker training prior to the implementation of PITC (Chandisarewa *et al.* 2007; Creek *et al.* 2007; Byamugisha *et al.* 2010), whilst others did not report on this (Kasenga *et al.* 2009). Some studies were the evaluations of interventions implemented in facilities, whilst others evaluated the influence of policy change on activities at facility level (Table 2). The information provided to women through pre-test education also varied: one study reported extensive community mobilisation (Chandisarewa *et al.* 2007), whilst two reported provision of leaflets (Simpson *et al.* 1998, 1999) (Table 4).

Missed opportunities for testing

Table 5 presents data on HIV testing uptake. Prior to the implementation of PITC, lost opportunities for testing ranged from 94.5% in Scotland (Simpson *et al.* 1998) to 21.3% in a study from Malawi (Kasenga *et al.* 2009). Following implementation of PITC, lost opportunities decreased substantially in all settings (Figure 2). Despite a significant decrease in lost opportunities, in Scotland, where the aim of the study was to determine uptake and acceptability of different methods of a universal offer of testing, the lost opportunities amongst women in intervention groups remained high at 65.2% ($P < 0.001$) (Simpson *et al.* 1998). The adoption of opt-out PITC further reduced missed opportunities to 11.7% (Simpson *et al.* 1999). In rural Malawi, implementation of opt-out testing reduced lost opportunities to test by 9.9%; the introduction of free maternity services in October 2006 reduced lost opportunities further to 1.2% (testing uptake 98.8% (n = 2,249/2,277);Kasenga *et al.* 2009). The lowest proportion of lost opportunities for testing was reported in Zimbabwe, where <0.1% of opportunities to test women were lost ($P < 0.001$) (Chandisarewa *et al.* 2007).

Components of the PITC process

Four studies presented results for the proportion of women provided pre-test counselling/information (van't Hoog *et al.* 2005; Chandisarewa *et al.* 2007; Byamugisha *et al.* 2010; Mirkuzie *et al.* 2010) (Table 6). Following implementation of PITC, pre-test counselling/information ranged from 91.5% in a study from Kenya (van't Hoog *et al.* 2005) to 100% in Zimbabwe (Chandisarewa *et al.* 2007). These four studies also presented results on the proportion of women tested and subsequently post-test counselled or received test results (van't Hoog *et al.* 2005; Chandisarewa *et al.* 2007; Creek *et al.* 2007; Mirkuzie *et al.* 2010). Prior to the implementation of revised PITC models the proportion of women receiving post-test counselling and test results ranged from 72% who received test results in Botswana (Creek *et al.* 2007) to 96.9% in Zimbabwe (Chandisarewa *et al.* 2007). Following implementation of revised PITC models post-test counselling/

Table 3 Study characteristics

Study characteristics	Frequency (n)
Study design	
Non-randomised study	9
Randomised controlled trial	1
Year of study initiation	
1995–1996	1
1997–1998	2
1999–2000	0
2001–2002	2
2003–2004	4
2005–2006	1
Study direction	
Prospective	5
Retrospective	5
Inclusion and exclusion criteria (individuals)	
Reported	1
Not reported	9
Reason for selection of clinic(s)	
Reported	1
Not reported	9
Results assessors blinded during interpretation	
Reported	0
Not reported	10
Intervention group	
Routine offer of testing *vs.* VCT	4
Routine offer of opt-out testing *vs.* routine offer opt-in testing	6*
Comparison group	
Before intervention comparison	6
Historical comparison	3
Controlled comparison	1
Study typology (Table 1)	
Group A	4
Group B	0
Group C	6

*For the study conducted in Ethiopia, public facilities adopted opt-out testing but private facilities adopted opt-in testing after VCT.

Table 4 Processes of interventions of included studies

Country, year of study	Intervention description (Panel 1)	Provision of training for providers	Information on HIV/ HIV testing	Offer of testing	Pre-test counselling	Description of diagnostics
Scotland, 1996–1997 (Simpson *et al.* 1998)	A	Training in offering of test	Testing advertised by posters and a letter, women in intervention groups received a leaflet with information about all blood tests or only HIV tests	Routine offer of opt-in testing to the intervention group	Individual minimal or comprehensive discussion	NR
Scotland, 1998 (Simpson *et al.* 1999)	C	Training in offering of test	Women received leaflets prior to ANC appointments	Routine offer of opt-out testing to all women	Individual discussion of benefits of testing using standard protocol	NR
USA, 1998–2000 (Stringer *et al.* 2001)	C	HIV update for all maternity providers – included information on benefits of HIV screening, current ART for adults, therapy for PMTCT and proposed policy change	Women referred to written material providing information on HIV	Routine offer of opt-out testing	Written materials available along with one page counselling form	NR
Kenya, 2001–2003 (van't Hoog *et al.* 2005)	A	Training in PMTCT	NR	Routine offer of opt-out testing	All first time ANC attendees received individual pre-test counselling from nurse-counsellor	RDT
Botswana, 2003–2004 (Creek *et al.* 2007)	A	Training for counsellors on group/ individual pre-test counselling with flipchart	NR	Routine offer of opt-out testing	Group pre-test information and discussion	Elisa, return after 1 month; RDT, return 1 week, depending on gestation period
Zimbabwe, 2004–2005 (Chandisarewa *et al.* 2007)	C	Two day training on data collection and interview techniques	Community mobilisation to create awareness: skit performed in clinics, colleges, churches and industrial facilities	Routine offer of opt-out testing to all women by PMTCT clinic counsellors	15 min group education	RDT
Malawi, 2004–2005 (Moses *et al.* 2008)	C	NR	Health information & education provided in waiting area	Routine offer of opt-out testing	Pre-test counselling in groups of 8–12 women	RDT
Uganda, 2002–2009 (Byamugisha *et al.* 2010)	A	One week refresher training on HIV C&T updates plus 5 day training on RDT	NR	Routine offer of opt-out testing as 'standard of care'	Group pre-test information with flip chart to facilitate discussion	RDT

Table 4 (*Continued*)

Country, year of study	Intervention description (Panel 1)	Provision of training for providers	Information on HIV/ HIV testing	Offer of testing	Pre-test counselling	Description of diagnostics
Ethiopia, 2004–2009 (Mirkuzie *et al.* 2010)	C	NR	NR	Routine offer of opt-out testing in public facilities from 2008	NR	NR
Malawi, 2005–2007 (Kasenga *et al.* 2009)	C	NR	NR	Routine offer of opt-out testing	Group pre-test counselling	NR

receipt of results increased significantly to 99.8% ($P < 0.001$) in Zimbabwe (Chandisarewa *et al.* 2007) and to 82% ($P < 0.001$) in Botswana (Creek *et al.* 2007). Five studies reported results for linkage to ARV for PMTCT (van't Hoog *et al.* 2005; Chandisarewa *et al.* 2007; Creek *et al.* 2007; Byamugisha *et al.* 2010; Mirkuzie *et al.* 2010) with three reporting increased uptake of ARV for PMTCT and four reporting an increase in the absolute number of patients identified as HIV positive and linked to ARV for PMTCT (van't Hoog *et al.* 2005; Byamugisha *et al.* 2010; Mirkuzie *et al.* 2010). Across all studies, at least 20% of women were not linked to ARV for PMTCT (van't Hoog *et al.* 2005; Chandisarewa *et al.* 2007; Creek *et al.* 2007; Byamugisha *et al.* 2010; Mirkuzie *et al.* 2010).

Discussion

Our review suggests that implementation of PITC as a standard component of clinical care in ANC settings decreased lost opportunities to test pregnant women for HIV. In 3/10 studies, lost opportunities were <10% following introduction of PITC, and in 8/10, lost opportunities were <20%. Adopting PITC in ANC closes the gap towards achieving universal voluntary HIV testing of pregnant women and consequently increases the opportunities for pregnant women to access PMTCT and appropriate treatment and prevention interventions. Many key components of VCT were retained such as pre- and post-test counselling, although we were not able to assess directly the quality of these components or the extent to which patients felt coerced into testing. Linkage to ARV for PMTCT was low, with at least 20% of HIV-infected women not linked to ARVs, highlighting the need for improved linkage to PMTCT services.

The studies included in the review were of variable quality and had significant heterogeneity, creating challenges in data synthesis and interpretation, particularly of the outcomes of the components of the PITC process, for which there was limited data. Consequently, our review may be subject to limitations. First, we included only published studies, and published research is more likely to present statistically significant findings than unpublished research (Dwan *et al.* 2008). Further, despite systematically searching databases to minimise bias, no data from Latin America and the Caribbean or Asia were identified, which may be due to restricting our review to English language studies or a lack of published data from these regions despite the adoption of PITC in ANC in these settings. Second, the studies included in our review are subject to limitations. Only ten studies were identified for inclusion, the majority being NRS. Challenges associated with reporting and synthesising evidence from NRS are

Table 5 HIV Testing Uptake

	HIV Testing Uptake Among Pregnant Women Presenting to ANC		
Country, (Author)	PITC model	Comparison group	Decrease (%) in lost opportunities to test
Scotland (Simpson *et al.* 1998), 1996–1997	34.8% (*n* = 707/2030)* (OR offered testing vs control 8.4 (6.2, 11.5)†	5.5% (*n* = 55/994)	29.3%
Scotland (Simpson *et al.* 1999), 1998	88.3% (*n* = 816/924)*	34.8% (*n* = 707/2030)	53.5%
USA (Stringer *et al.* 2001), 1998–2000	88%* (OR study year 2.3 (2.1, 2.7))‡	75%	13%
Kenya (van't Hoog *et al.* 2005), 2001–2003	75.8% (*n* = 3101/4089)*	61.6% (*n* = 2551/4142)	14.2%
Botswana (Creek *et al.* 2007), 2003–2004	94.8% (*n* = 914/964)*	76.6% (*n* = 377/492)	18.2%
Zimbabwe (Chandisarewa *et al.* 2007), 2004–2005	99.9% (*n* = 4547/4551)*	62.8% (*n* = 3058/4872)	37.1%
Malawi (Moses *et al.* 2008), 2004–2005	99%*§	73%	26%
Uganda (Byamugisha *et al.* 2010), 2002–2009	87.6% (*n* = 21 538/24 595)*	22% (*n* = 6570/29 834)	65.6%
Ethiopia (Mirkuzie *et al.* 2010), 2004–2009	85%¶	52.2%	32.8%
Malawi (Kasenga *et al.* 2009), 2005–2007	88.6% (*n* = 879/992)*	78.7% (*n* = 837/1063)	9.9%

*$P < 0.05$.

†OR – Odds ratio; adjusted for midwife, marital status (married vs being single), previous test, age.

‡OR – Odds Ratio; adjusted for age, education, ethnicity, smoking history, substance use and history of sexually transmitted infections.

§Unpublished results from conference abstracts results: PITC Model: 98.3% (*n* = 14 491/14 749)*; Comparison Model: 76.1% (*n* = 11 689/15 343) (Zimba *et al.* 2006).

¶Private facilities offered opt-in testing yet >90% of women attended public facilities, where opt-out testing was offered (personal communication, 2011).

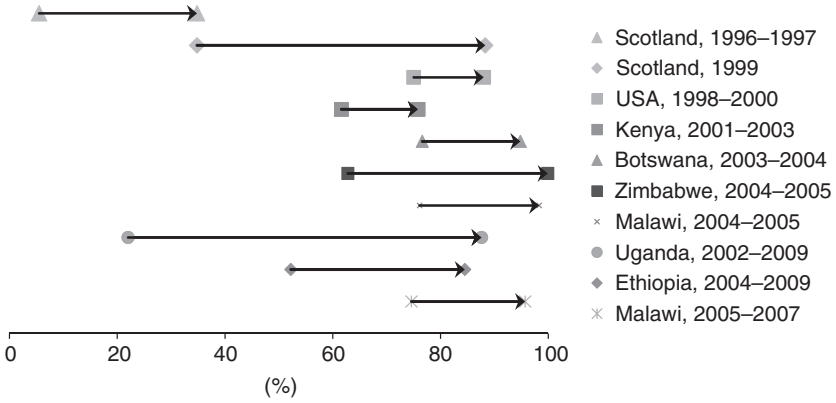

Figure 2 Achieving universal testing among pregnant women in ANC. The contribution of expanded PITC interventions to universal testing compared with pre-intervention testing uptake.

well documented (Deeks *et al.* 2003). A potential weakness of included studies is selection bias: there may have been differences between the intervention and 'control' groups at baseline, yet only one of the NRS controlled for these in analyses and only the study from Botswana compared groups to determine whether they had any significant differences in characteristics, including social and demographic characteristics (Deeks *et al.* 2003; Creek *et al.* 2007; Stringer *et al.* 2001). Hence, study results may overestimate the impact of PITC, as has been shown by other studies that compared evidence generated from NRS with results from RCTs (Deeks *et al.* 2003). In addition, NRS are vulnerable to time trends; to minimise the impact of these trends, we restricted our review to studies conducted within the same clinical settings with pre- and post-data as we felt that changes over time within the same facilities would most likely be a result of the interventions described. Finally, ambiguity in the use and differences in the interpretation of the terms opt-in, VCT and client-initiated may have implications on our classification of the model of testing in the control period of the studies.

Table 6 Outcomes of the PITC components

Pre-test counselled/information	PITC model	Comparison group
Kenya (van't Hoog *et al.* 2005)	91.5% (*n* = 3743/4089)*	77.4% (*n* = 3206/4142)
Uganda (Byamugisha *et al.* 2010)	98.3% (*n* = 24 171/24 595)*	62.3% (*n* = 18 583/29 834)
Zimbabwe (Chandisarewa *et al.* 2007)	100% (*n* = 4551/4551)	100% (*n* = 4872/4872)
Ethiopia (Mirkuzie *et al.* 2010)	94%	71.9%
Patients post-test counselled		
Kenya (van't Hoog *et al.* 2005)	90.3% (*n* = 2799/3101)	89.3% (*n* = 2278/2551)
Botswana (Creek *et al.* 2007)	82% (*n* = 753/914)*	72% (*n* = 272/377)
Zimbabwe (Chandisarewa *et al.* 2007)	99.8% (*n* = 4538/4547)*	96.9% (*n* = 2964/3058)
Ethiopia (Mirkuzie *et al.* 2010)	84.5%	50.7%
Linkage to PMTCT for women with positive results		
Kenya (van't Hoog *et al.* 2005)	70% (*n* = 471/673)*	56.6% (*n* = 302/534)
Botswana (Creek *et al.* 2007)	66% (*n* = 144/220)	70% (*n* = 87/125)
Zimbabwe (Chandisarewa *et al.* 2007)	73% (*n* = 663/908)	76.3% (*n* = 372/487)
Uganda (Byamugisha *et al.* 2010)	77.2% (*n* = 885/1147)*	55.8% (*n* = 316/566)
Ethiopia (Mirkuzie *et al.* 2010)	53.7%	33.8%

*$P < 0.05$.

Notwithstanding these limitations, we attempted to synthesis the findings of studies on similar primary outcomes assessed through similar study designs and in similar (ANC) settings. Most studies were from African countries with generalised epidemics. The overall direction and size of the effect provide evidence of the impact of this strategy on universal voluntary testing in ANC in similar contexts. National testing figures report substantial increases in HIV testing coverage where the testing model is PITC (WHO 2008, 2009, 2010): WHO 2010 Universal Access Report documents high coverage of HIV testing amongst pregnant women in Europe and Central Asia at 75% and in Latin America and the Caribbean at 57% (WHO 2010). In Eastern and Southern Africa, the region with the highest HIV prevalence, HIV testing amongst pregnant women reached over 50%, an increase from 43% in 2008 (WHO 2010). In Western and Central Africa, coverage increased from 16% to 21% between 2008 and 2009, with 54% [40–84%] of pregnant women with HIV in sub-Saharan Africa receiving ARVs for PMTCT compared with 45% [37–58%] in 2008 (WHO 2010). Consequently, although attributing reduced lost opportunities for testing to PITC is challenging in the absence of RCTs, as testing uptake is likely to be influenced by multiple correlated factors including the availability of rapid testing kits, increased availability of ART, healthcare providers expectations and attitudes, and the introduction of free services (Moses *et al.* 2008; April *et al.* 2009), the consistency and strength of association suggest that these results are reliable in terms of direction and magnitude.

A number of important questions remain. Reports of high HIV testing coverage and a reduction in lost opportunities where testing is routinely offered have been met with caution by some as concerns remain that, in the absence of written informed consent following individual pre-test information, intentional and unintentional coercion may confound patient choice (Gruskin *et al.* 2008; Becker *et al.* 2009). The process by which individuals decide to undergo testing is complex, being influenced not only by available information, but also by cultural, societal and individual beliefs and values and the potential individual and social implications of a positive test result (Gruskin *et al.* 2008). The routine offer of HIV testing in ANC settings might, however, simplify the decision-making process, through the normalisation of testing by removing fear of stigma, discrimination and moral judgements where testing is client-initiated (Oosterhoff *et al.* 2008). PITC has also raised ethical and human rights concerns in relation to testing and counselling and concerns regarding potential psychological consequences of a positive result in the absence of extensive pre-test counselling (Koo *et al.* 2006). Concerns exist that PITC will fail to adhere to the principles of consent, confidentiality and counselling inherent to VCT. Yet, anecdotal evidence suggests that where the testing strategy is VCT, pre- and/or post-test counselling is sometimes of poor quality or lacking (Paxton *et al.* 1999; Ayarza & Reyes 2002, Chopra

et al. 2005). In our review, we found that opt-out PITC adhered to the standards inherent to counselling and testing, with data indicating that women who were tested also receive pre-test counselling/information and that a majority of the women tested receive post-test counselling. The quality of these components was, however, not assessed, and additional research of the quality of the PITC components is warranted.

Although PITC closes the gap towards universal testing, a minority of women continue to refuse testing. An increased understanding of the factors associated with opt-out, such as age, ethnicity and ≥12 years of education in the USA (Stringer *et al.* 2001), and marital status in Scotland (Simpson *et al.* 1998), as suggested by evidence from studies included in our review, would ensure opportunities to test specific subpopulations within ANC settings are addressed (Homsy *et al.* 2007). Similarly, further research regarding the acceptability of services within ANC settings is required as, although we present evidence of the adherence to the standards inherent to good HIV testing conduct, our review provides limited evidence of women's perception and acceptability of the strategy. Studies included in our review suggest that the routine offer of testing is 'helpful' to women in Zimbabwe, with a majority of women in Scotland in favour of the availability of testing to all pregnant women (Simpson *et al.* 1998; Chandisarewa *et al.* 2007). In-depth personal perceptions regarding PITC processes were, however, not examined in the studies identified, and additional research is warranted.

Despite evidence that implementation of a PITC intervention may improve linkage to ARVs for PMTCT, at least 20% of women testing positive across five studies failed to access ARVs for PMTCT; in two studies conducted in Botswana and Zimbabwe, the proportion of women linked to ARVs for PMTCT decreased, albeit insignificantly. There is limited current published evidence of why a large proportion of women fail to be linked to ARV for PMTCT and of the effectiveness of linkage to ART, and subsequent adherence to ART regimens, for the management of the mother's infection for women testing in ANC and requiring treatment for their own health. The benefits of testing, in the absence of effective linkage to PMTCT, treatment and care services, are limited. Understanding these linkages, and their weaknesses, is crucial to ensuring the benefits of testing are maximised. The studies included in this review focus primarily on HIV testing uptake. The majority are early PITC studies, conducted during a transitional period when community and political support and healthcare provider confidence in conducting PITC may have been limited. Additional research of recent studies, which focus on PITC and the effectiveness of linkages to ARVs and ART in the era of ART scale-up and of increased support for PITC, through the availability of WHO guidance and national policies recommending PITC, is required. In addition, the costs associated with the introduction of PITC need to be assessed alongside assessments of any impact PITC has on overburdened services and service providers. For individuals accepting the offer of testing, sexual behaviours following a negative test result also need to be monitored and researched as concerns exist that a negative result may result in sexual disinhibition (Kiene *et al.* 2009). Finally, our review was restricted to the contribution of PITC to universal voluntary testing for pregnant women in ANC settings; additional research is needed to better understand how PITC might contribute to universal voluntary testing amongst different populations within different clinical contexts.

Acknowledgements

We thank Dr. Delia Boccia and Dr. Mishal Khan who were involved in determining eligibility and critically appraising studies identified for review. This study was funded by WHO and CDC.

References

Amornwichet P, Teeraratkul A, Simonds RJ *et al.* (2002) Preventing mother-to-child transmission. The first year of Thailand's national program. *JAMA* **288**, 245–248.

April M, Walensky R, Chang Y *et al.* (2009) HIV testing rates and outcomes in a South African community, 2001–2006: implications for expanded screening policies. *Journal of Acquired Immune Deficiency Syndrome* **51**, 310–316.

Ayarza R & Reyes B (2002) Changes in quality of life of people living with HIV/AIDS in Ecuador. *XIV International AIDS Conference*. Barcelona, Spain.

Bayer R & Edington C (2009) HIV testing, human rights, and the global AIDS policy: exceptionalism and its discontents. *Journal of Health Politics, Policy and Law* **34**, 301–323.

Becker J, Tsague L, Sahabo R & Twyman P (2009) Provider Initiated Testing and Counseling (PITC) for HIV in resource-limited clinical settings: important questions unanswered. *Pan African Medical Journal* **3**, 1–5.

Byamugisha R, Tylleskar T, Kagawa MN, Onyango S, Karamagi CA & Tumwine JK (2010) Dramatic and sustained increase in HIV-testing rates among antenatal attendees in Eastern Uganda after a policy change from voluntary counselling and testing to routine counselling and testing for HIV: a retrospective analysis of hospital records, 2002–2009. *BMC Health Services Research* **10**, 290.

Centers for Disease Control & Prevention. (2008) Provider-initiated HIV testing and counseling of TB patients – Livingstone District, Zambia, September 2004–December 2006. *MMWR – Morbidity & Mortality Weekly Report* **57**, 285–289.

Chandisarewa W, Stranix-Chibanda L, Chirapa E *et al.* (2007) Routine offer of antenatal HIV testing (''opt-out'' approach)

to prevent mother-to-child transmission of HIV in urban Zimbabwe. *Bulletin of the World Health Organization* **85**, 843–850.

Chersich M, Luchters SMF, Othigo MJ *et al.* (2008) HIV testing and counselling for women attending child health clinics: an opportunity for entry to prevent mother-to-child transmission and HIV treatment. *International Journal of STD & AIDS* **19**, 42–46.

Chopra M, Doherty T, Jackson D & Ashworth A (2005) Preventing HIV transmission to children: quality of counselling of mothers in South Africa. *Acta Paediatrica* **94**, 357–363.

Coates T, Grinstead O, Gregorich S *et al.* (2000) Efficacy of voluntary HIV-1 counselling and testing in individuals and couples in Kenya, Tanzania, and Trinidad: a randomised trial. The Voluntary HIV-1 Counseling and Testing Efficacy Study Group. *The Lancet* **8**, 103–112.

Creek TL, Ntumy R, Seipone K *et al.* (2007) Successful introduction of routine opt-out HIV testing in antenatal care in Botswana. *Journal of Acquired Immune Deficiency Syndromes* **45**, 102–107.

Deeks J, Dinnes J, D'Amico R *et al.* (2003) Evaluating non-randomised intervention studies. *Health Technology Assessment* **7**, 1–173.

Dwan K, Altman DG, Arnaiz JA *et al.* (2008) Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PLoS ONE* **3**, e3081.

Fetene NW & Feleke AD (2010) Missed opportunities for earlier HIV testing and diagnosis at the health facilities of Dessie town, North East Ethiopia. *BMC Public Health* **10**, 362.

Granich R, Gilks C, Dye C, De Cock K & Williams B (2009) Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. *The Lancet*. **373**, 48–57.

Gruskin S, Ahmed S & Ferguson L (2008) Provider-initiated HIV testing and counseling in health facilities – what does this mean for the health and human rights of pregnant women? *Developing World Bioethics* **8**, 23–32.

Higgins DL, Galavotti C, O'Reilly KR *et al.* (1991) Evidence for the effects of HIV antibody counseling and testing on risk behaviors. *JAMA* **266**, 2419–2429.

Homsy J, King R, Malamba S *et al.* (2007) The need for partner consent is a main reason for opting out of routine HIV testing for prevention of mother-to-child transmission in a rural Ugandan hospital. *Journal of Acquired Immune Deficiency Syndromes* **44**, 366–369.

Kasenga F, Byass P, Emmelin M & Hurtig A-K (2009) The implications of policy changes on the uptake of a PMTCT programme in rural Malawi: first three years of experience. *Global Health Action* **2**, 1–7.

Kharsany ABM, Karim QA & Karim SSA (2010) Uptake of provider-initiated HIV testing and counseling among women attending an urban sexually transmitted disease clinic in South Africa – missed opportunities for early diagnosis of HIV infection. *AIDS Care* **22**, 533–537.

Kiene S, Bateganya M, Wanyenze R *et al.* (2009) Provider-initiated HIV testing in health care settings: should it be client-centered counselling? *Journal des Sociaux du VIH/SIDA* **6**, 115–119.

Koo DJ, Begier EM, Henn MH, Sepkowitz KA & Kellerman SE (2006) HIV counseling and testing: less targeting, more testing. *American Journal of Public Health* **96**, 962–964.

Leon N, Colvin CJ, Lewin S, Mathews C & Jennings K (2010a) Provider-initiated testing and counselling for HIV – from debate to implementation. *South African Medical Journal* **100**, 220–221.

Leon N, Naidoo P, Mathews C, Lewin S & Lombard C (2010b) The impact of provider-initiated (opt-out) HIV testing and counseling of patients with sexually transmitted infection in Cape Town, South Africa: a controlled trial. *Implementation Science* **5**, 8.

Mirkuzie AH, Hinderaker SG & Morkve O (2010) Promising outcomes of a national programme for the prevention of mother-to-child HIV transmission in Addis Ababa: a retrospective study. *BMC Health Services Research* **10**, 267.

Moses A, Zimba C, Kamanga E *et al.* (2008) Prevention of mother-to-child transmission: program changes and the effect on uptake of the HIVNET 012 regimen in Malawi. *AIDS* **22**, 83–87.

Nieburg P, Cannell T & Morrison J (2005) *Expanded HIV Testing: Critical Gateway to HIV Treatment and Prevention Requires Major Resources, Effective Protections*. The Center for Strategic International Studies, Washington D.C.

Oosterhoff P, Hardon AP, Nguyen TA, Pham NY & Wright P (2008) Dealing with a positive result: routine HIV testing of pregnant women in Vietnam. *AIDS Care* **20**, 654–659.

Paxton S, Diaz J, Junga R, Pillai A & Thomas J (1999) APN+ Human Rights Initiative: participatory research into HIV/AIDS-related human rights violations in 10 Asian countries. 5th International Congress on HIV/AIDS in Asia and the Pacific. Malaysia.

Seipone K (2004) Introduction of routine HIV testing in prenatal care – Botswana, 2004. *MMWR. Morbidity and Mortality Weekly Report* **53**, 1083–1086.

Simpson WM, Johnstone FD, Boyd FM, Goldberg DJ, Hart GJ & Prescott RJ (1998) Uptake and acceptability of antenatal HIV testing: randomised controlled trial of different methods of offering the test. *BMJ* **316**, 262–267.

Simpson WM, Johnstone FD, Goldberg DJ, Gormley SM & Hart GJ (1999) Antenatal HIV testing: assessment of a routine voluntary approach. *BMJ* **318**, 1660–1661.

Stringer EM, Stringer JS, Cliver SP, Goldenberg RL & Goepfert AR (2001) Evaluation of a new testing policy for human immunodeficiency virus to improve screening rates. *Obstetrics and Gynecology* **98**, 1104–1108.

van't Hoog AH, Mbori-Ngacha DA, Marum LH *et al.* (2005) Preventing mother-to-child transmission of HIV in Western Kenya: operational issues. *Journal of Acquired Immune Deficiency Syndromes* **40**, 344–349.

Weigel R, Kamthunzi P, Mwansambo C, Phiri S & Kazembe PN (2009) Effect of provider-initiated testing and counselling and integration of ART services on access to HIV diagnosis and

treatment for children in Lilongwe, Malawi: a pre- post comparison. *BMC Pediatrics* **9**, 80.

WHO. (2003) *The Right to Know. New Approaches to HIV Testing and Counselling*. WHO, Geneva.

WHO. (2008) *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector*. WHO, Geneva.

WHO. (2009). *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector*. WHO, Geneva.

WHO. (2010). *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector*. WHO, Geneva.

WHO, UNAIDS. (2007) *Guidance on Provider-Initiated HIV Testing and Counselling in Health Facilities*. WHO, UNAIDS, Geneva.

Zimba C, Kamanga E, Chilongozi D *et al.* (2006) Impact of routine HIV counseling and testing with an opt-out strategy compared to voluntary counseling and testing in the implementation of PMTCT services, Lilongwe, Malawi *16th International AIDS Conference*. Toronto, Canada.

Zimba C, Kamanga E, Chilongozi D *et al.* (2010) *The Impact of Routine Counseling and Testing With an Opt-Out Strategy Compared to Voluntary Counseling and Testing in the Implementation of PMTCT Services in Lilongwe, Malawi*. UNC Project, Lilongwe.

Corresponding Author **Bernadette Hensen**, Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK. E-mail: bernadette.hensen@lshtm.ac.uk