

# **HIV Testing During Pregnancy**

## **A Literature and Policy Review**

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## I. INTRODUCTION

The US Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) and Joint United Nations Programme on HIV and AIDS (UNAIDS) recently revised their HIV testing guidelines in an effort to increase testing uptake (Centers for Disease Control and Prevention (CDC), 2006; WHO/UNAIDS, 2007). Although there is general agreement that increasing testing rates is an important goal, (e.g Gostin, 2006; Gruskin, Ahmed, & Ferguson, 2007), it is also widely recognize that HIV testing implicates important human rights concerns. As the WHO/UNAIDS Guidelines recognize, these concerns may be heightened for women, who “may be more likely than men to experience discrimination, violence, abandonment or ostracism when their HIV status becomes known” (WHO/UNAIDS, 2007). Because special attention has been paid to increasing testing rates in antenatal clinics (CDC, 2006; WHO/UNAIDS, 2007), it is particularly important to ensure that HIV testing policies include adequate human rights protections for pregnant women.

To address this concern, we reviewed policies for HIV testing during pregnancy from 19 countries representing all UN regions, with a focus on low- and middle-income countries. Using a standardized framework we review the policies to describe HIV testing approaches and the extent to which the policies consider the safety and human rights issues for women. This paper also synthesizes the public health, ethics, law and human rights literature on HIV testing during pregnancy. We conducted a systematic review of over 600 published papers and unpublished reports to understand and describe the ethical, legal, and policy debate over HIV testing of pregnant women as well as the research informing that debate.

## **A. Review Conclusions**

Consent, counseling and confidentiality (the 3 C's) are often heralded as the ethical and legal cornerstones of HIV/AIDS testing. We reviewed each country policy to assess whether the document discussed each of these components of testing and the extent to which each was discussed. First, across the 19 countries reviewed, we found that all policies require consent as a condition of testing (or at least require that testing be "voluntary"). In the majority of policies reviewed, the document allocates one or two lines to obtaining consent, without giving more consideration/attention to the issues of consent that have been raised in the policy literature. Second, all policies require "counseling" (some policies referred to this as "delivery of information") for clients prior to testing, although there was wide variation in the messages to be delivered and the audience to which messages should be delivered (some policies call for "counseling" to be done in groups, others for it to occur individually). There is a general trend among national policies to overemphasize the benefits of testing during these "counseling" sessions, with little or no attention to the risks to pregnant women. All policies that gave details about post-test counseling call for individual counseling. Third, a majority of the policies address confidentiality; although a number of policies allow for serostatus results to be shared amongst health workers, and the partner notification provisions of a few policies appear not to fulfill the requirements of international law.

In addition to reviewing the 3 C's, we also examined the policies for other ways in which they protect, fulfill and respect a woman's right to health and rights during HIV testing. Nine of the nineteen policies reviewed use the term "human rights" within their document; two of nineteen policies refer to "women's rights." Two policies state that a counselor should address potential risks of testing during pre-test counseling. Three policies state that a counselor should

consider violence as a risk of disclosure. Finally, sixteen countries discuss referral for treatment and care for HIV+ women.

In our review of the policy and research literature, we note three key findings. First, there is a gap between the policy and research literature: while much of the policy literature is dedicated to the question of what conditions are necessary to achieve informed consent, little research has attempted to answer that question. Second, both the policy and research literature would benefit from writers including more detailed information about the consent processes of the testing policies/models they are discussing. Third, studies that have compared different types of models do not describe the consent processes under each policy in sufficient detail to draw any conclusions about whether there is a trade-off between consent and testing uptake. It is also important to note that there is a great variation in the terminology used to describe testing models. This variation can be seen in the policy and research literature, as well as in the language of the policies we reviewed.

## **B. Review Recommendations**

A number of gaps were revealed during the literature and policy reviews, which may result in inadequate protection or harm to a pregnant woman who comes in contact with HIV testing policies. The reviews revealed that the policies lack sufficient procedural detail (e.g., monitoring and evaluation) and most notably, the majority of policies fail to address women's risk of violence in their testing approach. Furthermore, their content is not adequately informed by data related to: women's and providers' experiences under HIV testing models, minimum requirements for fully informed consent, and the impact of HIV testing on pregnant women's

uptake of additional health services. To address these deficiencies, we offer the following recommendations in three areas: policy, program, and research.

Policy recommendations. Policies should include: greater clarity in the definition of terms that are used to define testing approaches, and the consequences women face when they refuse to test; and more detail on: how consent should be obtained, potential risks of testing for pregnant women, greater clarity beyond HIV testing and prevention of mother-to-child transmission (PMTCT), monitoring and evaluation of testing, and the testing of newborns for mothers of unknown HIV serostatus.

Program recommendations. More information is needed on the following topics to better inform how HIV testing programs are being implemented for women. This includes: providers' experiences administering consent and counseling under current policies, women's experiences of consent and counseling received under current policies, how changes in testing policies affect women and providers' abilities to maintain serostatus confidentiality, how women and providers obtain information about policy changes, how equipped health services are to accommodate policy changes (e.g., are there adequate supplies of testing kits available), and better record keeping of the implementation of testing.

Research recommendations. Research is needed to understand: women's testing experiences under different models, the impact of culture on women and providers' experiences under different testing models, the minimum requirements for fully informed consent, other HIV

testing outcomes beyond uptake, and new testing models effect on women’s uptake of other HIV prevention and treatment/care services.

### **C. Human Rights Issues at Stake**

A number of international human rights laws exist to address HIV testing in the general population, and women specifically. Many national policies, as well as the WHO/UNAIDS HIV Testing guidance (WHO/UNAIDS, 2007), place a number of human rights issues at risk. Our review found that the majority of national policies recognized the 3 C’s--consent, counseling, and confidentiality—but fell short of meeting the full requirements imposed by international law. Moreover, even in instances where policies fulfill international legal requirements, there is concern whether human rights will be protected in practice. This policy review explores the extent to which national policies protect human rights and comply with international law; it does not, however, consider the extent to which these policies are put into practice.

## **II. METHODS**

There were two major components to the development of this paper, an extensive review of the policy and research literature and a review of policies and guidelines on HIV testing of pregnant women from 19 countries.

### **A. Literature Review**

We searched PubMed/Medline, LegalTrac, and Hein-On-Line’s Most Cited Law Journals and International & Non-US Law Journals in order to review the literature that has been

published on HIV testing of pregnant women since 2000. Our PubMed search consisted of the following search terms: HIV test\* policy; HIV test\* pregnan\*; HIV test\* human rights; HIV test\* ethics; HIV test\* antenatal; HIV test\* pre-natal; HIV test\* prenatal; HIV test\* law; HIV test\* legislat\*; HIV test\* guideline\*; HIV test\* infant; HIV test\* newborn; HIV test\* mother to child transmission; HIV test\* mtct; and HIV test\*violence. These searches yielded 1010 articles published since 2000. We reviewed all of the titles and many of the abstracts of these articles and excluded articles that focused on 1) testing of subpopulations, such as immigrants, drugs users, or sex workers; 2) testing of children and infants in state custody; 3) testing in hospitals, unless it was specifically related to testing of pregnant patients; 4) preventing HIV transmission by means other than testing, such as using vaginal microbicides and condoms; 5) HIV treatment or therapy; 6) prevalence of HIV testing of general populations or subpopulations other than pregnant women; 7) methods for determining HIV testing prevalence; 8) accuracy of testing methods; 9) the etiology of HIV transmission; 10) the history of the AIDS epidemic, either globally or regionally; and 11) knowledge and attitudes about STIs in general and that were not specific to HIV.

In LegalTrac, we conducted four searches: 1) all articles that include “pregnan\*” and “hiv testing” in their text; 2) all articles that include “pregnan\*” and “hiv screening” in their text; 3) all articles that included “pregnan\*” in their text and had “hiv” and “test\*” as keywords; and 4) all articles that included “pregnan\*” in their text and had “hiv” and “screen\*” as their key words. These four searches yielded 46 articles written since 2000. Hein-On-Line does not allow keyword searches, so we conducted a single, broad search: all articles that included “pregnan\*” and “hiv testing” or “hiv screening” in their texts. This search yielded 241 articles written since 2000. We reviewed the titles of all the search results from these two databases and skimmed

many of their texts. We excluded any article that did not contain substantial policy, ethical, or legal analysis (usually at least one page) related to HIV testing of pregnant women or newborns. Thus, we considered a total of 688 articles in our literature review.

We also considered the grey literature through a search of major international health organizations that focus on HIV/AIDS and in particular on women and HIV/AIDS. We searched the websites of the following organizations: WHO, UNICEF, CDC, American Public Health Association (APHA), American College of Obstetricians and Gynecologists (ACOG), American College of Nurse-Midwives (ACNM), American Academy of Pediatrics (AAP), Human Rights Watch and the Canadian HIV/AIDS Policy Network. Much of the relevant information we identified on the websites were commentaries or articles that appeared in our search of published material. We drew upon policy statements from professional organizations such as ACNM and ACOG in our review of the literature.

We divided the articles into two groups: “policy literature,” which included all ethics, law, and policy articles, and “research literature.” We reviewed the abstracts and texts of articles to distill the major findings or themes for summary and analysis in this paper. The organization of the literature review reflects the major themes that we identified in the literature.

## **B. Policy Review**

We identified 32 countries for which we sought national laws, policies or guidelines on HIV testing of pregnant women. Our first and primary aim in selecting countries was to achieve a global perspective, while focusing on countries with higher HIV prevalence or countries with concentrated epidemics among groups that include women. Second, we focused our attention on low- and middle-income countries. In order to ensure representation across regions, we

considered each UNAIDS region: 1. Sub-Saharan Africa, 2. Asia, 3. Eastern Europe and Central Asia, 4. Caribbean, 5. Latin America, 6. North America, Western Europe and Central Europe, 7. Middle East and North Africa, and 8. Oceania. We then identified countries within each region based on the following: highest HIV prevalence, identified by OSI as a priority country, UNAIDS highlighted the country in their 2007 surveillance report, and low- or middle-income status according to the World Bank classification. The number of countries sampled per region was dependent on the scope of the HIV epidemic; thus, more countries were selected from Sub-Saharan Africa which bears the highest burden of HIV prevalence than from the Middle East and North Africa region, where reported HIV prevalence is significantly lower. Table 1 shows the countries that were selected for this review.

**Table 1: Countries selected for the policy review\***

Sub-Saharan Africa	Asia	E. Europe/ Central Asia	Caribbean	Latin and Central America	N. America, West/Centr al Europe	Middle East/North Africa	Oceania
Botswana <b>Kenya</b> Lesotho Namibia <b>S. Africa</b> <b>Swaziland</b> <b>Tanzania</b> Uganda <b>Zambia</b> <b>Zimbabwe</b>	<b>Cambodia</b> <b>China</b> <b>India</b> Thailand	Georgia <b>Moldova</b> <b>Russia</b> <b>Ukraine</b> <b>Uzbekistan</b>	<b>Haiti</b> <b>Jamaica</b>	Brazil <b>Guyana</b> Honduras	Estonia Macedonia Spain <b>United States</b>	Djibouti Iran <b>Sudan</b>	<b>Papua New Guinea</b>

\*reviewed policy documents from countries in **bold**

We contacted representatives in each of the countries identified through OSI country and regional offices, UNAIDS representatives listed on the website, UNICEF representatives listed on the website, Ministries of Health, National AIDS organizations, CDC in-country representatives, and through our professional contacts. We sent a letter via email to representatives of institutions and organizations in each of the selected countries to request

information as to whether or not the country has a current policy on HIV testing of pregnant women. We also requested that if the policy does exist for it to be sent to us electronically or through postage mail. If a policy specific to testing of pregnant women was not available, then we requested a copy of any general HIV testing policies or guidelines that exists for that country. Although we initially solicited 32 policies, our analysis includes the policy documents of 19 countries. The remaining 13 countries were not included for one of the following reasons: (1) the country contact(s) did not respond to our request, (2) the country contact(s) sent us something that was not a national guideline or policy document, or (3) the country's document was in a language that we did not speak and did not have the resources to translate. Although most policies were available in English; we reviewed policies from five countries in their original language (Haiti, Russia, Ukraine, Uzbekistan, Moldova), and we were able to have one policy document translated for inclusion in our review (China).

We reviewed all of the policies using a single framework for analysis. We developed the framework based on the dictates of international law: 1) the right to informed consent (Office of United Nations High Commissioner, 2006); 2) the right to confidentiality (Office of United Nations High Commissioner, 2006); 3) the right to access treatment (Report of the Special Rapporteur, Paul Hunt, 2003) and follow-up support services, including services to protect women from violence (Office of United Nations High Commissioner, 2006)<sup>1</sup>). We also drew on the United Nations Development Programme's (UNDP) matrix for analyzing governments' obligations to protect health according to international human rights law. After completing an

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<sup>1</sup> The International Guidelines on HIV/AIDS and Human Rights do not state that there is a "right" to follow-up services, but they do enjoin countries to "promote a supportive and enabling environment for women, children and other vulnerable groups by addressing underlying prejudices and inequalities through community dialogue, specially designed social and health services and support to community groups.

individual framework for each country policy, we developed matrices to allow for cross-country comparison. These matrices were organized according to our primary themes. Subsequently, we reviewed the frameworks for all policies to determine any common themes not included in the matrices. We concluded that the information gleaned from the policy review can be divided into three matrices and have included them as tables in this report.

Based on the review of the literature and policies from various countries, we develop recommendations regarding further policy development, identify crucial gaps in the scientific research, suggest a research agenda around issues of implementation and highlight strategies for programmatic planning in regard to PMTCT and antenatal services.

### **III. LITERATURE REVIEW**

We conducted a systematic review of the published and unpublished literature related to HIV testing during pregnancy. We reviewed and synthesized 688 published papers, and we also reviewed guidelines from several organizational websites. Based on this review, we have divided the synthesis of our literature into two major sections. The first section reviews the policy literature, by drawing out some of the main themes in the ethical, legal and policy literature relevant (hereafter referred to as the policy literature) to HIV testing during pregnancy. The second section describes the research literature.

## A. Policy Literature on HIV Testing

- Despite disagreement over terminology and how to categorize testing policies, most commentators appear to advocate some form of “provider-initiated” testing policy in antenatal settings.
- Current testing policy terminology does not sufficiently capture the real question at the heart of the policy debate: how much emphasis should providers place on consent?
- Commentators who advocate provider-initiated testing and counseling vary widely over how much emphasis should be placed on consent
- Over the past seven years, there appears to be a trend among policymakers and commentators toward streamlining (i.e. deemphasizing) consent
- International law and many state laws impose minimum requirements for informed consent and may, therefore, limit the extent to which policymakers can streamline consent
- Although often framed as a simple argument between public health and individual rights, the debate over how much emphasis should be placed on consent also involves disagreements over which types of policies will best

### 1. Terminology used to describe testing approaches

There is substantial confusion within the literature over how to describe and categorize testing approaches. Table 2 provides a summary of the terms that are used to describe different types of testing policies and a brief explanation of some of the problems and confusion surrounding each term.

<b>Terminology</b>	<b>Definitions of the terms</b>
Client-initiated Testing & Counseling (CITC)	CITC is perhaps the only term over which there is little debate. It is used consistently to describe policies in which testing and counseling only occur if actively sought by the client (CDC, 2006; Jurgens, 2007; Rajkumar, 2007; WHO/UNAIDS, 2007) (Rajkumar refers to it as “patient-initiated”).
Voluntary Counseling & Testing (VCT)	Among those who define the term, VCT is synonymous with CITC. (e.g. Jurgens, 2007, 12; Rajkumar, 2007; WHO/UNAIDS, 2007) But many commentators use the terms “voluntary testing” and “voluntary screening” to describe provider-initiated policies (see PITC, below) (e.g. Gonen, 2001; Nicholson, 2002; Provincial Territorial Advisory Committee on Population Health 2002) ; or, even, any policy that is not mandatory, e.g. (Buchanan, 2000; Lazzarini & Rosales, 2002-2003, 71).
Provider-initiated Testing and Counseling (PITC)	Jurgens and the WHO/UNAIDS use this term to refer to policies under which testing is initiated by the care provider, but where the client has, in theory at least, the right not to be tested (Jurgens, 2007, 12; WHO/UNAIDS, 2007) One advantage of this terminology is that it draws a clear distinction between PITC and CITC policies. A disadvantage, however, is that, unlike routine, the term does not, by itself, indicate how often providers are supposed to initiate testing and counseling. Also, Tarantola and Gruskin have suggested that provider- <i>initiated</i> policies should be distinguished from provider- <i>recommended</i> policies (Tarantola & Gruskin, 2007).
Routine testing; Routine offer of testing; Routine recommendation of testing	Although frequently used, WHO/UNAIDS avoid using these terms, and Jurgens and Gruskin have both commented on the confusion surrounding these terms (Gruskin, 2004; Jurgens, 2007, 14). According to Jurgens, “routine testing,” should refer to policies under which testing is conducted regardless of individual consent. But writers often use it to describe policies under which testing is routinely <i>offered</i> but may be refused ( Jurgens, 2007) e.g. (Rajkumar, 2007).
Universal testing	We have seen this terms used—sometimes in conjunction with “routine”—in many articles, but we have never seen it defined.

	The implication is that testing would be conducted regardless of consent, but it appears to generally describe PITC policies.
Opt-in and Opt-out testing	“Opt-in” generally describes those policies under which the client must affirmatively agree to be tested, whereas “opt-out” describes policies where testing is conducted unless the client affirmatively declines to be tested (R. Jurgens, 2007). Some of the literature equates “opt-out” and “routine” testing and “opt-in” with CITC (e.g., Rajkumar, 2007), but Jurgens suggests using “opt-out” and “opt-in” to distinguish between different types of PITC policies (Jurgens, 2007). The problem with this approach is that whether a policy is opt-in or opt-out may have little bearing on the question of consent. Gruskin and Tarantola have criticized this terminology and WHO/UNAIDS generally avoid it (Tarantola & Gruskin, 2007).
Mandatory testing; Compulsory testing	According to Jurgens, “mandatory testing” refers to policies under which “testing occurs as a condition for some other benefit,” whereas “compulsory testing” refers to policies under which testing is conducted without consent and, sometimes, without the knowledge of the person being tested (Jurgens, 2007). Many commentators use these terms interchangeably (Jurgens, 2007). In the case of pregnant women, the distinction may not be important since it is questionable whether antenatal care should be characterized as a “benefit.”

As Table 2 indicates, there is no perfect way to categorize the different types of testing policies. Following Jurgens and WHO/UNAIDS, we divide policies into three broad categories: client-initiated testing and counseling (CITC), provider-initiated testing and counseling (PITC), and mandatory testing. Unlike Jurgens, however, we do not divide PITC policies into opt-in and opt-out, but instead attempt to place various PITC policies along a “consent spectrum,” according to how they define consent.

2. CITC and Mandatory Testing

There is limited support in the public health literature for either CITC or mandatory testing in the antenatal setting. Although CITC has been the dominant model for testing and counseling among the general population (Jurgens, 2007; Rajkumar, 2007), we found no one

who advocated this approach in the antenatal setting.<sup>2</sup> By contrast, we did find two articles advocating mandatory testing of pregnant women in countries with high HIV prevalence (Clark, 2006; Schuklenk & Kleinsmidt, 2007), and one article advocating mandatory testing of newborns in the U.S when the mother's status is unknown (Simpson & Forsyth, 2007). Though small in number, these articles may be part of a larger trend in the public health community to streamline or even abolish consent requirements.

### 3. PITC Policies

The vast majority of commentators as well as all the associations and agencies whose policies we reviewed support some form of PITC for pregnant women. There are, however, significant differences among specific PITC proposals. For this reason, perhaps, some commentators have tried to subdivide PITC policies according to different criteria: most common, are those who divide PITC policies into “opt-in” and “opt-out”, (see Gostin, 2006; Jurgens, 2007; WHO/UNAIDS, 2007); others have distinguished policies according to whether testing is routinely *offered* or routinely *recommended* (Csete & Elliott, 2006; WHO/UNAIDS, 2007); and others have contrasted “provider-initiated” and “provider-recommended” policies (Tarantola & Gruskin, 2007). At the heart of all these distinctions appears to be a desire to differentiate between PITC policies that emphasize consent and those that streamline the consent process. By themselves, however, these distinctions reveal very little about consent.<sup>3</sup>

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<sup>2</sup> Two articles did question whether non-CITC policies could be consistent with informed consent, but neither of these articles explicitly advocated CITC in the antenatal context (Bennett, 2007; Csete & Elliott, 2006)

<sup>3</sup> For example, Stuart Rennie and Frieda Behets have suggested that opt-out and opt-in policies can be ethically equivalent, but “only if the refusal is adequately informed and if the patient has sufficient liberty to say no” (Rennie & Behets, 2006); similarly the WHO/UNAIDS guidelines state that “[w]hether patients ‘opt-in’ or ‘opt-out,’ the end result should be the same: an informed

We, therefore, adopt a different approach to categorizing PITC policies and attempt to place the recommendations that we reviewed along a consent spectrum according to the number of conditions that must be fulfilled in order to achieve informed consent (see Table 3). On the one end, the New York City Department of Health's recommends to physicians that they tell their patients, "I am going to do an HIV test. Do you have any questions?" (Jurgens, 2007). On the other end, Rajkumar (Rajkumar, 2007) and WHO and UNAIDS (WHO/UNAIDS, 2007) hold that consent requires much more than the opportunity to ask questions, including information on the rationale for the testing and the risks associated with tests. Because much of the literature does not define "consent," it is impossible to know where to place many commentators. We included in our table those commentators, associations, and agencies that

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decision by the patient to accept or decline the health care provider's recommendation of an HIV test" (WHO/UNAIDS, 2007). These comments suggest the opt-in/opt-out distinction plays, at most, a minor role in determining the overall level of consent (and also that consent is the real concern).

**TABLE 3: CONSENT SPECTRUM**

More Emphasis Less

On Consent On Consent

Requirement	Rajkumar	WHO & UNAIDS	Wolf et. al. (2004)	CDC, ACNM, (& Gostin <sup>4</sup> (2007))	De Cock, ACOG, AMA, AAP IOM	NYC Dept. of Health (& Beckwith et. al. <sup>5</sup> )
Notification that test will be conducted	Y	Y	Y	Y	Y	Y
Opportunity to ask questions	NS	Y	N	Y	N	Y
Notify of right to refuse	Y	Y	Y	Y	Y	N
Rationale for/benefits of testing	Y	Y	Y	Y	N	N
Information on the Nature of HIV/AIDS	NS	NS	NS	Y	N	N
Risks/social implications of testing	Y	Y	Y	N	N	N
Follow-up services that are available (including treatment)	Y	Y	N	N	N	N
What to anticipate the implications of the results will be	NS	Y	N	N	N	N
Effect of testing on patient's ability to receive further services	Y	Y	Y	N	N	N

<sup>4</sup> Gostin's article does not specifically endorse the CDC's guidelines, but we included him in this table because the tone of his article suggests at least a cautious support for CDC's new guidelines.

<sup>5</sup> Beckwith et. al. do not discuss consent specifically. Their inclusion in this table is based on the following statement: "The HIV testing process can be performed with minimal counseling during the consent process. An opportunity to answer questions regarding HIV testing needs to be provided; however, in-depth counseling can occur when persons receive a positive HIV test result, when counseling is requested by the patient, or when counseling is deemed appropriate by the health care provider."

Explanation of the circumstances, if any, under which confidentiality may be overridden	Y	Y	Y	N	N	N
Reminder that patient can change her mind at any time & can seek a second opinion	Y	NS	N	N	N	N
Alternatives to testing	Y	NS	N	N	N	N
Risks and benefits to treatment	Y	NS	N	N	N	N
Private/Individualized Setting	NS	Y	N	N	N	N
Opt-in	?	N	N	N	N	N
Agreement must be in writing	Y	N	N	N	N	N
Name of the provider with overall responsibility for follow-up care	Y	NS	N	N	N	N
Details of costs or charges which patient may have to meet	Y	NS	N	N	N	N
Importance of informing anyone of ongoing risk of infection if the test result is positive	Y	Y	N	N	N	N

Y = Required      N = Not Required      NS = Not Specified—for those recommendations that lay out minimum requirements

?: Rajkumar refers to his recommendation as opt-out, but it is hard to imagine how a policy that requires written consent can be opt-out.

either specifically described their consent requirements or endorsed policies that did.

Several articles considered the implications of provider-initiated testing and counseling in the context of point-of-care testing. Point-of-care testing is testing that occurs at the time of delivery. Some commentators have argued that point-of-care testing deserves special attention because consent issues are exacerbated when a woman is in labor (Gruskin et al., 2007; Jurgens & Elliott, 2000). These issues include assessing a woman's capacity to consent, and the problems of implementing preventive measures to protect the infant without gathering informed consent. Jurgens and Elliott (Jurgens & Elliott, 2000) recommend that point-of-care rapid testing for women in labor only be offered to women in environments where the rapid testing implementation can be monitored and evaluated. In this way, informed consent can best be implemented and observed. In response to concerns raised about consent issues at point of care, Jamieson et al. (Jamieson et al., 2003; Schuklenk & Kleinsmidt, 2007) conducted a pilot study with 28 actively laboring women. Mock sessions were carried out to assess patients' comprehension of a rapid testing study protocol. The majority of women were able to state in their own words the purpose (71%) and benefits (68%) of the research study.

#### 4. Trends Toward Streamlining (and Possibly Eliminating) Consent

Many of the articles that we reviewed suggested that there is a trend within the public health community towards advocating for policies that deemphasize, or "streamline," consent (Csete & Elliott, 2006; Gostin, 2006; Schuklenk & Kleinsmidt, 2007; Wolf, Donoghoe, & Lane, 2007). Our review supports this theory. Since 2000, the CDC's 2006 revised HIV testing guidelines are perhaps the most prominent example of a shift to streamline consent. It is also noteworthy that the three articles we found that advocated for mandatory testing were all

published since 2006 (Clark, 2006; Schuklenk & Kleinsmidt, 2007; Simpson & Forsyth, 2007). As one of those articles noted: “After years of controversy, the scales seem to be tipping slowly toward the mandatory approach we advocate” (Schuklenk & Kleinsmidt, 2007). Still, there are many commentators who have criticized this trend (Csete & Elliott, 2006; Gruskin, 2004; Jurgens, 2007; Rajkumar, 2007; Tarantola, 2005).

### 5. Legal implications of Policies

Although there may be a growing push to reduce consent requirements, several articles suggest that, within the United States, state laws may prevent streamlined-consent policies from being implemented. Health care practitioners must follow the laws of their state, not CDC guidelines (Gostin, 2006; Lazzarini & Rosales, 2002-2003; Morin, 2000; Wolf, Lo, & Gostin, 2004). Therefore, although the new recommendations may influence state policy and the debate, they are not, by themselves enforceable (Wolf et al., 2007). The most recent study on state laws found that because many states had specific requirements for consent to HIV testing, written consent to testing, and disclosure of specific information during pretest counseling or the informed consent process, many states would need to change their laws to permit routine HIV testing as recommended by the CDC (Wolf & Lane, 2007).

A number of other commentators have analyzed HIV testing laws through a federal lens, considering whether certain testing policies might violate specific federal statutes or even the Constitution (Amana, 2005-2006; Angelletta, 2003-2004; Ayers, 2001-2002; Bryce, 2000-2001; Eden, 2001; Hanssens, 2007; Marsh, 2001). Of those, Catherine Hanssens, provided a unique analysis of a number of federal statutes that could inhibit implementation of CDC’s guidelines

(Hanssens, 2007). She also discusses the possibility that privacy protections within state constitutions and the Federal Constitution may also make implementation difficult.

The question of criminal liability for women who refused testing appeared in several articles (Amana, 2005-2006; Ayers, 2001-2002; Frautschi, 2001-2002; Lazzarini & Rosales, 2002-2003; Nicholson, 2002). Lazzarini's study of state laws found that among states that criminalize transmission of HIV only Oklahoma exempts in-utero exposure, suggesting that in states without such an exemption, women who transmitted HIV to their baby could theoretically be prosecuted (Lazzarini & Rosales, 2002-2003). Lazzarini found no instances of such a prosecution, but Schuklenk and Kleinsmidt noted that in Canada a mother was charged with negligence for withholding her HIV status from doctors (Schuklenk & Kleinsmidt, 2007).

Finally, a small number of articles in our review discussed how international law might impose at least minimal consent and confidentiality requirements on national testing policies (Durojaye & Ayankogbe, 2005; Flanagan, 2001; Gruskin, Roseman, & Ferguson, 2007; Straub, 2007). There is concern, however, that many countries are not abiding these requirements (Durojaye & Ayankogbe, 2005; Flanagan, 2001; Gruskin et al., 2007).

## 6. Arguments Behind the Policies

A number of articles frame the debate over testing policies as a choice between protecting public health *or* protecting individual rights (e.g., Bennett, 2007; De Cock, Mbori-Ngacha, & Marum, 2002; Gostin, 2006; (Rajkumar, 2007), but our review of the literature suggests that the debate is actually more complex and that there is disagreement about whether public health and individual rights necessarily conflict. Specifically, we found substantial disagreement over which types of policies will best protect individual rights and which will protect public health: as Table

4 shows, the same arguments are often used to support different policies. Thus, the debate is not merely about balancing individual rights and public health, but also about the impact that each type of policy will have on these values. Moreover, the purported “conflict” between public health and human rights is by no means straightforward: depending on which argument one finds most persuasive, a policy can be viewed as protective of (or harmful to) both public health and individual rights.

**Table 4: Arguments for and against streamlining consent**

Argument	How Argument Supports Policies that Emphasize Consent	How Argument Supports Policies that Streamline Consent
We need to increase uptake of testing	Streamlining consent may deter women from seeking prenatal care and testing. (e.g. (Angelletta, 2003-2004; Bryce, 2000-2001; Cameron, 2002; Eden, 2001; Wolf et al., 2004). Moreover, the women most likely to be deterred may also be those at highest risk of HIV. (e.g. Armstrong, 2008).	Streamlining consent has led to higher rates of testing uptake. (ACOG Committee on Obstetric Practice, 2004; Buchanan, 2000; De Cock et al., 2002; Lo, Wolf, & Sengupta, 2000; Schuklenk & Kleinsmidt, 2007).
We need to increase treatment	Women who feel coerced into testing are less likely to accept or comply with treatment (Wolf et al., 2004).	Higher testing rates will allow providers to identify more HIV+ women and provide them with treatment (De Cock et al., 2002); Schuklenk & Kleinsmidt, 2007).
We need to protect individual autonomy	Comprehensive pre-test counseling is necessary to ensure that women’s decisions to test are fully informed and truly autonomous (e.g. Dhai & Noble, 2005; Heywood, 2004; Lazzarini & Rosales, 2002-2003; Rajkumar, 2007).	Sexual partners also have a right to make informed choices and that depends, in part, on knowing their partner’s HIV status (Dixon-Mueller, 2007); Emphasis on pretest counseling can undermine autonomy by forcing patients to have counseling (Frith, 2005). <sup>6</sup>
We need to protect the	Women who are coerced into testing at the wrong time may face negative	Higher testing rates will lead to earlier diagnosis, and therefore

<sup>6</sup> It is important to note that Frith believes patients should get pre-test counseling if they want it, but she does not think pre-test counseling should be required. It is not clear whether she believes pre-test counselor should be offered, or simply available on request.

mother's health	social outcomes, including violence, depression, abandonment (Csete & Elliott, 2006; Wolf et al., 2004).	identify more women who are clinically eligible to start treatment (Cameron, 2002; Mills & Rennie, 2006; Nicholson, 2002; Schuklenk & Kleinsmidt, 2007).
We need to reduce stigma and discrimination aimed at PLWHA	A positive HIV test can result in substantial stigma and discrimination. Women may not be prepared to deal with these social consequences (Csete & Elliott, 2006; Wolf et al., 2004).	By making testing more routine, the stigma associated with asking for a test and being tested is reduced (De Cock et al., 2002; Ho et al., 2001; Rajkumar, 2007; Valenti, 2006).
We need to ensure a strong doctor-patient relationship	If a woman feels forced to test, it could cause her to lose trust in her provider (Armstrong, 2008; Bryce, 2000-2001; Gruskin et al., 2007; Provincial Territorial Advisory Committee on Population Health 2002).	Studies suggest that women feel more comfortable with their antenatal visits when testing is routine (Beckwith et al., 2005).

## **B. Research literature on HIV testing for pregnant women**

- Factors associated with the uptake of HIV testing among pregnant women are focused on: individual-level, provider-level, and clinic/system level barriers
- Among studies that compare opt-out versus other approaches to testing, opt-out models show significant increases in the uptake of testing; the language used in the research literature to describe different testing models is inconsistent making comparisons between models difficult
- Women face a number of adverse impacts of HIV testing, including: stigma, abandonment, violence, and loss of economic support
- Results of cost-effectiveness analyses of opt-out testing models are mixed

The published literature is replete with papers that describe HIV testing programs for pregnant women. We found 241 papers published between 2000 and 2008 that describe the implementation of HIV testing for pregnant women from Sub-Saharan Africa (96), North America (80), Europe/Eastern Europe (30), Asia/Oceania (27) and South America (8). These papers can be grouped according to four major categories; (1) papers that identify factors associated with the uptake of HIV testing during pregnancy; (2) papers that compare HIV testing uptake within opt-in and opt-out testing approaches; (3) papers that describe the implementation of alternative testing approaches to expand testing uptake among pregnant women; (4) papers that describe adverse impacts of HIV testing among women; and (5) papers that describe the cost-effectiveness of the opt-out HIV testing approach for pregnant women

### 1. Factors associated with the uptake of HIV testing among pregnant women

The factors that have been associated with the uptake of testing can be categorized into individual/patient-level factors, factors related to the providers, and factors related to the clinic/system.

*a. Individual-level factors*

The factors influencing testing uptake that were described most often in the literature were individual- and patient-level variables. Researchers identified demographic characteristics associated with testing uptake among pregnant women. They also described factors that women self-report as influencing their decision to test. The demographic characteristics that were most commonly associated with testing uptake in the literature included education, age, marital status and residential status. In general studies found that women with more education (Adeneye et al., 2006; Bajunirwe & Muzoora, 2005; Bakari et al., 2000; Dinh, Detels, & Nguyen, 2005; Fabiani et al., 2007; Magoni et al., 2007; Rakgoasi, 2005; Westheimer et al., 2004); women who were married (Daniel & Oladapo, 2006; Fabiani et al., 2007; Westheimer et al., 2004), women who were older (Enosolease & Offor, 2004; Magoni et al., 2007; Msuya et al., 2006; Rakgoasi, 2005; Rosa et al., 2006; Westheimer et al., 2004) and women who lived in urban areas (Creek et al., 2007; Karamagi, Tumwine, Tylleskar, & Heggenhougen, 2006; Rakgoasi, 2005) were more likely to accept HIV testing. In addition to these demographic factors, women's fear of negative reactions from partners (Baiden et al., 2005; Bajunirwe & Muzoora, 2005; Campbell & Bernhardt, 2003; Creek et al., 2007; de Paoli, Manongi, & Klepp, 2004; Dinh et al., 2005; Dorval, Ritchie, & Gruskin, 2007; Ekabua, Oyo-Ita, Ogaji, & Omuemu, 2006; Homsy et al., 2007; Karamagi et al., 2006; Kebaabetswe, 2007; Jones, 2004; Msuya et al., 2006; Pearlman, Averbach, Zierler, & Cranston, 2005; Pool, Nyanzi, & Whitworth, 2001; Romero-Gutierrez, Delgado-Macias, Mora-Escobar, Ponce-Ponce de Leon, & Amador, 2007; Sarker, Sanou, Snow,

Ganame, & Gondos, 2007), their low perception of risk (de Paoli et al., 2004; Daniel & Oladapo, 2006; Thierman et al., 2006; Yin, Shing, & Hung, 2003) and their fear of stigma from others (Castle, 2003; Fernandez et al., 2000; Kominami, Kawata, Ali, Meena, & Ushijima, 2007; Parra, Doran, Ivy, Aranda, & Hernandez, 2001; Peltzer, Mosala, Shisana, Nqueko, & Mngqundaniso, 2007) were reasons given for declining the HIV test. The studies that examine fear of negative social consequences are of particular importance in furthering our understanding of the complexity of individual level factors affecting testing uptake.

*b. Provider-level barriers to testing uptake*

Provider-level barriers were identified less often in the literature as barriers to HIV testing of pregnant women; however, several papers did identify factors at the provider level. From the perspective of women, uptake of testing was associated with discussions, encouragement and perceived endorsement of providers to test (Guenter, Kaczorowski, Carroll, & Sellors, 2003; Fernandez et al., 2000; Lansky, Sansom, Harrison, & Stancil, 2007; Sinha et al., 2008). Conversely lack of confidence in skill of provider was identified by women as a reason not to test (Castle, 2003; Pool et al., 2001) and concerns that women would not receive services if they did not test (Pool et al., 2001). From the perspective of providers themselves, their discomfort and lack of knowledge (Creek et al., 2007) as well as perceived lack of time, and competing priorities (Burke et al., 2007; Chambers et al., 2001). Finally, in a survey of 622 providers in the US, Guenter found that not providing written information or choice was independently associated with high testing rates (Guenter et al., 2003).

*c. Clinic/system-level barriers to testing uptake*

There were very few papers that identified systems- or institutional-level barriers to HIV testing. A few studies identified the clinic site as an important predictor of whether pregnant

women were offered HIV testing. They did not, however, specify what aspects of the site influence testing rates (Goldani et al., 2003; Westheimer et al., 2004). Lack of available sites for testing and lack of providers to perform tests were associated with low rates of testing (Karamagi et al., 2006; Sarker et al., 2007). One study from the US found that the odds of a woman reporting that she had been tested during pregnancy was positively associated with the amount of CDC funding to the states (Linac, Zheng, Losina, Walensky, & Freedberg, 2006).

## 2. Comparison of HIV testing uptake among opt-out and other approaches to testing

There was a category of nine published articles that assessed rates of HIV testing uptake among pregnant women counseled under an opt-out HIV testing approach. These articles were drawn from experiences implementing opt-out testing in Malawi (Manzi et al., 2005; Moses, Tosswill, Sudhanva, Poulton, & Zuckerman, 2008), Zimbabwe (Chandisaewa et al., 2007; Perez, Zvandaziva, Engelsmann, & Dabis, 2006) Botswana (CDC, 2004; Creek et al., 2007), Ukraine (Malyuta, Newell, Ostergren, Thorne, & Zhilka, 2006), the US (Stringer, Stringer, Cliver, Goldenberg, & Goepfert, 2001) and Canada (Yudin, Moravac, & Shah, 2007).

Among these studies five compared HIV-testing uptake under opt-out versus other approaches to testing: all showed statistically significant increases in testing uptake under opt-out approaches. Moses in Malawi found an increase in testing uptake from 45% to 75% (Moses et al., 2008). The CDC in Botswana reported increase in testing uptake from 75.3% to 90.5% (CDC, 2004). Creek also reported increase in uptake in Botswana following the adoption of opt-out testing policy from 47% to 78% of women in an ANC clinic (Creek et al., 2007). In Zimbabwe, Chandisaewa reported testing uptake increase from 65% to 99.9% following adoption of routine opt-out testing and the use of community counselors to provide counseling

and testing (Chandisarewa et al., 2007). Finally, Stringer reported difference in testing uptake of 75% and 88% among women enrolled in an opt-in testing model versus women enrolled in a model that has policy of routine HIV testing with active patient refusal (Stringer et al., 2001).

Manzi reported high testing uptake (95%) among women in rural Malawi, however they found a high rate of loss to follow up during PMTCT in their cohort. Only 45% of HIV-infected mothers and 34% of their babies received the nevirapine (Manzi et al., 2005). These findings indicate that while PITC may increase the rate of testing uptake, it does not necessarily positively impact rates of follow-up care. In their assessment of PMTCT programme data from 18 pilot sites in South Africa, Doherty and colleagues found much higher rates of HIV testing in KwaZulu-Natal province, the only province there was an opt-out testing policy in effect (90%), as compared to other provinces such as Eastern Cape that used an opt-in approach to testing and found 37% testing rate among pregnant women.

The research literature's use and operationalization of the testing terminology suffers from the same imprecision as the policy literature. In the nine studies in this section, a range of terms were employed to describe similar models. Opt-out, routine testing, and provider-initiated testing and counseling were all used to describe models with group pre-test counseling and active client refusal of an HIV test. Opt-in and voluntary testing and counseling were used to describe models with private pre-test counseling and active client consent of an HIV test. None of the studies however provided detailed descriptions of other factors relating to consent, such as the type of information provided during the pre-test counseling sessions. Therefore, it is impossible to draw conclusions about whether these studies actually found a trade-off between level of consent and testing uptake. Future comparisons of policies should provide more detail on all factors relating to consent in order to understand whether testing uptake and consent are truly in

conflict. They would also benefit from evaluating women's experiences under different types of policies.

### 3. Implementation of alternative HIV testing approaches to increase uptake

We found nine published papers that described strategies other than opt-out testing to increase uptake of testing during pregnancy. The papers described programs to increase partner involvement in Cambodia and China through partner participation in mother's classes and couple counseling (Kakimoto et al., 2007; Khoshnood et al., 2006); changing the flow of services to integrate testing and counseling and dispensing of nevirapine into regular antenatal care in Kenya (van't Hoog et al., 2005); community education and mobilization to increase couple counseling in Zambia (Semrau et al., 2005); utilizing community volunteers or traditional birth attendants to provider HIV testing services to pregnant women in Zimbabwe and Cameroon (Chandisarewa et al., 2007; Shetty et al., 2005; Wanyu, Diom, Mitchell, Tih, & Meyer, 2007; and adding an educational session with an HIV-focused nurse in the US (Anderson, Simhan, & Landers, 2004).

Statistically significant differences in uptake of testing were found in the interventions evaluated by Kakimoto in Cambodia (18.7% in control group vs. 85.1% in intervention group); van't Hoog (55% before intervention vs. 68% after intervention), Semrau (79% women counseled alone vs. 96% women counseled with partner); and Anderson (74.8% before the education session with nurse vs. 84.3% after education session with nurse).

Only one study in Zambia specifically assessed the risk of negative social reactions from partners as part of their evaluation of the new programs, and they found no significant differences in reported adverse events between couple and individual-counseled women (Semrau

et al., 2005). In Tanzania, Urassa and colleagues assessed the acceptability of a program to provide Nevirapine to pregnant women without HIV testing and counseling by interviewing 250 women attending antenatal care late in pregnancy (Urassa, Gosling, Pool, & Reyburn, 2005). Almost half of the women preferred to be offered Nevirapine without testing. Having a partner with history of sexually transmitted infection, having a partner who had another sexual partner in last year were positively associated with a preference to avoid testing. Presence of a partner living at home or feeling able to ask their partner to go for an HIV test were negatively associated with a preference to avoid testing.

In another approach to increase testing uptake among pregnant women, there have been calls for increasing rates of rapid testing at labor and delivery in the United States and internationally. Uptake of rapid testing by women in labor ranges from 84% (Bulterys et al., 2004) to over 98% ((Nogueira et al., 2001; Rahangdale et al., 2007; Sagay et al., 2006). Overall, the factors with increased uptake are age greater than 21 years, higher educational status, gestational age less than 32 weeks, and inadequate prenatal care during pregnancy (Bhore & Sastry, J., Parke, D., et al., 2003; Bulterys et al., 2004). The majority of women (90%) received their test results prior to delivery with late admission the primary reason for receiving results post-delivery (Kissin et al., 2008). In a retrospective medical chart review, 89% of women reported feeling satisfied with their decision to undergo rapid testing, and 83% reported no decisional conflict and 9% reported decisional conflict. Additionally, most of the women reported feeling sure of their decision to test (87%), feeling informed about testing (76%), and feeling supported in their decision-making process (76%) (Rahangdale, Sarnquist, Maldonado, & Cohan, 2008) While most implementation studies focus on the positive impact of rapid testing, Hillis and colleagues (Hillis et al., 2007) reported that women enrolled in a rapid-testing program

in St. Petersburg were significantly more likely to abandon their child post-test than women in the comparison group (50% versus 26%).

#### 4. Adverse impacts of HIV testing among women

A number of studies have addressed the risks of HIV testing for women. These risks include women's fears of stigma, discrimination, abandonment, violence, expulsion from the home, and partner accusations of infidelity (Farquhar et al, 2000; Homsy et al., 2007; Issiaka et al, 2001; Kilewo et al, 2001; Maman et al 2002; Martin-Herz et al., 2006; Nebie et al; 2001, Pool et al, 2001; Sigxaxhe & Matthews, 2000). Studies have also demonstrated the realities of women's disclosure of HIV tests: including abandonment, loss of economic support; stigma, blame, and violence (Gaillard et al., 2000; Gielen et al., 2000; Grinstead et al., 2001; Kilewo et al., 2001; Maman et al., 2002). Research conducted in sub-Saharan Africa and Southeast Asia found that between 3.5 to 14.6% of women reported a violent reaction from their partner following disclosure (Medley, Garcia-Moreno, McGill, & Maman, 2004). Research in Russia found pregnant women faced stigmatization from healthcare providers and received pressure to abort (Burns, 2007). And a study in the US revealed that while only 4% of women reported physical abuse following a disclosure event, 45% reported experiencing emotional, physical, or sexual abuse at some time after their diagnosis (Gielen, 2000).

Some studies have found a primary reason for women to refuse an HIV test was a fear of the difficulty of coping with a positive result (Creek et al., 2007; Homsy et al., 2007), needing more time to time to make a decision, or had already been tested and saw no need for another (Homsy et al., 2007). Because pregnant women are not necessarily seeking HIV testing when they attend an antenatal clinic, they may be unprepared to handle positive results when

confronted with the PITC model in their health care facility (Galletly, Pinkerton, & Petroll, 2008).

#### 5. Cost effectiveness of HIV testing programs

There are several cost-effectiveness analyses for HIV testing programs published in the literature (Paltiel et al., 2006; Paltiel et al., 2005; Sanders et al., 2005), and a few that have evaluated the cost-effectiveness of HIV testing programs for pregnant women specifically (Holtgrave, 2007; Immergluck, Cull, Schwartz, & Elstein, 2000; Lee & Wong, 2007; Postma et al., 2000). With regard to the cost-effectiveness studies for antenatal women, researchers in the US, the U.K. and Hong Kong have shown the cost-effectiveness of universal screening programs, in terms of pediatric HIV infections averted (Immergluck et al., 2000; Lee & Wong, 2007; Postma et al., 2000). In his cost-effectiveness analysis of antenatal HIV testing, Holtgrave estimated the cost and public health impact of opt-out HIV testing relative to testing accompanied by client-centered counseling, and relative to a more targeted counseling and testing strategy (Holtgrave, 2007). This was the only study we could identify that considered the impact of counseling on reducing risk behavior and transmission of HIV to sexual partners. Holtgrave found that at a 1% HIV seropositivity rate for the same cost, targeted counseling and testing services would be preferred to opt-out testing. He concludes that while opt-out testing may have benefits in terms of newly diagnosing individuals, the abandonment of client-centered counseling has real public health consequences in terms of HIV infections that could have been averted.

### C. Synthesis of Policy and Research Literature

- There is a gap between the policy and research literature: while much of the policy literature is dedicated to the question of what conditions are necessary to achieve informed consent, little research has attempted to answer that question
- Both the policy and research literature would benefit from writers including more detailed information about the consent processes of the policies they are discussing
- Research studies that have compared different testing models do not describe the consent processes under each model in sufficient detail to draw any conclusions about whether there is a trade-off between consent and testing uptake

A comparison of the policy and research literature reveals 1) a critical gap between what is being debated and what is being researched and 2) a need for more detailed testing policy/model descriptions in both the policy and research literature. The debate in the policy literature focuses primarily on the issue of consent, but little research is being conducted on the consent experiences of providers or pregnant women. Instead, most of the research literature focuses on testing uptake, which is only one facet of the debate over consent. Moreover, it is difficult to draw meaningful conclusions about the relationship between consent and uptake from the research that compares different types of testing models because the articles do not provide sufficient detail about the consent processes of the approaches being compared. As the policy literature made clear, labeling a policy as “opt-in” or “opt-out” reveals little about the overall consent process of the policy.

In the next section, we review how 19 different countries address consent and other issues relating to HIV testing of pregnant women.

## IV. POLICY REVIEW

- Review includes documents from 19 countries
- Titles of documents incorporate a wide array of terms:
  - Guidelines
  - Policy
  - Handbook
  - Order
  - Recommendations
- 9 of the policies reviewed are specific to pregnant women
- 10 of the policies reviewed are general HIV testing policies
- All 19 countries have released new or revised policies within the last 5 years
- South Africa released revised policies in 2008

We collected HIV testing policies from a total of 19 countries. Our selection of countries represents an expansion upon the current literature because most of the countries we reviewed had not been included in other cross-country reviews of HIV testing policies. Moreover, our review is the first attempt to collect and compare national HIV testing policies from countries in different continents. To our knowledge, only two other studies have conducted cross-country reviews of national HIV testing policies, and both of those studies focused on specific regions: Deblonde et. al. ((Deblonde, Claeys, & Temmerman, 2007)) reviewed the national antenatal HIV testing policies of 23 European countries, and Straub ((Straub, 2007)) conducted an extensive review of the HIV testing policies and laws of four Asian countries. Of the 27 countries included in those two studies, only one, China, overlaps with the countries included in our study.

The titles of the documents we collected varied greatly across countries, and the terminology used included words such as “guidelines,” “policy,” “handbook,” “order” and “recommendations.” For the purposes of our analysis, when we are speaking generally about the

documents reviewed, we will use the term “policy” to describe all of the different documents identified within the first column of the table. However, when we discussing country-specific documents, we will use the term identified in the title of the document.

Nine of the policies were specific to HIV testing of pregnant women. For the remaining ten documents in our sample, we reviewed general HIV testing policies, and subsequently focused our analysis on the sections that specifically addressed testing of pregnant women. Table 5 describes the countries from which we received policies, the titles of the documents we received and reviewed, the dates the documents were issued, and the specificity of the HIV testing policy to pregnant women. All of the countries reviewed have released new or revised policies within the last 5 years; Russia has had its current policy on HIV testing for pregnant women in place the longest (2003) and South Africa issued its current testing guidelines just this year (2008). The timing of issuing revised testing policies for pregnant women appears to corresponds with one or more of the following events: the adoption of the new WHO/CDC guidelines, increased knowledge about effective prophylaxis for PMTCT and/or the increased availability of antiretroviral medication in general.

**TABLE 5. Description of policies reviewed**

<b>Country</b>	<b>HIV Prevalence among Pregnant Women</b>	<b>Document(s) reviewed</b>	<b>Date Document Developed</b>	<b>General or Specific Document on HIV Testing of Pregnant Women</b>
Cambodia	0.90%	1) Ministry of Health's VCCT Policy 2) Ministry of Health's National Guidelines for PMTCT	1) Apr 2007 2) Oct 2005	1) Part of document specific to pregnant women 2) Document specific to pregnant women
China	0.05%	Ministry of Health's Handbook for Preventing AIDS: Mother-to-Child Transmission Techniques	1) Sept 2005	1) Document specific to pregnant women
Guyana	1.55%	Ministry of Health's National Guidelines for HIV Testing and Counseling	1) Dec 2007	Part of document specific to pregnant women
Haiti	3.80%	Ministere de la sante publique et de la population (MSPP)	1) 2005	Document specific to pregnant women
India	0.36%	Ministry of Health's Operational Guidelines for Integrated Counseling and Testing Centres	1) Jul 2007	Part of document specific to pregnant women
Jamaica	1.60%	National HIV/STI Programme Ministry of Health- Jamaica "Integrating Treatment Care and Support with Prevention of Mother to Child Transmission Services: Implementation Guidelines for Healthcare Workers"	1) Jun 2006	Document specific to pregnant women
Kenya	6.10%	Ministry of Health /National AIDS and STD Control Programme "Guidelines for HIV Testing in Clinical Settings"	1) 2004	Part of document specific to pregnant women
Moldova	1.10%	1) Plan for the Surveillance of HIV in Moldova 2005-2009 2) Standard Epidemiological Surveillance of HIV/AIDS (Ministry of Health & Social Protection Order No.20)	1) 2007 2) Jan 2007 3) Feb 2007	Part of documents specific to pregnant women

		3) Law on prevention and control of HIV/AIDS nr. 23-XVI		
Papau New Guinea	1.28%	1) Papua New Guinea Voluntary Counselling and Testing Policy & Guidelines 2) HAMP Act	1) Jul 2006 2) Jul 2003	1) Part of document specific to pregnant women 2) Part of document specific to pregnant women

**TABLE 5. Description of policies reviewed**

<b>Country</b>	<b>HIV Prevalence among Pregnant Women</b>	<b>Document(s) reviewed</b>	<b>Date Document Developed</b>	<b>General or Specific Document on HIV Testing of Pregnant Women</b>
Russia	1.10%	Order of Ministry of Health No. 606 "Instruction on the preventive measures of transmission of HIV-infection from mother to infant during pregnancy, delivery and infancy."	1) Dec 2003	Document specific to pregnant women
South Africa	18.80%	National Department of Health: Policy and Guidelines for the Implementation of the PMTCT programme	1) Feb 2008	Document specific to pregnant women
Sudan	1.60%	Federal Ministry of Health/Sudan National AIDS Control Program: National Guidelines for Prevention of Mother to Child Transmission	1) Jul 2007	Document specific to pregnant women
Swaziland	33.40%	Ministry of Health and Social Welfare: Prevention of Mother to Child Transmission of HIV Guidelines	1) 2006	Document specific to pregnant women
Tanzania	6.50%	Ministry of Health and Social Welfare: National AIDS Control Programme's "Guidelines for HIV Testing and Counselling in Clinical Settings "	1) Jul 2007	Part of document specific to pregnant women
Ukraine	1.40%	1) Ministry of Health's Order No. 786/796/4074/299/231 Prevention of Mother to Child Transmission and the Provision of Medico-	1) Nov 2006 2) Aug	Document specific to pregnant women

		Social Help to Children with HIV/AIDS 2) Ministry of Health's Decree #415 Protocol of Voluntary HIV/AIDS Testing	2005	
United States	0.60%	CDC MMWR: revised Recommendations for HIV Testing in Adults, Adolescents, and Pregnant Women in Health-Care Settings	1)Sept 2006	Part of document specific to pregnant women
Uzbekistan	0.20%	Ministry of Health's "Sanitary Laws and Norms on HIV Testing" no. 0187	1) Oct 2005	Part of document specific to pregnant women
Zambia	17.00%	DRAFT: Ministry of Health National Protocol Guidelines Integrated Prevention of Mother-to- Child Transmission of HIV/AIDS	1) Dec 2007	Document specific to pregnant women
Zimbabwe	20.10%	Zimbabwe National Guidelines on HIV testing and counseling	1) Oct 2005	Part of document specific to pregnant women

## *Review of trends in approaches to HIV testing across countries*

### *Terminology*

- None of the policies reviewed call for a mandatory HIV testing approach
- Policies describe their testing approach along 4 different categories:
  - 3 countries “recommend testing” for pregnant women
  - 9 countries call for “systematic” or “routine” testing of pregnant women
  - 4 countries call for “provider-initiated testing and counseling”
  - 7 countries identify their HIV testing strategy as “opt-out”
- It is impossible to classify policies as “opt-in” or “opt-out” as the terminology used to describe testing approach is not consistent across different country policies, even when different countries are describing a similar strategy

There are four main categories of terms used to describe HIV testing policies for pregnant women within the countries we included in our review. Uzbekistan describes its HIV testing policy for pregnant women as “voluntary.” Haiti, Russia and Ukraine’s policies call for “recommended testing” to pregnant women attending antenatal care. China, Guyana, Jamaica, Kenya, Moldova, South Africa, Swaziland, United States and Zimbabwe describe their testing policies for pregnant women as “systematic” or “routine.” The policies for Cambodia, India, Papua New Guinea and Tanzania use the term “provider-initiated testing and counseling”. “Opt-out” was used to describe the policies of Guyana, India, Kenya, Sudan, Tanzania, United States and Zimbabwe. In the guidelines for Guyana, India, Kenya, Sudan, Tanzania and the United States, opt-out is described as telling the women that HIV testing is offered as a routine part of standard care and that she may decline the test. Classification of testing policies as “opt-in” or “opt-out” was impossible given the different use of terminology based on the countries, regions, and also the dates of implementation. As noted in the literature review, the terminology and language regarding HIV testing policies is both confusing and changing. Countries that adopted

or changed HIV testing policies for pregnant women after the introduction of the terms “opt-out” or “provider-initiated testing and counseling” tend to use these new terms. Countries whose policies were adopted earlier than 2007 more commonly refer to testing as voluntary, routine, systematic. None of the countries included in our review state that HIV testing of pregnant women is mandatory. In fact, most countries’ policies include statements reinforcing either the “voluntariness” of testing or a stated requirement of verbal, written or verbal and written consent to testing.

- All 19 countries reviewed require consent as a condition of HIV testing; though few clarify if consent should be obtained before or after pre-test counseling
- Only Cambodia and India’s policies state that a woman should be advised of potential risks of testing prior to consent;
- Only India’s policy explicitly states that a woman should be informed that refusing to test will not affect her access to services
- Only Cambodia’s policy outlines a monitoring strategy to ensure that consent is being obtained in an ethical manner; none of the other countries provide such detail in their policy
- None of the policies stipulate any penalties for a health care facility that fails to ensure informed consent
- The Ukraine and the United States policies both indicate that a newborn is to be tested if a mother’s status is unknown. This mandate negates a woman’s right to not know her own status.

### *Consent*

All the policies require consent as a condition of testing<sup>7</sup> but descriptions of consent requirements vary widely among the policies. China and Kenya, for example, provide little to no guidance on how providers should obtain consent; by contrast, India specifically defines consent, explains when consent should be obtained in relation to pre-test counseling, and describes what information must be provided to a patient in order to ensure that consent is informed. Despite this variation, we can make some useful comparisons and generalizations about how the policies address the issue of consent.

First, most of the policies do not make clear whether consent should be obtained before or after pre-test counseling. Guyana's, for example, states only that pre-test counseling and the consent process should both occur during the "pre-test session." Papua New Guinea's policy is a little clearer: it provides a one page pre-test information checklist and includes "(g)et their consent for the test" a little over halfway down the list. Cambodia, India and South Africa's policies are the only policies that explicitly indicate that consent should be obtained after counseling.

Second, Cambodia and India's policies are the only ones that state that women should be advised of the potential risks of testing before they consent. This omission may not be significant for policies, like China's and Kenya's, which are relatively short on detail. But it is striking in policies such as Papua New Guinea's, Swaziland's and Zambia's, which all provide fairly detailed accounts of the information that should be included in pre-test counseling.

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<sup>7</sup> Haiti's and Uzbekistan's policies do mention that the test is voluntary but neither explicitly discusses consent.

Third, two policies, Cambodia and South Africa, require that consent be in writing; interestingly, South Africa requires counselors to also obtain verbal consent. Seven policies allow consent to be verbal, and ten countries do not specify how consent should be obtained.

Fourth, India's is the only policy that explicitly states that clients should be told that refusing to take the test will not affect their access to services.

Fifth, only Cambodia's policy outlines a monitoring strategy to ensure that consent is being obtained in an ethical manner; none of the other countries provide such detail in their policy. In the appendix for Cambodia's policy, there is a "checklist for PMTCT supervision," which details how a supervisor may monitor a counseling session and includes a number of items that would ensure informed consent. Although Cambodia has a monitoring strategy for ensuring consent, none of the policies provide detail as to how a health care facility might be penalized for failing to ensure a patient's right to provide informed consent for an HIV test.

Finally, two policies, the Ukraine's and the United States, indicate that newborns should be tested if the mother's HIV status is unknown. These policies raise concern over the extent to which pregnant women can consent to learning their HIV status, particularly in cases where a woman has previously declined an HIV test. Neither policy addresses this concern or provides guidance on how to balance the rights of the mother with the need for testing the infants.

### *Counseling*

- All 19 policies require "counseling" prior to HIV testing; some policies suggest this can be done in a group, others require individual pre-test counseling
- The United States departs from all other countries by adopting the term "pre-test information" instead of "pre-test counseling"
- A majority of the pregnancy-specific policies indicate that counselors should inform women during pre-test counseling both about how to prevent mother-to-child transmission of HIV and about available resources within the health care sector
- All 19 policies require individual post-test counseling sessions
- Most policies call for counselors to be "trained" or "certified"; however, few documents identify the training requirements for these individuals

### Pre-test counseling

All the policies indicate that clients should be given some information prior to testing, but they differ over what that information should be. A majority of the pregnancy-specific policies indicate that counselors should advise women about how to prevent mother-to-child transmission; these policies also indicate that counselors should advise women about available prevention resources within the health sector (including prophylaxis for them and their infants). China, Haiti and Sudan do not provide specific details about what is to be provided during the pre-test counseling session. Most policies also indicate that clients should be advised of the benefits of testing, the nature of HIV/AIDS and how to prevent sexual transmission. Other information that is included in some policies includes the importance of re-testing; descriptions of available services, including ART and family planning; and the importance of partner notification. As stated earlier, only Cambodia and India's policies address the risks of testing, and only India's policy states that clients should be told they can receive services even if they refuse testing. The United States departs from all other countries by adopting the term "pre-test information" instead of "pre-test counseling." This new terminology appears to be a reflection of the CDC's recent push to streamline consent and counseling requirements.

Policies vary on whether pre-test counseling should be conducted in groups or individually. Russia, Tanzania, Uzbekistan and Ukraine's policies all indicate that pre-test counseling should be offered individually and make no mention of group counseling. By contrast, India and Papua New Guinea's policies do not mention individual pre-test counseling, and Zambia only provides for individual pre-test counseling for women who have additional

questions or need clarifications. Other policies tend to fall in between these two poles. Cambodia and Guyana, for example, allow for group pre-test information sessions, but require some individual pre-test counseling, though Guyana's policy states that individual counseling may be abbreviated but "only if it is causing a barrier to testing itself." South Africa requires both individual and group pre-test counseling.

#### Post-testing counseling

All of the countries' policies regarding post-test counseling require individual sessions. In the cases of negative serostatus test results, the post-test counseling is usually brief with a focus on the importance of re-testing later in the pregnancy and explanation of the "window period" concept. When test results indicate positive serostatus, the primary focus as outlined in the policies is on the administration of prophylaxis during labor and post-partum to prevent HIV transmission to the infant. Post-test counseling may also include information on infant formula to replace breastfeeding (when appropriate), testing of the infant, and disclosure to spouses, partners and relatives. In Ukraine, where the HIV epidemic is fueled by injection drug use, the policy outlines the importance of referring the HIV-positive mother to drug abuse counseling services. Some of the policies make mention of the psychological, social and medical referral services available. Post-test counseling in South Africa includes information on stigma related to one's HIV positive serostatus. Family planning is a topic mentioned in several of the policies' recommendations for post-test counseling. Ukraine's policy mentions that reproductive choice, including possible abortion, should be discussed during the post-test counseling session. The

Ukrainian policy does not include specific information on what a counselor would provide in this setting and more operational research may provide insight into the types of discussions usually had between providers and clients on the topics of reproductive choice and family planning.

### *Counselor Qualifications*

Many of the policies discuss educational and training qualifications for counselors, but they differ widely on what is required. India's policy, for example, states that "[t]he counsellor should be a graduate in Psychology/ SocialWork/ Sociology/ Anthropology/ Human Development or hold a diploma in Nursing with a minimum of 3–5 years of experience in the field of HIV/AIDS," whereas Guyana's only educational requirement is that the counselor should have at least completed primary school. Several policies require counselors to be certified through national curricula (e.g. Guyana, Papua New Guinea), but for most policies, specifics of the training are not provided. Jamaica, Kenya and Swaziland do not provide specifics on who should provide the counseling. Other countries' policies refer to trained health care providers, including doctors, nurses, midwives, and psychologists. In some countries, for example Papua New Guinea, Zambia and Zimbabwe, trained community counselors may also assist in counseling pregnant women.

### *Confidentiality*

- 19 of the policies address the issue of confidentiality; China’s policy is the exception.
- In the following 8 countries – Guyana, Haiti, Moldova, Russia, South Africa, Ukraine, Zambia and Zimbabwe – the policies state that information about a person’s HIV status may be shared among health care worker. India’s policy includes conflicting information, both stating that a woman should consent to her status being shared and that a health worker has a right to know a woman’s status.
- In the following 5 countries – Guyana, Kenya, Moldova, Tanzania, and Zimbabwe – a woman’s HIV status can be shared with a sexual partner without the woman’s consent. In Jamaica, a contact investigator may trace and refer a woman’s sexual partner for HIV testing, though the guidelines state the woman’s confidentiality is to be protected.
- Cambodia’s policy is the only one that includes information on a woman’s right to address a breach of confidentiality

All of the policies address confidentiality except for China’s. As with consent and counseling, however, there is wide variation. Testing policies that are not pregnancy-specific tended to provide more detailed information regarding confidentiality. This is not surprising given that the specific policies for testing pregnant women are often considered in the context of the more general guidelines, and more detailed information on the steps to protecting confidentiality are outlined in the general guidelines. Often times the information included on confidentiality of testing results remains broad. For example, Sudan’s guidelines state that there is to be legal and ethical confidentiality around HIV testing. The United State’s recommendations state that counselors are to provide test results in a confidential manner.

Although all policies require confidentiality, a number of policies also allow for information to be shared among health care workers—“shared confidentiality”—or with partners. Guyana, Haiti, India, Moldova, Russia, South Africa, Ukraine, Zambia and Zimbabwe’s policies provide for “shared confidentiality.” India’s policy does state that

counselors should obtain consent before sharing a patient's status with another healthcare worker, but it also notes that healthcare workers have a right to know the HIV status of their patients. In Guyana, Kenya, Moldova, Tanzania and Zimbabwe, confidentiality can be broken in cases where an HIV positive person refuses to disclose his or her status to a sexual partner. Although Jamaica's general HIV/AIDS policy calls for the promotion of voluntary disclosure, the PMTCT guidelines are less clear. The PMTCT guidelines instruct a health worker to refer an HIV positive woman to a "contact investigator," who may trace sexual partners and refer them for testing. The health worker is also instructed to send all HIV positive test results to a Medical Officer, who is mandated to send them to the contact investigator. Thus, if the woman does not follow through on the referral of her own volition, the health system has its own system for disclosing her results and notifying her partners. Though the guidelines state that her confidentiality is to be preserved by the contact investigator, there is no further discussion as to how this should be done. In each of these cases the provider is permitted within the law to disclose to the partner without the source partner's consent. The testing policy in Cambodia includes information on a woman's right to address a breach of confidentiality. As the consent form indicates, test results are kept confidential, and women have the "right to file a complaint against anyone who discloses my HIV status without (their) permission."

**TABLE 6. HIV Testing approach and the three C's**

<b>Country</b>	<b>Approach to Testing Pregnant Women for HIV as Described in Document</b>	<b>Testing of Newborns When Mother's Status is Unknown</b>	<b>Confidentiality</b>	<b>Consent</b>	<b>Counseling</b>	<b>Pre-test Counseling</b>	<b>Post-test Counseling</b>
Cambodia	PITC for all women receiving antenatal care	No	Required; no exceptions discussed	Required; written	Required; health care personnel must have been trained in counseling	Individual session required; group session optional	Required
China	Routine testing with informed consent	No	Not mentioned	Required; details not specified	Required; no detail about who provides it	Required; no details mentioned	Required
Guyana	Routine testing with verbal consent	No	Required; exception within healthcare setting where 'shared confidentiality' may occur; additional exception where partner notification may occur	Required; verbal	Required; health care personnel must have been trained in counseling	Individual session required; group session optional	Required

Haiti	Recommended to all pregnant women	No	Required; exception within healthcare setting where 'shared confidentiality' may occur	Not explicitly mentioned; test should be voluntary	Required; health care personnel must have been trained in counseling	Required; setting not specified	Required
India	PITC with consent	No	Required; exception within healthcare setting where 'shared confidentiality' may occur	Required; verbal	Required; health care personnel must have been trained in counseling	Required; group session	Required

<b>Country</b>	<b>Approach to Testing Pregnant Women for HIV as Described in Document</b>	<b>Testing of Newborns When Mother's Status is Unknown</b>	<b>Confidentiality</b>	<b>Consent</b>	<b>Counseling</b>	<b>Pre-test Counseling</b>	<b>Post-test Counseling</b>
Jamaica	Routinely offered to all pregnant women	No	Required; contact tracing possible, protection of 'source' to be kept confidential	Required; verbal	Required; health care personnel must have been trained in counseling	Required; individual or group session	Required
Kenya	Routine testing	No	Required; exception whereby health care staff can disclose HIV+ status to woman's partner if she refuses to do so	Required; verbal	Required; no detail about who provides it	Required, setting not specified	Required
Moldova	"Systematic screening" or "mass screening" of pregnant women; written consent and voluntary	No	Required; exception whereby health care staff can disclose HIV+ status to woman's partner under specific circumstances	Required	Required	Required; setting not specified	Required

Papua New Guinea	Apparently PITC	No	Required; no exceptions discussed	Required; verbal	Required health care personnel must have been trained in counseling	Required; group session	Required
Russia	Recommended to all pregnant women; done twice during pregnancy with consent or rapid test at delivery with consent	No	Required	Required	Required; trained specialists and health care providers	Required; individual session	Required
South Africa	Routinely offered to all pregnant women	No	Required; exception within healthcare setting where 'shared confidentiality' may occur	Required; written and verbal	Required; no detail about who provides it	Required; individual and group session	Required

**TABLE 6. HIV Testing approach and the three C's (continued)**

<b>Country</b>	<b>Approach to Testing Pregnant Women for HIV as Described in Document</b>	<b>Testing of Newborns When Mother's Status is Unknown</b>	<b>Confidentiality</b>	<b>Consent</b>	<b>Counseling</b>	<b>Pre-test Counseling</b>	<b>Post-test Counseling</b>
Sudan	Opt-out recommended in ANC settings	No	Required; no specific details given	Required; details not specified	Required; must be done by a health care practitioner	Required; setting not specified	Required
Swaziland	Routinely offered to all pregnant women	No	Required; exception within healthcare setting where 'shared confidentiality' may occur	Required; verbal	Required; no detail about who provides it	Required; setting not specified	Required
Tanzania	Provider Initiated Counseling and Testing recommended to all pregnant women	No	Required; exception whereby health care staff can disclose HIV+ status to woman's partner if she refuses to do so	Required; details not specified	Required; must be done by a health care practitioner	Required; setting not specified	Required
Ukraine	Twice during pregnancy with consent or rapid at delivery with consent	Yes	Required	Required	Required; doctors, nurses, midwives, trained	Required; individual session	Required

					specialists		
US	Opt-out for pregnant women	Yes	Required; no exceptions discussed	Required; verbal	Required; no detail about who provides it	Required; called pre-test information	Required
Uzbekistan	Voluntary Testing	Yes	Required	Not explicitly mentioned; test should be voluntary	Required; must be done by a health care practitioner	Not specified	Required

**TABLE 6. HIV Testing approach and the three C's (continued)**

<b>Country</b>	<b>Approach to Testing Pregnant Women for HIV as Described in Document</b>	<b>Testing of Newborns When Mother's Status is Unknown</b>	<b>Confidentiality</b>	<b>Consent</b>	<b>Counseling</b>	<b>Pre-test Counseling</b>	<b>Post-test Counseling</b>
Zambia	Opt-out recommended in ANC settings	No	Required; exception within healthcare setting where 'shared confidentiality' may occur; additional exception where partner identification may occur	Required; verbal	Required; normally done by a health care practitioner	Group session required; individual session only if necessary	Required
Zimbabwe	Routinely offered to all pregnant women	No	Required; exception within healthcare setting where 'shared confidentiality' may occur; additional exception where partner notification may	Required; details not specified	Required; health care personnel must have been trained in counseling	Individual session required; group session optional	Required

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## *Review of trends in the attention to protecting, respecting and fulfilling rights across countries*

### *Human Rights*

In our policy review, we highlight policy and program components that uphold and protect human rights and specifically, components that uphold women's rights related to health and the act of HIV testing. We consider any direct use of the terms "human rights" or "rights to" in each policy's text. Although the presence of "rights-based" language in policies does not automatically equate to actual protection of rights in practice; it is unlikely that rights are going to be protect without a commitment to rights at the policy level. We present our findings regarding terminology in two categories: general testing policies and policies specific to testing of pregnant women. We found that the inclusion of terms "human rights" and "women's rights" within documents depended on the type of document reviewed. General HIV testing policies tended to be more inclusive of human rights terminology and also discussed these issues to a greater extent than was found in the policies specific to pregnant women.

In order to fully assess whether a woman's rights to health are upheld, we consider the level to which our policies address the following: a woman's right to be free from violence, the need for an enabling and supportive environment for women, the issue of access to medication and the need for monitoring and evaluation. The findings regarding violence, access to treatment and care and implementation will be discussed in a summative fashion as these topics did not differ by document type.

## *“Human Rights” Terminology in General Testing Policies*

- The term “human rights” is used in Guyana, India, Papua New Guinea, Tanzania, Uzbekistan and Zimbabwe’s policies
- No explicit use of the term “human rights” was found in Kenya, Moldova or the United States’ policies
- Tanzania and Zimbabwe’s policies state that every individual has a “right” to know her status
- Guyana, India, Papua New Guinea, Tanzania, Uzbekistan and Zimbabwe’s policies describe an individual’s “rights” as they relate specifically to the act of HIV testing
- India, Papua New Guinea and Zimbabwe’s policies explicitly state that an individual has the “right” to refuse the offer of an HIV test
- Only Papua New Guinea and Zimbabwe discuss “human rights” that are specific to the sub-population of pregnant women among general testing policies; all other policies speak of “human rights” for the general population

In the general testing policies, the term “human rights” is mentioned by Guyana, India, Papua New Guinea, Tanzania, Uzbekistan and Zimbabwe. “Human rights” are not explicitly mentioned by Kenya, Moldova or the United States in their policies. The degree to which the term “human rights” is contextualized within policies varies widely and tends to focus on the right of an individual to know his/her status and a patient’s rights within the act of HIV testing itself, including the right to refuse testing. Tanzania and Zimbabwe’s policies state that every individual has the “right” to know his or her status. India, Guyana, Papua New Guinea, Tanzania, Uzbekistan and Zimbabwe all describe some “rights” as they relate to the act of testing. Only India, Papua New Guinea and Zimbabwe are explicit in stating that an individual has the right to refuse the offer of an HIV test.

The level of detail in each policy regarding an individual’s “human rights” during the act of testing varies considerably. For example, Uzbekistan’s policy calls for services to be “carried out on a voluntary basis with doctor’s confidentiality, anonymity, human relations, and

upholding human rights”. However, there is no further clarification or elaboration on the statement “upholding human rights.”

In other cases, the inclusion of the term “human rights” is generally followed by a lengthier discussion about the act of HIV testing itself. Both Tanzania and Zimbabwe’s policies’ state the following: 1) that every individual has the right to know his or her status, and 2) that services are to be provided in an environment where rights are observed and respected. Both policies detail the human rights principles that should provide a foundation for the service provision and state that both providers and patients should be aware of these principles, which, include the following: the right to informed consent, the right to make choices about one’s health and well-being, the right to education, to privacy, to non-discrimination, equal protection and equality before the law, the right to marry and found a family, and the right to the highest attainable standard of physical and mental health. Similarly, Guyana states that at the heart of the country’s HIV testing programs is a commitment to respect, protect and fulfill human rights norms and standards. The policy then identifies a number of ways the country can ensure an enabling environment so that it might uphold these rights, such as through the provision of an adequate healthcare infrastructure and ensuring a supportive legal and policy framework.

It is also important to note that the majority of general HIV testing policies discuss human rights in the broader context of HIV testing for all citizens and are not specific to pregnant women in their discussion. Only Papua New Guinea and Zimbabwe’s policy mentions pregnant women specifically, by stating that a pregnant woman has a “right to decline testing”. The other countries do not specifically mention pregnant women as a sub-population within their discussion on “human rights.”

## *“Human Rights” Terminology in Pregnancy-Specific Policies*

- The term “human rights” is only mentioned by South Africa, Cambodia and Swaziland
- No explicit use of the term “human rights” was found in China, Haiti, Jamaica, Russia, Sudan, Ukraine or Zambia’s policies
- South Africa’s policies states that all interventions to prevent HIV should be framed within a human rights paradigm
- Cambodia states that a woman has the “right” to file a complaint if her confidentiality is breached. This is the only policy that focuses on how protection of rights can be enforced
- Only Swaziland’s policies explicitly states that an individual has the “right” to refuse the offer of an HIV test

In the policies specific to testing pregnant women, “human rights” is only mentioned generally by South Africa and specifically related to the act of HIV-testing by Cambodia and Swaziland. “Human rights” are not explicitly mentioned in the policies of China, Haiti, Jamaica, Russia, Sudan, Ukraine or Zambia. According to the South African guidelines, all interventions for both the woman and child are supposed to be framed within a human rights paradigm. The guideline asserts that this approach will lead to the optimization of the woman and infant’s health. The guidelines also state that it is the duty of health care workers to identify HIV+ women, and her exposed and infected children and partner(s) so that they can access HIV prevention care, and that this practice, within a human rights framework, will optimize the health and survival of all. Finally, there is also discussion within the document on the rights of the child to be protected from infection.

Both Cambodia and Swaziland’s guidelines discuss rights that are specific to testing. Cambodia’s guidelines state that a woman has the right to file a complaint if her confidentiality is breached. This is the only policy to focus on how the protection of rights can be enforced.

Swaziland’s guidelines state that a health worker has to respect a woman’s right to decline the HIV test.

*“Women’s Rights” Terminology in General Testing Policies*

- The term “women’s rights” is only mentioned by Papua New Guinea
- No explicit use of the term “women’s rights” was found in Guyana, India, Kenya, Moldova, Tanzania, United States or Uzbekistan
- HIV+ women in Papua New Guinea who transmit HIV to their infants are not criminally liable.

In the general policies, “women’s rights” are mentioned by Papua New Guinea and women’s vulnerability is recognized in Zimbabwe. “Women’s rights” are not explicitly mentioned in the policies of the following countries: Guyana, India, Kenya, Moldova, Tanzania, United States or Uzbekistan. The HAMP Act in Papua New Guinea includes more detailed information on the protection of rights than other policies; notable to women’s rights is that the Act exempts women who transmit HIV to their infants from criminal liability. Zimbabwe’s guidelines acknowledge that as a patriarchal society, the role of males in the decision-making process in Zimbabwe is so important for married women that it is the government’s duty to inform and educate men so that they can understand and support programs like PMTCT.

*“Women’s Rights” terminology in pregnancy-specific policies*

- The term “women’s rights” is only mentioned by South Africa’s policy
- No explicit use of the term “women’s rights” was found in China, Cambodia, Haiti, Jamaica, Russia, Sudan, Swaziland, Ukraine or Zambia’s policies
- South Africa stresses the importance of rights to information and an enabling environment within its policy
- Ukraine and South Africa’s policies also support a woman’s reproductive right to choose her pregnancy, regardless of her HIV status

In the pregnancy-specific policies, “women’s rights” are only directly mentioned by South Africa. The South Africa policy states that one of the documents founding principles is based on the “rights of women, pregnant women and mothers to information, treatment, management and care.” The document continues, “Pregnant women and mothers have a right to HIV-related information, and to access treatment, management and care that will optimize their health and survival and prevent MTCT.” It is important to note that South Africa’s policy outlines the environment needed to enable a woman to exercise autonomy regarding her health. Although other policies discussed access to information and the creation of enabling environment, this is the only one that explicitly framed access to information as a “woman’s right”.

This specific terminology (i.e. “women’s rights”) is not used in the policies of the following countries: Cambodia, China, Haiti, Jamaica, Russia, Sudan, Swaziland, Ukraine or Zambia. A number of issues critical to understanding the government’s regard for rights specific to women, however, are evident in a number of the policies reviewed. For example, South Africa and Ukraine’s pregnancy-specific policies proffer support for a woman’s “reproductive choice” if she tests positive or wants to plan future pregnancies after learning of her HIV status.

### *Violence Against Women*

- Only India and Cambodia’s policies state that a counselor should address potential risk of testing prior to the act of testing; however, neither policy identifies violence as a potential risk
- Only Guyana, Kenya and Papua New Guinea consider violence as a risk of disclosure
  - Guyana and Kenya’s policies reminds counselors that the testing population needs to consider risk of violence and social instability when choosing the where and how to disclose
  - Papua New Guinea’s policy recognizes that disclosure may not be appropriate for women in violence relationships and encourages counselors to help such women identify alternative support within their social networks
- South Africa states that one of its primary strategy in HIV prevention is to reduce gender-based violence; however, there is no other discussion of violence against women throughout the rest of the policy

The policies reviewed generally provide very little information regarding the protection of rights and welfare associated with violence and other negative outcomes of HIV testing. As highlighted previously, only India and Cambodia’s policy state that a counselor should address the potential risks of testing prior to the act itself, and neither policy explicitly states that violence may be a risk.

The only three policies that consider violence a risk of disclosure are Guyana’s, Kenya’s and Papua New Guinea’s. Guyana and Kenya’s policies involves the general population and state that "settings and methods of disclosure should take into account the risks of violence and social instability." Papua New Guinea’s policy stresses that disclosure may not be appropriate for women who experience partner-based violence. The policy encourages the counselor to help the HIV-positive woman explore her support networks to find an alternative person to disclose to if disclosure to her partner is not feasible.

The only other policy to make any mention of violence against women is South Africa's policy. One of South Africa's major goals as stated in its policy is to prevent HIV among women of child-bearing age; one of the strategies identified to reach this goal is to fight against gender-based violence. However, this is the only time violence is directly mentioned in the policy.

Given what is known about women's increased risk for violence and fear of violence from disclosure of HIV status, it is problematic that policies on HIV testing do not more thoroughly address this issue and other potentially adverse outcomes of HIV testing for pregnant women

#### *Access to Treatment and Follow-up Services*

- 16 countries made reference to referral for treatment and care for women who test positive for HIV
- China, Kenya and Uzbekistan did not discuss referral for treatment and care
- Treatment is free in a number of countries, though it is not always clear within each policy document as to who should bear the cost of treatment.

Policies consistent with a rights-based approach to HIV policies should include a provision that discusses an HIV-positive woman's ability to access ART's and follow-up care in order for a government to fulfill its obligation to respect a woman's right to health ((2006)(Report of the Special Rapporteur, Paul Hunt, 2003)). Often, the countries make reference to their adherence to international or WHO standards in PMTCT programs. Many of these descriptions include algorithms for the timing of testing and the process for administering medication. Most countries state that referrals should be made to treatment and care for those testing positive; China, Kenya and Uzbekistan are exceptions.

The treatment and care available varies widely by country. The US guidelines, which do contain a pregnancy-specific section, indicates that access to clinical care, prevention counseling and support services is essential, but does not specify who should bear these costs. Some countries outline that the mother and child are entitled to receive ART after delivery, and this therapy is free in a number of countries. In addition to PMTCT and ART therapy, HIV-positive mothers in Moldova and South Africa are provided with infant formula. In India's policy it is not clear whether treatment is free for everyone, but the guidelines do tout the fact that "more than 75,000 people who are HIV-positive access the antiretroviral therapy (ART) programme and receive free treatment for HIV/AIDS." Attempts to make ART affordable and available marks a commitment on behalf of individual governments to comprehensively addressing the needs of the HIV-infected women, and the overwhelming inclusion of treatment for women in these policies is laudable.

### *Implementation*

- Cambodia and Papua New Guinea are the only policies that have any discussion of ways their policy will be enforced.
- A number of policies state that a woman who declines the first offer of testing will be repeatedly offered the test throughout the duration of antenatal care, at the time of delivery and immediately following delivery.
- In general, policies do not provide instructions for assessing why a woman is declining an offer of testing
- Monitoring and evaluation (M & E) plans as stipulated in policies are generally restricted to gathering data on uptake of testing rather than broader indicators on the counseling process as a whole

In order to fully assess how an HIV testing policy protects and fulfills human rights, it is important to examine the implementation of the policy. We are obviously limited in our capacity to fully assess implementation without witnessing first-hand how these policies are used on the

ground. Nonetheless, we can examine the cursory plans for implementation as they are laid out in many of the countries' policies. A more thorough and much-needed approach would involve further research that examines the implementation of the policy on the ground level for each of the 19 countries reviewed. To ascertain the degree to which a country's policy considered implementation within the policy itself, we reviewed whether or not the following were mentioned: a) enforcement mechanisms to ensure policies is being implemented according to protocol, b) repercussions of refusing to test for HIV, c) monitoring and evaluation, d) who is responsible for implementing the document and e) if the policy discusses logistics relating to training of professionals, procurement and/or distribution of supplies as well as laboratory needs. Each of these provisions will enable local actors to maintain the program as it is outlined in the national document.

The extent to which implementation is addressed in the policies on HIV testing of pregnant women varied greatly. Neither China, Haiti, nor Uzbekistan's document provide any information on implementation of HIV testing and counseling. Other policies, discussed one or two aspects of implementation, but the attention to detail varied greatly. For example, in Sudan, the guidelines state that the purpose of the document is to provide health care providers with standards for delivery of the program, but no other aspects of implementation are discussed. Finally, a number of other policies, such as India and South Africa, include extensive discussion of all the topics identified above.

Of the nineteen policies reviewed, only Cambodia and Papua New Guinea's policies discussed any enforcement mechanisms to guarantee the implementation according to protocol and thus, the protection of HIV-related human rights. Papua New Guinea's policy includes an accreditation system that testing sites must undergo in order to operate, and the accreditation

criteria include a number of human rights protections, such as a locked cabinet to keep confidential records and an ability to provide ongoing counseling and support. This process appears to act as both a monitoring and enforcement mechanism as members of the National VCT Committee conduct annual site visits to make sure sites adhere to the policy. Cambodia, as mentioned earlier, has a mechanism whereby women can file a complaint if they feel their confidentiality is violated. While it is possible that the remaining seventeen countries have enforcement mechanisms in place, they are not articulated in the policy documents themselves.

As discussed in the previous table, no documents identify penalties or consequences for a pregnant woman who refuses or declines HIV testing. Furthermore, there is virtually no discussion of monitoring a women's right to informed consent (Cambodia being the exception), and no penalties for denying consent are stipulated in any of the policies reviewed. Only India states that a woman has the right to refuse testing with the assurance that her refusal will not affect future receipt of services. It is interesting to note that a number of policies do state that a woman who declines the first offer of testing will be repeatedly offered the test throughout the duration of antenatal care, at the time of delivery (within the first stage of labor) and immediately following delivery. While the intention of this repetition may be to increase access to testing, one might question whether the repetition itself calls into question the woman's right to consent to not test for HIV over time. Additionally, it is worth noting that while testing should be offered repeatedly there are no specific instructions for assessing why a woman is declining the offer. Understanding the reasons women decline tests is crucial to recognizing potential risks and adverse outcomes for pregnant women under the changing approaches to testing.

Monitoring and evaluating program implementation is key to ensuring that a policy is implemented according to protocol. Details about a country's proposed M&E strategy was

present in ten of the policies reviewed; most policies described the need for and use of a common set of indicators to collect data on program implementation and the eventual generation of reports based on these numbers. One of the more stringent monitoring techniques discussed was that of Papua New Guinea's accreditation process, which mandates that a site be accredited prior to providing HIV testing and counseling. In Ukraine, health care providers complete lengthy forms and keep records on the different aspects of the counseling and testing process. Individuals who receive counseling and testing are also asked to complete feedback forms on their experiences. In Russia, women must sign an informed consent outlining their understanding of their course of treatment and their responsibilities as patients receiving PMTCT. It is interesting to note that these forms are included in the testing policy, but no such documents are included regarding consent to testing. Some of the countries keep detailed records and statistics on the uptake of testing. For example in Guyana, these statistics include individual indicators such as ethnicity, gender and age. The monitoring and evaluation information often focused on the collection of statistics on the uptake of testing, rather than the counseling process.

In general, there is recognition that the success of HIV testing is dependent upon necessary resources. For the most part, policies focus on the personnel needed for testing and counseling and refer to "trained specialists" or "certified counselors". Health care personnel, such as doctors, nurses, midwives, obstetricians, and psychologists are included as necessary resources; however, very few documents identify the training needs of these individuals. In addition to human resources, other information on necessary resources for implementation of PMTCT includes lab equipment, space, test kits, and PMTCT drugs.

In order for a government to fulfill a woman's rights to health, it is important that a policy document identifies whose duty it is to implement which or all aspects of the policy. Most

of our documents were developed and issued by the Ministry of Health, who often takes on some responsibility in implementation. For example, in South Africa, the National Department of Health is responsible for the development of policy guidelines, the provision of resources (both technical and financial), and also the monitoring and evaluation of PMTCT programs, but the Social Development Department oversees social safety network aspects of the program and the provincial departments are responsible for program implementation. Tanzania also divides the responsibility between national and locally governing bodies. The Government of Tanzania is similarly charged with providing managerial and financial leadership at the national and local levels in response to the HIV epidemic and will fund HIV activities annually. The National AIDS Control Programme (NACP), operating within the Ministry of Health and Social Welfare will coordinate PITC services, set standards, and provide training guidelines and protocols for PITC. Regional and district level teams will be responsible for coordination of PITC implementation through existing health structures, training providers, and providing supervision and quality assurance.

On the contrary, in the United States, the authors of the policy (CDC) play no role in implementation of the policy. Furthermore, the CDC acknowledges that the existence of state and local level legislation related to HIV and AIDS may conflict with the current recommendations. In these situations, the CDC recommends that jurisdictions will have to consider how to implement these guidelines within existing local parameters.

**Table 7A. Rights and Implementation within Pregnancy-specific Policies**

Country	Human Rights	Women's Rights	Violence Addressed	Access to treatment	Implementation of Document
Cambodia	Consent form in Appendix A states that signer has “a right to file a complaint against anyone who discloses my HIV status without my permission” and “the right to deny any points in this consent form.”	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Discussion of who is to implement policy is identified; monitoring and evaluation needs identified; procurement and distribution of supplies discussed.
China	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	No specifics on how to implement counseling and testing of pregnant women
Haiti	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	No specifics on how to implement counseling and testing of pregnant women
Jamaica	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and	<i>Information exists; currently unable to access this document</i>

				treatment	
Russia	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Discussion of who is to implement policy is identified

**Table 7A. Rights and Implementation within Pregnancy-specific Policies (continued)**

Country	Human Rights	Women's Rights	Violence Addressed	Access to treatment	Implementation of Document
South Africa	<p>1) "All interventions for pregnant women and their infants should be framed within a human rights paradigm and should take a life-course approach; interventions that optimize physical, mental and psychosocial health and development through pregnancy, infancy, childhood, adolescence and adulthood are needed. The family unit should be prioritized at all times."</p> <p>2) "It is the duty and responsibility of ALL health care workers to identify HIV positive women and their partners, HIV exposed infants and HIV positive infants so that they can access HIV care. Practiced within a human rights framework, this critical intervention should prolong life and optimize maternal and child survival."</p> <p>3) The child has "the right to be protected from acquiring a preventable infection"; also "all children have the right to be fed in the safest possible way that optimizes child health and reduces mother-to-child transmission of HIV",</p>	<p>"Rights of women, pregnant women and mothers to information, treatment, management and care: women of childbearing age have the right to receive info that helps to prevent HIV infection. Pregnant women and mothers have a right to HIV-related information, and to access treatment, management and care that will optimize their health and survival and prevent MTCT."</p> <p>Supportive of women's "reproductive choice" regarding pregnancy regardless of HIV status</p>	<p>One of the major goals of the policy is to prevent HIV among women of child-bearing age, and a sub-goal of this is to 'support the implementation of women empowerment programs and fight against gender-based violence.'</p> <p>No further details discussed in policy.</p>	<p>HIV+ women are referred for care and treatment</p>	<p>Discussion of who is to implement policy is identified; monitoring and evaluation needs identified; procurement and distribution of supplies discussed.</p>
Swaziland	<p>The health worker is supposed to respect the right to decline testing and then repeat the offer at subsequent visits.</p>	<p>Not specifically mentioned</p>	<p>Not specifically mentioned</p>	<p>HIV+ women are referred for care</p>	<p>Monitoring and evaluation needs identified Procurement of supplies</p>

				and treatment	discussed
Sudan	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Monitoring and evaluation needs identified
Ukraine	Not specifically mentioned	Supportive of women's "reproductive choice" regarding pregnancy regardless of HIV status	Not specifically mentioned	HIV+ women are referred for care and treatment	Monitoring and evaluation needs identified
Zambia	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Monitoring and evaluation needs identified

**Table 7B. Rights and Implementation within General Policies**

Country	Human Rights	Women's Rights	Violence Addressed	Access to treatment	Implementation of Document
Guyana	<p>"By declaration of Guyana Ministry of Health, all CT services provided in Guyana...must be grounded in sound public health practice and respect, protection, and fulfillment of human rights norms and standards and that consent and confidentiality in testing must remain at the heart of all HIV policies and programmes, both to comply with human rights principles and to ensure sustained public health benefits."</p>	<p>The right to marry and family, regardless of HIV status.</p> <p>Sample referral sheet for supporting women who are victims of Gender Based Violence included in document</p>	<p>Counseling should include a discussion on potential violence related to disclosure. Also has a sample referral sheet for women who test HIV+ which includes referrals for women who experience gender-based violence</p>	<p>HIV+ women are referred for care and treatment</p>	<p>Discussion of who is to implement policy is identified; monitoring and evaluation needs identified; procurement and distribution of supplies discussed.</p>
India	<p>1) Right to refuse testing; 2) Right to confidentiality (but balanced against right of hospital staff to work in a safe</p>	<p>Not specifically mentioned</p>	<p>Not specifically</p>	<p>HIV+ women are</p>	<p>Discussion of who is to</p>

	environment); 3) Right to privacy "except in circumstances when disclosure to another person is required by law or ethical considerations"		mentioned	referred for care and treatment	implement policy is identified; monitoring and evaluation needs identified; procurement and distribution of supplies discussed.
Kenya	Not specifically mentioned	Not specifically mentioned	Counseling should include a discussion on potential violence related to disclosure	Not specifically mentioned	<i>Not totally legible in original document</i>
Moldova	The law includes punishment for medical staff who breach confidentiality	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	The surveillance plan outlines algorithms for testing.
Papua New Guinea	Policy states the following rights: 1) Right to be tested; 2) Right to opt out of testing. Constitutional as recognized by HAMP Act: 1) life, liberty, security of the person and protection of the law; 2) freedom from inhuman treatment;...3) employment and freedom of movement....; 4) prevention of the spread of HIV/AIDS....5) protection from discriminatory practices of people living with HIV/AIDS and of people who are affected by or believed to have HIV/AIDS; 6) protection of public health.	HAMP Act: exempts MTCT from criminal liability	Post-test counseling should include a discussion on potential violence related to disclosure	HIV+ women are referred for care and treatment	Discussion of who is to implement policy is identified; monitoring and evaluation needs identified; procurement and distribution of supplies discussed.

**Table 7B. Rights and Implementation within General Policies (continued)**

Country	Human Rights	Women's Rights	Violence Addressed	Access to treatment	Implementation of Document
Tanzania	3 Cs; states most relevant human rights that should be observed by PITC provider; right to know HIV status is "basic human right"	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Discussion of who is to implement policy is identified.
United States	Not specifically mentioned	Not specifically mentioned	Not specifically mentioned	HIV+ women are referred for care and treatment	Recommendations for implementation are provided but it is up to local jurisdictions to determine implementation; Discussion of who is to implement policy is identified.
Uzbekistan	Point 11: medical assistance and prevention activities are carried out on a voluntary basis with doctor's confidentiality, anonymity, human relations and following human rights	Not specifically mentioned		Not specifically mentioned	No specifics on how to implement counseling and testing of pregnant women
Zimbabwe	The guiding principle is that it is every Zimbabwean's right to know his or her HIV status. In Zimbabwe, HIV testing and counseling services are provided in an environment where human rights are respected. This reduces vulnerability to HIV infection and AIDS, for those infected or affected by	Gender inequalities mentioned; government aims to protect women against vulnerability by increasing male involvement in health	Not specifically mentioned	Nothing specific about treatment for women, though there are general	Discussion of who is to implement policy is identified; monitoring and evaluation needs

	<p>HIV and AIDS so that they live a life of dignity, without discrimination. The personal and societal impact of HIV infection is also alleviated.</p> <p>“A pregnant woman has a right to consent or refuse HIV testing should she choose to do so”</p>	<p>care.</p>		<p>goals for treatment coverage.</p>	<p>identified; procurement and distribution of supplies discussed.</p>
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## **Discussion**

The most important findings from our reviews of national policies and the HIV testing literature can be grouped into two categories: 1) Compliance with International Law and 2) Barriers to Policy Debate and Research Progress.

International human rights law recognizes the following protections related to HIV testing: the right to health, the right to privacy (including consent and confidentiality), the right to be free from violence, the need for monitoring and evaluation, need for an enabling and supportive environment for women, access to medication (Office of United Nations High Commissioner, 2006, para 119, Guidelines 8 and 11; Special Rapporteur, 2003, para 25). The UNDP has developed a matrix which allows for examination of government's obligations to protect the right to health according to international health rights law. With the guidance of the UNDP matrix, we analyzed each country's HIV testing policy to evaluate whether it is in compliance with international law and protective of individual human rights. UNDP has outlined the need for a human rights analysis of HIV policies and programs to ensure that they are consistent with international human rights law, to understand who is controlling resources, and to examine the impact these policies and program have on individual lives (UNDP). UNDP presents a matrix for examining governments' obligations to protect the right to health according to international human rights law, which includes the following three components: obligation to respect, obligation to protect, and obligation to fulfill. These three obligations should be considered in the development of HIV testing policies for pregnant women.

The obligation to respect “requires the State and all its organs and agents to abstain from carrying out, sponsoring or tolerating any practice, policy or legal measure violating the integrity of individuals or impinging on their freedom to access resources to satisfy their needs” (Office of

United Nations High Commissioner, 2006, p12). Issues to consider in HIV testing recommendations include the following: making sure that pregnant women have the opportunity to learn their HIV status, ensuring that women have the autonomy to decline HIV testing without penalty in the health care setting, protecting the confidentiality of testing results to third parties, and if a woman learns she is HIV-positive, then she should have the opportunity to prevent transmission to her children through access to adequate PMTCT services, follow-up ARV therapy for herself and her child, replacement infant formula and access to necessary psychological and social support services. Many of the countries in our review focus on the women's right to knowing her status. It is less clear from the policies, however, the extent to which women's right to refuse the test without consequences is upheld under the new testing policies. Some countries, like Ukraine, have provided an extensive outline of the follow-up services offered to women who test positive for HIV during pregnancy.

The obligation to protect "obliges the State and its agents to prevent the violation of rights by other individuals or non state actors" (Office of United Nations High Commissioner, 2006, p12). Implications for HIV testing policies include: limiting the ability of providers to test a woman against her will or without her knowledge, protecting a woman from breach of confidentiality to third parties, ensuring adequate measures are in place to address potential adverse consequences from testing and/or disclosing one's status, including stigma, discrimination and violence, and protection from health care providers coercively influencing a woman's reproductive choice. In our policy analysis, though confidentiality is mentioned in all of the policies, many of them include references to putting results in medical records or in some instances notifying partners. Furthermore, the overwhelming majority of the policies we reviewed pay little or no attention to protection from stigma, discrimination and violence. The

minimal attention paid to a woman's risk of violence related to receiving an HIV test and subsequent disclosure to her partner and family is particularly problematic given what we know about the role violence and fear of violence in HIV testing. Until more information on whether the scale-up of HIV testing in antenatal clinics is conclusive and evidence-based on the belief that HIV testing can become normative and thereby reduce and eliminate the stigma and discrimination associated with testing, policies must recognize the risks associated with testing and the potential for adverse outcomes to a woman being tested for or diagnosed with HIV.

The obligation to fulfill “involves issues of advocacy, public expenditure, governmental regulation of the economy, the provision of basic services and related infrastructure and redistributive measures” (Office of United Nations High Commissioner, 2006, p13). Implications for HIV testing policies of pregnant women include: provision and distribution of testing kits, ARTs, infant formula, counseling services, and referral for follow-up counseling services. Some countries in our review are able to outline a plan for providing the necessary resources; however, these vary greatly. For example, one country suggests adding a tax on items that specifically allocates revenue to HIV/AIDS; another discusses its reliance on outside donors for funding of PMTCT programs. Countries with larger epidemics and less financial resources, however, are more limited in their capacity. These issues must be adequately addressed prior to pushing for an uptake in HIV testing or routine testing of pregnant women.

### Compliance with International Law

In addition to considering broadly how HIV testing policies protect, fulfill and respect human rights, we assess whether country policies reflect international legal norms. Our review of national policies suggests that many countries may be falling short of international legal

standards. We found that although almost all the policies acknowledge the ethical and legal cornerstones of HIV testing—consent, counseling, and confidentiality—many fall short of meeting the full requirements imposed by international law. Below, we discuss two areas where we noted shortcomings and possible violations of international law: the right to informed consent and the right to confidentiality.

Informed Consent: *The right to privacy encompasses the obligation to seek informed consent to HIV testing...* (Office of United Nations High Commissioner, 2006, para 119)

Under international law, providers must seek informed consent before testing for HIV. Consistent with this requirement, all policies indicated that consent must be obtained prior to testing or that testing must be voluntary. As we have emphasized throughout this paper, however, there is substantial disagreement about what constitutes “informed consent,” and a close review of the policies suggests that none of them fully meets WHO/UNAIDS Guidelines’ requirements for informed consent. Specifically, those guidelines indicate that included among the *minimum* requirements for informed consent is:

- 1) Information on “[t]he potential risks [of testing], such as discrimination, abandonment, or *violence*”; and
- 2) Assurance that “declining an HIV test will not affect the patient’s access to services that do not depend upon knowledge of HIV status.”

Despite these Guidelines, only two countries in our review, India and Cambodia, require that women be informed of the potential risks of testing prior to obtaining consent. Neither of these countries, however, explicitly requires providers to inform women that those risks include

violence. Furthermore, only one country, India, requires that women be reassured that they will still have access to other health services if they refuse testing. These omissions are striking and may signal violations of international law.

*Confidentiality: The right to privacy encompasses the obligation[] to... privacy of information, including the need to respect confidentiality of all information relating to a person's HIV status. (Office of United Nations High Commissioner, Para. 119) . "Public health legislation should authorize, but not require, that health-care professionals decide...whether to inform their patients' sexual partners of the HIV status of their patient. Such a decision should only be made in accordance with the following criteria:*

1. *The HIV-positive person in question has been thoroughly counseled;*
2. *Counselling of the HIV-positive person has failed to achieve appropriate behavioral changes;*
3. *The HIV-positive person has refused to notify, or consent to the notification of his/her partner(s);*
4. *A real risk of HIV transmission to the partner(s) exists;*
5. *The HIV-positive person is given reasonable advance notice;*
6. *The identity of the HIV-positive person is concealed from the partner(s), if this possible in practice; and*
7. *Follow-up is provided to ensure support to those involved, as necessary.*

Five of the policies that we reviewed address partner notification, but only Guyana's policy requires that the above criteria be met before partners are notified. Jamaica's policy does not provide sufficient detail on the process of partner notification to know whether it requires that the criteria be met before partners are notified. Kenya, Tanzania, and Zimbabwe's policies, however, all indicate that the first four criteria must be met, but make no mention of giving the patient notice, concealing her identity, or providing her with follow-up support. The fact that these policies do address the notification process in some detail suggests that these omissions are reflective of these countries' policies and that the policies, therefore, violate international law.

*Monitoring and Enforcement: States should ensure monitoring and enforcement mechanisms to guarantee the protection of HIV-related human rights, including those of people living with HIV,*

*their families and communities. (Office of United Nations High Commissioner, 2006, Guideline 11)*

Ten of the nineteen policies included sections on Monitoring and Enforcement, but we found that the monitoring and enforcement of HIV-related human rights did not receive sufficient attention. Instead, most policies focused on collecting data on testing uptake. Without a deeper look at how policies are being implemented, it is impossible to conclude whether the lack of attention to the monitoring and enforcement of human rights protections constitutes a violation of the International Guidelines. As we have discussed, there was wide variation in how policies address monitoring and enforcement, nearly half of the policies did not address it at all. Therefore, omissions may be reflective of the scope of the document and not of the policy itself. These omissions do, however, highlight an area for concern and further research.

Follow-up Treatment and Services:

*The right to health is a broad concept that can be broken down into more specific entitlements such as the rights to... [t]he prevention, treatment and control of diseases, including access to essential medicine (Special Rapporteur, 2003; Para 25).*

*States... should promote a supportive and enabling environment for women, children and other vulnerable groups by addressing underlying prejudices and inequalities through community dialogue, specially designed social ad health services and support to community groups (Office of United Nations High Commissioner, 2006, Guidelines 8).*

As with the monitoring and enforcement provisions, it was hard to assess whether the policies we reviewed complied with the legal injunction to provide follow-up treatment and

services. Only three policies failed to address the issue, but this failure appeared to be reflective of the scope of the document, rather than the actual policy. In fact, even the policies that did state that patients should be referred for follow-up treatment and services were generally short on detail about how patients were to access the treatment and services. Therefore, to assess whether countries are complying with other international legal requirements, more in-depth research is still required.

### Barriers to the Policy Debate and Research Progress

The policy and research literature suffer from a failure to describe testing policies clearly. This lack of clarity results, in part, from imprecision in the terminology that is used to describe testing policies. For example, some writers use the word “voluntary” to describe only client-initiated policies, while others use it to refer to any policy that is not compulsory or mandatory. This imprecise use of terminology can make it very difficult to understand what a policy writer is advocating or a researcher is assessing. It, therefore, impedes communication among policy writers and between the policy and research literature.

Lack of detail in addressing factors related to consent may present an even greater barrier to communication. As we argued in the literature review, the debate over different testing policies is ultimately a debate over consent, and it may be impossible to capture the complexity of “consent” in a single term. To provide a more concrete example: even if everyone agreed on the meaning of “opt-in” and “opt-out,” labeling a policy as “opt-in” or “opt-out” reveals nothing about other factors relevant to consent, such as whether women are advised of the risks of testing or are told that they will still be allowed to receive medical services even if they refuse testing. While not everyone agrees that such information is *necessary* for informed consent, there can be

little doubt that such information is at least *relevant* to the issue of consent. Therefore, in addition to defining terms clearly, articles that assess testing policies should make an effort to describe in detail all the ways in which the policy addresses (or fails to address) the issue of consent. Otherwise, policy writers and researchers risk talking past one another, and the potential for progress in this debate will be significantly limited.

A second finding from our literature review is that there is a gap between what is being debated in the policy literature and what is actually being researched. Specifically, although there remains substantial debate within the policy literature over how attempts to streamline consent are impinging upon individual autonomy, the research on HIV testing among pregnant women is mainly focused on how to increase testing uptake. To close this gap, more research is needed on women's experiences—especially with respect to the issue of consent—under different types of testing policies.

### **Limitations**

There are limitations to both our literature and policy review that need to be acknowledged. With regard to our literature review, though our paper is meant to reflect HIV testing policies globally, we limited our literature review to English-language journals. As such, we may have overlooked important implementation, ethics, human rights and law articles published in non-English language journals.

There are a number of limitations with regard to the policy review. First, obtaining copies of the policies was more difficult than we initially anticipated, despite the fact that we had a systematic method for obtaining the policies. On average, we contacted 4 people (range was 1-9 people) before we obtained a policy for the review. Nine of the policies that we received were in English; the remaining ten were in their language of origin. We had the capacity within our

team to review six of these policies in their original language (Russia, Moldova, Ukraine, Uzbekistan, Haiti, Brazil), one we had translated for our review (China) and the remaining three we received too late to be able to translate and include in this review (Macedonia, Djibouti, Estonia). Despite our efforts to obtain policies from every country, we did not receive current policies from ten countries and thus were not able to include them in our review.

Second, there was variation in the type of documents that we received. Nine of the nineteen documents that we collected were policies or guidelines specific to pregnant women. The remaining ten documents were general HIV testing policies for the country that included some details on testing during pregnancy. Depending on the type of document and the region, the documents we collected varied in their detail and specificity. In some cases, such as South Africa, the document we received and included in our review was the national PMTCT guidelines which included more details about the implementation of PMTCT programs. Whereas from Russia, for example, we obtained the policy specific to testing and treatment during pregnancy and it did not contain the same amount of detail. In synthesizing the documents it was challenging to apply a standardized framework to documents of varying types and lengths.

Third, the scope of the legal authority underlying most of the policies is unclear. The policies we received did not specify whether service providers were legally bound to conform to the policy or what the legal implications for failing to conform would be. Some policies did indicate that particular provisions were legally binding: Papua New Guinea's policy document, for example, made clear that under the country's HIV and AIDS Management and Prevention (HAMP) Act, no one can be forced to take an HIV test, and Cambodia's policy indicates that confidentiality requirements are legally binding. But no document explicitly states that the

policy *as a whole* is legally binding. Nevertheless, all the policies we reviewed were issued by national governments—usually ministries of health—and many include enforcement provisions, such as national supervision and accreditation. Therefore, although we cannot know whether the policies are legally enforceable, it is clear that the policies carry some political weight.

In addition, the confusion of terms used to describe testing approaches was reflected in our policy review. In our synthesis of policies, we used the terms that were used in the policies themselves to describe the approaches in each country (i.e. routine testing) but often due to lack of operational details in the policy documents it was difficult to determine whether the terms being used to describe the testing approaches were being used consistently across all settings. Furthermore, it became clear that policies developed since the 2007 WHO PITC guidance document was released have adopted terms such as opt-out, however, policies that were developed before the release of this document may have used a similar testing approach but described the approach using a different term.

A final and important limitation of the policy review is the fact that it was impossible to determine from reviewing these documents how the policies are implemented and the extent to which they are upheld in practice. Many of the concerns raised about the changes in HIV testing policies have to do with what occurs in practice.

### **Implementation questions**

The review of the literature and of HIV testing policies for pregnant women raises a number of implementation questions that we feel need to be addressed to fully understand how the shift in HIV testing policies is impacting women. Below we highlight a few important

research questions that need to be answered with regard to the implementation of new testing approaches:

### *Consent*

- *From the perspective of providers:* What do providers feel are the minimum requirements for informed consent for pregnant women? How do providers obtain consent from pregnant women for testing? To what extent do providers methods of obtaining consent follow what is specified in the policies regarding consent? What do providers do when women decline HIV testing during pregnancy? What are the consequences of declining an HIV test? How do providers communicate these consequences to women? To what extent do providers who have been trained to administer consent under one approach to testing adapt when the policy changes to a different approach?
- *From the perspective of pregnant women:* What do women recall about the consent process for HIV testing during pregnancy? Do women feel they had a choice to test when they were consented for the HIV test during pregnancy? What are the perceived risks of declining a test under new testing approaches? Are there things that women wish counselors told them in helping them make a decision about HIV testing during pregnancy?

### *Counseling*

- *From the perspective of providers:* Do providers feel they have adequate time and training to implement counseling as specified in the policies? How do providers (or counselors) talk about the benefits and potential risks of HIV testing

to women during counseling sessions? What type of training is being provided to counselors? How is training for counselors updated when policies regarding HIV testing change? What are current practices with regard to referring women for ongoing psychosocial and medical support? And legal support? Are there opportunities to insure that women are making use of these referrals?

- *From the perspective of pregnant women:* Do women feel the counseling they received is adequate to address their issues surrounding risk reduction, disclosure, and other psychosocial issues? Did women feel there was time and did they feel comfortable under the current counseling procedures to talk with their counselors about the possibility of adverse events related to testing and disclosure? Do women feel like they had adequate information on what they could do if they needed additional support after the HIV counseling?

#### *Confidentiality*

- As greater numbers of women are tested during antenatal care, how does this influence women's ability to insure that her results are kept confidential? Do women feel they can keep this information confidential from partners/family/friends who know she will be offered the HIV test results?
- Are antenatal care standards different for HIV positive mothers? (i.e. place of delivery) How do these different procedures affect women's ability to maintain confidential her HIV status?
- What are current practices with regard to partner notification?

#### *Other implementation issues:*

- How do the experiences of women testing in settings with specific policies for testing of pregnant women compare to women who test in settings without specific policies for testing of pregnant women?
- What knowledge do staff and women have of the existing policies? How do they obtain information on the policies?
- What other operational guidelines exist to guide implementation of programs? To what extent are these implementation guidelines applied consistently across types of health care facilities within a given country? Across regions of a country?
- What type of monitoring and evaluation is being done to insure that counseling, consent and procedures for confidentiality are being conducted in the way that they are specified in policies?
- To what extent is the health system prepared to offer all services specified in HIV testing policies: Are there adequate counselors available on days when pregnant women come to the clinic for ANC, are test kits consistently available at ANC clinics? Is formula available as an option for HIV positive pregnant women? Is nevirapine available for mothers and infants?
- How can governments be held accountable for insuring that informed consent remains a requirement in practice for testing under all provider-initiated testing and counseling models?

## **Recommendations**

Based on this extensive review of national policies and the scientific literature we have identified the following policy, program and research recommendations.

### *Policy recommendation:*

#### *Policies should include:*

- greater clarity in definition of terms that they use to define testing approach
- more detail on how consent should be obtained
- more detail on how potential risks of testing should be addressed with women
- greater clarity on what happens to women who refuse to test
- more detail on what happens to women beyond HIV testing and PMTCT
- more detail on monitoring and evaluation beyond recording uptake of testing by pregnant women, including monitoring/evaluation of how counseling, consent and confidentiality procedures are being implemented according to guidelines, and monitoring adverse consequences of testing for women
- more detail on testing of newborns for mothers of unknown HIV serostatus. Policies should specify whether parental consent is required for testing of newborns.

*Program recommendations. We need more information on the following to inform the implementation of HIV testing programs for women:*

- What are providers' experiences administering consent under current policies?  
How do these experiences differ according to the different testing approaches?

- What are providers' experiences implementing counseling under current policies?  
How do these experiences differ according to different testing approaches?
- What are women's experiences consenting to test under different testing approaches? How do these experiences differ according to the different testing approaches?
- What are women's experiences with counseling under different approaches? How do these experiences differ according to the different testing approaches?
- How do changes in testing approaches affect women's ability and provider's ability to keep information about their serostatus confidential? What are current practices with regard to partner notification under different testing approaches?
- How do providers and clients obtain information on changes in HIV testing policies?
- To what extent is the health system prepared to accommodate changes in policies regarding HIV testing of pregnant women? (Are test kits available, are counselors available, is prophylaxis available, etc.)
- More record keeping of testing including who gets tested, who refuses, reasons for refusal, who is tested at labor/delivery, what happens to women who refuse testing,

*Research recommendations: We need more research to understand:*

- women's experiences testing under different models
- the impact of culture context of the experiences of women and providers under different testing models
- minimum requirements for fully informed consent

- other outcomes of HIV testing approaches beyond uptake
- new testing approaches effect on women's uptake of other HIV prevention and treatment/care services (major benefit of increased uptake of testing has always been that it is a gateway to getting people in treatment).

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