Report on the ICRW/John M. Lloyd Foundation Consultation On the Expansion of HIV Testing

The John M. Lloyd AIDS Project at Stony Point Center

May 18 – 20, 2007

Stony Point Conference Center, Stony Point, NY

By

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Overview

WHO/UNAIDS released the draft "Guidance on Provider-Initiated HIV Testing and Counseling in Health Facilities" in November 2006 for public comment. In drafting the Guidance, efforts were taken to integrate both human rights and public health priorities, but there continues to be contestation around key points. As there is a dearth of research data to support the Guidance, and it is generally agreed that there exists a need to generate evidence around the implementation of provider-initiated testing, namely how it is being implemented and what its impact is on health systems and clients alike. It was with this concern in mind that ICRW sought support from the John M. Lloyd Foundation to convene a meeting on this issue at their annual conference at Stony Point in New York. Further funding for the meeting was provided by the Elton John AIDS Foundation.

The goal of the 2007 John M. Lloyd AIDS Project Consultation on the Expansion of HIV Testing (hereafter, Consultation), convened at the Stony Point Conference Center in the state of New York (USA), was to devise a research agenda to determine whether all aspects of the Guidance on Provider Initiated Testing are being effectively implemented and build an advocacy strategy for the expansion of testing and counseling, which incorporates both human rights and public health principles and practices. It was a priority to ensure that a wide range of stakeholders was at the table, and to include policy makers from WHO and UNAIDS as well as human rights advocates, academics currently involved in research on this issue, activists from the community of people living with HIV, those implementing provider initiated testing programs, and donors with an interest in funding such work. We also sought to obtain a wide regional representation, with particular focus on sub-Saharan Africa where provider-initiated testing has made the most in-roads already. For a list of participants and invitees, see Appendix A.

The event preceded release of the final Guidance on May 30, 2007.

All of the twenty participants attended the full day and a half, residential meeting at the Stony Point Center. The workshop was professionally facilitated, and included a mixture

of formal plenary presentations, large and small-group discussions, and informal discussions over meals and social gatherings. Because the issues under discussion remain controversial, efforts were made to allow time and space for the full range of perspectives and opinions to be expressed and to identify common ground.

Having aired a range of concerns in the first plenary, including the fear that this would be just another meeting that would not produce anything of consequence or meaning for those living with HIV, there emerged consensus that increasing collaboration, and thus interconnectedness, of the diverse groups represented at the table would be advantageous for the following reasons:

- To produce better outcomes in terms of research design, inclusiveness, applicability, and accessibility;

- To more effectively share new information; and,

- To provide a solid foundation for seeking funding and supporting advocacy.

As a result, a decision was taken to form a working coalition.

The five primary results of the Consultation are:

1. Transformation of the participants into the **Advocacy in Research on HIV Counseling and Testing Coalition (ARCAT)** with ICRW serving as an operations and communications hub and participants as the Steering Committee.

2. The initial design of a **framework for research projects** replicable across all projects, to include the interests of all stakeholders and to be adhered to by each research project design team.

3. An **initial research concept** developed during the Consultation and arising from discussions of the various policy, advocacy, and systems levels surrounding the implementation of PITC [see Appendix B]. A number of **additional research topics** were also identified [see Appendix C].

4. A **Press Statement** featuring key points of the Consultation to be released in conjunction with the final Guidance on May 30, 2007 [see Appendix D].

5. Agreement to proceed with the creation of a manuscript to submit to the Journal of the American Medical Association for publication.

These specific efforts reflected the participants desire to achieve short-term results while laying groundwork for the longer term.

Results and Conclusions

1. ARCAT

On the final day of the Consultation, participants discussed and agreed to carry forward the work of the Consultation, formalizing as an entity with participants constituting the Steering Committee and ICRW as the coordinating body.

The participants recognized that, depending upon the nature of each effort being undertaken by the group (e.g., future research or advocacy projects), involvement may vary from contributing on an individual basis, as representative of the participants' organization, or limited involvement, as will be the case for participants from WHO and UNAIDS.

Beyond the four other results, the on-going work of the Steering Committee includes development of mid and longer -term goals and a formal vision -- one that goes beyond the final Guidance while still including HIV testing and counseling as its core -- as the

basis of both the strategic and funding plans. Participants also addressed immediate logistical issues, such as a Steering Committee meeting timetable and options for short-term funding.

Additional topics of discussion included the following:

- What methods exist for building on other relationships, research, and other efforts to avoid duplication and 're-invention' ?

- Since there are many people involved in various ways in the testing debate (as researchers, activists, clients and providers), how can more be included, in what ways, and which are particularly significant?

- What is the most effective form of decision-making for this working effort?

The Steering Committee will continue to discuss these issues. Not all the participants at the Consultation will be part of the research coalition. Seema Paul (UNAIDS) and Donna Higgins (WHO) will be interested observers, but cannot participate to avoid conflict of interest.

2. Framework for Research Projects

During the second day of the Consultation, one of the "breakout" groups constructed a "framework" to be applied across research projects that will enable the Coalition to address research-related concerns of different stakeholders (e.g., individuals 'on the ground,' non-local academic researchers, policy makers, advocates, among others). The framework for each project will include the following four-part structure:

(1) Research hypothesis
(2) Utilization of the community as a full partner, and engagement of the local

Ministry of Health, service providers, and other key stakeholders.

(3) Standardized format and questions for capturing legal, social structure, general health system, and public policy status.

(4) Qualitative and quantitative components.

The framework will facilitate comparison across projects to identify best practices, trends, decision-making, future research design, as well as for insuring transparency, if a centralized repository exists.

The framework was endorsed by the participants as a whole; as was the concept of a centralized repository for research data.

3. Initial Research Concept

Participants developed a Project Description of a multi-site/-region study to document the experiences of those testing positive through PITC and compare according to whether the testing occurred at clinics that offer comprehensive (one-on-one) counseling, to participants who test positive after undergoing provider-initiated testing at clinics that **do not** offer comprehensive counseling [see Appendix B].

The study will be developed within the standard **Framework for Research Projects** created by the coalition, so for each site/country, the study will map the legal services environment, policy, legal protections in force, healthcare infrastructure, national human rights institutions, and provider perceptions.

4. Additional Research Topics

A number of other potential research foci were developed during the course of the Consultation [see Appendix C]. These research foci were grouped into four over-arching 'themes,' with the two "breakout" groups of participants addressing two each. The four

themes were:

(1) Informed Consent Process – related to legal, public policy, regulatory, and ethical concerns as impacting provider-initiated testing and counseling.

(2) Enabling Environment – related to the social, economic, legal, and political climates surrounding research conducted on provider-initiated testing and counseling.

(3) Implementation -- related to both intentional and unintentional consequences affecting rights, care, treatment, and prevention.

(4) Systems – related to those surrounding providers and testing in particular healthcare delivery settings.

The research discussion of the Consultation used the WHO draft Guidance and the comments submitted by the UNAIDS Reference Group on HIV and Human Rights to WHO and UNAIDS on the draft Guidance to provide parameters. However, a part of the on-going work of the Steering Committee will be to discuss the relevance of a larger range of testing-related issues to research. The group expressed a strong preference for the focus to be implementation of HIV testing broadly, rather than be constrained to focus only on implementation of the Guidance.

Advocacy and communications strategies will be developed in the context of individual research projects.

5. ICRW Press Statement

ICRW proposed that the ARCAT issue a press release to coincide with the formal launch of the finalized Guidance. There was general agreement on this, and participants offered several points to be included. ICRW drafted an initial statement, which was sent round

for feedback from participants, and the press release was issued on May 31st.

6. **Publication submission**

Dr. Jonathan Fishbein (ICRW) discussed the need for ARCAT to quickly establish itself by appearing in publication. A publication could address such issues as the gaps in research, monitoring and evaluation, and engaging Civil Society in implementing the Guidance. The opportunity for an initial piece in JAMA has arisen through an expression of interest to ICRW from the Editor in Chief, and moving this forward will constitute an early effort by the Coalition.

Immediate Next Steps

Unless otherwise noted, Drs. Jessica Ogden and/or Jonathan Fishbein (ICRW) are responsible for coordinating the following:

1. ARCAT

ICRW will coordinate on-going communications of the Steering Committee, creation of a web-based communications mechanism to support teleconferences and to serve as an internal information exchange, and solicitation of funding and/or service donations.

2. Framework for Research Projects & Initial Research project/Additional Research Themes

The Steering Committee will further develop project concept by creating a "concept note" and "general proposal" to be disseminated to potential funding sources. At the first teleconference of the Steering Committee, timeframes will be established.

The initial research project will be constructed using the framework. Future research proposals, potentially based on the additional research themes that were identified, will

also use the framework

3. Press Statement

Drafting process began the week of May 21st by ICRW and was finalized by May 29th [see Appendix D].

4. **Publication submission** to the Journal of the American Medical Association

Contact with the Editor-in-Chief of the Journal of the American Medical Association to discuss the desired format and content of an article as well as drafting of this article began the week of May 21st; Steering Committee review and finalization of submission to be concluded in late June or early July."

APPENDIX A

The John M. Lloyd AIDS Project at the Stony Point Center
18 – 20 May, 2007

Attendees

1. **Sandra Bunch**, Communications Manager, International Center for Research on Women

2. **Leslie Calman**, Vice President External Relations, International Center for Research on Women.

3. **Thomas Coates**, Professor of Medicine, UCLA and Member of the Board, John M. Lloyd Foundation.

4. **Vince Crisostomo**, Coordinator, The Seven Sisters.

5. **Joanne Csete**, Executive Director, Canadian HIV/AIDS Legal Network.

6. **Jonathan M. Fishbein,** Special Assistant to the Deputy Director National Institute for Allergy and Infectious Diseases *and* Senior Fellow International Center for Research on Women

7. **Sofia Gruskin**, Director of the Program on International Health and Human Rights, Associate Professor on Health and Human Rights in the Department of Population and International Health. Harvard School of Public Health.

8. **Melanie Havelin**, Executive Director, The John M. Lloyd Foundation

9. **Donna L. Higgins,** Treatment and Prevention Scale Up Team, Department of HIV/AIDS, World Health Organization.

10. **Suzanne Maman,** Assistant Professor, Health Behavior and Health Education, School of Public Health, University of North Carolina, Chapel Hill.

11. **Promise Mthembu,** Global Advocacy Officer, Sexual and Reproductive Rights, International Community of Women Living with HIV.

12. **Jessica Ogden,** Technical Specialist HIV/AIDS and Senior Technical Advisor to the President, International Center for Research on Women.

13. **Seema Paul,** Chief, Policy Coordination, UNAIDS Secretariat.

14. **Freddy Perez,** Senior Public Health Programme Officer, Institut de Santé Publique, d'Epidémiologie et de Développement (ISPED), Université Victor Segalen.

15. **Marie Salatti**, Meeting Facilitator, IMPACT, LLC

16. **Christine Stegling**, Director of the Botswana Network on Ethics, Law and HIV/AIDS (BONELA).

17. **Mary Tobin**, Meeting Facilitator, IMPACT, LLC

18. **Nafuna Wamai,** Technical Advisor HIV Counseling and Testing, Global AIDS Program, CDC Uganda.

19. **Matt Whalen,** Meeting Facilitator, IMPACT, LLC

20. **Sarah Wyckoff.** Researcher, UNC

APPENDIX B

Sunday, 05/20/2007: Initial Research Project Description

Research Concept: Documenting the experiences and consequences of PITC, comparing PITC comprehensive counseling (individual/ 1 on 1 counseling) with PITC without comprehensive counseling.

VCT with comprehensive counseling will also be included, but described through a desk review of existing data.

Study will be primarily qualitative in nature, but will otherwise be developed within the standard framework created by the Coalition, so for each site/country, the study will map the legal services environment, policy, legal protections in force, healthcare infrastructure, national human rights institutions, and provider perceptions.

The study will follow individuals who test positive as a result of PITC. Follow-up was suggested at some variation of 6, 12, and/or 18 months with final follow-up at 24 months.

The study will document a range of experiences including

- Client perceptions of providers
- Client access to ART/maintenance
- Client Adherence
- Client Risk behavior
- Psychosocial impacts, including
    - Education
    - Violence
    - Discrimination
    - Social support

Outcomes:

- Recommendations
- Optimal interventions
- Identify core set of conditions needed in order to ensure positive outcomes
- Hypotheses for further studies

Possible sites where strong Country Partners and strong on-the-ground Qualitative Researchers could be identified:

China
India
Vietnam
Caribbean
Brazil
Peru
Ukraine
Uganda
Botswana
Malawi
South Africa
Zimbabwe

Tanzania
APPENDIX C

Saturday, 05/19/2007: Research Concepts

These points are abbreviated concepts proposed by the participants and captured on newsprint in a brainstorming session to identify key research themes. *Italicized* words were added to clarify concepts, based upon other notes taken during the session.

- *The quality of implementation of the Guidance* (operational research question)

- Impacts of stigma and discrimination [*What is the impact on stigma and discrimination?*]

- Impact of testing on specific rights [*How do we test the impact of HIV testing on sexual and reproductive rights? on employment discrimination? freedom from violence?*]

- Exploring the role of government in ensuring protection of human rights, including right to live free from HIV-related stigma and discrimination, in context of PITC

- [*What is the*] nature of training for service providers? How [*are they*] evaluated and tested for HIV?

- [*Is there*] criminalization of non-disclosure? [*What's the impact of criminalization of non-disclosure?*]

- Good practices of pre-test counseling---*impact?*

- Legal services---where can we study and see *impact* linked to testing? [*Is there a place where good legal services are available and we can measure their effectiveness?*]

- [*What is the*] *e*vidence on VCT [*'s effectiveness/failure?*]

- Testing of "criminalized" people (men + women); [*What is*] the impact of the guidance? *I*s it making it better or worse [*?*]. [*In places where the majority of men and women who have or are likely to have HIV are engaged in activities considered "criminal" (eg. drug users in the former USSR, prostitution), is provider initiated testing leading to treatment, counseling and care, or increasing the risk of incarceration and human rights abuses?*]

- [*What is the*] impact of testing on adolescents[*? Consider the*] legal status of adolescents [*and consider*] human research protections in infectious* disease clinical

trials. [*We have lots of questions about what adolescent's need/understand/what do they do with the information/ how do they integrate knowledge into their sex lives?*]

- [*What are the*] strategies for measuring the effectiveness of entire spectrum of human resources [*needed to implement PITC? Can we work with lay counselors? Primary health care workers? Is PITC sustainable if only health care workers are utilized? What is the nature of training for service providers that will enable them to make recommendations in appropriate ways? And how is that evaluated/tested etc.?*]

- When lay workers are used what are their legal protections?

- What countries have policies [*regarding routine testing*] or are not guided by policies [*?*] What are acceptable policies?

- [*What is the*] difference between Policy Guidance and the [*actual*] implementation on the ground?

- Does counseling and testing actually lead to more access to treatment? [*Expanding access to testing is being pushed to improve access to care and treatment, but we don't know if the two are actually linked. Does having more diagnosis lead to more care and treatment?*]

- [*What are the*] social "costs" of expanded HIV testing (e.g. *more* violence? [*What are the implications? How much stress does it add on to already stressed out communities?*]

- [*What is the*] minimal level of health care facility for effective testing and sustaining supply (logistics)*?*

- [*Examine*] the issue [*of*] normalization [*of HIV and the*] whole issue [*of*] adverse effects [*of testing. Does normalization of HIV reduce stigma and discrimination? Does it lead to the violation of people's rights?*]

- Human rights framework vs. stigma/discrimination framework

- Cost/Benefit regarding negative impact [*and the*] amounts tolerable. [*Does the "good" outweigh the "bad"? What can we do to mitigate "the bad"? What is the*] evidence [*of*] PITC [*'s*] positive/adverse impacts [*on*]

    - Care + treatment

    - Prevention

    - Differences in population [*What do we consider the evidence of PITC among different populations? What do we consider adequate evidence that it's working in terms of access and care treatment?*]

- Stigma/discrimination/human rights abuses

- We had a number of questions relating to the right to decline and the nature of informed consent in the context of PITC, including:

  - Understanding of "informed consent" in the absence of pretest counseling. [*How exactly is informed consent going to be obtained? What does it mean to be "informed"? Under what conditions do people feel they have the right to say "no"? We need to understand what people understood when they said "yes"*]

  - [*Understanding*] the relationship between person providing testing and person receiving it [*we need an explicit recognition of the power differential between the person "offering" the testing and the patients – and therefore how do we insure that the right to decline is being understood and exercised?*].

  - How can we ensure that the right to decline occurs and [*what are the*] issues around this? [*What are the]* strategies to ensure proper implementation?

- [*What is an*] effective rollout in face of resource constraints?

- [*How can we assure*] dissemination of research results on the ground? "On the ground" people are *not* included as partners in the research process [*but should be. There is a need for action –oriented research that we can use with our civil society and our service provider partners*.]

- [*In the context of PITC, do "positive' results change behaviors more than "negative" results?*]

- [*There is a*] deep need for participatory research.

- [*The impact of the Guidance on*] home testing. Door-to-door testing, couple testing may be health-care worker initiated: lots of other models [*need*] to be explored, [*not just those that are*] clinic-based.

- [*What is the*] impact of PITC on community discussions---*how acceptable* [*is it*] to talk about mandatory testing, etc.?

- [*What are the*] unintended consequences of abbreviated counseling?

- [*What's the impact if, in addition to PICT, other kinds of testing and services are ALSO available? Does having a spectrum of testing options influence uptake and long-term engagement with services*?]

- How do the perceptions of providers impact the availability and acceptance of PITC?

- Process of policy formulation + transfer. [*How are international policies made and then "transferred" to national governments? How much do they have an impact on national programs?*]

- How does the Guidance impact testing among mobile populations?

APPENDIX D

Wednesday, 05/30/2007: Press Release

FOR IMMEDIATE RELEASE
Contact: Sandra Bunch, ICRW (202) 742-1240; sbunch@icrw.org; www.icrw.org
Shanta Bryant Gyan (202) 412-4603; shanta@sbgcommunications.com

NEWLY LAUNCHED COALITION TO ADVOCATE FOR RESEARCH ON PROVIDER-INITIATED HIV TESTING

~ Coalition advocates for an evidence-based approach to HIV testing, counseling ~

WASHINGTON, D.C. May 30, 2007 – With today's release of international guidelines from the World Health Organization (WHO) and UNAIDS on provider-initiated HIV testing and counseling in health facilities, a new international coalition was launched to advocate for further evidence about its advisability.

Globally, HIV experts have acknowledged a lack of research on the operational effectiveness and health and social outcomes, whether positive or negative, of provider-initiated HIV testing – two key issues related to the approach.

The coalition, Advocacy and Research on HIV Counseling and Testing (ARCAT), recently organized to help fill these research gaps toward building an evidence-based approach for HIV testing. Its research agenda will include assessing the approach's impact on adolescent psychology and behavior, and the availability of and access to legal services of people being tested. The coalition also will examine whether provider-initiated testing leads to greater access to treatment.

"Though this official guidance on HIV testing and counseling in health facilities is based on the best evidence to date for assuring quality care and patient protections in the context of HIV testing and counseling, in fact, there is much that we do not know about these issues and the possible adverse affects of provider-initiated testing," says Jonathan M. Fishbein, M.D., a senior fellow at the International Center for Research on Women (ICRW). Fishbein also serves as a special assistant to the deputy director, National Institutes for Allergy and Infectious Diseases.

"This guidance presents an opportunity for the new coalition to further examine the consequences of provider-initiated HIV testing, particularly in ensuring that stigma is reduced and human rights are respected and observed in all HIV testing," Fishbein adds.

Heath practitioners, global health experts and AIDS activists continue to debate the pros and cons of provider-initiated counseling, also called "routine testing," which would require health professionals to incorporate HIV testing and counseling into routine medical care. The current standard for identifying people with HIV is through voluntary counseling and testing, a practice that offers patients counseling on the HIV test and AIDS treatment and care, but relies on individual initiative to seek the testing.

The coalition was formed during a two-day forum, held May 18-20 in Stony Point, New York, which brought together top global health experts and AIDS activists to discuss evidence and best practices for HIV testing and counseling in anticipation of the final guidelines. Draft guidelines were released for public comment last November. The forum was an initiative of the annual John M. Lloyd AIDS Project with additional funding from the Elton John AIDS Foundation. ICRW organized the forum, led by Fishbein and Jessica Ogden, ICRW technical specialist in infectious diseases.

The official guidelines on HIV testing provide countries with basic operational guidance as health facilities expand HIV testing and counseling. The final WHO/UNAIDS guidance recommends HIV testing and counseling linked with access to health services as a standard of routine medical care for all patients in health facilities in all epidemic settings displaying symptoms of a possible HIV crisis, and for all patients in health facilities in high risk settings.

The guidance recommends that countries should consider administering HIV testing in a limited range of countries with low- and concentrated-levels of the epidemic. The guidance emphasizes the continued importance of ensuring confidentiality and counseling in the context of provider-initiated testing, which have been standard recommendations for all forms of testing and counseling. The guidance also features an "opt out" clause for patients who do not wish to be tested.

The WHO/UNAIDS guidelines also recommend that countries ensure specific conditions are in place before provider-initiated testing and counseling is introduced. These conditions include policies, laws and procedures for informed consent, confidentiality, the right of privacy, beneficial disclosure and partner notification as well as anti-discrimination laws.

Coalition members have expressed concern about the lack of oversight of health facilities implementing the guidance and the failure of donor agencies to include resources for monitoring and evaluation. ARCAT will advocate to ensure that research into key questions surrounding testing and counseling continue – particularly the potential harmful consequences of provider-initiated HIV testing – and that this evidence informs program implementation. The Washington, D.C.-based ICRW will be the lead organization coordinating the coalition's work.

Only about 10 percent of people living with HIV worldwide are aware of their status. Advocates of provider-initiated testing say the expansion of HIV testing is a critical step, alongside continued expansion of voluntary counseling and testing, toward achieving universal access to prevention, treatment and care.

For more information about the coalition and the ongoing debate on provider-initiated HIV testing and counseling, please visit www.icrw.org.
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The International Center for Research on Women (ICRW) *is a private nonprofit organization working to improve the lives of women and girls in poverty. ICRW works throughout the world and has offices in India and Uganda.*