HIV Point-of-Care Testing

Workshop held at the Lord Elgin Hotel, Ottawa, Ontario
March 29 - 31, 1999
**Table of Content**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction, Workshop Objectives</td>
<td>1</td>
</tr>
<tr>
<td>Monday, March 29, 1999 - Evening Session</td>
<td></td>
</tr>
<tr>
<td>Opening Remarks</td>
<td>2</td>
</tr>
<tr>
<td>Special Presentations</td>
<td>3</td>
</tr>
<tr>
<td>Tuesday, March 30, 1999 - Morning Session</td>
<td></td>
</tr>
<tr>
<td>Consideration of Special Topics</td>
<td></td>
</tr>
<tr>
<td>Detuned (Sensitive/Less Sensitive) EIA</td>
<td>4</td>
</tr>
<tr>
<td>Regulatory Issues and Point-of-Care HIV Rapid Testing</td>
<td>5</td>
</tr>
<tr>
<td>Counseling Issues and Point-of-Care HIV Rapid Testing</td>
<td>5</td>
</tr>
<tr>
<td>Beyond Viral Load: The Role of the Retrovirology Laboratory in Patient Care</td>
<td>5</td>
</tr>
<tr>
<td>Tuesday, March 30, 1999 - Workshop Discussions</td>
<td>6</td>
</tr>
<tr>
<td>Wednesday, March 31, 1999 - Workshop Discussions (Continued)</td>
<td></td>
</tr>
<tr>
<td>Topic: Testing Performance</td>
<td>7</td>
</tr>
<tr>
<td>Topic: Testing Practice</td>
<td>7</td>
</tr>
<tr>
<td>Topic: Counseling</td>
<td>9</td>
</tr>
<tr>
<td>Topic: Reporting / Surveillance</td>
<td>11</td>
</tr>
<tr>
<td>Topic: Legal and Ethical Issues</td>
<td>12</td>
</tr>
<tr>
<td>Topic: Enforcement and Compliance</td>
<td>12</td>
</tr>
<tr>
<td>Topic: Benefits and Risks with Respect to POC Testing</td>
<td>14</td>
</tr>
<tr>
<td>Conclusion</td>
<td>15</td>
</tr>
<tr>
<td>APPENDIX A - Participants’ expectations</td>
<td>16</td>
</tr>
<tr>
<td>APPENDIX B - “As-It-Was-Said” Workshop Report</td>
<td>17</td>
</tr>
<tr>
<td>APPENDIX C - List of Participants</td>
<td>30</td>
</tr>
</tbody>
</table>
Introduction

The medical Devices Bureau of the Health Protection Branch of Health Canada is in the process of approving HIV test kits for use in point-of-care testing. The introduction of this type of test raises many issues for all stakeholders.

In light of such concerns, the Bureau initiated a consultation workshop on March 29th, 30th, 31st, 1999. This consultation workshop brought together a broad range of stakeholders, including clinicians, laboratory personnel, representatives from various provincial and territorial government and representatives from non-government organizations.

Workshop Objectives

The workshop had three principal objectives. They were:

1. To provide information regarding the HIV Rapid Test Kits currently under field trials;

2. To identify the issues raised by the availability of HIV point-of-care testing;

3. To understand stakeholder's perception with respect to the conditions necessary to successfully deploy HIV point-of-care testing.

Workshop structure

The workshop took place over the evening of Monday March 29th, Tuesday March 30th and Wednesday March 31st. The evening of March 29th was structured so that the representatives from the manufacturer's could present data that had been accumulated over the course of the trials. Following their presentation they were invited to remain in the workshop discussions as observers.

This workshop was designed to bring together multiple stakeholders. The intent of the workshop was to hear the issues and concerns of all involved and not necessarily arrive to a consensus. It is therefore natural to read through this report and find contradictory points.

Reporting on the workshop proceedings

The following report attempts to capture the proceedings from the workshop. Some segments of this report are intended as a summary report of a presentation made by various speakers. Other sections are the report from discussions that were assisted by a facilitator - these segments are the "As-It-Was-Said" portion of this report. In such cases, facilitators captured the direct words of participants and duly noted the points onto flipcharts. Given the nature of such a report, the reader may find some of the points difficult to understand.

Over the coming months, additional reports will be circulated. Dr. Choquet will complement this report by issuing the outcomes from this meeting, detailing outstanding issues and future directions.
**Monday, March 29, 1999 - Evening Session**

**Opening Remarks**

After a brief message of welcome by Ms. Beth Pieterson\(^1\), and an overview of the meeting agenda for the next two and a half days by Intersol facilitator Alain Rabeau, participants and observers (approximately 80 people) were invited to help themselves to a buffet dinner. After the meal, introductory comments were heard from Dr. Christian Choquet\(^2\), Dr. John Kim\(^3\) and Dr. Chris Archibald\(^4\).

Dr. Choquet explained the purpose of the meeting, that is to obtain information and suggestions from participants on HIV point-of-care (POC)\(^5\) testing. It is the wish of Health Canada representatives that issues surrounding point-of-care testing will be discussed and that feedback will be provided. Since various interest groups are represented at the meeting, it is also important for Health Canada to have feedback on what should be in place, if and when HIV rapid test kits become available for point of care testing. Dr. Choquet also gave a brief overview of the licensing process for HIV test kits (manufacturer's application for authorization to proceed with investigational testing; investigational testing in designated sites; and subsequent licensing).

In his remarks, Dr. Kim gave a brief overview and explanation of terms that need to be clearly understood (such as rapid HIV testing and predictive values).

Dr. Archibald touched on the public health implications of point-of-care rapid HIV testing. His presentation included topics such as the uses of HIV testing and the issues that need to be considered (i.e. accuracy, access to testing, counseling, impact on surveillance, economical and ethical costs, and settings best suited to use of rapid testing).

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1. Ms. Pieterson is the Acting Director of the Medical Devices Bureau.
2. Dr. Choquet is the Section Head, *In vitro* Diagnostic Section, Device Evaluation Division, Medical Devices Bureau.
3. Dr. Kim is the Acting Chief of the National Laboratory for HIV Reference Services, Bureau of HIV/AIDS, STD & TB.
4. Dr. Archibald is the Chief, Division of HIV Epidemiology, Bureau of HIV/AIDS, STD & TB.
5. Point-of-care (POC) testing is defined as testing in the presence of a health care professional. It does not include home testing.
Special Presentations

The second portion of the evening consisted of two special presentations of the on-going Canadian clinical trials of rapid HIV test kits for point-of-care testing.

The first presentation was given by Dr. Stephen D. Shafran\(^6\) on behalf of Merlin Biomedical & Pharmaceutical. Dr. Shafran’s presentation touched on a number of relevant issues such as global HIV statistics, identification of potential rapid HIV testing centres, definitions that need to be understood to better comprehend the issues of rapid HIV testing, screening confirmation and purpose of HIV tests, EIA test, problems with current laboratory-based screening, the need to establish test design criteria, reporting of HIV screening, test results, comparison of EIA and rapid test, rapid test advantages, explanation of the Immediate HIV 1 & 2 rapid test review of current safety and efficacy data of the Immediate HIV 1 & 2 rapid test including clinical results, presentation of the clinical protocol and the clinical sites across Canada, and other characteristics of the Merlin Immediate HIV 1 & 2 rapid test.

Following his presentation, Dr. Shafran answered a number of questions of clarification and points of information.

The second presentation of the evening was given by Dr. Yvan P. Côté\(^7\). Titled Fast Check HIV - 1 & 2 Whole Blood, Serum and Saliva (Kits), Dr. Côté’s presentation described the clinical trial and clinical performance of his company’s three devices (whole blood, serum and saliva) and how they work. His talk touched on the following points: a presentation of the assay design, interpretation of the results, intended use of these devices, clinical performance (independent investigative studies realized), locations of the worldwide studies, evaluation conducted by CDC, study design of the clinical trial, results of the Canadian clinical trial (Vancouver, Calgary, Toronto and Montreal), results of the prospective study, data analysis for each device, summary of the clinical performance of each of the three devices, and arguments as to why the Fast check HIV - 1 & 2 should be used. Dr. Côté concluded his remarks by posing two essential questions: where should the test be performed and how long should it take.

Following Dr. Côté’s presentation, points of information and questions of clarification were answered.

\(^6\) Dr. Shafran is the Director, Division of Infectious Diseases, University of Alberta.

\(^7\) Dr. Côté is the Assistant Director, Research and Development, BioChem ImmunoSystèmes Inc., in Montréal.
Tuesday, March 30, 1999  -  Morning Session

Getting Under Way

Following a few housekeeping items, Dr. Christian Choquet reiterated his message of the previous evening as to the purpose of the two-and-a-half day meeting. The facilitator then asked participants to take a few moments to consider their expectations of the meeting. Participants were seated at eight tables; each of the tables was to brainstorm its expectations and identify the top three. The results of this exercise are found in Appendix A.

Consideration of Special Topics

Detuned (Sensitive/Less Sensitive) EIA

The first presentation on this topic was made by Dr. John Kim. His presentation of the assay touched on the principle behind diagnosis of early HIV infection (JAMA 1998;280:42-47), the dual EIA’s (Abbott), an explanation of the sensitive (standard) Abbott 3A11 EIA and the less sensitive LS - 3A11 EIA, the dual EIA antibody testing strategy and its validation studies, the investigational and research uses of the assay by enrolling in the CDC - IND program for 3A11 - LS, the detuning by avidity assay, validation of the protocol and additional pertinent raw data, and his conclusions of this particular assay.

The second presentation was made by Ms Carol Major$. She indicated to participants that the HIV Laboratory where she works does all the HIV diagnostic testing for the Province of Ontario and went on to present their experience with the Abbott 3A11 less sensitive assay (detuned) kit (procedure modifications, standard aspects, laboratory results, test validation, and their concerns about such issues as test reliability, sensitivity, specificity and performance for non B subtypes or HIV - 2 cases).

Dr. Chris Archibald was the third presenter on this topic. He addressed the potential uses of the detuned EIA HIV test on a public health setting. He dwelled on such questions as the reasons to detect recent HIV infection, HIV incidence (rates of new infections), ways to measure HIV incidence, the formula to estimate incidence, the advantages of the detuned assay for estimating incidence, the caveats or cautionary notes, identification of the possible sources of samples HIV for HIV incidence estimation, and examples of its use (U.S.A. and Brazil studies). He concluded by saying that the assay will provide us with a potential tool to monitor the epidemic and to improve and guide our Provincial Programs.

Questions of clarification and points of information were responded to.

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$ Ms Major is the Head of the HIV Laboratory, Central Public Health Laboratory, Ontario Ministry of Health.
Regulatory Issues and Point-of-Care HIV Rapid Testing

Dr. Christian Choquet made this presentation on the Medical Devices Regulations (MDR). Following a quick overview of the roles of Health Canada’s Health Protection Branch (HPB) and Health and Promotion and Programs Branch (HPPB), Dr. Choquet addressed such topics as legislation under the Food and Drugs Act and under the Medical Devices Regulations, types of sales under MDR, the risk-based classification system, an overview of the licensing process for HIV test kits, pre-market and post-market activities, background information on investigational testing, the process used for license application, and the scope of the MDR which is to ensure the safety of medical devices as it pertains to the use of the device, effectiveness as it concerns the performance and quality as it applies to performance and consistency.

Questions of clarification and points of information were responded to.

Counseling Issues and Point-of-Care HIV Rapid Testing

Dr. Gerry Bally addressed such matters as the development of clinical practice guidelines, and HIV counseling and testing (“Technology will never be as important, commented Dr. Bally, as the human skills needed, such as comfort, art of educating, informing, and caring for the patient.”). Other topics addressed by Dr. Bally included the objectives and outcomes of HIV counseling and testing, the principles behind counseling guidelines (i.e. voluntary, informed consent, confidentiality), pre-test counseling (educational opportunity, testing options, discussing implications for testing, discussing the process of testing, determining the timing of testing, obtaining informed consent), technology and process, overview of post-test counseling, and consideration of the unique features of counseling for women and special populations. Dr. Bally then invited attendees to consider two case studies (Sara and Steven). Dr. Bally concluded his presentation by going over the implications of rapid HIV testing and the considerations for rapid HIV screening, such as the need for clinical research and development of protocols and guidelines as well as resource development, implementation of guidelines, training and skill development.

Questions of clarification and points of information were responded to.

Beyond Viral Load: The Role of the Retrovirology Laboratory in Patient Care

The final presentation of the morning was made by Dr. Brian Conway. The topic of his presentation touched on how the laboratory can be helpful in the management of HIV infected individuals. Through a series of charts, graphics and data tables, Dr. Conway addressed such issues as the basis for anti-viral therapy, the hypotheses of his collaborative research (features of the quantitative assay, methods used, summary of results, conclusions), the findings reported by an International Panel, the theoretical basis of their recommendations, measure of antiretroviral drug resistance, what the data say and do not say, the relative advantages and limitations of genotypic and phenotypic assays, and

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9 Dr. Bally is Health Canada’s Senior Medical Advisor, Care Treatment and Support Unit, HIV/AIDS Policy, Coordination and Programs Division.

10 Dr. Conway is a clinician with the Viridae Clinical Studies, University of British Columbia.
the clinical uses of drug resistance testing. He also spoke briefly about two clinical studies: the VIRADAPT Study (Europe) and the Genotypic Antiretroviral Resistance Testing (GART) Study (U.S.A.). He ended his presentation with a few take-home messages on resistance testing.

Questions of clarification and points of information were responded to.

**Tuesday, March 30, 1999 - Workshop Discussions**

**Afternoon Session**

The afternoon’s agenda provided for working group process. After the afternoon’s program had been presented, the facilitator framed the working group sessions. Dr. Christian Choquet spoke once again to the purpose of the meeting, the identification of relevant issues and the provision for feedback on these issues. He informed participants that their comments and suggestions would be incorporated into the report that would be prepared following this meeting. No consensus was required on the issues pertinent to HIV point-of-care testing, only open and frank discussion. The facilitator presented the ground rules and roles for the working group sessions and a list of topics to be considered by the five working groups was presented. Two, or possibly three, of the following topics were to be discussed. A first topic had been pre-assigned to each of the groups. The remaining topics were to be selected by the groups.

- Counseling
- Testing Performance
- Testing Practice
- Reporting / Surveillance
- Legal and Ethical Issues
- Enforcement and Compliance
- Benefits and Pitfalls (or Risks) of Rapid Testing

Participants went into their respective groups to engage discussion on the issues for the rest of the afternoon. (Manufacturer’s representatives were granted observer status for the breakout sessions). The suggestions emanating from the group discussions were recorded on flip chart sheets. These suggestions can be found in Appendix B.

**Wednesday, March 31, 1999 - Workshop Discussions (Continued)**

**Reviewing and Establishing the Process**

After realizing that attendance at the meeting was somewhat dwindling, conference organizers and the facilitator reviewed the process for the remainder of the meeting. A proposed revised agenda was set and submitted to the participants for consultation. An overwhelming number of participants opted for a plenary for the remainder of the meeting. It was therefore decided that a period of approximately 25 minutes would be set aside for each of the seven topics. Groups that had discussed these topics on the previous day would be invited to present the results of their deliberations. Plenary participants would then be invited to further add to the issues identified for each topic. The following therefore includes the group reports (Tuesday’s group discussions) as well as the feedback obtained in Wednesday’s plenary session.
**Topic: Testing Performance**

**Focus Statement:** What are your expectations with respect to the performance characteristics of the point-of-care test kits?

The first group to report presented the following assumption: “The group does not agree that universal access to POC is appropriate.” They added the following points:

- POC tests should be as good as the current diagnostic screening tests.
- The assay should not be subjective; a methodology with a numeric output would be preferable (i.e. glucometer).
- The assay must be robust with respect to temperature variations, lighting conditions, outdating (long shelf life).
- The assay should be run with positive, negative controls every time.
- Higher specificity may be required (than current screen assays) in low prevalence populations (adverse effect).

After the presentation - The following points were discussed:

A second group and plenary participants had the following additional suggestions:

- Test should be as good as current test.
- Time limit - 15 to 20 minutes (discussion about that).
- Subjective nature of test: is this a real problem? Track record so far with one test shows no problem. Placing a number on test results places aura of objectivity which may not be the case.
- How does kit work with seroconverters?
- There is a need for the kits to be foolproof!
- Mini-certification of testers.
- There is a definite role for POC testing.
- Need to provide lots of information with the kit that is communicated to the user (beyond the manufacturer's information).
- Need for further evaluation (overall patient acceptability and outcomes, counseling, consequences of false positive, ability to deliver post-test results, follow-up resources).
- Two conditions: availability of information on POC testing; training of test users.

**Topic: Testing Practice**

**Focus Statement:** What are the issues and concerns related to the testing practices in HIV point-of-care testing?

The first group to report had the following suggestions on testing practices (including benefits for the individual being tested):

- Who should be performing the test? (liability issues & quality control)
- Maintaining confidentiality is a condition.
- Clinical judgement is paramount (not to be replaced by rapid test result).
- There are concerns expressed over the inappropriate use of tests.
Concerns raised with respect to benefits for individual.
Impact on anonymous testing (probably minor).
Situations requiring “stat” results (Post-exposure prophylaxis (PEP), women in labour, etc.)? Links with actual system for testing organ donors.
There are issues of Biomedical waste disposal (in sites not previously handling biomedical wastes).
Issues of quality control.
Question: Who pays for these tests?

One group had discussed this topic by identifying issues and possible solutions.

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<tr>
<th>ISSUES</th>
<th>POSSIBLE SOLUTIONS</th>
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</thead>
<tbody>
<tr>
<td>S  Control of where and when the kit will be used</td>
<td>S  Education of health professionals:</td>
</tr>
<tr>
<td>S  Legal liability of testers</td>
<td>• when to use it; how to interpret: limitations</td>
</tr>
<tr>
<td>S  Test kit quality (post market surveillance)</td>
<td>S  Training</td>
</tr>
<tr>
<td>S  Public Education</td>
<td>S  Enforcement / compliance (MDB / TPP)</td>
</tr>
<tr>
<td></td>
<td>S  Professional regulatory bodies will need to address changes to the scope of practice and insurance issues (malpractice)</td>
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<td></td>
<td>S  Each lot must be approved in Canada prior to release (who, how?)</td>
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<td></td>
<td>S  ongoing quality assurance (major issue for POC)</td>
</tr>
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<td></td>
<td>S  Targeted for sub-population</td>
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<td>S  Control advertising by manufacturer</td>
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Other groups and plenary participants had the following additional comments:

- The impact of the approval of this device in Canada and other countries is not yet fully understood as well as the impact on care givers.
- How to improve the training of the tester. This is a major concern.
- Defining appropriate populations upon which test is most suitable.
- Impact of licensing.
- There are changes recommended to clinical guidelines.
- How to improve practice of tester (through existing methods and nurses).
- Preferential placement based on rate of return.
- The control of distribution of the test is a concern. (possibly through the provincial labs).
- How could people who produce positive results on the rapid test, be fast-tracked for the confirmatory test.
**Topic: Counseling**

**Focus Statement:** On the subject of counseling, what issues and concerns are raised by HIV point-of-care testing?

The first group to report addressed the question by identifying the issues and possible solutions or considerations.

1. **Issue:** Guidelines on how to do counseling and the nature of the test.
   - Define procedure for counseling; standardize.
   - Impact of test.

2. **Issue:** Puts pressure for good pre-test counseling.
   - Must take time.
   - Professional education on the importance of pre-test counseling.
   - Recommendation to provinces.

3. **Issue:** In some populations there is an historic low rate of return.
   - Rapid POC testing will circumvent this problem.

4. **Issue:** The rapidity of the test should not diminish the post-test counseling of a negative result.
   - Professional education.

5. **Issue:** Legal liability of the counselor.
   - Agreed upon standards of practice.
   - Research on legal liability.

6. **Issue:** Do not follow available guidelines at present.
   - Carried out only in places with good pre- and post-test counseling.
   - Performed in identified sites; can be used to gather more information for future use.
   - Phased-in implementation.

7. **Issue:** Potential harms of new technology due to problems with counseling.
   - Consult with people who are HIV+, and people who do testing and counseling.
   - More field trials.

A second group submitted the results of its discussions. The group identified two key issues: (1) training for counselors; and (2) guidelines on counseling for HIV rapid testing. It went on to suggest that these issues be considered with the following aspects of counseling in mind:

1. Appropriate to site of testing (e.g. doctor’s office, HIV testing sites vs outreach programs).

2. Appropriate to the population being tested (situation of testing) (e.g. “high risk” groups, “routine” testing).

3. Adapted to the issue of a short time period for the sequence: pre-test counseling → testing → results → post-test counseling.

4. Importance of counseling for both positive and negative tests (rapid test might be appealing to
some populations / individuals).

5. Two questions were raised by the group who felt that there should be an evaluation of the counseling process: (a) Who should develop these guidelines? (b) Evaluation of counseling.

Finally, plenary participants had the following additional suggestions to make:

- Counseling must consider capacity of individual to deal with the results of being found HIV positive.
- Time to prepare in delivering a result to a patient is short under POC. How can providers prepare?
- CMA guidelines should be adapted.
- Guidelines are there, but not everybody uses them (concerns expressed with respect to POC testing). How can we ensure use of guidelines?
- Issue of access to other counseling resources should be addressed. Availability of counseling resources and counselors is also an issue of concern. More use of test = more negative results = burden/pressure on resources that have to do counseling.
- Impact of current Canadian health care economics; may play a role in distribution of test, more may be placed in publicly-funded clinics; comes back to question of who pays.
- Test could be creating two standards of care.
- Fee structure of testing will have an important impact on use of test.
- Defining the population for whom counseling is appropriate is an issue.
- POC testing and counseling is a great need in remote and northern communities, but the use of rapid tools might create more harm than good.
- Should counseling establish some link with confirmatory testing and test results? (e.g. pointing to timelines, not feasible in remote locations).
- If the technology is available, would counselors offer a choice between standard and rapid testing?
- Not asking acceptability of test to informed health consumer - gap in how consumers view this.
- Limited resources in some provinces.
- Limited time to deliver both counseling and medical services (how much time will this take?). MD remuneration must allow for appropriate time for counseling.
- Importance of follow-up even with negative results. This should not be underestimated in time and effort.
**Topic: Reporting / Surveillance**

**Focus Statement:** What are the reporting and surveillance issues and concerns related to HIV point-of-care testing?

One of the groups reported on the results of its deliberations. It presented issues and possible solutions.

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>POSSIBLE SOLUTIONS</th>
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</table>
| Positive POC - patient leaves without providing blood for confirmatory testing. Results in:  
S poor case management  
S under reporting  
S loss of epi data (positive or not, strain staging) | Try to track patient (not possible if anonymous)  
S Can report “suspect” case to public health (still issue of specimen)  
S Collect venipuncture prior to POC |
| S No access to POC negative specimens needed for patient management when follow-up testing is positive. | S Collect venipuncture prior to POC and store it  
S Ask for specimen for possible “window” cases  
S Ask for voluntary specimen for storage |
| S Loss of denominator data for POC negative testers (significant impact on knowledge of the epidemic) | S Public health lab - or other agency - could oversee POC testing program:  
• administer/manage  
• select sites/venues  
• distribute QA kits  
• collect data for all tests used |
| S What type of record with what data is required regarding the testing? Where is it stored? How long? | S Needs to be defined  
• record of test, kit lot, result, tester  
• in chart  
• to central data base  
• on-site |

Additional feedback from plenary participants included the following:

- Concerns as to who has access to the data (positive and negative results).
- Issue of privacy.
- Legal liability if you have information on positive results (increased burden with reporting).
- Confidentiality issue (in a small clinic or doctor’s office).
- Need to capture data on quality variances of kit lots.
- How to ensure data reliability in transfer of data from physician to reporting.
**Topic: Legal and Ethical Issues**

**Focus Statement:** What are the legal and ethical issues pertaining to HIV point-of-care testing?

One of the groups that had considered this topic reported on its conclusions.

1. **Limiting Liability/Harm**
   - need a risk analysis (i.e. harms vs benefits)
   - liability issues:
     - provider → accuracy
     - provider → giving the equipment to others
     - informed consent

2. **Access: client’s choice → “paternalism”** (Are we being over protective?)
   - obligation to provide
   - creating two standards of care?
   - black market

3. **Informed consent: will clients be pressured?**

4. **Confidentiality:**
   - public health reporting
   - private insurance reporting

Plenary participants added to this:

- Potential for abuse in matters of consent (e.g. women in labour, incarcerated population, access of information to police officers, employers screening employees, schools screening students, athletic teams screening athletes, etc.).
- Recommendation that research should be examined, related consultation in the country. Canadian HIV/AIDS network could offer some suggestions/direction in this matter.

**Topic: Enforcement and Compliance**

**Focus Statement:** What issues need to be addressed with respect to enforcement and compliance as it pertains to HIV point-of-care testing?

One of the groups that had considered this topic shared the fruit of its deliberations with participants:

<table>
<thead>
<tr>
<th>Issues</th>
<th>Possible solutions</th>
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<tbody>
<tr>
<td>Labelling</td>
<td>Should identify who does the test.</td>
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<tr>
<td>Training</td>
<td>Guidelines; accreditation</td>
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<tr>
<td>Compliance:</td>
<td>Only safety, efficacy and quality.</td>
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<tr>
<td>Can Health Canada</td>
<td></td>
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enforce?

<table>
<thead>
<tr>
<th>Who has access to kits?</th>
<th>Regulation by provinces.</th>
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<tbody>
<tr>
<td>Compliance to protocols</td>
<td>Accreditation or designation.</td>
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<td></td>
<td>Counselling guidelines.</td>
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<tr>
<td>Labelling.</td>
<td>Kit instructions</td>
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<tr>
<td>Compliance for use</td>
<td>Increase Health Canada staff.</td>
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<td>Develop protocol with other regulatory agencies</td>
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Plenary participants added to the above:

- What is Health Canada’s role in this area (enforcement and compliance)? Note: Dr. Choquet explained.
- Questions pertaining to Health Canada’s restrictions in sale of devices, labelling requirements.
- There is a feeling that POC testing not done through the auspices of a laboratory is unregulated. Recommendation that POC testing be better defined and implications for patients be looked at.
- Regulations required for point-of-care testing? Both at the provincial/territorial and federal levels.
**Topic: Benefits and Risks with Respect to POC Testing**

**Focus Statement:** What are the benefits and the risks involved with point-of-care testing?

Note: The remaining participants for the afternoon session felt that consumers were not well represented at this meeting and that this question could not be adequately discussed without their input. Because attendance had dwindled over the lunch hour, it was also felt that the written report of this meeting should reflect this fact and not conclude that all participants attending the HIV TESTING ISSUES MEETING were present.

The remaining attendees then addressed the question of benefits and risks. What follows is the result of their feedback.

**POTENTIAL OR PERCEIVED BENEFITS OF POINT-OF-CARE TESTING**

- More results delivered.
- Potential for human resources efficiency.
- Convenient for a major portion of patients.
- Reduced anxiety for patients waiting for results (negative results, PEP, labour and delivery).
- May result in better care management (labour and delivery, women with no pre-natal care, PEP, emergency room).
- Appropriate in Outreach setting with street people (some differences of opinion on this point).
- Better access to health care system for people who don’t return.
- Everything done in one visit.
- Some people prefer finger prick to venipuncture.
- Ease of dealing with dangerous goods related to HIV testing.
- Freeing up significant numbers of human resources in labs.

It was also felt that a measure of these benefits would be required.

**POTENTIAL OR PERCEIVED RISKS OF POINT-OR-CARE TESTING**

- Inadequate counselling.
- Lack of appropriate informed consent in a number of settings (labour, emergency, needle stick, etc.).
- Potential for refusal to treat (in dental care, for example).
- Non sanctioned or illicit uses of the test.
- Deny insurance.
- Various forms of abuse.
- Great potential risks for false positive results.
- Potential of patients misunderstanding results.
- Impact of short time frame (on counselling component of visit, on misunderstanding of results, on patient’s lack of time to digest what results mean, psycho-social needs, etc.).
- Not controlling the use and distribution of the kit.
- False security around negative test result might increase undesirable behaviour → validates
behaviour that puts people at risk.

- Counselling will get lost if negative.
- Black market realities (secondary distribution).
- Main streaming testing may lose its significance and undervalue other important supports, such as counselling.

**Conclusion**

Finally, participants were asked to spend time on future considerations or next steps. The following suggestions were made:

**FUTURE CONSIDERATIONS OR NEXT STEPS**

- Knowing right up front what this POC testing involves.
- Consideration of these matters and options in provincial, territorial and national jurisdictions; broader consultation with consumers; seeking consensus.
- Field trials to determine the impact on clients at field level.
- Federal regulations - are guidelines clear with respect to this test?
- Concerns that CMA guidelines do not address all of the issues with reference to the realities of POC testing.
- If there is scientific and technical consensus, and if the proposed technology meets the criteria, HIV antibody testing in Canada should move forward (point of view expressed by one participant).
- Need for a broader consultation on the benefits of this testing.
- Technology should not be driving on this matter.

Participants then heard closing remarks from:
- Manufacturers’ representatives, Dr. G. Cullen and Dr. M. Houde, were invited to comment on the proceedings of the workshop
- Dr. John Kim; and
- Dr. Christian Choquet.
APPENDIX A

Participants’ expectations from the HIV TESTING ISSUES MEETING
held in Ottawa from March 29 to 31, 1999

These are the expectations identified by participants at the beginning of the Workshop, on Tuesday morning.

<table>
<thead>
<tr>
<th>TOP THREE EXPECTATIONS FROM EACH GROUP¹¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
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<td>Group 2</td>
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<td>Group 3</td>
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<td>Group 4</td>
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<td>Group 5</td>
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<td>Group 6</td>
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<td>Group 7</td>
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<td>Group 8</td>
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</tr>
</tbody>
</table>

¹¹ There were eight groups. Each group was to identify its top three expectations. Two groups added a fourth expectation.
**APPENDIX B**

This appendix consists of the flip chart notes taken by individual facilitators throughout the Tuesday afternoon discussions. They are presented with minimal editing.

**Group 1**  
**Topic: Legal Issues**

**Focus Statement**

*What are the ethical/legal issues and concerns related to HIV Point-of-Care Testing?*

<table>
<thead>
<tr>
<th>Issues and Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal liability</td>
</tr>
<tr>
<td>a) for Health Care provider regarding test accuracy</td>
</tr>
<tr>
<td>b) Informed consent - legal and ethical</td>
</tr>
<tr>
<td>Confidentiality legal and ethical</td>
</tr>
<tr>
<td>Obligation of institution to provide the test</td>
</tr>
<tr>
<td>Moral issue of pressuring patient to be tested</td>
</tr>
<tr>
<td>Patient has equal right to request testing</td>
</tr>
<tr>
<td>Counselling (related to inform consent) - legal as it relates to informed consent</td>
</tr>
<tr>
<td>Two standards of care exists</td>
</tr>
<tr>
<td>Ethical and legal issues surrounding reporting</td>
</tr>
<tr>
<td>Potential harm and benefits may need discussion</td>
</tr>
<tr>
<td>If no proper consent, could face liability</td>
</tr>
<tr>
<td>“Standard of Care”</td>
</tr>
<tr>
<td>Risk analysis</td>
</tr>
<tr>
<td>What limits Health Care provider to give test Kit to others</td>
</tr>
<tr>
<td>Potential for black market for Kits - will rapid testing increase or decrease existing black market</td>
</tr>
<tr>
<td>Are we being too “paternalistic” about this issue?</td>
</tr>
<tr>
<td>If physician instructs nurse to do the test - who is liable? Physician or nurse? - Physician responsible</td>
</tr>
<tr>
<td>Access to funding - who will fund</td>
</tr>
<tr>
<td>Reporting to insurance companies</td>
</tr>
</tbody>
</table>
**Group 1**  
**Topic:** Enforcement and Compliance

<table>
<thead>
<tr>
<th>Issues/Concerns</th>
<th>Suggestion - What can we do?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Labelling</td>
<td>• Identify who can do the test</td>
</tr>
<tr>
<td>• Training</td>
<td>• Guidelines</td>
</tr>
<tr>
<td></td>
<td>• Accreditation</td>
</tr>
<tr>
<td>• How much can Health Canada really enforce?</td>
<td>• Safety</td>
</tr>
<tr>
<td></td>
<td>• Effectiveness</td>
</tr>
<tr>
<td></td>
<td>• Quality</td>
</tr>
<tr>
<td>• Who has access to KitsWhere?By whom?</td>
<td>• Regulation by provincial association</td>
</tr>
<tr>
<td>• Compliance to provide</td>
<td>• Accreditation QA</td>
</tr>
<tr>
<td>• Protocols i.e. counselling guidelines</td>
<td>• Designation</td>
</tr>
<tr>
<td>• Kit instruction</td>
<td>• Labelling</td>
</tr>
<tr>
<td>• Compliance with indication for use</td>
<td>• Develop a protocol in consultation with other regulatory agencies</td>
</tr>
</tbody>
</table>
Group 2  
Topic: Testing Practices

• What situations to use the rapid test in? - pop-ins, setting
• Where the test will be used; suitable settings - outreach clinic versus physician’s office
• Should be available in centers where notion of time is important but not to the exclusion of standard test Kits where appropriate
• What are we going to gain, what will be lost - we will lose performance (increase FP, increase FN)
• Who should be doing the test? (Performing test protocol)
• What training required?
• Who is appropriate for a given setting?
• Basic background in lab technology
• Difficulty in reading results even for lab staff if reading unclear - indefinite results
• Inclusion of pictorial examples of non standard results
• Distinction of negative (when not a clear positive but not clearly negative)
• Interpretation of test result once test read
• What does a positive result mean in different situations?
• How can this be clarified? User protocols developed by clinician could help with this - not the manufacturer’s responsibility?
• Way testing is done now is regulated provincially
  S rules, inspections of labs
  S legal sanctions
  ▶ Who takes the fall for a worst case scenario - false positive result when patient not prepared
  ▶ Who is legally liable here?
  ▶ Who is responsible for maintaining confidentiality?
• Adding a second test to be done in tandem may not necessarily raise the positive predictive value - it is unlikely that both Kits will pick up the same FP result
• Giving access to Kits to people who might not have the knowledge to read the results accurately may be dangerous
• We have to recognize that once a rapid test is done, we should also have the opportunity of taking serum to commence confirmatory testing
• In some jurisdictions, blood work is not collected, i.e. patients are referred to hospital, therefore may be incurring costs unnecessarily
• Liability is high in sites where physicians are not doing the test - how will non-profit insurers feel about his? How will RN associations deal with this!
• Rapid test results should not take over clinical judgement
• What are the true indications for a rapid test?
• Clinical judgement is paramount!
• What is worse - waiting 2 weeks to find out positive or negative or wait 2 weeks to find out is one really positive?
• Positive rapid test results - patients may opt out of confirmatory testing
• What is different for positive treatment when using rapid test
• Risks and benefits of each situation e.g. mother presents for delivery - high risk of transmission to newborn, no time for 2 week test
• Practical decisions of risk versus benefit
• Post injury prophylaxis (testing to determine if prophylaxis is needed)
• But guidelines are clear that if patient is HIV positive, injury should be treated as high risk - is this really a needy population for rapid testing? What is the true incidence of high risk needle sticks.
• Fearful of rapid testing without patient’s consent
• Who is going to pay for the Kits?
• Impact on anonymous testing
• Perhaps none, only difference is quicker results
• concerns over inappropriate use
• Testing should only be done with patients who have access to proper care
• What are we going to do with people who test positive?
• Use as supplementary testing (complementary to existing tests) or use in stat/after hours testing
• Could rapid testing replace existing testing in cases of urgent organ donation tests?
• Disposal - becomes a concern (waste disposal) for centers normally not testing now.
• Financial consideration of bio-hazard waste disposal
• Whole blood testing versus saliva
• No mechanism for QC of test Kits once in the lab setting
• Provincial control would be logical but does this mean that provincial labs are responsible for ensuring Kits used in a certain province are OK?
• Some method of QC - national body???
Group 2
Topic: Counselling

Training
There is a need for consistent training across the board
• Whole range of counsellors
• Talk the same language
• Physicians, nurses, other clinicians

Solution
Visual examples, pictures of test results in the package insert
• Need to be able to explain to patient that this is a preliminary result - odds of being a true positive
• Negative test results are not considered here - handled same as standard testing
• Standardization of training
• Whole concept of counselling shouldn’t change from standard to rapid testing
• Training has to be centered on the how between test and being given result
• “Rapid” testing doesn’t mean that it should be rushed into
• Pretest versus waiting period versus post test
• Counselling has to be adapted to this scheme
• Give patients the option of getting the result when they want it
  S  Judgement of test practitioner
• Option of an instant test is appealing to some populations
• Who do we determine can have these tests?
• 2 settings: Long term relationship with patient (likely to come back for result); (more common) - patient with high risk of being HIV positive
• Only come in to get status (decrease chance of follow-up)
• Counselling will be different for 2 pop-ins
• Data shows (in Ontario) that there is a high rate of return with high risk patients who go to anonymous test clinics
• Setting can determine reason why patient is seeking testing
• What is the reason patients want rapid testing
• Who should develop training? CMA, provincial medical bodies
• Consider specific issues surrounding rapid testing
• Evaluation mechanism for counselling
• General principles and look at some specific cases
• Jurisdiction specific and institution specific
• Standard testing allows a lead time (preparation time before results are given)
• Therefore onus on counsellor to be able to immediately respond to patient reaction
• Counselling sessions are not cut and dried in terms of time frame
• What will the clinics who use these Kits do - have a plan in advance
• Resources for counselling
• We don’t know how the Kits will be received
• In Québec, counselling is used primarily for prevention
• What will happen when rapid testing comes in, will the focus be pulled away from prevention and more on doing the test
• Concern over negative result negative impact to patient/what does a negative result mean
• Counselling has also to be directed to negative results
• Patients who come in for a “quick fix” result will be encouraged
• Delay in waiting for result in standard test is a “*” because it encourages change in behaviour while waiting for result
• Counselling must not result in a sense of false security
• Emphasis on getting the patient to understand that a negative result means a chance to change behaviour
• In certain cultures, will rapid testing encourage husbands to send wives in for testing (when suspecting of an affair)
• Effect on coercive behaviour
• What is included in “point-of-care” ; i.e. HIV clinic people on the street etc.
• Counselling recommendations may need to differ for marginalised populations
• Training will depend on where counselling will take place
• Rapid testing may be desired in certain situations (patient groups, settings) - what are the indications
### Group 3

**Topic: Testing practice**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
</table>
| 1. - Define patient populations where rapid test should/should not be used | S Provinces define  
S Part of Kit application  
S Expert panels advise  
S At least level of government (HC) recommendation  
S Don’t rigidly define pop-ins  
S Need to consider provincial reimbursement ($) |
| S E.G. blood donors, routine prenatal - no benefit rapid test since blood analysed for other things  
S Less reliable for low risk  
S Clinician needs to know prevalence (PPV) | |
| 2. - Inconsistent terminology (e.g. reactive, non-reactive, positive, negative) | S Pretest counselling: negative screen = negative standard if positive = define next steps  
S Make sure word guidelines to address |
| S For screening tests, standard test | |
| 3. - How to devise guidelines for counselling? | |
| 4. - What to do with patients that demand test? (From pop-ins where wouldn’t do rapid test) | |
| 5. - Provinces may be slow to reimburse or restrictive (impacts availability) promotes “testing markets” | S Provincial lab could control Kit distribution  
S Provinces “fight” not feds |
| 6. - Stereotypes of risk to women and unknowns (therefore not easy to categorize risk for women) | S Urgency versus honours |
| 7. - Kits for non-N.A - strains HIV | S Strain detection needs to be defined  
S Label for approval |
| 8. - Specify practice is for professional use not home use | S Manufactures should be responsible (e.g. in labelling)  
S Log of record (where sell distribution)  
S Tester submits record of Kit use to provincial lab — discourage out of bounds-use |
<p>| 9. - Impact of approval Kits by Canada and use in other countries | |
| 10. Can have same person do sample, test and counselling | |</p>
<table>
<thead>
<tr>
<th>Issue</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. Access to information</td>
<td>• Provincial designate where use Kits and get information out/reach to main users</td>
</tr>
</tbody>
</table>
| 12. Need for caution/or warning — implications of receiving informative test — scheduling of test | • Contingency plans  
• Make follow-up appointment — plan how to deal in interim |
| 13. Disposal of Kit components | • “Sharp containers”  
• General provincial guidelines — bio-hazards |
| 14. Issues on where test is conducted — e.g. van | |

**Testing Practice**

1. Formal training of testers — audit performance
2. Quality assurance program to address new issues raised by R. tests
3. Certification of testers — can this requirement be written into regulations?
4. Provinces should use R. Kits in defined circumstances
Group 3
Topic: Testing performance

Desirable Characteristics of the Rapid, Point-of-Care test:
1. Must be as good as HC approved EI test — irrespective of body fluid — screening test
2. High sensitivity — don’t want to miss true positives — accept a “low” false positive rate
3. Good overall performance — balance sensitivity and specificity
4. Some would consider a slight trade-off in “spec” — below standard
5. Still do confirmatory testing on positive rapid test
6. True performance versus field performance — will test perform in field? — recognize that field use may be very rudimentary
7. Fool-proof use of equipment/test Kit — e.g. Merlin — Kit design — fool-proof
8. Simplicity — no treatment or preparation of sample
9. a) Kits stable at room temperature
    b) Long shelf life
10. Quality assurance programme
11. Upper time limit — 15-20 minutes
12. 100% of those tested will get answer — benefit higher follow-up than standard — may be a track-off consideration for other test process — parameters — to assess performance
13. Not sure if positive screen will increase follow-up for repeat confirmatory testing
14. Need to know how RT Kits work with sero-converters in high risk patients — user must know how it performs compared to standard
15. Performance characteristics available to users — validated P.C. so are clearly understandable to all users
16. Information Kits for users useful, easy to understand
17. Design work: type lancet used — type bulb/pipette — consistent delivery clear internal controls — what controller e.g.:
   • performance of Kit
   • positive control — all conditions critical — for adequate sample — correct amount whole blood
18. Able to detect HIV 1 & 2 and major “clade” — e.g. sero-converters
Group 4
Topic: Counselling

Counselling
Focus statement: What issues and concerns are raised by HIV point-of-care testing?

Issues / Concerns
- Counselling of positive results is very similar
- Time to process the question of testing
- Pre test counselling
- Post test counselling
- Offer choice
- Look at positive/negative pre test

Pre-Test
- Integrate information of relative performance
- Elements of choice — rapid test today of standard test
- Assessment of personal capability to deal with result
- Not enough time between results and counselling
- Rapid test could be used as an excuse to shorten the pre-test counselling — or comprise the counselling
- Free up time of counselling — 1 visit process rather than 2 visit process
- Single visit may be assumed to be cost effective
- Guidance on how to do the test and counselling — rapid versus standard test guides

Solution
- Increase the access to practitioner who may not understand the implication of testing
- Post-counselling issue
  - no time for patient to think
  - no time for Dr. to think
- In some population there is a history very low rates of return
- Counsellors don’t follow available guidelines
- What the potential harm of the new technology because of problems with counselling
- Physician may not want to do testing in office
- Various sites and expertise
- P -of-C testing and counselling are related
- Labelling on package inserts could be used

Post-Test (Phase)
- Negative result post-test counselling should not be affected: there is still a need to do a thorough job of counselling
- Positive — how to give someone a positive result?
- Risk of less of diagnosis because of confirmation testing
- Rapidity of test not diminish post-test negative result
- Get standard advice to client — professional education
- Big challenge: giving test results when the physician/counsellor has a lack of knowledge of the person and their history
- Legal liability of counselling
- There is a need for greater research on legal liability
• Agreed upon standards of practice — Provincial
• Phased implementation
• Only done in places where there are good pre and post test counselling
• Identified sites can be used to gather more information for future use
• Greater consultation with people who are HIV positive and people who do testing and counselling
• Do more field trials

Solution (pre-test)
• Need to define a mechanism
• Good performance
• Take time
• Professional education on the importance of good pre-test counselling
• Recommendation to Provinces
• Deploy in populations with low rate of return — may improve low rate of return

General Parking Lot
• What are the implications of rapid testing?
• Do not put P-of-C in practice
• To insure good counselling must restrict access to test to places where you know good counselling is taking place

Group 5
Topic: Test Performance

Focus Statement: “What are your expectations with respect to the performance characteristics of the test Kits?”

• Should be as good as the current diagnostic screening tests
• Should not be implemented as a test of record if not as good as the current diagnostic screening test
• How will the results be reported and recorded
• Should be positive and negative controls in every test run
• Want evidence that prove the rapid tests are as sensitive as the current test of records
• They should exceed current tests for shelf-life
• Easy to perform
• Rapid results
• Easy to read
• Minimal hands-on
• Robust assay with temperature, lightening, out-dating
• Cheap
• Assay more like a glucometer reading — numerical output versus colour change
• Idiot-proof
• Minimal equipment required
• High sensitivity in low prevalence populations
• Higher specificity in low prevalence populations
• Assumption — the group does not agree that universal access to rapid point-of-care HIV tests is
### Issue/Concern

<table>
<thead>
<tr>
<th>Issue/Concern</th>
<th>How to Overcome or Minimize</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Where and when the Kit will be used</td>
<td>• Better educate Health Care providers vis-à-vis</td>
</tr>
<tr>
<td></td>
<td>• When to use it</td>
</tr>
<tr>
<td></td>
<td>• How to interpret it</td>
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<tr>
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<td>• Limitations of the test</td>
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<tr>
<td></td>
<td>• Training</td>
</tr>
<tr>
<td></td>
<td>• Protocol</td>
</tr>
<tr>
<td>• Controls over the test Kit itself — i.e. monitoring from lot to lot — high level responsibility</td>
<td>• Quality assurance</td>
</tr>
<tr>
<td>• Public education</td>
<td>• Targeted sub-populations for education</td>
</tr>
<tr>
<td>• Marketing of the test by manufacturer</td>
<td>• Post market enforcement/compliance</td>
</tr>
<tr>
<td>• Post licencing regulation</td>
<td>• Education</td>
</tr>
<tr>
<td></td>
<td>• Post market enforcement/compliance</td>
</tr>
<tr>
<td>• Legal liability for person performing the test</td>
<td>• Professional Regulatory bodies need to address the issue</td>
</tr>
</tbody>
</table>

appropriate
**Group 5**  
**Topic: Reporting**

**Focus Statement:** “What are the reporting issues and concerns related to the HIV point-of-care testing?”

<table>
<thead>
<tr>
<th>Issue/Concern</th>
<th>How to Overcome or Minimize</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Loss of data around surveillance i.e. data around negative testers</td>
<td>• The public health lab system would oversee the implementation of point-of-care rapid testing and would manage it so that all data is collected</td>
</tr>
<tr>
<td>• Significant impact on epidemiological data (6)</td>
<td>• Everyone must work together</td>
</tr>
</tbody>
</table>
| • Lose access to negative specimens (7)                                    | • Perform a follow-up vena-puncture before the rapid test is done  
|                                                                              | • Voluntary follow-up vena-puncture  
|                                                                              | • At risk patients in the window period encouraged to provide specimen                                                                                 |
| • In the absence of a (positive) confirmatory test, there would be under reporting and poor case management and loss of strain sub-typing (8) | • Current regulations require reporting of suspect cases  
|                                                                              | • Track patients using existing data — name, telephone etc.                                                                                              |
| • What is the minimal record of testing that is required to be kept and where (4) | • Define the responsibilities for this                                                                                                                                 |
| • Reporting mechanism for reports (1)                                      | • Define a process whereby positive and negative results get rolled up into a database                                                                  |
## APPENDIX C

### HIV TESTING ISSUES MEETING
(1999, March 29-31, Ottawa)

### LIST OF PARTICIPANTS

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
<th>Address</th>
<th>Telephone</th>
<th>Fax</th>
<th>Email</th>
</tr>
</thead>
<tbody>
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</tr>
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<td></td>
</tr>
</tbody>
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