Training Issues for Cervical Cancer Prevention in Low-Resource Settings

editors
Paul Blumenthal
Sonia Elabd
JHPIEGO, an affiliate of Johns Hopkins University, is a nonprofit corporation working to improve the health of women and families throughout the world.

JHPIEGO Corporation
Brown’s Wharf
1615 Thames Street, Suite 200
Baltimore, Maryland 21231-3492, USA
http://www.jhpiego.org

Editors: Paul Blumenthal
        Sonia Elabd

Printed in the United States of America

TRADEMARKS: All brand names and product names are trademarks or registered trademarks of their respective companies.

Funding is provided by the Bill and Melinda Gates Foundation through the Alliance for Cervical Cancer Prevention. The opinions expressed herein are those of JHPIEGO.

April 2001
# TABLE OF CONTENTS

## WORKSHOP SUMMARY

## WORKSHOP PRESENTATIONS

### Training in Screening Techniques

- **Non-Magnified Visual Inspection of the Uterine Cervix with the Aid of Acetic Acid for the Detection of Cervical Intraepithelial Neoplasia** (Jerome Belinson)  
  
- **Visual Inspection with Acetic Acid** (R. Sankaranarayanan)  

### Training in Treatment of Precancerous Disease

- **Performing and Training for Loop Electrosurgical Excision Procedure (LEEP) and Large Loop Excision of the Transformation Zone (LLETZ) in Low-Resource Settings** (Thomas Wright)  

- **Training in Cryotherapy** (Paul Blumenthal)  

### Training in Cervical Cancer Management

- **Training for Cervical Cancer Management in Low-Resource Settings** (F. J. Montz)  

### Training in Quality Assurance

- **Quality Assurance for Test and Treat Services: Training and Monitoring Issues in Low-Resource Settings** (Lynne Gaffikin and Patricia Ringers)  

## APPENDICES

- **Appendix A: Clinical Gynecologic Oncology Training Program Curriculum and Management Algorithm**  

- **Appendix B: Workshop Participants**  

- **Appendix C: Workshop Agenda**
ABBREVIATIONS

ASCUS Atypical Cells of Uncertain Significance
CECAP Cervical Cancer Prevention
CIN Cervical Intraepithelial Neoplasia
ECC Endocervical Curettage
HGSIL High-Grade Squamous Intraepithelial Lesion
HPV Human Papillomavirus
IARC International Agency for Research on Cancer
LEEP Loop Electrosurgical Excision Procedure
LLETZ Large Loop Excision of the Transformation Zone
QA Quality Assurance
SAFE Safety, Acceptability, Feasibility and Program Effectiveness
SCJ Squamocolumnar Junction
SIL Squamous Intraepithelial Lesion
SPOCCS Shanxi Province Cervical Cancer Screening Study
TZ Transformation Zone
VIA Visual Inspection with Acetic Acid
WORKSHOP SUMMARY

INTRODUCTION

On 15 September 2000, JHPIEGO, in collaboration with the Alliance for Cervical Cancer Prevention, sponsored a workshop to explore training issues for cervical cancer prevention in low-resource settings. Workshop participants included representatives from the Alliance for Cervical Cancer Prevention and other reproductive health professionals from the US and 10 developing countries. (See Appendix B for a complete list of workshop participants and Appendix C for the workshop agenda.)

The objectives of the workshop were to:

- Share experiences among those providing training in techniques for cervical cancer prevention, especially in low-resource settings;
- Gain consensus on training methods, approaches and terminology; and
- Identify training-related quality assurance mechanisms.

ORGANIZATION OF THE WORKSHOP

The workshop opened with an overview highlighting the problem of cervical cancer in developing countries and the importance of prevention. Primary presentations focused on training experiences involved with screening techniques, treatment methods, cancer management and quality assurance mechanisms.

Participants then divided into four discussion groups. In the afternoon, each group reported on its discussion.

Both during the discussion sessions and after each presentation, a variety of observations and recommendations were made and consensus points were reached. Although many of these points do not relate directly to training issues, it is important for trainers and those responsible for organizing training to be aware of these issues. The discussion points and recommendations have been included at the end of the section to which they are most closely related.
CONSENSUS POINTS AND RECOMMENDATIONS

A summary of the main consensus points and recommendations on training issues is presented below.

■ Critical components of training in visual inspection with acetic acid (VIA) should include:
  ■ A standardized set of definitions for test negative and test positive results, and
  ■ As much clinical practice as possible.

■ Training physicians and non-physicians (e.g., nurses) in VIA and cryotherapy is both feasible and practicable.
  ■ Such training is possible in a finite period of time (e.g., 2 weeks) if providers are given adequate opportunities to practice on models and in the clinic.

■ Training in cancer management in low-resource settings is possible, but is likely to be most effective only when:
  ■ The available human and physical resources have been assessed, and
  ■ Training programs have been designed and adapted to correspond to those resources and be sustainable.

■ Training in quality assurance should be integrated into the cancer prevention program so that program supervisors are proficient in the screening methods and treatment techniques being implemented.
TRAINING IN SCREENING TECHNIQUES

NON-MAGNIFIED VISUAL INSPECTION OF THE UTERINE CERVIX WITH THE AID OF ACETIC ACID FOR THE DETECTION OF CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN)

Jerome Belinson
Department of Gynecology and Obstetrics
The Cleveland Clinic Foundation

The Shanxi Province cervical cancer screening study (SPOCCS) in China was designed to determine the true sensitivity and specificity of six screening technologies for pre-invasive and invasive cervical cancer. The objective of the study was to design a cervical cancer screening algorithm for developing countries that was highly sensitive for CIN II, III and cancer, and highly specific for CIN II and III, making it possible to ablate the transformation zone (TZ) without histologic confirmation.

Unaided VIA was included in SPOCCS because of its known potential as a low-cost yet effective screening technique. Prior to beginning the trial, none of the physician participants had any formal, large volume experience with VIA. For VIA, everyone to be involved was required to have experience with colposcopy. This decision was believed to preserve the overall goal of the study and eliminate the need for specific training in VIA.

The technique used for VIA was as follows:

- Acetic acid (5%) was applied to the cervix.
- After waiting 1 minute, the provider performed VIA. A single tungsten bulb in a goose-neck style lamp was used to illuminate the cervix.
- Observations were recorded by quadrant.

For the pilot study, VIA was collectively performed by clinical gynecologic oncology fellows and junior oncology staff, and senior gynecologic oncologists from both China and the US. Instead of formal training, during the pilot phase, the criteria for test-positive
and negative were frequently discussed among the investigators and the examinations were often performed so that “co-examination” and comparison of findings was possible.

By the completion of the 200-patient pilot, the senior investigators were confident that the junior staff and fellows would provide reproducible results from VIA. Even during the full study, there were generally two individuals performing VIA for each patient and discussing their opinion before a firm diagnosis was made. The diagnostic criteria for test-positive or negative results were posted on the wall in clear view of all examiners. In an attempt to shorten the learning curve and avoid specific training, the diagnostic criteria were purposely made similar to colposcopy (see Table 1).

Table 1. SPOCCS Diagnostic Criteria for VIA

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>No visible white lesions</td>
</tr>
<tr>
<td>Low-grade squamous intraepithelial lesions</td>
<td>Pale white lesions, might or might not abut the SCJ</td>
</tr>
<tr>
<td>High-grade squamous intraepithelial lesions (CIN II, III)</td>
<td>Dense white lesions, sharp borders, abut the squamocolumnar junction</td>
</tr>
<tr>
<td>Cancer</td>
<td>Friable mass, irregular surfaces</td>
</tr>
</tbody>
</table>

All abnormal VIA results were photographed, in addition to several normal VIA results, for future educational purposes. During the full study, no feedback occurred during the examination. Each of the physicians, however, maintained a diary of problematic cases to review when the data were tabulated at the end of the study.

All diagnoses were made by quadrants. This planned protocol was thought to create an orderliness to the diagnostic process. The reference standard for our trial was cervical biopsy. Acetic acid 5% was applied to the cervix, colposcopy was performed and observations were recorded by quadrant. Each quadrant of the cervix was classified as normal or abnormal. If a quadrant was abnormal, the data sheet reflected the most severe abnormality within that quadrant. If the examination showed no abnormalities in a quadrant, a biopsy was taken from that quadrant at 2, 4, 8 or 10 o'clock positions on the exocervix at the squamocolumnar junction (SCJ) depending on the quadrant. If there were abnormalities, it was acceptable to take more than one biopsy per quadrant. All biopsies were performed with a bronchoscopy biopsy instrument that has 2 mm jaws and is virtually painless. An endocervical curettage (ECC) was also done for every patient.
In SPOCCS, based on biopsy, VIA had a sensitivity of 71% and a specificity of 74% for CIN II and higher. Sensitivity for CIN III and higher was 79% and for cancer it was 67%. The study provided a potential 7988 quadrants for evaluation, and there was perfect agreement between VIA and colposcopy in 87.6% of the quadrants.

VIA and colposcopy both perform relatively poorly when only a single quadrant is involved. Cytology had the same difficulty because, for biopsy proven CIN II lesions that were limited to one quadrant, the ratio of Papanicolaou smears reported as Atypical Cells of Uncertain Significance (ASCUS) to those reported as high-grade squamous intraepithelial lesion (HGSIL) was higher than if more than one quadrant was diseased. VIA, however, correctly identified 67–100% of the subjects when two or more quadrants were involved. Colposcopy, on the other hand, correctly identified all such subjects.

In this project, the training provided for VIA was minimal and informal yet, based on our experience, the technique of VIA was quite easy to learn, possibly easier than the proper placement of a vaginal speculum, especially in heavier women. The human and financial resources available in any particular country or region of a country will determine who will need to learn VIA. In China, there are enough gynecologists to do the screening, but in other parts of the world, nurses would be more appropriate. In all regions, VIA practiced by non-physicians will be less expensive than other currently available methods or other laboratory techniques under consideration.
A good, comprehensive training program is absolutely essential to provide reliable screening examination using VIA. The objective of VIA is to recognize acetowhite lesions that harbor high-grade CIN II–III and early preclinical, asymptomatic invasive cancer.

A summary of the important components of a VIA training course is listed in Table 2. Both IARC and JHPIEGO have included these components in their training courses.

Table 2. Essential Training Components for Training in VIA

<table>
<thead>
<tr>
<th>TRAINING COMPONENT</th>
<th>IARC</th>
<th>JHPIEGO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anatomy of the female genital tract</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Physiology: Normal secretions, development of TZ, squamous metaplasia</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Pathology: Infection and inflammation, cervical carcinogenesis and its natural history</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Clinical: Techniques of pelvic examination Recognize: normal anatomical components; clinical signs of metaplasia, polyps, leucoplakia; signs of infection and inflammation; acetowhite changes; gross appearance of invasive cancer</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Assessment of provider skills</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Model-based clinical practice</td>
<td>☑</td>
<td>☑</td>
</tr>
<tr>
<td>Use of visual aids (cervical images)</td>
<td>☑</td>
<td>☑</td>
</tr>
</tbody>
</table>

A lack of knowledge of the anatomy and pathophysiology of the female genital tract may affect the way the provider administers and interprets the test. The training course, therefore, should first assist the provider in learning the anatomy, physiology and pathology of the female genital tract, as well as the skills needed to identify significant acetowhite lesions, leading to the early detection of high-grade cervical neoplasia.
A training course should help the provider to recognize and become familiar with:

- the anatomy of the cervix, including the exocervix, endocervix, external os, cervical canal, squamous epithelium, columnar epithelium, SCJ and the TZ;
- the difference between a nulliparous and multiparous cervix;
- squamous metaplasia and its appearance;
- commonly seen variants, including Nabothian cysts, polyps, healed tears, ectropion, inflammation and chronic cervicitis;
- normal and abnormal secretions and discharges, particularly dense, sticky, thick mucus, and their association with physiological functions and infectious diseases of the genital tract; and
- leucoplakia, warts and condylomata.

Eight to ten hours should be devoted to the theoretical aspects of VIA, using quality audiovisual materials. IARC has prepared a simple manual describing those aspects, which is a valuable companion for training purposes.

The theoretical part of the training should:

- Explain cervical neoplasia, their causal relationship with human papillomavirus (HPV) infection and other risk factors for cervical cancer.
- Describe the natural history of CIN and invasive cancer, and the cytological and histological criteria for their recognition. It is also important to emphasize how content of nuclear DNA material and nuclear proteins increases as the CIN progresses.
- Explain the conventional methods of diagnosis and treatment.
- Describe how acetic acid reacts with nuclear proteins and the pathophysiological basis of the acetowhite appearance.
- Emphasize the role of non-neoplastic conditions, such as immature squamous metaplasia and chronic infections causing non-significant acetowhite lesions. It is important to stress that significant lesions are those dense acetowhite lesions located near the SCJ in the TZ.

- Help providers learn the clinical signs of invasive cervical cancer to give them the necessary skills to recognize and differentiate between early, preclinical and advanced invasive cancers.

After the theoretical training, providers should be introduced to the equipment and consumables required for a proper speculum examination of the cervix and positioning of the woman for vaginal speculum examination. The preparation of 4–5% dilute acetic acid as well as disinfectants should receive attention. The techniques for performing a comfortable and satisfactory speculum examination and for performing VIA should be demonstrated. A clear description of the procedures and definition of outcome categories of VIA are very important in this context.

A minimum of 24 hours of practical demonstrations in vivo, spread over 3–5 days, is essential. These sessions should involve around 150 women, aged 30–60 years, who are in good general health. Drawings and photographic or digital atlases should be considered supplementary to demonstrations in vivo and not as alternatives. In vivo demonstrations will allow realistic appreciation of the normal, as well as abnormal, findings discussed in the theoretical sessions.

The VIA training should also incorporate exposure to techniques of obtaining adequate and uncrushed biopsy specimens from abnormal areas. The importance of using biopsy punch forceps with sharp cutting edges should be emphasized. Procedures for how to clean and maintain the equipment should be thoroughly explained.

There is a learning curve in providing VIA competently. Whether the provider’s skills in performing VIA improve depends on: (I) the innate interest of the provider, and (ii) the increasing number of screening examinations performed. The proportion of false positive test outcomes significantly decreases with most well-trained providers after they have examined over 500 women. In studies that were conducted in India, there was a steady decline in the proportion of test positive rates from 35% to around 15% without significant loss in sensitivity to detect high-grade lesions (Table 3). Documenting test positivity rates, sensitivity and false positivity
rates through external and self-monitoring of providers may provide objective parameters to assess the skills of the provider and the outcome of training.

Table 3. Outcome of VIA by Blocks of 2000 Participating Women in Calcutta, India

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>1–2000 WOMEN</th>
<th>2001–4000 WOMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIA test positivity</td>
<td>30.4%</td>
<td>10.8%</td>
</tr>
<tr>
<td>Sensitivity to detect CIN II</td>
<td>65.7%</td>
<td>62.2%</td>
</tr>
<tr>
<td>Specificity</td>
<td>70.9%</td>
<td>90.2%</td>
</tr>
<tr>
<td>False positive rate</td>
<td>29.1%</td>
<td>9.8%</td>
</tr>
</tbody>
</table>
GROUP DISCUSSION ON SCREENING TECHNIQUES

The presentation of training issues portrayed two very different approaches to VIA training, admittedly in projects with differing objectives. A summary of the two training experiences is presented in Table 4. The JHPIEGO training experience to date was raised during discussion, and the overall impression was similar to that of Dr. Sankaranarayanan.

Because the majority of people being trained to provide field services are from the nursing corps, less emphasis has been placed on attempting to develop a thorough understanding of physiologic and pathophysiologic processes (e.g., squamous metaplasia, HPV pathophysiology) and more emphasis on need-to-know information, such as actual recognition of likely abnormal areas and counseling about offering treatment.

Table 4. Summary of Training in Screening Techniques

<table>
<thead>
<tr>
<th>TRAINING IN SCREENING TECHNIQUES</th>
<th>BELINSON</th>
<th>SANKARANARAYANAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadre of trainees</td>
<td>Doctors</td>
<td>Nurses/doctors/biology graduates</td>
</tr>
<tr>
<td>Formal training provided</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Standard of results</td>
<td>Discussion</td>
<td>Individual</td>
</tr>
<tr>
<td>Categories of criteria</td>
<td>Adapted from colposcopy</td>
<td>Specific to VIA based on density of acetowhite change</td>
</tr>
<tr>
<td>Assessment of competency</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

CONSENSUS POINTS AND RECOMMENDATIONS FOR SCREENING TECHNIQUES

- In order to eliminate some of the confusion with differentiating between positive and negative results, a positive VIA test result should be defined as a lesion that is located close to the SCJ and is distinct, dense (opaque) and acetowhite.
The indeterminate result category should be eliminated. Results should be classified as positive or negative. If a provider is uncertain about the results, s/he should report the result as positive because, to date, both public health authorities (Ministries of Health) and clinicians in developing countries feel that offering treatment to potentially positive cases is programmatically more desirable than the recovery or avoiding “overtreatment.”

Alternatively, in some settings if a provider is not certain about the VIA results, s/he could prescribe antibiotics and ask the woman to return at a later date to see whether a lesion still appears. Different approaches may need to be adapted based on the country setting and prevailing public health attitudes.

The classification of an “unsatisfactory” test should be eliminated. If the SCJ cannot be completely visualized, the presence or absence of a characteristic acetowhite lesion should determine the examination results.

Individual programs will adapt treatment recommendations consonant with their needs and attitudes. The recommendation in the JHPIEGO manual of not offering immediate treatment to women with disease that extends beyond visualization into the cervical canal and offering referral for more complete assessment or treatment seems reasonable.

Although women can develop precancerous lesions before the age of 30, countries should assess their own age-specific rates of cervical cancer and its precursors to decide whether screening younger women would have a public health benefit. After menopause, the SCJ is more difficult to see, and therefore makes detection of cervical cancer and precancerous lesions using VIA in women over 45 years old less practicable. Instead of screening all reproductive age women, the JHPIEGO reference manual states that women between the ages of 30 and 45 should be screened and “because cervical cancer rates peak between the ages of 40 and 50, testing should take place during the ages in which detecting a precancerous lesion is most likely.”

---

It is unclear what minimum training providers need to become competent to provide LEEP. In the US, gynecologists often learn how to perform the procedure during a 2-day training course. It is suggested that gynecologists perform the first two or three procedures in an operating room under general anesthesia or while they are observed by an experienced clinician.

Although many family practitioners and nurse practitioners in the US perform colposcopy and cryosurgery, only a few are comfortable with performing LEEP. Most providers, therefore, refer HGSIL to obstetrician/gynecologists.

The barriers to training non-surgeons to perform LEEP include:

- LEEP appears much more invasive than cryosurgery.
- When serious complications occur, they may be severe, including major bleeding.
- LEEP equipment and followup visits are expensive. Some steps can be taken to decrease the cost, but LEEP is still likely to be more expensive than cryotherapy.

Ob/Gyn residents were trained in the US through behavior modeling. Many second-year residents, who were performing eight LEEP procedures in a year, did not feel comfortable performing the procedure. By the third year, however, the residents were competent and comfortable performing LEEP.

The optimal training approach would provide a didactic course that consists of several days of standardized curriculum and behavior modeling for an appropriate number of cases.

A training course should include the following:

- Discussion of pathobiology and management of squamous
intraepithelial lesion (SIL),

- Discussion of safety issues and theory,
- Lectures on equipment and technique,
- Hands-on practice with inanimate objects to simulate the procedure, and
- Videos of case presentations on complications.

There are several limiting factors for using LEEP/LLETZ in developing countries. Followup visits after surgery, which are required at 1, 4, 6 and 12 months, can be very costly, often more expensive than the procedure.

The cost of the LEEP equipment may be prohibitive for developing country use. LEEP requires more equipment and consumables than cryosurgery and is usually performed in a mid-level facility or a surgical procedure room.
In comparison with other methods of treatment for cervical precancer, the relative ease with which providers are able to learn cryotherapy is often cited as one of its programmatic advantages. Although different cadres of providers have been trained to perform the procedure, the nature of the training provided has not been routinely described in the literature. In the US and most other countries, cryotherapy training is usually provided as:

- Individual preceptorships undertaken by a mid-level practitioner with a mentoring physician, or

- A component of residency training wherein the resident may work with either a senior resident or attending (supervising) faculty member.

In either situation, the training tends to be conducted according to the mentor’s preferences, often with considerable variation in what is taught, and also occurs over an extended period of time. For training larger groups of trainees, especially in inservice settings, a standardized training method is needed to provide an intense training experience over a relatively short time period and to obtain a consistent level of understanding and skill among the trainees. With respect to cryotherapy, there has been little recent documented experience in providing this kind of focused intensive training to large groups of mid-level providers.

As part of a cervical cancer prevention demonstration project undertaken in Roi-et Province, Thailand, 12 nurses (with a variety of nursing backgrounds) received training in VIA and cryotherapy. The purpose of this project was to assess the safety, acceptability, feasibility and programmatic effectiveness of performing VIA as a primary means of cervical cancer (precancer) testing and linking it to the offer of cryotherapy (or referral if indicated) for those who tested positive.
Competency-based training in cryotherapy was thus provided in conjunction with VIA training over a 2-week period and involved:

- Classroom work: principles of cryotherapy, physiology, mechanism of action, review of the literature in terms of safety, effectiveness, expected side effects and management of complications;
- Demonstrations and practice using the ZOE® pelvic model and sausages to which a “live” cryoprobe was applied and the sausage frozen; and
- Practice in clinic among patients test positive by VIA, after competency had been demonstrated on the model.

By the end of this 2-week training, all of the nurses had achieved competency in VIA and cryotherapy according to the learning guide and procedural checklist approach common to all JHPIEGO training courses.

As a quality assurance measure, when the training concluded and the nurses began to apply their skills in the field, a group of physician supervisors trained in both colposcopy and cryotherapy made regular visits to the project sites to oversee the quality of the service being provided. By agreement, if a nurse did not demonstrate competent cryosurgical technique during these visits (on two observed cryotherapy procedures), arrangements were made to retrain that team of nurses at the central training site.

As part of this project, over 700 cryotherapy procedures have been performed by these nurses, working at either the village healthcare center level or a district hospital in this mostly rural area of Thailand. Data from followup at 3 months have been collected for approximately 60% of the subjects and almost all have been followed for at least 1 month. There have been no major complications, and no instances in which retraining was required. Minor complications, mostly limited to complaints of irregular bleeding and abdominal cramping, have been scarce and have occurred in fewer than 4% of subjects.

**Conclusion**

Using competency-based techniques and a standardized training approach, intensive, focused cryotherapy training can be successfully provided to nurses in a developing country in a limited time period.

**GROUP DISCUSSION ON TREATMENT TECHNIQUES**

The presentations on LEEP and cryotherapy training are summarized in Table 5.
Much of the discussion centered on both technical issues related to the treatment procedure and criteria for competency.

The experience required for clinicians to competently perform cryotherapy depends on the level of provider, their previous training and their level of practice. Three to five cases performed competently may be adequate experience, but some countries may have a higher requirement, depending on the cadre of provider (i.e., physician, nurse, midwife), their skill level and regulatory requirements. For example, in South Africa, nurses were required to perform 10 procedures during training because nurses typically do not perform cryotherapy. This number was felt to correlate with likely achievement of competency.

The shape of the cryoprobe was discussed. Consensus was achieved that for purposes of keeping training simple and procedures reasonably safe, a probe with a shallow nipple was desirable. Such probes offer the provider the chance to stabilize the probe centrally at the cervical os, and may minimize the likelihood of stenosis if the nipple is shallow. In addition, providing multiple probes will not only increase costs for the programs, but may increase the chance that the provider will not become confident or competent with using all of them.

Consistent with training in VIA, when offering or providing treatment, providers should focus on the lesions that are on the
Training Issues for Cervical Cancer Prevention in Low-Resource Settings

exocervix rather than on lesions deep in the cervical canal. Providers should refer women for excisional procedures if lesions are in the endocervix.

In order to determine whether a lesion covered more than 75% of the surface of the cervix, a diagram was used that divided the cervix into concentric circles. A four quadrant approach may be easier to use, but it is also possible to have disease in four quadrants that covers a relatively small proportion of the cervix. This issue may need further study.

Before there was a “defrost” feature on the cryoprobe, it was helpful to put a lubricant on the tip (e.g., K-Y jelly®), but now that the probes have a “defrost” feature, it is not necessary to use a lubricant.

CONSENSUS POINTS AND RECOMMENDATIONS FOR TREATMENT TECHNIQUES

- For LEEP, based on experiments to date, the required number of cases should be five, assuming that the provider is competent performing cervical procedures.

- It is likely that, given adequate clinical practice, nurses can be trained to competency in either LEEP or cryotherapy. In general, cryotherapy has been believed to have a shorter learning curve than LEEP, with fewer serious immediate complications. Whether to train providers to perform LEEP or cryotherapy is best determined locally based on local resources and the programmatic setting into which it is being integrated.

- The use of anatomic models in training for either cryotherapy or LEEP is recommended. These models are very helpful and important in reducing patient exposure to providers who perform the procedure poorly or without confidence. As a substitute for a cervix, sausages, beef-tongues and pickles have all been useful.
In low-resource settings, the management of cervical cancer is limited by inadequate facilities, lack of adequate staff trained in staging procedures or surgery for cervical cancer and the limited number of women whose cancer is discovered early enough to make surgical management an option. In turn, this makes training for the surgical management of cervical cancer even more difficult. To be sure, radiation therapy is likely to be the mainstay of management in many developing country settings, assuming that functional equipment is available and that the service is not so overwhelmed with patients as to make attention to detail difficult. Even in such settings, however, training for cancer management must include the transfer of skills necessary to do a thorough clinical staging procedure and, perhaps through multi-disciplinary cancer care clinics, allow the best choices available to be offered to the patient.

Appendix A contains a proposed training program curriculum for clinical gynecologic oncologists and a management algorithm for invasive cervical cancer.

In considering how to best provide cancer management training in low-resource settings, this presentation reviewed a variety of models that could be utilized in low-resource settings and make the best use of both visiting faculty and local staff. An experience in Honduras that was part of a comprehensive cervical cancer prevention intervention will serve as an example of an intervention in which skills were transferred and services are ongoing.
GROUP DISCUSSION ON CANCER MANAGEMENT

The group was concerned about the sustainability of country programs in cancer management. Because many developing countries and governments are struggling to manage the problem of cervical cancer, many people feel that it is not realistic to provide specialist services. The consensus was that programs should focus on primary and secondary prevention (precancer treatment) as opposed to tertiary prevention (cancer treatment). Strategies are needed to convince policymakers in low-resource countries of the value and importance of implementing a sensible, sustainable program for cervical cancer prevention and treatment.

The group also discussed several issues that are important to cancer management programs that should be considered.

Although there are not enough gynecologic oncologists working in developing countries, there may be trained gynecologists, urologists or other types of physicians who can be trained to perform pelvic cancer or surgical procedures. The challenge is to keep these doctors working in their own countries rather than pursuing professional opportunities abroad. It is important that they undergo training that is resource-specific to their countries. There is no reason that surgeons should be trained to do radical pelvic surgery if there are radiation therapy units available.

Regarding ancillary services, a provider should not perform surgery unless the facility has blood, anesthesia, etc. A list of baseline requirements needs to be established for the provision of cancer-related surgery.

Assuming that a person has experience in basic surgical skills, it would take 1 year to produce a surgeon capable of performing radical pelvic surgery. Individuals selected for this path should be mid-career faculty rather than junior faculty.

It may be better to build surgical capacity for simple excision procedures and then build the capacity for advanced cancer management.

As cancer management programs are implemented, a program devoted to palliative care should be implemented and integrated into the overall program.
CONSENSUS POINTS AND RECOMMENDATIONS FOR CANCER MANAGEMENT

- A country assessment of the skills required to perform radiation therapy and surgery, as well as the available facilities, should be performed prior to establishing a cancer management training program. By doing this assessment, program staff can determine whether radiation therapy or surgery should be emphasized and will know the skill levels among those proposed for training. If resources are limited (given that in all of sub-Saharan Africa there are only five radiation therapy units), however, it may not be best to emphasize radiation therapy. Although training to competency in radiation treatment is not difficult, availability of resources may dictate having to choose one kind of treatment over another (surgery versus radiation).
Quality assurance (QA) involves continuous monitoring of relevant quality of care indicators in a particular service delivery setting and the resolution of identified problems. For test and treat VIA-based cervical cancer prevention services, care can be broken down into five domains:

- overall service,
- counseling,
- testing with VIA,
- clinical decision-making, and
- treatment with cryotherapy.

In the context of JHPIEGO’s SAFE (safety, acceptability, feasibility and program effectiveness) projects, indicators of the overall service include recruitment rates and initial and final followup visit rates. In terms of the counseling domain, indicators include: the proportion of women receiving counseling in all important points (covered during training); the proportion of providers covering all of these points during supervised routine service delivery; and the proportion of patients adhering to home care requirements. The test-positive rate and the proportion of providers able to delineate the extent of the acetowhite lesion are two indicators of the quality of VIA testing. The proportion of providers making appropriate case management recommendations (relative to the project clinical protocol) is a key indicator in the clinical decision-making domain. Indicators of the quality of cryotherapy treatment include cryotherapy rates, minor and major complication rates, rates of anticipated side effects and problem visit rates (the latter is also an indicator of the quality of counseling).
Data to measure quality of care indicators for the SAFE Project derive from a variety of sources. These include participant intake forms, supervisory checklists and project monitoring forms. For a QA system to lead to appropriate action, target indicator values should be established as a priority, above or below which (depending on the indicator) action to investigate and resolve possible problems is warranted. Target indicator levels for a particular service delivery setting need to be established considering the characteristics of the local population and the clinical guidelines followed during training, and with an understanding of the latest scientific literature. The frequency with which changes in indicator values need to be measured depends on a number of factors including the frequency with which data can reasonably be collected and processed and the likelihood that clinically meaningful changes will occur during a specified time period (versus random fluctuations in the data).

For the SAFE Project in Thailand, for which a QA system has been in place for almost 8 months, intake forms are collected on a daily basis and project monitoring forms are collected and forwarded to the incountry project office on a weekly basis. Supervisory visits are scheduled bimonthly and supervisory reporting forms are returned to the central office after each visit. Incountry project staff manually review the data on an ongoing basis and copies of relevant data are forwarded to the JHPIEGO Cervical Cancer Prevention (CECAP) Program office via hard copy and electronic file transfer on a biweekly basis. Recommended actions to investigate potential problem areas are made by both teams and results of all investigations are discussed via phone or e-mail, as needed.

As an example of how the QA system can identify potential problem areas, an analysis of QA action thresholds (Table 6) at week 6 of the project revealed variations in provider-specific cryotherapy rates (one of the providers had a treatment rate more than 20% above that of all other providers). With this information, a supervisory team was dispatched quickly to where that provider was posted to assess her/his skills/competency level, and provide additional training if needed. Although this action was possible because the QA system was in place, identifying deviations from “the normal” was difficult to do in a timely fashion because establishing baseline averages requires sufficient data (thus time) to be meaningful. As this example demonstrates, the use of a QA system, while contributing to success, also poses challenges. These need to be considered before expanding test and treat services outside the context of a demonstration project.

<table>
<thead>
<tr>
<th>QA ACTION THRESHOLD</th>
<th>RESULT</th>
</tr>
</thead>
</table>

Table 6. Sample QA Action Thresholds
### Training Issues for Cervical Cancer Prevention in Low-Resource Settings

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIA test positive rate</td>
<td>&lt; 10% or &gt; 30%</td>
</tr>
<tr>
<td></td>
<td>&gt; 20% difference from overall average and running average for that clinic</td>
</tr>
<tr>
<td>Referral rate</td>
<td>&gt; 20% women</td>
</tr>
<tr>
<td>Refusal rate</td>
<td>&gt; 20% women eligible for immediate treatment do not consent</td>
</tr>
<tr>
<td>Cryotherapy rate</td>
<td>&gt; 20% deviation from test positive rate</td>
</tr>
<tr>
<td>Minor complications</td>
<td>&gt; 5%</td>
</tr>
<tr>
<td>Major complications</td>
<td>&gt; 1%</td>
</tr>
<tr>
<td>Loss to followup at initial followup visit</td>
<td>&gt; 20%</td>
</tr>
</tbody>
</table>
GROUP DISCUSSION ON QUALITY ASSURANCE

Just as a QA mechanism has been incorporated into cytology screening programs, cameras could be used to record a supervisory visit and give feedback to the providers.

It may be necessary to apply a “high-tech” QA mechanism to a low-tech test and treat approach because a high standard of quality is desirable. Countries need to define their own standards for QA according to costs.

When a set of indicators is established, not all of them have to be covered all of the time. QA has to be high-quality now, but may not need to be as intense later. Just as for cytology, people performing the screening should get feedback on cases they have referred for treatment. The program should try to ensure that results are both reliable but accurate.

The evidence shows that programs with at least a 70% coverage rate of all women have had a measurable effect on the cervical cancer rate. It takes a long time to see the effects of cancer screening. Randomized controlled trials, which are being conducted in India, need to be large and are difficult to do.

CONSENSUS POINTS AND RECOMMENDATIONS FOR QUALITY ASSURANCE

- Although VIA appears to demonstrate the qualities of a practicable, practical test, some concern remains about the overall efficacy of reduction of high grade cervical disease by cryotherapy performed by nurses. Ongoing studies should provide response to some of these concerns in the future.

- Ultimate efficacy rates (cancer mortality reduction and reduced incidence) need to be studied before a recommendation can be made about VIA and cryotherapy. It may not be cost-effective to do all this training for less than a 50% reduction in cases. Even without such evidence, representatives from some developing countries stated that the test and treat approach may still be worthwhile because it is better than doing nothing and does not appear to be harmful.
Although the technical evidence and tools to prevent and/or treat cervical cancer can be programmatically provided, the advocacy has to begin in-country. The information on whether linking the testing and treatment is effective and practicable must be made available after brief but intensive training, and the results of such programs are awaited. Regional workshops, designed to orient policymakers, opinion leaders and clinicians to cervical cancer prevention programs appropriate to low-resource settings, may be a first step in generating support for advocacy and regional or local project implementation.
INTRODUCTION

This curriculum was developed by the Kelly Gynecologic Oncology Service, Departments of Gynecology and Obstetrics and Oncology of the Johns Hopkins Hospital and Medical Institutions.

The following text is a proposed training program to develop clinical gynecologic oncologists who have mastered the necessary skills to meet the Gynecologic Oncology needs of an under-served developing country population.

Although the graduate of this 1-year program (hereafter called the “graduate”) should be conversant with the depth and breadth of the Discipline of Gynecologic Oncology as outlined in the “Guide to Learning in Gynecologic Oncology” developed by the Division of Gynecologic Oncology of the American Board of Obstetrics and Gynecology, Inc., summer 1997, it is anticipated that the graduate will have only mastered a segment of the information outlined in that guide. The segment that should be mastered focuses on the skills needed to care for the affected at risk population in the local or regional community.

OBJECTIVES

The Terminal Objectives of the curriculum are:

1. The graduate shall have mastered the essentials of screening and prevention of cervical cancer especially considering local resources and capabilities.

2. The graduate shall have an intimate understanding of the anatomy and applied physiology of the pelvis and abdomen as applicable to the management of gynecologic disease.

3. The graduate shall have mastered the performance of:
   - type I-IV radical abdominal hysterectomy,
   - pelvic and para-aortic lymph node dissection,
   - non-continent urinary diversion,
- diverting colostomy, and
- diverting ileostomy.

4. The graduate shall have a full and thorough understanding of the principles and practices of radiation therapy. The graduate should be able to manage radiation-induced complications.

5. The graduate shall be able to describe the anatomy of the cervix.

6. Choice of Treatment: The graduate should be able to discuss the available methods of evaluation and management of malignant disease in all groups of patients. Some examples of the types of problems with which the graduate should be familiar are listed below.

7. Cervix: The fellow should be able to discuss available methods of evaluation and management of:

- Cervical intraepithelial neoplasia.
- Stage IA cervical carcinoma when a biopsy shows:
  - 0.5 mm depth of invasion,
  - 2.5 mm depth of invasion, or
  - capillary-like space involvement with nests of tumor cells.
- Stage IB cervical carcinoma, all cell types.
- Stage IB cervical carcinoma when:
  - a lymphadenectomy shows two positive notes in each obturator, fossa
  - two positive para-aortic nodes are found at the time of exploration for radical hysterectomy, and
  - the same patient has a positive scalene node.
- Stage II, III, IV cervical carcinoma.
- Recurrent carcinoma of the cervix following standard pelvic radiation therapy.
- Recurrent squamous cell carcinoma in the vagina following radical hysterectomy and node dissection.
- HPV sub-typing is positive for types 16, 18 and other types associated with squamous cell carcinoma.
8. The graduate shall be thoroughly conversant with HIV and disease-related process, specifically:

- Transmission
- Prevention
- Pathophysiology
- General management
- Specific management (e.g., gynecologic cancers)
- Unique aspects of surgical care of the HIV-positive patient

REQUIRED TEXTBOOKS

Required textbooks include:


ESSENTIAL OPERATING ROOM EQUIPMENT

- Buchwalter Retractor
- MD Anderson Clamps
- DeBakey pickups/Singley pickups
- Heaney clamps or equivalent
- Electrosurgical generator for electro-coagulation/cautery
- Head light
ACTIVITY SCHEDULE

- Daily bedside teaching rounds with visiting professor
- Daily case review conference
- Three times per week formal didactic lectures based upon specific objectives of each visiting professor
- Continuous surgical procedure performance with gradation of independence and complexity based upon progressive mastering of skills
- Visiting professor/master surgeons will come in 2-week blocks (minimum)

RANGE OF EXPERTISE AMONG VISITING PROFESSORS

- Pelvic surgery
- Cancer surgery
- Pathology
- Radiation therapy
- HIV
- Epidemiology/Prevention/Treatment of precancer
MANAGEMENT ALGORITHM FOR INVASIVE CERVICAL CANCER

The algorithm presented below displays a possible management scheme for patients diagnosed with or suspected to have cervical cancer. It was developed by Dr. Robert Bristow of the Kelly Gynecologic Oncology Service of Johns Hopkins Hospital in collaboration with the Cervical Cancer Prevention Program of the JHPIEGO Corporation. It is tailored specifically to the resources likely to be available in developing countries.

Figure 1. Proposed Management Algorithm for Invasive Cervical Cancer

- Initial patient evaluation by physician with strong suspicion of cancer
- Patients referred directly to radiation oncology
- Biopsy performed if not done previously
- Order staging studies

- Patient presented/examined at MC³ [GYN/Rad Onc/Gen Surg]
  - Assign clinical stage
  - Schedule combined EUA if necessary
  - Treatment disposition

- Stage IA1
  - Conization or Simple hysterectomy

- Stage I A2-IVA
  - Curative Intent Radiation Therapy
    - Stage IA2-IIA: WPRT, CDDP
    - Stage III-IVA: WPRT, EFRT, CDDP

- Stage IVB
  - CDDP palliative WPRT

- MC³ followup schedule
  - Pelvic Exam q 4 months X 24 months
  - CXR at 12 and 24 months
  - Pelvic exam q 6 months X 36 months

- If disease free or without recurrence for 5 years, examine patient annually.

- If disease worsens or recurs, refer for salvage therapy.

- If salvage therapy is neither available nor of likely benefit, refer for palliative care.

---

MC³ - Multidisciplinary Cervical Cancer Clinic
CXR - Chest X-Ray
WPRT - Whole Pelvic Radiation Therapy
EUA - Examination Under Anesthesia
EFRT - Extended Field Radiation
CDDP - Cis-diamminedichloroplatinum (chemotherapy drug)
APPENDIX B: WORKSHOP PARTICIPANTS

Jerome Belinson, MD  
Department of Gynecology and Obstetrics  
The Cleveland Clinic Foundation  
Cleveland, Ohio

Paul Blumenthal, MD  
Medical Director  
Cervical Cancer Prevention Program

Fredrik Broekhuizen, MD  
University of Wisconsin Medical School  
Madison, Wisconsin

Jean-Robert Brutus, MD*  
Haitian Institute for Health and Community Action  
Port-au-Price, Haiti

Hugo de Vuyst, MD  
International Centre for Reproductive Health  
Ghent, Belgium

Anderson Sama Doh, MD  
University of Yaounde  
Yaoundé, Cameroon

Lynne Gaffikin, DrPH  
Director for Scientific Affairs  
Cervical Cancer Prevention Program

Audrey Garrett, MD  
Harvard University  
Boston, Massachusetts

Silvia Bomfim Hyppólito, MD*  
Ceará Federal University  
Fortaleza, Brazil

Martha Jacob, MD  
EngenderHealth  
New York, New York

Jose Jeronimo, MD  
Pan American Health Organization  
Washington, DC

Robert J. I. Leke, MD*  
Royal College of Surgeons  
Yaoundé, Cameroon

Valentino Lema, MD  
University of Malawi

Khunying Kobchitt Limpaphayom, MD*  
Royal Thai College of Obstetricians & Gynaecologists  
Bangkok, Thailand

Noel McIntosh, MD, ScD  
President  
JHPIEGO Corporation

F. J. Montz, MD  
Kelly Gynecologic Oncology Service  
Johns Hopkins Hospital

Behire Ozek, MD  
Turkey Regional Office  
JHPIEGO Corporation

Lydia A. Palaypay, MSN*  
Far Eastern University  
Manila, Philippines

Patricia Ringers, PhD  
Program Manager  
Cervical Cancer Prevention Program

Abdul Bari Saifuddin, MD*  
University of Indonesia  
Jakarta, Indonesia

Harshad Sanghvi, MD  
Medical Director  
JHPIEGO Corporation/MNH Program

R. Sankaranarayanan, MD
APPENDIX C: WORKSHOP AGENDA

15 SEPTEMBER 2000

0900 Welcome and Introduction  
Paul Blumenthal, Cervical Cancer Prevention Program  
Noel McIntosh, JHPIEGO Corporation

0915 Objectives and Expectations  
Paul Blumenthal

0930 Training in Screening Techniques

Non-Magnified Visual Inspection of the Uterine Cervix with the Aid of Acetic Acid for the Detection of Cervical Intraepithelial Neoplasia (CIN)  
Jerome Belinson, Cleveland Clinic Foundation

Visual Inspection with Acetic Acid  
R. Sankaranarayanan, IARC

1030 Break

1045 Training in Treatment of Precancerous Disease

Performing and Training for Loop Electrosurgical Excision Procedure (LEEP) and Large Loop Excision of the Transformation Zone (LLETZ) in Low-Resource Settings  
Thomas Wright, Columbia University

Training in Cryotherapy  
Paul Blumenthal

1145 Training in Cervical Cancer Management

Training for Cervical Cancer Management in Low-Resource Settings  
Frederick Montz, Kelly Gynecologic Oncology Services

1230 Lunch  
Discussion
1330  Training in Quality Assurance

Quality Assurance for Test and Treat Services: Training and Monitoring Issues in Low-Resource Settings

*Lynne Gaffikin, Cervical Cancer Prevention Program
*Patricia Ringers, Cervical Cancer Prevention Program

1415  Discussion of Working Group Reports

1530  Conclusions
Next Steps