Physician Attitudes Toward Dissemination of Optical Spectroscopy Devices for Cervical Cancer Control: An Industrial-Academic Collaborative Study

Eileen Shinn, PhD1; Usman Qazi, PhD2; Shalini Gera, PhD2; Joan Brodovsky MS2; Jessica Simpson, PhD2; Michele Follen, MD, PhD3; Karen Basen-Engquist, PhD, MPH1; and Calum MacAulay, PhD4

1Department of Behavioral Science, The University of Texas M. D. Anderson Cancer Center, Houston, Texas; 2Frost and Sullivan Incorporated, San Antonio, Texas, and MarketResearch.com, Rockville, Maryland; 3Department of Obstetrics and Gynecology and the Center for Women's Health Research, Drexel University College of Medicine, Philadelphia, Pennsylvania; 4Department of Integrative Oncology, Cancer Imaging Unit, British Columbia Cancer Research Center, Vancouver, British Columbia, Canada

ABSTRACT

Background: Optical spectroscopy has been studied for biologic plausibility, technical efficacy, clinical effectiveness, patient satisfaction, and cost-effectiveness.

Objective: We sought to identify health care provider attitudes or practices that might act as barriers or to the dissemination of this new technology.

Methods: Through an academic–industrial partnership, we conducted a series of focus groups to examine physician barriers to optical diagnosis. The study was conducted in 2 stages. First, a pilot group of 10 physicians (8 obstetrician gynecologists and 2 family practitioners) was randomly selected from 8 regions of the United States and each physician was interviewed individually. Physicians were presented with the results of a large trial (N=980) testing the accuracy of a spectroscopy-based device in the detection of cervical neoplasia. They were also shown a prototype of the device and were given a period of time to ask questions and receive answers regarding the device. They were also asked to provide feedback on a questionnaire that was then revised and presented to 3 larger focus groups (n=13, 15, and 17 for a total N=45). The larger focus groups were conducted during national scientific meetings with 20 obstetrician gynecologists and 25 primary care physicians (family practitioners and internists).

Results: When asked about the dissemination potential of the new cervical screening technology, all study groups tended to rely on established clinical guidelines from their respective professional societies with regard to the screening and diagnosis of cervical cancer. In addition, study participants consistently agreed that real-time spectroscopy would be viewed positively by their patients. Participants were positive about the new technology's potential as an adjunct to colposcopy and agreed that the improved accuracy would result in reduced health care costs (due to decreased biopsies and decreased visits). Although all participants saw the potential of real-time diagnosis, there were many perceived barriers. These barriers included changes in scheduling and work-flow, liability, documentation, ease of use, length of training, device cost, and reimbursement by third-party payers.

Conclusions: Barriers exist to the dissemination of optical technologies into physician practice. These will need to be addressed before cervical screening and diagnosis programs can take advantage of spectroscopy-based instruments for cancer control. (Gend Med. 2012;9:S67–S77) © 2012 Elsevier HS Journals, Inc. All rights reserved.

Key words: cervical intraepithelial neoplasia, dissemination, fluorescence and reflectance spectroscopy, optical spectroscopy physician attitude, physician satisfaction.

Accepted for publication November 8, 2011.

© 2012 Elsevier HS Journals, Inc. All rights reserved.

doi:10.1016/j.gendmed.2011.11.004

1550-8579/$ - see front matter
INTRODUCTION

Advances in optical technologies for the detection of cervical cancers and precancers have shown life-saving potential. In vivo optical spectroscopy, including fluorescence and reflectance spectroscopy, has been subjected to formal technology assessment such as biologic plausibility, technical efficacy, clinical effectiveness, patient satisfaction, and cost-effectiveness. Nearly all these reports show better performance compared with white-light scoping in experienced hands.

Despite its superiority, the dissemination of optical spectroscopy into mainstream practice is hardly a given. Many effective technologies take years to diffuse: a meta-analysis by Balas demonstrated that just 14% of all technical innovations will be incorporated into routine medical practice and this small proportion will need an average of 17 years to diffuse. Because passive diffusion is inefficient, the National Cancer Institute recommended that dissemination research be incorporated into the development of new technology.

Theoretical models are particularly useful guides for this challenging task. Rogers’ Model of Diffusion is one of the earliest and most frequently cited models of dissemination (Figure 1). Rogers lists 5 characteristics that increase an innovation’s likelihood of successful dissemination: (1) if the innovation is relatively better than existing technologies; (2) if the innovation is simple to adapt; that is, its complexity; (3) the ease of trying the innovation and discarding it if it does not work; that is, its triability; (4) its compatibility with the potential adopters’ existing needs, values, and past experiences; and (5) the observability of the innovation’s positive results.

In light of its potential to greatly improve the detection of cervical cancer, we collaborated with an industrial group to study the potential dissemination of optical spectroscopy devices in clinical practice, focusing particularly on the technology’s compatibility, triability, and complexity from the vantage point of physicians who routinely screen for and diagnose cervical cancer. A total of 55 physicians were interviewed to identify the benefits of spectroscopy-based technologies and the barriers and critical issues relevant to their adoption in their own clinical practices.

MATERIALS AND METHODS

Study Design

We used a 3-phase study design. In the first phase, we developed a semistructured questionnaire guide with our internal experts and later refined the guide with the scientific advisory board of a private company, Remicalm, Inc., formed to patent and license optical spectroscopy for the use of cervical cancer detection. Once the semistructured questionnaire guide was tested and refined, a series of individual interviews were conducted with 10 representative family practitioners and obstetrician gynecologists (phase 2). Finally, we conducted 3 focus groups across the United States with obstetrician gynecologists, family practitioners, and internists (phase 3) (Figure 2).

Phase 1 Questionnaire Development

As part of an academic-industrial collaboration, a group of academic scientists involved in technology assessment were interviewed and suggested potential barriers to the dissemination of cervical spectroscopy. Separate sessions were held with 2 gynecologic oncologists and 2 gynecologists to further suggest barriers. Feedback from these sessions was used as a basis for a semistructured questionnaire and interviewing guide for scientists at both Remicalm and at Frost and Sullivan, a testing and marketing company contracted by Remicalm to gather information on all aspects of the optical spectroscopy device’s potential for adoption into
mainstream practice. The objective was not to obtain statistically sufficient information for analysis, but rather to characterize the range of opinions and to understand various blocking points that could affect the subsequent focus groups (a Supplemental Appendix listing the phase 1 questionnaire can be found in the online version at doi: 10.1016/j.genm.2011.11.004).

**Phase 2 Discussion Guide**

Frost and Sullivan further developed materials for focus group sessions and elicited feedback from academic scientists at M.D. Anderson Cancer Center. The teams at M.D. Anderson, Remicalm, and Frost and Sullivan agreed on a final version of the discussion guide before the second and third phases of this study. The discussion guide asked participants about current practices in cervical cancer diagnosis, factors in their evaluation of new technologies, and the pros and cons of adopting optical spectroscopy (a Supplemental Appendix listing the discussion guide can be found in the online version at doi: 10.1016/j.genm.2011.11.004).

**Phase 2 Recruitment**

We used Dr. 411, a directory of professional organization membership databases with contact information for various physician groups, to obtain a weighted convenience sample of 10 obstetric gynecologists and family practitioners from a national sample of 500. Because we wanted a sample that was 80% obstetric gynecologists and 20% family practitioners, we weighted the random sampling strategy to obtain 4 obstetrician gynecologists for every 1 family practitioner.

**Phase 2 Interview Procedure**

Interviews were conducted with individual physicians by interviewers employed by Frost and Sullivan (8 gynecologists and 2 family practitioners). Each individual interview lasted 60 minutes. Aspects of each physician’s practice, such as number of Papanicolaou (Pap) smear tests and colposcopic examinations performed each month, were verified. Each physician was shown a presentation about the guidelines for the current management of screening and detecting cervical cancer. Physicians were then shown a presentation of the potential clinical effectiveness of optical spectroscopy for the screening and detection of cervical cancer and were asked a standardized set of interview questions regarding current practices with Pap smear, human papillomavirus (HPV) testing, colposcopy, biopsy, ThinPrep cytology, attitudes toward new technologies, importance of real-time results, and factors affecting adoption of optical spectroscopy into their clinical practice (eg, reimbursement from insurance companies, cost, and training needs).

**Phase 3 Recruitment**

Focus groups with primary care physicians and obstetrician gynecologists were recruited in 3 different cities in the United States. Focus groups were done in Bethesda, Maryland; Rosemont, Illinois; and Santa Clara, California.
Phase 3 Focus Group Procedures

Focus groups were conducted at national meetings of family practitioners, obstetrician gynecologists, and primary care internists. The discussion guidelines had the following objectives: (1) characterize physician adherence to cervical cancer screening guidelines; (2) study the influence of real-time cervical diagnoses from 3 perspectives (ie, patient, physician, and payor); (3) establish interest in real-time diagnosis; (4) establish interest in optical technologies making cervical diagnosis; (5) present spectroscopy and spectroscopic approaches (ie, point probe spectroscopy that touches the tissue, large field of view spectroscopy that sees the whole cervix at 3-fold magnification, and their combination); (6) explore adoption of optical spectroscopy; (7) discuss acquisition scenarios; and (8) characterize the overall reception to such devices.

RESULTS

Phase 1 Sample and Factors identified as Salient Issues in the Dissemination of Optical Spectroscopy

The sample questions generated by study group included questions of length of practice, familiarity with cervical screening and diagnostic guidelines, number of female patients seen annually, the age range of patients seen, the number of Pap smears obtained annually, the number of colposcopies performed annually, if the physician treated cervical lesions or referred them for treatment, and if treatment was conducted what treatments were conducted and how many annually.

Phase 2 Sample

The recruitment of the 10 physicians, randomly sampled from 500, yielded 8 gynecologists and 2 family practitioners. These physicians had been in practice 14 to 31 years and were recruited so that equal numbers of those in solo, single specialty, and multiple-specialty practice settings were represented. As seen in Figure 3, most of the sample physicians practiced near the site in which they trained. Figure 3 also shows the geographic diversity of the sample.

Phase 2 Reaction to Current Screening Guidelines

The 10 physicians followed the guidelines currently approved by both the American College of Obstetricians and Gynecologists and American Academy of Family Physicians. All 8 obstetrician gynecologists performed colposcopy and cervical treatments, but the 2 family practitioners preferred to refer their patients to gynecologists for colposcopy. All 10 physicians routinely obtained liquid cytologies for Pap smears. Seven of 10 physicians reported that they performed routine HPV testing only in women <30 years old. All performed HPV testing when cytologic abnormalities were present, per guidelines. When asked about barriers to the implementation of current accepted technologies all 10 agreed that: (1) liquid cytology was deemed expensive, (2) HPV testing was expensive, (3) the waiting period for both cytology and HPV testing was too long, and (4) colposcopy was nonspecific and led to many unnecessary biopsies and/or procedures. All physicians agreed strongly that the time and cost involved in the evaluation made patients anxious. Both family practitioners commented that they would be more likely to adopt spectroscopy if it was first adopted by gynecologists. There was disagreement on what should be the gold standard for cervical cancer diagnosis: a Pap smear test result, an HPV test, or colposcopy. None in the group insisted upon colposcopically directed biopsies as a gold standard. The doctors...
seem confused about current evidence-based screening guidelines and these results point to the evolving status of the HPV test in terms of diagnosing.

**Phase 2 Reaction to Changes in Medical Practice**

All 10 physicians agreed that guidelines from the American College of Obstetricians and Gynecologists and American Academy of Family Physicians were the most influential source of change in their practice of medicine, compared with: (1) reading peer-reviewed journal articles, (2) hearing about the product from patients, (3) hearing about the product from industry representatives, (4) hearing conference presentations, and (5) learning about the product from fellow physicians. They were less likely to trust product reviews in trade magazines and hearing about a product from patients, but were willing to think about results from sales representatives at conferences and hearing discussions and presentations by colleagues at conferences. Real-time diagnosis was appealing to the group because it would accelerate evaluation, decrease patient anxiety, decrease costly and unnecessary biopsies, and decrease follow-up visits.

**Phase 2 Reaction to Optical Spectroscopy for Cervical Diagnosis**

Each physician was shown a brief presentation about optical spectroscopy using 3 separate devices: (1) a probe that touches the cervix, (2) an imaging device that takes images of the entire cervix at 3-fold magnification, and (3) a combined device using both approaches. Physicians commented that these devices could be useful adjuncts to colposcopy and they could envision real-time diagnosis being helpful when colposcopy was indeterminate. All believed it was critically important for liability that documentation be provided and included in the medical record. Key purchasing factors included insurance reimbursement, the device paying for itself within a year, and consensus among their partners before purchase. Key adoption factors included device ease in implementation, a site visit by company representatives, and a clear reimbursement strategy.

**Phase 3 Focus Groups’ Recruitment Results**

The larger focus groups were carried out in April 2007 in Santa Clara, California; Bethesda, Maryland; and Chicago, Illinois. **Table 1** describes the location and composition of the focus groups. The sample’s number of years of practice were assessed in quintiles of 5 years from 0 to 5 years to 41 to 45 years in practice. There were 25 primary care physicians combining family practitioners and internists, and 20 obstetrician gynecologists. The mean number of years in practice for the gynecologists was 16 to 20 years, whereas the median was 20 to 25 years. The primary care physicians’ mean years of practice was 16 to 20 years, whereas the median was 11 to 15 years. The obstetrician gynecologists performed 11 to 90 Pap smear procedures per week (mean = 50, median = 50), whereas the primary care physicians performed <10 to 30 Pap smears (mean = 10, median = 10). All of the obstetrician gynecologists reported performing colposcopy, whereas only 1 primary care physician performed colposcopy. The obstetrician gynecologists performed <2 to 10 colposcopies per week (median = 3).

**Phase 3 Focus Groups’ Reaction to Current Screening Guidelines**

When asked about practice guidelines, most followed the American College of Obstetricians and Gynecologists and American Academy of Family Physicians and were familiar with the American So-

---

**Table 1.** Results of the recruitment, interviews, and locations of the larger focus groups.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Obstetrician Gynecologist</th>
<th>Family Practitioner</th>
<th>Internist</th>
<th>Total No. of Doctors</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/19/2007</td>
<td>California</td>
<td>6</td>
<td>2</td>
<td>7</td>
<td>15</td>
</tr>
<tr>
<td>4/21/2007</td>
<td>Maryland</td>
<td>8</td>
<td>4</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>4/23/2007</td>
<td>Illinois</td>
<td>6</td>
<td>4</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45</td>
</tr>
</tbody>
</table>
American Society for Colposcopy and Cervical Pathology guidelines (Table II). Obstetrician gynecologists tended to perform yearly Pap smears for all patients, whereas primary care physicians as a whole tended to perform screening tests every 3 years in low-risk patients, thus adhering more closely to American Society for Colposcopy and Cervical Pathology guidelines. Some physicians followed up indeterminate results of liquid cytology Pap smears, HPV testing, and colposcopy in 3 months rather than 6 months. Like the former focus group, all physicians tended to use cytology, HPV tests, and colposcopy.

### Phase 3 Focus Groups’ Reaction to Changes in Medical Practice

During the discussion, the physicians agreed that key opinion leaders would be an important source for information about changing their practice of medicine in this group, especially regarding the role for optical spectroscopy in the screening and diagnostic paradigm. Questions were raised as to whether or not spectroscopy had the potential to replace cytology, or the HPV test, and/or colposcopy. Other questions raised were: How would one deal with the endocervical canal? How would one prepare to use the device, discuss the results, and possibly treat the patient, all in 1 session, in a time-efficient manner?

When asked to brainstorm the attributes of the perfect screening and diagnostic device, the physicians prioritized device accuracy at the top of the list, defined as a metric using both sensitivity and specificity. However, when asked about trade-offs between sensitivity and specificity, it was noted that participants’ level of understanding was insufficient as to be of great value in the analysis.

Also important was patient and provider safety and patient comfort. Others commented that the whole exam should not take more than 10 minutes, and that the ideal length of physician training range from 4 to 8 hours. In general, participants tended to spend a large proportion of time discussing issues of reimbursement, liability, and other economic issues related to their practice.

## Phase 3 Focus Groups’ Reaction to Optical Spectroscopy for Cervical Diagnosis

There was consistent agreement that the patients would prefer real-time diagnosis, and it was noted that one could discuss findings with the patient at that same visit rather than over the telephone. All acknowledged that patients were nonadherent to follow-up colposcopy visits, largely due to inconvenience, forgetting, lack of communication about the importance of follow-up by the provider, lack of understanding of the disease process, psychological distress leading to denial, and fear of the diagnosis and treatment.

Spectroscopy was seen as very advantageous for patients, especially for busy patients who desire to be screened and treated at the same visit. Delivery of a result was also seen as improving the quality of care. Gynecologist and primary care providers were in agreement about the patient advantages and reduction in health care costs. Both groups believed that if the device had higher sensitivity than current screening devices, then patients would be even more
enthusiastic. Accuracy was considered very important to adoption by all physicians sampled.

The largest barrier the physicians saw to the adoption of spectroscopy was how the device would affect work flow; many were concerned that a visit with real-time results would take >30 minutes, if treatment were included, and thus scheduling could be problematic. Because most returning patients were scheduled in 30-minute increments, device visits would potentially need 45- to 60-minute appointments (if a positive screen test was obtained). Unlike the gynecologists, many of the primary care providers believed that if they used spectroscopy instead of the Pap smear test, patients would want a second opinion. This would require a referral to a gynecologist, and thus would not save a visit. A third barrier was that physicians tended to doubt that spectroscopy would replace HPV testing. Fourth, physicians consistently expressed concern that spectroscopy not be an additional cost to the patient but rather one that received reimbursement by third-party payors. Finally, several physicians expressed concern about the device’s inability to sample the endocervical canal.

All physicians acknowledged that spectroscopy could save health care costs and in principal should be considered advantageous to payors. There was universal agreement that spectroscopy could be cost-saving, but there was was mild disagreement about payor acceptance. Some believed payors discouraged in-office procedures, some believed insurers did not support preventive care, and others worried about the entire gamut of reimbursement aspects of use. For example, if spectroscopy were used for screening it was important to the participants that the visit would be reimbursed at the cost of the office visit plus the cost of the Pap test or its rough equivalent, rather than reimbursement for the office visit alone. Others expressed fear that relationships between payors and central laboratories might discourage reimbursement. All physicians believed that if the spectroscopy device had higher sensitivity than the liquid cytology Pap test and HPV screening, then it would probably receive reimbursement. On a related note, some physicians expressed concern that they would be liable for those patients who had results that were falsely negative or falsely positive. However when asked about the high rate of loss to follow-up after colposcopy and if this was a source of liability, the physicians tended to acknowledge this to be true and agreed that the device would decrease current losses to follow-up.

DISCUSSION

Physician acceptance is critical important factor in the speed of technology dissemination. The average time for new technologies to be disseminated is ≥17 years. In this study, the physicians were most concerned about the accuracy of the device, the potential for reimbursement from insurance companies, and the overall cost of the device itself.

Accuracy

Despite their intense interest in accuracy, participants did not display a detailed understanding of the tradeoffs in sensitivity and specificity, the meaning of receiver-operating characteristic curves, nor quantitatively meaningful improvements in sensitivity and specificity.

The Food and Drug Administration states that the accuracy standards for new screening technologies depend on if they will be used as (1) adjunct to colposcopy, (2) replacement for colposcopy, (3) adjunct for triage of atypical squamous cells of undetermined significance, or (4) replacement of the Pap smear for screening. To replace screening, spectroscopy must be better than both the liquid cytology Pap and the HPV test. To replace colposcopy, spectroscopy must be as good as or better than colposcopy in well-trained hands. Existing studies have examined spectroscopy as either adjuncts or replacements for colposcopy. One study has evaluated spectroscopy to have a sensitivity of 50% and specificity of 90% (and performed no better than colposcopy alone), and another, using a different preliminary classification algorithm, shows that spectroscopy has a sensitivity of 95% and specificity of 55%. Participants in this study may have been more familiar with data using the technology as adjunct to colposcopy. With the numbers in the literature so strikingly different, it would be difficult to assume that participants would have already had a positive view of...
spectroscopy. Had we asked about their previous exposure to the literature and to Food and Drug Administration indications, the focus groups might have produced more specific recommendations about the desired levels of accuracy before implementation into their own practices.

Overall, the sensitivity of the Pap (liquid or regular) smear test has been estimated at 53% to 78% and its specificity at 90% to 96%. These studies found the sensitivity of HPV testing was 96% to 100%, whereas the specificity was approximately 90%. Colposcopy consistently shows very high sensitivity so few cancers are missed. However, specificity is low, 50%, resulting in many patients without disease needlessly referred for additional testing and/or treatment. If spectroscopy’s accuracy must be higher than Pap, HPV testing, and colposcopy to be integrated into standard care, its sensitivity should be at least 90% to 95% and its specificity at least 90%. Thus far, no research groups have achieved that level of accuracy with spectroscopic devices. However, studies of research spectroscopic devices suggest that optical spectroscopy has test characteristics comparable to liquid cytology Pap, the HPV test, and/or colposcopy, depending on the selected classification algorithm. Studies are yet to be done using commercial scopes.

None of the existing studies have studied a combined approach of multispectral imaging of the entire cervix plus measurement with the point probe. The combination of the 2 approaches, will we hope allow maximization of sensitivity and specificity. A reasonable gold standard for studies of new technologies is colposcopically directed biopsies of abnormal and normal areas. One should consider endocervical curettage in everyone to rule out any involvement of the canal.

Perceived Advantages and Disadvantages Regarding Reimbursement and Costs

Study participants were quick to grasp the concept that real-time diagnosis would greatly reduce anxiety in patients; allow treatment at 1 visit; decrease the liability that comes from missed appointments; and in general, reduce the costs associated with unnecessary biopsies and treatments. They also saw some barriers. The barriers described in these surveys were: (1) the effect on scheduling, (2) concerns about malpractice, (3) the inability of the current device to sample the endocervical canal, (4) uncertainty about third-party payors’ willingness to reimburse, and (5) device cost. Other advantages mentioned included: (1) patient satisfaction through decreased anxiety waiting for results, (2) the potential to eliminate unnecessary biopsies and loop excisions, and (3) possible earlier detection of lesions.

Limitations and Strengths

There were 3 principal weaknesses of this study: (1) the sample size was small, (2) the use of spectroscopy for screening versus diagnosis was not delineated clearly during the discussions, and (3) understanding of the participants’ sensitivity and specificity was not detailed.

The principal strength of this study is the in-depth approach applied to the interviews, the geographic diversity, and the multispecialty approach. The manner in which the study was conducted allowed for a great deal of spontaneity, creativity, and detailed discussion.

CONCLUSIONS

This qualitative study of physician attitudes represents an initial step toward dissemination of optical spectroscopy into routine care. A larger study, including more diversity of providers, is planned. Future studies should also address payor satisfaction, which is beyond the scope of this work. Another area that should be explored in more depth is physicians’ working understanding of screening paradigms and the inherent tradeoff between optimal sensitivity and specificity in balancing limited health care resources.

ACKNOWLEDGMENTS

Drs. Shinn and Follen were principally responsible for the conception and design of the study. Drs. Simpson, Gera, and Ms. Brodovsky conducted data acquisition under the advice of Dr. MacAulay. Data were interpreted by Drs. Qazi, Basen-Engquist, and MacAulay. All authors were involved in manuscript revisions, with Dr. Shinn taking the lead, assisted by Dr. Brian Crain (Drexel University). The manuscript was princi-
pally drafted by Drs. Shinn and Follen, with indispensable assistance from Ms. Hernandez.

SUPPLEMENTAL MATERIAL
Supplemental material accompanying this article can be found in the online version at doi:10.1016/j.genm.2011.11.004.

CONFLICTS OF INTEREST
This supplement is based on the proceedings of the annual Drexel University College of Medicine’s Institute for Women’s Health and Leadership held at the Bossone Research Center on Drexel University’s main campus, March 4, 2010. This event honored Helen I. Moorehead-Laurence, M.D., a North Philadelphia family physician and former faculty member of the Woman’s Medical College of Pennsylvania.

Drs. Qazi, Gera, Simpson, and Ms. Brodovsky are employees of Frost & Sullivan, a private research firm employed by Remicalm, LLC to conduct the reported study. David Burns, Dr. Follen’s spouse, owns a non-controlling interest in Remicalm, LLC.

REFERENCES


38. Cárdenas-Turanzas M, Freeberg JA, Benedet JL, et al. The clinical effectiveness of optical spectroscopy for the in vivo diagnosis of cervical intraepi-


Address correspondence to: Eileen Shinn, PhD, University of Texas M.D. Anderson Cancer Center, Unit 1330, 1515 Holcombe Boulevard, Houston, TX 77030. E-mail: e.shinn@mdanderson.org
Supplemental Appendix. Optical spectroscopic techniques for cervical cancer detection.

I. Discussion Guide for Individual Physician Interviews  
April 3, 2007

Name __________________________________________________________  
Address  ________________________________________________________  
Telephone number ________________________________________________  
Email address: ________________________  
Specialty _________________

I’d like to discuss the potential impact of a disruptive technology on how you screen and diagnose for cervical cancer. This technology exploits the difference between the fluorescence signature of normal and abnormal tissue in the cervix.

Did you receive some images we sent you by email? Would you just bring them up on your computer or print them out?

Analyzing Patient Flow

❖ Practice Profile:  
➢ What is your specialty? ____________  Where did you do your residency ____________  
and fellowship _____________? How long have you been practicing?__________  
➢ How would you describe your practice setting. _________________  [Hospital, multi- 
physician clinic, single physician clinic]  
• How many patients do you see each week? _________  Female _____  
• Does your patient population have any particular demographic characteristics?  

[Ask for family history, medical history or age.]

Verify response given on fax  
➢ How many patients do you screen for cervical cancer each week? _____  
➢ And you do diagnostic procedures on how many patients? _______ for cervical cancer 
each week on the basis of a positive screening test?  [Procedures are almost always 
colposcopies]

❖ On the follow up to cervical screening, what do you do for ...  
• Screened patients who are found healthy: ____________________  

Probe:  How are they examined? _____ By whom [by you]? _____  At what type of 
facility _____________[Your clinic or somewhere else]?  

• Screened patients who are called in for a follow up: ____________  

How are they examined? __________ By whom? __________ At what type of 
facility? __________  
• Screened patients who test positive for HPV: _________________  

How are they diagnosed? _______________ By whom? __________  
At what type of facility? _________________  
[Understand reflex]
Which of the following screening/ diagnostic procedures for cervical cancer screening do you use?

- Liquid based cytology (thin prep)
  - For which type of patients is it used? ______________ age ___ clinical history
  - What percentage of all your female patients are they? _____
  - What % is routine screening (a) _____ and what % is based on a risk factor? (b) __________ a/b = ______
  - What do you do when the result is negative? ______________ positive? __________ other (such as indeterminate?) __________
  - Why do you use the thin prep instead of some other technique? ______________ (pros and cons)

- Traditional Pap Smear [Almost completely discarded in favor of ThinPrep]
  - For which type of patients is it used? ______________ age ___ clinical history
  - What percentage of all your female patients are they? _____
  - What % is routine screening (a) _____ and what % is based on a risk factor? (b) __________ a/b = ______
  - What do you do when the result is negative? ______________ positive? __________ other (such as indeterminate?) __________
  - Why do you use the traditional Paps instead of some other technique? ______________ (pros and cons)

- HPV-DNA
  - For which type of patients is it used? ______________ age ___ clinical history
  - What percentage of all your female patients are they? _____
  - What % is routine screening (a) _____ and what % is based on a risk factor? (b) __________ a/b = ______
  - What do you do when the result is negative? ______________ positive? __________ other (such as indeterminate?) __________
  - Why do you use HPV-DNA instead of some other technique? ______________ (pros and cons)

- Colposcopy
  - For which type of patients is it used? ______________ age ___ clinical history
  - What percentage of all your female patients are they? _____
  - What % is routine screening (a) _____ and what % is based on a risk factor? (b) a/b = __________
  - What do you do when the result is negative? ______________ positive? __________ other (such as indeterminate?) __________
  - Why do you use colposcopy instead of some other technique? ______________ (pros and cons)

- Cervicography? [Rare: If the interviewee uses it ask for a description]
  - For which type of patients is it used? ______________ age ___ clinical history
  - ______________
What percentage of all your female patients are they? _____

What % is routine screening (a) ____ and what % is based on a risk factor? (b)
_________ a/b = __________

What do you do when the result is negative? ________________
positive? ________________ other (such as indeterminate?) ________________

Why do you use colposcopy instead of some other technique? _____________ (pros and cons)

Speculoscopy? [Rare: If the interviewee uses it ask for a description]

For which type of patients is it used? __________ age ___ clinical history

What percentage of all your female patients are they? _____

What % is routine screening (a) ____ and what % is based on a risk factor? (b)
_________ a/b = __________

What do you do when the result is negative? ________________
positive? ________________ other (such as indeterminate?) ________________

Why do you use colposcopy instead of some other technique? _____________ (pros and cons)

What are the drawbacks of the cervical cancer screening method you use?
_______________________________________________________

What are the strengths of the cervical cancer screening method you use?
_______________________________________________________

For gynecologists:

What percentage of patients you screen (i.e., with liquid cytology 'Pap' smears) are
referred by other physicians? __________ Which types of physicians? __________ Why do
they refer? _________________

What percentage of patients whom you diagnose with cervical cancer are referred by other
physicians? __________ Which types of physicians? __________ Why do they refer?
_________________________________

When you perform colposcopy, in which cases do you use a visualization aid (HAc)? __________
Why? Or why not? _________________

What other aid do you use to help you determine the status of the tissue?
_____________________________________________________

In what percent of cases do you perform a simultaneous LEEP? __________
Why do you perform loop excisions? _________________

In what percent of colposcopies do you conduct a biopsy? __________
Why do you do it? _________________

How do you proceed depending upon various biopsy outcomes? ___________
_____________________________________________________

For both GPs/Ob/Gyns:
Please rank the following statements on a scale of strongly agree, agree, are neutral, disagree, strongly disagree.

1. Liquid cytology "Pap smears" are problematic screening tests because of the high rate of false positives
   SA  A  N  D  SD
2. A screening or a diagnostic test for cervical cancer that could provide results in real time would be preferable
   SA  A  N  D  SD
3. If patients inquire about a specific diagnostic test (such as HPV-DNA), I am more likely to recommend it to them
   SA  A  N  D  SD
   a. Do those patients have to be over 30? Yes ____ no ____
4. Colposcopy results can be subjective, depending a lot upon the experience of the physician conducting the test
   SA  A  N  D  SD
5. (For FPs/GPs) I am more likely to adopt a new screening test for cervical exams if it has been recommended by gynecologists
   SA  A  N  D  SD

Of what new technique being developed for cervical cancer screening are you aware?
_________________________________________

How do you find out about new technologies for cancer screening or diagnosis?
____________________________________________

What can motivate you to try a new test? ________________________________

Please rate how important the following sources of information are when you consider using a new test:

Very important, important, neutral, rarely influential, not at all important. Please explain your response.

☐ Reading about the test in a clinical study in a scientific research journal
  (which ones? name a few) VI I N RI N
☐ Reading about the test in a trade magazine
  (which ones? name a few) VI I N RI N
☐ Hearing about it from a fellow physician
  VI I N RI N
☐ Hearing about it from patients
  VI I N RI N
☐ Getting information from a sales rep
  VI I N RI N
☐ Getting information from a company's booth at a conference
  Which ones do you commonly attend? VI I N RI N
☐ Following guidelines of professional organizations like ACOG
  (Is it ACO? ________)
  VI I N RI N
☐ Other reasons
  Which ones? ________________________________
  VI I N RI N

Advantages of Real Time Results

➢ How would a clinically-validated technology for cervical cancer screening and diagnosis that provided results in real time improve the quality of care for your patients?

➢ What clinical advantage and cost savings would come to the physician?
How could this technology cut down on medical errors (such as those caused by misfiling patient information?)

What clinical advantage and cost savings would come to the patient?

Could it significantly reduce patient anxiety?

What advantage or cost savings would flow to the healthcare system (insurance payer)?

Desirable features, applications:

What kind of patient (demographics, state of malignancy?) would be suitable for early application of this technology?

For Routine screening? , confirmation of colposcopy? 

What training time would you expect to need for this device?

For a physician? For nursing and technical staff?

What clinical outcome data would you like to see for this device?

If initially testing this device, would you want it for low or high grade carcinoma?

If you were comparing this device against existing technologies, considering the advantages provided by its real-time operation,

Would you be more interested in seeing lower false negatives or lower false positives?

For the device to be effective in the clinic:

How should the rate of false negatives (sensitivity) compare with that of Pap smear? and false positives (specificity)?

How should the rate of false negatives (sensitivity) compare with HPV DNA? and false positives (specificity)?

How should the rate of false negatives (sensitivity) compare with Colposcopy? and false positives (specificity)?

Introduction to technology (put on pdf)

Fluorescence imaging is used to determine whether a tissue is normal, pre-cancerous or cancerous. The Remiscope, the main instrument, can be thought of as a colposcope with added functionality.

Illumination containing a particular blend of colors is used to obtain fluorescent images with the highest contrast between normal and abnormal tissues.

The diagnosis is done by looking at a white light image, a blue light image and three colored fluorescence images. We can add a camera to record images. A fiber optic probe that directly contacts the tissue allow the doctor to get much higher sensitivity and specificity than for the entire image.

With the probe, instead of receiving two or three wavelengths, we are getting a few hundred. A single number indicates whether the tissue is healthy or diseased.

So in the exam, first the entire cervix is visualized. The probe is used to look at suspicious areas.

The process for a repeat exam following an initial Pap smear can be shortcut. False negatives can be eliminated and a more detailed exam with the probe can be conducted in real time. And the delay in waiting for a pathology report is avoided. The gynecologist conducting the exam can take a biopsy.
Two versions of the device: The one with a probe and the handheld version without one.

Thoughts on adoption

- If reimbursement were available:
  - Which device should be used at which stage of the screening and diagnosis process?
    - Handheld version with no probe: _________________________
    - Device with probe: ________________________________
  - Why is it important for fluorescence signals from columnar and epithelial tissue to be different? ____________________________
  - Can any clinician expert in acquiring cytology samples detect the difference anyway? ____________________________
  - Why would you like to use just the handheld device- Remiview- as an adjunct to Pap smears? ____________________________
  - Why would you like the Remiscope as an adjunct to colposcopy? ____________________________
  - How would you promote these devices to PCPs? ____________________________
  - ... To Ob/Gyns? ________________________________________

- If the Remiscope cost $15K and the Remiview, $7K:
  - Why would you be interested in acquiring one of the devices for your facility? Remiscope? ____________________________
  - Remiview? ____________________________
  - If reimbursement is available, what will be the purchase and evaluation process for this device at your facility? ____________________________
  - Who makes the final decision? ________________________________________
  - What comparable equipment have you bought for your facility? ________________________________________
  - How did you evaluate it for purchase? ________________________________________
  - What are your thoughts on an arrangement under which the manufacturer supplies the equipment for free, and keeps 50% of the Medicare reimbursement for each test performed with it? ________________________________________
  - How would you use the device? ________________________________________
  - For how many patients each week? _____
    - What percentage of your female patient population does that represent?