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Physician attitudes toward dissemination of optical spectroscopy devices for cervical cancer control: An Industrial-Academic collaborative study

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Abstract

Introduction—Optical Spectroscopy has been studied for biologic plausibility, technical efficacy, clinical effectiveness, patient satisfaction and cost-effectiveness. We sought to identify healthcare 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 two stages. First, a pilot group of ten physicians (8 obstetrician gynecologists and two family practitioners) was randomly selected from 8 regions of the US and interviewed individually. They 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 of a questionnaire (provided in Appendix A) which was then revised and presented to three larger focus groups (n=13, 15, 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

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colposcopy and agreed that the improved accuracy would result in reduced healthcare costs (due to decreased biopsies and decreased visits). However, while all 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.

Conclusion—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.

Keywords

physician attitude; physician satisfaction; dissemination; cervical intraepithelial neoplasia; fluorescence and reflectance spectroscopy; optical spectroscopy

1. Introduction

Advances in optical technologies for the detection of cervical cancers and precancers have shown lifesaving potential. In vivo optical spectroscopy, including fluorescence and reflectance spectroscopy, has been subjected to formal technology assessment including biologic plausibility, technical efficacy, clinical effectiveness, patient satisfaction, and cost-effectiveness (1–51). Nearly all these reports show better performance compared to 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: Balas et al.'s meta-analysis 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 (52). Because passive diffusion is inefficient, the National Cancer Institute recommended that dissemination research be incorporated into the development of new technology (53, 54).

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 (See Figure 1; 55). Rogers lists five characteristics which increase an innovation's likelihood of successful dissemination: 1) whether the innovation is *relatively better* than existing technologies; 2) whether the innovation is simple to adapt, i.e., *complexity*; 3) the ease of trying the innovation and discarding it if it does not work, *trialability*; 4) its *compatibility* with the potential adopters' existing needs, values, and past experiences; 5) the *observability* of the innovation's positive results.

Therefore 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, trialability, 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 three-phase study design. In the first phase, we developed a semi-structured 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 ten representative family practitioners and obstetrician gynecologists (phase 2). Finally, we conducted three focus groups across the US with obstetrician gynecologists, family practitioners, and internists (phase 3; please see Figure 2 for depiction of the study's design).

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 two gynecologic oncologists and two gynecologists to further suggest barriers. Feedback from these sessions was used as a basis for a semi-structured 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. The Phase I questionnaire is presented in Appendix A.

Phase 2 Discussion Guide

Frost and Sullivan further developed materials for focus group sessions and elicited feedback from academic scientists at M. D. Anderson. The teams at M. D. Anderson, Remicalm and Frost and Sullivan agreed on a final version of the discussion guide prior to 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. The discussion guide is included in Appendix A.

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 ten obstetric gynecologists and family practitioners from a national sample of five hundred. As we wanted a sample that was 80% obstetric gynecologists and 20% family practitioners, we weighted the random sampling strategy to obtain four obstetrician gynecologists for every one family practitioners.

Phase 2 Interview Procedure

Interviews were conducted with individual physicians by Frost and Sullivan, eight gynecologists and two family practitioners. Each individual interview lasted 60 minutes. Aspects of each physician's practice, such as number of 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. They 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, 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 (e.g., reimbursement from insurance companies, cost, and training needs).

Phase 3 Recruitment

Focus groups with primary care physicians and obstetrician gynecologists were recruited in three different cities in the U.S. Focus groups were done in Bethesda, MD; Rosemont, IL, and Santa Clara, CA.

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 impact of real-time cervical diagnoses from three perspectives (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 (point probe spectroscopy that touches the tissue, large field of view spectroscopy that sees the whole cervix at three-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 Papanicolaou smears obtained annually, the number of colposcopies performed annually, if the physician treated cervical lesions or referred them for treatment, if treatment was conducted what treatments were conducted and how many annually.

Phase 2 Sample

The recruitment of the ten physicians, randomly sampled from five hundred, yielded eight gynecologists and two family practitioners. These physicians had been in practice 14–31 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. The figure also shows the geographic diversity of the sample.

Phase 2 Reaction to Current Screening Guidelines

The ten physicians followed the guidelines currently approved by both the American College of Obstetricians and Gynecologists (ACOG) and American Academy of Family Physicians (AAFP). All eight obstetrician-gynecologists performed colposcopy and cervical treatments, but the two family practitioners preferred to refer their patients to gynecologists for colposcopy. All ten physicians routinely obtained liquid cytologies for their Papanicolaou smears. Seven of the ten physicians reported that they performed routine HPV testing only in women under 30 years old. All performed HPV testing when cytologic abnormalities were present, as per guidelines. When asked about barriers to the implementation of current accepted technologies; all ten 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 non-specific and led to many unnecessary 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 were 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 ten physicians agreed that guidelines from ACOG and the AAFP were the most influential source of change in their practice of medicine, compared to: 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: 1) product reviews in trade magazines and 2) hearing about a product from patients, but willing to think about results from: 1) sales representatives at conferences and 2) 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 individual physician was shown a brief presentation about optical spectroscopy using three separate devices: 1) a probe that touches the cervix, 2) an imaging device that takes images of the entire cervix at three-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 indeterminant. All felt 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 of 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 five years from 0–5 years to 41–45 years in practice. There were twenty-five primary care physicians combining family practitioners and internists, and twenty obstetrician gynecologists. The mean number of years in practice for the gynecologists was 16–20 years, while the median was 20–25 years. The primary care physicians' mean years of practice was 16–20 years, while the median was 11–15 years. The obstetrician gynecologists performed 11 to 90 Papanicolaou smear per week (mean=50, median=50), whereas the primary care physicians performed less than 10 to 30 Papanicolaou smears (mean=10, median= 10). All of the obstetrician gynecologists reported performing colposcopy, while only one primary care physician performed colposcopy. The obstetrician gynecologists performed less than 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 ACOG, AAFP, and were familiar with the American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines (Table 2). The obstetrician gynecologists tended to perform yearly smears in all patients while the primary care physicians as a whole tended to perform screens every three years in low-risk patients, thus adhering more closely to ASCCP guidelines. Some physicians

followed up indeterminate results of liquid cytology Pap smears, HPV testing, and colposcopy in three months rather than six 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 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 one 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 phone. All acknowledged that patients were non-adherent 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 in one visit. Delivery of a result was also seen as improving the quality of care. Both gynecologist and primary care providers were in agreement about the patient advantages and reduction in health care costs. Both groups felt 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 over 30 minutes, if treatment were included, and thus scheduling could be problematic. Since 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 thought that if they used spectroscopy instead of the Papanicolaou smear test, patients would still want a second opinion. This would require a referral to the gynecologist, and thus would not save a visit. A third barrier was that the physicians tended to doubt whether 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 the 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 mild disagreement about payor acceptance. Some felt the payors discouraged “in office” procedures, some felt 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 Papanicolaou test or its rough equivalent, rather than reimbursement for the office visit alone. Others expressed a 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 Papanicolaou 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 that had results that were falsely negative or falsely positive. However when asked about the high rate of loss to follow-up after colposcopy and whether 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.

4.0 Discussion

Physician acceptance is critical important factor in the speed of technology dissemination. The average time for new technologies to be disseminated is seventeen years or longer (53). 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, the participants did not display a detailed understanding of the tradeoffs in sensitivity and specificity, the meaning of Receiver-Operating Characteristic (ROC) curves, nor quantitatively meaningful improvements in sensitivity and specificity. The FDA states that the accuracy standards for new screening technologies depend on whether they will be used as 1) adjunct to colposcopy, 2) replacement for colposcopy, 3) adjunct for triage of ASCUS, or 4) replacement of the Papanicolaou 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% (56–57). 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 the FDA indications, the focus groups might have produced more specific recommendations as to the desired levels of accuracy before implementation into their own practices.

Overall, the sensitivity of the Pap (liquid or regular) has been estimated at 53–78% and its specificity at 90–96%. These studies found the sensitivity of HPV testing was 96–100% while the specificity was approximately 90% (58–59). 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 in order to be

integrated into standard care, its sensitivity should be at least 90–95% 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 (56). Studies are yet to be done using commercial scopes.

None of the existing studies have studied a combined approach of multi-spectral imaging of the entire cervix plus measurement with the point probe. The combination of the two 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

The study participants were quick to grasp the concept that real-time diagnosis would greatly reduce anxiety in patients, allow treatment at one 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 the payor's 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 three principal weaknesses of this study: 1) the sample size was small, 2) the use of spectroscopy for screening vs. 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 multi-specialty approach. The manner in which the study was conducted allowed for a great deal of spontaneity, creativity, and detailed discussion.

Conclusion

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 which 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.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Rogers' Model of Dissemination.

Figure 2.
Study Design.

Figure 3.
Place of residency training and practice sites for each of the ten physicians in the initial focus group.

Table 1

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

Date	Location	Obstetrician Gynecologist	Family Practitioners	Internists	Total number of doctors
4/19/2007	California	6	2	7	15
4/21/2007	Maryland	8	4	5	17
4/23/2007	Illinois	6	4	3	13
Total					45

Table 2

ASCCP Cervical Cancer Screening Algorithm Reviewed in Larger Focus Groups.

Liquid Cytology Result	HPV-DNA Test Result Positive	HPV-DNA Test Result Negative
Normal	LC and HPV testing in 6 months	LC and HPV testing for women less than 30 years old LC and HPV test every 2–3 years for women greater than or equal to 30 years old
AS-CUS	Colposcopy	Repeat LC in 12 months possibly with HPV test
ASC-H, LGSIL, HGSIL, or AGC	Colposcopy	No HPV Test
All other abnormalities	See ASCCP guidelines	

Sources: <http://www.arhp.org>; <http://www.asccp.org/pdfs/consensus/algorithms.pdf>