Advocating for Patient Preference in Cervical Cytology Screening

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Cervical cytology is the prototype of a successful cancer screening test, yet debates continue as to the optimal frequency of screening and the use of new technologies. The article by Raab et al entailed “Willingness to Pay for New Papanicolaou Test Technologies” illustrates a new area of investigation for pathology. Too often in the past, pathologists have been stereotyped as preferring tissue over live patients. This study on patient preferences highlights the roles pathologists can have in test selection and even patient advocacy issues.

Decisions by government and private payers on whether to cover a new test and at what rate ultimately drive the types of tests ordered by physicians and offered by laboratories. Indeed, such coverage decisions may determine the viability of a new technology. While pathologists have always been involved with influencing test selection, these discussions generally occur with other professionals or providers, not at the level of the patient. As patients become more educated about health care, they are likely to have more influence on decision making, especially in the choice of screening tests.

Providers usually call for outcomes data when determining coverage policies. Cost-effectiveness studies are preferred, so payers can judge whether a new technique will save lives at a “reasonable” cost. However, “cost per life-year saved” is a crude measure; most recent studies on Papanicolaou (Pap) test cost-effectiveness do not consider indirect costs and quality-of-life issues such as morbidity, patient time spent away from work or home, convenience, and patient preference. Furthermore, there is no threshold that can be considered cost-effective, and policy decisions also should consider patient expectations and the regional standard of practice.

For cervical cancer screening, the goal is to detect precancerous conditions early when they can be treated. Conducting a study with no screening or intervention in the control arm is unethical. Given the success of conventional Pap smear screening, a huge study over many years would be required to demonstrate any change in cervical cancer mortality related to using a new technology. Thus, most new Pap technologies have used surrogate methods to demonstrate effectiveness, such as increased detection of precursor lesions. Arguments against this approach are that many low-grade lesions will regress without therapy (meaning more sensitive tests may result in more false-positive results), and many studies do not verify either positive or negative results. Perhaps the best current proof of success of liquid-based Pap (LBP) testing is the increased detection of biopsy-proven high-grade lesions and cancers. Two studies with colposcopic/histologic verification of both abnormal and normal cytology results show that LBP screening is about 94% sensitive for biopsy-proven high-grade lesions when a threshold of atypical squamous cells (ASC) is considered positive. In the Costa Rica study, the sensitivity of the conventional Pap smear was 78%, but previous estimates of conventional Pap sensitivity have been as low as 51%.

The “Duke” study funded under contract with the Agency for Healthcare Research and Quality demonstrated via modeling techniques that either more sensitive screening tests or more frequent screening would save lives. For example, a screening test with 40% fewer false-negative results performed annually would lead to 50% fewer cervical cancer cases and deaths than the annual conventional smear. Author conclusions to these models vary tremendously, however. The modeling study by Montz et al demonstrated...
that substituting more sensitive LBP could have a larger impact on cervical cancer incidence than increasing compliance to meet the US government screening targets for Healthy People 2000 and 2010 using the conventional smear. In contrast, the discussion in one of the “Duke” study papers concluded “New tests with improved sensitivity led to substantially greater cost than health benefit.”8 In their discussion of the impact of new technologies, Sawaya et al11 conclude that “more abnormalities may be discovered at the cost of an increase in the number of healthy women who are unnecessarily alarmed by a false report of an abnormality and who subsequently undergo needless diagnostic procedures and interventions.”

Studies of risk perception and preference are another vital component in policy-making decisions, as the article by Raab et al3 illustrates. Slovic12 demonstrated that experts and policy makers perceive risk differently from the public. For example, voluntary risks such as sports activities and driving a car are readily accepted, yet uncontrollable risks such as nuclear reactor accidents are not. Patients may judge risk according to the degree to which they “dread” an outcome, and irreversible, uncontrollable, or lethal outcomes are associated with a high dread factor.12,13 Cervical cancer and other cancers are likely viewed with dread, hence the findings by Raab et al3 that women were willing to pay for more sensitive Pap technologies. Women may accept more false-positive results and follow-up tests than the experts prefer simply for more reassurance that they will not get cancer. The dangers of false-positive results may be exaggerated, as many of the low-grade abnormalities detected will be ASC, now very readily handled by triage via human papillomavirus (HPV) DNA testing.14 The dread factor is illustrated further by the tendencies for women with more children and women who perceive themselves to be at higher risk to have a greater willingness to pay. According to Slovic,12 the public may lack scientific information about hazards, but “their basic conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments.”

Other cancer screening tests have not faced cost-effectiveness hurdles to the same degree. Screening tests for prostate cancer generally are covered at higher rates, despite limited evidence of effectiveness. Other cancer screening strategies also acknowledge the role of patient preference. For example, the American Cancer Society recommends that men be informed about the benefits and limitations of prostate cancer screening, with earlier testing offered to high-risk men.15 Colorectal cancer screening is widely recommended, but there is debate about which testing strategy to use. Fecal-occult blood screening improves outcomes by decreasing cancer mortality, but colonoscopy maximizes sensitivity for a single screening event.16 Furthermore, any given colorectal screening method may be viewed as inconvenient or uncomfortable by the patient, and thus, specific guidelines may not be followed despite scientific evidence. Woolf17 states that the selection of screening test may depend on personal values. “Those who advocate a specific screening test for colorectal cancer have taken a position—reflecting their priorities with regard to scientific certainty, accuracy, the magnitude of benefit, safety, costs, and feasibility—that they presume is universal. This approach is justified only when it can be safely assumed that most people, given the same facts, would make the same choice...the best choices are made when patients, physicians and insurers weigh the trade-offs from their own perspectives.”17 Similarly, in an editorial about colorectal screening, Detsky18 says “patients ought to be informed of the risks, the benefits, and the quality of the evidence and given a description of the screening techniques. Patients should then be allowed to choose.”

The study by Raab et al3 found that women were willing to pay a median of $50 to $100 more for more sensitive Pap technologies. Current Pap payment rates average much less, even for new LBP technologies. Nevertheless, the questionnaire findings do not justify charging more for LBP just because of patient preferences. The higher charges for new technologies should be based on a careful accounting of increased supply, instrumentation, and personnel costs. A new technology cost may eventually decrease with increasing competition, recovery of development costs, and more efficient production by manufacturers.

The article’s discussion acknowledges several possible limitations of the study technique. For example, women may agree to pay more for a new technology knowing that they will not actually be opening their pocketbooks.3 The comparison with other health benefits (in vitro fertilization) is helpful in this regard, but future studies could investigate other, more parallel patient choices. Women’s reactions to possible false-positive results also could be evaluated.

On the other hand, the study may have underestimated the value of LBP testing to women, as other potential advantages of LBP testing were not investigated. HPV triage on Pap tests interpreted as ASC can be performed readily on remaining liquid specimens without a return patient visit.14 How much more would women pay for the potential convenience of not returning for at least 2 office visits? Costs of missing work and paying a sitter are very real to any woman patient, yet cost-effectiveness studies usually consider only direct medical costs. In the future, we may be able to offer even more sensitive Pap testing methods using HPV or other molecular testing methods. For example, the combination of HPV and LBP testing approaches 100% sensitivity in the detection of high-grade squamous lesions and cancers6 (oral communication, Mark Schiffman, MD, April 2001). Adenocarcinoma
also is increasing in incidence, but the conventional Pap smear has shown underwhelming results in detecting this often deadly disease.\textsuperscript{1,19} If new screening techniques are available that will prove more successful in detecting all malignant neoplasms, will we permit women to choose such techniques at a higher price?

In the past, providers have generally told women what type of cervical cancer screening test they will receive, as in “we know what’s best for you.” Once the public is aware of the potential of increased sensitivity from new screening strategies, it may be increasingly difficult for providers to take this conservative paternalistic approach. We should expect women to be informed of the risks and benefits of various cervical cancer screening approaches. We should expect patient preference to be considered, as for other cancer-screening decisions. The pathology community has the greatest access to test performance and outcomes measures and is in an ideal position to influence test selection and decision-making policies. Studies of risk assessment and patient preferences, such as that by Raab et al,\textsuperscript{3} are a welcome addition to other outcomes analyses and should help pathologists be viewed as advocates for optimal patient care.

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References