Whatever Happened to the Annual Pap Smear?

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The reading programs at Rhode Island College, Providence College and Roger Williams University selected the book, *The Immortal Life of Henrietta Lacks* by Rebecca Skloot, as required summer reading for incoming freshman last year. This book is a nonfiction biography of a poor, black, working mother of five children who died of cervical cancer at the age of 31. The work is a masterpiece of investigative reporting because it reads like fiction, weaving together the life of a patient whose cancer cells became known as "HeLa" cells and the scientific history of how these cells helped scientists unravel the mystery of DNA, find a cure for polio, and produce medications for leukemia, influenza, and many other diseases.

In 1951, when Lacks was diagnosed with inoperable cervical cancer, screening for cervical cancer was in its infancy. George Papanicolau had first reported that cervical cancer could be detected by means of a vaginal smear in 1928, but his work was not recognized until 1943, when he and Herbert Traut reported that smears could be used to diagnose cervical cancer at an early stage.

At the beginning even pathologists were generally opposed to the Pap smear because it was an extremely complicated, time-consuming test with uncertain results. In 1952, the American Cancer Society's (ACS) medical director, Charles S. Cameron, MD, wrote an editorial to the *New York Times* complaining that most physicians were not willing to cooperate with his organization's efforts to promote cancer checkups that included the Pap smear. Over time the Pap smear campaign became overwhelmingly successful, due in part to the efforts of the ACS, but also due to the momentum of the women's movement and books like *Our Bodies Ourselves*, which promoted the annual Pap test. In 1960, only 30 percent of American women had ever had a Pap smear, and 40% had never even heard of it. By the mid-1970s, over 50% of women were having annual Pap smears, and by 1980 the figures had jumped to 80%. Over the same interval, deaths from cervical cancer declined by almost 70%. Today, there still are over 4,500 new cases of invasive cervical cancer diagnosed annually, with most of these occurring in women who have never had a Pap smear.

Despite its success, there is actually very little science to support the choice of an annual screening interval for cervical cancer screening. This particular screening interval was adopted somewhat arbitrarily to mirror the rhythm of refilling annual birth control prescriptions, but it became an annual ritual for millions of American women. In 1976, the Canadian *Walton Report* challenged the annual screening interval by suggesting that cervical cancer screening every 3 years was as effective as annual screening and in 1980 a National Institutes of Health panel advocated that all women have a Pap smear every one to three years.

By 1992, it was apparent that cervical cancer was causally related to the human papilloma virus (HPV) virus. Terminology for the interpretation of Pap smears was standardized in 2001, eliminating much confusion about the interpretation of smears; and by 2003 it became possible to detect the HPV virus from the Pap smear sample itself, enabling doctors to identify high-risk women. In 2003, both The ACS and the American College of Obstetrics and Gynecology changed their cervical cancer screening recommendations to take into account the biology of cervical cancer as well as the evidence that a longer screening interval was as effective as the annual smear for women who had previously had three consecutive negative smears. In 2006, the Food and Drug Administration licensed the first vaccine to prevent cervical cancer caused by certain strains of HPV. Now, with both the HPV vaccine and virus testing available, the possibility of reducing the interval for Pap smears even further has become a reality.

New guidelines

In early 2012, the ACS, the American Society for Colposcopy and Cervical Pathology, and American Society of Clinical Pathologists released new consensus guidelines for cervical cancer screening. The guidelines were released separately last March by the United States Preventive Services Task Force (USPSTF) and by the ACS. The new guidelines recommend against routine yearly testing.

This is especially beneficial for adolescents. The new screening recommendations are to start Pap smears at age 21, regardless of sexual history. This is important because HPV infection is very common among young sexually active adolescents, but HPV is generally a transient infection among adolescents and it is cleared by the immune system within 24 months. Irreparable harm has been done to adolescents over the past few decades by invasive gynecological procedures which damage the cervix and increase the risk for preterm birth.

Women over 65 do not need continued screening if they have previously had negative smears for an entire lifetime,

even if they are involved in a new relationship. This is because the HPV virus is a latent virus, which can take 20-30 years to develop into a high grade dysplasia, which is a precursor to cancer of the cervix.

The options for women aged 30-65 are easy to explain to patients. For women who have only one sexual partner, or who are non-coital, the option of a Pap smear every three years is the most cost-effective and logical option, and it is what has been the standard of care since 2003. For women who have multiple sexual partners, or who have a history of HPV or atypical smears in the past, the option of co-testing every 5 years with Pap smear and HPV testing can be very appealing as long as they understand that the HPV test may be overly sensitive and may lead to further testing. Doing co-testing will identify many women who are HPV positive, but who have no evidence of high-grade precancerous lesions. Negative tests are very reassuring, but the psychological distress of a positive test may be harmful, especially to some patients. Physician discretion is essential.

The new guidelines do not apply at all to women who have a history of in-utero diethylstilbestrol (DES) exposure, a personal history of high-grade cervical dysplasia, or women who are immunocompromised by HIV, chemotherapy, or transplants. Women over 21 who have never been screened for cervical cancer should definitely have a Pap smear, regardless of age or sexual history. Primary care physicians should refer patients to a gynecologist for consultation if they are unsure of the guidelines or if they do not do Pap smears. Obstetrician/gynecologists and other doctors who do Pap smears should remember their roles as educators to help patients understand the new guidelines and the reasons why eliminating unnecessary testing reduces costs for everyone.

Unfortunately, at the same time that recommended screening intervals for Pap tests are getting longer, many American physicians are still not following guidelines and/or are not aware of them. A study published in *Annals of Internal Medicine* in 2009 found that most physicians who did Pap smears were still doing annual smears.[1] Although most of these same doctors reported that they followed guidelines in their practice, the study found that only 16% of OB/GYNs, 21% of family practice physicians, and 27% of internists actually followed the guidelines. Most doctors interviewed were overusing the Pap smear, and not doing too few tests.

The reasons for this are complex. One of the reasons cited is that doctors and patients are accustomed to the ritual. They know that Pap smears can detect cancer at an early stage and they equate an annual exam with a Pap smear. Some third-party payers send reminders and sometimes monetary rebates to patients to have an annual Pap smear. Medical laboratories engage in direct-to-consumer marketing medical tests like the HPV test, which fuels even more demand for the Pap smear. The Affordable Care Act has mandated that all preventative services, including annual well-woman exams, be covered by insurance without deductibles or co-pay. Although not directly stated, the implication is that an annual Pap smear for cervical cancer screening is a necessary service.

Doctors themselves are very confused about what to do. Between 2002 and 2004, 5 sets of cervical cancer screening guidelines were published by professional associations and consensus groups. At the same time, direct-to-consumer advertising for the HPV test fueled patient requests for HPV testing and Pap smears.[2] It has been found that physicians frequently acquiesce to patient demands, especially if there is no financial incentive to refuse to do what the patient requests. On the contrary, in the case of Medicare, the Pap smear is a separate reimbursable service in addition to the annual exam, so there is actually a financial incentive to do the Pap smear. Talking a patient out of an unnecessary Pap test is time consuming and costs the primary care doctor money because the time could be better spent seeing another patient. In addition, the worst-case scenario is for a doctor to miss a cervical cancer, especially after doing a recent pelvic exam without a Pap smear. The American College of Obstetrics and Gynecology has reported that 75% of its members have been sued at least once, and after one lawsuit, most doctors do not want to repeat the experience. So patient demand, financial incentives, time constraints, the effects of

NEW SCREENING GUIDELINES FOR CERVICAL CANCER 2012

- All women should begin cervical cancer screening at age 21.
- Women between the ages of 21 and 29 should have a Pap test every 3 years. They should not be tested for HPV unless it is needed after an abnormal Pap test result.
- Women between the ages of 30 and 65 should have both a Pap test and an HPV test every 5 years. This is the preferred approach, but it is also acceptable to have a Pap test alone every 3 years.
- Women over age 65 who have had consistently normal results for many years should discontinue screening for cervical cancer. Women who have been diagnosed with cervical pre-cancer should continue to be screened.
- Women who have had their uterus and cervix removed in a hysterectomy and have no history of cervical cancer or pre-cancer should not be screened.
- Women who have had the HPV vaccine should still follow the screening recommendations for their age group.
- Women who are at high risk for cervical cancer may need to be screened more often. Women at high risk might include those with HIV infection, organ transplant, or exposure to the drug DES. They should talk with their doctor or nurse.

Adapted from American Cancer Society at http://www.cancer.org/Healthy/FindCancerEarly/CancerScreeningGuidelines/american-cancer-society-guidelines-for-the-early-detection-of-cancer

direct-to-consumer marketing, and a litigious environment all conspire together to keep the annual Pap smear going.

So, why follow the guidelines? I have found that most women are happy to eliminate the dreaded annual ritual, which is embarrassing and uncomfortable. When given the information that the new guidelines are evidence-based, and offer outcomes that are as good as or better than current screening recommendations and when information is given about the unintended harms of false positive tests, most patients are relieved. I have found the discussion about guidelines and unnecessary tests is a healthy discussion, engaging my patients in the dialogue about healthcare reform. It is estimated that about $8 billion a year is spent on preventative yearly physicals alone. Patients understand that this money could be better spent on extending benefits to the needy, or at the very least, toward reducing our health insurance premiums. The Pap smear itself is not an expensive test, but it should be viewed by physicians as a surrogate for what is wrong with our healthcare system. It is our responsibility to stop doing unnecessary repetitive tests, with due respect to Henrietta Lacks and the extraordinary success of the Pap smear in saving lives from cervical cancer.

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