Experts say annual pap tests can cause harm
Yearly testing may not be right for you

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Published Aug 24, 2014

Pap smear samples are processed by Central Oregon Pathology, which handles about 17,000 tests a year.

Photo by Meg Roussos / The Bulletin

For years doctors have urged women to come in for annual pap smear testing to screen for cervical cancer. But over the past decade, women’s health experts have recognized that such frequent testing not only doesn’t provide greater protection from cancer, it may be causing serious medical harm.

Guidelines from groups including the American Cancer Society, the U.S. Preventive Health Services Task Force and the American College of Obstetricians and Gynecologists recommend less frequent testing for women at low risk for cervical cancer. Yet physician surveys and analyses of medical and billing records show that a significant percentage of doctors are still bringing women back year after year for a pap test.

“We understand the natural history of cervical cancer much better than any other cancer,” said Dr. Mark Einstein, director of clinical research for women’s health and gynecologic oncology at the Albert Einstein Cancer Center in the Bronx, New York. “And what we’ve learned is the way we used to do pap testing, while it was highly effective, we were also causing a lot of potential harm to patients.”

The pap test has been in place for more than 50 years and has been remarkably successful in driving down rates of cervical cancer. Before pap testing, cervical cancer was the No. 1 cancer killer of women, Einstein said, and now it doesn’t rank in the top 10.

“We’ve gotten to the point where we’ve realized we can’t do much better (at preventing cancer) with our current screening,” he said. “But maybe we could do better by just eliminating harm, and so we started spacing out how we do this.”

Harm arises when a woman has a false positive pap test result and is referred for colposcopy, a more extensive test to look for cancer or precancerous lesions. Guideline-setting groups use the number of colposcopies as a measure of harm, because the procedure is a necessary prerequisite for more invasive treatments. They start women down the road toward biopsies and treatments that carry a risk of bleeding and infection in the short term, and an increased risk of pregnancy complications, such as preterm delivery or infertility, later on.

Although the risk of harm is small, and certainly outweighed for women who actually have cancer, the high rate of false positives in pap tests means many women undergoing colposcopy are subjected to unneeded treatments and their resulting risks. One review found that women who undergo treatment for cervical lesions have a 70 percent to 160 percent increased risk for preterm delivery, as well as higher risk for low birth weight, premature rupture of membranes and C-sections.

In the 2012 guidelines, the groups calculated that screening women every three years instead of every year would result in two to five additional cancer diagnoses for every 1,000 women, although with the high survival rate, only two additional deaths per 100,000 women. On the other hand, annual screening would result in nearly three times as many colposcopies.
Physicians have been slow to adopt the new guidelines. In 2012, researchers from the Feinberg School of Medicine at Northwestern University mined electronic health records at one Midwestern clinic to see how well doctors were following the screening guidelines. They found that out of 1,705 women who met the criteria for extended screening, 66 percent had a second pap test done within the following two years, and 25 percent had tests done both years.

Those additional 1,551 pap tests resulted in 21 women undergoing colposcopy, with 20 women getting negative results. The additional tests identified one woman with adenocarcinoma in situ, a precancerous condition that is generally treated with hysterectomy. It is possible the woman could have had the same outcome had she waited. It can take months or years for invasive cancer to develop from this initial stage. But the researchers acknowledged the woman might have been harmed if she had not been screened for another year.

“This is a predictable consequence of less frequent screening,” the researchers wrote.

Trade-offs like these make the balance of benefits and harm in screening a tricky business. Doctors could do such frequent screening that virtually no cancer would escape detection, but that could come at a heavy financial cost and with many unintended patient harms. Instead the guidelines try to find the screening interval that will offer the best mix of maximizing cancer protection while minimizing harm.

That balance could be upset when physicians opt for shorter screening intervals. Yet a 2011 survey of physicians by researchers at the Centers for Disease Control and Prevention found either widespread ignorance or woeful disregard of the screening guidelines. Less than a third of doctors reported that they would lengthen screening intervals to three years in a 35-year-old woman with three normal pap test results and no new sexual partners, as the 2003 guidelines recommended. Fewer than one in five would lengthen screening intervals to three years in the same patient with a normal pap test and a negative HPV test as recommended starting in 2004.

Doctors may be reluctant to move to less frequent testing because of the financial incentives. (Read more about this Monday.) Or they may believe they are providing women better protection with annual screening.

“Old habits die hard,” said Dr. Natalie Hoshow, a gynecologist with St. Charles Health System in Bend. “That’s true for physicians as well.”

Hoshow said she customizes screening intervals according to a woman’s age and risk. In women over 30 with negative pap and HPV tests, she will screen again in three years. For women age 21 to 30, with a high risk of HPV infection, she will conduct pap tests every year or two.

There are some signs that more doctors and patients might be coming around. In Oregon, cervical screening rates for women 18 to 39 dropped from 33 percent in 2009 to 25 percent in 2012.

“Most of that decline,” said Dr. Sean Schafer, an epidemiologist with the Oregon Department of Human Services, “happened in women 18 to 20,” who are too young to be screened under the guidelines.

Three protocols

The variability in screening may intensify now that the FDA has approved the first HPV test that can be used alone for primary cervical cancer screening, potentially eliminating pap tests altogether for those patients. Studies have shown that HPV screening alone is almost as good as doing both tests, and that adding a pap test may not be worth the added costs.

Professional societies plan to issue interim guidance for the HPV test this summer. They must still sort out the best age to start screening with HPV tests, and how to manage women who test positive for an HPV strain, but then have a normal follow-up pap test. And they must determine which screening interval will provide the greatest benefits with the least amount of harm.
Patients who have become accustomed to yearly tests, however, can see a longer screening interval as less protection.

“When we interview women, they think that the provider who is telling them to extend the screening interval is doing it to save money and it’s not really in their best benefit,” said Dr. Mona Saraiya, a CDC epidemiologist. “(They believe) it’s more about the government cutting back.”

Providers who take the time to explain why an extended screening time is safer, however, have found women are generally receptive. Kaiser found that 92 percent of women were fine with the longer intervals.

“When these extended intervals came out, we heard from women in droves who were like, ‘Oh my gosh, what do you mean I don’t need to get my annual pap smear?’” said Fred Wyand, director of communications for the National Cervical Cancer Coalition. “There’s a big piece with both providers and patients to make sure they understand not only what the new guidelines are, but the rationale behind it.”

It represents a major pivot for women’s health advocates.

“We finally feel we’ve got the message across and now we’re changing the recommendation,” said Dr. Wendy Brewster, an associate professor at the University of North Carolina School of Medicine and spokeswoman for the Society of Gynecological Oncology.

… [For the full report, click the title or photo on the COMS website]

“I really do hope the annual pap goes away,” Brewster said. “I do think we have other tools that are better.”

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**Markian Hawryluk’s Review of Cervical Cancer Screening Part II**

**Part II: Annual Pap test more risk than prevention for some**

Financial issues may slow change to new Pap smear recommendations

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Published Aug 25, 2014

With the realization that a Pap test every year may expose women to greater harm than benefit, guidelines have shifted toward less frequent screening. But with so many women still being tested annually, experts are wondering whether physician reluctance to adopt the new screening schedule may be fueled by legitimate concerns about women’s health or by financial concerns.

Pap testing is not a particularly lucrative procedure. Medicare pays physicians about $46 to collect the sample, Medicaid an average of $28. But it has served as a way to get women into the clinic on an annual basis. New guidelines that extend the screening intervals to three or even five years could result in a substantial loss of patient volume and revenue, upsetting the traditional gynecology business model.

“The office’s contact with patients revolves around using the Pap as a reason to get the patient in,” said Dr. Mark Stoler, a professor of pathology, cytology and gynecology at the University of Virginia School of Medicine. “You’re used to filling your office five days a week with people who are coming in for annual screenings, so that you can also touch base with them on other health issues.”

Physicians have been urging women to come in for an annual Pap smear for the past 50 years, but that started to change in 2002. Now guideline-setting groups including the American Cancer Society, the U.S. Preventive Health Services Task Force and the American College of Obstetrics and Gynecology all recommend that Pap tests be conducted every three years as long as the tests are normal. Women who have a normal Pap test and a negative HPV test can wait five years between tests.
Changing deeply ingrained practice patterns is always challenging, but can be particularly difficult when the change runs counter to the financial incentives in play.

A 2012 study from Johns Hopkins University found that 26 percent of women with a negative Pap test were nonetheless called back for a second test within one or two years.

The researchers suggested the over-screening could be due to patient preferences or physician desire to see those patients every year, but also noted that “in many settings, there is no financial disincentive for performing the repeated tests.”

Under the Affordable Care Act, insurance companies cannot charge copays or other cost sharing for Pap tests and other preventive health services. That not only removes financial barriers for patients but underscores in their minds the importance of those tests. So there is little push-back from patients when doctors want to do annual testing.

Many states have laws requiring insurance companies to pay for annual Pap tests, a holdover from days when access to such testing was no sure thing, and annual testing was still the norm. And most physicians are still paid on a fee-for-service basis that rewards them for doing more tests and procedures.

**Business model**

Pap tests have become so routine that the Centers for Disease Control and Prevention has found physicians continue to do Paps on 60 percent of women who no longer have a cervix after a total hysterectomy. And a study released last week showed doctors continue to screen elderly women with a limited life expectancy.

Some clinics will not renew prescriptions for birth control pills unless a woman comes in for a Pap screen each year.

The screening has become the backbone of a $2.6 billion industry around women’s preventive care. In 2010, 5 percent of all appointments for women in the U.S. included a Pap test, and another 0.7 percent included an HPV test. Oregon alone spends some $66 million for routine cervical cancer screening each year, and another $4 million for treatment.

The business model is further stressed by the recent call to eliminate another annual ritual, the pelvic exam. Earlier this year, the American College of Physicians concluded there was little value in a pelvic exam for healthy women who are not pregnant. Doctors have traditionally done pelvic exams to look for things like ovarian or uterine cancer. But evidence shows the exam is not an effective way to find such cancers.

The recommendation against pelvic exams has remained controversial. The American College of Obstetrics and Gynecology issued a response acknowledging there is no scientific evidence supporting a routine pelvic exam, but nonetheless maintained it was a good idea and urged women to continue to see their gynecologists for annual well-woman visits.

“I have diagnosed more than one case each of ovarian cancer, colon cancer and malignant melanoma metastatic to the cervix all at the time of routine annual exam,” said Dr. Natalie Hoshow, a Bend gynecologist with the St. Charles Health System. Several other women’s health physicians contacted by The Bulletin declined to comment.

In a survey of 1,250 primary care providers, more than three-quarters said they still perform pelvic exams as part of the well-woman visit, and 95 percent of gynecologists in a separate survey said they would perform a pelvic exam even if a woman wasn’t due for cervical cancer screening.

Survey results also showed gynecologists who do annual Pap tests are more likely to also do annual pelvic exams. But with those tests potentially off the table, it’s unclear whether women will continue to see a need for a gynecologist visit each year or whether they’ll shift their primary care visits to family practice doctors or internists who deal with a broader range of health issues.

“OB/GYNs, in particular, need to develop new practice rationales in terms of how often do we need to see patients,” said Stoler, who conducted some of the research used to approve the stand-alone HPV test. “If you have a good medical reason to get a patient in, get them in, but don’t do cervical cancer screening more often.”

Gynecologists counter that it’s often women themselves who are reluctant to give up annual screening, and that the guidelines are still too new to have fully changed long-established practice patterns. And with more
institutions shifting to new models of care that reward quality of care over quantity, they say physicians are influenced less by such financial concerns.

**Financial impact**

While many physicians will bristle at the notion that their care decisions are influenced by money, Dr. Paul Marantz, director of the Center for Public Health at Albert Einstein College of Medicine in Bronx, N.Y., says doctors must always keep the financial conflict of interests in mind.

“For the people whose livelihood is affected by whether Pap smears are done annually or triennially, that’s a huge difference,” he said. “That’s unquestionably going to color their interpretation of the literature and their decisions about what’s right.”

Marantz, who is married to an OB/GYN, rejects the notion that doctors make decisions solely based on financial considerations. That’s not the way doctors are trained, he says, nor the ethos of the profession.

“They worry about the lack of women’s health care, which is generated through the Pap test. The way a gynecologist sees a female patient is because they come in once a year for the Pap test,” he said. “But if the choices you make have a direct relation to the amount you earn, it’s got to have an influence on your thinking.”

Jeffrey Clemens, an economist with the University of California, San Diego, said physicians do respond “fairly strongly” to financial incentives. If a price of a test or service goes up, doctors will provide more of that service, and both public and private insurance plans often use such financial incentives to drive certain practices they want to encourage.

Similarly, doctors will adjust their practice patterns to make up for shortfalls in patient volume or payments.

“If the gynecology biz is drying up to some extent, for the patient who does come through the door, they are likely to have more time and be more likely to provide the full suite of services,” he said.

Clemens cited research done in the 1990s that looked at how obstetricians reacted when birth rates dropped in their local area. The study found doctors increased the number of C-sections they did to make up for the drop in patient volume.

“If some of your customers disappear,” he said. “Then the ones who are still around get the red carpet treatment.”

The frequency of screening has come to the forefront now that the Food and Drug Administration has approved an HPV test that can be used without also doing a Pap test. Doctors are now awaiting guidance on how best to use the test and how often. But experts acknowledge that HPV testing will increase the burden of false positives for women if doctors don’t also shift to longer screening intervals.

“I think it would do more harm than good,” said Dr. Mona Saraiya, an epidemiologist with the CDC.

If stand-alone HPV screening gains ground, Pap tests would only be used to follow up with women who test positive on the HPV test. That could eliminate 85 percent of the Pap tests done in the U.S., affecting both the cytology technicians who analyze the Pap tests and the pathologists who review any abnormal results.

**Central Oregon Pathology Consultants, which processes most of the Pap and HPV tests in Central Oregon**, has seen an increase in HPV testing and a commensurate drop in Pap testing, suggesting that more local providers are moving toward doing both tests with longer screening intervals.

“Five years ago, we were lucky if we did 100 HPV tests a month. Now we do over 100 HPV tests per week,” said Dr. Cheryl Younger, a pathologist with the group. “We are seeing a lot more co-testing in Bend. We’re seeing longer screening intervals. Are they doing five years? No, because at this point, I think they just don’t feel comfortable with it.”

Cheryl Younger, of Central Oregon Pathology Consultants.
The group handled more than 25,000 Pap tests a year eight to nine years ago, she said, but now handles about 17,000.

Younger said the new guidelines remain controversial among gynecologists and pathologists who worry about the impact on patients.

“I am concerned about women’s health care and where it’s being driven, and the supposed over-screening for cervical cancer as well as breast cancer,” she said. “We’re not going to know whether we’re right or wrong for another 10 years or so.”

Jen Sturdy, 31, of Bend, processes samples of pap smears inside Central Oregon Pathology in Bend.

Legal issues

Some believe that doctors continue to do annual testing as a way to protect against expensive malpractice lawsuits. Pap tests have a high rate of false negatives, so a fair percentage of women with normal Pap test results still develop cervical cancer. Doctors may feel that annual testing, as opposed to less frequent screening, reduces the risk of false negatives.

Malpractice suits often target the physician collecting the sample, the technician analyzing it and the pathologist interpreting the results. The Pap smear is somewhat of a subjective test and thus subject to human error. The automated HPV testing, on the other hand, provides a positive or negative result. That could shield the technician running the test, but lawsuits might still claim the physician improperly collected the sample.

From a systemwide perspective, longer screening intervals might also save money. Several groups are working on cost-analyses that estimate not only the cost of testing, but also the cost of follow-up tests and treatments that would result from moving to stand-alone HPV testing.

Before the ACA, many cervical cancer screening programs for uninsured women ran out of money each year, leaving many eligible women unscreened. Oregon’s Breast and Cervical Cancer Program is primarily funded by the CDC’s National Breast and Cervical Cancer Early Detection Program. The program has funding to screen about 5,000 women a year or about 15 percent of women with income under 250 percent of the federal poverty level. In the past, the program struggled to meet the demand for services, although that has changed in 2014 due to the ACA.

“We’re seeing fewer women coming in to our program because they are getting on the Oregon Health Plan,” said Kristin Kane, manager of the screening program in Oregon.

Eventually, both public and private insurance companies may drive the shift to longer screening intervals, for both medical and financial reasons. But after years of being hammered for making decisions based on cost, health plans may be wary of cutting back on screening without a stronger recommendation from professional societies and guideline-setting groups.

There is now, experts say, sufficient evidence to support using HPV testing as part of the cervical cancer screening protocols, whether alone or in conjunction with Pap tests, and with longer screening intervals. That’s why so many question the motives of doctors who cling to annual Pap tests for their patients.

“The failure to recognize the well-documented limitations of (Pap tests) can only be explained by a choice to ignore the obvious or by motivated self-interests,” Dr. Lee Schulman, an OB/GYN professor at Northwestern University, said at an FDA advisory committee meeting on the HPV test. “It cannot be explained by a desire to provide optimal health care for women.”

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