

High-tech DNA-based alternative to Pap smear sparks medical debate

Many feel smear is best testing method to prevent cervical cancer

By **MATTHEW PERRONE**
AP HEALTH WRITER

WASHINGTON — A high-tech screening tool for cervical cancer is facing pushback from more than a dozen patient groups, who warn that the genetic test could displace a simpler, cheaper and more established mainstay of women's health: the Pap smear.

The new test from Roche uses DNA to detect the human papillomavirus, or HPV, which causes nearly all cases of cervical cancer. While such technology has been available for years, Roche now wants the FDA to approve its test as a first-choice option for cervical cancer screening, bypassing the decades-old Pap test.

But a number of women's groups — including the American Medical Women's Association and Our Bodies Ourselves — warn that moving to a DNA-based testing model would be a "radical shift" in medical practice that could lead to confusion, higher costs and over-treatment.

"It replaces a safe and effective well-established screening tool and regimen that has prevented cervical cancer successfully in the U.S. with a new tool and regimen not proven to work in a large U.S. population," state the groups in a letter to FDA Commissioner Dr. Margaret Hamburg. The letter is signed by 17 patient advocacy groups, including Consumers Union, the Cancer Prevention and Treatment Fund and the National Alliance for Hispanic Health.

Chief among the advocates' concerns is that HPV-only testing could lead to overtreatment of younger women who carry the virus but have little risk of developing actual cancer. Most sexually active young people will contract HPV, though their bodies usually eliminate the virus within a few months. Only years-long infections develop into cancer.

"Unfortunately the HPV test by itself isn't very useful because so many young women have HPV that will disappear without any treatment," said Diana Zuckerman of the Cancer Prevention and Treatment Fund. "Having an HPV test without also getting a Pap smear to check for problems is going to scare a lot of women who are not developing cervical cancer."

An FDA spokeswoman said the agency could not comment on the letter since it deals with a product under review.

For decades the Pap test was the only screening option for cervical cancer — and it's had a remarkably successful track record. The number of cervical cancer cases reported in the U.S. has decreased more than 50 percent in the past 30 years, primarily due to increased Pap screening. Still, an estimated 12,000 cases of cervical cancer are expected to be diagnosed this year, a fact that has spurred development of genetic tests like the one from Roche and other test makers.

Medical guidelines have been evolving rapidly to try and incorporate both techniques. Under the latest guidelines from the American Cancer Society, a Pap test is recommended every three years for women 21 to 29 years old. Women 30 and older should have both a Pap test and an HPV test every five years, or a Pap test alone every three years. Women who have had an HPV vaccine should still follow screening guidelines.

HPV screening is not recommended for women in their 20s because it increases the odds of more invasive testing that can leave the cervix less able to handle pregnancy later in life.

But Roche is seeking FDA approval to market its test to women age 25 and up.

That approach was endorsed unanimously last month by a panel

of FDA advisers who voted 13-0 that Roche's cobas HPV test appears safe and effective as a first-choice screening tool. The FDA is weighing that recommendation as it considers approval of the company's application.

Despite the overwhelming endorsement, patient advocates say FDA approval would fly in the face of current medical guidelines, none of which recommend testing with HPV alone for younger women. They point out that the U.S. Preventive Services Task Force, which sets federal medical guidelines, gave HPV testing a "D" rating in women under age 30, warning that testing could lead to "unnecessary treatment and the potential for adverse pregnancy outcomes."

Even physicians who support HPV testing as an important option warn that introducing a DNA-only testing regimen may lead to confusion that disrupts care. The American College of Obstetricians and Gynecologists says many physicians are already confused by the two existing testing options: Pap alone or Pap with HPV testing.

"Introducing a third screening alternative will likely further increase confusion, and the risk to women of getting either over or under screened," the group said in comments at the FDA meeting last month. The group, which represents 57,000 U.S. obstetricians and gynecologists, did not sign the letter sent to FDA.

Finally there is the cost. An HPV test costs between \$80 and \$100, at least twice as much as a \$40 Pap. And under Roche's proposal, women who test positive for HPV would be referred for colposcopy, a more invasive testing procedure that can cost up to \$500.

All these factors have consumer advocates urging the FDA to break from its advisers and deny first-choice status to the Roche test.

"Sometimes the FDA overrules the advisory committee and it's OK," said Dr. Susan Wood, a former FDA official who now directs the Jacobs Institute of Women's Health.

Mental Health Moment

By **DIONNE KINNINGER**

People with autism spectrum disorders may experience communication difficulties, a reliance on routine, repetitive behaviors, sensory issues, difficulty understanding humor and trouble identifying or expressing emotions.

One in 88 children have autism spectrum disorders.

April is National Autism Awareness month. There are several exciting efforts that are increasing autism awareness and providing assistance to families in our area.

Proceeds from the second annual Pancake Breakfast for Autism hosted by Pierce's Crew, held April 5 at Waldo Pepper's in Findlay, went to Pierce's Crew Foundation (piercecrew.weebly.com).

Heather Waite, Pierce's mother, created the foundation with help from Sarah Crisp and Awakening Minds Arts (awakeningmindsart.org) to help families with the cost of therapy.

Another local boy with autism was the focus of a short film, "Go Jackson Doll" (<http://www.timberandframe.com/portfolio-items/go-jackson-doll/>). The film tells the heartwarming story of Jackson's struggles and triumphs.

The Hancock County Autism Focus Team consists of representatives from Blanchard Valley Center, Blanchard Valley School, Hancock County ESC, Findlay City Schools and Century Health.

Among other accomplishments, the team is making it possible for infants and toddlers to be assessed and diagnosed here. In addition, Blanchard Valley Center has launched a website that provides education and local resources (hcalc.org).

With diagnostic changes, concerns about insurance, treatments such as social skills groups and sensory issues all being highlighted in the media, the day to day struggles remain unpublicized.

The children of Hancock County ESC, who have autism spectrum disorders, and their families are the real heroes. The appointments involved in helping autistic children succeed in a neuro-typical world is overwhelming.

I am so proud of the children and families that I work with and others that are managing autism spectrum disorders and are just trying to get through the day without a meltdown. You are the true heroes!

Kininger specializes in working with children and families. She is a clinician with Century Health, Findlay. If you have a mental health question, please write to: Mental Health Moment, The Courier, P.O. Box 609, Findlay, OH 45839.

Weekend Doctor

By **DR. MICHAEL DENIKE**

Not all heart attacks happen abruptly and dramatically the way we see on the big screen. In fact, most heart attacks start slowly with mild or unclear symptoms.

Discomfort in the chest is the most common symptom of heart attacks. Chest pain may feel like tight pressure, squeezing or fullness in the center of the chest.

Pain may come and go or it may last for more than a few minutes at a time.

Victims may also experience pain in other areas of the body.

Upper-body discomfort in the upper back, the neck, one arm (more commonly the left), or both arms can occur. Headaches, toothaches and aching in the jaw may also indicate a heart attack.

Other symptoms sometimes include shortness of breath, sweating, cold sweats, lightheadedness, nausea, vomiting, heartburn and/or indigestion. These symptoms may occur with or without body or chest pain.

Some sufferers experience silent heart attacks, with no pain and no new symptoms.

Awareness of the early signs of heart attacks is important because a matter of minutes can be the difference between life and death.

Many people are hesitant to seek medical attention when they experience early signs of a heart attack because they do not understand what is happening. They often attribute their discomfort to stress, tiredness or an upset stomach and try to ignore the symptoms, which can be fatal.

Some early signs of a heart attack are more vague and discreet than others.

For example, an individual may be more likely to recognize chest pain than they would recognize shortness of breath as an indicator of a heart attack.

However, heart attacks with vague symptoms can be just as fatal as an attack with severe symptoms.

It is important to always take these symptoms seriously and to contact emergency medical services right away.

If you or someone you know begins feeling symptoms of a heart attack, do not hesitate. Immediately dial 911.

Heart disease is the leading cause of death in America, but knowing the early signs of a heart attack and understanding how to quickly respond to the symptoms can save lives.

Denike is a cardiologist with the Blanchard Valley Health System. Questions for Blanchard Valley Health System experts may be sent to Weekend Doctor, The Courier, P.O. Box 609, Findlay, OH 45839.



Denike

Electrical device helps paralyzed men move legs

By **MARIA CHENG**
AP MEDICAL WRITER

LONDON — Three years ago, doctors reported that zapping a paralyzed man's spinal cord with electricity allowed him to stand and move his legs. Now they've done the same with three other patients, suggesting their original success was no fluke.

Experts say it's a promising development but warn that the experimental treatment isn't a cure. When the implanted device is activated, the men can wiggle their toes, lift their legs and stand briefly. But they aren't able to walk and still use wheelchairs to get around.

"There is no miracle cure on the way," said Peter Ellaway, an emeritus professor of physiology at Imperial College London, who had no role in the study. "But this could certainly give paralyzed people more independence and it could still be a life-changer for them."

In a new study published in the British journal *Brain*, researchers gave an update on Rob Summers, of Portland, Ore., the first to try the treatment, and described successful results for all three of the other men who have tried it. All had been paralyzed from below the neck or chest for at least two years from a spinal cord injury.

The study's lead author, Claudia Angeli of the Kentucky Spinal Cord Research Center at the University of Louisville, said she believes the device's zapping of the spinal cord helps it to receive simple commands from the brain, through circuitry that some doctors had assumed was beyond repair after severe paralysis.

Dustin Shillcox, 29, of Green River, Wyo., was seriously injured in a car crash in 2010. Last year, he had the electrical device surgically implanted in his lower back in Kentucky. Five days later, he wiggled his toes and moved one of his feet for the first time.

"It was very exciting and emotional," said Shillcox. "It brought me a lot of hope."

Shillcox now practices moving his legs for about an hour a day at home in addition to therapy sessions in the lab, sometimes wearing a Superman T-shirt for inspiration. He said it has given him more confidence and he feels more comfortable going out.

"The future is very exciting for people with spinal cord injuries," he said.

The study's other two partici-



UNIVERSITY OF LOUISVILLE / The Associated Press

KENT STEPHENSON, THE SECOND person to undergo epidural stimulation of the spinal cord, voluntarily raises his leg while stimulated at the Human Locomotion Research Center laboratory. The study takes place in the University of Louisville's Kentucky Spinal Cord Injury Research Center, Frazier Rehab Institute, in Louisville, Ky.

pants — Kent Stephenson of Mount Pleasant, Texas and Andrew Meas of Louisville, Ky. — have had similar results.

"I'm able to (make) these voluntary movements and it really changed my life," Stephenson said. He said the electrical device lets him ride on an off-road utility vehicle all day with his friends and get out of the wheelchair.

"I've seen some benefits of (the device) training even when it's turned off," he added. "There have been huge improvements in bowel, bladder and sexual function."

The new study was paid for by the U.S. National Institutes of Health, the Christopher and Dana Reeve Foundation and others.

Experts said refining the use of electrical stimulators for people with paralysis might eventually prove more effective than standard approaches, including medicines and

physical therapy.

"In the next five to 10 years, we may have one of the first therapies that can improve the quality of life for people with a spinal cord injury," said Gregoire Courtine, a paralysis expert at the Swiss Federal Institute of Technology in Lausanne, who was not part of the study.

Ellaway said it was unrealistic to think that paralyzed people would be able to walk after such treatment but it was feasible they might eventually be able to stand unaided or take a few steps.

"The next step will be to see how long this improvement persists or if they will need this implant for the rest of their lives," he said.

The National Institutes of Health is investing in more advanced stimulators that would better target the spinal cord as well as devices that might work on people who are paralyzed in their upper limbs.

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FOOT FACTS

By **Dr. Thomas F. Vail**

Why Do We Get Calluses on Our Feet?

Hyperkeratosis simply means thickening of the skin. This thickening occurs as a natural defense mechanism that strengthens the skin in areas of friction or excessive pressure. Abnormal anatomy of the feet, such as hammertoe or other toe deformities, can lead to callus formation as can bony prominences in the feet. Footwear that is too tight or that exerts friction at specific points can also cause skin thickening that leads to calluses. Abnormalities in gait or movement that result in increased pressure to specific areas can also be the cause.

TREATMENT

Calluses can be treated with many types of medicated products to breakdown the thickened, dead skin. These products all share the same active ingredient — salicylic acid, an ingredient used for wart-removal.

Salicylic acid is a keratolytic, which means it dissolves the protein (keratin) that makes up most of the thick layer of dead skin which often tops it. Salicylic-acid treatments are available in different forms including: applicators, drops, pads, and plasters. Physician formula strengths will be more effective than over-the-counter products. All of these treatments will turn the top of the skin white and allow you to trim or peel away dead tissue.

It generally is recommended that salicylic acid not be used by people with diabetes or when there is frail skin or poor circulation (because of concern about how the skin can heal). In these situations, application of salicylic acid can potentially lead to ulcer formation on the skin. Your Podiatrist can help you determine whether salicylic acid-based products are safe for use on your skin.

You should not attempt to cut or shave away corns and calluses at home or at the nail salon. This can lead to potentially dangerous infection of the surrounding tissues. This should only be performed by a podiatrist. Your doctor may also prescribe antibiotics for any corns or calluses that have become infected. If you notice any calluses on your feet, make an appointment at the Step Alive Center of Excellence to get your feet the proper treatment you need. Our foot and ankle specialist can get your feet feeling soft and beautiful once again.

Dr. Vail is a board certified foot surgeon and on staff at the Blanchard Valley Hospital and the Findlay Surgery Center. He can be reached at the Step Alive Center of Excellence: 1725 Western Ave., Findlay, OH. 419-423-1888



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