For now, first still last in primary HPV testing

Karen Titus

October 2015—Not long after the FDA approved a primary HPV screening algorithm for women age 25 and older, in April 2014, things began to stir on the Western front—specifically, in Bellingham, Wash., where Northwest Pathology is based.

"We started offering it pretty much right after the FDA approved it," says Ryan Fortna, MD, PhD, director of molecular pathology at the regional, independent anatomic pathology group. Though he hasn't tracked the numbers closely, he estimates primary HPV testing now accounts for maybe five percent of the lab's overall women's health testing. The algorithm is based on use of the Roche Cobas HPV assay, and Dr. Fortna says Roche has told him his group was the first in the United States to start offering it. "Which surprised me."

But all is quiet on the Eastern front—specifically, at Massachusetts General Hospital, reports director of cytopathology Martha Pitman, MD. (She is also associate professor of pathology, Harvard Medical School.) "In our conversations with our GYN clinicians, they have said they're more interested in cotesting." She adds, "We really haven't had a whole lot of conversations about it. They haven't come to me asking for it. We have never had a request for it."

There's still time to beat the rush, in other words.

Mark Stoler, MD, says that based on what he's hearing from laboratory and clinical colleagues, the algorithm has "slow but steady adoption." Dr. Stoler, professor emeritus of pathology and clinical gynecology, University of Virginia Health System, Charlottesville, says he knows of a few local clinicians who have started using it, and he's heard of other large institutions that are close to starting or are at least discussing whether to offer it.

"Slow" is a relative term, of course. In medicine, taking a decade to bring about a change in practice can also be called "normal." (One pathologist jokes that making changes at her institution is "like moving the Titanic.")

Dr. Davey

Says Diane Davey, MD, of the University of Central Florida, Orlando, “It takes awhile for any new testing to percolate down, unless it’s the only test out there.” (Clearly not the case with cervical cancer testing.) “So unless you have a clinician or pathologist who’s promoting it, or clinicians are promoting it in their own practice, it may take a long time,” says Dr. Davey, interim chair, clinical sciences; assistant dean, graduate medical education; and professor of pathology, UCF College of Medicine. She’s also a member of the CAP Cytopathology Committee.

Adds Dr. Stoler: “I think the slowness is a natural byproduct of the fact that we spent 10 years educating people about the advantages of, and the need for, cotesting.”

Breaking from the past

HPV may have the FDA’s blessing as a standalone screen, but it’s not a standalone topic. It’s nearly impossible to talk about primary HPV testing without delving into cotesting, which carries its own baggage. Little wonder, then, that the topic continues to raise its fair share of questions, in addition to reviving old doubts.

In one sense there’s nothing new about the HPV test. “We offered the test anyway, as part of cotesting,” says Dr. Fortna. But it wasn’t business as usual in the primary setting. That’s why Dr. Fortna took careful steps when he began offering the test and asked clinicians to read the fine print (as written by the lab).

The lab retained the HPV testing options already available, but has separated them, spatially, from the new primary testing option, “to make it very clear we’re talking about two different things,” Dr. Fortna says.

“We were very careful with how we worded it on the requisition form,” Dr. Fortna says. This included explaining, in a footnote, what the FDA approval entails. Clinicians can order HPV testing in other scenarios as well, he notes, but the lab wanted to make sure its clients knew exactly what the FDA was stamping with its imprimatur.

Results reporting also underwent a makeover. In cotesting, the cytology result is listed first, with the HPV result below. The recommended action is directly below that. “It follows the logic of, ‘how did you come to this recommendation?’” Dr. Fortna says.

They wanted a different look for reporting primary HPV results, since the logic is different. So “HPV comes first. And in many cases you’re not even reporting a Pap cytology result,” he says. “If you are, it was a reflex from the HPV result.” Consequently, they had to create a new pathway, so to speak, in their laboratory information system. “I don’t know that it’s critical, but we like our reports to make logical sense.”

In this case, finicky follows function. Cervical cancer screening remains a complicated subject, says Dr. Fortna, and he’s found that his clinical colleagues still need help sorting through all the testing options.

“I field questions all the time from clinicians who have trouble understanding the ASCCP algorithms,” says Dr. Fortna. “There’s a whole spectrum with how clinicians deal with this subject.” Some want to follow the algorithms to a T, he says. Others—certain OB-GYNs, for example—use some parts of the algorithms but not others. Family practice physicians, who typically don’t perform as many Pap tests, might want to follow the algorithms but aren’t quite sure how to do it. “And now we’re adding a different algorithm.”

Dr. Fortna isn’t the only one who’s watched physicians go off-roading. Consider:

- “We’re still seeing people do annual Paps, which to me makes no sense

when you've got cotesting," says David Wilbur, MD, pathologist, MGH, and professor of pathology, Harvard Medical School.

- "We're still receiving a significant proportion of patients who are getting cotesting every year, which is overkill if you go by strict recommendations," says Mohiedean Ghofrani, MD, director of cytopathology, PeaceHealth Laboratories, Vancouver, Wash., and a CAP Cytopathology Committee member.
- Dr. Davey notes that low-risk HPV is not indicated for any kind of cervical cancer screening, yet some physicians may be doing it annually. "That's not part of any guideline," she says.
- And from Barbara Crothers, DO, program director of the pathology residency, Walter Reed National Military Medical Center, Bethesda, Md., and chair of the CAP Cytopathology Committee: "We continue to see women who have had a hysterectomy and no history of dysplasia or carcinoma get cotested."

Nonetheless, the trudge toward modern cervical cancer screening continues. Dr. Stoler says that in debates he's had with colleagues who are more committed to cytology than to HPV testing, "Nobody is talking about cytology alone. It's cotesting versus primary HPV as the choice. So that means everybody is getting HPV testing," he says. "That's real progress."

Dr. Ghofrani agrees. The emerging discussions will be whether cotesting will remain the preferred method, or whether primary HPV testing should replace it, he says.

If only it were as simple as deciding which approach is best. It's not. Physicians need to understand the tradeoffs that accompany each choice, says Dr. Crothers, who led a CAP '15 panel on HPV testing this month, including an exploration of that topic. "That doesn't mean that molecular testing primary HPV screening isn't the way to go," she says. Rather, physicians need to understand the many issues involved, she says, "so we keep them on the radar screen and make changes down the road as necessary. It's easy to get lackadaisical and say, 'OK, issue solved—now we have primary HPV screening.' It's actually more complicated than that."

Getting the word out

Dr. Fortna

Before physicians can choose, they need to know choice exists. After changing the requisition forms, Dr. Fortna and his colleagues at Northwest Pathology sent a letter to all their clinicians who perform Paps, telling them that primary HPV testing was now available. The client services team was also educated so they could talk about it during their visits with physicians. Nonetheless, "Getting the word out is pretty difficult," says Dr. Fortna, "unless they happen to be particularly interested themselves." He's found that some seem interested, and others aren't.

“To be honest, I don’t particularly care if they choose this or cotesting, but we wanted to make it available.”

Dr. Fortna says he regularly fields two questions from clinicians asking about primary HPV testing:

- Why do I want to do this, instead of what I’ve been doing?
- How do I follow up on results?

To the first question, Dr. Fortna’s reply is blunt: “There’s no really good reason, to be honest,” although he immediately adds it has potential to save women money. And, he says, to the extent that people follow the recommendation by starting at age 25, not 30, studies have shown it should help identify a subset of patients with high-grade CIN lesions who would otherwise be missed.

As for the second question, Dr. Fortna says answers have become clearer now that the ASCCP (with the Society of Gynecologic Oncology) has issued its interim guidance on primary HPV testing. (It hadn’t when the laboratory first offered the test.) It basically endorses the short algorithm in the FDA’s publication, says Dr. Fortna.

The report, as listed on the ASCCP website (www.asccp.org), recommends:

- Primary HPV testing can be considered for women starting at age 25.
- Women under age 25 should continue to follow current guidelines that recommend cytology alone beginning at age 21.
- Women with a negative primary HPV test result should not be retested again for three years. This is the same screening interval recommended under current guidelines for a normal cytology test result.
- An HPV test positive for HPV 16 and 18, two types associated with a higher risk of future disease, should be followed with colposcopy.
- A test that is positive for HPV types other than 16 and 18 should be followed by reflex cytology testing.

Dr. Pitman of Massachusetts General hasn’t been encountering questions about primary HPV screening, because no one’s even asking for the test. But she suspects many of her colleagues are waiting to see data from Australia, where the National Cervical Screening Program is shifting, starting in May 2017, to have women age 25 to 74 undergo an HPV test every five years. “It will be interesting to see the outcome of their studies, and how it affects disease detection.”

They may be harboring other reservations as well. Some worry about false-negative HPV test results and what might happen in those intervening three years, Dr. Pitman says.
Finally, she says, “I just don’t think the gynecologists want to completely lose touch with their patients.”

The pull of Pap

Dr. Pitman reports that as cotesting has gained acceptance, her lab has seen a decline in the number of Pap tests and an increase in the number of HPV tests, though the numbers are stable right now. But, as she hints at (and as

others have observed), the tug of the annual Pap test remains strong.

Dr. Pitman

Even as she sees cotesting expanding, Dr. Crothers still sees traditional Pap testing exert influence on how cotesting is done. She blames the complex algorithms. “They’re confusing. Some health care providers may just figure, oh, OK, we’re now doing Paps and HPV. On everybody. Every year,” Dr. Crothers laughs. “That message, that one-year message to get a Pap test, is very ingrained in society.”

There is also an emotional attachment to the Pap test, on the part of clinicians, patients, and perhaps even pathologists.

“Rightly so,” says Dr. Stoler. “It’s been the best cancer screening test in the history of medicine.” But, he says, it hasn’t kept up with evidence-based medicine.

Dr. Fortna suggests the attachment comes from the Pap’s historic link to annual exams. Patients, he says, have traditionally thought of that visit as “going for their Pap.” The test also connected women to regular health care. (Men, Dr. Fortna jokes, won’t show up at their doctors’ offices until middle age, when they injure themselves playing sports on the weekend.) And few would argue with the Pap test’s success, which Dr. Fortna compares to that of vaccines. In short, “The word ‘Pap’ is in people’s brains,” he says.

But is that attachment rational? Dr. Fortna suspects it’s mostly not. “Is it the Pap’s responsibility to get people to see their doctor? You can still schedule a patient to come in every year even if they’re not repeating the Pap.”

On the other hand, depending on what clinicians glean from the test, there could be reasons to keep it in the picture. Strictly speaking, the Pap is a screening test for cancer. But the truth is, many clinicians rely on the Pap for other findings as well, says Dr. Fortna, such as endometrial cells, infections, CIN1, etc. “But that’s not the fundamental reason for screening,” he reiterates. “The fundamental reason, at least according to ASCCP, would be to pick up the high grades you need to excise, which HPV testing typically does.”

Some pathologists may prefer the Pap for reasons that Dr. Fortna calls “personally protective.”

“Frankly, a large number of cytotechnologists have their jobs because they have to screen Pap tests,” he says. “When we start doing away with that, people understandably get scared.”

Dr. Wilbur

Dr. Wilbur is familiar with those worries. “There’s grave concern that you’re going to destroy your cytology infrastructure.” He sees that as alarmist. Pap test numbers have declined in general because of cotesting, so contraction in the work force has already occurred. “I guess if I were working for a large private laboratory and all I ever looked at was Pap smears, I’d be a little worried for my job at this point,” he concedes. But at MGH, he notes,

cytotechnologists are kept busy with non-GYN specimens and fine needle aspirations; they're also being trained in molecular and non-cytology morphologic procedures, "actually leading to ever expanding roles."

Dr. Crothers understands the apprehension. "I think we're all subject to internal bias, based on what we do. There's just no avoiding that." When some look at the declining numbers of Pap tests, they see only a red flag. "But my greater concern isn't so much about the Pap. It's about the skill set of cytotechnologists," and the dismantling of the cytotechnology school system. Redefining the role of cytotechnologists (as has happened at MGH) "is the direction we're trying to head. We're not trying to fend off anything like HPV that's going to threaten the Pap test."

False-negatives and other fears

Like nervous new parents, physicians have no difficulty imagining what could go wrong with primary HPV testing. The conversation gallops from one momentous worry to the next, like a Schubert symphony. Patients will be lost to follow-up. Costs will go up. Not everyone will use the FDA-approved method. Samples may be insufficient. Long-term studies are missing. HPV alone lacks a morphology control. We're not Europe, with its various national screening programs.

Dr. Wilbur says the biggest concern he hears relates to false-negative results. At various meetings he's attended over the years, "I've heard this commentary back and forth from the podium half a dozen times," he says. Some point to studies looking at HPV tests done prior to a diagnosis of invasive cancer, which found that anywhere from 20 to 30 percent of cases were HPV negative two to three years prior to diagnosis. Others will say that the point of Pap testing isn't to find invasive cancer but to identify CIN3 or high-grade dysplasia, because these are the most prevalent and the direct precursor to invasive carcinoma—and almost all of those cases are HPV positive. Since HPV-negative cancers are so rare in comparison to CIN3 (the argument continues), high-risk primary HPV screening is indeed effective.

Not all cervical cancers are HPV-driven, and that's another worry. Others voice concern that even when HPV is the culprit, it may involve a mutation that's undetectable using current testing methods.

Dr. Zhao

Chengquan Zhao, MD, a professor of pathology and associate director of cytology, Magee-Womens Hospital, University of Pittsburgh Medical Center, has overseen three recent studies looking at HPV screening at three major institutions in China: Guangzhou KingMed Diagnostics (that country's largest independent, CAP-certified pathology laboratory); Obstetrics and Gynecology Hospital of Fudan University, Shanghai (its largest women's hospital); and China-Japan Friendship Hospital (one of Beijing's largest general hospitals). The studies were done independently but show similar results, says Dr. Zhao—the development of invasive cervical cancer despite a negative HPV test.

In a small number of cases, Pap cytology was also negative, Dr. Zhao says. But only in very few cases (nine of 231 patients in the OGHFU study, for example) were both tests negative. In his view, such results continue to support the idea of cotesting.

It may be difficult to compare patients in China directly with those in the United States, of course. And it's worth noting that the HPV testing in these studies did not use the Roche Cobas, but rather other assays, including Hybrid Capture 2, which has not been FDA approved for primary screening. "But there's value in looking at what happens in the real world," says Dr. Zhao, who is a member of the CAP Cytopathology Committee.

Dr. Davey agrees. “These are data from clinical settings, and they’re large studies,” she says. The OGHFU study, for example, looked at 3,714 patients with invasive cervical carcinoma, 525 of whom had prior HPV testing within three years, and 238 of whom had Pap cytology within one year before the histological diagnosis.

While there seems to be no shortage of studies, some physicians would like to see more. As Dr. Pitman mentions, there’s considerable interest in Australia’s move to primary HPV testing. And Dr. Davey, who’s concerned about using HPV testing in older women, says she’d eventually like to see long-term data on using HPV screening over a woman’s lifetime, though she concedes such studies may be hard to do, given the low incidence of invasive cervical cancers in the United States.

At least one pathologist says it would be helpful to see a noncompany-financed study, arguing that companies have incentive to pick through the data and that they tend not to publish negative studies. Given that, however, “The ATHENA study [the source of the FDA-approved algorithm] was done about as well as a corporate study could be in terms of being free of bias. And studies from Europe, including Italy and the Netherlands, show similar data.”

Adds another pathologist: “I have some personal concerns just about how testing tends to be vendor driven. The vendor with the most money can corner a market and end up dominating [it] for a considerable time—maybe at the expense of better testing development.”

Dr. Fortna, however, says he’s not waiting for more studies. In his opinion, the current data are good. “Obviously we made it available right away, so we’re not doubting the data.”

Nor does Dr. Stoler see a need for additional studies to prove the value or safety of primary HPV screening. “If I had a concern, I wouldn’t be an advocate of it.”

What he would like to see are data on how to optimize triage. “I think we can do a better job than cytology for the triage of HPV-positive cases, to focus on who’s at risk.” He points to the Ventana-Roche p16/Ki-67 dual-stain product, currently in use in Europe, as one possible subject for a U.S. clinical trial. “I think you’re going to see other companies entering the market as HPV testing becomes more entrenched.”

And though this isn’t study material, Dr. Stoler says he hopes the HPV discussions with physicians will start occurring on a practice- or systemwide basis. “Right now, my sense is that individuals are making their own decisions, or even letting their patients decide.”

Those decisions are likely to turn on perception of risk, and whether one argues from a per-patient or a public health perspective.

Dr. Stoler, in his talks with clinical colleagues, says the best approach is to address the concern of the moment. That said, “I think most of the concern from clinicians has to do with their understanding of the issue of harms versus benefits.”

Dr. Ghofrani

No such discussion is complete without talking about money. To provide an example, Dr. Wilbur parses the data from the ATHENA trial, which, he says, clearly demonstrates that HPV testing is more sensitive than Pap testing for detecting high-grade abnormalities. But the comparisons had an apples-to-oranges-to-bananas aspect to them. The primary HPV testing was done in a group of women age 25–30, which was compared to cotesting in women over 30, as well as to Pap testing alone in a 25–30 age group.

In that three-way comparison, Dr. Wilbur says, primary HPV testing in the over-25 group is better than cytology in the 25–30 group *and* cotesting in the over-30 population. Would it make sense to do cotesting starting at 25, he asks, as a way to pick up HPV-negative lesions, even though that's not part of any current guideline? While such lesions are exceedingly rare, he says, in the current scheme they won't be picked up. "But to find those very rare cases of HPV-negative cancer, you would have to spend a lot of money," Dr. Wilbur says.

Those high costs may not seem worth it to some, says Dr. Ghofrani. "They'll say it's a risk we're willing to accept. Now, obviously, for one patient who has developed cancer, that's not an acceptable argument."

It's not just patients who will object, says Dr. Wilbur. "I think the problem is the physician mentality: *Why would we prefer a test that we know is going to miss something?"*

More questions

That could be one of many questions pathologists will face when discussing primary HPV testing with clinicians as well as one another.

The longer follow-up intervals remain a pervasive concern. The new algorithm, as noted, follows the three-year guidance already suggested for normal cytology test results—and clinicians still aren't fully comfortable with that, either.

Based on MGH's own records, says Dr. Wilbur, "When you recommend a two-year repeat, it's likely to be a four-year repeat." He recalls one study that showed women underestimated the time since their last Pap anywhere from 50 to 100 percent. "So there is great concern that the algorithms fall apart if you go beyond the testing period, because you're going to have new cases of CIN3 that come to the fore during that follow-up period."

Dr. Stoler has a ready answer to such doubts. He says because the algorithm includes genotyping, it allows physicians to focus on high-risk patients. No one gets lost to follow-up because the right patients are referred to colposcopy. "Remember, so much of this disease is found in patients you find in the first round with either cotesting or primary HPV testing," he says. Even when the cytology is normal, HPV can identify a 16/18 genotype. The real power of HPV testing and/or cotesting, he suggests, is reassuring the 90 percent of patients who don't have disease or a high-grade lesion, and getting the right women to colposcopy, while reducing the risk of overtreatment for those who will be fine without it.

In his own practice, Dr. Ghofrani is stepping gingerly, in part because of prevailing confusion about screening intervals. "People are getting on the cotesting bandwagon, but they're still not adopting the extended screening interval," he says. "Right now, if they're doing it every year, we're trying to persuade them to do it every three years." Adding yet another algorithm when some clinicians are still trying to navigate current ones might be overwhelming, so he's reluctant to "abandon cotesting," as he puts it, for primary HPV screening.

He's sharing that cautious message with his clinical colleagues in educational presentations, which include an overview of current data and the recommended consensus guideline. "When they ask us questions about HPV primary screening, we tell them it is an acceptable option, and if they want to take that route we will accommodate them," Dr. Ghofrani says. "But we tell them that right now, probably the strongest evidence that we have available to us is recommending cotesting as the ideal method."

Not every clinician is confused by current algorithms. Dr. Pitman says her MGH clinical colleagues are quite savvy. Dr. Crothers says much the same thing, noting, "I don't think most of us worry about our gynecology colleagues."

But those without that deeper understanding, she fears, might feel compelled to overtest when faced with uncertain results (a positive HPV followed by negative cytology, say). "They may go ahead and do a colposcopy and possibly implement the very thing we're trying to prevent, which is inadvertent harm to women from colposcopy, biopsies, LEEPs, and cones that aren't really necessary." Colposcopy, Dr. Crothers notes, is especially worrisome because it lacks the QA and QI infrastructure of the Pap test. "We know in certain hands colposcopy

isn't as good as it is in other hands," she says. If colposcopists take charge of capturing lesions—versus use of a Pap—after a positive HPV test, "that's scary," she says.

She's particularly concerned about misuse of primary HPV screening in younger women, who are likely to clear the virus. It's plainly not effective in that group, she says. "We don't want them tested. We ask people to just forget you even did an HPV test if you did one in a woman under 21, because you're more likely to harm her from that information than to benefit her."

Dr. Davey shares that unease. While she says she's not opposed to primary HPV screening, she asks if it makes more sense to use it in a slightly older group. "I'm concerned about overtreatment in young women." At the other end of the age spectrum, she's concerned that for women over 50, the HPV test may not be sensitive enough.

Dr. Stoler

Those who want to do primary HPV testing need to be schooled on one more matter: The approved algorithm is based on the Roche Cobas assay, using ThinPrep specimen collection, says Dr. Davey. "It's going to be confusing to some laboratories, and even more to clinicians, who in most instances might know they want to order a test but don't understand the nuances of one test versus another."

Dr. Crothers agrees. "We don't want clinicians to get the impression that now they can use any HPV test as a primary test."

Dr. Wilbur is even more forceful. The math is easy, he says. Cotesting is two tests; primary HPV screening, one. Those who choose the one-test route "need to be sure that the test is working the way it was presented to the FDA, so the bar is much higher for self-validation than it is for cotesting or triage testing with HPV."

Dr. Stoler supports—quite emphatically—that notion. Why would anybody do a homebrew laboratory test for HPV when there's an FDA-approved test and literature about clinical validity, he asks. "Why are we even having discussions about what it takes to do a clinical validation? If you look people in the eye, and everybody says, 'We try to do the best thing for our patients,' well, then, do you really understand the data? Are you being honest about your conflict of interests?"

Looking ahead

For all the discourse, Dr. Wilbur says there eventually may be an easy way out of the woods: He predicts that at some point insurance companies will mandate use of primary HPV screening.

What else might the future bring?

Dr. Fortna looks well beyond the current issues to ask a provocative question: Should women self-collect for HPV testing? There's no reason they can't, he says. "Everybody outside the U.S. is talking about it. Go to an HPV conference, and all the European countries are already doing large-scale studies for self-collection." So are Third World countries, he says.

For women unlikely to receive regular health care, self-collection for HPV might make sense. "When you see squamous cell carcinoma of the cervix, which is rare, it's usually women who haven't come in for 10 years," Dr. Fortna continues. The problem isn't missing an annual exam, in other words; it's missing a decade or more. Studies, both from the United States and abroad, show self-collection works, he says. "Now get that FDA approved. Then you're going to catch the women who actually end up with cancer."

Then there's HPV vaccination. If rates rise, prevalence will drop. That will affect both HPV and Pap testing, says Dr. Wilbur, but the latter will likely be harder hit. "The more you look at negative cases, the more you call everything negative," he says. "There's a definitive prevalence effect in cytology—we've shown that in our own lab." That in turn boosts the need for a more sensitive test—thus giving the advantage to HPV testing.

Not that the United States has been a vaccination superstar. Coverage has been "abysmal—less than 40 percent for all three shots," says Dr. Stoler. His prediction: Unless rates improve, the U.S. will still be doing annual Paps while countries with high vaccination rates—Australia, for example—will be either dismantling their screening programs or moving to 10-year or three-times-per-lifetime testing, because of the low prevalence. "We're just going to be embarrassed," Dr. Stoler says, gloomily.

If HPV vaccinations gain ground, asks Dr. Crothers, will the depletion of serotypes 16/18 result in the emergence of other serotypes to fill that ecologic niche? "We can't predict that, obviously," she says. "That's not a reason not to do vaccinations, and it's not a reason not to do primary HPV screening. But it's an issue that should remain on our radar screen while we're looking at the future of cervical cancer screening."

Given the mosh pit of questions, concerns, reluctance, confusion, and dismay that attends primary HPV screening, it's hard to believe that yet another approach could actually simplify matters. Believe it, says Dr. Crothers. Researchers now better understand the biologic event that results in cervical cancer—incorporation of the viral genome into the host genome. New markers might be better than merely detecting the presence of the virus. "Our current methods are just a little bit immature," says Dr. Crothers. Ideally, as molecular platforms evolve, pathologists might be able to identify a smaller group of women who are at significant risk, who have viral integration. "It's crazy chasing the virus."
Until then, however, laboratories will continue to ponder primary HPV screening—the test that's launched a thousand discussions.
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