

- Medscape
- eMedicine
- MedscapeCME
- Medscape Connect
- Find a Physician...

Medscape MedscapeCME eMedicine Drugs MEDLINE All

SEARCH

O Eichhorn
Account Settings | Log Out | Newsletters

LATEST | NEWS | CONFERENCES | JOURNALS | RESOURCE CENTERS | VIEWPOINTS

Medscape Conference Coverage, based on selected sessions at the:

American Society for Clinical Pathology (ASCP) 2009 Annual Meeting

This coverage is not sanctioned by, nor a part of, the American Society for Clinical Pathology.

From Medscape Medical News

Repeat FISH Testing of Breast Tissue Not Cost-Effective for Her-2/neu Determination

Caroline Helwick

[Authors and Disclosures](#)

 Print This  Email this



RELATED ARTICLES

News

- [Earlier Breast Cancer Screening for Black Women May Be Warranted](#)
- [Reminder Program Boosts Mammography Rates](#)
- [Digital Mammography Boosts Breast Cancer Detection](#)

Articles

- [New Diagnostic Techniques for Breast Cancer Detection](#)
- [Cost-Effectiveness of Breast Cancer Screening in Women on Dialysis](#)
- [Inorganic Nanoparticles for Predictive Oncology of Breast Cancer](#)

November 4, 2009 (Chicago, Illinois) — Universal testing of breast cancer tissue for Her-2/*neu* status with fluorescence in situ hybridization (FISH), as some have proposed, does not increase the identification of candidates for Her-2/*neu*-directed therapy and is not cost-effective, investigators from Loyola University Medical Center in Maywood, Illinois, announced here at the American Society for Clinical Pathology 2009 Annual Meeting.

There is currently no consensus about Her-2/*neu* testing on specimen type, the use of multiple-specimen testing (dual testing), or the utility of universal FISH, noted lead author Kelli Ann Hutchens, MD, who is now a dermatopathology fellow at State University of New York in Brooklyn. The senior author of the study was Henry Brown, MD.

"The American Society of Clinical Oncology and College of American Pathologists algorithm provides a standard for testing (FISH for immunohistochemistry [IHC] 2+ or equivocal), but it is not conclusive with regard to testing additional specimens or the use of universal FISH," Dr. Hutchens said.

"At our institution, we have frequently been doing universal testing, that is, using FISH regardless of the immunohistochemistry results, and have been testing more often, doing IHC and sometimes FISH on both biopsy and excision specimens," she said. "We usually did this because of the clinician's or patient's request. It's hard to say no to a breast surgeon."

But the pathology department became concerned about an "unvalidated approach," she said, which led them to evaluate the sensitivity and the cost of Her-2/*neu* testing on biopsy and excision specimens and the use of universal FISH.

The study involved 45 patients with invasive breast cancer found on both core biopsy and excision specimens; each specimen was tested for Her-2/*neu* with IHC and some specimens were tested with FISH. Cases were evaluated for frequency of FISH testing, regardless of IHC result, dual FISH testing on biopsy and excision specimens, and concordance of IHC and FISH results.

They also determined the cost of testing to the laboratory, the standard reimbursement for testing, and the patient expense. Cost of IHC was assessed at 2.5 times the direct cost, and standard reimbursement from Medicare and unreimbursed costs were determined. The cost of FISH was obtained from the reference lab and calculated as a patient cost for the unstained slides sent to a reference lab for analysis.

Concordance Very High Between Tests

There was 95.5% concordance (43 of 45) when IHC was performed on both biopsy and excision specimens, 100% concordance (12 of 12) when FISH was performed on both, and 97.5% concordance (39 of 40) between determinant IHC and FISH.

There were 2 discordant cases. One patient overexpressed the protein without gene amplification (i.e., IHC-positive and FISH-negative), which is reported in the literature to occur in about 3% of cases. The second patient was IHC-positive on the biopsy and negative on the excision sample, which could represent a fixation error, thickness of tissue, or other factor, she suggested.

These concordance rates were "acceptably high and similar to [those in] the literature," Dr. Hutchens noted.

Importantly, universal FISH testing did not result in the increased identification of tumors that would potentially be trastuzumab-responsive, she reported. Nor did dual testing of the biopsy and excision specimens with IHC or FISH result in increased identification of Her-2/*neu* positivity.

Universal FISH Not Cost-Effective

"Testing beyond using IHC on a single excision specimen and FISH for equivocal cases only results in unwarranted costs to laboratories and patients and should not be performed," Dr. Hutchens concluded.

Each IHC test cost the laboratory \$194.56, for which the standard reimbursement is \$52.36, resulting in a \$142.20 loss for each test performed. FISH testing is directly billed to the patient, at a cost of \$794.00 per test.

"Dual testing on the biopsy and excisional specimens did not yield a significant increase in sensitivity, and resulted in \$6399 in unreimbursed costs to the laboratory," she said. "Performing FISH on determinant IHC specimens resulted in \$31,760 in additional costs to patients."

Had clinicians followed the algorithmic guidelines for Her-2/neu testing, unreimbursed costs to the lab would have been reduced by \$6399, and costs to patients would have been reduced by \$41,288. The total savings would be \$47,687 for these 45 patients, translating into a savings of \$105,971 per 100 patients, the investigators concluded.

"Excess testing has cost us and our patients," Dr. Hutchens observed. "Our goal is now to use this study as a platform to say that additional testing is unnecessary and is costing our labs, our patients, and our healthcare system."

Session moderators agreed that pathologists are often pressed by surgeons and oncologists to do multiple tests for Her-2/neu, and said this information could help them abide by current guidelines. "This information is valuable in the current healthcare environment, to be able to say to your clinicians that we have evidence that allows you to do fewer studies and expect the same results," said Dennis O'Malley, MD, from Clariant Diagnostics in Aliso Viejo, California.

Rohit Bhargava, MD, from Magee-Women's Hospital of the University of Pennsylvania Medical Center in Pittsburgh, pointed out that in cases of ductal carcinoma in situ, universal FISH testing is clearly not indicated "and you can plainly so 'no' in this case," he said. With neoadjuvant chemotherapy becoming the norm, IHC testing is increasingly being recommended for the core needle biopsy, rather than the excision biopsy. "FISH should be done on a case-by-case basis," he said.

Dr. Hutchens and Dr. Bhargava have disclosed no relevant financial relationships. Dr. O'Malley is an employee of Clariant Diagnostics.

American Society for Clinical Pathology (ASCP) 2009 Annual Meeting: Abstract 86. Presented October 30, 2009.

 [Print This](#)  [Email this](#)

MORE ON THIS TOPIC

eMedicine Clinical Reference

- [Breast Cancer, Mammography \(Radiology\)](#)
- [Breast Cancer Evaluation \(Obstetrics and Gynecology\)](#)
- [Breast Cancer, Ultrasonography \(Radiology\)](#)

Medscape Resource Centers

- [Biologic Therapies in Cancer](#)
- [Breast Cancer Resource Center](#)

Medscape Medical News © 2009 Medscape, LLC
Send press releases and comments to news@medscape.net.

[Medscape](#) [MedscapeCME](#) [eMedicine](#) [Drugs](#) [MEDLINE](#) [All](#)

[About Medscape](#) | [Privacy Policy](#) | [Terms of Use](#) | [WebMD Health](#) | [WebMD Corporate](#) | [Help](#) | [Contact Us](#)

All material on this website is protected by copyright. Copyright © 1994-2009 by Medscape. This website also contains material copyrighted by 3rd parties.