



American College of Surgeons

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November 17, 2006

Andrew von Eschenbach, MD, FACS
Acting Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

RE: Regulation of Stereotactic Breast Biopsy Under the MQSA

Dear Dr. von Eschenbach:

On behalf of the 71,000 Fellows of the American College of Surgeons and the 2,100 members of the American Society of Breast Surgeons, we would like to take this opportunity to discuss our concerns regarding the possible regulation of stereotactic breast biopsy under the Mammography Quality Standards Act (MQSA). It is our understanding the Mammography Quality Standards Advisory Committee (Advisory Committee) has recommended that the definition of mammography be changed in the MQSA regulations to include stereotactic breast biopsy. This action would have the effect of regulating stereotactic breast biopsy under the MQSA. We do not support the Advisory Committee's position and strongly oppose the federal regulation of stereotactic breast biopsy.

Background

Congress passed the Mammography Quality Standards Act of 1992 to provide a general framework for ensuring national quality standards in facilities performing screening mammography.¹ Under the Act, all facilities that provide screening or diagnostic mammography services, including physician offices, must be credentialed. A review of the Congressional Record demonstrates that the purpose of this legislation is to reduce the frequency of false

¹ Institute of Medicine and National Research Council, *Improving Breast Imaging Quality Standards*, 2005, page 82



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positives and false negatives in these types of mammograms by regulating facilities in the areas of quality, personnel training, equipment evaluation, and medical records and reports.²

Definition of Mammography

There are two recognized types of mammography in the medical community: screening mammography and diagnostic mammography. A screening mammogram is an x-ray exam of the breast in a woman who has no symptoms. The goal of a screening mammogram is to find cancer when it is still too small to be felt by a woman or her doctor. A screening mammogram usually takes 2 x-ray views of each breast.³ A diagnostic mammogram is an x-ray exam of the breast in a woman who either has a breast complaint (for example, a breast mass, nipple discharge, etc.) or has had an abnormality found during a screening mammogram. During a diagnostic mammogram, more xrays are taken to carefully study the breast condition. The purpose of the MQSA is to improve quality of both screening and diagnostic imaging.

Stereotactic surgery is a minimally-invasive form of surgical intervention that uses a three-dimensional coordinates system to locate small targets inside the body and to perform a procedure such as ablation, biopsy, injection, , simulation, implantation, etc. There are many surgical procedures that are now being performed with stereotactic or other radiologic imaging, including breast biopsy, and none of those are regulated by the FDA. While imaging is used in stereotactic breast biopsy to guide the biopsy instrument, it is not a screening or diagnostic mammogram, as described above. In fact, almost all patients who are having stereotactic breast biopsy have already had a screening and diagnostic mammogram, which has led to the need for a biopsy. In stereotactic breast biopsy, the imaging modality itself is being used to neither screen nor diagnose breast cancer, but it is instead merely the avenue used to provide the surgeon the visual access needed to perform an interventional procedure.

The American College of Surgeons and the American Society of Breast Surgeons strongly believe that the imaging platform and technique used in stereotactic breast biopsy does not meet the definition of mammography as intended in the MQSA and, therefore, cannot and should not be regulated under the MQSA. The current FDA regulations on the MQSA recognize there is a difference between a screening or diagnostic mammogram and the imaging techniques used when performing invasive

² Congressional Record, September 18-23, 1992

³ American Cancer Society, Mammograms and Other Breast Imaging Procedures, 2006



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procedures like stereotactic breast biopsy. The FDA regulations define mammography in the following manner:

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

We agree with this definition and do not believe it should be changed.

The MQSA Requirements

A review of the actual MQSA requirements further demonstrates that it was never Congress or the FDA's intent to regulate stereotactic breast biopsy under this law. Many of the key requirements of the MQSA are essential to improving the quality of screening and diagnostic mammograms, but are inappropriate for stereotactic breast biopsy. For example, the regulations related to clinical imaging attribution have specific requirements related to positioning and compression. These requirements are contrary to the very technique of stereotactic breast biopsy, which is to use imaging in a very precise manner to localize the area being biopsied, but not to screen the entire breast for abnormalities. In addition, the regulations related to storage of mammograms and patient notification are also inappropriate for stereotactic breast biopsy imaging.

Quality Improvement

When the MQSA was passed in 1992, there was a recognized and documented problem with the quality of screening and diagnostic mammography. This is not the case with stereotactic breast biopsy. Recent studies indicate that stereotactic breast biopsy is as effective as open biopsy and has a negative predictive value of 99.95 percent.⁴ More importantly, the factors that determine success and quality include

⁴ Kettritz U, *Stereotactic vacuum-assisted breast biopsy in 2874 patients: a multicenter study*. Cancer, Jan. 2004



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proper patient selection, proper lesion selection, implementation of standard surgical practices, proper handling of the histological specimen, and ideal tissue sampling. The MQSA does not address any of these issues. We do not believe federal regulation is the proper pathway to improve the efficacy or outcome of any surgical procedure, including stereotactic breast biopsy.

Furthermore, we note the Advisory Committee did not cite any specific concerns related to quality when making its recommendations, but instead based its decision on the fact that there is now a potential program available to administer such regulations. The program in question was developed by the American College of Surgeons, and as the proprietor of that program, we do not support its use in this manner. When making its decision the Advisory Committee did not ask our opinion on the status of this program or the appropriateness of using it to regulate stereotactic breast biopsy under the MQSA, and, therefore, we question the thoughtfulness of its recommendation.

The Future of Image Guidance

In the long term, we believe FDA regulation of stereotactic breast biopsy will severely limit patient access to these procedures as well as development of the entire field of image guided surgery. The implementation of regulations will cause many physicians, especially surgeons, to stop performing stereotactic breast biopsy because they will not accept an imposed duplicative regulatory and administrative burden in addition to the host of patient safeguards that are currently in place. These surgeons will have no choice but to revert to open biopsy procedures. In addition, there is already a shortage of physicians willing to perform breast procedures and unnecessary regulations are going to fuel this problem.

Image guided surgery is an ever-changing field. While once stereotactic imaging was limited to one or two methods of biopsies, today surgeons across the country are using stereotactic imaging for laser ablation, placement of needle localization wires and placement of brachytherapy catheters for treatment of breast cancer after surgery. We strongly believe these examples are only a mere hint at what the future will bring and believe greater use of image guidance will lead to better outcomes, less invasive procedures and higher patient satisfaction. We are concerned that regulation of stereotactic breast biopsy under the MQSA will have a chilling affect on these advancements, which are almost always discovered by surgeons in search of new methods to improve old techniques. Finally, we note that x-rays are only a small aspect



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of the field of image guided surgery, which includes ultrasound, MRIs and other imaging techniques, and we believe limiting use of one type of imaging modality through regulations is both illogical and threatens to hamper advancements in other areas of image-guided surgery.

Conclusion

As the physicians who primarily treat breast disease in this country, the American College of Surgeons and the American Society of Breast Surgeons strongly support the MQSA and believe it has improved the quality of screening and diagnostic mammograms. However, we do not believe the intention of the MQSA is the regulation of surgical procedures like stereotactic breast biopsy and believe the FDA's current regulations reflect this fact. We do not believe the regulatory changes suggested by the Advisory Committee will improve quality but instead will just regulate for the purpose of regulating. Furthermore, we strongly believe additional regulations will severely limit patient access to this valuable procedure and will have a chilling affect on future advances in this field. We urge the FDA to maintain the current definition of mammography in its regulations.

Sincerely,

Handwritten signature of Thomas Russell in cursive.

Thomas Russell, MD, FACS
Executive Director

Handwritten signature of Helen A. Pass in cursive.

Helen A. Pass, MD, FACS



DEPARTMENT OF HEALTH & HUMAN SERVICES

DEC 7 2006

Food and Drug Administration
Rockville MD 20857

Thomas Russell, M.D., FACS
Executive Director
American College of Surgeons
1640 Wisconsin Avenue, NW
Washington, DC 20007

Dear Dr. Russell:

This letter is in response to your letter of November 17, 2006 to Dr. Andrew von Eschenbach, Acting Commissioner of the Food and Drug Administration. The issue of possibly modifying the definition of mammography as it exists in the Mammography Quality Standards Act (MQSA) regulations is currently under consideration. As part of that process, this matter was discussed at a meeting of the National Mammography Quality Assurance Advisory Committee (NMQAAC) on September 28 and 29, 2006. This issue was only one of approximately 170 items reviewed with the committee to ascertain their thoughts on modifying the current regulations.

On September 28, a letter from a consumer advocate recommending MQSA regulation of stereotactic-guided breast biopsy as well as regulation of ultrasound-guided breast biopsy was read into the record. On September 29, Dr. David Dershaw, representing the American College of Radiology (ACR), gave a presentation during the open public session advocating MQSA regulation of stereotactic-guided breast biopsies. He proposed using the current ACR voluntary accreditation program as the basis for such regulation. Committee discussion of this topic took place on September 29. Many of the issues you raise in your letter were brought up during that discussion by Dr. Philip Israel, the surgical member of the committee. Following this discussion, FDA asked two questions in order to assess the general consensus of the committee. The first question was whether interventional mammography, which in addition to stereotactic-guided breast biopsy also includes needle localization using mammographic guidance and galactograms, should be regulated under MQSA. The committee split on their advice on this matter with the majority advising against regulation. The second question dealt specifically with regulating stereotactic-guided breast biopsy. Again, the committee was split, with the majority advising for regulation.

At this time, the FDA has not made a decision as to whether or not it should propose regulating interventional mammography or stereotactic-guided breast biopsy. We are currently in a fact-finding mode to answer a number of questions that were not fully addressed at the NMQAAC meeting or in other forums. These questions include:

1. What are the real problems, if any, with interventional mammography and stereotactic-guided breast biopsy and is regulation the best way to deal with those problems?
2. Can non-governmental programs, whether voluntary or mandatory, adequately deal with any problems?
3. How many stereotactic-guided breast biopsy units are in use in the United States?
4. How many stereotactic-guided breast biopsy procedures are performed each year?
5. How many ultrasound-guided breast biopsy procedures are performed each year and will regulation of stereotactic merely shift any problems to that unregulated procedure?

6. What are the standards that need to be implemented in order to assure the public of the safety and efficacy of stereotactic-guided breast biopsy?
7. If implemented, should a regulatory program focus on performance and clinical based outcomes rather than specific equipment and personnel requirements as does the current MQSA program for non-interventional mammography?
8. What are the concordance and discordance rates for stereotactic-guided breast biopsy and how do they compare to those for surgical biopsy?

Any information you could provide at this time would be incorporated into our decision-making process. Please send your specific comments on the above matters or any issues that you believe would be pertinent as soon as possible.

As previously stated, the NMQAAC is an advisory committee. However, the authority and responsibility for actually proposing changes to the regulations resides with the FDA. The process that the FDA uses is one that is open to the public with the NMQAAC meeting being just one part of that process. Our plan is to issue a list of proposed amendments sometime in 2007, at which time the public would have 90 days to comment on those proposed changes. Only after reviewing those comments would the FDA issue final regulations.

Sincerely yours,



Charles A. FINDER, M.D.
Associate Director
Division of Mammography Quality and
Radiation Programs (HFZ-240)
Office of Communication, Education, and
Radiation Programs
Center for Devices and Radiological Health

cc:

Helen Pass, M.D.
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March 20, 2007

Charles A. Finder, MD

Associate Director

Division of Mammography, Quality and Radiation Programs

Office of Communication, Education and Radiation Programs

Center for Devices and Radiological Health

Food and Drug Administration

Rockville, MD 20857

Dear Dr. Finder:

We are responding to your December letter that replied to our November 17, 2006 letter regarding the possible modification of the definition of mammography in the regulations implementing the Mammography Quality Standards Act (MQSA). In your letter, you posed a series of eight questions that will address in this letter.

First, however, we have several concerns about how your letter characterized the September 28, 2006 National Mammography Quality Assurance Advisory Committee (NMQAAC) meeting. Specifically, we would like to clarify the following points:

1) The presentation by David Dershaw, MD, advocated using the "ACR voluntary accreditation program" as the basis for regulating stereotactic breast biopsy. The program being referenced is a joint American College of Surgeons/ American College of Radiology program and ACR does not have its own program. We were not informed of the request for information about the program until days before the meeting occurred; we were not invited to speak; Dr. Dershaw did not consult the ACS when developing his presentation; and we were not given the opportunity to provide formal comment to the NMQAAC on this subject before its vote. In short, while Dr. Dershaw may have been representing ACR at the meeting, he was not representing the joint ACR/ACS stereotactic breast biopsy accreditation program or the surgical community. More importantly, we do not agree with his assessment that the joint ACR/ACS program could be used to accredit programs as required by the MQSA. The requirements of the MQSA and the ACR/ACS program are not parallel or necessarily compatible. In addition, the program has many short-comings (as acknowledged by the NMQAAC and the Institutes of

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Medicine), and, recognizing this, the American College of Surgeons (ACS) and the American Society of Breast Surgeons (ASBS) have been working for several years on alternative quality programs in breast surgery that aim to ensure all breast patients receive the highest quality care throughout the entire spectrum of treatment. We believe the NMQAAC was disadvantaged by our inappropriate and inexplicable exclusion from this meeting and had NMQAAC heard this information prior to its vote, the outcome may have been different.

2) While we certainly appreciate the effort of Phillip Israel, MD, FACS, during the NMQAAC meeting to bring forward some of the issues involved in applying the MQSA to stereotactic breast biopsy, we have reviewed the minutes of the meeting and certainly do not feel he was given adequate time to assess the currently available evidence and articulate a thorough line of reasoning. It is our understanding that Dr. Israel asked to give a formal presentation following Dr. Dershaw's presentation and was denied this request. Again, we believe that had this occurred, the NMQAAC would have received a fuller and more balanced presentation of evidence and analysis on this topic and might have reached a different decision.

Below, please find the answers to the questions you asked in your December letter. We have tried to provide an appropriate citation when appropriate and possible, and have acknowledged limitations with our answers as well.

FDA Question One: What are the real problems, if any, with interventional mammography and stereotactic breast biopsy and is regulation the best way to deal with those problems?

This is a vitally important question from a legal, policy, and scientific perspective. We regret that it was not articulated and addressed in a scientific manner at the NMQAAC meeting.

When the MQSA was passed in 1992, there was a documented problem with the quality of screening and diagnostic mammography in the United States.¹ The purpose of the MQSA is to address these quality issues through accreditation and this approach has worked.² However, the same quality problems do NOT exist in stereotactic breast biopsy. Our review of more than 600 articles on stereotactic breast biopsy published in peer review journals in the past 10 years reveals no evidence of mammography-related quality issues when performing this procedure. In fact, almost every single article written in the past 10 years concludes stereotactic breast biopsy is a safe and effective procedure with a very low

¹ IOM, Improving Breast Imaging Quality Standards, 2005, pg. 1

² IOM, Improving Breast Imaging Quality Standards, 2005, pg. 1



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rate of discordant outcomes regardless of cause. We have included for you review Attachment A, which lists major articles on stereotactic breast biopsy.

Moreover, the few problems that have been identified in the literature involve patient selection for the procedure, and not use of equipment or mammographic technique. For example, stereotactic breast biopsy is not the preferred biopsy choice for cystic or liquid masses, but is the preferred method for microcalcifications. There is no evidence or basis in science for concluding that regulation of stereotactic breast biopsy under the MQSA would help physicians select the best biopsy choice for an individual patient or otherwise increase the safety or accuracy of this already successful procedure. It would instead reduce the likelihood that the patient would receive the most optimal procedure by reducing the availability of the stereotactic breast biopsy.

Finally, we acknowledge that several prestigious organizations have recently called for the regulation of stereotactic breast biopsy under the MQSA, including the Institutes of Medicine and the American Cancer Society. However, we note that none of these organizations have identified any quality problems with stereotactic breast biopsy, much less a problem that could be addressed by mammography standards under the MQSA. On pages 104-105 of its Improving Breast Imaging Quality Report, the IOM calls for regulation of stereotactic breast biopsy without a single citation or word about any perceived problems with quality, outcomes or patient safety, much less mammography standards that could resolve any such problems. Instead these groups merely argue that stereotactic breast biopsy includes mammography and mammography is regulated, therefore stereotactic breast biopsy should be regulated.

FDA has acknowledged that, with regard to interventional mammography, there should not be regulation merely for the purpose of regulating. There must be a scientific, evidence-based justification for federal standards. *See* 61 Fed. Reg. 14,856, 14,862 (1996). This entails, at a minimum, two elements:

- 1. A Clinically Significant Mammography-Related Problem.** FDA must make an evidence-based determination that there is a clinically significant negative outcome from the procedure that is caused, or is likely to be caused, in whole or in part by the mammography element of the procedure.
- 2. Mammography Standards that Can Address the Problem.** FDA must make an evidence-based determination that there are reasonable standards that can be implemented under the MQSA with regard to the mammography element of the procedure that will have a significant effect on the negative outcome.



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FDA Question Two: Can non-governmental programs, whether voluntary or mandatory, adequately deal with any problems?

We strongly believe that not only can non-governmental programs improve the overall safety and efficacy of breast biopsy, but such programs already have improved the quality of care for breast disease patients. In addition, we believe any problems the FDA identifies with stereotactic breast biopsy can be addressed by our professional standards, accreditation programs, and educational programs.

The American College of Surgeons was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS is a founding partner of the Joint Commission for Health Care Organizations, and continues to be a major participant in this organization with three commissioners on its board. A major division of the ACS is the Division of Research and Optimal Patient Care. Within this division, there are three subdivisions: Cancer Programs, Continuous Quality Improvement, and Trauma Programs, all of which are headed by physicians employed by the ACS. The mission of this division is to:

- To develop and maintain an easily accessible repository of the highest quality scientific information to support surgical care.
- To encourage and facilitate clinical research especially prospective randomized clinical trials.
- To encourage and facilitate the work of surgeon/scientists in the laboratory.
- To develop surgical practice guidelines or standards supported by the best evidence.
- To encourage application of practices of proven value.
- To discourage application of practices of no proven value.
- To improve the quality of surgical care by applying statistically rigorous, validated, risk-adjusted measurement of outcomes.
- To promote safety in surgical care by careful investigation of human factors and system factors that contribute to errors.

A summary of each of the three subdivisions is included below:

Cancer Programs: A standing committee of the College since 1922, and administered by the Cancer Programs office, the Commission on Cancer (CoC) is a consortium of professional organizations dedicated to reducing the morbidity and mortality of cancer through education, standard setting, and the monitoring of quality care. The CoC Approvals Program sets standards for quality, multidisciplinary cancer care delivered in more than 1,400 hospital



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settings. The CoC's National Cancer Data Base (NCDB) is a nationwide oncology outcomes database for more than 1,400 hospital cancer programs in the 50 states. Currently, there are more than 2.5 million breast cancer cases in the database. In addition, the CoC has formed twelve multidisciplinary Disease Site Teams (DSTs) to provide expertise in three areas: review and publish National Cancer Data Base (NCDB) data on treatment patterns, trends, and outcomes; propose hypothesis-based special studies; and identify opportunities for educational interventions to improve cancer care. The 2006 Year in Review for the Committee on Cancer is included as Attachment B.

Continuous Quality Improvement: Continuous Quality Improvement provides the infrastructure for conducting health services research, clinical research, laboratory research, meta-analyses, clinical trials, outcome studies, research hypothesis generation, and the development of evidence-based practice guidelines. CQI encourages surgeons to participate in clinical trials through collaboration with the American College of Surgeons Oncology Group (ACOSOG). Additionally, CQI oversees a variety of research grants in both clinical trials and health service research. CQI is responsible for the American College of Surgeons National Quality Improvement Program (ACS/NSQIP), which is the first nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The program employs a prospective, peer controlled, validated database to quantify 30-day risk-adjusted surgical outcomes, which allows valid comparison of outcomes among all hospitals in the program. Medical centers and their surgical staff are able to use the data to make informed decisions regarding their continuous quality improvement efforts. Currently, the database includes data on almost 25,000 breast surgeries and the information has been used to enhance care and improve outcomes for breast cancer patients.

In 2005, representatives from medical oncology, pathology, radiology, surgery, and patient advocacy established the National Accreditation Program for Breast Centers (NAPBC) to develop and implement a multidisciplinary accreditation process for breast centers and programs. A consortium of 15 national professional organizations, the NAPBC is dedicated to improving the quality of care and to monitoring outcomes of patients with diseases of the breast. The goals of the NAPBC will be pursued through standard-setting, scientific validation, and patient and professional education. Three levels of breast centers will be eligible for participation – Clinical Breast Center (CBC), Breast Evaluation and Management Center (EMC), and Comprehensive Breast Evaluation and Management Center (CEMC). Thirty-one program standards have been defined under 7 subject areas. The NAPBC pilot program will run between March and June of 2007 to test and validate center definitions, components, and program standards in a variety of settings. Approximately 10 centers will serve as pilot sites. Official program launch is expected to occur in the latter half



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of 2007. The NAPBC Board is committed to developing a program ultimately designed to improve the evaluation and management of patients with diseases of the breast.

Trauma Programs: This subdivision organizes educational programs and publications in trauma and supports the Advanced Trauma Life Support Course, the National Trauma Registry (NATIONAL TRACS), the National Trauma Data Bank, the Verification/Consultation Program for Hospitals, the Trauma System Consultation Program, and a Regional Trauma Organization of State/Provincial activities. The Committee on Trauma is also active in pre-hospital trauma care, injury prevention and control, performance improvement and patient safety, rural trauma, disaster management, and outcomes studies.

In addition, both the ACS Division of Education and the American Society of Breast Surgeons provide a host of continuing medical education programs on breast surgery and breast imaging.

These are but a few of the examples where non-governmental organizations can and are dealing with the raising the standard of care for patients. We strongly believe the programs run by the ACS and the ASBS have led to the dramatic advancements in breast cancer diagnosis and surgery and, ultimately, improved outcomes and life expectancy for breast cancer patients. Finally, we note that these types of programs were not in place for screening mammography in 1992 when the MQSA was passed.

FDA Question Three: How many stereotactic-guided breast biopsy units are in use in the United States?

Unfortunately, we do not have access to this type of information. However, we believe the FDA may be able to generate this information through its regulation of device manufacturers. It is our understanding that there are several major manufacturers of stereotactic breast imaging equipment:

- 1) The Lorad stereotactic table, currently manufactured by Hologic, Inc.
- 2) The Fischer stereotactic table, recently acquired by Siemens, Inc.
- 3) Various upright add-on units manufactured by Hologic, GE and others.

The first two, which are “prone” tables, are much more frequently used than the upright units as they are more flexible and avoid problems of patients feeling light-headed during the procedure. The FDA may be able to verify the total number of units sold and in operation by contacting the manufactures directly.



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These units should be distinguished from the breast biopsy devices frequently utilized in conjunction with these tables, such as the “Mammotome” (Ethicon-Endosurgery) or other similar devices by other manufactures (e.g., Suros, Senorex, Bard), which are designed for use with stereotactic, ultrasound or MRI guidance. In short, there are two pieces of equipment used in stereotactic breast biopsy: the actual table that includes a mini-digital camera connected to a computer and the actual needle biopsy equipment used to collect the sample. The stereotactic unit provides two pictures of the breast, which the computer uses to calculate the location of the targeted lesion in three-dimension. The stereotactic unit provides guidance for the biopsy tool and is the mammographic correlate to ultrasound. A stereotactic unit is not meant for diagnostic use like a mammogram machine, but rather to guide a device once the diagnostic imaging has been completed. Federal regulation of the table under the MQSA would be unwarranted and illogical. There is no known problem or issue in the biopsy procedure related to the table. Clinical success is rather a function of the skill of the surgeon or radiologist in using the actual biopsy device. We note that, while several of the articles in Attachment A discuss various biopsy devices, none discuss the actual stereotactic table used. This reflects the general view of breast surgeons that the characteristics of stereotactic platform are not a factor in the success of this procedure.

FDA Question Four: How many stereotactic-guided breast biopsy procedures are performed each year?

Again, we do not have this type of information and we do not believe any overall, inclusive number currently exists. We do, however, have frequency data on Medicare beneficiaries. Below is a chart showing frequency data breast biopsy procedures on Medicare beneficiaries between 1995 and 2005.

CPT Code	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
19100 ³	49,747	54,354	51,382	36,574	35,497	36,050	23,001	17,543	15,121	13,717	12,585
19101 ⁴	13,654	15,682	20,729	40,732	52,626	61,390	17,455	9,359	7,098	6,199	5,415
19102 ⁵	N/A	N/A	N/A	N/A	N/A	N/A	28,996	39,733	43,587	48,329	50,387
19103 ⁶	N/A	N/A	N/A	N/A	N/A	N/A	43,684	59,375	66,912	74,999	79,448
Total	63,401	70,036	72,111	77,306	88,123	97,440	113,136	126,010	132,718	143,244	147,835

³ CPT code 19100: Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)

⁴ CPT Code 19101: Biopsy of breast; open, incisional

⁵ CPT code 19102: Biopsy of breast; percutaneous, needle core, using imaging guidance

⁶ CPT Code 19103: Biopsy of breast; percutaneous, automated vacuum assisted or rotating biopsy device, using imaging guidance



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However, after analyzing the statistics of several surgeons who practice exclusively in breast surgery, we have found that biopsies in the Medicare population are often handled differently than in the under age 65 population. For example, below is the data from one Tucson, Arizona breast surgery practice:

	<i>Ultrasound Biopsy</i>	<i>Stereotactic Biopsy</i>	<i>Open Biopsy</i>	<i>Total</i>
<i>Under 65</i>	460 (37.4%)	273 (22.2%)	496 (40.4%)	1229
<i>65 or greater</i>	205 (47.2%)	101 (23.3%)	128 (29.5%)	434
<i>Total</i>	665	374	624	1663

Using an extrapolation method, we estimate that approximately 278,408 stereotactic breast biopsy procedures were performed in 2004.

We believe the chart on Medicare frequency demonstrates two important trends:

- 1) Overall, more biopsies are being performed. We believe this trend is a result of both an aging population and public education campaigns aimed at early detection. While we praise these early detection programs, the result is an increasing number of non palpable breast lesions that must be evaluated.
- 2) A trend away from open biopsies and toward minimally invasive procedures. We strongly believe this trend is positive for patients and saves healthcare dollars in the long run.

FDA Question Five: How many ultrasound-guided breast biopsy procedures are performed each year and will regulation of stereotactic merely shift any problems to that unregulated procedure?

The frequency number for ultrasound-guided breast procedures is included in the chart above. It should be noted that there is not a specific CPT code for “ultrasound breast biopsy” and, therefore, the exact number is difficult to determine. Surgeons performing an ultrasound breast biopsy will use CPT codes 19102 or 19103 (as they also will when performing stereotactic breast biopsies), as well as a secondary code for the ultrasound guidance for needle placement. Unfortunately, the second code used is a general ultrasound code that is used for all types of biopsies, including those of the prostate and thyroid, as well



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as ultrasound procedures on the legs and other body parts. This code is literally billed more than a half billion times a year in the Medicare population and we have no way of ascertaining how many of these procedures are for breast biopsies.

We do not believe there would be a shift from stereotactic breast biopsy to ultrasound guided biopsy because these procedures are not clinical alternatives for the same conditions. Ultrasound biopsy procedures are commonly performed on patients with solid or liquid masses while stereotactic breast biopsy is performed on patients with microcalcifications. In short, if a surgeon does not have access to stereotactic breast biopsy, he/she will be forced to perform an open biopsy, not an ultrasound biopsy.

In addition, we do not have to imagine the effect that regulation of stereotactic breast biopsy could have on patients. Instead, we can look to our neighbors to the north where, because of Canadian regulations, stereotactic breast biopsies are limited to hospital facilities. As a result, women in Canada wait on average of 15 weeks for a diagnosis when undergoing a biopsy after an abnormal screening mammography.⁷ This dismal statistic has led to public outrage and the provincial health quality councils have been called on to develop a plan for fixing this public health crisis. While we do not believe it is the intent of the FDA, nor the patient groups calling for regulation, to impose such a severe restriction in the United States, federal regulatory restrictions will almost certainly have a negative effect on availability. We are already concerned that the workforce shortages in radiology and general surgery combined with the litigious environment in breast cancer detection will have a chilling affect on the availability of stereotactic breast biopsy. Federal regulation will aggravate this problem with no certainty – or even reasonable likelihood – of better clinical outcomes.

FDA Question Six: What are the standards that need to be implemented in order to assure the public of the safety and efficacy of stereotactic-guided breast biopsy?

We assume FDA is asking whether there are federal standards *related to mammography* that are necessary to ensure the safety and efficacy of this procedure. As discussed above, there are none. There is no negative outcome associated with this procedure that is known to relate to the mammography component of the procedure. Discordance and false negative rates are extremely low and have never been associated with mammography. There is no necessary mammography standard because there is no identified mammography problem for which a standard can be developed.

⁷ Olivotto, Ivo; Waiting Times from Abnormal Breast Screen to Diagnosis in 7 Canadian Provinces, CMAJ; Aug. 2001; 165 (3). See also, Hanley, C., Quality of a diagnosis and surgical management of breast lesions in a community hospital: room for improvement? Can J Surg, 2006 June; 49(3): 185-92 (focusing exclusively on Canadian hospitals)



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With regard to the overall safety and efficacy of the procedure itself, federal standards are inappropriate and outside the intended scope of the MQSA. Moreover, as we noted in our answer to question two, the ACS and ASBS have numerous programs aimed at ensuring the safety and efficacy of stereotactic breast biopsy. In addition, we are currently developing a Breast Cancer Centers of Excellence program that is aimed at improving the entire realm of breast cancer care in a specific institution and not just regulating one piece of equipment. This program will focus on proper patient selection; proper patient follow-up; adequate sample sizes and sample quality; and encompassing the entire team of providers in the care of the patient. In addition, the ASBS is developing practice guidelines in this area. Finally, we believe the area of breast cancer detection is prime for the outcomes and quality improvement programs currently being developed by the Centers for Medicare and Medicaid Services (CMS) as well as many private payers. Federal regulation of stereotactic breast biopsy as a medical procedure is not authorized under the MQSA and there is no evidence whatsoever that such regulation would improve outcomes or quality in stereotactic breast biopsy.

FDA Question Seven: If implemented, should a regulatory program focus on performance and clinical based outcomes rather than specific equipment and personnel requirements as does the current MQSA program for non-interventional mammography?

Any regulatory program under the MQSA must focus on the mammography-related characteristics of the procedure that are known to affect clinical outcome. If negative outcomes were associated with quality of imaging related to design or function of equipment, there might be a focus on equipment. If negative outcomes were associated with experience, training, or some other personnel factor, this would be the appropriate focus. It is unclear, however, how focusing on outcomes in any general sense can identify a mammography-related problem and suggest an MQSA standard for addressing the mammography-related problem. In the absence of an identifiable mammography-related problem, the focus on outcomes is nothing more than federal regulation of the medical procedure itself, without regard to mammography and the purpose behind the MQSA. This would constitute an unwarranted and unlawful federal intrusion into the practice of medicine, and would be subject to judicial challenge.

Of course, professional programs aimed generally at improving the quality of stereotactic breast biopsy should focus more on performance and clinical based outcomes than on specific equipment and personnel requirements. In the past two years, the ACS has spent countless hours developing surgical performance measures for use in quality reporting and we firmly believe programs focused on stereotactic breast biopsy should be included in this realm. These programs can encompass all types of breast biopsy and can set standards



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related to any aspect of care, including patient selection, sample size, and follow-up procedures. In addition, breast biopsy performance measures can also coincide with other breast surgery measures to ensure a seamless continuity of high level care. It is important to recognize that regulation under the MQSA would not only ineffective, but administratively burdensome and counterproductive to have multiple sets of standards, regulations and quality measures applying to the same family of procedures.

The ACS is committed to improving quality for all surgical patients, including breast surgery patients, and is currently involved in the following national quality initiatives:

- Member of the AQA Steering Committee;
- Member of the Quality Alliance Steering Committee;
- Member of the Executive Committee and lead organization of the Physician Consortium for Performance Improvement;
- Voting Member of the National Quality Forum;
- Founder the Surgical Quality Alliance; and
- Advisory Council Member of the National Committee for Quality Assurance

FDA Question Eight: What are the concordance and discordance rates for stereotactic-guided breast biopsy and how do they compare to those for surgical biopsy?

These rates are remarkably low, as reflected in the list of publications in Addendum A.

Conclusion

The American College of Surgeons and the American Society of Breast Surgeons are completely committed to providing the best possible care to patients in need of breast biopsy. Our goal is to provide the most accurate and appropriate type of biopsy required in the most expeditious manner possible. Not only do we believe regulating stereotactic breast biopsy will not help achieve this goal, we maintain that it will hurt patient access and patient care. Federal regulation of interventional medical procedures is unwarranted and inappropriate under the MQSA in the absence of a finding that there is a clinically significant mammography-related problem and an MQSA standard that can address the problem. No such problem or associated standard has been presented to the agency. This federal intervention would, moreover, be detrimental to the interests of patients. It would reduce the number available providers because many surgeons and small providers cannot go through the administrative burden and cost of becoming certified. In many communities, this would lead to delays in diagnosis while patients back-up at the few willing providers or will require



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providers to choose either a more invasive open biopsy procedure or a less clinically effective ultrasound procedure for certain types of lesions.

To the extent that there are general (non-mammography) or unsubstantiated concerns on the part of the FDA or outside groups regarding stereotactic breast biopsy, such concerns should be addressed by either the combined efforts of the ACS and ASBS or through the CMS or private payer led quality measurement programs. These programs have improved outcomes and survival rates for women with breast disease and will be hampered by federal intervention. For these reasons, federal intervention under the MQSA would be unwarranted and contrary to the interests of the patients Congress sought to protect.

Sincerely,

Thomas R. Russell, MD FACS
Executive Director
American College of Surgeons

Helen Pass, MD FACS
President
American Society of Breast Surgeons

WO:TRR:HP/bp

Appendix A:

Scientific Literature on Stereotactic Breast Biopsy

Rotter K; Evaluation of mammographic and clinical follow-up after 755 stereotactic vacuum-assisted breast biopsies; *Am J Surg*, 2003 Aug; 186 (2) 134-42 (concluding a benign diagnosis of quality assured VB is very reliable and leads to no or minimal scarring)

Senn Bahls E; Multitarget stereotactic core-needle breast biopsy (MSBB)—an effective and safe diagnostic intervention for non-palpable breast lesions: a large prospective single institution study. *Breast*. 2006 Jun; 15 (3): 339-46 (concluding MSBB was technically successful in 415 out of 426 (97.4%) procedures and the sensitivity for malignancy was 94.6%. Concluding, further, that MSBB is qualified as a remarkably reliable, patient-friendly, and economic diagnostic breast intervention and was well tolerated and highly accepted by virtually all female patients involved in this feasibility and effectiveness study).

Dillion, MF; The accuracy of ultrasound, stereotactic and clinical core biopsies in the diagnosis of breast cancer, with an analysis of false-negative cases. *Ann Surg*, 2005 Nov; 242 (5): 701-7 (finding an overall false negative rate of 6.1 percent and concluding ultrasound guidance should be used to perform core biopsies in evaluating all breast abnormalities visible on ultrasound).

Riedl CC; Lesion miss rates and false negative rates for 1115 consecutive cases of stereotactically guided needle-localized open breast biopsy with long-term follow-up. *Radiology*, 2005 Dec; 237(3); 847-53 (finding a lesion miss rate of 1.1% and a false-negative rate of 1.0% and concluding NLOBB with stereotactic guidance is an accurate method of diagnosing breast lesions).

Leifland K, Stereotactic core needle biopsy in non-palpable breast lesions. What number is needed? *Acta Radiol*. 2004 Apr; 45 (2): 142-7. (concluding three s-cnb samples were enough for a correct diagnosis of masses, architectural distortions or stellate lesions without microcalcifications and in microcalcifications and a mass, but were not sufficient in microcalcifications only).

Fajardo LL, Stereotactic and sonographic large-core biopsy or nonpalpable breast lesions: results of the Radiologic Diagnostic Oncology Group V study. *Acad Radiol*. 2004 Mar; 11 (3): 293-308 (concluding percutaneous, image guided core breast biopsy is an accurate diagnostic alternative to surgical biopsy in women with mammographically detected suspicious breast lesions).

Kettritz U. Stereotactic vacuum-assisted breast biopsy in 2874 patients: a multicenter study. *Cancer*, 2004 Jan 15; 100 (2): 245-51 (concluding VAB is highly reliable and effectively identified patients with benign lesions and assisted therapeutic decisions. A close interdisciplinary approach assured optimal results).

Hatmaker AR. Cost-effective use of breast biopsy techniques in a Veterans health care system. *Am J Surg* 2006 Nov; 192 (5):e37-41 (concluding the options of image guided percutaneous biopsy techniques is a cost-effective alternative to open surgical biopsy)

Mariotti C. Digital stereotactic biopsies for nonpalpable breast lesions. *Surg Endosc*. 2003 Jun; 17 (6):911-7 (concluding percutaneous biopsy is a valid method for the diagnosis of nonpalpable breast lesions and VACB is the method of choice because it is easy to perform and has adaptability).

Cawson JN. Fourteen-gauge needle core biopsy on mammographically evident radial scars: is excision necessary? *Cancer*. 2003 Jan 15; 97 (2):345-51 (concluding patients with SNCB-proven radial scars among the screened population can be managed safely by mammographic follow-up, provided there is no associated DCIS, ADH, or lobular carcinoma in situ. Spiculated abnormalities with discordant SNCB results require surgical biopsy).

Liberman L. To excise or to sample the mammographic target: what is the goal of stereotactic 11-gauge vacuum assisted breast biopsy? *AJR Am J Roentgenol*. 2002 Sep; 179 (3): 679-83. (concluding complete excision rather than sampling of the mammographic target was associated with lower frequencies of discordance and ductal carcinoma in situ underestimation but had no other advantage or disadvantage).

Bail CG. Effect on biopsy technique of the breast imaging reporting and data system (BI-RADS) for nonpalpable mammographic abnormalities. *Can J Surg*. 2002 Aug; 45 (4):259-63. (concluding SCNB should be applied to BI-RADS categories 3 and 4 (<50 yr of age). FWLB should be reserved for category 4 (>50 yr of age) and category 5 cases).

Verkooijen HM. Diagnostic accuracy of stereotactic large-core needle biopsy for nonpalpable breast disease: results of a multicenter prospective study with 95% surgical confirmation. *Int J Cancer*, 2002 Jun 20; 99 (6): 853-9. (concluding stereotactic large-needle biopsy is an accurate diagnostic instrument for nonpalpable disease).

Verkooijen HM. Diagnosing non-palpable breast disease: short-term impact of quality of life of large-core needle biopsy versus open breast biopsy. *Surg Oncol*. 2002 May; 10 (4): 177-81. (concluding stereotactic large core needle biopsy affects quality of life to a lesser extent than open breast biopsy).

Kirshenbaum KJ. Stereotactic core needle biopsy of nonpalpable breast lesions using a conventional mammography unit with an add-on device. *AJR Am J Roentgenol*. 2003 Aug; 181 (2): 527-31 (concluding biopsy with an add-on unit is safe, reliable, accurate and cost-effective with results comparable to those reported for dedicated prone biopsy devices).

Charles M. Effect of stereotactic core needle biopsy on pathologic measurement of tumor size of T1 invasive breast carcinomas presenting as mammographic masses. *Cancer* 2008 May 1; 97 (9):2137-41. (concluding, for soft tissues masses, the difference between

mammographic size and pathologic size of invasive carcinoma at excision does not appear to be affected by use of SCNB. Except in the circumstance of complete removal of the cancer by SCNB, the pathologic size and sate of the excised tumor after SCNB is not altered significantly by SCNB).

Koskela AK. Add-on device for stereotactic core-needle breast biopsy: how many biopsy specimens are needed for a reliable diagnosis? *Radiology*. 2005 Sep; 236 (3): 801-9. (concluding more than three samples are needed for a histologic diagnosis of a mass lesion by using an add-on stereotactic biopsy device).

Jackman RJ. Breast microcalcifications: retrieval failure at prone stereotactic core and vacuum breast biopsy – frequency, causes and outcome. *Radiology*. 2006 Apr; 239 (1): 61-70. (finding a failure to retrieve microcalcifications was least common with 11-gauge directional vacuum-assisted biopsy and occurred in 1% of lesions.)

Burns RP. Stereotactic core-needle breast biopsy by surgeons. Minimum two-year follow-up on benign lesions. *Ann Surg* 2001. 232 (4). 542-48. (concluding SCNB is an alternative to open biopsy and the false negative rate and negative predictive value in this series compares favorably with those in other reports, supporting the fact that surgeons can confidently use SCNB in the evaluation and treatment of breast disease).

COMMISSION ON CANCER

2006

Year in Review



Commission
on Cancer

*A multidisciplinary program of the
American College of Surgeons*

MISSION STATEMENT

“The Commission on Cancer (CoC) is a consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard-setting, prevention, research, education, and the monitoring of comprehensive quality care.”

2006 Year in Review

Objectives

- ⊙ Establish standards to ensure quality, multidisciplinary, and comprehensive cancer care delivery in health care settings.
- ⊙ Conduct surveys in health care settings to assess compliance with those standards.
- ⊙ Collect standardized, high-quality data from CoC-accredited health care settings to measure cancer care quality.
- ⊙ Use data to monitor treatment patterns and outcomes and enhance cancer control and clinical surveillance activities.
- ⊙ Develop effective educational interventions to improve cancer prevention, early detection, care delivery, and outcomes in health care settings.

CoC Stats

- ⊙ There are currently 1,433 CoC-approved cancer programs in the United States and Puerto Rico, treating 80% of newly diagnosed cancer patients annually.
- ⊙ A total of 453 cancer programs surveys were conducted in 2006.
- ⊙ Twenty-two new cancer programs joined the Approvals Program.
- ⊙ The Commission exhibit was presented at 11 national professional meetings.
- ⊙ Ten new State Chairs were appointed.
- ⊙ More than 250 new Cancer Liaison Physicians were appointed.
- ⊙ The CoC Disease Site Teams using data from the National Cancer Data Base (NCDB) published four papers, and five abstracts were presented at national meetings.
- ⊙ More than 3,000 inquiries related to cancer program and data standards were processed through the Inquiry and Response System.



Charles M. Balch, MD, FACS, delivered the CoC Oncology Lecture at the 2006 Clinical Congress.



Recipients of the State Chair Outstanding Achievement Awards (from left): Danny Takanishi, Jr., MD, FACS; Alan G. Thorson, MD, FACS; and Michael S. Bouton, MD, FACS.



Frederick L. Greene, MD, FACS, chair of the CoC, addressed participants at the June Quality Conference.



Survey Savvy Workshop participants.



Mitch Stoller, President and Chief Executive Officer, Lance Armstrong Foundation.



Members of the National Partnership for Comprehensive Cancer Control.

KEY ACCOMPLISHMENTS

January

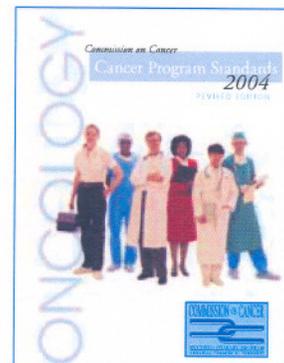
- ⊙ The NCDDB experienced its most successful **Call for Data** since its inception, with more than 1,306 of the 1,427 CoC-approved cancer programs submitting more than 3.5 million cancer cases for data years 2004, 1999, 1994, and 1989—on time! In addition, only 5% of the 2004 cases submitted included outstanding data quality problems requiring correction.
- ⊙ More than 587 cancer registrars representing CoC-approved cancer programs participated in the November 2005 **Collaborative Staging (CS) Reliability Study**. Participants were asked to code CS for 12 cancer cases: three each for breast, colon, lung, and prostate. The scenarios used for this study were actual cases submitted by registrars in a call for cases. Results of the study led to additional clarification to the CS Manual coding instructions and to the development of additional educational materials. Results were reported at the annual meetings of the National Cancer Registrars Association and the North American Association of Central Cancer Registries, and an article summarizing the results will be published in a future issue of the *Journal of Registry Management*.

February

- ⊙ Forty CoC-approved cancer programs were awarded the **2005 CoC Outstanding Achievement Award** recognizing them as cancer programs that strive for excellence in providing quality care to cancer patients. The 40 programs, featured on the CoC Web site at www.facs.org/cancer, demonstrated a commendation rating for the seven standards that represent the full scope of the cancer program, as well as a compliance rating for the remaining 29 standards. These 40 programs represent 10% of the more than 400 programs surveyed in 2005.
- ⊙ The **NCDDB Hospital Comparison Benchmark Reports** and **Public Benchmark Reports** were updated with cases diagnosed through 2003. The Hospital Comparison Benchmark Reports contain more than 3.7 million cases diagnosed in the years 2000 through 2003, reported by 1,376 CoC-approved cancer programs. This application attracts approximately 50 queries daily. The Public Benchmark Reports contain more than 3.6 million cases diagnosed between 1998 and 2003. This application attracts more than 65 queries daily. The comparison reporting tool that allows access to site-specific American Joint Committee on Cancer (AJCC) stage-stratified, five-year observed survival rates was updated to include cases diagnosed in 1998.
- ⊙ The CoC established an important **partnership with Aetna, Inc.** Aetna, a national provider of health care coverage, has incorporated information about the CoC and its approved cancer programs into the DocFind Referral Directory available to consumers on its Web site at www.aetna.com/docfind. The CoC Approvals Program is listed on the site as a “Quality and Patient Safety Resource.” The CoC values Aetna’s recognition of CoC-approved cancer programs as a resource for its members in obtaining quality cancer care, close to home.

March

- ⊙ **Cancer Program Standards 2004, Revised Edition** was made available for use by all CoC-approved cancer programs and facilities working toward approval. The revision incorporates all changes made to the standards since the original release in 2004 and includes modified interpretations and requirements for pediatric facilities, pediatric components within larger facilities, Veterans Affairs facilities, and National Cancer Institute (NCI)-designated Comprehensive Cancer Centers. The revised edition was required for use in all programs beginning in 2006.
- ⊙ Two **“Survey Savvy” workshops** were offered for staff from NCI-designated Comprehensive Cancer Centers and from Veterans Affairs facilities. The workshops offered education on CoC standards, preparing for survey, and improving cancer program performance, and were directed to cancer program staff committed to the provision of high-quality cancer care. These workshops were tailored to these specific audiences and are beneficial to facilities seeking initial approval or who are preparing for reapproval.
- ⊙ CoC-approved cancer programs received copies of the newly revised **Cancer Liaison Program brochure** describing changes to the role of the Cancer Liaison Physician introduced in October 2005. In addition to the brochure, Cancer Liaison Physicians received an executive summary of their role, a list of detailed strategies to assist them in their role, and a checklist of how to get started. These materials are available on the CoC Web site at www.facs.org/cancer.



April

- ⊙ The CoC released **two special studies** to programs—Glioblastoma Multiforme: Relationship between Resection and Survival and Implications for Phase II Trial Design for Novel Surgically Implanted Agents; and Chemoradiation and Treatment of Nasopharyngeal Cancer. The glioblastoma study garnered participation by 90% (343/382) of approved programs requested to participate and resulted in a return of 82% (1,710/2,086) of requested case reports. The nasopharyngeal study garnered a participation rate of 93% (890/957) with a case report response of 94% (3,431/3,651). Data analysis for each study is under way.
- ⊙ The first of three **Phase III Leadership Institutes** for Comprehensive Cancer Control, hosted by the National Partners for Comprehensive Cancer Control, was held in Atlanta, GA, for states in the Southeast Region. These three-day summits are planned to assist states in developing and implementing their state cancer plans. The CoC staff served on the workgroup that provided input on the agenda, module content, and logistics for the institutes. Phase III Leadership Institutes are content focused and include modules on clinical trials, survivorship, colon cancer, tobacco control, palliative care, and the cancer workforce. Four CoC State Chairs attended the April institute. Additional institutes were held in June in Boston, MA, for the Northeast Region in which six State Chairs attended, and in October in Seattle, WA, for the Northwest Region with

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eight State Chairs attending. The fourth and final institute will be held in 2007 for the Southwest and Midwest Regions. Six State Chairs currently serve as the chair of their respective comprehensive cancer control coalitions, and 25 state cancer plans include objectives or strategies involving the CoC.

May

- The CoC launched a formal **public awareness campaign** through a series of newspaper ads that focus on enhancing public awareness, appreciation, and understanding of what it means to be treated at a CoC-approved cancer program. The initial ad placement focused on markets with the highest concentration of approved programs, and the campaign launched on May 14 with a full-color ad in the *USA Weekend* magazine supplement distributed in Sunday newspapers in the mid-Atlantic, central Great Lakes, and southeast regions of the U.S., and in California. This ad was followed by black-and-white ad placements in community newspapers in the greater Chicago, Los Angeles, and New York areas through the remainder of the year.
- In partnership with the AJCC, the Commission launched the new **Online Education Center** as an educational resource to meet the continued demand for training and education on CoC requirements and AJCC staging. The fee-based, online education resource, with discounts provided to staff from CoC-approved cancer programs, offers a library of audio/slide presentations that can be purchased and viewed to earn CME and CE credits. Ten programs were included in the launch and focus on CoC cancer program and data standards. Additional programs on TNM and collaborative staging will be added in January 2007.
- The National Quality Forum (NQF) called for quality of **cancer care measures** for breast and colon disease in 2005.

Have you or someone you love been diagnosed with cancer?

If so, you have many decisions to make. We can help. By choosing a Commission on Cancer-Approved Cancer Program, you will receive:

- Comprehensive cancer care and services
- A multispecialty, team approach to treatment
- Clinical trials information
- Access to cancer-related information, education, and support

And, most importantly, **Quality Care Close to Home**

COMMISSION ON CANCER
THE AMERICAN COLLEGE OF SURGEONS

FIND A COMMISSION ON CANCER-APPROVED CANCER PROGRAM NEAR YOU. VISIT THE AMERICAN COLLEGE OF SURGEONS WEB SITE:
www.facs.org/cancerprogram/

The CoC responded with four specific measures for breast and three for colon. Following initial review by the NQF, six measures (shown in the table) proposed by the CoC were selected for additional scrutiny. Under contract from the NCI, an extensive assessment of the sensitivity of six potential measures of cancer care, three for breast and three for colorectal disease, was undertaken during 2006.

- The CoC released the enhanced **Cancer Program Profile Practice Reports (CP³R)** with updated tables and charts to improve user interpretation and navigation and with additional comparison groups. The Web-based CP³R provides comparative information for facilities to determine if adjuvant chemotherapy (ACT) has been administered

to or considered for patients following the resection of Stage III colon cancers. The purpose of this quality improvement initiative is to provide facilities with information (1) for cancer committee review of concordance with patient care guidelines; (2) to improve data and charting accuracy at the facility level; and (3) to enable facilities to demonstrate their quality of patient care using cancer registry data. The update reflected 1998–2002 data reconciliation efforts of facilities as they have reviewed and validated reported treatment practices for Stage III colon cancer patients. Programs were also provided the opportunity to review and reconcile 2003 cases. The CP³R will be updated on a quarterly basis allowing facilities to track reconciliation efforts. Since the launch of the CP³R in 2005, facility feedback has been overwhelmingly positive and supportive.

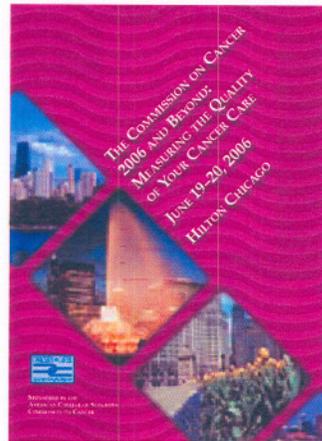
- The Cancer Liaison Program expanded its **Web conference offerings** directed at supporting the role and success of the Cancer Liaison Physician. In addition to the “Role of the Cancer Liaison Physician” Web conference offering, the program was expanded to include Web conferences that focused on “Maximizing Your Use of the National Cancer Data Base,” “American College of Surgeons Oncology Group Locally Advanced Breast Cancer,” “TNM Staging as an Integral Part of Providing Quality Care,” and “E-QuIP—Electronic Quality Improvement Packet—What’s It All About?”
- The Commission hosted the second annual **FORUM** in conjunction with the National Cancer Registrars Association Annual Conference. More than 200 cancer registrars from CoC-approved cancer programs participated in the FORUM where issues and concerns related to Commission activities at the facility level were reviewed and addressed.
- The **annual meetings of the committees of the Commission** took place in Chicago along with the annual meeting of the State Chairs. A summary report of committee deliberations was included in the May issue of *CoC Flash*.
- The **National Consortium of Breast Centers** was added as the newest member organization of the CoC.

CoC Quality of Cancer Care Measures Submitted to NQF	
ORGAN SITE	MEASURE DEFINITION
BREAST	Patients undergoing breast conserving surgery and who are under the age of 70 should be considered for or receive radiation therapy.
	Patients with Stage I (tumor size > 1 cm and N0) and Stage II/III (any tumor size and N+), ER/PR- breast tumors should be considered for or receive combination chemotherapy.
	Patients with Stage I (tumor size > 1 cm and N0) and Stage II/III (any tumor size and N+), ER+ or PR+ breast tumors should be considered for or receive hormonal therapy (tamoxifen or third-generation aromatase inhibitor).
COLORECTAL	Resected colon specimen should have at least 12 regional lymph nodes pathologically examined.
	Adjuvant chemotherapy should be considered or administered to patients with lymph node-positive colon cancer.
	Radiation therapy should be considered or administered for surgically resected Stage II and III rectal cancer.

KEY ACCOMPLISHMENTS

June

- ⊙ The CoC held a successful two-day conference, *The CoC 2006 and Beyond: Measuring the Quality of Your Cancer Care*, in Chicago. The conference covered a variety of topics related to providing and measuring the quality of care delivered in hospital programs, the spectrum of supportive services available to patients and care givers, and clinical trial participation. More than 300 participants included cancer program team members, health care executives and administrators, quality managers, and payers.



July

- ⊙ The CoC-approved cancer program *Performance Report* system was updated to include performance reports for individual programs surveyed in 2004 and 2005. The updated reports include comparison data for all standards for this two-year period. The new system allows multiple Performance Reports to be archived and accessible to participating programs at any time through CoC Datalinks, the CoC's password-protected Web portal.
- ⊙ As a National Partner in comprehensive cancer control, the CoC now serves as a partner on *Cancer Control PLANET*. PLANET (*Plan, Link, Act, Network with Evidence-based Tools*) is a Web portal that provides access to data and resources to help planners, program staff, and researchers to design, implement, and evaluate evidence-based cancer control programs. In addition to state and county level profiles and research-tested interventions, PLANET provides state lists of program partners in cancer control. In that regard, CoC State Chairs are now listed as a resource.

September

- ⊙ Access to the online *Survey Application Record (SAR)* for all CoC-approved cancer programs all of the time was announced. With continual availability, the SAR may be used by cancer programs on an ongoing basis as a tracking tool for program activity between surveys.

October

- ⊙ The CoC released the *Electronic Quality Improvement Packets (e-QuIP) for breast cancer* as a benefit to CoC-approved cancer programs. To coincide with October Breast Cancer Awareness month, this Web-based application provides individualized case summary reports for breast cancers diagnosed in 2003 and 2004, as submitted to the NCDB by each cancer program. The aim of this report is to enable facilities to review and address data completeness for cases eligible for concordance measurement with current standard-of-care guidelines for breast cancer. With the NQF endorsement of measures for breast

and colorectal cancer care on the horizon, and the Centers for Medicare & Medicaid Services (CMS) exploring precursors to pay-for-performance (P4P) measures, the CoC is well positioned to assist CoC-approved cancer programs in preparing for the arrival of these quality-focused measures. The e-QuIP for breast cancer will be followed by one for colon cancer scheduled for release during Colon Cancer Awareness Month in March 2007.

- ⊙ The *Commission on Cancer Annual Meeting* featured Murray F. Brennan, MD, FACS, from Memorial Sloan-Kettering Cancer Center in New York, NY, as the keynote speaker addressing "Lessons Learned from Organized Medicine." A member feedback session was held to elicit thoughts and opinions regarding emerging cancer quality measures and the pay-for-performance movement. In addition, Tom Kean, MPH, executive director of C-Change, addressed the *Cancer Liaison Program meeting* participants on the topic "Liaison Physicians as Integral Leaders in Comprehensive Cancer Control."
- ⊙ *Leadership changes* were announced at the CoC annual meeting. Frederick Greene, MD, FACS, from Carolinas Medical Center in Charlotte, NC, was reappointed to a second term as CoC Chair; Diana Dickson-Witmer, MD, FACS, from Christiana Care in Wilmington, DE, was appointed as chair of the Committee on Approvals; and Miguel Rodriguez-Bigas, MD, FACS, from M. D. Anderson Cancer Center in Houston, TX, was appointed as chair of the new Committee on Education. Lastly, the Society of Nuclear Medicine was added as the newest member organization of the CoC.
- ⊙ *The State Chair Outstanding Achievement Awards* were presented at the Cancer Liaison Program meeting to Michael S. Bouton, MD, FACS, for consistent communication with Cancer Liaison Physicians; Danny Takanishi, Jr., MD, FACS, for spearheading support of Commission activities; and Alan G. Thorson, MD, FACS, for collaborations with the American College of Surgeons chapter, American Cancer Society division, and state cancer plan team.
- ⊙ Charles M. Balch, MD, FACS, delivered the *Commission on Cancer Oncology Lecture* on "Melanoma—Model of Evidence-Based Oncology Practice." The lecture was delivered at the American College of Surgeons Clinical Congress and was attended by more than 300 participants.
- ⊙ More than 75 surgeons participated in a *CoC-sponsored postgraduate course* delivered at the American College of Surgeons Clinical Congress. Entitled "Principles of Cancer Surgery," the course was chaired by Frederick L. Greene, MD, FACS.

November

- ⊙ A successful *annual training meeting* with the Commission's 40 physician surveyors and 30 independent cancer program consultants took place in Chicago. The meeting focused on strategies to enhance the level of interaction that takes place between the surveyor/consultant and the cancer program staff and that results in a positive educational experience for the participating facility.
- ⊙ The *Cancer Liaison Physician Awards program* was announced to recognize outstanding performers who go above and beyond their regular scope of duties and have made a positive impact on their cancer program and/or their community. Nominations were solicited from CoC State Chairs, surveyors,

American Cancer Society staff, and CoC-approved cancer program staff. The award criteria, nomination form, and submission deadline are posted on the CoC Web site. The first awards will be presented in the fall of 2007.

December

- More than 175 individuals participated in the new workshop “*Survey Savvy: Beyond Compliance*” that reflected current standards and information set forth in *Cancer Program Standards 2004, Revised Edition*. The workshop focused on using and customizing best practice examples to go beyond basic compliance with the CoC standards.
- The *new histology and multiple primary rules* developed largely by SEER were endorsed for use beginning in 2007, along with the capture of five new data items: Ambiguous Terminology Dx, Date of Conclusive Dx, Multiple Tumors Reported as One Primary, Date of Multiple tumors, and Multiplicity Counter. An errata sheet to the Commission’s *Facility Oncology Registry Data Standards (FORDS) Manual* will be posted on the CoC Web site and made available to hospital cancer registrars for abstracting purposes beginning in January 2007.
- The American Cancer Society launched a CoC community on its intranet site called *The LINK*. The CoC community provides an opportunity to facilitate the exchange of ideas, information, and best practices among American Cancer Society national home office, division, and CoC staff for nationwide collaborative efforts. The intention of the community is to foster internal collaboration, reduce duplication of effort, and serve as an easily accessible online support for resources, proven processes, and other aids to strengthen existing and initiate new relationships with CoC partners.
- As part of the ongoing *public awareness campaign*, the Commission had diorama billboards placed in the baggage claim areas of Chicago O’Hare and Atlanta Hartsfield airports in December to educate the public about the benefits of seeking care at a CoC-approved cancer program. Ads will also appear in the major airline in-flight magazines during 2007.



- State Chairs and Cancer Liaison Physicians were called on throughout the year to targeted “*calls to action*” in support of the Commission’s programs and activities. State Chair calls to action included best practices for working with the registry community, nominating Cancer Liaison Physicians, methods for increasing communications with Cancer Liaison Physicians, becoming further involved in the state cancer plan, engaging Cancer Liaison Physicians in comprehensive cancer control, providing one-on-one support to Cancer Liaison Physicians, participating in the Phase III Leadership Institutes, encouraging Cancer Liaison Physicians to release Facility Information Profile System site and stage data for use by the American Cancer Society, joining the American College of Surgeons Oncology Group and participating in trials, and communicating with Cancer Liaison Physicians regarding the most common cancer program deficiencies identified during survey. Cancer Liaison Physicians were called on to work with the cancer committee to review the e-QulP application for breast cancer; work with the cancer committee to overcome the most common deficiencies identified during survey; facilitate facility release of site and stage data to the American Cancer Society; review the facility’s Cancer Program Practice Profile Reports; advocate for complete and accurate staging; become involved in comprehensive cancer control; facilitate American Cancer Society participation on the cancer committee; use the NCDB to illustrate successes and areas for improvement in the cancer program; and participate in Web conference offerings.
- Last, but not least, you may have noticed the new CoC logo. This logo reflects a new, modern look for the Commission and maintains the “links” from our previous logo that connect the past, present, and future. We are currently updating all CoC materials, including the Web site, to the new logo during the first quarter of 2007.

2006 NCDB Publications and Presentations

Published Articles/Book Chapters

- Hoffman HT, Porter K, Karnell LH, Cooper JS, Weber RS, Langer CJ, Ang K, Gay EG, Stewart AK, Robinson RA. Laryngeal cancer in the United States: Changes in demographics, patterns of care, and survival. *Laryngoscope*. 116(9):suppl 2:1-13, 2006.
- Newman LA, Lee CT, Patel-Parekh L, Stewart AK, Thomas CR, Beltran RA, Lucic A, Green B, Ota D, Nelson H. Use of the National Cancer Data Base to develop clinical trial accrual targets that are appropriate for minority ethnicity patients: A report from the American College of Surgeons Special Populations Committee. *Cancer*. 106(1):188-195.
- Fong Y, Wagman L, et al. Evidence-based staging: Changing American Joint Committee on Cancer (AJCC) staging by analysis of data from the National Cancer Database (NCDB). *Ann Surg*. 243(6):767-774, 2006.
- Pezzi CM, Patel-Parekh L, Cole K, Franko J, Klimberg VS, Bland K. Characteristics and treatment of metaplastic breast cancer: Analysis of 892 cases from the National Cancer Data Base. *Ann Surg Oncol*. 14(1): 166-173, 2007.
- Gay, E Greer. The Commission on Cancer, American College of Surgeons’ Response to HIPAA, Chapter 11. In *Cancer Clinical Trials: Proactive Strategies*, Leong, SPL (ed). Norwell, MA: Springer Publishers, pp 209-218.

Presentations

- Limited Small Cell Lung Cancer: Observations from the National Cancer Data Base on the Impact of Age and Gender on Survival*. Gaspar LE, Gay EG, Crawford J, Putnam JB, Herbst RS, Bonner JA (ASTRO, November 2006)
- Expectant Management Among Early-Stage Prostate Cancer Patients: The American College of Surgeons Special Study*. Richey J, Spencer BA, Miller DC, Stewart AK, Litwin MS, Wei JT (American Public Health Association [APHA], Medical Care Section, November 2006)
- Prostate Cancer Quality of Care: The American College of Surgeons Special Study*. Spencer BA, Miller DC, Richey J, Stewart AK, Litwin MS, Wei JT (American Urological Association, May 2006)
- Treatment Choice and Quality of Care for Men with Localized Prostate Cancer*. Miller DC, Spencer BA, Wei JT, Richey J, Stewart AK, Dunn RL, Sandler HM, Litwin MS (American Urological Association, May 2006)
- Surveillance of Transitional Cell Carcinoma: Stage Migration and Survival Trends, 1993-2003*. David KA, Nanus D, Richey J, Carroll PR (American Urological Association, May 2006)
- Perioperative Chemotherapy Treatment Patterns in Stage III Transitional Cell Carcinoma (TCC) (1998-2003): A Report from the National Cancer Data Base (NCDB)*. David KA, Nanus D, Richey J, Carroll PR (ASCO, June 2006)



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2006
Year in Review