The Use of Ultrasound in Diagnosing Ovarian Cancer:

Can We Improve on Current Practice?

May 14, 2002

Final Workshop Summary

Division of Cancer Prevention and Control

National Center for Chronic Disease Prevention and Control

Centers for Disease Control and Prevention

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The Use of Ultrasound in Diagnosing Ovarian Cancer:
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Workshop Agenda

Purpose of Workshop: To review current ultrasound practices and identify potential areas for improvement in the diagnostic evaluation of ovarian cancer using ultrasound

8:30 Introduction and Charge. *Christie Eheman, Ph.D.*

Session I: Review of Current Ultrasound Practices

9:00 The Use of Ultrasound to Evaluate Women for Possible Ovarian Cancer: Technical Capabilities and Limitations. *Arthur C. Fleischer, M.D.*

9:30 Gynecologic Ultrasound: Education, Standards, and Accreditation. *Barry B. Goldberg, M.D.*

10:00 Break

10:30 The Advantages and Limitations of Three-Dimensional Power Doppler Ultrasound and Other New Imaging Technology in Diagnosing Ovarian Cancer. *Leeber Cohen, M.D.*

Session II. Areas for Improvement in the Diagnostic Evaluation of Ovarian Cancer Using Ultrasound

11:00 Begin Roundtable Discussion

12:00 Lunch

1:30 Roundtable Discussion (continued)

2:30 Break

2:45 Roundtable Discussion (continued)

3:30 Wrap-up

4:15 Workshop Adjourned

Introduction/Purpose

Beginning in 1999, the Centers for Disease Control and Prevention (CDC) initiated an ovarian cancer program that is led by the Division of Cancer Prevention and Control (DCPC), National Center for Chronic Disease Prevention and Health Promotion. In November 2001, the DCPC convened a workshop to identify and prioritize public health needs for ovarian cancer. The workshop included leaders from state health departments, ovarian cancer advocacy groups, and physicians and scientists from state, federal, and nongovernmental organizations. Participants explored a broad range of potential research topics and public health activities and identified several opportunities for improving the quality of diagnostic ultrasound examinations that DCPC could explore further. Important topics raised included the age and quality of ultrasound equipment in some settings; the expertise, training, and board certification of medical specialists conducting, reading, and evaluating ultrasound exams; and the methods used to report results.

To begin addressing concerns related to diagnostic ultrasound, DCPC convened a workshop entitled *The Use of Ultrasound in Diagnosing Ovarian Cancer: Can We Improve on Current Practice?* on May 14, 2002 in Atlanta, Georgia. Participants included physicians; leaders from ovarian cancer advocacy groups; and scientists from academic medical centers, cancer treatment groups, and CDC. The purpose of this workshop was to review current practices and identify potential areas for improvement in the diagnostic evaluation of ovarian cancer using ultrasound. Specifically, the workshop was designed to identify key issues related to this topic and areas needing further investigation.

The ultrasound workshop consisted of a roundtable discussion as well as presentations covering the technical capabilities and limitations of using ultrasound to evaluate women for

ovarian cancer; education, standards and accreditation related to gynecologic ultrasound; and the advantages and limitations of three-dimensional power Doppler ultrasound and other new imaging technology in diagnosing ovarian cancer. The roundtable discussion covered a wide range of topics related to gynecological ultrasound. Although ultrasound is being tested for use as a screening tool for ovarian cancer, the discussion in this workshop was focused on the diagnostic use of ultrasound. Summaries of the key topics and potential activities discussed during the meeting are presented below. Brief synopses of the presentations and a list of workshop participants are provided in appendices.

Summary of Roundtable Discussions

Factors Affecting the Quality of Ultrasound Examinations

Participants identified four basic factors that affect the quality of ultrasound examinations in the diagnostic evaluation of ovarian abnormalities: the quality of imaging equipment; provider training and credentialing; knowledge about appropriate follow-up of identified ovarian abnormalities; and lack of standardized reporting. They also identified several possible strategies to improve the quality of ultrasound examinations, including creating a second tier of medical evaluation for ovarian abnormalities; establishing requirements for training and certification for conducting or interpreting ultrasound examinations; developing provider guidelines; and developing a standard reporting form or minimum requirements for ultrasound examinations.

Equipment age and type can fundamentally limit the quality of an ultrasound examination. Several workshop participants pointed out the large disparity between the highest and lowest quality equipment. Cost of equipment is an important consideration for providers

when they are deciding to buy new equipment or replace older ultrasound machines. Consequently, the highest quality equipment is usually found in specialty centers rather than in individual providers' offices. Participants generally thought that the equipment used by many health care practitioners who do not specialize in the use of ultrasound is adequate to detect an ovarian abnormality; however, this equipment is not good enough to assess accurately whether the abnormality is likely to be a serious condition requiring surgery such as a potential ovarian cancer or a less serious condition requiring less aggressive follow-up. This problem is exacerbated if the health care provider is inexperienced in evaluating ovarian masses using ultrasound. Even when the type of abnormality is correctly identified, workshop participants expressed concern that inappropriate, and generally over-aggressive, follow-up may be recommended. The potential problems in using diagnostic ultrasound are magnified when they are used with older women because of the difficulties associated with imaging post-menopausal ovaries. Participants thought that management of women who are at higher risk of ovarian cancer due to family or personal history (for example, those with a BRCA1 or BRCA2 gene mutation) raises additional issues that were not addressed at this meeting. Considerable concern was expressed at the workshop about the number of women who could undergo unnecessary surgery because of the combination of lower quality equipment in some settings; inadequate provider training on the use and/or interpretation of gynecologic ultrasound; and providers' lack of knowledge about appropriate follow-up and referral practices for ovarian abnormalities.

While acknowledging that the current utilization of ultrasound in many office settings poses serious potential problems, some participants thought that current practice would be difficult to change. Specifically, they thought that providers were not likely to buy more expensive equipment, that they would continue to evaluate women with symptoms using their current equipment, and that additional training and certification requirements would not be

accepted or were not necessary. To address these problems, they recommended establishing a more formal and better utilized second tier of evaluation and triage at specialty centers for women with ovarian abnormalities and suggested that timely referral of patients to the second tier of evaluation would improve diagnostic accuracy and reduce unnecessary surgeries. The impact this second tier might have in reducing delays in the diagnosis of ovarian cancer was not fully explored during the discussion. However, when a mass is likely to be ovarian cancer, participants generally agreed that the patient should be referred to an appropriate surgeon. They considered complete information from the first gynecological examination to be critical to providing appropriate second tier imaging assessment or recommendations on appropriate follow-up. There are currently no standard reporting requirements for gynecologic ultrasound examinations.

Specialty centers currently exist that provide access to up-to-date equipment, trained ultrasonographers, and specialists trained in the interpretation and proper follow-up of identified abnormalities. However, participants acknowledged that some geographic regions may not have easy access to specialty centers and that cost would limit the access of some women. In addition, these specialty centers may be underutilized. Participants in favor of the two-tier system agreed that the second tier of evaluation would consist of a second examination performed by a specialist who would be provided with all of the information collected during the first examination. This second evaluation might also involve a higher resolution ultrasound, Doppler or other imaging technique (positron emission tomography [PET], magnetic resonance imaging [MRI], or computed tomography [CT]). In order for a two-tier system to be successful, a method for facilitating the referral to specialty centers would need to be developed. It would also be necessary to establish requirements for the types of skills that providers at each tier

would need to have. Remaining questions about the two-tier system included how the two tiers of the system would be defined and how this type of system would be implemented.

Other participants presented arguments against a two-tier system and proposed that physicians and other health care providers conducting initial ultrasound examinations be appropriately trained and certified to do so. They noted that implementation of a formal two-tier system might mean that some women would receive a first examination of lower quality than they would have had in the absence of the two-tier system. Other potential drawbacks of a two-tier system that were discussed included the possibility that a second scan would not show a mass, that there might be long waits for referrals, and that insurance companies might not be willing to pay for multiple imaging examinations. There was some feeling that there is an informal two-tier system in place already, but that some physicians do not use this system as effectively as they could.

Activities Proposed for Improving the Diagnostic Use of Ultrasound

Below we have summarized the activities, projects, and actions that workshop participants discussed as possible steps in improving the use of ultrasound for diagnosing ovarian cancer. These activities range from major initiatives to small projects that could add to our current knowledge. We have tried to provide a complete list of suggested activities or approaches to best represent the discussion without making decisions about what activities are most appropriate or best suit CDC's mission.

Evaluate the feasibility and usefulness of a two-tier system. Participants expressed considerable interest in further exploration of a two-tier system for evaluating women using ultrasound. Preliminary steps they cited as necessary before this approach could be adopted included evaluating the cost-effectiveness of such a system, capacity, geographic and other

barriers, assessing acceptability to physicians and patients, and defining appropriate skill requirements for each tier.

Improve training of ultrasound providers. There was some discussion about the need to train more physicians in the proper techniques of conducting and interpreting ultrasonography of the ovaries, particularly in post-menopausal women. A possible barrier to implementing provider training is that some physicians might resent being required to participate. There was also some discussion of requiring physicians and others who perform ultrasonography to be board certified. Technologists who commonly perform ultrasound examinations can already be certified as diagnostic ultrasound professionals. The qualifications for receiving this certification are set forth in a document developed by the Society of Diagnostic Medical Sonography (SDMS) and the Society of Vascular Technology (SVT) entitled *Standards for Assurance of Minimum Entry-Level Competence for the Diagnostic Ultrasound Professional.* There is also a certification system for laboratories set by the American College of Radiology (ACR) and the American Institute of Ultrasound in Medicine (AIUM) that includes continuing medical education requirements for both physicians and sonographers. Participants were unclear about what physicians without certification would be allowed to do if physicians were required to be certified and this uncertainty was not resolved.

Develop a standard reporting form or minimum requirements for reporting. Participants thought that a standard reporting form or minimum requirements/checklist for ultrasound examinations of the ovaries would improve the information available for optimal follow-up or surgical consultations. These guidelines might be similar to the Breast Imaging Reporting and Data System [BI-RADS] guidelines. Minimum reporting requirements would likely include such features as the size and morphology of the ovarian abnormality. If a two-tier system were to be implemented, standardized reporting would facilitate the transfer of

information from first-tier to second-tier providers as well as to gynecologic oncologists or other specialists treating the patient.

Develop guidelines for follow-up of women with abnormalities. Because of their concern about the specific knowledge and training needed to evaluate and follow-up women with ovarian abnormalities appropriately, participants expressed considerable interest in the development of specific practice guidelines for primary care and other health care providers. There was some feeling that, if ultrasound reporting of ovarian masses was standardized, then guidelines for follow-up would be more straightforward. A number of participants thought that guidelines would help to promote better triage of women with symptoms and avoid unnecessary surgeries. However, they also thought that a wide range of experts and organizations would need to be involved in developing the guidelines, and consensus would be needed on a wide range of issues. A consensus conference could be used to discuss the development of such guidelines. A starting point for the development of the guidelines might include a systematic review of guidelines that are already in place, such as those endorsed by large health maintenance organizations and professional medical groups (e.g., guidelines for referral to gynecologic oncologists).

The needs of women who are at high risk for developing ovarian cancer were considered a special case and participants did not specifically address these needs in their discussion of the development of guidelines for primary care providers. A complete and accurate medical history should identify high risk patients, who would need appropriate follow up. The National Cancer Institute (NCI) has guidelines on follow-up of high-risk women and their guidelines should be applied to this population.

Study the quality of ultrasound exams by credentialed and noncredentialed sonographers. Participants discussed a study proposed by the Agency for Health Care Policy

and Research (AHCPR, now the Agency for Healthcare Research and Quality [AHRQ]) that would compare the quality of ultrasound exams performed by credentialed and noncredentialed sonographers to determine if there are truly disparities in the quality of ultrasound examinations performed by these groups of providers. A protocol was developed for this project but the study was unfunded and could not be conducted as planned. A study modeled after the AHCPR study could provide essential information about the importance of training and certification in conducting quality ultrasound examinations.

Evaluate the effectiveness of diagnostic ultrasound in detecting early stage ovarian cancer. Some participants expressed uncertainty about the potential for high-quality diagnostic ultrasound to reduce ovarian cancer-related morbidity and mortality. The stage at diagnosis is dependent on a number of factors including aggressiveness of cancer, timing and type of symptoms, and delays in diagnosis due to the patient, the provider or the system. The risk of mortality is associated with the stage at diagnosis, but type of treatment, cell type, co-morbid conditions and other factors play a role as well. The potential impact of improvements in the quality of ultrasound examinations on morbidity and mortality from ovarian cancer is difficult to assess. One workshop participant suggested that a literature review and analysis be undertaken to assess the effectiveness of various tests, including ultrasound, in detecting ovarian cancer. Another helpful analysis would be to examine cancer registry data to identify the number of ovarian cancers that were detected using each type of diagnostic test.

Develop methods to improve patient access to quality ultrasound examinations. Participants briefly discussed the fact that patients do not have equal access to quality ultrasound examinations. In particular, women with low income or with low levels of education are less likely to have access to high quality ultrasound examinations at tertiary care centers.

Educate patients and physicians about quality ultrasound. Participants disagreed about whether educating women about the quality of ultrasound used for the evaluation of possible ovarian cancer would be useful to them. Several attendees thought that the most receptive targets for educational materials would be women in whom an ovarian mass had been discovered. Education topics suggested by attendees who thought that education would be beneficial included the capabilities and limitations of ultrasound, criteria for identifying the best ultrasound centers, improving access to specialty centers, and what types of questions women should ask their physicians. Some attendees suggested that a patient educational campaign would need to be accompanied by a simultaneous educational campaign for physicians.

Summary

The roundtable discussions for the ultrasound workshop emphasized factors affecting the quality of ultrasound examinations used for the diagnostic evaluation of ovarian cancers. In an effort to increase the quality of ultrasound examinations, many attendees supported the implementation of a two-tier evaluation system, while others thought that requiring training and certification of those doing ultrasound was a better solution. Another possible method for improving the quality of ultrasounds discussed at length was the development of provider guidelines to ensure appropriate follow-up of women with abnormal ultrasound findings. Standardized reporting of the results of ultrasound examinations of ovarian masses would, perhaps, make the development of guidelines for follow-up more straightforward. Speaker presentations emphasized the need for improved imaging technology, additional research, and physician education in ultrasound techniques and interpretation.

The Division of Cancer Prevention and Control appreciates the interest and effort devoted to this workshop by those who participated and looks forward to continued collaboration on the use of ultrasound examinations to identify ovarian cancers. The ultrasound workshop was an

important first step in addressing concerns about this significant public health issue. The DCPC will review the public health activities discussed during the meeting and assess how to best incorporate these activities into its plans concerning ovarian cancer. Some activities may be best achieved through collaboration among CDC and private organizations, medical institutions, and other federal agencies.

Appendix 1
Summaries of Presentations

The Use of Ultrasound to Evaluate Women for Possible Ovarian Cancer: Technical Capabilities and Limitations. ***Arthur C. Fleischer, MD, Professor of Radiology and Radiological Sciences and Professor of Obstetrics and Gynecology, Vanderbilt University Medical Center***

General considerations in the use of ultrasound to evaluate women for possible ovarian cancer include cost versus (vs.) widespread use; availability of sonographers and sonologists with sufficient expertise; and intrinsic factors, such as tumor growth, and lead time/length time bias.

Transvaginal sonography is improving detection of abnormal ovarian morphology as operators gain expertise and better equipment becomes available. Major medical centers usually have more advanced equipment than in-office scanners. Scanning equipment can have either a tight convex array or larger linear footprint transducer heads.

Transvaginal color Doppler sonography (TV-CDS) is used to confirm the benign or malignant nature of cystic masses or diagnose stable hemorrhagic masses. TV-CDS can also be applied to detect ovarian cancer in morphologically equivocal masses and to diagnose torsion. The types of abnormal morphology that can be detected include papillary excrescences, wall thickening, and echogenic foci. Level of detection is influenced by a patient's body build, the size of her ovaries, and previous surgeries she may have had.

TV-CDS is improving specificity for distinguishing between benign and possibly malignant lesions, but it requires greater operator expertise. The equipment is more complicated and costly, although the cost is becoming more reasonable. TV-CDS derives its improved

sensitivity from enhanced detection of tumor vascularity, including vessel arrangement and flow/enhancement kinetics.

The detection of ovarian cancers and their characterization can be improved even more through enhancements in pre-processing (i.e., using sono CT) and post-processing (i.e., using X-res software designed to bring out subtle patterns obtained from soft tissue structures) detection of microvascularity; development of sonographic parameters which reflect tumor response; contrast enhancement in distinguishing benign from malignant lesions; 3-D representation of vessel networks to detect abnormal branching in tumor neovascularity; and detection and evaluation of normal vs. abnormal contrast kinetics.

In conclusion, Dr. Fleischer stated that TV-CDS is clinically useful but the information it provides must be integrated with morphology and patient history. TV-CDS is used most successfully in post-menopausal women since there are fewer physiologic masses that can mimic cancer. Future research is needed to examine flow patterns and quantification of flow.

Gynecologic Ultrasound: Education, Standards, and Accreditation. ***Barry B. Goldberg, MD, Professor of Radiology, Director, Jefferson Ultrasound Research & Education Institute, Thomas Jefferson University Hospital***

Dr. Goldberg presented the current status of ultrasound training and education in the U.S. Although Continuing Medical Education (CME) requirements vary, generally physicians and sonographers must acquire 30 CME credits specific to ultrasound every three years.

Dr. Goldberg also spoke about ultrasound laboratory accreditation. Accreditation is presently not required by the government, but being accredited can be beneficial in ensuring maintenance of laboratory quality. There are presently several entities involved in the accreditation of ultrasound laboratories.

The goals of ACR accreditation are 1) to improve ultrasound performance, 2) to provide educational information by raising awareness of ultrasound issues, 3) to recognize ultrasound facilities that meet program objectives, 4) to collect national data about the practice of ultrasound, and 5) to be of service to people inside and outside the industry.

The AIUM has recommended standards. It requires that physicians keep up their knowledge regardless of the patient volume they see and encourages them to participate in quality assurance programs designed to increase proficiency and ensure quality. Like the ACR, the AIUM provides training guidelines for physicians who evaluate and interpret diagnostic ultrasound examinations as well as accreditation for ultrasound faculties.

The American Registry of Diagnostic Medical Sonographers (ARDMS) offers examinations for sonographers. These examinations evaluate knowledge, but not practice (e.g., hand-eye coordination, interpretation of results). The need for inclusion of a practical component on these examinations is being addressed.

Transvaginal sonography is becoming the accepted technique for initial evaluation of suspected gynecologic abnormalities. Technological advances in ultrasound include improved imaging capabilities, 3-D ultrasound imaging, and ultrasound contrast agents. Ultrasound users need continuous education and training to ensure that they are able to use these new ultrasound techniques and technologies properly and to optimize medical services.

In conclusion, Dr. Goldberg stated that the education of physicians and sonographers is vital. Although many improvements in ultrasound technology have been made, physicians and sonographers still require an adequate level of expertise in performing ultrasound examinations and interpreting images of the ovaries.

The Advantages and Limitations of Three-Dimensional Power Doppler Ultrasound and Other New Imaging Technology in Diagnosing Ovarian Cancer. ***Leeber Cohen M.D., Associate Professor, Northwestern University, Department of Obstetrics and Gynecology***

Several methods have been used for detecting early-stage ovarian cancer. Detectable low impedance flow has been used successfully in finding late-stage cancers, but borderline tumors and some stage I cancers often do not show abnormal blood flow. CA125 has limited efficacy. To date, 3-D power Doppler imaging has been used primarily as an investigational tool in ovarian cancer screening protocols. 3-D power Doppler imaging may improve specificity in predicting malignancy, however there are currently no data available to determine whether 3-D power Doppler imaging improves the diagnostic accuracy of 2-D Doppler ultrasound in predicting benign or malignant pathology. Dr. Cohen performed a non-blinded prospective study from April 1999 to June 2000 in order to determine if transvaginal 3-D power Doppler improves the specificity of prediction of adnexal malignancy. His study included 71 women with adnexal masses, 40 of whom were pre-menopausal and 31 who were post-menopausal. Age, medical history, and results of a physical exam were taken into consideration. Results of this study suggested that 3-D resolution is presently not as good as 2-D resolution. Of the 71 masses examined, 14 were found to be malignant and 57 were benign. 2-D gray scale achieved a sensitivity of 100% and specificity of 54%. Adding 3-D imaging increased the specificity to 75%.

Dr. Cohen concluded that there is room for improvement of 3-D Doppler technology. Although 3-D and color Doppler can assist physicians with their investigations, both physicians and patients both need to be educated in order to avoid unnecessary surgeries.

Appendix 2
Workshop Attendees

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